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CENTERS FOR MEDICARE AND MEDICAID SERVICES
Medicare Coverage Advisory Committee

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Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland

Panelists

Chairperson
Ronald M. Davis, M.D.

Vice-Chairperson
Barbara J. McNeil, M.D., Ph.D.

Voting Members
Edgar R. Black, M.D.
David J. Margolis, M.D., Ph.D.
Catherine A. Glennon, R.N.
Angus M. McBryde, Jr., M.D.
Harry B. Burke, M.D., Ph.D.
Steven N. Goodman, M.D., M.H.S., Ph.D.
Jonathan P. Weiner, Ph.D.

HCFA Liaison
Steve Phurrough, M.D., M.P.A.

Industry Representative
Kim K. Kuebler, M.N., R.N.

Consumer Representative
Charles J. Queenan, III

Panelists (Continued)

Non-Voting Guest Panelists
Harold Brem, M.D.
Susan D. Horn, Ph.D.
William B. Greenough, III, M.D.
Elizabeth A. Ayello, Ph.D., R.N.

Executive Secretary
Kimberly Long

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PANEL PROCEEDINGS

(The meeting was called to order at 8:06 a.m., Tuesday, March 29, 2005.)

MS. LONG: Good morning, panel chairperson, members and guests. I am Kimberly Long, the executive secretary. We are meeting here today to discuss the evidence, hear presentations and public comment, and make recommendations regarding usual care of chronic wounds.

We ask that all presenters please adhere to their time limits. We have a large number of presenters to hear from today and a very tight agenda, and therefore cannot allow extra time. There is a timer at the podium that you should follow. The light will turn red when your time is up. Please note that there is a chair in front of the stage for the next speaker. Please proceed to the chair when it is your turn.

I will now turn the meeting over to Dr. Steve Phurrough.

DR. PHURROUGH: Good morning. I am Steve Phurrough. I am the director of the Coverage and Analysis Group here at Medicare, and the CMS liaison to this particular advisory committee. I want to thank you for your presence. We think we have a very

interesting and a challenging discussion today. My special thanks to the panel members who have taken their time to join us today.
This particular MCAC is different than most. In most of our advisory committees, we have a particular decision, particular coverage issue that someone has requested of us and then we have this meeting to go over the evidence around that particular technology. However, in this instance, we have been evaluating the kinds of technologies, the kinds of services that are being provided to our Medicare beneficiaries around the issues of chronic wound care. We also, in our review of the technology and our review of the evidence, have become concerned that perhaps the evidence base for a particular technology is not as strong as it needs to be and therefore, we are beginning with this particular MCAC a series of discussions around the appropriate methods of treating chronic wounds.
This particular meeting is to provide advice to us from the panel and from you the public on the appropriate basic care of chronic wounds. We will not be addressing today any specific secondary technologies, we're not discussing anything other than basic care for wounds, so hyperbaric oxygen,

electrical stimulation, so and so, are not issues for today. We're interested in the time for public presentations, both scheduled and open, your comments on what basic care should be. So please, if you elect to make comments, we are not interested in hearing about your specific technologies today. We will do that in the future, but what we hope to end today with are some recommendations from our panel as to what basic care should be, what are those groups of services that ought to be applied to beneficiaries who have one of the kinds of chronic wounds that we are discussing today, what are the basic services that should first be applied to all wounds. And then, what are the gaps in evidence, what kinds of evidence should we be looking for as we evaluate other technologies that may be applied to those wounds that do not heal after the basic therapy has been applied. And then we will discuss those in other future forums, whether through national coverage determinations, through other MCACs, through open door forums, expert panels, and there may be a number of meetings later this year or next year where we will address those issues.

So again, thank you for your interest.

This is a significant problem in our Medicare

population and we look forward to hearing comments today on it. With that, I will turn it over to our chairman today, Ron Davis.
DR. DAVIS: Thank you very much, Steve, and I would like to also thank everyone for being here and thank the members of the panel for participating in this process. My only purpose at this point is to ask the members of the panel to introduce themselves as we go down the table, and also ask you to disclose any potential conflicts of interest that you may have.
So I will begin. I am Ron Davis, I'm a preventive medicine physician at the Henry Ford Health System in Detroit, and I have no conflicts of interest.
DR. MCNEIL: I'm Barbara McNeil, with the Department of Health Care Policy at Harvard Medical School and a radiologist at the Brigham and Women's Hospital, and I have no conflicts.
DR. MARGOLIS: I'm David Margolis, I'm a dermatologist, I also treat chronic wounds, and am an epidemiologist. In terms of conflicts of interest, since we are not discussing new products, do you mean conflicts with standard therapies?
DR. DAVIS: I leave it up to your

discretion as to whether you think you may have a conflict.
DR. MARGOLIS: Because I certainly have done consulting work with companies that are investigating products, to include Keene Pharmaceuticals, (inaudible), Neptune and others, but none of their products to the best of my knowledge will be discussed today.
MS. GLENNON: I'm Cathy Glennon, I'm an oncology nurse at Duke University, and I have no conflicts of interest.
DR. MCBRYDE: Angus McBryde, professor of orthopedics at the University of South Carolina School of Medicine in Columbia, South Carolina, and I have no conflicts.
DR. BURKE: Harry Burke. I am associate professor of medicine, biochemistry and microbiology at George Washington University, and I have no conflicts.
DR. GOODMAN: I am Steve Goodman, I'm associate professor of oncology at the Division of Biostatistics at Johns Hopkins, and I have no conflicts.
DR. WEINER: I am Jonathan Weiner, professor of health services research at the Johns

Hopkins School of Public Health here in Baltimore, and I have no conflicts.

MR. QUEENAN: I am Charlie Queenan, the consumer representative. I'm an independent consultant and also a member of a company that's developing software for diabetes, and I have no conflicts.

MS. KUEBLER: Good morning. My name is Kim Kuebler, I'm a nurse practitioner (inaudible) and I have no conflicts.

DR. BREM: Good morning. My name is Harold Brem. I'm a surgeon and I direct the wound healing program at Columbia University in New York. I have done some speaking over the years for different companies and occasionally I do some consulting with regard to Genesis.

DR. HORN: Susan Horn. I am with the Institute for Clinical Outcomes Research in Salt Lake City and I have done research in wound care that was partially funded by Ross Laboratories (inaudible).

DR. GREENOUGH: I'm William Greenough, professor of medicine and international health at Johns Hopkins and chair of the division of geriatric medicine, and work with the wound team in the long-term care facility there. I have no conflicts

of interest.
DR. AYELLO: Good morning. I'm Elizabeth Ayello. I'm a senior advisor to the John A. Hartford Institute for Geriatric Nursing in New York, and faculty member at Excelsior College in Albany, New York. I'm also the executive editor of the World Council of Enterostomal Therapy Journal that is the journal for the international nursing organization for nurses who specialize in ostomy, incontinence and wound care. I just completed a research grant that was funded by ConvaTE out of Yale University and have participated in doing consultations for a variety of companies, including Smith & Nephew, Ross, Sage, Coloplast, Hill-Rom, Gaymar and others.
DR. DAVIS: Thank you very much. And given the heavy agenda, we will proceed to the next item on the agenda, which is CMS summary and presentation of voting questions. Dr. James Rollins.
DR. ROLLINS: I would like to say good morning to the members of the MCAC committee as well as the general public. Also, I would like to thank the members of CMS's chronic wound team, thank you. In my presentation I would like to provide a general overview of chronic wounds and its impact on the U.S. population, CMS's coverage position on

chronic wound therapy, problems encountered in the literature evaluating treatment for chronic wounds, and goals as well as questions for the MCAC committee.

As shown here, CMS defines chronic wounds as wounds which take longer than 30 days to completely heal. This definition is consistent with our coverage policies. Also based on a review of literature, we have restricted our wound discussion to three types, venous ulcers, pressure ulcers and diabetic ulcers.

From an epidemiological perspective, chronic wounds have had a significant impact on our population, as well as causing a significant financial burden. There are over six million chronic wound patients in the United States involving two percent of our population, $8.5 billion for wound care products and services, and more than $20 billion just for the treatment of these chronic wounds. 15 percent of our elderly population suffers from chronic wounds. Two percent of ulcers are caused by diabetes and while the number of patients with pressure ulcers is increasing by five percent annually, the incidence of diabetic foot ulcers is growing at a rate of 14 percent per year and accounts

for 80 percent of all chronic wound costs. And as noted in a study by Allman, the prevalence of chronic skin lesions increases with age.

First, I would like to discuss venous ulcers. Venous ulcers are a chronic cause of chronic wounds, especially in the lower extremity. We have a high incidence of venous ulcers in the United States with a significant recurrence rate.

Next I would like to discuss pressure ulcers. One study based on MedPar data estimates that between 1.0 and 1.7 million pressure ulcers occur annually. Some authorities feel that this number is low. Studies also confirm that a significant number of pressure ulcers are becoming more severe. Again, as noted before, these ulcers place a significant financial burden on the U.S. healthcare system. In a hospital setting pressure ulcers are common, not only because a large cohort of patients are admitted to the hospital with pressure ulcers, but also because of the development of pressure ulcers once patients are admitted to the hospital.

Spinal cord injury patients are particularly prone to pressure ulcers. They have a high incidence and the number of pressure ulcers

increases life-long. As noted in this slide, they require 50 percent more nursing time, remain hospitalized for longer periods of time, and contribute significantly to hospital charges. Over time, the incidence of hospitalized patients with pressure ulcers has significantly increased. A large portion of patients suffering from pressure ulcers can be found in the critical care setting. Also, studies have documented that pressure ulcers have significant costs. Staas notes the estimated costs of over $1 billion in expenditures resulting in an additional 2.2 million Medicare hospital days. Bergman notes the cost of treatment of a single pressure ulcer can range between $2,000 and $40,000. Patients with pressure ulcers are more likely to have longer hospital stays than patients without pressure ulcers. Beckrich used MedPar data to explore this relationship and was able to demonstrate that pressure ulcer patients on average had two to five times more hospital days than non-pressure ulcer patients.

Now we will discuss diabetic ulcers, which have a high incidence as well as a high prevalence in our population. According to the ADA, 18.2 million people in the United States, or 6.3 percent of the

population, have diabetes, and while 13 million have been diagnosed with diabetes, unfortunately 5.2 million people, or nearly one-third, are unaware that they have the disease.

Foot ulcers are a common complication of this condition, commonly resulting in amputation. Also, the recurrence of foot ulcers is high in this population. Diabetic foot problems also result in high hospital utilization and expenses. Limb amputation, which is a common complication of diabetic foot ulcers, costs the country more than $350 million per year. For diabetes, most lower limb amputations are preceded by foot ulcers; according to Cohen and Powderly, in the Infectious Disease text, of all amputations in people with diabetes, 60 percent are preceded by an infected ulcer. Pecoraro and colleagues were also able to demonstrate that lower limb amputations are commonly preceded by foot ulcers. And as noted by the ADA, once a diabetic loses a limb due to ulcer, long-term survival is compromised. Not only do diabetic ulcers result in increased chance of amputation of the same extremity, they also can result in increased chances of ulcers developing in the contralateral extremity, as well as death.

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The next set of slides looks at national coverage decisions that CMS currently has for chronic wound care. The first of these NCDs is used for hyperbaric oxygen therapy for diabetic wounds in the lower extremities. Based on the literature, CMS feels that there is sufficient evidence to conclude that HBO therapy is clinically effective and is, thus, reasonable and necessary in the treatment of certain patients with limb-threatening diabetic wounds in the lower extremities. For HBO therapy to be covered, the patient must meet the following criteria: The patient must have Type I or II diabetes and have a lower extremity wound that is due to diabetes; a patient has a wound classified as Wagner grade III or higher; and the patient has failed an adequate course of standard wound treatment.

CMS also has coverage positions on electrostimulation of wounds. Medicare allows for the coverage of electrical and electromagnetic stimulation for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous ulcers. All other uses of electrical and electromagnetic stimulation for the treatment of wounds is not covered.

CMS also feels that electrical stimulation, electromagnetic stimulation for the treatment of wounds will not be covered as an initial primary treatment modality. CMS has coverage positions also for both autologous blood-derived products for chronic non-healing wounds, as well as non-contact normothermic wound therapy. Those are not covered due to the lack of sufficient evidence demonstrating effectiveness.

The use of hydrotherapy for the treatment of decubitus ulcers is covered when treatment is reasonable and necessary. Other forms of treatment which are not safe or effective are not approved by CMS for the treatment of decubitus ulcers.

Porcine skin dressings are covered when reasonable and necessary for the individual as an occlusive dressing for burns, donor sites of a homograph, and decubiti and other ulcers.

And finally, pneumatic compression devices are covered in the home setting for the treatment of chronic venous insufficiency of the lower extremity only if the patient has one or more venous stasis ulcers which have failed to heal after a six-month trial of conservative therapy directed by the treating physician.

As noted in the previous slide, CMS defines chronic wounds as wounds taking longer than 30 days to heal, and as previously stated in our policy on chronic wound care, before adjunctive care may be initiated, usual care must have failed. Based on textbooks and a review of the literature, we have identified a number of components of what we consider to be usual care. These components consist of debridement, cleansing, dressing, compression, antibiotics, and last, off-loading.

But one question that we are faced with is how do we define usual care. One reason why it might be difficult to define usual care may be related to problems in evaluating the evidence. We found that with other technologies, a hierarchy of evidence is available which can be used to assess them. Does a paucity of evidence exist when evaluating treatments for chronic wound care? When we were doing studies and evaluating the evidence concerning wound care therapy, some problems identified include lack of blind assessment, inadequate sample size, lack of documentation of baseline data, duration of study too short, and lack of documentation or recurrence and adequate follow-up. Other problems include a paucity of data, methodological flaws, as well as no defining

of end points and outcomes.
A number of international organizations have performed technology assessments and evaluated the evidence related to chronic wound treatment. Also, national guidance documents as well as individual assessments have been performed. A Cochrane collaborative that was performed in 2000 to evaluate the evidence concluded, quote, even though systematic reviews are available, evidence is strikingly scarce regarding local wound care, although this is a worldwide problem, end quote. One recommendation that was made was the development and conduction of good methodologic randomized clinical trials which are the basis of systematic reviews. Based on a hierarchy of evidence, randomized clinical trials are considered the gold standard, but is this research design appropriate for evaluating chronic wound care treatment or are other research designs more appropriate? More on this later.
The United Kingdom also commissioned a technology assessment to evaluate chronic wound care treatment. Its purpose was to provide a comprehensive review of the evidence of different wound care interventions using systematic reviews.

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This technology assessment did not make a specific recommendation for standard of care. The conclusion from this analysis revealed that there was little evidence to indicate which dressings or topical agents are the most effective in the treatment of chronic wounds.

Earlier this year another technology assessment was performed by the Cochrane collaborative and again, it concluded that there is insufficient evidence to determine whether the choice of topical dressings affect the healing of leg ulcers. It also noted an inadequate description of the people in the clinical trial, which means that the results cannot be easily applied to other clinical populations.

The FDA also developed a guidance document addressing chronic wound care. This document was designed to address the number of different types of ulcers and specific proposals on trial design, outcome measures and labeling claims for the developing products.

DARE also performed a technology assessment which consisted of a systematic review. Its purpose was to assess the clinical and cost effectiveness of antimicrobial agents in prevention

and healing of chronic wounds. It noted several methodological problems, the most common being inadequate sample size. It concludes, there is no existing evidence to support the use of systemic antimicrobial agents for chronic wound care. It also commented that most of the research conducted in this area needs replication with well-designed randomized controlled trials.

And finally, there was a study by Alvarez which addresses the gaps in treatment options for non-healing wounds. After assessing the literature, he made a number of recommendations, which include using a research design which will collect outcome data on large groups, establishing standards that are universally applied, the establishment of non-healing end points in products and treatment testing, and the establishment of a validated tool or process by which all clinicians can reliably determine the value of non-healing end points.

As noted earlier, these are the components identified as part of the usual care. How do we define usual care? Today's meeting is the first in a series of meetings to help define this question.

Ultimately we have a number of goals, which include to identify current problems with the literature on

the evidence of chronic wound care; describe a baseline of what good care is for treatment of chronic wounds so that CMS can develop standards for evidence in future national coverage decisions; to define evidence standards for future evaluations; and to improve health outcomes for Medicare beneficiaries.

Questions for the MCAC committee. Usual care for chronic wounds commonly includes debridement, cleansing, dressing, compression, antibiotics, and off-loading. Is there sufficient evidence to assess the benefit of those modalities? Are there other modalities that provide benefit?

Second question. The following outcomes are commonly used to assess healing of chronic wounds: Complete healing, partial healing rates, recurrence rate, elimination of infection, amputation rate, reduction of pain, resumption of normal activities. Are these appropriate outcomes to be considered to assess the benefit of usual care of chronic wounds? Are there other outcome measures that should be considered? And, as new technologies arise, are new end points needed to demonstrate a benefit in the treatment of chronic wounds?

Third question: Based on the evidence

reviewed, how likely is it that the treatments discussed in Question 1 will positively affect the outcomes discussed in Question 2?
Fourth question: Based on the evidence reviewed, do the treatments reviewed in Question 1, singly or in combination produce clinically significant health benefit in the treatment of chronic wounds?
Question five: Based on the evidence reviewed, how likely is it that the usual care used to treat chronic wounds will be generalized to the Medicare population, as well as providers, facilities, physicians in community practice?
Question number six: What are the knowledge gaps in current evidence pertaining to the usual care of chronic wounds?
And the final question, what trial designs will support the development of sufficient evidence to determine the appropriate treatment of chronic wounds? What units of analysis and covariates can be considered?
DR. DAVIS: Thank you very much. Let me pause and see if there are any questions from members of the panel. If not, we'll proceed to the next item on the agenda, which is the presentation of the

technology assessment by Dr. Tom O'Donnell.
DR. O'DONNELL: Thank you, and good morning. I'm Tom O'Donnell, and I'm a senior surgeon at Tufts-New England Medical Center. I was formerly the chairman of the department of surgery there for ten years, and served as the CEO and president of the hospital.
This morning my task is to present the results of a technology assessment in the usual care and management of chronic wounds as derived from the recent literature. CMS had requested a technology assessment report from AHRQ and the Tufts-New England Medical Center evidence-based practice center participated and collaborated with AHRQ in analyzing and compiling this data.
CMS, as Jim Rollins was saying, was interested, what is the usual care for chronic wounds? It's very important to understand that our task was not to look at efficacy. We did not address that, nor were we charged to develop clinical practice guidelines. We were looking merely at the usual care. The charges summarized on the next two slides were to review clinical trials to develop: What are the usual care; the evidence and rationale for each element; what were the common modalities

across the different wound types, diabetic, venous and pressure; what unique modalities were noted for a particular wound type; and then, how did the 20 largest studies conform to the FDA recommendations? As Jim mentioned, the NHS-sponsored health technology assessment program in the UK did a major review of studies up to 1999 and were impressed by the methodologic weaknesses of this trial, so we started our review from the date that they concluded their review. The methods were to address clinical practice guideline recommendations from the National Guideline Clearing House and MEDLINE. Not an exhaustive, but a review of surgical, dermatologic and rehabilitation medicine textbooks. And most importantly, review of usual care in randomized controlled trials published since 1997. And then, apply it to the 20 largest studies that the FDA had set up.

A chronic wound is one where there is persistent loss of epithelial coverage or integrity, or the wound appears to be stuck in the inflammatory or proliferative phase, subjecting it to repeated injury, infection and inflammation. The types of chronic wounds that will be addressed today, as Jim outlined, are neuropathic diabetic foot ulcers,

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chronic venous insufficiency secondary to that, and pressure or decubitus ulcers. We will not be discussing ischemic or other types of wounds. The first phase was to identify common modalities derived from clinical practice guidelines and from expert reviews. The National Guideline Clearing House Search was utilized. 117 guidelines addressing wounds were assessed. 11 guidelines were available on the specific wounds of interest, the majority on pressure ulcers, two on diabetic, one on arterial, and none on venous. Subsequent to this study review, there were two others developed for venous ulcer, and one additional for diabetic. As I stated, there was a nonexhaustive review of textbooks. In general, the basic textbooks were very vague and only when you got to specialty textbooks did you see some specifics on the common elements for wounds. These are the common modalities that were identified from this review: Cleansing, debridement, either sharp or non-sharp, antibiotic treatment, dressings, and physical measures for diabetic and pressure, off-loading, and for venous, compression. The type of wound dressings, since a lot of the studies address the type of wound studied, and

again to emphasize, we were only looking at the control arm, are classified along Winter's classification, passive, interactive or active. We will be focusing on this side and will not deal with biologic or active dressings. And they are further subdivided into non-occlusive, semi-occlusive and occlusive. The latter definition is related to the dressing's ability to decrease moisture vapor transmission rate from the wound, and anything below 35 MVTR leads to a moist wound. And Winter in a series of experimental clinical studies showed a 40 percent increase in epithelialization rate over dry wounds, so that hydrocolloid falls below this, impregnated gauze and woven gauze do not. Saline wet to dry, depending on the water content, flows anywhere, and certainly if it's moist, it would be below the 35 standard. And further subdivision into the types or classes of products is shown on this slide.

Many of the studies addressed, at least the experimental arm addressed these active or biologic products. We will not be addressing those today, but they were part of the RCT.

The review of randomized controlled trials, and we picked randomized controlled trials

because they most likely had the most rigid study design to define the modalities. And research, as stated on this slide, identifying 277 articles out of nearly 3,000 unique citations. Again, we are focusing on the control group, the modalities of care used in the control group. The inclusion criteria for the RCTs was published in the English language; again, as Dr. Rollins said, chronic wound of 30 days or more; mixed duration ulcers without clear duration were included; and trials of any duration of treatment were assessed.

148 qualifying studies with over 12,000 patients. We'll focus on the trials to the left. The largest were in venous ulcers, almost twice as much as the number of patients in diabetic ulcers and a great magnitude greater than the 33 pressure ulcer trials.

The data was collected to obviously characterize usual care by the treatment modalities that I outlined for you, but also patient demographics, country where the study was conducted, study size, ulcer duration, and trial objectives were also studied.

Now if you look at the characteristics of the three types of ulcers, the largest sample size

was in diabetics where there was one trial of 922 subjects; seven of the trials were greater than 100 in the diabetic; and 17 trials were greater than, as far as sample size, greater than 100 for venous, and pressure tended to be smaller.

The diabetic population tended to be younger and predominantly male, whereas equally distributed in the other two ulcers, and obviously in the older population.

When we look at the country of origin, 50 percent or so of the diabetic and pressure were conducted in the United States, followed by the UK. Conversely, though, a look at the randomized controlled trials of venous ulcers, about 30 percent were done in the UK. It's very interesting that Italy had a very significant number of diabetic and venous ulcer trials. No randomized controlled trial, or very few tended to be multicountry in nature.

When we look at the maximum treatment duration for the various ulcers, you will see that venous, the study duration tended to be the longest, 24 months at 70 percent. 60 percent of the diabetics fell in between 12 to 23, and the pressure ulcer studies, 85 percent were of the shortest duration.

These series of slides will be color coded

with diabetic blue, pressure red, and venous yellow. This is the frequency of reported wound care modalities in the various groups. As far as surgical debridement, 80 percent of the diabetic ulcer trials were reported, followed by about 35 percent of the pressure, very infrequent in the surgical trial, and nonsurgical debridement, less than 10 percent. 50 percent of both the pressure and venous reported cleansing with fluid of the wound, less so in the diabetic. Compression, obviously used for venous ulcers, reported in over 85 percent. And off-loading of pressure for diabetic feet, again, reported in comparable proportions, and less off-loading but still a significant proportion in the diabetic. It should be remembered that these are what is reported. The authors could have assumed that the customary care did not need to be reported, so that is the weakness of an analysis like this. Dressing was reported in over 90 percent of the trials for the three groups.

This slide demonstrates the specific wound dressings across the various types of ulcers, dry gauze, ointment, paraffin accounted for less than 10 percent of, or less than 15 percent of the various trials, i.e., the non-occlusive dressings. By far

and away, saline wet to dry and hydrocolloid were the most frequently used dressings, and certainly favored in the diabetic foot ulcer and the pressure ulcer, whereas in venous ulcer and the pressure ulcer, hydrocolloid accounted for about 40 percent of the wounds. In venous ulcers, the combination of dressings plus rigid compression, Unna's boot, was used in about 15 percent. Of significance is greater than 20 percent of the diabetic and venous ulcers did not report what dressing was used.

When we look at the frequency of dressing changes and how frequently they were reported in the various trials, over half of the diabetic and nearly half of the pressure reported the frequency of dressing changes and a very small proportion in the venous patients. Obviously, this is a problem in larger study design. When we look at the frequency of dressing changes, in the diabetic and the pressure changed more frequently, one to two times per day, probably related to the dressing product used, whereas in the venous ulcer group, it tended to be change one to twice a week, again related to the type of dressing used.

How did these studies conform to the FDA draft guidance document? To review the various

characteristics, what we did was take the 20 largest studies and analyzed how they matched as far as outcome on measurements, particularly proportion of wounds completely healed, time to initial healing or healing rate, and most importantly, something that's been ignored in many of these studies, incidence of recurrence. Hopefully they would record in life table analysis form the ulcer healing rate. When we look at how they conform to the FDA document as portrayed in this slide, you see that complete wound closure was found in about 80 percent of the trials, so that's pretty good. However, 45 percent of the diabetic and 25 percent of the venous still used partial wound closed as an outcomes measurement. What is a little disappointing is shown by the low proportion in the reporting of wound size pre-and-post debridement, use of antibiotics during the study, which were not mentioned. So other than telling us that they had complete healing, the studies failed to live up to many of the requisites of the FDA document.

When we look at the summary of the usual care modalities, we see that nonsurgical debridement is infrequent and comparable among the three ulcer types. Cleansing occurs in 50 percent or so of

pressure and venous, less in the diabetic. Dressing, as stated earlier, used in the majority of these ulcers. Antibiotics reported more frequently, three times as much in the diabetic versus venous and pressure ulcers.

And I will talk a little bit about surgical debridement and physical measures, which are a unique modality, but again, our task was to look at, in addition to common, what were unique. In diabetic foot ulcer, off-loading was reported in 80 percent of the studies. In addition, sharp debridement was reported in 80 percent of the studies, here using a scalpel to remove tissue around the rim of the ulcer.

An important study prior to our view was that of David Steed, which showed that using the recombinant becaplermin growth factor would seem to be a better healing rate in diabetic ulcers. What was of interest is that a post hoc analysis showed that scalpel debridement also was associated with a greater healing rate. Obviously this is retrospective and would have to be proven by doing a prospective trial, but it suggests that scalpel debridement is important.

Far and away the most important modality

in venous ulcers is compression, and about two-thirds of the studies either used wrap, generally high compression, multi-layer, as shown on this limb. In addition, about 15 to 20 percent of the studies used elastic stockings, obviously difficult sometimes when you have ulcers present, and this was reported in 83 percent of studies.

Some form of off-loading, and shown here is a special bed, in the pressure ulcers was reported in 50 percent of ulcers. It could be a special cushion or whatever, to remove the point pressure over the ulcer.

When we look at the summary of the wound dressings for all the randomized controlled trials, we see that saline wet to dry is found in about 50 percent of diabetic and pressure, infrequent in venous. Hydrocolloid, more common in pressure and venous. Unna's boot used in about 15 percent of venous. Again, related probably to the type of dressing, it is more frequently changed in the diabetic and pressure ulcer.

So, we would conclude from this review that there is general consensus on the basic treatment modalities, but recommendations are vague, they are not comprehensive, and unfortunately lack

details. The randomized controlled trials had considerable variation in the frequency of reported use and treatment modalities, across different ulcer types as well as for specific ulcers. There were a large number of RCTs available but that's deceptive because they yield at times limited information regarding the treatment modalities to be used. In addition, we have shown that conformance with FDA draft guidance is low, and the quality of information is generally poor, leading to a significant variation in the reporting of the use of specific modalities. We would conclude that the low rate of reporting is either related to the investigator didn't employ it or he or she considered it was so basic that they didn't need to bother to report it. Jim Rollins asked me to review some study design characteristics and since I'm under my time, I'll present this. So two or three days ago, I reviewed the 20 largest studies that were applicable to diabetic, pressure and venous, and looked at study design characteristics. About 80 percent of the venous had an a priori calculation of sample size, less than diabetic and less than pressure. This is up from the 6 percent in the NHS assessment in 1999. Baseline comparability of groups is pretty good but

in venous they failed to look at the incidence of venous insufficiency, and diabetic many times they did not look at the location of the ulcer on the leg or foot. Intention to treat, quite low, 35 percent in the diabetic, 42 percent in the venous. Providing the number withdrawn and the reasons for withdrawal, over three-quarters. And using an end point as far as percent ulcer healed, diabetic three-quarters, pressure only a third, and venous about 70 percent. As I say, comparing this to the earlier review by the NHS, it's improved but certainly not satisfactory to make judgments on.

Thank you. This concludes my presentation. I will be glad to answer any questions.

DR. DAVIS: Thank you very much.

Questions? All right. Well, we will have the opportunity I think later on in the morning to ask questions to any of the speakers, so if you think of a question later on this morning, please hold and it and we will have a chance to come back to it.

So, we will now proceed to the next presentation by Dr. Susan Horn.

DR. HORN: Good morning. I am going to share with you today some results of a study done in

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the actual practice of care to look at what was associated with healing of pressure ulcers in long-term care settings. The study has been called the National Pressure Ulcer Long-Term Care Study. To give you a framework of what it involved, there were six large long-term care providers of which, or in which there were 109 long-term care facilities located all across the United States. We studied almost 2,500 residents. A little more than half of them had a pressure ulcer; the others were at risk of developing a pressure ulcer. They were largely female, as is typical in long-term care populations, and their average age was almost 80 years old. In studies on the actual practice of care, you can look at many different outcomes, so we looked at who developed pressure ulcers if they didn't start out with one, how did pressure ulcers heal with various definitions of healing, which is what I will concentrate on; but then also issues such as who was hospitalized and issues about systemic infections. Just to give you a flavor of the types of data that were collected, we tried to get lots of details about the residents themselves, and you see the factors listed here. In particular, we were able to control for how sick they were for each of their

diseases and all of their relevant signs and symptoms, and whatever their signs and symptoms, the higher the score, and that could be controlled for in subsequent analysis.

We also looked at details about the staffing associated with them, and then what factors were used and the timing of them for preventing pressure ulcers if they didn't have one, and for treating pressure ulcers if they did have one.

Although this is not our focus today, I thought I would just very quickly share with you some of the things that come out of doing studies like this. In this case, this slide and the next one show you the factors that were associated with developing a pressure ulcer. In general assessment I have factors about the residents, and if they have a positive sign in front of them, that means they were associated with greater likelihood of developing pressure ulcers.

So, though some of the previous comments have shown you that definitely the older population, it turns out males in addition, sicker patients, have a history of a pressure ulcer, et cetera, were all factors associated with greater likelihood of developing pressure ulcers in long-term care.

There's nothing you can do about those differences, but they are important covariants to account for when you are trying to determine what are the best things to do if you're going to intervene to prevent pressure ulcers.

If the residents were incontinent, what the data showed us was using disposable briefs was associated with fewer pressure ulcers, or using antidepressant medications was associated with fewer pressure ulcers developing. Also, those that had fluid, sufficient fluids, were taking nutritional supplements or taking enteral supplements, had fewer pressure ulcers developing.

And subsequently in studies where we implemented these changes in long-term care, we have found outcomes that were predicted, and we have been able to improve the decrease in development of pressure ulcers by more than 50 percent in long-term care settings.

But our focus today is on healing. In this same study for those residents who developed pressure ulcers, we also looked at what was associated with getting them to heal more quickly.

Now the patients I'm going to share with you, the residents I'm going to share with you today had

either Stage II, Stage III or Stage IV ulcers. We followed them for a 12-week period of time, taking the data out of their medical records or medication logs, or the central dataset data, and the outcomes that I'm going to focus on today is change in pressure ulcer area from one assessment to the next assessment. More than 76 percent of the assessments were less than seven days. So we looked at the area at one time and the area the next time that they assessed it to see if it had gotten larger or smaller, because of course the goal was in healing these ulcers to have them get smaller and smaller over time. And as you know, in the actual practice of care, they usually don't keep the same treatment on for a very long period of time, they keep changing them from assessment to assessment, and so we wanted follow what was associated with improving there. In terms of the data I'm going to share with you, there were over 2,600 assessments of Stage III or IV pressure ulcers, and that's what I'm going to display today. The factors that were associated with healing in this case, the area of the pressure ulcer getting smaller from the first assessment to the next assessment, so there is improvement over time. If something is negative here with regard to

the general assessment, it was associated with less improvement. If it's positive, it's associated with greater improvement.

So in particular, some of the things that we found is that you have to be very careful about residents that have depression, particularly dementia and depression, which is very widespread in long-term care facilities, and concentrate on making sure you do the right treatment for them because they have less improvement over time. Also not surprising, the sicker patients had less improvement over time.

But then with regard to dressings, nutrition and bed surfaces, this is what we found. Moist dressings were definitely associated with best healing from one assessment to the next. Dry also worked, but not as well, as I will show you in a moment. Another factor we found that was highly significant was having sufficient feeding, and the definition that we used as a threshold was more than 30 kilocalories per kilogram over a 21-day period of time. Finally, we found that Group 3 bed surfaces were associated with better healing from one assessment to the next.

Let me show you what that means in terms of size from one assessment to the next on average.

You see many episodes of care where moist was used, and the mean healing area from one assessment to the next was greater than one centimeter squared during each of the assessments, as compared to less than that for dry, for other kinds of dressings, for no dressings at all. And for any dressings that also used collagenase, which was quite widely used as we see here, we found actually the least amount of healing from one assessment to the next when those were used. So moist dressings were definitely what we found to be better.

With regard to feeding, we found better healing rates when patients were fed sufficiently compared to not.

With regard to the various kinds of surfaces they were on during those episodes from one assessment to the next, we found far better healing if they were on Group 3 surfaces, compared to being on Group 2 or Group 1 surfaces.

Finally, with regard to cleansing agents, we found saline or soap and water associated with better healing compared to not being recorded, or antiseptic antibiotics or other commercial products.

So those are some of the findings that have come out in the actual practice of care of what

seems to be associated with the healing of pressure ulcers.

The next question that we were asked to address was what kind of studies should we consider doing in the future to be able to assess what works best for whom, and I would like to share with you some of the experiences that we have had very quickly to address that. There's a study design that was not used in the study I just described to you but in many other clinical areas is one that we call clinical practice improvement study design, where we look at multiple outcomes. Of course the main focus is getting the best clinical outcomes, and what our studies usually show is when we get the best clinical outcomes we also simultaneously get the lowest cost in terms of treatment and care. So finding out what's best to do to get the patient or resident well as quickly as possible does end up being cost efficient.

In order to figure out, though, what is associated with those outcomes, we need to know what we've done with a great deal of detail, and when we've done it, and what we've done in combination. And also, we have to adjust for whom we are doing it to, so we collect great amounts of detail on both

patients, the treatments and the outcomes. By putting this comprehensive data together, then, we're able to look at residents or patients that have comparable comorbidities, same ages, gender, location of wounds, et cetera, to be able to be sure that we're talking about the same kind of people and what works for them. And by putting that together, then, we're able to go beyond the restrictions in a randomized trial that usually limit what patients we can look at to examining all patients or residents in that condition, controlling for how sick they are by measuring in great detail about all of their illnesses as you see represented here, and then also rather than guessing at what treatments or single treatment at a time might be associated with better healing in a small group of people, we can look at combinations of what's done in the actual practice of care to determine what combinations are associated with best outcomes. Thank you.

DR. DAVIS: Any questions? Dr. Horn, I had a question. You showed a history of tobacco use being associated with healing?

DR. HORN: No, development.

DR. DAVIS: Development of ulcers. Did you stratify that by current user versus former user,

did you have any current users in the patient population?

DR. HORN: That's the way the data were collected, in terms of have they ever used tobacco, or when, or whether they stopped, or things of that sort. And so we tried a number of different ways to quantify that variable, and it came out the way you saw it there, which was any past use of tobacco seemed to be associated with a greater likelihood of developing pressure ulcers, after controlling for all the other variabilities that you saw there on that slide. So there may be something to do with what happens to a person's body even if they stopped smoking, because most of the time they don't allow them to smoke in long-term care settings, but we could not find anything, any other kinds of definitions that for some subset it would be significant and for others it wouldn't.

DR. DAVIS: Thank you.

MS. KUEBLER: There is a lot of data showing patients who have smoked for a period of time, there is a cascade that probably contributes to some of that wound development.

DR. DAVIS: Other comments or questions?

MR. QUEENAN: I do have a quick question.

How long did it take you to sort of design and execute that particular study? And in particular, if one were to think about translating that sort of study where you have access to people who are already under care into a different environment or other kinds of wounds, I'm wondering if you could comment on whether that might be easy or hard in light of what you learned from that study.

DR. HORN: For the first question, it was how long did it take us to put it together. In each one of the studies that we've done of this nature, we gather together experts in the area, look at the literature and guidelines, and also people who are in the actual, who are actually treating those kinds of patients.

So for example, we had a number of certified nursing assistants, directors of nursing, et cetera, from existing long-term facilities that participated in our studies. And we asked them, what do you do, what are you doing in the actual practice of care, so we can be sure we're defining things exactly in ways that they will understand what it means when the data are analyzed. They also told us a lot about nutrition. People who work in this area for a long time, they have a lot of intuition about

what works and what doesn't, and they have very differing intuition depending upon what part of the country they're from.

So what we do is, we never say to someone, so, you have to show us there is some study that says that the data you're asking for have been useful in the past. We say whatever you think, we're going to collect. So that's the way these data instruments get put together. And frankly, it often will take six months to a year to be able to get everybody to say, you know, I think we've got a comprehensive way of looking at these patients or residents.

Then you go into charts and collect the data if the data are there. Most of the studies that I've reviewed recently, even in long-term care but also in stroke rehabilitation, et cetera, we have found that once people find the data they want, we find a lot of it isn't in existing medical records. And consequently then, we put together a prospective data collection system.

Then the next question is, can this kind of design be used widely? I have had experience using that same conceptual three-component study in inpatient care, surgery or medicine, pediatric care, long-term care as you've seen, stroke rehabilitation,

hospice care, and in every one of the areas that we have ever conceptualized this kind of a model, we have found amazing things in terms of associations, and it always seems to address the issues that are relevant in those particular areas, so I found it very widely applicable.

DR. GOODMAN: I was struck by the role of the nutritional status both in development and in healing. In any of these care facilities or to your knowledge in the guidelines, is nutritional supplementation or minimum intake part of the care protocol?

DR. HORN: I have the guidelines that go toward prevention of pressure ulcers and also treatment of pressure ulcers. I have seen nutrition addressed but in a way guidelines usually address things, such as if someone is nutritionally impaired, make sure that you consider that in ways. What we have found in our data is that when you get into the details of what was actually done, you can find what of those multiple interventions are associated with better outcomes. And we particularly found for prevention, if we use standardized medical nutritional products, those are the complete products that have the right combination of proteins, lipids

and carbohydrates, or enteral feeding, did much better in terms of the prevention of pressure ulcers than things like nutritional snacks or other things. So that's what you're able to differentiate when you're using data of this nature. And we've actually, or that prevention study have implemented that in a number of long-term care facilities across the country, and we have found a great decrease in development of pressure ulcers by focusing on those few things, like sufficient nutrition, sufficient fluids, using disposable briefs, and making sure they have appropriate staffing and medications.

DR. GOODMAN: In terms of the treatment, you also had it accelerating wound closure. Were you able to distinguish the effect in those who they documented were underweight or had nutritional deficiencies, versus those who didn't have obvious deficiencies.

DR. HORN: That measurement of how impaired they were in terms of weight and other things like that was over in our severity measurement.

DR. GOODMAN: Right. I guess the question is, was there an interaction, that is, was it more likely to have an effect if they had deficiency

versus not?
DR. HORN: No. That was kind of interesting. Even people who had heavy body mass index, we found that for healing pressure ulcers, they even were better off having sufficient nutrition. So that was interesting in that very specific case that we looked for that and couldn't find the association. In other words, it looks like everybody needs nutritional support to get their ulcers healed.
DR. DAVIS: Dr. Greenough.
DR. GREENOUGH: I'm interested in your staffing iteration. I'd like you to expand on the key issues, how much money you spend on the very expensive mechanical devices versus staffing. As we know in nursing, if you have a nurse-to-patient ratio in acute hospitals of less than four to one, or five or six to one, then mortality increases, and I notice you didn't have any comments to the fact of increased staffing except for nursing assistants, so could you comment further on that?
DR. HORN: Yes, actually those, when we first did that analysis, or I reported to you the published analyses here. We did not go any further than to just cross the threshold. But subsequently

we have and have a paper that's going to be appearing on that issue. And what we found was, it was RN staffing that was most associated with, higher RN care was more associated with better outcomes. And in particular, it was 30 to 40 minutes of direct RN time per resident per day that was associated with significantly less pressure ulcer development, significantly less hospitalization, significantly less urinary tract infections. So every one of the outcomes that we looked at, less declines in activities of daily living, better outcomes all across the board.

We've also undertaken a study of the economic evaluation of RN staffing. I think -- well, I will finish that piece. For the RN staffing, it turns out that for increasing -- most of the facilities had less than ten minutes of direct RN care time per day, and 30 to 40 was what we found to be the best for our outcomes that we looked at. The cost savings per long-term care at-risk resident was about $3,200 per year if we would increase the RN staffing, and I can tell you more details about that in our subsequent discussions, but that was really rather striking. In other words, we as a society are paying $3,200 more per resident per year to get

poorer outcomes because we have, I think, understaffing in some cases, and significant understaffing.
CNA and LPN time were only associated with the prevention of pressure ulcers, they were associated with none of the other better outcomes, they were not significant to any of them.
DR. DAVIS: Let's try to wrap up questions before moving on. Dr. Weiner.
DR. WEINER: Just one quick question. You identified starting out with a large ulcer, very large ulcer, and if it was associated with improvement, obviously there is more room to improve. Did you control for that?
DR. HORN: Yes, that was over in the side with the general assessment, Jonathan, because we did find that larger ulcers, the healing change in area is greater, so we had to control for that.
DR. WEINER: So when you reported the observed change, you took that into consideration.
DR. HORN: Yes, that was adjusted for that when I reported the results.
DR. DAVIS: Thank you very much. We'll move on to the next presentation by another member of our panel, Dr. Elizabeth Ayello.

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DR. AYELLO: Thank you very much, and good morning. I appreciate the opportunity to talk a little bit about what's going on in wound care clinics across America to take care of the number of people who have diabetic foot ulcers.

As we've heard before, diabetes is a worldwide epidemic if you look up the numbers for Americans, and we've heard from Jim Rollins already that they're up to several million Americans with diabetes, some of which are already diagnosed and some of which have yet to be discovered. What is even more concerning is the number of people with Type 2 diabetes is increasing in younger people, the diabetes that we did not see in our young people and children in the numbers that we're seeing now, as well as the expected increase in the number of people in the United States over the next 22 years with projections as high as 60 percent.

We heard about the importance of ulcerations and how they lead to hospitalization, but we've also heard the ADA numbers in terms of 15 percent of people with diabetes will develop a foot ulcer. But even more alarming is the fact that the international working group for diabetic feet has projected that it may be as high as 25 percent rather

than 15 percent that the ADA has projected. Our patients, particularly our patients over 60 years old, it's documented that around 15 percent of them will develop neuropathy, and the usual components that will be there, the underlying pathology is the loss of sensation, which hopefully as we are assessing or protecting our patients, clearly will increase their ability to have even minimal (inaudible) which result in a foot ulcer, the motor deformities which result in shuffle foot and wasting of muscles and changes in the foot, deformity, as well as autonomic shunting of the blood which results in dry scaly skin, cracking, which again, predisposes a person to ulceration. Most of us in the clinical realm are familiar with this definition of chronic wounds, that they fail to progress to a normal, orderly, and timely sequence of repair, or wounds that pass through the repair process without restoring anatomic and functional results. It's well quoted by the Wound Healing Society and was first mentioned by Lazarus in 1994, and diabetic ulcers certainly fall in that category. The Wagner classification has been used, and I would point out, we've heard about the

recurrence of ulcers, and they are graded as grade zero, and the importance of preventing this high recurrence rate, because they need to be treated as well as ulcers delineated in terms of the development of the tissue and the underlying problems.

In terms of diabetic ulcers, when you look at the deformities that happen with the foot, they are most at risk for what's called tip-top-toe syndrome, as a result of pressure on the top of the toes from shoes that are usually not well fitted for them, as well as the head of the metatarsal can push down through the bottom of the foot. We've seen classic ulcers developing on the head of the metatarsal.

We've heard about amputations, and certainly amputations are available in other populations other than people with diabetes, but they occur 10 to 30 times more often in diabetics than in the general population. We also have heard different percentages of numbers, but 83 to 85 percent of patients who have an ulcer will then follow with an amputation, where diabetic ulcer amputation accounts for about 66 percent of all nontraumatic amputations. What this tells us is the importance of screening patients with diabetes to identify their ulcerations

early and then intervene in an appropriate early aggressive manner. Besides the emotional trauma and loss of limb by a patient, and the importance of wound salvation, we've heard about the high cost of treating diabetic foot ulcers. This is just some of the recent data showing some of the numbers in the United States in 2001 in terms of how much it cost to treat an uninfected ulcer versus infected ulcer, and you see how the cost increases with osteomyelitis. The other study on the bottom actually looked at (inaudible) data as well as informational data, and you can see that there is a little bit lower difference in the cost of treating, probably because of a more global perspective. The important thing to remember is the mortality rates increase with amputations, and that gives us another reason why it is important to address diabetic foot ulcers. We know that from some of the best research that's being done that there is a difference in the way chronic wounds behave as opposed to healing wounds. We know with the diabetic patients that the neuropathy and ischemia certainly contributed, but what we're learning more about is the decreased angiogenic response in diabetic

patients, that there is actually an increase in growth factors and that the growth factors needed to regrow vasculature may be diminished in this patient population.

Because these patients have diabetes, control of the disease is important. Measuring the glycosylated hemoglobin and controlling the diabetic blood sugar is an important part of their treatment. The DCCT trial showed that by controlling glycemia with tight control, there was a 57 percent reduction in neuropathy in those patients, and in the UK prospective diabetic study published in 1998, by good control of those patients with their glycemia, there was a 25 percent reduction in the microvascular complications for each one percent mean reduction in hemoglobin A1C. Of great importance is the multidisciplinary team approach. In the clinics that I've been involved with consulting, the importance of having appropriate team members and the team members communicating with each other cannot be underscored enough. Education of the patients and appropriate intervention is critical, and there are several guidelines that are published out there, the ADA and the WOCN recently published guidelines for care of neuropathic ulcers.

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This is one of several protocols that are out there which have shown that strict adherence to the protocol for wound care in clinics did reduce and heal diabetic foot ulcers, but it takes a great deal of commitment by a team and enough persons for this to happen. The components of that plan include appropriate measurement and photography of the wound at each visit of the patient; evaluation for ischemia, ruling out any osteomyelitis, since infection is the enemy of the diabetic foot; debridement, especially sharp; moist wound healing with appropriate dressing; pressure redistribution, which for the diabetic is usually referring to an off-loading of the foot; and complete elimination of cellulitis, infection, callus and drainage. Ischemia needs to be evaluated, basically noninvasive closed studies. ABI has been found to be unreliable due to the calcification of the blood vessels in the diabetic. Toe blood pressures may be useful, and certainly revascularization. The importance of proper debridement, particularly sharp debridement has already been listed, and certainly the work by Dr. Steed is one of the quintessential studies out there. It requires removal of all the callus in the wound.

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Infection for diabetic patients, early aggressive treatment is critical. We have seen some of the data about that. Nearly 50 percent of the amputations result from infection. Deep cultures can be obtained at the time of surgical debridement. Infections in a diabetic are polymicrobial, so therefore, antibiotic treatment with a wide spectrum of antibiotics is needed.

Pressure in the foot, patients need preventive shoes and off-loading once an ulcer occurs, and certainly evaluation by some method, whether it's pressure mapping the foot or ultrasound, reducing the plantar pressure is important.

Pressure redistribution, there are a variety of techniques that are out there. Certain indications require custom footwear and orthotics to reduce the pressure and accommodate foot deformities. Total contact casting has been looked at as the gold standard in the past, but some new data such as looked at here by Cavanaugh, has looked at instant contact casting versus total contact casting and found that there was no difference, probably that you couldn't take off the total contact cast, as well as comparing the instance of contact casting using pre-available walkers to remove pressure, and again

found that there was an increased rate of ulcers that healed.
Topical treatment, moist healing and dressings, we have many dressings available that are applied. If the wound is not healing, then we go to cell therapies and growth factors.
So where are we now? Our problem is that a very, very large study with 20-some thousand patients found that 53 percent did not heal at 20 weeks. Our treatments must be multifaceted, simultaneous, not sequential. We need a national policy that will look at outcomes and accountability, and healing must be expected.
So in conclusion, will the number of chronic wounds with diabetic foot increase as the numbers increase, and what will happen with amputations? We need multidisciplinary team approaches, early aggressive treatment, biological therapies, debridement often, and pressure redistribution, for which the best technique is yet to be determined.
DR. DAVIS: Thank you very much.
Questions from the panel? Let me ask one as somebody who does not deal with this problem in his practice. For an early foot ulcer like Wagner grade I or II,

before you get abscessed and gangrenous and so on, what is the impact of quality of life, how much do they restrict mobility.

DR. AYELLO: Of course every patient is individual. There are some patients that will have a great deal of pain because of the neuropathy, and others do not have a great deal of pain. What happens is many of these patients, some of them become reclusive and will not go out, will not have mobility. Actually one of the problems is, the more that they walk on the foot at that point, particularly as it is formed, that's really going to prevent healing, so one of the strategies is, which is going towards off-loading, is to get the pressure off the foot. But these patients can have -- and there are many studies out there impacting the quality of life on these ulcers, which can be there for months, years, and really have a negative impact on the patients.

DR. DAVIS: Thank you. Dr. Margolis.

DR. MARGOLIS: Hi. I guess I'm the last speaker, so I'm standing in the way of your break, so I will move quickly. A lot of what I was going to speak about has been covered already and addressed quite nicely.

There are four major chronic wounds, venous leg ulcers, diabetic foot ulcers, arterial insufficiency and pressure ulcers. The numbers that I usually point to say that they will affect between one to three million individuals in the U.S. per year, and I will be concentrating in my talk on venous leg ulcers. If you look at the prevalence of those wounds themselves, there aren't many great studies done in this country, the best studies are actually done in Europe, and in Europe somewhere between 0.2 and 1.3 percent of the population suffer a lower extremity ulcer. Of those lower extremity ulcers, somewhere between about 40 and 80 percent will be due to a venous origin, and most recent studies in Europe showed about 70 percent. That supposedly transmits in the U.S. to between half a million and a million wounds per year, although that number is not well substantiated in this country. They are generally more common in people over 65 years of age and women, although there is at least one study looking at whether or not it is more common in women or men, and it basically shows they are probably more common in women than men only because there are more women in older age groups. If you were just looking at those over 65 years of age,

there is at least one prevalence study in the UK that shows that about 1.2 percent of the population will have a venous leg ulcer.

Venous leg ulcers can be treated in the outpatient arena, they are often treated in wound care centers, and certainly the number of wound care centers in the U.S. has increased dramatically in the last 10 years. Treatment for venous leg ulcers really needs to include both prevention and actual treatment of the wound itself.

In terms of the cost of these wounds, again, there aren't great U.S. studies. The most recent study that was published was actually one from the UK and the Netherlands, and came out to about $900 to $2,600 per ulcer. They also noted the cost of the ulcer increases as the prognosis, or the poor prognosis of the wound increases.

So this is a typical venous leg ulcer, but this one is also part of the spectrum as well, so you can imagine how one standard therapy or one therapy may not be a treat-all.

In terms of what causes the venous leg ulcer, that's also not well established, but many of the models argue that it's the calf muscle pump and that abnormalities of the muscle pump are what cause

the wound itself. The calf muscle pump includes the calf muscle itself and the superficial and deep venous system, as well as perforating veins and valves in those systems. As those things become abnormal, you increase the pressure on walking to the superficial system.

There are multiple imaging and diagnostic techniques that are available. Having said that, if you actually look in most wound care centers, many of these techniques often aren't used to determine whether or not somebody has a venous leg ulcer.

Having said that, there is at least one large cohort study that was done in Southern California that looked at one of the supposed gold standards for diagnosing venous leg ulcers or venous disease, and demonstrated that the clinical exams and the results from their testing do not always correlate both in terms of the fact that somebody might have a venous leg ulcer and have a relatively normal exam, and somebody else could have a normal exam and have a very abnormal test.

Standard therapies that have been quoted in the literature show a healing rate or success rate somewhere between 50 and 80 percent, sometimes even 90 percent, at about four to six months. Those

numbers are very dependent on how well the patients are followed, how long they are actually followed for, how severe they were in terms of prognostic factors. In most studies that are being conducted in this country and the UK, there's multiple things that commonly come up, common factors in terms of wounds that aren't getting healed that are exposed to standard therapy. These include duration of the wound, how old the wound is itself, size of the wound, and the arterial flow to the limb.

In terms of the standard therapy, there's multiple consensus conferences, or at least consensus conferences that I've heard, although they weren't represented earlier, which all discuss about the same thing which actually was represented earlier, that for venous leg ulcers, the wound needs to be cleaned or cleansed in some way, and many ultimately wind up with debridement. Unlike diabetic foot ulcers and pressure ulcers, often major and surgical debridement is included as part of the therapy for venous ulcers. You also have to have good wound care and good limb care. Good wound care was earlier described in the moisture retentive dressings. Good limb care is also important, the wound mass rate and surrounding skin index related to the wound can cause surrounding

problems. And compression, this is a typical compression bandage or multilayer compression bandage.
This is one of multiple studies that have been done with large cohorts of patients demonstrating the importance in early episodes on prognostic factors, the size of the wound on presentation, how old the wound was on presentation, and the adequacy of the lower limb arterial flow.
These factors have also been used by multiple centers when trying to develop prognostic models, and these are what the models say are reasonable areas under predicting how well the person is going to do at about 20 to 24 weeks.
With respect to standard therapies that may be used or are used, there's multiple Cochrane reviews that have come out in the last several years. I was actually on the editorial board for Cochrane, so I guess that might be a potential conflict of interest. These include looking at topical dressings for pain, and the conclusion of this RCT-based review was that a eutectic mixture of topical anesthetic may be helpful in debridement, therapeutic ultrasound it was thought might lead to some possible benefit.
Skin grafting, which in this case also includes

cell-based therapy or artificial skin, enhanced the chance of healing. It should also be noted that within these artificial skin studies, at least one study was published showing the differential effects of whether they were treating good prognostic wounds or bad prognostic wounds.

There was a review looking at laser therapy which supposedly showed no evidence of benefit. Intermittent pneumatic compression, in which the conclusion was that further trials are required. Electromagnetic therapy, which again showed no reliable evidence. And then compression bandage, which showed that they were helpful. And one of the things that needs to be clarified here, there is a difference between limb compression bandages, and a single-layer bandage is not as efficient and not as effective as multilayer bandages, and I'm not sure if that was the confusion in the earlier report, that they were all being lumped, but (inaudible).

There is a Cochrane review looking at compression for recurrence, which showed that individuals who weren't wearing compression was associated with recurrence. The use of oral zinc showed no reliable evidence, and the use of

pentoxifylline with compression was shown to actually have a benefit.

There are, again, also multiple studies that looked at other endpoints aside from wounds being fully healed. Most clinical trials that are published do look at wounds fully healed, which is consistent with the FDA guidance documents, and because of that other endpoints have been looked at. What some people have discussed in the literature and what is represented in some cohort studies is whether or not the wound base is prepared properly, sometimes also called graft-ready, whether or not there is less pain, whether or not the wound was smaller over time as was presented in earlier in the pressure ulcer report, and whether or not the limb was salvaged. Again, there are multiple cohort studies of 20 to 30,000 individuals with venous leg ulcer changes in area over time. Most of these studies concluded that at about four weeks, using different formulas to try to stabilize the sites of the wound, that if somebody does improve by a certain amount, we can actually predict fairly well that they are going to heal 20 to 24 weeks later, and in that study they were just looking at about 15,000 people treated in different ways to sort of stabilize and standardize

the wound site, and about two-thirds of the time we can accurately tell at four weeks whether or not the wound would heal in 20 or 24 weeks.

So again, to be brief and get us back on track and let everybody run to the bathroom, chronic wounds are actually very common in the population that Medicare is interested in, and venous leg ulcers are especially common in that up to 1.2 percent of the population will have them in any given year.

There are some well-established therapies, the therapies really are generically somewhat similar in that the wound needs to be cleansed in some way, the wound needs to be cared for well, including moisture retentive dressings, and a pressure bandage needs to be put on. There are some therapies in the Cochrane reviews that might be helpful adjuvant therapies and are fairly well established at this point. There are some things much less likely to be established, and the bottom line for these wounds is we need to identify people at high risk to compress them to try to prevent the wounds, you have to compress them when they have the wounds, and you have to compress them afterwards to prevent recurrences, and I will stop there.

DR. DAVIS: Thank you very much.

Questions? Yes, Dr. McNeil.
DR. MCNEIL: David, I missed what you were saying about the difference between the different types of compression, and you indicated something that might be confusing.
DR. MARGOLIS: In the very first presentation, I'm sorry, I forgot his name, Dr. O'Donnell, he noted that in the RCTs with these leg ulcers, the majority of them used compression and called it a Unna boot. My argument would be that probably you are lumping all compression bandages as being the same, where other studies have shown that Unna boots are probably not as effective as multilayered compression.
DR. O'DONNELL: Let me clarify that. Over two-thirds of the studies that I have reviewed for the RCT used compression; only one-third used Unna boot. I would agree with you that the Unna boot is a rigid device that requires the patient to walk and is not as effective as layered compression.
While I'm up here, I wonder if you might mention about the role of surgery, particularly the recent trials on which the Lancet perspective was found.
DR. MARGOLIS: Yeah, that's an interesting

study. If you look at other studies that have been done, particularly cohort studies, the argument or what you see from many of these studies is that long-term the results may be the same whether you have surgery up front or not. I think it's a nice first study, it would be nice to see it replicated.

DR. DAVIS: Dr. Margolis, you mentioned at the beginning that prevention is also critical, in addition to treatment, and I don't recall that you spoke much about prevention strategies. What are some of the predictors for venous ulcers and how can we prevent them?

DR. MARGOLIS: In general, I didn't think Medicare was all that interested in prevention.

(Laughter.)

DR. DAVIS: They are getting more and more interested in prevention.

DR. PHURROUGH: We are interested in what Congress tells us to be interested in.

(Laughter.)

DR. DAVIS: But in defense of CMS, they just announced a new coverage decision for tobacco cessation counseling, so they are trying to push the envelope.

DR. MARGOLIS: Yeah. I mean, there are

some studies that have shown that people who have multiple abnormalities, have a condition called (inaudible) sclerosis, who have these types of problems are more likely to develop venous leg ulcers. Certainly there are many things to try to sort of reverse or control the impression. What's interesting and concerning pressure ulcers as well, is that a key part of treatment is also a key part of prevention. With pressure ulcers you have off-loading mattresses, the non-weight bearing mattresses or whatever you want to call them, and turning is a key element in treatment and also a key element in prevention. The same thing is true on the venous side, and with limb compression, the bandages are more likely, the stockings are very helpful in terms of alleviating some of the abnormalities that you see clinically, and it helps with the dressing of the wounds themselves.

DR. DAVIS: And are most of these wounds just occurring spontaneously, or do they begin with an abrasion or some external pressure?

DR. MARGOLIS: Back when I was younger, I was always told that venous do occur spontaneously. When you talk to a lot of patients, I don't know if any good studies have really looked at this, but

there are actually some that peripherally have looked at what causes them. If you talk to a lot of the patients, they will tell you that they've been sore and painful for a long time, they often had this precursor or sclerosis, or they might then scratch themselves and then several days later then, the ulcer occurs. There is no great study that I know that has really looked at this, but it's what I just happen to hear from them.

DR. DAVIS: Yes, Jonathan.

DR. WEINER: Your next to last slide is very interesting, suggesting that you could develop, that's the one with predictive values and deals with specificity.

DR. MARGOLIS: Yes, for four weeks.

DR. WEINER: And it suggests that where there are data for over 30,000, you could develop guidelines or predictive models, but did you find that in practice, and perhaps later on when we discuss it --

DR. MARGOLIS: We actually recently finished a cluster randomized trial where we were working with a computerized database and within their database they reported the wound age and wound size, and similar to what happens when you get a

cholesterol level and evaluate the risk of a heart attack, we had patients who would on their second visit receive a piece of paper that said this is your likelihood of healing within this system, and not actually telling them to do anything, that's all it was. For the group of patients who received the piece of paper which talked about the prognostic factors, those patients at the end of 20 weeks were about 10 percent more likely to heal than the group that didn't. If you look at the four-week marker which is also used, you see about the same 10 percent.

What's interesting about that trial, and it's certainly not been written up yet, is that many of the physicians claim that the paper wasn't helpful, although you know, you have at least some evidence that it was mildly helpful. And it was only one piece of paper and there was no discussion of what they should do with the patients, just looking at, you know, this is the likelihood this person's going to heal. So against that background, I really can't tell you much more, except that was what this cluster trial was about, and there was about 4,000 patients enrolled.

DR. DAVIS: Thank you very much. We will

take a ten-minute break and that will help us get back on target.
(Recess.)
DR. DAVIS: We'll reconvene at this point. The next item on the agenda is scheduled public comments and we do have a relatively long list of people who are scheduled to give public comments, which is good, but we do need to stick to our timetable. We are about ten minutes late at the time, and we've already asked all of the public commenters to limit their remarks to two minutes each. And I realize that's difficult; however, you always have the right to submit written public comments and they will certainly be taken into account by CMS staff, so let me implore each public speaker to please limit their remarks to two minutes, otherwise we're going to get way behind.
So we will begin with several representatives of the Alliance of Wound Care stakeholders, beginning with Dr. Diane Krasner.
DR. KRASNER: Good morning. I am Diane Krasner, president of the Association for the Advancement of Wound Care. I've been a wound and ostomy continence nurse here in Baltimore for 20 years and am currently a regional clinical manager

for a company that manufactures wound and ostomy incontinence products.

On behalf of the Alliance of Wound Care Stakeholders, thank you for the opportunity to present this morning. Seven of us from multiple disciplines will highlight key points from our written submission to the MCAC. Representatives of the Alliance have been meeting over the past two months to consider the questions posed by MCAC. We have concluded that there is data to support current practices for the usual care of chronic wounds. My colleagues will address specifics to that momentarily.

I would like to take a moment to thank Marcia Nusgart, the executive director of the Alliance, for coordinating our efforts for this presentation today, providing a collective voice for the MCAC.

There are three overarching issues that I would like to address. The Alliance has over 15 member groups; here you see nine of those groups and here are an additional nine. Clinical evidence for usual care of chronic wounds is supported by data and we will be addressing a variety of levels of evidence this morning.

The first issue that I want to address is the phrase usual care. We found the term usual care to be frankly, unusual, especially when it comes to chronic wound care, where each person's care must be individualized because there is so much variability between wounds and between people. But based on the questions you posed, we have restricted our discussions today to the six components of the usual care that you have identified. We do believe, however, that there are other important aspects of usual care that are not on your list, including nutritional support, vascular testing, societal and social support, and others that we mentioned in our written comments to you.

The second issue I want to speak to relates to the working definition of chronic wound. The Alliance is concerned that the definition posed is too narrow. Major groups of wound patients that are prevalent in the Medicare population have been excluded, and these include the six categories listed below on this slide.

Additionally, we are concerned that the 30-day time frame is unrealistic. For example, the moment a surgical wound reaches day five, it becomes a chronic wound, so 30 days is really a very

arbitrary time frame and does not match our clinical reality.

I would like to conclude by emphasizing that chronic wounds are symptomatic of other underlying conditions. These conditions must be addressed before chronic wounds can be jump started to heal. Chronic wound patients are complex, with multiple comorbidities that vary widely from patient to patient and wound to wound. Their complex needs warrant an interdisciplinary approach to wound care. Thank you. I will now turn the podium over to Dr. John MacDonald.

DR. MACDONALD: Thank you very much. I'm Dr. John MacDonald, I'm speaking as president elect of the Association for Advanced Wound Care. I think a little background is in order so you can understand where the multidisciplinary aspect of wound care comes from. For 30 years I was a cardiovascular surgeon in the south Florida area and for the past 15 years I have been heavily involved in the field of lymphedema and wound healing, both in Haiti and in the United States. I am now, of all things, a member of the faculty of the department of dermatology at the University of Miami, involved in wound care and wound treatment there.

The AAWC, we are the Association for the Advancement of Wound Care. It is the premier international society for wound care, with over 1,600 members. It is a multidisciplinary nonprofit association headquartered in the United States. The AAWC was conceived in 1995 to accomplish and promote excellence in its patients, clinical practice, public policy and research. We are dedicated to fostering the best practice and evidence-based care for management of people with complex, acute and chronic wounds. We provide forums that promote excellence in clinical practice, education, research, public policy and international initiatives. Over the past year we have launched the Advance of Practice Campaign to heighten the awareness about the specialty practice of wound care with seven partner organizations. We have submitted to the commission three documents that will outline many of the things that we are standing for and that we will provide for your information. The most important thing that I have to say is that wound care is multidisciplinary. Due to the complexity of most chronic wounds, it is imperative that a comprehensive multidisciplinary approach to care be taken in order to adequately address each contributing factor, to optimize care

and to improve outcomes. There is substantial wound care research demonstrating positive qualitative outcomes and the value of comprehensive multidisciplinary wound care. The nature of the chronic wound demands comprehensive multidisciplinary care. Wound care professionals enhance the quality of their treatment and their value on the team with specialized training and board certification in wound care. Thank you very much.

DR. EDSBERG: Hi. My name is Laura Edsberg. I'm here representing the National Pressure Ulcer Advisory Panel. We are a group dedicated to the management and prevention of pressure ulcers. Pressure ulcers can occur in a very short period of time with unrelieved pressure whether a person is sitting in a chair, a wheelchair, laying on a support surface or a bed, or even on the operating table. And I think what's important to consider is when you look at the usual care for chronic wounds and the clinical health care, what's really critical is that we address pressure redistribution and how we relieve that pressure and how do we support that person without creating a pressure ulcer. Additionally, we have to consider the importance of shear and the relevance of shear to creating pressure

ulcers even faster.
Additionally, I think we should look at the outcome measures that were discussed and consider some additional outcome measures. Some of those might include reduction of exudate, decrease in odor, and most importantly a reduction in the complications associated with pressure ulcers, including pneumonia or infection, and if possible, reduction in hospitalization and our ability to avoid institutionalization as a result of chronic wounds.
I think there are new outcomes that are going to be appearing on the horizon shortly as our research continues. We will start to see that biomarkers are going to be a new outcome measure and I think with the direction that the research has gone in the last year or so, you'll start to see that not only markers looking at MMPs and TIMPs but looking at the complete biochemistry of the wound will soon be the biomarkers relevant to the field and the outcome of pressure ulcers. Thank you.
DR. WARRINER: Good morning. I'm Robert Warriner and I'm here representing the Undersea and Hyperbaric Medical Society, whose members include a number of physicians who practice wound care as their primary discipline, and that is my reason to speak

with you today. I'm also a physician whose medical practice for the past 15 years has involved solely patients with wound healing problems in both the inpatient and outpatient care setting.

I'm here to speak with you today about debridement, which has already been well addressed by previous speakers, debridement being defined as the removal of necrotic tissue and foreign material from the wound bed by a variety of means. I mention this because some of the considerations related to debridement include not only controlling the wound bioburden but perhaps also adjusting the wound geometry in such a way that wound healing may be facilitated.

There are a variety of methods that are typically used in debridement, including topical applications of autolytic agents, chemical agents, and local mechanical debridement. Those are frequently performed by non-physicians. I'm not here to address those specific areas, they have in fact been reviewed recently by Cochrane, and there is little differentiation in the relative value of these debridement approaches one from another.

I want to spend my limited time speaking about sharp surgical debridement and I want to speak

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to that from two perspectives. Very briefly, one is the initial excision of a necrotic infected wound, and I'm going to lay that aside, that is certainly a surgical procedure generally done in the operating room. The other form of debridement is that debridement which may occur in a wound care clinic or at the patient's bedside, may be performed by a wound care physician, not necessarily a surgeon, or may be provided by other licensed health care professionals in a variety of settings related to maintenance of a wound bed with minimal bioburden and appropriate geometry.

I think it is fair to say that at this point subjecting wounds to a randomized controlled trial of surgical debridement versus no debridement would be unacceptable as debriding necrotic wounds is certainly the standard of care and has been since I was a surgery resident in 1976. I think that it may also be very difficult today to do a comparative trial with surgical debridement in cases where that is possible to other forms of debridement, given our significant experience within surgical care.

Now this study has already been mentioned by Dr. O'Donnell, this was the post hoc review by Dr. David Steed published in the Journal of the American

College of Surgeons looking at the unexpected finding in subsequent clinical trials that those patients who had more frequent debridements, at their follow-ups are at higher healing rates. My take from this data is that that really reflects a benefit of repetitive debridement in diabetic foot ulcer patients who are receiving some form of active topical agent, where the agent, whatever it is, must be in full contact with the wound surface for optimal effectiveness. I'm not sure that from this limited data we could extrapolate that debridement would seemingly be beneficial for all wounds in this case. However, Saap and Folanga recently reported in Wound Repair and Regeneration a retrospective review of diabetic foot ulcer trials looking at specific criteria of those wounds, looking for periwound callus, undermining of the wound edge and tissue necrosis. And what is interesting about this data is that when wounds met the requirements for debridement, having any one of those criteria, and were sharp debrided, or had none of the requirements for debridement, their outcomes were improved in both treatment and control arms over those patients who did not have those wound abnormalities addressed by aggressive sharp debridement.

I think that it is impossible for us to extrapolate from the diabetic foot ulcer debridement data to all wounds, although I spoke with Dr. Horn just a few moments ago, and she pointed out that debridement was a negative factor in the integral change in wound size. Debridement of pressure ulcers was correlated ultimately to a higher healing rate. We certainly don't have similar debridement data for venous leg ulcers, but you can take the Saap and Folanga view of looking at specific criteria in the wound and do assessments in the future relative to the specific appearance of debridement in different wound types and using different wound modalities. Thank you.

DR. MARSTON: Thank you very much. My name is Bill Marston, and I'm an associate professor of surgery at the University of North Carolina and I'm here to represent the American Venous Forum. The American Venous Forum is an organization of academic and private physicians dedicated to researching venous disorders and improving the treatment of patients with venous disease. They asked me to highlight the fact that venous ulcers occur due to a specific etiology that must be treated when assessing open wounds; this is

an elevation of the ambulatory venous pressure that occurs when valves in the veins become dysfunctional, allowing reflux down towards the foot. This results in an increase in venous pressure and as this pressure increases, the incidence of ulceration does as well.

Currently there are only two known methods to treat elevated ambulatory venous pressure. One is surgical correction of the venous reflux, which can be accomplished in about 20 to 30 percent of the patients, or with compression techniques. There are numerous forms of compression therapy and I don't think it's very important to look at the different types. There's Unna boots, short stretch bandages, multilayer compression. It is probably more important that the practitioner using these techniques is well educated on their use so that they can be applied properly.

Now Dr. Margolis has looked in detail at the evidence about venous compression therapy, and I think the Cochrane library and the UK Health Technology Assessment Programs have both recommended that compression therapy is effective in dealing with venous leg ulcers. More recently, there was an international leg ulcer advisory panel commissioned

with representatives from Europe, the UK, Australia and the United States, and they came up with an algorithm after evaluating the literature in detail. Their algorithm is represented here, I'm not going to go through it for the sake of time, but this is for clinicians, nurses, and physicians treating venous leg ulcers to appropriately use techniques of management. Their conclusion was the same, that multilayer compression is first line therapy for venous leg ulcers. There have been some further randomized trials not on compression, but on different modes of compression to see which may be best.

I think the more important question is not whether we should use compression, but why don't we use compression, which occurs in approximately 30 to 40 percent of venous leg ulcers treated in the United States. I think the two main reasons are, number one, lack of education and training of the clinicians and, number two, lack of adequate reimbursement for the use of the products required for compression.

So in conclusion, the Venous Forum asked me to recommend that the panel confirm compression as first line therapy for venous leg ulcers, and to assist us in the training of and reimbursement for

these specialists who use these products. Thank you very much.

DR. LAVERY: My name is Larry Lavery. I am a podiatrist at the Texas A&M University Health Science Center, and I am here representing the American Diabetes Association Foot Care Council. I want to first address a few of the issues that were discussed earlier. I think that there is a dearth of evidence in this area and primarily it's because these are very expensive studies to do, and for small centers or small societies their costs are prohibitive.

If you look at the industry studies, often they require more than 20 centers to reach their sample size. So I would encourage, like everyone else, more money from the federal government for research into this area to identify the issues that we raise today.

Another concern is that often some of the complicating factors in diabetic foot wound healing are systematically eliminated from clinical trials. Often patients with peripheral vascular disease or poor glucose control are eliminated as part of the exclusion criteria in these studies, and I think to represent the Medicare population, they need to look

more at the population in general. I'm going to primarily address off-loading, which I think was nicely addressed earlier. This is a typical factor in the etiology and treatment of diabetic foot ulcers. I want to emphasize that this is not necessarily just a treatment for chronic wounds, this should be a treatment for diabetic foot wounds at their initiation. This is a basic element of foot care. There is relatively strong data both descriptive and increasingly in randomized clinical trials to support its effectiveness. Most of these are unfunded or underfunded by CMS and other health care providers. I make that point because most patients in the community get no off-loading, they leave with a thousand dollars worth of new tissue in the same shoes that they ulcerated in. This is a less effective -- or less expensive and more effective modality than a number of things that are currently funded. I have three slides that summarize about 13 studies with off-loading devices. In the past, total contact casting was thought to be a gold standard. These are a number of descriptive studies, are retrospective, and I'll show you some prospective

cohort studies, that have surprising similar results for the average time for healing and proportion of patients that heal. Subsequently there have been descriptive studies that report modifications of casting techniques, padded dressings, which show longer periods of time for wound healing, but still support evidence that off-loading is an important issue. And then finally, there are a growing number of randomized clinical trials with different off-loading techniques that suggest that there is a high proportion of patients that heal when these techniques are used in a relatively timely fashion. And then most recently, I guess I don't have that slide, I think it was presented, some of the information that is evolving using removable cast products that will fit in the hands of most physicians and make them easy to apply, and have demonstrated that simple modifications of those devices can be as effective as total contact casts. Thank you.

MS. WEIR: Good morning. My name is Dot Weir. I am a registered nurse and board certified in wound healing by the WOC as well as the American Academy for Wound Management, but my real job is that I'm a clinical manager for three outpatient wound

centers in the Orlando, Florida area.
I am speaking today on behalf of the Coalition of Wound Care Manufacturers, an alliance of leading manufacturers of products and devices that we use in chronic wound care. I do want to say, though, that I am not employed by any of these manufacturers, I will disclose that I am on a speaker panel for many of them.
My primary goal today is to look at the role of topical dressings in the treatment of chronic wounds. While gauze is still the predominant material perhaps used in wound care and wound management today, the goal of wound management is primarily to preserve tissue viability by establishing and maintaining optimal tissue (inaudible). So in answer to question 1.A, is there sufficient evidence to assess health benefits of dressings, I think the answer is a resounding yes. There is a growing body of evidence, a growing number of randomized clinical trials, and in the interest of time, we did submit these comments to the panel in writing.
The well-known AACPR treatment guidelines that were published in 1994 resulted in 11 recommendations related to topical treatment of

dressings and adjunctive therapies. And in a 1998 review of the same guidelines, it was found that all 11 of those remained valid, but four had advanced in terms of the efficacy levels. There were several that advanced from level B to level A through additional randomized controlled trials that were found in the more recent literature, and again, it again addressed the fact that we need to keep the ulcer bed continuously moist, that we need to use clinical judgment based on our assessment when choosing the appropriate dressing, and Dr. Horn made a very good point about that this morning, and that we should also always consider caregiver time when selecting our dressings.

There was an additional recommendation that went from a level C to a level B, and this relates to the ever-challenging problems of keeping dressings in place on certain anatomical areas.

And then there were recommendations that remained at a level C, and this is just in choosing a dressing material that provides optimal moisture levels that keep the wound moist, also to protect the wound bed from continued trauma, additional trauma to the wound.

So in terms of the evidence for moisture

retentive dressing, we certainly have a lot of them out there. As we look at the gold standard, which tends to still be gauze dressings, I think we do have to eventually address the role of gauze in chronic wound care. But often when we look at the dressing trials, the gold standard is a randomized controlled trial and one of the challenges that I have when I'm looking at it as a practicing clinician is that I'm looking at a trial, or even involved in some of these trials, I'm looking at a trial that's going to do the same treatment at week eight, week 12, week 20, and this in my everyday clinical practice, it's very rare that I actually continue to use one product from initiation of treatment all the way through the healing of the patient. My time is up and I thank you very much.

DR. LI: Good morning. My name is Vincent Li, and I'm a member of the WHCG, the Wound Healing Cooperative, a national group that coordinates clinical studies in real world settings, to help make wound healing best practices. We represent different disciplines and geographic areas. Three of us are here today to present to you. Dr. Vickie Driver will present after me, followed by Dr. Bill Ennis. There has been a steep rise in knowledge

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about wound healing published over the past five decades, ranging from passive interventions to biologically active interventions. We now know many factors that impede wound healing. All chronic wounds show common abnormalities at (inaudible) levels. Different abnormalities may result from the person's different disease states and between individuals. This may be seen in diabetic leg ulcers where certain impairments may play a more prominent role. Venous leg ulcers also share (inaudible), likewise, in pressure ulcers. In fact, standard therapeutic interventions do address the factors that affect wound healing. Interventions such as dressings, debridement and pressure off-loading and antimicrobials address different wound healing impairments. We also know that these interventions can improve outcomes. Debridement as one example, has been shown to improve healing in the placebo as well as treatment arm of clinical trials, sharp debridement particularly significantly increases healing, and the adequacy of debridement is independently predictive of wound healing.

In summary, we have seen an expanding volume of scientific and clinical data that allows with specific factors that impair healing, and wound

care and management that address these factors can lead to improved clinical outcomes, and Dr. Driver and Dr. Ennis will address these outcome measures in further detail.

DR. DRIVER: It's an honor to be here this morning. The pioneer of outcomes is complete wound closure, as used by the FDA for wound healing in clinical trials, but many factors influence the outcome of wound care, especially the setting of care and timely selection of proper interventions. A major challenge of wound healing end points is one size does not fit all and there are different standards for different types of wounds and a spectrum of possible end points exist, such as patient-directed end points, for example, and wound-directed end points.

Although complete healing is without question an important and valid end point, this can often require long periods of time to assess in practice and in clinical trials. The clinician needs to have intermediate and shorter-term measures that assess progress for its closure. These measures are known as surrogate end points, which are characteristically objectively measured as an indicator of biologic response to a therapeutic

intervention or fixed clinical benefit. They're important because the sooner a clinician knows an intervention is working or isn't working, the sooner it's possible to select an efficacious therapy. In fact, many predictors and surrogates of healing have been studied and presented in the literature, such as wound velocity as shown here, where the speed of healing clearly shows the wound is healing faster or slower. Present day wound velocity is clinically used in therapy selection for individual patients. Maybe a future surrogate study would be gene expression at the tissue level. In fact, WHCG members are already engaged in profiling gene expression in both acute and chronic wounds by taking biopsies and analyzing them using microarrays. For example, in venous leg ulcers studied by Dr. Kirschner and colleagues, they are revealing a number of genes that are (inaudible) wounds. Other studies that we are looking at involve correlating gene expression with wound type, age, presence of diabetes versus no diabetes, and the different advanced modalities. These studies set the stage for the future of evidence-based wound care. Today, most of the evidence comes from important but costly randomized controlled trials

sponsored by industry, the existing gold standard for evidence. However, it is important to recognize that RCT trials are carefully designed and controlled in a way that's usually not representative of the wounds that are treated in real world clinical practice. In fact, a paradox exists. As clinicians, we all know that the interventions that work efficaciously in clinical trials often do not have the same degree of efficacy across the board in our practices, while interventions that are highly effective in healing patients in our clinics may not achieve statistical significance in controlled clinical trials. So, how do we address this paradox? One way is to refine the way we design trials such as, employing therapies for wound healing that are controlling for factors like debridement, underlying disease, dressings, level of results achieved, off-loading, wound size and location. In summary, complete wound closure is an important outcome in wound care, but other clinically beneficial end points need to be considered by CMS. We believe that surrogate end points may contribute value to evidence-based clinical decision-making in wound care practice and clinical trials. Thank you.

DR. ENNIS: In closing for the Wound

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Healing Cooperative Group, there are many available treatment options, but is the knowledge required to make such decisions available at all points of care? For example, does a hospital-based wound care team know the expertise, products available and treatment options of the subacute or home health agency? Our group studied this question in three different clinical settings, using the same clinical team and medical records, and found between a 72 and 74 percent wound healing rate in hospital-based outpatient wound centers, versus a 23 percent in dedicated subacute wound units. This was statistically significant.

Our focus should be more on the interrelatedness of care. For example, a wound with impaired perfusion changes that patient's individual clinical needs and potentially the site of care where this treatment is performed and provided, where that type of therapy might be standard of care and available through advanced supply chain initiatives or expanded hospital formularies. The formulary is therefore directly related to state regulations and decisions made right here at CMS.

In other words, treating an individual patient actually occurs within the larger health care

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system and this needs to be considered. And in the future, as we mentioned in our prior talk, surrogates might be useful in moving us down that street more rapidly. I will therefore add to our prior summary statements by stating that complexities do exist in the real world that further complicate this situation.
Our solutions are listed here as recommendation to CMS. Number one, reimburse interventions that address impairments in wounds. For example, debridement is efficacious in improving the wounds, and so we need to insure that it's reimbursed appropriately. Convene periodic reviews of evidence-based scientific and clinical outcomes data, engaging wound healing experts to do so. Support the validation and study of clinically meaningful surrogate outcomes. Evaluate the available RCT studies for their strengths and weaknesses. Fund cooperative group studies in order to validate best practice and promote the integration of wound care, especially as it's delivered across settings. The Wound Healing Cooperative Group would like to thank CMS for the opportunity to address this committee today.
DR. BRIGIDO: Good morning. My name is

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Dr. Steve Brigido. I'm a foot and ankle surgeon in northern Pennsylvania. The thing that I want to talk to you about is looking at the new exciting technology that we have in chronic wound care, focusing on diabetes, and how these wound care treatments compare with some of the more traditional modalities that we have, and how we can standardize that.

When we look at the traditional modalities for treatment such as debridement, dressings, compression and off-loading, you know, there have been numerous studies and papers performed that demonstrate their benefit to the physiology of wound healing. When we look at some of the newer technologies such as alpha graft, thermograph, and (inaudible) such as graft charging, when we look at some of these things, we don't as physicians really know where they fit in and what kind of role they have in the treatment process, and that's what I want to talk with you a little bit about today.

When we look at assessment of wound healing, these are some of the parameters we look at. We look at time to wound healing, we look at partial healing rate and recurrence, these are all important factors. We also look at the elimination of

amputation, reduction, resumption of normal activities for the diabetic. But I want to talk to you about some of the other factors that we don't look at and we should probably start to consider doing so.

First is variability of activity, and I think this is important because what it does is it gives us an idea of how we can prevent ulceration from recurring, and it gives us an idea as to why certain patients break down and why other patients don't. It also leads us and it gives us an idea of how people break down after they have already had an ulcer.

The second is reduction of wound depth, and I think this is also very important because as a physician, it is always my goal to get the wound reduced as quickly as possible, and there are certain things that we have as far as technology goes today such as (inaudible) as well as standardized off-loading techniques that can reduce the wound depth very rapidly with minimal cost. Going along with the reduction of wound depth is the number of applications of some of these newer thermobiologics and we have to look at how many times we had to apply them and what are the costs associated with that.

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When we looked at the literature that we've cited and that's been talked about today, we made two assumptions. There needs to be a systemic approach to all wound modalities, and working together to do this, we can positively affect the beneficial treatment outcomes, and two, work in concert to produce clinically significant health benefits, and benefits not only to the patients but to the socioeconomic system around us.

But how do we make it happen? The first way to make it happen is for us to continue to educate the patients, that's first and foremost. There are two important studies that I want to quickly talk about. The first is (inaudible) in 1996 and this study demonstrated that when diabetics were given free footwear, only 20 percent of them wore it, and it was given to them for free. And the second paper done in 2003 demonstrated that off-loading devices that were removable were only worn about 20 percent of the day in patients that had diabetic foot ulcer, and these two things just don't cut it as far as getting wounds closed.

And when you look at it from a provider's standpoint, the application of debridement and standardized off-loading have to be stressed. We

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can't forget these, even with newer technologies. And then we have to take these newer technologies such as thermal (inaudible), negative pressure environments, (inaudible), we have to define a role for them and then create a systemic approach where we apply them to the healing process.

So again, as physicians, we really have to understand where these processes fit and where these treatment options fit in our overall treatment of chronic wounds for venous stasis or diabetes. In conclusion, when we look at the trials, again, we can't forget about early treatment being provided for adequate pressure relief while incorporating these newer therapies into our protocol. Thank you again for your time.

DR. BARBUL: My name is Adrian Barbul, I am professor of surgery at Johns Hopkins and a surgeon in Baltimore. I'm speaking as president-elect of the Wound Healing Society and speaking this morning on behalf of Dr. Vince Falanga, the president of the Wound Healing Society, who couldn't be here unexpectedly.

As some other speakers have pointed out, we also would like to point out that not only chronic wounds but also other types of wounds would benefit

from the treatment modalities that are under discussion today and need to be considered in the final resolution.

In order to help the committee, the Wound Healing Society sent a survey to the membership. Although it was short notice, we received 92 responses and I would like to share some of that data with the committee. The first question we asked, is there sufficient evidence for basic standard treatment modalities, and again, as you can see, there was an overwhelming sense among the members of the Wound Healing Society that indeed there is.

The next question addressed, are treatments tested in prospective randomized clinical trials effective, and we split them out into growth factor, bioengineered skins, and again, the preponderance of answers were positive. And lastly, we asked, are the randomized trials, are there standard levels of evidence, and the majority of people agreed with that question.

The next question we asked, are other treatments effective? And we included things like hyperbaric oxygen, hydrotherapy for debridement, and again, you can see that for most of these, the positive response was in the 50 to roughly 70 percent

of the time. And lastly, we asked them if markers other than complete closure should be used to determine effectiveness, and again, the membership of the Wound Healing Society agreed that reduction in size, healing rates, graftability and quality of life are important end points to be considered aside from wound closure in evaluating treatment modalities. Further, the question was internal comparisons to other treatment modalities such as established care, retrospective analysis of expert opinion, what was their value in evaluating therapies, and again, most of these, at least 50 percent met the test of validity in the opinion of the Wound Healing Society membership. There are individual comments which we have included in the submitted forms, I will not reiterate them individually, and I thank you for your attention.

MS. UNGER: Good morning. I am Pamela Unger, a physical therapist and a certified wound specialist through the American Academy of Wound Management, and I presently serve as the president of the clinical electrophysiology and wound management section of the American Physical Therapy Association, which is who I represent today. The American Physical Therapy Association has about 60,000 members

including physical therapists, assistants and PT students. More importantly, I am a clinician that operates a physical therapy-directed wound care center that concentrates on the treatment and care of chronic and acute wounds in the outpatient setting. Now, I don't know need to discuss prevalence, incidence or barriers to wound healing, as most people have already reviewed those things this morning. We do all recognize, though, that usual care for wounds is provided across the spectrum of care, and physical therapists are present in all of these settings and are an integral member of this multidisciplinary team. Physical therapists provide and play a role in the assessment and treatment of chronic and acute wounds.

We strongly believe that CMS should expand chronic wound categories to include the post-surgical traumatic-incurred wounds, particularly with respect to the Medicare patient population, and those complicating factors related to healing. As a member of the multidisciplinary team, we do agree that cleansing and debridement, dressing, particularly at the conclusion of treatment to maintain, increase or decrease wound moisture that is ideal for healing, these patients are limited to interventions that are

supported by a larger knowledge base, but we need to utilize appropriate therapies. Certainly compression and off-loading also belong and have been addressed and will be further addressed by other colleagues. We have data out there that tells us the healing rates in the initial phase of intervention, specific to venous ulcers, pressure ulcers and diabetic ulcers. Therefore as clinicians, if we're not reaching those expectations, I would ask the question of CMS, why not institute things like electrostimulation, negative pressure, vacuum-assisted closure, as well as exercise, as part of usual care? Exercise promotes better vascular circulation and tissue health, muscle strength, as well as cardiovascular function. This intervention is crucial to all wound types mentioned and supports the preservation function, the prevention of health risks and increased quality of life.

In respect to the 30-day period, we believe 30 days is far too long to wait for this particular intervention. You have received a lot of information today and one of the things that comes to mind as a physical therapist who serves as part of that multidisciplinary team is there is an awful lot of interventions out there, and from my perspective,

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usual care may be different from other clinicians that are out there, because I have a specialized clinic and practice that offers my patients the most optimal care for good outcomes. When the final decision is made on usual care or the minimal standard of care, we truly believe that there will be a very large educational initiative that will have to be done to not only clinicians, providers of care and payers, but also to patients as to those wound care interventions that are necessary. Thank you for your time.

DR. ARMSTRONG: Mr. Chairman, ladies and gentlemen, I am David Armstrong, from (inaudible) and I represent the American Podiatric Medical Association. I also have the privilege of being on the national board of directors of the American Diabetes Association, so I sort of have an interorganizational thing going on in speaking to you.

I think I'm preaching to the choir when I mention that diabetes is an epidemic. There have been a number of people that have already mentioned this and were far more informed than I am. However, we also appreciate that the most common use for our patients with diabetes will be admitted to hospitals,

not for DKA or MI or CIA or whatever letters you want to string together, but for an infected hole in the foot, and we see these in sort of a cursory meta-analysis of data collected over the past several years.

This has caught the attention of a number of organizations, not the least of which is in the United States, but the World Health Organization and the International Diabetes Federation, which has declared this year's Diabetes Month, Diabetes Day, and even the year the Year of the Diabetic Foot, and there are a number of regional and international precedents that are focusing on this area, and I think it's about time, since we all know this is a significant health care concern.

There are a number of questions that you posed to us, we will attempt to answer some of these just very very briefly based on the information that we have. First, in terms of usual care for chronic wounds, there are really three basic questions that the pragmatic physician has to ask when dealing with the most common kind of injury he sees in diabetes, what are we going to take off the wound, what are we going to put on it, and how are we going to prevent recurrence. We don't have time to discuss the latter

two in our time together, but we can focus on number one. And unfortunately, this receives the least amount of attention in many clinical trials in this space. There are a number of modalities for which there are various levels of data to support. Most of the data actually is quite poor in this area; however, there are data that do suggest that two specific modalities, namely the total contact cast and the removable do seem to offload about as well as other modalities. However, the total contact cast seems to heal patients much better.

Now this is the preferred method for off-loading the foot but it is exceedingly rarely used by most clinicians. It is difficult to put on, it's expensive and it takes a little bit of training. The removable cast does not receive as much attention; however, it does seem that the reason it does not treat patients as well is because as you heard earlier from several speakers, it seems that patients are taking it off and not wearing it; hence, the term removable. We have come up with a method of wrapping the cast and making it less easily removable. This is a very simple technique that seems now in two parallel studies just published a couple of weeks ago to be bearing some fruit in terms

of data and clinical common sense.
The issue is, I think is an area of common sense as we said, with much of the clinical trials that are happening. Very often we think of what to put on the wound before we think of what to take off of it. I think what we have to do in academics or in industry, and in just plain old clinical practice is to marry what we see frequently in the diabetic foot this equally effective if less easily removed off-loading, having the story that the data are now telling us.
And now we move forward. How do we assess the healing of chronic wounds? I think we've already addressed this question, and there are a number of methods to do this, and I will not just reiterate them in the interest of time.
I do not believe that recurrence is an issue that we should be addressing in terms of wound healing, I think it is extraordinarily important but I do believe it's something that should come at another session dealing with quality of care afterwards, rather than quality of care during the wound healing process, and that's a topic where others may feel free to disagree on that.
These three, four and five questions, the

answer to me is a resounding yes, that's the Cliff Notes version of that.

Finally, though, the last two questions, there are a myriad of gaps in current evidence and treatment, but again, where gaps exist, we have to deal with them and use common sense, and I think how trials should be conducted in the future, I think absolutely we have to have randomized trials. They are impractical but they are not impractical in some cases and they are extremely expensive in other areas.

There are necessarily, and unfortunately, the softer end points that you hear discussed, and there may be a place for sort of a touchy feely term, which is patient outcomes and experiences matter, and I think there may be some area of discussion there. I think we have to look at the strength of the evidence, not only the level of evidence as we move forward. And I think if we do that and we work together, not only in government and academics, but in industry and in clinical practice, if we do all this, I think that ultimately we will heal a lot more of these wounds and keep a few more legs on a few more bodies. Thank you, Mr. Chairman.

DR. LAREDO: My name is James Laredo and I

am here to testify on behalf of the American College of Surgeons. I am a surgeon in the division of vascular surgery at Georgetown University Hospital. I do not have any conflicts of interest to disclose. I'm going to address the evaluation of patients with chronic wounds and the process measures used to assess their healing. This is an assessment for arterial and venous insufficiency. Venous sufficiency is a dramatic driver of wound healing and yet, we find that a substantial portion of patients have not undergone these evaluations. The adoption of a process measure will help assure that this subject will be considered in all cases. Documentation of an arterial pulse examination should be present for all patients who have nonhealing wounds. Likewise, all patients with chronic ulcers in the lower calf should be assessed for the possibility of chronic venous insufficiency. This protocol is spelled out in the College's written testimony.

In order to assure quality, these vascular examinations should be performed in accredited facilities and/or by accredited vascular technologists. We believe that the data and knowledge gap is sufficiently powered through all

these randomized clinical trials to demonstrate that sophisticated and expensive new nonsurgical debridement methods addressing ulcers will result in faster and/or better healing compared to the older and less expensive treatments. Often studies are not advanced randomized clinical trials but case studies that show that one end point, a well healed wound. The conclusions regarding these therapies are more difficult to draw because these therapies are provided to a variety of patients and providers. Finally, many of these studies are sponsored by manufacturers or suppliers of these products and are therefore suspect to some degree, which emphasizes the need for independently funded wound care studies. We are aware that CMS will be issuing guidelines and protocols for evaluating treatments in the near future. Thank you.

DR. OVINGTON: Good morning. I am Lisa Ovington. I am currently a medical scientist liaison with Johnson & Johnson Wound Management and am speaking on their behalf, as well as past president of the American Academy of Wound Management, a national organization which administers an examination and certifies the fund of knowledge regarding wound care for multidisciplinary test-

takers.
I really want to speak to the diversity of comorbidities and contributing conditions to the failure to heal in many types of wound technologies that have been alluded to by many of the speakers this morning. Wound healing is actually a relatively young science. While we know a lot about the wound healing process, we are continually and still learning about the various conditions and comorbidities that basically derail the various processes that result in what we call chronic wounds, and regardless of whether these wounds have the underlying etiology of being diabetic foot ulcer, pressure ulcer or venous ulcer.
I wanted to share with you this morning a tool for teaching that was developed by a panel of clinicians and scientists sponsored by Johnson & Johnson, and three of the scientists have addressed you this morning at the podium. What the tool does is take into account some broad categories of conditions of comorbidities that may not have caused a chronic wound but that will definitely impair its healing process.
The graphic that's shown here is a series of concentric hexagons delineated by color related to

broad categories of factors. This is the tool itself. I realize this is hard to read from where you are so on the following slides I have kind of broken out some of the factors on each frame. Here you see systemic or patient factors, some of which were alluded to by Dr. Warriner this morning, many of which you may not be able to change, but which need to be assessed and if possible addressed in patients to optimize healing and really to optimize the performance of basic wound healing modalities. The next ring focuses on physical aspects of the wound itself or the limb that contains the wound, which have been shown to impact wound healing. In the center of the ring we really go down another level and start looking at macroscopic and microscopic aspects of the wound, biochemical, cellular and molecular factors that can impair the wound from healing. These are some of the newer conditions that have been discovered in the research agreement that have an impact on the wound healing process, not all of which can be addressed, but many of which we can, all of this to emphasize that there are many conditions that impair wound healing and that cut across etiology and contribute to the presentation that presents challenges both in

clinical management as well as in the objective evaluation of new modalities designed to expedite the healing of patients with these wounds.

We think that this diversity of factors really speaks to a number of issues. The diversity of clinicians that may be necessary to optimally manage a patient. The diversity of products and technology that may have a critical role to play in expediting healing in these patients. And the challenges in the standard way randomized controlled trials are done, as was alluded to, most clinicians participating in randomized controlled trials are forced to use a single modality from start to finish of the healing process in a patient for 12 weeks, 20 weeks, 24 weeks, and this happens very rarely in clinical practice. Clinicians are more and more using a diversity of products and technology either sequentially or simultaneously to expedite healing in patients, and I think that this argues, again, for an adjustment in the way we run our trials, and the subsequent improvement as a result of these modalities as described by Dr. Horn may be a very valuable modality in trying to assess the relative importance or relative usefulness of the various products and technologies and the management of

different types of patients. So, thank you.
MS. STOKES: My name is Maryangela Stokes, and I am a representative of JUZO, a Julius Zorn company which manufactures compression dressings, compression stockings, and gloves, and I would like to address the committee today regarding prevention of recurring vascular ulcers by wearing graduated compression stockings.
As we found out, the cost of treating ulcers primarily in the Medicare population by Medicare is phenomenal, especially considering that up to one percent of all adults will develop a venous leg ulcer at some time. The goal of compression treatment is to control symptoms, promote healing of ulcers, and to prevent recurrence of ulcers, and restore normal ability to walk.
In the Cochrane Library, Issue 3, 2003, an abstract review prepared and maintained by a collaboration states, the majority of leg ulcers that are venous in origin are caused by high pressure in veins in the legs. Prevention and treatment of venous ulcers requires reducing the pressure whether by repairing the veins or by applying compression bandages or stockings to reduce the pressure in the leg. The vast majority of venous ulcers are healed

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using compression bandages. Once healed, they often reoccur because a patient didn't continue compliance with compression bandages, stockings or socks in order to prevent recurrence. Compression bandages are often applied for ulcer prevention. Is there an optimum pressure to prevent recurrence of pressure ulcers? A search of 19 databases in June of 2000 reveals the following randomized controlled trials: No trials compared recurrence rates with and without compression, unfortunately.

One trial, 300 patients, compared high or type three compression therapy with moderate class two compression therapy; an analysis found no significant reduction in recurrence at five years follow-up with those using high compression compared with moderate compression hosiery. This analysis would tend to underestimate the effectiveness of high compression hosiery because a significant proportion of people changed from high compression to medium compression hosiery. One trial, 166 patients, found no difference in recurrence between two types of medium compression hosiery. Both trials reported that not wearing compression hosiery was strongly associated with ulcer recurrence and is

circumstantial evidence that compression reduces ulcer recurrence. No trials were found which evaluated compression bandages for preventing ulcer recurrence. The maxim that prevention is better than the cure holds true for venous ulcers. We respectfully request that you consider the addition of class two and class three graduated compression stockings to be allowed by Medicare for the prevention of recurring vascular ulcers. Thank you.

MR. GATEWOOD: My name is Joseph Gatewood, I'm here on behalf of AdvaMed, the Advanced Medical Technology Association. AdvaMed appreciates the opportunity to provide comments to the Medicare Coverage Advisory Committee on the topic of usual care for chronic wounds. We commend CMS and the committee for holding these meetings to increase the knowledge and understanding of the scientific and clinical rationale behind the effective management of chronic wounds. AdvaMed is a trade association representing more than 1,100 innovators and manufacturers of medical devices, diagnostic products and medical information systems. Our members produce more than 90 percent of the $71 million of health care costs for wound care products in the United States.

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Chronic wounds are a major concern of the health care system, obviously we have heard a lot about that today. There are an estimated five to seven million complex or chronic wounds in the U.S. with an annual cost to manage some of these wounds over $20 billion. Chronic wounds take weeks, months and in some cases years to heal, and they occur disproportionately in the Medicare population. After a diagnosis, they must be provided the appropriate intervention. Wound care begins with accurate diagnosis, alleviation of causes for tissue damage, and providing care interventions and treatment for the wound care.

Usual wound care interventions involve management of the wound and reducing tissue damage, and are more detailed in the full text of my comments. For recalcitrant and chronic wounds, usual care may not result in healing and in these cases, advanced wound care approaches may be needed. Clinical efficacy is supported by data, and usual wound care is supported by a combination of randomized clinical trials, outcome studies and case studies as cited in the full text of my comments. Although AdvaMed believes that while usual wound care has sufficient evidence of effectiveness,

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not all assets in what we consider usual wound care are adequately covered by Medicare in all health care settings. Further, since the healing process of chronic wounds often occurs over a longer time frame than the period of time a patient is in a particular care setting or pain setting, advanced medically safe technologies that produce cost effective benefits and superior outcomes in the long run are often at a disadvantage.

Providing access to usual wound care that can effectively heal chronic wounds is essential, since the Medicare population is more prone to chronic wounds than the general population. Payment policies that do not account for or provide access to this effective modern technology may eliminate or curtail access to effective treatment under certain circumstances. Equal access to evidence-based advanced wound care technologies across all care settings is cost effective to the health care system and would benefit these patients.

Wound care must be shared with CMS's common goals of continuous improvement in health outcomes and lower total costs of care through the use of evidence-based practices. AdvaMed has been involved in two initiatives to help meet these goals,

including revisions to the surgical dressing policy and creation of a wound severity index. I would like to thank you for your time and attention to these important issues, and I commend the remainder of my written comments to the committee. Thank you.
DR. DAVIS: I would like to thank all of the speakers from this morning for the excellent information that they provided to us, and also for sticking to the two-minute time frame, which has gotten us back on track. We now have half an hour scheduled for questions to presenters by the members of the panel, which would include any of the presenters scheduled, and of the public presenters. Yes, please.
DR. BREM: This concerns the point of off-loading. It sounds like it's a controversial point that people need to be off-loaded. In our clinic it would be impossible for somebody in New York to come in and not be off-loaded immediately with presentation of a diabetic foot ulcer. It's reimbursed by Medicare, Medicaid, no question about it. The work that we're doing in the field is how to do it better, but is that not the case in other states.
DR. DAVIS: Could you please identify

yourself, just to help with the transcribing?
DR. LAVERY: My name is Larry Lavery, representing the ADA. I think, I mean, I've spent my career in tertiary wound centers and often the wounds that I've seen that have been around for 20 or 30 or 50 weeks are not off-loaded, and I think if you ask other people on the panel, all of their observations will be similar. I mean, they are sitting around talking, discussing those problems. And I think the two things that I see commonly for wounds that fail are people that aren't off-loaded and people who have never had a vascular assessment.
DR. BREM: But CMS can't mandate people to do their job correctly, but it is available. If a physician or whoever else is treating the wound wants to do their job, the question is, the implication is that it's not covered.
DR. LAVERY: I think you --
DR. BREM: I mean, we can offload any way we want for anybody we want any time we want. Is that not the case anywhere else? I mean, every Medicare and Medicaid patient -- I agree with you, it's horrific and commonly, and no less than ten times in a day on a clinic day we will see somebody with it ready for amputation, was treated for years

somewhere. Everybody agrees with the problem, but the solution seems to already be in place by following your work and publications, that we are off-loading. So the direct question is, is there a problem in that off-loading is not covered? Because it's a simple solution and it is being practiced or should be practiced.

DR. LAVERY: I think for a number of forms of off-loading, it's not reimbursed. I don't think removable casts are reimbursed for wounds, I think they are reimbursed by CMS for fracture care, but not for sprains or ulcer care. And I think for the general community, total contact casting, to get reimbursed in Texas, I can tell you the reimbursement is about $84 for a total contact cast, and the materials are about 40, and the time commitment is quite high. So we're probably one of the few centers in central Texas that do full contact casting because it's technically demanding.

And so, I mean, I don't think it's controversial if you should offload a foot if it has a wound on it, but I think it's not done in private practice because physicians often unfortunately do things they get paid for and don't do things that they don't, and sometimes people don't do the right

thing.
DR. BREM: Absolutely.
DR. ARMSTRONG: I'm David Armstrong from Chicago. Most places, you're giving patients Cadillac care, and I think here again, maybe once in a while in your clinic you're off-loading every single one of them, either with a removable or total contact cast, with or without approval. The fact of the matter is that around the country, indeed around the world, contact cast, while it may be our favorite method of off-loading for the foot, are not used very frequently. In fact, I'm sure those data may be available to you, and they are paid for. I don't know how well they're paid for, God knows I'm not a billing expert. But what I can tell you is that many of the open methods that with some modification do seem to work well if they are made less easily removable, are not reimbursed well.
And we are here today talking about many different forms of wound care, but the one that's most talked about is off-loading and when it comes to foot service, they tend to compromise where the rubber meets the road in the office setting, because this is so poorly reimbursed and people get enamored with high technology, which is very effective, but

frankly, only when married with common sense off-loading and debridement as well.

DR. KRASNER: Diane Krasner. I think the longer you're in chronic wound care the more you respect McDonald's, because it is really hard to get consistency across the continuum of care. I'm reminded of a comment that a British colleague of ours made when he came to visit the United States, and he said that the problem with wound care is that there are centers of excellence in a sea of mediocrity, there are islands of excellence in a sea of mediocrity. And so our challenge, every one of us as we move forward in trying to figure out how we're going to spread the knowledge and the evidence is to make, to assure that there is a minimal standard of usual care that's accorded to all patients in the United States who have chronic wounds.

DR. DAVIS: Dr. McNeil.

DR. MCNEIL: I'm not sure who to address this to, so whoever wants, please answer. I understand from the remarks of most of you that you addressed in some form or another the data associated with the usual components of wound care, including the off-loading. A number of you also addressed the issue of other modalities that might be important,

and two of them that were mentioned several times in both vehicles included electrical stimulation and negative pressure, and I don't think that I heard any data supporting the use of either of those in your presentations, written or oral. And I wonder, since they seemed to generate some enthusiasm, if you could address why they would be useful and what the underlying data are.

MS. UNGER: This is Pam Unger. I think the reason that there wasn't a lot of data given in that aspect was that the Alliance group had determined that that wasn't in most cases usual care. I think some of the other reasons that there was not data presented was that since we received the national coverage decision in electrical stimulation, the criteria placed on that was the patient had to have the wound for 30 days and the patient had to have received standard care for that 30 days demonstrating non-healing, at which point you would be able to intervene.

The point I would like to make in that particular case, I have had patients that arrive in my arena that had had their wound for way more than 30 days but they had not had standard care for 30 days. Yet, I know initially looking at that patient

what they need at that point is electrical stimulation, but I'm held to a criteria limiting me to 30 days, because that's what the national coverage decision states.

From the perspective of pressure therapy, that being something that we do primarily in acute care, but because of the mobility of our patients and when our patients move to a health care system when they are in an advanced phase. Many of our open surgical wounds that are not closed become candidates for pressure therapy, and that is done at home and coming in in an outpatient arena. Again, we intervene immediately but we don't have the data, because we haven't had in the past any method from a clinician's perspective for billing for the work associated with that procedure.

We understand that there, again, are policies that pay for the supplies, but the clinicians themselves have not had any method or process for reimbursement. So while in clinical practice, which is one of those common sense type things, we treat chronic wounds and we're doing as Diane said, in the islands of excellence where we're giving them excellent care, that should be part of the care that you provide them with right away.

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Because of the conditions your patients present with, the chronicity that's there, we end up having a dilemma of not having enough data being presented at this point in time.

DR. MCNEIL: I want to be sure I understood what you said. We're going to be asked later in the day to answer the question, are there other modalities that provide health benefits beyond usual care, so that's a question that we have to answer.

MS. UNGER: I understand your question.

DR. MCNEIL: I haven't asked it yet.

MS. UNGER: I'm sorry.

DR. MCNEIL: So the question I'm asking is, I know that there is a list of other modalities, but I didn't quite understand from your response where the data existed, whether these modalities should be used if a patient truly has the true armamentarium of whatever ingredients are used to treat him in the initial phase of chronic care, or whether you throw them in at the end because somehow the initial treatment had been botched. So maybe you could give me the data for that.

MS. UNGER: Well, I don't know that anybody has actually prepared that data. I can only

tell you from clinical experience my preference and what I believe is clinically best for the patient's outcome. If the patient presents with all the signs and symptoms, and it's required or known from clinical experience that the patient will benefit, I think it should be part of usual care not to wait for 30 days when it comes to negative pressure therapy, when it comes to electrical stimulation or when it comes to exercise. Now we could go retrospectively in my clinic and come up with data, we have about 11 years of patient data relating to electrical stimulation, negative pressure and exercise, and certainly could produce some information. Today I can't present anything to you.

DR. MCNEIL: Okay.

DR. DAVIS: I wanted to just mention for the record that Dr. Black has joined us after a cancelled flight, so welcome, and would you introduce yourself and tell us of any conflicts.

DR. BLACK: My name is Edgar Roy Black. My clinical background is in primary care, internal medicine. Currently I am the chief medical officer for the Rochester Excellus Blue Cross Blue Shield. And other than my contacts with various folks pertaining to my previous role as medical director, I

have no conflicts of interest.
DR. DAVIS: Thank you. Yes.
DR. BARBUL: Adrian Barbul. I want to go back to Dr. McNeil's question because I think it raises some important issues that were touched on before. The (inaudible) dressing, an appropriate paradigm, for example, that if one applies a standard of wound closure to that particular treatment modality, I am not aware of anything that would show it to be superior to gauze.
However, as a clinician, I can tell you that thousands and thousands of patients and their families have had their lives made much more comfortable using this modality and its ability to control secretions and whole wound environment in a manner that gauze does not accomplish. So it brings this whole issue of depending on how you look at a treatment modality rather than whether it necessarily achieves the one standard that's applied right now, which is wound closure, and that must be considered.
DR. DAVIS: Further questions?
DR. WARRINER: I'm Robert Warriner, from Houston, Texas, and representing the Undersea and Hyperbaric Medical Society. You had asked about the issue of additional modalities and when we look at

randomized trial data, those are carefully selected patients whose comorbidities substantially are limiting, whose wounds are typically well defined and of known severity. In fact, that's how the trials are designed, so that single factors can be assessed. Before I came yesterday, I pulled some data from three wound care clinics and I just want to give you a picture of what the real world is in relation to your question about 30 days time for what's usual care and the time for intervention.

A typical wound care patient at an ambulatory wound care clinic, mean age is 68, the number of comorbidities that that patient has when they present is 4.75 and runs anywhere from one to as many as 18, things like congestive heart failure, peripheral vascular disease, comorbidities affecting etiology of the wound, diabetes, and about 80 percent of those patients have a systemic inflammatory disease found in fact.

So those patients that we typically see that Medicare supports, are careful about providing coverage policies and payment, are not the patients typically addressed in the randomized clinical trials. These patients in fact are sometimes barely ambulatory, they are quite ill, they have complex

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medical problems, and to achieve successful outcomes relative to wound healing and limb salvage, involves a very aggressive management posture. Dr. Brem made that point I think very clearly, we have to be extraordinarily aggressive to assure best outcomes. And when we look at a mandatory waiting period for certain interventions in patients that by all available evidence have a high probability of continued wound healing failure, and in fact in the diabetic foot ulcer world it's well defined that the longer the ulcer is open, the more likely it will progress to an osteomyelitis not originally present, which is a major risk factor for amputation, and the longer the wound is open, the more likely we are to have a less favorable outcome. But we're locked into a 30-day very arbitrary standard before the other modalities that you alluded to could be considered. I think that if we were to do one truly important thing here today, other than to decide to continue to aggressively pursue this whole arena, it would be to look at eliminating the 30-day time base requirement and look more at the issues of the condition of the wound in the patient. There is some published data that we could look at that would give us guidance in that regard. I think that 30 days for

a diabetic foot ulcer consists of standard therapy only in a patient who has significant comorbidities and a high probability of failure by objective indications. But you shouldn't wait 30 days for a patient who should receive the other interventions that are not on the list of usual standard of care. Thank you.

DR. PHURROUGH: Before you leave, can I ask a follow-up question? Since you are proposing this elimination of 30 days, could you sort of outline -- you made a related comment that the randomized trials don't include the standard patients that we all, that you all treat and we all pay for, and we agree with that. Could you outline what would be an appropriate trial that would include all of those patients and that would give us some data that shows less than 30 days would in fact be beneficial?

DR. WARRINER: I'm not sure that an appropriate trial to adequately address those questions in fact can be developed, because we're looking at multiple comorbidities. The number of patients that would have to enroll in a trial like that is astronomical. On the other hand, there are several, not just the curative database that Dr. Margolis has looked at, there are several large

repositories of wound patient data that exist. I have one, a number of other wound care providers have them, that probably in total would include the number of patients included in that curative database or larger, and I think that careful analysis of that data may be the most reasonable way to give us direction.

And we have information about prognostic factors that are associated with wound healing data. Why take the patient who falls into that category, venous leg ulcer, large size, recurrent, long duration, without resolution, associated with (inaudible), why should that patient be in some 30-day holding pattern receiving standard therapy that's unlikely to produce an effective result, why do that, why not move that patient forward? I don't know how that randomized prospective trial assessing that issue would be developed, but a diabetic foot ulcer patient, deep Wagner II with malperfusion and abnormal pulse exams, abnormal arteriograms, some vascular intervention, is not the Wagner II ulcer that we see in those clinical trials that had to have normal perfusion, normal transcutaneous CO-2 values, no indication of significant vascular disease. So you're looking at a

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circumstance which our typical patients are not single etiology kinds of patients who have limited comorbidities. They are very complex patients at high risk of failure; they are or we wouldn't in fact be seeing them. I don't know if that really answers your question, I think the study would be extraordinarily difficult to do.

DR. DAVIS: Dr. Horn, did you want to jump in here, and Dr. Burke as well?

DR. HORN: Well, from my experience, I don't think these studies would be that hard to do. There are thousands of patients and when you collect data from what's going on in the usual practice and care, if people are doing this variation in terms of practice, or if they are not but you change the payment system to allow them to, but again collect data from the usual practice and care, you can measure and then subsequently control for and adjust for all or any of the factors that you and I and the rest of the group here would say would possibly be confounders in that, and gather the data to ultimately convince yourself that it is the best.

DR. WARRINER: Although a lot of that data collection would be retrospective initially, because someone would have to define the relative impact of

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those other factors in order to design some prospective look. And you had access to a defined, fairly large patient population. Most of this wound care is distributed amongst relatively small environments, relatively small numbers of patients at any one time. I think that in the ambulatory chronic wound world it's much more difficult to do that. I agree it should be done, I agree we should be looking at that data, but I'm not sure how we can prospectively look at that.

DR. HORN: It wouldn't be through a prospective randomized double blind study, it would be through looking at and measuring what is going on in care processes that don't have all those other screening --

DR. WARRINER: It would just be confirming data.

DR. HORN: And then you would do an analysis of those data and I think we could learn some very critical things that ultimately would really be able to show were causal to the wounds and their associated care.

DR. DAVIS: Dr. Burke, and then we'll take the next question.

DR. BURKE: Just two points. I mean, you

have a payment bias in your data. I don't know how you addressed the bias, who pays, and how you're going to adjust for that.

DR. HORN: Well, they're not Medicare patients.

DR. BURKE: If you're looking at wound care in the Medicare patient population with the coverage decision, then you've got a built-in bias that I'm not sure you can adjust for.

And secondly, risk stratification, the idea that we're going to treat, we're going to treat people based upon some risk stratification system, that it will mandate certain levels of treatment based on certain severity of criteria, is that it?

DR. WARRINER: Well, I think that is certainly an option. Bill, you can answer that.

DR. MARSTON: Bill Marston, Chicago. The question, I think leads to a common theme that we try to go to, hopefully fairly readily. As Bob said, I have been involved with companies as well that have multiple sites of care and data sets that I think Dr. Margolis has looked through, and I would propose that even within those organizations, even within those centers, there is tremendous diversity in the level of knowledge and care provided.

However, the consistency is way greater than that at the third tier, which is the community-based practice. And so one of the things that I would like to propose is the consideration for not only gathering that grass-roots knowledge base, needs, requirements, looking at databases like Bob Warriner's, mine and others, but then going prospectively. I mean, I do this in a long-term care environment, and that is exactly the kind of stuff we're doing in our facilities. We're doing this as sort of a demonstration project prospectively at a center of excellence that we can define. Like Dr. Brem said, every patient is off-loaded at Columbia. Well, that's where we need to look at off-loading, and that's where we need to take what we learn retrospectively from the mid-level practice which, again, is the wound healing centers across the country that are providing need-based standard of care. And then if there are things such as the 30-day moratorium, we can look at that in a prospective fashion, add some retrospective concepts in how to design it, but not in an RCT fashion, in a real world algorithm-driven center of excellence. And I would also propose that that needs to be across the continuum of care. If we look at

just the acute care hospital outpatient wound clinic and do not include or incorporate the subacute study, the home health agency, and make this into an entire continuum, looking episodically at how much does it cost you all to treat this person across from point A to point B, then I'm not sure that we're really going to be able to address it. Many of these modalities work, as Pam Unger spoke to, in certain instances in time, and we need to have the entire treatment time in order to collect that, so I just throw that out.

DR. DAVIS: Dr. Black.

DR. BLACK: Just curious, a question that I hope will help us somewhere in our discussion this afternoon. I'm curious about what information we have out there about the expected healing for these common wounds, the diabetic foot wound, pressure ulcers, leg ulcers, what do we know about when usual care is given, what percentage heal in a certain period of time? And I think Dr. Margolis, you began to address that somewhat this morning with your data. And then the second part to my question would be, and when that expected healing doesn't occur, does anybody understand that that was a failure of usual care or whether it was a misdiagnosis, and what were the barriers here? Do we

have certain expectations and if those aren't met, why, and what happens at that point?

DR. O'DONNELL: Let me just tee up that question, because we were not asked to look at efficacy, we were looking at frequency of various modalities. And the very problem with the randomized controlled trials, particularly in pressure ulcers and diabetic patients as brought out by other speakers, is it can be responsive for very short periods of time with fairly low healing rates. So to get that information, except from some of the venous trials where patients were in a trial for a longer period of time where the healing rates of venous ulcers with compression was anywhere from 60 to 70 percent in the Cochrane review, et cetera. You can sort of get at it for venous, but for randomized controlled trials in pressure and diabetic ulcer, because the period was so short, you can't really say a whole lot. Maybe Dr. Margolis would have something to say.

DR. BLACK: And just, if I could do a quick follow-up, I would think that this is also where we are mostly just talking about databases. I would think that most of the results, you could get a good enough answer from some analysis of the

databases that are available.
DR. DAVIS: Dr. Margolis?
DR. MARGOLIS: Can I be part of the public?
DR. DAVIS: Fair enough.
DR. MARGOLIS: We have actually done a meta-analysis on diabetic foot ulcers which is fairly open, and based mainly on studies that were done looking at thermograph and then at the control arm, and done in a full meta-analysis fashion, and also a meta-analysis for venous leg ulcers, again looking at the control arm. The problem with any analysis like that is, one, you need to adjust at the very least for reasons why they just don't heal, which is duration of the wound, size of the wound, and for diabetic wounds, how deep it is using various grading scales. A problem on the diabetes side is that the really deeper wounds, anatomically deeper wounds are often excluded from trials. So that's a problem with those numbers.
And things have changed over time, so it's really tough to know if a study that we did five years ago really reflects what's going on today. I can tell you from a recent cohort study that we just finished looking at the rate of healing in 20,000

patients, that there's a real change in the number of diabetic foot ulcers that's healed today as compared to healed ten years ago, but the primary emphasis was that although they're healing somewhat better, we're getting to them earlier in the course, so the healing rate is also much, much better. But the vast majority of that improvement is that we've gotten better at educating people or educating physicians, or doing whatever we could. So many of these are difficult to exclude.

There's also multiple people who have their own cohorts and databases, and you will see great disparity, and almost always the randomized clinical trial rates are the worst and the cohort studies are the best, and it also has to do with patient selection. Not every human being is going to volunteer for a randomized controlled trial, and although they may have fewer comorbidities, there may be something else which prevents them from staying in somebody's office and be willing to participate in a clinical trial. Based on the venous side, there is also discussion about getting to see about ten patients for a randomized trial and only being able to enroll one, and that's at least an indication of selection bias.

DR. DAVIS: Dr. Weiner, were you going to chime in on this issue or were you going to ask another question?
DR. WEINER: I'll wait.
DR. ENNIS: Bill Ennis, from the University of North Carolina. In answer to your question in relation to venous ulcers, the International Leg Ulcer Advisory Panel had recommended initial compression therapy for four weeks and then reevaluating the patient. If there wasn't satisfactory improvement, which we defined rather arbitrarily as a decrease in size by approximately 20 percent, that the patient should be either reevaluated or referred to a specialist. This was primarily done at the urging of the UK and European members of the panel because they had already defined nurse one clinics with relationships to specialists. The members of the Canadian and the U.S. groups felt that they will heal if the patients get initially compressed well; it's because they don't get compressed well, that's why they fail. So the reassessment wasn't really what we should focus on, as much as education of our primary care people.
SPEAKER: Hi. Paula (inaudible) from Curative. In your packet you did get a complimentary

issue with the Margolis study that he spoke about dealing with traditional care. You also in your packet show (inaudible) what's called a shadow analysis where we took the intent to treat and then followed up with a study there. And then finally I put in your packet our outcomes report for 2004 and it showed about 70,000 wounds, and we just passed our millionth wound.

So the point is, to answer your question, if we couldn't find what outcomes you were looking for and we tracked it, we could go back into our database and get that information, we just need to understand what you're looking for. Did that answer your question? Okay.

MR. NICHOLS: Good morning. My name is Kevin Nichols, I'm the CEO of a medical device company that actually came to visit CMS a couple years ago with a 510(k) product that we actually raised money to go out and conduct a 23-site randomized trial on diabetic foot ulcers, 31 exclusion criteria. We maintained the protocol that the FDA had required for 12 years. We did obtain statistical significance. I met with Dr. Sean Tunis a couple years ago. Quite an experience.

The reason I wanted to stand up here today

was the fact that if you don't provide higher degrees of reimbursement you will not get the new innovative technologies. We've got a product that obtained the P values that you were describing in an RCT, actually I would say to Dr. O'Donnell's data, we exceeded every one of your expectations. Physicians don't want to adopt it as rapidly because the reimbursement is so low, and frankly, the venture capitalists won't continue to invest in this market if you guys don't step up and do something about this. There is this paucity of data because these studies are hard and they are extremely expensive. Ours cost about $7 million. I encourage you guys to really think about this. We've got technology at my company that can save you billions of dollars over the next 20 years and I don't know how well it will fare in the adoption process because of the reimbursement.

DR. DAVIS: Dr. Weiner.

DR. WEINER: Jumping back a few comments, sorry for the interruption, but back to the public health aspect. I'm always very interested in population-oriented studies and studies that aren't necessarily linked to the vagaries of various payment systems, be it Medicare or Blue Cross or Medicaid. Is there any group clinician in the room that,

whether or not it's Kaiser Permanente or Group Health, or VA or perhaps the military, that could comment, or perhaps in another country, that could comment on how they do things differently, not worried about Medicare reimbursement, but just based on the evidence and what the views are in a payment-free system, if you had unlimited resources, what would you do?

DR. LAVERY: Before, in a previous life I was medical director for a diabetes disease management group that now has a CMS demonstration project or two in Texas and Tennessee. And when we posited that program with private practice groups in Texas, we were basically able to say, you know, we're just going to do what's right for the patient, similar to what we talked about with off-loading, if the patient needed it, we were going to do that. And the philosophy was that we were going to save money by healing wounds faster and keep people out of the hospital, no matter what the treatment costs. So we have a database of about the first 1,700 people we evaluated, all those looking for hospital stays, wound healing, applications, and infections, that we were able to separate who pays us and when and why. And I think probably that exists

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in other academic medical centers, maybe Columbia. The group I'm in now, we probably spend in orthopedics and in surgery $100,000 for removable cast boots that we don't get reimbursed for because it's the right thing to do, and I think in those centers that have that opportunity, you know, the line is blurred between payment issues.

DR. ENNIS: Bill Ennis again, from Chicago. I would like to address the question, because this is basically paramount to what our team has been doing for the past 15 years. I'm a member of Advocate Health Care in Chicago, probably the fourth largest not-for-profit system in the country. It consists of eight hospitals, three of them are academically affiliated in the community. The program that I started eight years ago at the facility was fairly overreaching on their part. The way it works is that we are all employed physicians in the Advocate network, everyone on the wound care team is, whether it's nurses or technicians, so we're not tethered to any modality, any treatment protocol, anything at all. We are charged with prevalence and incidence studies, obtaining magnet certification for our hospitals and nurses, reducing nosocomial wounds, reducing the cost

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to our hospitals for the inpatient side of wound care.
Patients come through a center, an outpatient hospital-based wound care center, and then are brought into clinic, either the PT department or the outpatient setting. If they need admission, those admissions are run by the wound team as the quarterback. Specialists that are in private practice, vascular surgeons, plastic surgeons that make their living doing flaps, skin grafts, et cetera, get to participate and are on that team, however, for that procedural event. As soon as that event is over, that proceduralist has completed their component of care. We have aligned with but do not own a subacute care facility across the street from the hospital, which is a 35-bed dedicated wound unit that is staffed very differently than the nursing issues that you've described, for obvious reasons the flexibility of care is slightly higher. That transition from the hospital to subacute back and forth has two main boards where we follow these cases across the street.
I've got seven years and about 1,200 admissions worth of contribution margin data, actual costs, directs and variables for all those

admissions. And we can track over time the healing rates which we've already published, ranging around 75 percent for all comers, all patients. It's that type of longitudinal study that we have also included in our home health department to train them so that there are specific nurses that only do that home care for those patients. It's a virtual organization in fact because we no longer own the home health agency, but we find that because there is such a sub-cohort, all eight hospitals use the same wound care products, the hospital formulary is involved.

$1.5 million was spent to purchase self-powered air mattresses for every admission, so that there is no question about what the support surface is, everyone is on them. The only decision to make from there is whether or not to move up to an alternating air mattress.

So these things can be done, but I tell you, although I know you say it's easy to do, Dr. Horn, I think it's difficult to do when there are economic disincentives and economic, just malalignment. But when there's economic alignment of the centers, I think this thing can be done, but I think it has to be done in a socio and academic environment such as Dr. Brem's or myself, where one

team is in charge and I am on the line for excessive admissions or costs. Someone has to be accountable. So that's one of the things that is missing from the modalities and treatment protocols.

DR. DAVIS: I have Dr. Goodman and Dr. Margolis, and a couple of other people who probably wanted to reply to the earlier question. Do you want to chime in on this?

DR. GOODMAN: I was going to ask another question.

DR. DAVIS: Okay, let's have the response and then we'll move on.

DR. KRASNER: Diane Krasner, just a very brief comment. I think instructive from the United Kingdom is the work of Steve Thomas, who runs a group called Testing Dressings Laboratories, he has done that for over a decade, preparing dressings within categories. Before dressings get on the national formulary in the UK, they are tested in a consistent way across a category, so a hydrocolloid is compared to a hydrocolloid compared to a hydrocolloid. That data is published, Dr. Thomas has a web site, Worldwide Wounds, where that information is posted worldwide so that other people can share in that. I think that's a model for us as to the kind of work we

promote or aspire to do, but again, getting that consistency across our country is a difficult thing to do.

DR. DAVIS: Okay, Dr. Margolis?

DR. MARGOLIS: I have some work with UK databases and at least in terms of the rate of venous leg ulcers, in terms of the publications, the wound care centers do better than general practitioners. They claim in the literature that their wound care centers do much better than probably even the rates that are reported here. Having said that, if you look at some of the clinical trial data and look at the wound care center-based data from the UK and Europe, I don't really see it doing better than centers in the U.S. So from what's published, it appears that their system is doing better, but whether or not that's true, I'm not sure, because you don't necessarily see that in other literature. But patients certainly do get care faster, you see more uniform care, nurses tend to provide the care even to the patient's house in fulfilling that care.

DR. DAVIS: Dr. Driver, did you want to chime in on this?

DR. DRIVER: Yes. I work at a military medical center where we treat all branches of the

military, family members and retirees from all the western states as well as some other countries. What we've done is -- of course there is no incentive for dollars but there is an incentive to reduce amputations. What we have done is we designed a multidisciplinary or interdisciplinary department that is focused on limb preservation, and we set it up with the notion that we will collect data as outcomes, so we are trying to understand better what is driving the cost of care, what's driving the care. What we've done is we've taken, for example, the University of Texas Health Science Center Classification for Diabetic Foot Wound, broken it down, and we have extracted the data one patient at a time, looking at different levels of wounds. For example, what does it cost to treat a wound that is not infected versus infected, not just in dollars, but in care, product, et cetera.

DR. DAVIS: Dr. Driver, while you're there, if Dr. Goodman will allow me, I have one question about what you presented. You had a comment that treatments may be effective in traditional clinical practice but then would not be found to be effective in a randomized control trial. Can you explain why you think that's the case?

DR. DRIVER: Yes, sir. Often in RCT trials, as you know, they are heavily organized and monitored and structured to disallow many patients that would normally be in your clinic, first of all. Secondly, you might include investigators that are not trained in wound healing or wound preservation, so on and on it goes. Our clinics, most people that treat wounds outside of the wound care community do not have the resources that we might have in a trial, so perhaps they might try a magic goo, but they have no ability to offload, maybe they don't have the experience, maybe they don't have casting material, maybe they don't even have boots.

DR. DAVIS: Thank you. Dr. Goodman.

DR. GOODMAN: I heard a few comments about the difficulty of doing RCTs in this area because the patients are so complex. I don't understand that at all and I want some clarification. The whole point of randomization is that you balance off in the two groups the different, the multiple different factors. It sounds to me like some of the problems involve the very strict eligibility criteria, so what I would like to hear is why couldn't there be RCTs? And I don't understand why they would have to be any larger than any normal RCT would be, with very broad

eligibility criteria in a normal practice setting where you introduce only one or two practice variations, for example, making certain technology available at 15 days versus 30 days, that was the only thing, everything else would be at the discretion of the caregivers under some protocol conditions. That's the first question. So, I would like to hear why RCT as a methodology isn't appropriate and why we couldn't do it as a practical matter, that is, keep all the other aspects of care unaffected or let it be modified according to the course of admission and see if the introduction of a particular technology or modality at some particular point actually made a difference.

And the second very closely related question is just informational, and maybe Dr. Phurrough can answer, but what is the source of funding for randomized controlled trials other than industry? Is there any motivation for studying the practices of usual care here? There's no national institute of wound care at the NIH like there is for various diseases. That would affect a lot, I would think, the "structure" and incentives to design a trial.

DR. BARBUL: I'll take the second question

first. Adrian Barbul. First of all, the NIH for the last 15 years has said that it encourages very much human submissions. I've been funded by the NIH for the last 25 years, not a single human study has been funded and there have been human studies that have been turned down. If you remove the human studies and the same plan gets resubmitted, it gets funded.

DR. BREM: So you do a study in what, mouse?

DR. BARBUL: You submit a study in rats or mice, or whatever, correct. So I think that there is a disconnect between the stated goal versus how it actually gets funded and how the study sections view it in my opinion, but that's very limited.

Going back to the randomized trials, I think it all starts with (inaudible) of industry, and if you're going to look at the effect of a single product, we find that minimizing the noise in that study, we try as much as possible to reduce it to one variable, which is the treatment. The kind of studies that you're suggesting, which are population-based studies to see how people behave, are not going to be sponsored by industry because it doesn't bring them any information that as far as they are concerned is worth having. And I think that

there have been several both subliminal and sort of forthright messages today that we do need a different response mechanism or funding mechanism for these studies in order to obtain data that's meaningful and helpful at the policy level.

DR. ARMSTRONG: David Armstrong. Just to emphasize what Professor Barbul just said, this field is a fairly large public health issue now, but it's treated by NIH and by other federal not-for-profit entities as an unwanted foster stepchild. And I think all of the data that you see about modality X or Cytocon Y is funded entirely by industry. I think your point is really brilliant when you get to the core of the procedure. The sample sizes that you're seeing here pale in comparison to what you might see for a statin or something very large which is a known public health issue, where issues need to be answered.

I think what has to happen is, I absolutely think we need to continue the innovation we're seeing with industry but I think an infusion from not-for-profits and from the government, which may be happening, I'm maybe a little more sanguine than Professor Barbul, is the way forward here because there's no way we can get at these questions

that you're asking, these pragmatic questions don't fit in a zero gain setting like Medicare in terms of funding until we up the ante.

DR. KRASNER: I'm Diane Krasner. There's another issue related to who the people are that are attracted to wound care and wound care research, and it's not glamorous, it's not well respected by other members of the health care community. You see a select few here who have committed their life's work to chronic wound care and understand this issue, but we are a very small group of people, and we all know each other because we've all been doing this for 20, 25 years. But you know, the support isn't there as it is in cardiology, and that's a real problem.

I know of a first dressing study that is currently underway where they decided to allow all comers across 12 countries with their usual care, comparing it against one dressing, and their intent is to enroll about a thousand patients, and they are about two-thirds of the way through. And there is such variability in so-called standard care, I don't think they are going to be able to do a statistical analysis because they are going to have to triple their number of enrollees, and the company that's sponsoring this one study can't afford to do that.

So you know, it's a great idea, but the variability of standard practice across 10, 12 countries is so great that it has just been impossible.

So you know, Dr. Tunis has written about using cohorts plus MDMC sets to kind of create big retrospective or even prospective studies, and I think there is hope for that if the definitions of wounds are such that you can get meaningful information out of that database. I tried to do it when I was a young doctoral student at the University of Maryland, I came here and I tried to tease out the incidence of skin breakdown in pressure ulcers, and I couldn't do it, and I said I would just do something else.

DR. DAVIS: Dr. Phurrough?

DR. PHURROUGH: Let me see if I can answer Dr. Goodman's question. I appreciate you painting a target on me, Steve.

(Laughter.)

DR. PHURROUGH: CMS is a payer, our job is to pay for health care. Congress has not given us broad resources or authority to pay for research. They have given that 20 to $30 billion a year to NIH who as we have heard, likes to look at rats and mice.

(Laughter.)

DR. PHURROUGH: There are options we have to pay for clinical costs in trials. We have no ability to pay for the administrative costs of trials. In those instances in which we do have the ability to pay for clinical costs, in many cases we don't have the ability to pay for what it is that is experimental within that particular trial. So if it's around a specific technology service, we may commonly pay for other costs within that trial but not the administrative costs or that specific investigational cost. So if you were doing a trial on platelet growth factors, we may pay for all of the routine care of the patient, but we would not pay for the growth factor.

However, over the last few months we have released a few of our coverage determinations where we have said we don't think the evidence is sufficient at this moment to say that it meets our standard for providing broad coverage, but we will in fact pay for the particular technology as long as it is involved in some kind of data collection program. We have done it in through the National Cancer Registry, a couple PET decisions, and some specific trials, in one case trials that were identified by NCI. It's a new concept, it's a concept that may fit

here, but it's a concept that we have to find those parameters completely and in fact at some time in the future, the near future hopefully, produce a draft guidance document that explains how we may try to move forward with this particular concept.

Having said that, I would like to add to Dr. Goodman's comments that it does seem to me that there are, compared to a whole list of other kinds of trials, some simple means of in fact answering some of these questions that don't require huge bureaucracies that are sometimes required of trials.

I think when we say randomized controlled trial, we sometimes have misconceptions of what in fact may be complicated trials, because many of the randomized trials that are used to determine the efficacy of certain technologies are very complicated and do require a lot of screening of patients.

In this particular case we are looking for patients who aren't screened, the patients who walk into your door on a regular basis and are just committed to one group or another group, on a fairly simple basis. That doesn't mean that they are cheap trials, I'm not sure that exists, but I'm sure there certainly are simpler ways to do some of that, and we are interested in paying for the clinical costs

involved in that and we are certainly interested in, are there ways that the administrative costs can be made as low as possible.
DR. DAVIS: Here's what I would like to do with the agenda. We have four people who have requested to speak during the item on the agenda labeled open public comments, so if we adhere to our two minutes per speaker that would be eight minutes, and I want to do that before we break for lunch. After lunch we're scheduled to have open panel deliberations from one to 3:15. We may not need that whole period of time, and what I'd like to do is come back after lunch and allow us to continue to ask questions of presenters. Even though as planned, this would just be a closed discussion among the panel. The last time we had an MCAC meeting we extended the questions to the presenters to the after-lunch portion of the meeting and I think that will work fine. So, for those who can stay here until the afternoon session, we will continue this for a while longer after lunch, but I do want to take the people who signed up for open public comments before we break for lunch.
Now, if you have a quick comment?
DR. MARSTON: A very quick comment. Bill

Marston, from the University of North Carolina. A simple trial still requires submission to the IRB, requires consent of every patient you put in that trial, and that requires a huge amount of time, so that's a real detriment to doing those kinds of studies.

DR. DAVIS: Very quickly, please.

DR. WARRINER: I want to close the loop on the 30-day period. I just polled a group of experts in the audience because I challenge you to find a scientific basis of 30 days of failed care as a definition of wound chronicity. In fact, it's not the Lazarus article, which was the first article that fully described basic features of chronic wound healing failure, it was actually a concept that appeared in the late '80s, early '90s, in reference to a recommended interval for referral of patients to a tertiary wound care center. It had no basis in science, it was pragmatic, and yet it is being adopted as a standard definition, and I would challenge you. You are appropriately challenging us to develop evidence. My challenge to you is prove to us that 30 days of failed standard therapy represents an appropriate, clinically significant, beneficial definition to your beneficiaries, our patients.

Thank you.
DR. DAVIS: Thank you. Patty Smith is the first one on the list, and I would ask those who are presenting before lunch to introduce yourselves and mention your affiliation, if any. Thank you.
MS. SMITH: My name is Patty Smith and I am the current medical director for ATI. The comments that I prepared actually have been addressed quite frequently here with the presenters previously, but I would like to emphasize one of the points. There is a difference between good prognostic wounds and poor prognostic wounds, I understand (inaudible) and responds to the therapeutic interventions that we provide to the patients are going to be different in each patient and across populations and groups.
When we look at this issue of local care, I think that there is some confusion about local care versus wound healing, and I've heard even today the two terms used interchangeably when they actually are not. Local care is the application of a therapeutic modality at the wound site in order to get an outcome in terms of what's going on with the wound.
Wound healing is that process of nutritional support, off-loading, arterial assessment

and improvement, the whole host of making an appropriate diagnosis and following a projected wound care healing outcome algorithm. And we have a projection of what we want to get as an outcome that may take a wound therapeutic intervention that may be topical. (Inaudible) assess that one wound modality that may be better for just (inaudible). However, RCTs are designed to take the wound healing modality from the very beginning all the way through 52 weeks to the very end, across all the spectrums with inappropriate therapeutic treatment modalities.
So consequently, looking at the cost criterion or surrogate markers to look for granulation of tissues, the quality of granulation tissue, the quality of the wound condition, the change in the inflammatory markers may have to reiterate (inaudible) maximize the granulation, maximize the epithelialization is what we have to look for.
There was one question as a medical director that you asked about negative pressure wound therapy in terms of randomized trials. These trials are ongoing, but they are very difficult since a product may not go through the whole spectrum, but the request for the RCT (inaudible) and the outcome

at the end may not give you a statistically significant difference. If you use the modality for what it's designed to be used for and then take your (inaudible) intention to treat, it may be a surgical closure, it may be a graft, it may be bioengineered tissue, it may be something else, but if you put it in the trial and take it from beginning to end, you may get the answers to many of these questions.

DR. DAVIS: Thank you. Kathleen Schaum, I believe.

MS. SCHAUM: I'm Kathleen Schaum, president of Kathleen Schaum and Associates, and I thank you for the opportunity. I have the opportunity to work with many of the people in this room as far as providers and manufacturers who bring the technology and the knowledge to the wound care industry. And it's been amazing to me because this morning I heard us talking about usual care and I just really wanted to mention to you that there are some things we pay the physicians for and there are some things we expect and that we don't pay them for, and this is a labor of love for most of these people. They are very passionate about what they do and it's not a glamorous job.

Just to mention to you, we do pay them at

CMS for the initial evaluation of a wound care patient. And then after that, unless they do some very special thing like hyperbaric oxygen, or debridement, or compression, or skin substitute, or acute wound care management, which are all unique to patients, we don't give them the opportunity to get paid for the coordination of care. In fact, when they do debridement, we expect them, in that amount of dollars that they get, we expect them to pay for all of these dressings that they have to use and they have to acquire. We expect the same thing when they do hyperbaric oxygen. When they do compression, as you've heard mentioned today, if they are to do the multilayer compression system, the amount of dollars that they get paid to them for the work hardly will pay them to buy the products.

So I think we have a false expectation in what we ask them to do when they are coordinating care and what we pay them for. For example, we do not pay them to really do their ongoing coordination of care in the way that they really need to do it, and it's very very difficult for them to find a place, a code, or any way to get themselves paid for their work.

Dr. Ennis is in a very unique situation

where he gets to get paid a salary and gets to do what he wants, and that's the greatest thing ever and I applaud that. However, most of our physicians don't have that opportunity. I really feel that in their practices, they do not have the opportunity to buy most of the advanced products that we would like to see them use, because we expect that to be bundled into a very low level evaluation and management code, or we suspect that to be bundled into a debridement code, where they have to do the work, they have to buy the products, et cetera.

So in my opinion, what I hear them suffering from, and I see that every day in the work I do with them, is that this usual care, we have no way to identify that, and no way to pay them for that work. Then when that patient moves to a hospital outpatient department, if they're not being seen in a physician's office, if you think about it, and in these hospital outpatient wound care centers, there are five levels of care supposedly being given, but there are only three levels of care paid for. In addition to that, those levels of care expect them, again, to buy all of their products, these advanced wound products that they need to use. They are expected to buy those in the very small dollar amount

that comes to them, in a $50 or $60 range, which is very difficult for them to do.
In addition to that, there is a code called acute wound care management that many outpatient departments, we don't even pay for that in these wound care departments because it does not track to the APC group. So I look at this, I say oh, wow, this is really an amazing thing, we expect them to do a lot, but we don't have a way for them to acquire their dollars.
When the patient does move to the outpatient setting and they do go home, CMS has done a great job of paying for their dressings once they go home. We don't really necessarily need a national coverage decision for that, DMERC has done a wonderful job of doing a surgical dressing policy to pay for the dressings for the patient at home, but there is a problem when the patient comes into the outpatient department or the patient comes into a home health agency, or the patient comes into a physician's office. There is no payment of those products for them.
And -- okay.
DR. DAVIS: Thank, you, I appreciate it.
The next two and final two speakers before lunch are

Diane Krasner and Dot Weir, who spoke before, but are going to speak again wearing different hats, if I understand correctly.

DR. KRASNER: Diane Krasner, and I'm wearing my own hat right now. While beefing up the evidence for practice for chronic wounds is critical, I would like to address another issue that I believe is equally important, and these comments are based upon my experience for many years now as a clinician here in Baltimore and in York, Pennsylvania. It is essential that evidence and knowledge be translated for all clinicians in practice, physicians, nurses, physical therapists, everybody. You can have the best outcomes reviews in the world on compression therapy but if a patient in Baltimore has a venous ulcer and is not offered adequate compression therapy year after year after year, like the paradigm case in one of my patients, seven years in Baltimore, no compression offered, there is a problem, and it happens all too often. Within the last six months, I saw the worst case of an untreated pressure ulcer in my entire career. Admitted from a nursing home in York, Pennsylvania to the York Hospital wound care center. She was septic, delirious, and in excruciating pain,

and unfortunately the patient was beyond the point where we could help her and she died. Nobody at the nursing home had a clue. That's a problem. So it's not just about more or better evidence or knowledge, it's about translating the knowledge and evidence that we have into practice, so we can assure a consistent level of quality for the usual care of chronic wounds in this country. Thank you.

DR. DAVIS: Thank you.

MS. WEIR: My name is Dot Weir, and my comments will be short because Kathleen Schaum already addressed the dressing, but I wanted to go on record and say that this committee should also look at access. A national coverage decision, I never actually thought of it coming this way because for years now, since 1994, with the DMERC policy, it made a big difference in the access that my patients have to these products. I live in central Florida and have a huge number of what we call active adults, active older people who, because of their activity and the fact that they're not home-bound do not qualify for home care, although many of them could use that help. And if they're not qualified for home care or are not covered by Medicare because they're lying on a nursing home bed, they would not otherwise

have coverage for their dressings if we did not have the DMERC policy to fall back on, so that's made a huge difference in our patient population. But by the same token, I think we need to put in some sort of active support services. I didn't get to that part of my presentation today, but there is the NTRP, the ACPR, the WOCN, we know the clinical importance of addressing the external factors of pressure, shear and friction. And so, in order to prevent those kinds of external forces from culminating in the formation of a pressure ulcer, we have to look at active support services, and certainly we have the evidence at this point in time for use of these support services in the patients who we treat. Thank you.

DR. DAVIS: Thank you. We'll break until 1:10, and the CMS cafeteria is off the lobby, and I think they have the monopoly on food.

(Luncheon recess at 12:12 p.m.)

DR. DAVIS: Why don't we take a little bit of time to continue allowing members of the panel to pose questions to the presenters if they like. Any other questions that people would like to raise? Maybe I will ask one and wait for others to get warmed up a little bit.

We touched upon the issue of some patients, I guess, not being offered some main-line treatment, certain patients not being prescribed off-loading therapies, for example. Now another aspect of that is when patients are prescribed the recommended treatment but then don't adhere, and Dr. Brigido, did I pronounce that correctly, is he still here? Well, I will propose this and others may wish to comment on it.

He presented some data on one of his slides, one paper published by Knowles, et al., 1996, that indicated when given free of charge footwear, only 20 percent of patients wore the shoes. And then another paper by Armstrong, et al., 2003, a removable off-loading device was only worn during 28 percent of daily activities in patients with wounds. So there we get into a compliance issue, and I wonder if anyone might want to comment on why we apparently have some compliance problems with a device like this. Is it the discomfort of using the devices, is it a health literacy issue and patients not understanding what they need to be doing, is it a copayment issue, what is going on here?

DR. ARMSTRONG: David Armstrong, from Chicago. Obviously we have a little interest in this

area, having worked in the area of compliance issues, but we're specifically not focusing on the diabetic foot. When you talk about this issue of compliance with preventive modalities like shoes, you mentioned the Knowles study and some work we did fairly recently, about two years ago, with removable off-loading devices.

Paul Brand, who is an orthopedist by trade and ran the Carsville Leprosarium in Louisiana, a PHS hospital, said about 25 years ago that pain is a gift that no one wants, and it is absolutely true in diabetic foot. These patients will wear a hole in their foot just like you would wear a hole in a shoe. And so the painful feedback that they normally have is not there, and so these patients, while they look and dress like us, are not acting like us. And so this issue of compliance, it's probably not fair to apply to them because they're not going to behave in a certain way.

And if you put a big clunky device on them, most of them -- I've worn one of these on a dare from residents on various occasions and I can tell you, I hate them. They are big, bulky, they limit activities, sleep, whatnot, and to that end it impacts your activities of daily living, much more

than that hole in the bottom of your foot seems to do that.

And so many of these patients will take this device off, which is why a fairly simple modification to a removable cast, which by the way are really not utilized, are not paid for to my knowledge by Medicare for this specific indication, for wound healing, seems to, based on some very recent data, and I think you see the reason for this, just by increasing adherence to care, by wrapping it, making it harder to remove seems to help these wounds heal faster. That's probably why the total contact cast works so well.

DR. DAVIS: I mean, the point you made about not experiencing pain and so on, I suppose that's comparable to treatment of hypertension.

DR. ARMSTRONG: Exactly.

DR. DAVIS: I would think that if you show your patient, okay, here's what your ulcer looks like now, if you don't comply with this recommended treatment here's what it's going to look like in a month or six months, and here's what it's going to look like when you have lost half your leg, and the cascade. Are the patients not getting that education or are they getting it and it doesn't make a

difference?
DR. ARMSTRONG: If I may, Mr. Chairman, that is really a brilliant question and it does, how we get to these patients is very, very important. There is a very important work right now going on by Vilekyte, V-I-L-E-K-Y-T-E, and coworkers, who are looking now at educational paradigms and how they may affect people with diabetes and neuropathy. It does seem, by the way, and again, gathering these data are crucial, but it does seem that frightening a patient initially seems to have the most impact on them initially. That's open to some debate in the literature, but I think there are more and more robust data addressing that specific question about how do we have sensory substitutions, if you will, to get past this issue of teaching these patients. But again, even with that, there is this disconnect and these patients, they don't consciously accept -- this is very touchy feely in my view, but they don't consciously accept, they kind of disconnect themselves from their limb, and it's very difficult to articulate, but you see that in the clinic on a daily basis.
DR. DAVIS: Thank you. Dr Brem.
DR. BREM: I can tell you from studied

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personal experience the difference between compliance in off-loading across the board. My patients did not use to offload, and I was convinced it was because they were not being compliant because that's exactly what I was taught. It took me about six years to learn how to talk to them properly, how to educate them properly, mostly how to set up an entire room with them where we could spend a couple of hours explaining to them what it was, told them what could happen to them. There's no question about it, if they have an ulcer, you're absolutely correct, they are not going to put the shoe on, they're not going to put whatever you put on them 100 percent of the time.

But it's really, you know, 93 percent of the time people with diabetes, what about the hemoglobin, A1c, hypertension control? I mean, we have to accept that as a field and move on. They are not complying often because, at least in my practice, because we didn't spend the time nor were we educated on how to do it properly. Once we did that, I made that service available and I have, you know, I don't speak the language, so we have interpreters. There are many, many reasons, but the failure was virtually exclusively mine. As a program director, I'm

embarrassed by that, but that's probably the biggest variable.

DR. DAVIS: I mean, it's interesting to note that Medicare pays for diabetes education, and even though it's promulgated by an act of Congress, if I remember correctly, to deal with these same issues, across nutrition and presumably foot care and other things. Yes?

DR. MACDONALD: John MacDonald, University of Miami. I think when we talk about the general patient population that we all treat, we shouldn't just talk about the diabetics. Pediatricians take care of babies, obstetricians take care of pregnant women, but we take care of noncompliant patients across the board. I think venous patients, once when I was in medical school, or actually, I think it was in medical school, they said that the size of a patient's venous ulcer is inversely proportional to his insurance or his grades in high school, that these patients are patients that just don't take care of themselves. And it covers everything we do, not just for diabetics, for lymphedema patients, for venous ulcer patients, for these patients with chronic wounds. Most patients with a chronic wound get off their feet, raise their feet, try to elevate

and help, but most of our patients are noncompliant, and this colors everything we do with our research as well. So it's not just the diabetics, it's all our patients.

DR. DAVIS: Dr. Phurrough.

DR. PHURROUGH: So if what we're hearing is in fact the case, the patients are noncompliant, it takes two hours to educate them to get them to be compliant, we have good data about total contact cast, we have less than good data about removable, why ever use a removable rather than total contact?

DR. BREM: We don't do any -- totally impractical. Total contact cast is the -- the removable is the only practical way. It's the -- it works. The data is there. You have off-loading, but the practical presentation, it's just too cumbersome for the patient to have total contact casting except a few select centers. We did it, there are some downsides to it. It is also a matter of what's useful. The work on removable cast walkers looks very, very well, the patients all heal on that, you know, providing the other standard cares are provided as well.

Total contact casting, although I've published that it was the gold standard, it's not

practical, there is a better alternative. It's hands across the board in everybody's hands, unequivocally removes the pressure, it's practical. And it may not have some of the problems that total casting may or may not have were it to be done in a big ulcer, in other words, depressing an area that's infected, that may or may not have bacteria. So you have a practical boot too that patients will wear as we get better with education in other areas on to it. If we take Dr. Armstrong's work and others, and tape it or not tape it, whatever we do, we can definitely make it better. But practically speaking, there will never be a time when we do total contact casting, it's not necessarily great for patients, and most of the patients are disabled enough that they wouldn't be candidates for it.

There was brilliance behind it in that it provided a great idea that if you do proper off-loading, that alone will contribute to healing. That was a significant contribution, but like all things in medicine, something better came along that improved on that concept. Does that answer your question?

DR. PHURROUGH: Obviously, people flipped through slides very quickly today, but the slides

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that were up there all showed that total contact casting had better results.

DR. BREM: Not than removable walkers, that was never shown versus the other, that has never been shown in a study.

DR. DAVIS: Let's go to Dr. Margolis and then Armstrong.

DR. MARGOLIS: Dr. Armstrong was up first.

DR. DAVIS: Go ahead.

DR. ARMSTRONG: Let me just state, Dr. Brem, there have been studies. There was a randomized trial that showed exactly what you're saying, that a total contact cast, those patients improved significantly more in 12 weeks in this case, than a removable cast walker. Subsequent studies showed that (inaudible) suggested that in a lab, both of those take pressure off the bottom of the foot. Subsequent studies then showed that people with that removable device removed the device a lot. So how do you convert that device, how do you make that removable device which is very easy to apply, can be used anywhere in the United States, or abroad for that matter, it does not take special training, it is not potentially as dangerous as a contact cast, and is much less expensive, and make it

work? Perhaps by making it less easy to remove it. Some very recent data that you may have seen, and again, we breezed through these data because we didn't have enough time, was that it appears that making the removable device less easily removable seems to improve prevalence of wound healing in these contexts. That's the story and it seems to be telling a very consistent story in that process. While I love the contact class, this is my favorite method. I would love to see everyone using it. It's only used in three to five percent of diabetic foot centers in the United States, the ones that are focusing on that, so you have 95 percent of those centers that have to do something else, and I think you have a removable cast walker which is used a whole lot, it's not paid for to my knowledge, but perhaps just modifying that ever so slightly by wrapping it may improve wound healing and may be the first step when combined perhaps with some of the more advanced wound healing as well, might lead to higher levels of healing.

DR. MARGOLIS: Just to add something to what Dr. Armstrong just mentioned. Contact casting has really been available for almost 40 years. It was really first described in the '60s. The fact

that it may, quote, be the best therapy, may well be true, but the fact that it has been so unaccepted by so many people means that there is probably some problem, either that physicians don't feel comfortable applying it or the patients don't feel comfortable receiving it, except in the centers where the physicians can make a compelling argument to use it, so there is a problem with that therapy and people don't seem to want to use it, both from the clinician side and the patient side.

In terms of the adherence issues, you need to realize there is also adherence issues with pressure ulcer patients, and it's an across-the-board thing. And some of the people (inaudible) you're asking these people to do something that they may not really want to do. And a contact cast is this huge cast that they are now walking around with, and while they realize that they may get amputated, they're still walking around with their foot any way they want. And they have been told that if it gets worse it might be amputated, but it's very difficult for those people.

The compression bandage for venous leg ulcer, the bandage is changed once a week. It smells after a few days. And again, while it's a great

therapy, it's not a therapy that people regularly want, and there is often resistance. You often have this wound that the patient hasn't looked at for years, it's just oozing and seeping, and all of a sudden you're telling him he has to look at it, change the bandage twice a day and wash it. So there are huge changes that they are going through, and while we can say that they are not compliant, we can say whatever we want about the physicians not offering the therapy, but there really are some huge adherence things and they need to be controlled to make some of these patients better.

SPEAKER: (Inaudible) issue of education at our particular center (inaudible) significant educational program that's being supported, and we still have a 30 percent rate of utilization of the product when given to the patients free. And so even though there's been hours and hours educating the patients, there is a significant cultural component, the pain receptor changes occur. The patients don't recognize the wound on their foot and it's part of their disease process to ignore it, because then they don't have to focus on the change in their life, how they're going to die younger than everyone else, so it's something that they place aside, regardless of

the education. And then to have the information given to them by providers, change it every day, look at it every day, and by the time token, leave it closed and don't touch it. And so they feel it's easier to ignore it and then go back to their life style that they had previously. So it's not a compliance issue, it's an issue of socialization with the treatment process.

DR. KRASNER: Diane Krasner. I would challenge any of you who would want to wear a compression bandage for a week to try it. I lasted about 12 hours before I had to take it off, I couldn't stand it. My leg was twice as big as my other one.

And just indulge me for a second, but I'll pick on Elizabeth here because I know her best of all the people on the panel. And imagine if Elizabeth had a diabetic foot wound and she were in a removable device and she had to come here today to be on this panel. Would she have worn that for all of you to see under her skirt? Probably not. Like many of our patients, she would have taken it off for the day, for the wedding, for the special anniversary party, and potentially in the course of that day, done months and months and months worth of damage to all

the healing that we had tried to accomplish. And that happens all the time because people need to go on living, so it's always this balance and a real challenge. Now we're trying to get away from the word noncompliance and talking about adherence and things like that. But our real challenge as providers who want to be sensitive to our patients' needs is to find that balance of effectiveness that they will use, and it's sometimes going for the less effective modality because we know they will wear ten millimeters of compression even though they probably should have 30. Or they will put hydrocolloid on because they can buy it and still buy the food, because we know they need nutrition to heal, and so we compromise the dressings so that they can buy food. So it's always a balance like that, and those of us that are in chronic wound care arena make it work in the real world, but that's the reason, that's why it's so hard to do those studies, and we keep going back to this issue of organizing and individualizing care.

DR. AYELLO: I would like to respond to Diane, but I think in the 15 years I actually worked in a diabetic outpatient service, and I have to say that are some gender issues here, speaking for the

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female patients, if you don't mind, Pam, me jumping in in front of you. That's a very real consideration in terms of how to motivate people and I think that Dr. Brem mentioned a component of communication and really truly listening to what people who have the wound or are at risk for the wounds are saying to us. And one of the problems, at least for females and for younger people is their personal appearance, and it amazes me how people will sacrifice what some of us may think truly is a sacrifice, but I can remember very clearly a number of patients that said to me, I will wear my blank-blank shoe until they chop off my foot because that is really important to me, being able to go out there and live a life and not everybody saying there goes the diabetic because I have on a cast or have on an orthotic shoe or something that for women is much more visible, it's unattractive to the majority of people out there.

MS. UNGER: As Dr. Brem mentioned, we do a lot of diabetic foot ulcerations in my clinic and our gold standard is total contact cast. 50 percent of our patients are not candidates for total contact cast, even though we consider that to be the best intervention. And what we like to approach with diabetic foot ulcers are the two best interventions,

because we can't always put a total contact cast on. It may be directly related to wound drainage so it's inappropriate to do it. It may be related to what we know the patient's compliance is going to be. Any of our patients who leave with total contact cast are brought back in three weeks to have the fear put into them of what might happen if not for the total contact cast. And other times, it's directly related to the patient's safety in ambulation and as a physical therapist, that becomes a very succinct reason as to why to choose off-loading with the use of boots or removable walkers versus a total contact cast. And although we may give that patient the device, the device may not have the desired effect, it may alter their balance. So there's lots of reasons why that, even though the literature tells us, and we know we get out best results and we can use that, not all patients, at least 50 percent of our patients are not candidates for total contact cast.

MS. SILVIA: Good afternoon. My name is Cindy Silvia, and I wear a couple different hats, but I'm going to speak from the personal hat at this moment. I'm a certified WOCN nurse, wound ostomy and continence nurse, have been for close to 30 years,

and I am completing some research, my dissertation in the clinical experience of the WOCN nurse in wound care. I think one of the themes that is emerging from the research that I'm doing seems to be a thread that's running through what everyone is talking about here today in terms of compliance. The theme, or one of the themes that is emerging is the fact that the nurses that I interviewed found that they had successful outcomes when they had developed relationships with their patients. And I think it's very easy to look at patients in terms of whether or not they are complying when you're seeing them at brief intervals, but I think that good things can come when relationships are built and patients become invested with the caregiver and together can partner with them, and I think that goes across all different interventions that we're seeing, both for prevention and for treatment, and I think it was brought out with Dr. Ennis this morning when he talked about his care-giving across continuums, and I think that goes back to relationships.

DR. DAVIS: Can you answer a question for me, if you could stay at the microphone? When you talk about relationships between providers and patients, it made me think about the case management

or care management that we talk about people with chronic illnesses like asthma, diabetes, congestive heart failure and depression, and this approach of course being the rave in managed care and in many health care systems. Is the care management approach part and parcel of wound care now or not?

MS. SILVIA: It does tend to be, especially when the specialty nursing organization is involved, when one of their caregivers, be they in an acute care setting, home care setting, we tend to be resources within settings, perhaps just one to each setting, but we have a very, very strong network and we utilize each other across networks. And I think that's the important thing, not only to develop relationships one on one with patients. It is a matter of building relationships one on one, and it does take that one success to build on another, but I think then we have to go horizontally outwards and work together with those of us who do similar care-giving but in different care settings, and I think part of that is care management.

DR. DAVIS: Thank you.

DR. LAVERY: Larry Lavery. A few comments. The removable cast studies, two randomized clinical trials have just been published a month ago

or two months ago. Those weren't listed on your references that were listed on the Internet, mostly because they're new, and I think it's an evolving area with more research being done.

That being said, I want to say that if you look at the plethora of removable casts on the market, there are obviously products that are not very good at reducing pressure on the sole of the foot, and there were actually some gait lab studies that we conducted when I was at the University of Texas. There is a clear difference, and the cam walker, which is kind of the Kleenex of removable casts, is probably the least effective at doing that. There are a couple specialty removable casts designed to treat diabetic foot ulcers, they aren't fracture boots like most of the products that are clinically available, so in the decision to use these products, there are clearly products made for people with wounds and other products that probably aren't.

DR. BREM: Dr. Lavery, could you while you're up there, could you and Dr. Driver both comment? Clearly off-loading is necessary and you're bringing out optimal ways that everybody needs to learn. One issue that wasn't touched upon that's highly glamorous and extremely important is fungal

nail. Could you in an ideal world, to repeat your question, could you tell us exactly how to treat fungal nail so we don't get into these horrible nails and then, you know, we're doing these crazy things. Could you tell us how early on in a perfect world we should treat fungal nail in every diabetic patient?

DR. LAVERY: I don't think there is. I think a lot of money is spent on a problem without looking at a recurrence rate.

DR. BREM: Not even one solution, not like cutting or --

DR. LAVERY: Well, I think a lot of people have to have their nails cut and most patients, you know, haven't seen their feet in years. So I mean, I think people come in with nails that are literally an inch thick and going around to the sole of their foot, obviously they have to be debrided or cut by someone, or at the end stages they become ulcerous. For the most part they probably don't, though. Vickie may have some comments.

DR. DRIVER: Before I address that I would like to talk about total contact cast. From a military perspective we have a very large department that if they wanted to, could do nothing but put on total contact casts, and two times a week we have

maybe 30 put on each day that I write the prescription for. But these don't come without high risks in these patients. There are several contraindications for the total contact cast, which would be many of the risk factors mentioned by speakers today, neuropathy of course is a risk factor, infection, on and on and on, obesity, edema. These people have trouble with balance, all those issues, but let's talk sometimes about costs, okay? Now in a military hospital, we don't worry about that as much but in the real world you're probably talking about 80 bucks, okay? Do that times 12 weeks, 20 weeks, how long does it take you to buy a boot? A boot is maybe a hundred bucks. So if you really just look at cost, now that we know that a boot is as effective as a total contact cast, it just doesn't make sense to continue to place total contact casts in most patients.

Plus, they're reusable. Many of these patients, as you know, develop a new ulceration as soon as they heal one. They have their boot at home, they pull it out of their closet, they put it back on, they put something around it to make it irremovable.

DR. PHURROUGH: The problem is we're

getting away from evidence, just to speak as a payer again, it's a bit disconcerting to recognize that these removable boots are going to be sitting on the wheelchair next to the oxygen tank next to the nebulizer in the garage. You know? We could solve the problems if we hold a garage sale.

DR. DRIVER: That's a good point. Most of these patients also have walkers and wheelchairs, you know. These people have their boxes of pills. I mean, these patients, as we know, get one ulcer to heal and then get another one. So if we can find answers like irremovable casts that they can have parked in their closet, that's a great resource for them to have.

SPEAKER: I think what we haven't heard a lot about here is depression. Approximately 30 percent of these patients have depression; when they loss their job that number goes up to approximately 60 percent. And so if we're discussing where they're storing all the equipment that they are supposed to be using, I think we also need to as part of the total component look at nutrition and assess their depression, and that may actually get their walker out of the garage and into the patient's hands or onto their foot.

DR. DAVIS: Thank you very much. If people on the panel have more questions of the speakers, we can certainly entertain those. Otherwise, we can have some open discussion among the panel members and then move to the questions and try to narrow our discussion. If people don't have any open discussion that they would like to engage in now, then we can move to questions and start focusing on our comments. Yes, please.

DR. GREENOUGH: I have, out of all the information, I have heard mentioned only once by the next to last speaker, it's one thing to educate someone at a sanitized clinic and another to build continuity within the home, it's quite a different situation. How much of the wound care education is going on to follow-up, are people told that if you follow up with patients with wounds at home and home situations, it often gives you a lot more information than seeing someone from the clinic? No matter how intensive and how much time you spend with them at the clinic, you spend five minutes at home and you find out what the problem is and why they don't know. How much of this goes on at home?

DR. DAVIS: Now, are you referring to visits to the home or telephone calls to the home?

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DR. GREENOUGH: No, I'm talking about physically going to the home to see what the situation is and doing the education where it's needed, is that done?

DR. KRASNER: Dr. Greenough, the only study I know of is one that Martha Hill and her team did at the Hopkins School of Nursing. They looked here in Baltimore at VNA case load. 50 percent of the patients that the VNA was seeing, as is typical across the country, were wound patients. So you see this huge movement among home care agencies to hire on wound ostomy continence nurses because it's such a big part of their case load. So you know, they go through the system, they end up at home and then they go back into long-term care or they get infected, and then sometimes they are being seen once a week at the wound center, so they're all in and out across the continuum. But certainly that information gets translated from the home care nurse to the wound center nurse, for example.

DR. GREENOUGH: It sounds like a highly fragmented system, and I heard the word, not continuity, but establishment of a relationship between the educator and the patient in this case, and I think this is one of the things that I see many

things dropped between each segment of the system when there's a change of the level of care, et cetera, et cetera, and I've heard very little about continuity, except one person did mention developing relationships in order to get some of the therapy implemented, that would be good for them. And certainly having someone at least physically know the patient in the home situation seems to me is critical. Has anyone studied the educational impact of the site of education or the continuity of someone who actually knows the patient, is there any data on that?

DR. KRASNER: I don't know the answer to that one.

DR. DAVIS: Dr. Phurrough.

DR. PHURROUGH: For the panel, most of you are advisors or wound care experts or working in some special clinic and have groups of folks around you who are experts in doing what it is that you do. And we've heard that you see a lot of folks who are referred to you and have not taken advantage of the care that was offered to them or were not offered good care. So the question is, how likely is it that a patient presenting with one of these kinds of wounds to a practitioner, a non-wound practitioner is

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going to heal without the services that are offered at some special clinic? Can you train a physician or a provider well enough in a private practice, non-wound practice that they're going to get patients to heal?

DR. BREM: I think that question comes up every day. It comes up with many of our residency programs from general practice to internal medicine to others, and the answer is yes, you can. When the home care doctor wants to learn wound care, they can learn it, they can know when they have gone beyond their bounds and they can refer. The reality is, the reason there is all this conflicting evidence in wound healing is the wound is programmed to heal; it gives a lot of confidence to people because there's a lot of them if not the vast majority who believe the wound is going to heal no matter what you do, providing very simple basics, which most people do. So people can be trained. I think if people are trained, though, at their earliest level if they're not getting better in a very short time, within four days or five days or six days, they will know. But I know from our own experience, we do train people, they start to refer all the diabetic foot ulcers, the venous ulcers and pressure ulcers

early on when they realize they're not going to get better. Their traumatic wounds and the others, they learn simple wound healing principles and are able to do just terrific with the home care nurse or a short term in the hospital. Depending on the wound, they can be trained, but for the most part, part of the training is when to refer properly.

DR. MARGOLIS: I think you also need to realize that there are three different types of wounds that we're talking about, we're not talking about one disease. So some of the pressure ulcers are going to be in the hospital or nursing homes or some acute care or long-term care facility. Venous leg ulcers and diabetic neuropathic foot ulcers may be out in the community, and you truly can train people to do it, but there's lots of obstacles. They have to have an office that's set up that has the bandages. Right off the bat, these aren't bandages that people have around their offices, so they have to have those bandages in their office. They have to have somebody trained to put the bandages on. You need to see the patients back with some frequency. And there is often, at least when patients get referred to me, and this is not based on any study, but they may feel they are not getting

properly reimbursed. It now takes half an hour or 25 minutes to see a patient, when they normally see one in five or ten minutes, and they don't necessarily understand how to put it at the proper level, or they're not getting reimbursed for their bandages, assuming they even have the bandages in their office. So they get referred to a wound care center, which has really proliferated over the past few years. The question was asked earlier, is there teams, and the teams are often in the wound care centers. So as Dr. Brem just said, often what the primary care doc does is refer somewhere else.

DR. AYELLO: I would like to speak from a nursing perspective, and I probably should disclose that I'm the current chair of the WOCN accreditation committee, which accredits all the specialty programs in the United States for nurses who want to specialize in wound ostomy and continence care nursing.

There is some data that I presented with my co-investigator, Dr. Karen Zulkowski at the University of Montana, it has yet to be published, but we have presented it at several wound care arenas, which addresses I think some of the education issues that we're seeing in nursing. One of the

things that we were interested in was particularly who is really doing a lot of the wound care in the United States. So we looked at the average staffing in long-term care and in the home care setting to see what knowledge they did have, and this was related to pressure ulcers.

And we were surprised at some of the findings that we found in terms of, we used a standardized tool which measured knowledge of pressure ulcers, which has been used in a lot of studies and been reported in the literature, so this tool has been well used. And what we found when looking at the average practitioners out there, data collected in the New York Tri-State area and then Montana, to see if there was a difference between rural and urban nurses, and we found that there were significant gaps for practicing nurses and their knowledge of wound care. That's one piece of the study.

Another study which I did with a clinician from the New York area was to look at what nurses in their general nursing education get, and if we think about, again, in hospital or across settings, who's doing a lot of the wound care, because specialists in wound care don't exist in every city. We looked at

the textbooks. We heard earlier about the physician textbooks that were referred to in a presentation we had this morning, from Tufts. The nursing textbooks, we looked at them, and depending on which textbook is selected, somebody could be exposed to as little as 45 lines of text about pressure ulcers if that faculty member picks that particular textbook. Obviously, I think most of us would agree that this is insufficient information given the complexity of care for patients with pressure ulcers. And that is published, that study is published in the WOCN journal, I think it was 2003 that that was published. There is more data. We just did a study on the advancements of wound care Nursing, 2005, about what practitioners that deal with wounds feel about certain practice issues. One of the questions included in that survey had to do with whether people felt they were adequately educated to take care of wounds. This data hasn't been published yet but I can tell you that they were just approving it last week. And again, people did not feel that they initially got the appropriate education in their initial whatever it was, A.D., baccalaureate, wherever they came from, to do wound care, yet this was a huge part of their practice on a daily basis.

So we have a disconnect between what people are being taught and what people are asked to be done, at least in the realm of nursing, but that's the data that I have.

DR. DAVIS: Thank you. Other general comments before we move on to the questions?

DR. BREM: I think it's a terrific opportunity to say, I think what everybody's strong consensus is that if we were to combine in a way, and it might be an idealistic way, just to start with what the goal would be, if we could test your expertise, which I think is enormous. I personally learned from Dr. Vlada, who mentored me before he ran CMS, the enormous respect for this institution, and that there is a passion for taking care of patients and outcomes. And that was what CMS represented, was that they could do one thing, they didn't want to treat people with complications that were too far gone and they didn't want necessarily physicians fighting with each other about what is the best treatment but if people could come together to provide the best treatment modalities, that that would save costs and improve outcomes. And the mission of this institute as far as I was taught was ideally to try to make sure that people had the

proper services available.
I think if you take a look, let's say we're paying 25 to $30 billion for wound care, I appeal to you, assuming that we're all in agreement, that if we were to treat every patient early and we were to combine inpatient, nursing home, outpatient, home care nursing and clinic APC system together, and we were to be unified, that on the whole, we could knock off 6, 7 or $8 billion from that. But more importantly, we might be able to eliminate most Stage IV pressure ulcers, dramatically reduce amputation rate.
Since you're providing the money for us in this situation and we are extremely well reimbursed when they come to the hospital setting with multiple problems, which is a very daily occurrence, and it's a horrible thing when you have a patient coming in when pressure ulcers are occurring, since we have not all, but many of the technologies, how can we, and you as a provider, how can we come together as a field and perhaps be accountable for our actions and get reimbursed on what solution we might be reimbursed for on outcomes. Is there any other ideas that you have that we can come together so that each patient gets treated now? And then we can maybe in

future years discuss among ourselves how to do it faster and better, but now I think we have so many solutions that are out there and it is so fragmented, and you are generously, I think, paying for a lot of these things.

DR. PHURROUGH: What we're beginning today is, as I alluded to earlier, is sort of step one in a multistep process. We certainly are not going to resolve all the issues today, in fact, we're not going to resolve any payment issues today. The goal is to, as you've alluded to, there are these myriad of treatments out there, many that have good evidence, some that have less than good evidence. Perhaps the gaps that we have already assessed are less of what works and what doesn't work, versus when does it work best. So the goal today is to say whether one of our beneficiaries either is at risk or presents early, or presents at any time with a wound problem, what should be done to it, what are the standard things that should be offered to providers that would allow them to best treat this disease process? And the recommendations, we're looking for broad recommendations.

We are not necessarily looking to say, in spite of what many in the field think, how could we

not pay for e-stim so that we can pay for this other stuff first, or how could we not pay for hyperbaric oxygen. The goal is, what should be paid for, what are those things that work, in what order do they work, so that patients are getting what they need first, and then whatever time period they need them, they get the other things.

And sort of the next step to take is to create at least what we think will be some guidance to the field, saying here's what we expect when we're paying somebody to take care of wounds. And we'll probably put that out as a draft to say we've had this meeting, here's what the world of wound care said and here's our condensation of that, what do you think of it. And then we move from that, here is what should be done to the question of how do we do it.

And there has been a mix of that discussed today and we do need to get to the how, but I think the what do we need to do is what we need to go over today, what are those treatments that need to be offered, when do they need to be offered.

You've mentioned the 30 days and to be honest, I have no idea where we came up with 30 days, it has been on the books a while, before I got here,

so I really don't know. Maybe that's not perfect. So those are the types of questions we would like to ask today, what should we be doing, what should we allow you to do.

And my last question, the question I just asked the panel I think is another question that I think perhaps ought to be added today, and that is who should be doing it. But I think there is a real, we're asking that question more and more about decisions we make every day here in the Agency. We just announced last week a decision on the coverage of carotid stent as an alternative to endarterectomy in certain patients. And we're not letting everybody do that; just because you think you're good at putting stents in, we're not okay. You have to demonstrate to us through certain mechanisms that we outline that you're in fact competent to do it.

Now, is that something we're going to do here too? It's a little bit more difficult in that people with ulcers are showing up at every physician's office and not just at certain places, so that is more difficult, but it's a general question of how do we ensure that not only are patients getting what they need, but the people that are

treating them are in fact competent to do what we're paying them to do.

So again, the goal today is not to answer all the questions that you need more money to get done what you want to do, those are questions that need to be asked, but I think the questions today are what needs to be done, what order should it be done, and finally, if we are going to be an evidence-based organization, how do we go about filling these gaps. If 30 days isn't the right answer, how do we determine what is the right answer? And we're not going to accept the answer that it's just too tough to do those, that research. That's not an acceptable answer. We have used that answer for decades. We give hormone therapy to women and they die from heart disease, or we do bone marrow transplants for breast cancer and women die, so that's not an acceptable answer to say you can't do the research. I don't know the answer of how to do it, that's why we're asking the question. So those are the questions today, what should we do, how do we get better at doing it.

DR. DAVIS: Dr. Brem raised the idea that outcomes could be taken into account in regards to payment. Put another way, I guess you could ask the

question, is wound care ready for a pay for performance model, and of course CMS is administering several pay for performance demonstrations. And it seems to me that at least two requirements for a pay for performance approach are a strong evidence base and a consensus around what recommended treatment is, and I'm not the expert in this area, but those of you who are could probably take a stab at answering that question. Anyway, Dr. McNeil was next.

DR. MCNEIL: I actually found part of the discussion this early afternoon, late morning confusing, because the conversation was blending both reimbursement and treatment, and therefore it was very hard for me to find out what treatments were limited. Because for example, this cast was reimbursed at $80, as I understood it, and the supplies were 60, and it cost some hours and labor. And at the same time, that was on the one hand, and on the other hand the patient didn't like it so it didn't get done, so I was getting very confused trying to assess the effectiveness of the various approaches and given the interpretation of the data. So is it possible, Ron and Steve, just to go forward now, and I don't even know if we could do this given the questions that we have, but to answer

the first question, just putting money totally, just not on the table, not up for discussion, and just say what are the data and do they support the effectiveness of the various basic therapies? Then when we get to the last question which says, what trials would support the development that there is sufficient evidence, it may very well be there that money has to come in in some way, because if there is some model that says what kinds of treatment is a function of reimbursement, then it would have to be a very good randomization technique to allow for that. So I'm just wondering if we could just get rid of the money discussion now for a moment and talk about just the data.

DR. DAVIS: Well, looking at the agenda and at the clock, I do think, and at the mood of the members of the panel, I do think it's just about time to move forward and start looking at the questions, but if you do have a burning statement or question that you wanted to pose, go ahead.

MS. MORRIS: Thank you. My name is Susan Morris, I'm the vice president of reimbursement policy and compliance for KCI. I am not a clinician, I look at health policies, but one other gap that I would like you to consider is the long-term facility

and the patient under Medicare who is not in a Medicare Part A skilled bed. When you talk about the prevalence of pressure ulcers, they are higher in long-term care facilities than anyplace else. We heard from Dr. Horn this morning that patients treated with support services have faster healing rates.

The reason those services are not used in long-term care facilities outside the Part A stay is that capped rental equipment covered under Part B, which is normally available to patients in the home is not available to patients whose home happens to be a long-term care facility. And there are other parts of wound care that are not available to those patients, and that's 90 percent of the patients who actually reside in long-term care. They pay the Part B premium, they get other Part B benefits, but they don't get these wound care benefits simply because of the definition of home. You can't change it today but I thought you might want to add that to your list of gaps.

DR. DAVIS: Thank you. Yes, please.

DR. BURKE: I just want to get a focus on what, the question seemed a little simplistic, at least my take, you get into the who, what, when,

where, why, who should be treated, what should the treatment be, when should they get treatment, where should the treatment be provided, and why should we do the treatment at all. Those seem to be pretty complex questions and it seems to be a pretty heterogeneous patient population, with heterogeneous treatments. And so taking this like global, you know, all these diseases in one fell swoop seems to me to offer or simplify a complex situation.

DR. DAVIS: Dr. Goodman.

DR. GOODMAN: This is just to underscore that. The very first question, usual care includes, and it has all these medical procedures, but we've heard about the importance of counseling, integrated team management. It's very, very difficult to imagine that you could actually talk about any of these in isolation from those other things and they are not mentioned. So you could with any of these modalities put into the wrong hands or with the wrong care situation, they simply don't work. So it's a very difficult thing to talk about, the medical procedure in isolation, or care setting, I think that's one of the messages that we got there.

DR. DAVIS: Since a few of you have jumped in on Question 1, why don't we confine our discussion

to Question 1 for now and continue to the discussion.
DR. MCBRYDE: I don't know if this was on a slide, but the 30-day bit, it looks to me like when you hear all this, and I've been doing this for 30 years, that the personality of a wound that's 30 days old now is a lot different than it was just five years ago, for numerous reasons. One is the different treatments, one is the fact that before 30 days, many carriers are covering growth factors, e-stim and so forth. So there's a lot of information there that has made the situation from before your time, Steve, this way. So I don't see how we can just ignore the 30 days and figure out if that's the right thing or not, but we certainly ought to revisit that and make sure that we still feel comfortable, and so there are a lot of issues that make the, personality might be a bad word for it, but that would make the wound at 30 days today in 2005 a whole lot different than it was in 1995.
DR. BLACK: And again, I think the comments were made earlier by David that we have to be careful about lumping these types of wounds together, and I think that by trying to consider my response to question one, I think we really need to look at it. My suggestion is we try to really look

at it as individual types of wounds, because I think they're all different. And while we talk about usual care, I think based on the evidence just using compression as one, I think most people would say that compression is clearly necessary for venous, I'm not sure that there's any evidence that we're talking about diabetic or pressure wounds. So I think we really need to talk about this in terms of which represent usual care for specific types of wounds, and I actually wonder whether we ought to talk about the specific wound types and sort of, can we omit the term chronic? Can we just talk about what's the evidence, what works for treatment of diabetic wounds or venous leg or pressure ulcers?

DR. DAVIS: I see Dr. Margolis nodding his head, so we ought to stratify the question according to the type of wounds we're discussing. Would people feel more comfortable doing that? I see a lot of nodding heads. Steve, any objection?

DR. PHURROUGH: No objection.

DR. DAVIS: Well, shall we begin with diabetic ulcers? Would anybody like to comment on question one in regards to diabetic ulcers?

DR. MARGOLIS: But again, even here, you're talking about diabetic neuropathic foot

ulcers, you're not talking about anybody with diabetes who has a leg ulcer, for example an ischemic ulcer. So you need to say diabetic neuropathic foot ulcer, and what was discussed was off-loading with total contact casts or removable walkers or other things along that leg, which is different than ischemic ulcers and diabetes, and I think there was some confusion in some studies.

DR. DAVIS: Any objection to that, just focusing on diabetic neuropathic foot ulcers? Comments? Steve.

DR. GOODMAN: One comment here. On debridement, and this would apply not just to diabetic neuropathic ulcers, but one of the questions, I don't think, is who should be doing the debridement. I know working with pressure sores, you're not going to get a surgeon to come over to a long-term care facility to treat a pressure sore. You would certainly expect a physician's assistant or nurse practitioner to be able to do that once they have been supervised. So one of the things that we don't have evidence, I think we all agree that debridement is an essential part of treatment of any wound, but what we don't know is who should be doing the debriding, does it have to be someone who has had

nine years of classical surgical education post med school or could it be a wound nurse or someone who a wound nurse has taught. I would like more information on that and also, I consider debridement as crucial.

DR. DAVIS: That does sort of get into Question 5 about generalizability to providers in community practice, I suppose. But yes, Harold?

DR. BREM: I do think taking the focused answer, is there sufficient evidence to assess the health benefit of these modalities? I think the answer is for debridement, yes, regardless of the provider right now, to remove all the hyperkeratosis up to the living edge, skin edge; cleansing, yes; dressing is sort of nebulous, but yes; compression, not applicable; antibiotics, certain antibiotics, aggressive medicine for certainly some infections, you would have to make the decision based on organism; and off-loading, yes, and I think the point, the removable walker, which type of off-loading clearly needs to be addressed, but everybody would agree to off-loading's health benefit, and yes.

DR. DAVIS: Other modalities?

DR. BREM: Yes, I think there are other

modalities for usual care. It depends on what the other is, and of course -- in other words, I'm assuming these are the controversial areas, pre-FDA approved drugs that are utilized and the question becomes for ones that haven't gone RCT, does (inaudible) have a role, does hyperbaric have a role, and then the answer is yes, they have a role, and the question is how to find the best studies and when they should be ideally implemented. Clearly somebody with osteomyelitis with partial ischemia is going to have different care than a Wagner Type II. But to me it's very cut and dry, there's nothing nebulous about this, if you provide the standardized care early on, then you will get to that, and that's a critical issue here. So if you just get these things done that we do have evidence for, we would be in a cost savings and decreased amputations.

DR. PHURROUGH: We've had a lot of conversations today about nutrition, team care, those kinds of issues as part of the issue of care, which are not listed in the first part of Question 1, and I guess the question is as we go through each of these three wound types, does the evidence demonstrate that being part of your usual care, as a health benefit for the beneficiaries.

DR. BREM: They are the mandatory minimum requirements and I think it's a terrific question, because the point is if we were to have to discuss those things, we would be saying those are the standards of care for all fields of medicine, the team approach, all cost analysis, all medical problems are lack of communications, team approach, I think that's where medicine has gone. And that's probably the only area where a particular new national policy has to be regional, but for the rest of this, it would be a national policy. But to answer your question, nutrition and team approach has overwhelmingly been shown to be beneficial to the patient. Now, do you want to say nutrition accelerates healing in an ulcer, well, Dr. Barbul is probably one of the foremost to discuss other things in local wounds here, but I think practically, we all think our patients should be well nourished, and it comes up every day, and my answer is that those are the minimum standards.

DR. DAVIS: Dr. Burke.

DR. BURKE: A point of comparison. Is this all chronic wounds with any degree of is severity, Wagner I, II and III, is it the same chronic wound care for all severity of wounds? We

didn't differentiate and I gathered you were saying this one is evidence for chronic wounds of all types.
DR. BREM: That's right. In the goal of being supportive to finish through the question, I think there are many common things that we all participate, either run or participate in, just on each different type. I mean, I have been in all-day conferences on osteomyelitis, and each of these issues are brought up.
DR. BURKE: So the qualifier is?
DR. BREM: It does depend on the stage, it depends on the level of ischemia, it depends on the comorbidities, it depends on their hemoglobin A1c, it depends on the nursing care available, it depends on debridement. But at the end of the day, we can come away with a national policy for minimum standards that would decrease amputation rates.
DR. AYELLO: To add to that database, the select two studies that were published on off-loading which I referenced in my presentation, which were (inaudible) using off-loading, the level of diabetic ulcer that was in there was a Level I and Level II using Wagner grades, and it was simply looking at those two particular kinds of ulcers, so those databases showed that off-loading contributed to

healing for those two specific grades.
DR. BLACK: And I wonder if we need to say something about diabetic control. We talked about nutrition, but I guess my clinical sense is if a diabetic has A1c above 12, or an A1c of 15, the likelihood of getting healing is probably significantly less. So, should we assume another part of usual care is something of that category or acceptable, this control of diabetes and blood sugar?
DR. BREM: Absolutely, you have to optimize all of those things as part of minimum care.
DR. MARGOLIS: I'm just -- I don't know what I'm doing. You know, there is really no good study that shows that blood level controls of A1c that somebody needs with diabetes has an effect. In the randomized trials that exist, people have been included with A1c ranging from 6 to 15 on admission to the trials. An analysis was done a while ago and the admitting A1c was not predictive of whether or not the wound would heal. It doesn't mean that controls aren't good, but not all levels of evidence address them, so that's clearly an area that we need to explore, because the modern wisdom would be that with better control, they should do better. Having said that, I don't know if somebody out in the real

world there has better choices on this.
DR. KRASNER: I don't think there is evidence, but empirically we see all the time that there is no correlation between the level of control and the relentlessness of their wounds.
DR. MARGOLIS: But that's not what any of us wants to believe. In studying the use of dermograph for the diabetic foot ulcer setting, we have looked at that question, and the initial hemoglobin A1c did not relate to healing, given the control group and the dermograph group. If you look at the change of hemoglobin A1c over 12 weeks, if it improved and there was no difference in the control group versus an increase in the dermograph, then in the dermograph group where you're applying an active matrix to the wound itself, if the hemoglobin A1c went down, the healing rate was up. So that's the only data that I'm aware of.
DR. PHURROUGH: Perhaps I could propose a somewhat modification of the question and maybe resolve answering all the medical questions. I'm sorry I brought that up. Is there sufficient evidence to assess the health benefits of the following modalities as usual care for chronic wounds in patients whose medical conditions are being

optimally managed? So then we're getting nutrition, taking care of all the other problems that we aren't going to delineate; does that help? So then we're back to debridement, cleansing, dressing, so and so. And then sort of that category of treatment having taken care of the medical problem, are there other modalities that ought to be added to that list other than the ones that Dr. Brem mentioned, I guess.

DR. MARGOLIS: And again, you're still talking about usual care, so usual care, for the other modalities, are people calling -- I guess the question is, needs to be addressed, addressing usual care, does usual care include thermograph, cell-based therapy, growth factors, hyperbaric oxygen, VAC, everything else, or is that sort of the next level?

DR. PHURROUGH: We put that into the next level of care in our thinking. We are certainly willing to have our thinking challenged, we're used to it and we would expect no less.

(Laughter.)

SPEAKER: I'm Will (inaudible), president of the (inaudible) foundation. I think the questions are all cogent and relevant to CMS and among the experts here, I think what we're getting to at least in terms of that last point is the horse is already

out of the barn. In the past decade, particularly since biological therapies have become available widely in the community, the opportunity to try to isolate those away from standard of care has to some degree been lost. In practice, real life practice, a clinician will tell you that they will use advanced modalities like (inaudible) therapy, or VAC to assist in closure or tissue adherence with great success. I just want to call the panel's attention to the fact that we are in a paradigm shift period of time in not only wound care, but also oncology, cardiology and a number of other medical specialties where suddenly there are instructive technologies that challenge the way you practiced before.

And so, right now is an awkward moment in time to struggle with what is usual, and I think that is one of the critical natures of the discussion and the presentations, what was usual may no longer be usual, and what we're doing today really doesn't have firm guidelines. So somewhere along the line the questions need to be framed to address what, you know, to better identify our current situation.

DR. MARGOLIS: But the question is still standard of usual care, and at least from my knowledge of what's being done in wound care, the

most common adjuvant therapies is currently either growth factor cell-based therapies, and that market share is around 12 percent. So if 12 percent of neuropathic foot ulcers are receiving this and this is the most common of these therapies, are you trying to tell me that's usual care?

SPEAKER: I think that needs to be mapped out in terms of, target penetration needs to be mapped out against outcome information in a particular population of the therapy. So I think, you know, one of the frames was that this meeting was supposed to try to separate advanced modalities from the grouping of interventions that were previously mentioned. So again, I think what I'm hearing in the discussion is a little bit of mission creep away from what is intended to be a pretty clear set of questions regarding debridement, compression, antibiotics, and I think somewhere along the line we need to be refocused on those particular areas.

SPEAKER: The question came up earlier about randomized trials. We're having difficulty in randomized trials because of the advanced modalities or the adjuvant care therapies where we place the patient and randomize them, and then if they're not responding, the providers are taking them out of the

study and placing them into the therapy that works, so there's a dropout rate that's significant that compromises our ability to even do these randomized trials.

DR. O'DONNELL: It's nice to hear about all this modern treatment, but there's still that 51 percent of the diabetic group that gets saline wet and dry dressings, for instance. So I mean, you would like to see that move on to hydrocolloid or some form of semiocclusive dressing. I think the growth factor story is really still yet to be written as far as evidence-based medicine, if we do take that as a gold standard.

DR. DAVIS: Are people ready to move on to venous?

DR. BLACK: Well, I don't mean to prolong this discussion, but I think there were a lot of good comments earlier about, the idea about dressings, and that as wounds heal, they don't necessarily need to stay the same. And I wonder whether other folks on the panel think we need to capture that idea, that is, what's the best dressing on day one, is it the best dressing on day 28 or day 58, or whatever it is. Again, I heard that a number of times, I think we heard about the changing nature of wounds, the

various phases, and what is usual care but also at the same time trying to change these things. So I think that was some sort of additional footnote to the comments related to dressings as usual care.

DR. GOODMAN: Maybe I'm wrong, but what I heard was that it was the requirements of the RCTs that forced the use of particular dressings and in fact the usual care as provided in these centers or the community does not use that, so it was the artificiality of the RCT situations where they may have been industry funding, they may have looked at only a particular dressing, that made those particular RCTs not so relevant to actual practice. So I don't think we need to say that you change dressings, I think that's already done, but I would appeal to other people in the audience that were telling us that, and we've got lots of them.

DR. DAVIS: Do any members of the panel have any problem with what they see on the screen for diabetic neuropathic foot ulcers? If not, why don't we move on to venous ulcers and also answer Question 1. Would anybody like to jump in on that? Dr. Margolis.

DR. MARGOLIS: I think you could probably put Y's in probably all the same places and then

off-loading becomes N/A, or just put Y's everywhere. You're going to have debridement that may be more surgically oriented, and certainly wound cleansing, you're going to have wound dressings that are specialized, you're going to have compression and so forth.

DR. GREENOUGH: Just a word about antibiotics, I think it's important to recognize that many of the organisms that grow out of wounds we don't really, we don't know much about, and some of them are symbionic, some of them are supplemental, and some of them are basic pathogens. The wounds that are basically pathogenic (inaudible) so I think, I don't know what people do, but cultures are only useful in looking for things that are invasive, and (inaudible) I'd like to hear some comment on that.

DR. DAVIS: Dr. McNeil.

DR. MCNEIL: I'm wondering if we're getting into too much detail at this point. Under dressings for the first one and under antibiotics, we have a blue asterisk to say they obviously require further elucidation in terms of cultures, whatever. Otherwise, we are never going to be able to fill out this table. We have to assume that with antibiotics, obviously people have done the appropriate workup.

DR. DAVIS: And the comments are obviously being recorded and will be transcribed. So what I'm hearing is all cases are going to change as part of good medical care for other medical problems, and antibiotics for diabetic foot ulcers, as you have shown for ulcers that are infected, antibiotics can be used if the surrounding tissue is infected, but not necessarily for the wound itself.

So off-loading becomes N/A for venous.

Any other changes while we fix the computer? Let's move on. Any other changes, Dr. Margolis or anybody besides the off-loading one for venous? Yes.

DR. KRASNER: Just some comments that came up in our discussions in the Alliance. Usually when we talk about off-loading in our specialty areas, we're referring to footwear to offload the diabetic foot. So we're not clear where pressure reduction, pressure relief for a pressure ulcer comes in. For us it would be a different category, we call it pressure relief reduction. So there would be an N/A in that off-loading, but somewhere you have to capture pressure reduction relief.

The other issue that was difficult for us was antibiotics. Again, it goes to antibiotics for infection control, but it misses, then, the whole

issue of bio control for crucial compensation, which is a big issue in our arena, and you haven't captured that. So those were two issues for us as we looked at that table that jump out at me, so off-loading could be slash pressure relief, and then it would be yes for pressure ulcer.
DR. DAVIS: Thank you. Go ahead.
SPEAKER: My other hat is I work as the educational services administrator for Gaymar Industries, and what Diane just brought up exactly was something that had been irking me since I read these questions, and the fact that off-loading is very, very specific to a particular type of wound, and in the greater scope of things when we look specifically at pressure ulcers, we're looking at what we're now calling pressure redistribution. And if you look to the literature, there is a significant amount of work going on now within the National Pressure Ulcer Advisory Panel, the corporate advisory group that works with them looking at this support service initiative, and one of the three committees is looking at terminology in pressure redistribution. So maybe in the greater scheme of things, maybe particular to the diabetic community, off-loading is the correct term, but

pressure redistribution would probably be and even might be a better term that could be all-inclusive and then broken down into subheadings.

DR. DAVIS: Thank you. Any final comments on this grid that appears on the screen? If not, shall we move on to Question 2? Yes, ma'am.

SPEAKER: Wait, before we move, are we going to keep compression for pressure ulcers?

DR. DAVIS: The grid was filled in for pressure, and I think Dr. Margolis might have commented on that sort of globally. Do people want to comment now on pressure ulcers?

DR. BREM: Two things about pressure ulcers. Number one is that we need to go back to that screen, or not. A couple of things. Dr. Horn pointed out in terms of cleansing, the data she presented, some funding is thoughtful, but things like hydroperoxide may be harmful to a pressure ulcer, there are certain specific qualifiers that need to be set for cleansing. Of course you need a clean wound but the specific cleansing, a topical antimicrobial might be very different than a toxic H2O2.

Secondly, antibiotics are often not used in pressure ulcers, particularly if you have a Stage

IV pressure ulcer, you've done adequate debridement, you're never going to get rid of bacteria, but only going to promote resistance, so antibiotics, you need to use caution there, and I would change, if I had to choose between yes or no, I would insist on a no because the most common way pressure ulcers are treated in a hospital with antibiotics, it often brings them back in even a more effective state.

DR. AYELLO: And I would change the compression to N/A for pressure ulcers.

DR. DAVIS: Thank you. Did you want to comment on that?

MR. SANTORO: Yes. Joe Santoro, Health Point. It occurs to me as I look at that grid under the pressure ulcers that it is possible where the dressing category is listed that there are certain pressure ulcers that present that may not require dressing, and I'm not sure if that's been acknowledged here, but when you have a Stage I or II pressure ulcer, reduction of pressure is the appropriate treatment and no dressing is required, and so, I suppose there should be some awareness of that variability there.

DR. DAVIS: Thank you. Yes.

DR. HORN: Although I didn't present this,

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we did look at (inaudible) and it turns out even there, moist dressings are far better than no dressings. We did have patients on many types of dressings, and moist dressings did better.

DR. DAVIS: Dr. Ennis, did you want to add something?

DR. ENNIS: Well, I just wanted to agree with Dr. Brem on the antibiotics with pressure sores, if you use antibiotics thinking it will do the job, you've got to debride, drain the pus, and I will say if you have done a good job debriding, you should never have to use systemic antibiotics for pressure sores, but this is I think an important point.

DR. DAVIS: Yes, please. Dr. Armstrong.

DR. ARMSTRONG: Not to prolong this, and I do apologize, but to speak to the issue of antibiotics, surely you are not suggesting that a patient that comes into you who is septic with a pressure sore doesn't need antibiotics after a medical debridement. And just to soften that, I will tell you, I'm fully with you that antibiotics use is attenuated, but I think that to throw the baby out with the bath water seems a little, at this stage, and you know, foregoing clinician's judgment --

DR. BREM: The point is, in the absence

of, if you were just to use antibiotics --
DR. ARMSTRONG: Oh, with that statement, I'm not sure that that's being made clear in the transcription.
DR. BREM: You are correct, it's a very important point. If a patient is septic, that sepsis should be treated, but as an independent variable for pressure ulcer with no other factors, it should probably not.
DR. PHURROUGH: Remember, we changed the question to medical problems as being managed, and the systemic problem would be managed as we were addressing the non-systemic problems.
DR. DAVIS: Further comments on pressure ulcers? Now, let's proceed to Question Number 2. I don't know if we have to stratify this one by type of ulcer, do we? Talking about outcome measures, process measures, unless somebody tells me we have to consider these measures separately by type of ulcers, why don't we just have a general discussion about measures to be used.
Question A, are these appropriate main or intermediate outcome measures to be considered when assessing the benefits of usual care of chronic wounds? Are there any measures on this list that

shouldn't be used, or are there any that are not on this list that should be used?
DR. BURKE: Some are pretty presumptuous that it's pretty evident what that actually means.
DR. DAVIS: Are there any validated constructs for that measure?
DR. GREENOUGH: How about return to baseline activity?
DR. BURKE: I mean, if they are in an extended care facility and they've got bed sores, that's one thing, and what is (inaudible) pressure sore in an extended care facility.
DR. DAVIS: Yes, Steve.
DR. GOODMAN: I think first of all, that speaks to maybe the subtle differences between the clinical situations of the people who tend to have the different kinds of wounds. So it might be completely, less ambiguous than the neuropathic as opposed to pressure. The question is a little bit ambiguous, and we heard the presentations related to this, commonly used to assess healing. The ambiguity comes in the clinical assessment where someone has made the decision in mid-course about how well are things going and do I need to change my decision, and we're using it in a very technical sense which is how

do we sort of evaluate this, what is the appropriate end point for a research study to figure out whether one modality works better than another, and that's the way I'm reading this. It's clear that clinicians view this in a different way, and maybe we want to just clarify this because there are many things that are looked at as an ulcer heals, to figure out what the next course of therapy should be. And that goes under assess healing, although it is clearly by definition before the ulcer is healed. So, I just want to make that distinction very, very clear.

DR. DAVIS: Well, I asked about validated constructs and we are talking about quality of life basically, and we hear about SF-36 and what is it, SF-12 or 15, so I guess I'm wondering whether something like that is appropriate or is there something that corresponds to that that has been used for research purposes. Dr. Margolis.

DR. MARGOLIS: They haven't been used a whole lot. There's been attempts to use some of those measures and I think from my recollection and from my recent lecture, for venous leg ulcers there is often depression, so a depression heading seems to work better than some of the others, but there is certainly nothing wrong with having that there. The

other things you might want to add would be this whole concept of wound bed preparation or is the wound bed ready for another modality, which, you know, certainly could be helpful. If you can improve it so the graft is closed using grafting tape, you could be moving on to other adjuvant therapy that would work better, so people certainly argue that as an important outcome as well.

DR. AYELLO: And I don't know that we need to stratify this by wound type, but within pressure ulcers, there are scales that have been used to measure healing outcomes, and by looking at changes over time, and it's one way that you could quantify the healing of pressure ulcers, the size of the wound, amount of scab.

DR. WEINER: A quick comment. Sure we should try to address patient preferences, the SF-36 isn't that good, but I'm hearing all types of places where the patient preference would be a factor, but I doubt there is any formalized generalized scale. The question that I have is clearly the partial healing is very important to the degree of health care, and I know in dermatology they are also using new technologies, digital things, and I assume they're used in wound studies as well. But to me,

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that seems like a critical area, if not the most critical applied point to measure, but I will defer to others.

DR. BURKE: I think the first one is clear. The second, or third one, if you couldn't find an ulcer in the same spot, or in another spot, that would be an excellent outcome as well. Partial healing rate would depend on the scale that you use. Elimination of infections is very difficult. Amputation, sure, but you could do that. Reduction of pain, that's okay, and resumption of normal activity as well.

DR. DAVIS: And Dr. Brem.

DR. BREM: Again, I ask you this question using the power of CMS, but I think in no other area of medicine would you be able to increase outcomes, decrease amputations, help patients if you insisted on digital photography. It is no longer, you know, the EMR of some sort or another, it becomes a standard part of practice. And I know five years ago when I was part of a local MCAC, that was an issue because that would be too hard to implement. Nowadays, if you insist on a picture, you would find that people would go pretty darned quickly to the right treatment, or if we see some type of electronic

record. I would appeal that it is possible now in 2005 to insist on a digital photograph as part of the care. If reimbursement were an extra three to five, or seven, whatever it was, you would find much more rapid healing, people getting to it.
DR. DAVIS: Is that usual care at wound centers?
DR. BREM: It certainly is in many wound centers and it would be almost impossible not to be in a state of the art center.
DR. O'DONNELL: Just from the evidence-based area, assessment of wound size using photographic digital imaging was used in 25 percent of the diabetic RCT trials, 60 percent of the pressure, and 35 percent of the venous, so it's not that high.
DR. DAVIS: How many of those that did not use it were older studies?
DR. O'DONNELL: Well, these are all since 1997.
DR. BREM: I participated in several, and those started basically in, were designed, the trials in the mid-90s when it just wasn't available. Our camera in 1998 cost $18,000, so your timing is exactly correct. But now it has become, it has just

become really -- I'm just like a Final Four referee, I'm just calling fouls.
DR. DAVIS: I'm just wondering if you looked at RCTs from 2001 to the present, would they be excluding --
DR. BREM: The answer is, they are still copying what was on imagery and tracing, some people still use tracing, but the answer is, it is time to change.
DR. AYELLO: I have two points. First of all, when talking about the Bush scale, there actually is one study done in Brazil and published that looked at using the Bush scale, although it was designed for pressure ulcers, whether it would indicate healing in venous ulcers. That was published and is out there.
The other thing, having spent a great deal of time in long-term care, I'm sitting here thinking about how we would, if photography was something that we wanted to use in all settings, I don't see how it would be easily applied in a long-term care setting or in a home care setting, where, I mean, just from a practical point of view, there really are some problems. It might be ideal in a wound setting, I know, Dr. Brem, you're ready to jump right in, but I

think we need to realize where some of these wounds are being treated. Some of these long-term care facilities can't even get a VCR, let alone any other kind of complicated equipment such as a camera.

DR. DAVIS: Dr. Black, did you want to jump in on this issue?

DR. BLACK: No, different.

DR. DAVIS: Then can you wait for Dr. Brem and Dr. Greenough?

DR. GREENOUGH: I think this is a technology issue. In many ways there are going to be more technologic measures of healing rates and partial healing rates, and the camera is not an adequate tool, there are new tools coming along that will look at the results, so I think to include this on this list would complicate things enormously. I think you want to leave it simple, there are ways to measure healing rate, there are different technologies to do it, the simplest may be what you're using, it's not the best, but why complicate this list by putting technology into it?

DR. DAVIS: Dr. Brem, do you want --

DR. BREM: Very straightforward. It's strongly argued at long-term facilities that I've gone into, if you don't have a picture,

Medicare-Medicaid will continue to pay an exorbitant fee, thousand or tens of thousands dollars in fees for treatment of that patient. If you have a picture, you have documentation for why it's not being treated. There is resistance, it is change, change is hard. It's a simple cost effective tool. You're paying the bill. It may be hard for them to get a VCR, but pressure ulcers is something that they are, that is a major issue for every nursing home. There are still 15,000 long-term care facilities that are treating pressure ulcers, that's where they are. There are a lot of people, they have a lot of finances coming in, so to add a couple hundred dollars on for a camera is not much since this will decrease costs and help so many patients.

DR. DAVIS: Did you want to comment on this issue?

SPEAKER: Yes. I think to suggest one concept that may actually tie together this line of thought is of course, clinics have both images and digital photography, but of course these are static images of a snapshot in time. What we're looking at is the integral change from time to time and I think where our group is headed because of that, I would suggest that we might look beyond that at velocity of

change. That's totally different from just a pure rate change in the surface area over a given time, and that could be accomplished both by digital photography or by acetate skin tracing, and that goes to something that has the meaning that we're looking at, not just a snapshot.

DR. DAVIS: Let me just make a point here, again, keeping my eyes on the clock, and there's a number of questions we have to go through. This time is reserved for discussion among the committee members, so let me suggest to members of the audience that if there is some huge important point that we are missing up here, then go ahead and approach the microphone, but otherwise if you could restrain yourself, I would appreciate it very much.

DR. KRASNER: A quick comment, that whether it be a picture or a RIC score or a number, unless it's linked to an intervention, it's just one more piece of unimportant data on a chart, so it's got to be linked to some intervention.

SPEAKER: I just think there's confusion about what is complete healing and what is partial wound healing.

DR. GOODMAN: I wanted to ask about the recurrence. I mean, it was mentioned, it seems quite

possible that that is measuring issues that occur after healing. It's not obvious to me that is what we want to use as a way to assess healing of a chronic wound unless we want to say the quality of healing or quality combined with the care afterwards, that does seem to be a different issue, and I just would like to hear other comments on that.

DR. DAVIS: Dr. Margolis.

DR. MARGOLIS: I would agree. One of the concerns at the FDA in the early wound care trials was the recurrence argument that it wasn't good enough because of multiple wound breakdowns even after therapy. This is different than a wound that has healed, or a new wound on the foot or a new wound on the leg, which has to do with the same underlying disease but has nothing to do with the original wound. So maybe the unifying thing for partial healing rate is that some change of the wound over time might be a reasonable outcome. How we define that, either through use of an acetate tracing or digital photography, or area loss, whatever it is, the concept is that you want to see a change over time. That may be appropriate, to change that phrase to encompass everyone's concerns.

DR. DAVIS: I see some nodding heads. Any

other comments?
DR. GOODMAN: Again, elimination of infection, is that really outcomes or is that to assess the healing? I mean, that would seem to be a means to that end.
DR. BURKE: That's a surrogate outcome, it isn't a true outcome.
DR. GOODMAN: Yeah. I mean if you, if somebody wasn't feeling great, or any of the other outcomes, and had a different infection rate, would we view it with any difference? I see how healing velocities might affect outcomes, but ultimately, the only outcome we're really interested in is complete healing, so that's a surrogate outcome, and some of the others are as well. But elimination of infection, it's not obvious to me that that is really the same sort of surrogate.
DR. GREENOUGH: I don't think we have a good definition. If you're really serious about elimination of infection, you've got to have a biopsy to see what has colonized in this category and how many of these colonizations are infection. You can't without some other marker in the wound, so this becomes terribly difficult to have in there as a marker, unless you're going to go for biopsy or show

cellulitis to, et cetera, very difficult.
DR. DAVIS: So we've heard a number of concerns about elimination of infection, but nobody asking to drop keeping that measure there. I think in the interest of time we should probably move on, unless there is objection.
DR. BLACK: Related to other potential measures, just a couple of clarifications. And again, whether this is getting too proscriptive in terms of what we really want, we heard comments that perhaps devices don't work because people don't use them. So it is important, and again, it doesn't relate to wound healing per se, but the understanding is if something doesn't work, is it because people don't use it. Similarly, is the nature or are the nature of resources that go into a particular device an important part of all the significance for that issue? For example, a pressure wound dressing that needs to be changed every six hours by a specialized person versus something that a patient can change one time a week.
And then the final comment is, I think I'm hearing that time to wound, the time to complete healing is what we're viewing as a primary measure, is that correct? Then, is that easily translatable

for time to look at other studies, percent healing, percent healed by X amount of time, whether it's percent healed by 12 weeks, percent healed by 26 weeks, percent healed by six months, are those two interchangeable or is that another variable that we need to consider?

DR. MARGOLIS: Again, the data are recorded by cutoff date, it may be 12 or 24 weeks depending on wound type, but the other is to the rate of healing, there are other type of analyses as well, so you want to be technically classifying the outcome so you know what the conclusion really is at the end of the study.

DR. DAVIS: Okay.

DR. BLACK: Comments about the adherence, the idea about the shoes should be captured in our report and, you know, we'll just figure it out.

DR. GOODMAN: I think the issue goes to whether or not -- I don't know, I mean, that is a process measure. It's a little bit like extending the means to an end as part of understanding whether something works or doesn't work, but in the end accepting whether it works. These are the end points that, you know, may or may not be something that's measured. I mean, that's the kind of thing that

actually came from some of these trials, very extensive, and we try to capture that. So that involves a trade-off in the research to understand exactly why or why not particular modalities are working. I don't think that is what this is trying to capture, even though I do think it's an important thing for our understanding, but that's another issue.

DR. DAVIS: I agree and see a lot of nodding heads.

DR. PHURROUGH: I'm not sure what's on the list and what's not on the list. Could we summarize what should be on the list and what should be taken off? If you could just say yes or no to each one, which ones do we want and which ones do we not want?

DR. DAVIS: All right. Well, why don't we first ask which ones people think ought to come off the list, and elimination of infection was one that people seemed to agree should come off the list. Recurrence, there was concern about recurrence, but does anybody want to argue to keep recurrence on there?

MR. QUEENAN: What would be the consequence of saying it should not be on the list? The reason I'm asking that is that I think that it's

clear that there are some there that would be more relevant and some that would be potentially informative but not decisive as it were, but if the consequence of saying it should not be on the list is that you would sort of lock down these studies and intentionally not include or collect that information, I'm not sure where that would take us.

DR. DAVIS: My sense is, and Dr. Phurrough can comment on this, is that CMS will come up with some list based upon the action of the committee, and those measures will be given more weight when the staff looks at the research that's out there, and perhaps there might be some guidance in the field as well.

DR. PHURROUGH: If people wanted to take a step and we're not paying for it now, these are the kind of outcomes that their evidence needs to address. These are not clinical outcomes of how you take care of patients, these are the outcomes that we want to see in the evidence that's going to be given to us to make a decision about whether they are or are not beneficial.

DR. MARGOLIS: The reason this question was brought up was when we were talking about a prevention strategy, and I thought we were talking

about that.
DR. DAVIS: No, I just brought up that that was a measure about which concern was expressed.
DR. BURKE: (Inaudible) I think that would, to be measured and quantified properly, so I think one of the issues is can you measure it, can you quantify it sufficiently to lead to good outcomes. So when I say it's difficult, I'm saying it would be hard to quantify it, to quantify that measure such that it would be good evidence.
DR. DAVIS: Does anybody want to argue for keeping recurrence on the list? There were several people arguing against it, so we will give that a no. We have taken off elimination of infection. There was some concern about definition of resumption of normal activity, I don't know if we decided one way or another on that.
DR. GOODMAN: Well, I think that is just one of the number of quality of life measures. I think what we should say there is quality of life measures are relevant, I don't think we should specify one particular one. We in fact have had many patients return to their normal activity the next day wearing the same shoes and that's one of the problems, so I think that maybe what we want to open

the door to there is quality of life is an issue, and that there should be an appropriate measure, an appropriate validated measure. Resumption of normal activity is just one very narrow definition and one dimension of that, so I would think that what we should say is relevant and validated quality of life measures.
MS. KUEBLER: And we could include pain in the quality of life, so maybe patient-perceived quality of life would identify both.
DR. DAVIS: Any objection to that? So appropriate validated quality of life measures, something to that effect.
DR. PHURROUGH: For the people on the computer, below amputation, the other two are replaced by validated quality of life measures.
DR. GOODMAN: And relevant. You can have lots of quality of life measures that don't measure anything that's affected by this.
DR. DAVIS: So relevant validated quality of life measures. Dr. Margolis was suggesting adding something.
DR. MARGOLIS: Actually, I think there are two items, one is the percent of patients whose wounds have healed, and the second one, which is the

first one up there, is the time to complete healing. So, I think you were suggesting that there were two separate contexts that are frequently measured and reported separately.

DR. DAVIS: Could the blue screen be brought back? Okay. Could you, Barbara, or --

DR. MARGOLIS: Percent healed at study end, or whatever magic. But there is one other that I think probably needs to be added based on some of the comments made earlier today, that there are some agents that are important in cleansing and are used in preparing the wound bed, preparing it either for a graft or making the wound bed a better milieu for healing. So you need some sort of outcome that would be representative of wound bed prepared or wound bed debrided, or whatever catch phrase you might want.

DR. PHURROUGH: How do you measure that?

DR. MARGOLIS: That's a good question. Well, people talked about the benefits of an outcome and then you have to validate that outcome by actually grafting it, but if you're going to do that, preparing the bed is important, i.e., at some point along the line debridement is an important outcome, but again, I don't know how to measure that.

DR. PHURROUGH: What do you want?

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DR. BURKE: That's for a specific treatment, that is not just usual care. Clearly with a specific treatment you might have specific conditions that need to be --
(Inaudible colloquy.)
DR. MARGOLIS: There's people that would argue that there is some consensus where you can perhaps look at it and tell if it's properly prepared.
DR. GOODMAN: Wouldn't that come under C, if it comes in at all?
DR. BURKE: Yes.
DR. DAVIS: So, is it the sense of the committee that we would encourage the development of validated measures for a wound bed being prepared? Okay.
DR. PHURROUGH: For the people on the computer, add percent healed, delete reduction of pain and resumption of normal activity. Is that okay? Amputation was yes.
SPEAKER: If I may?
DR. DAVIS: Just one moment. So we're adding percentage healed to the list of items, and then for item C --
DR. BURKE: (Inaudible.) So percent

healed is in addition to the partial healing rate.
DR. GOODMAN: Healing rate is healing rate, so it's talking about velocity and yeah, isn't it -- how quickly.
DR. MARGOLIS: Healing velocity is specifically looking at multiple points along a curve, but what people are often looking at is just in terms of partial healing or healing rate is some scale change after four weeks or six weeks, and they want to identify them.
DR. GOODMAN: So you're saying that partial healing rate is those who produce a surface area change by 50 percent or --
(Inaudible colloquy.)
DR. DAVIS: Percent healed.
DR. BURKE: What's that?
DR. MARGOLIS: The most commonly used parameter in the study.
DR. BURKE: (Inaudible.)
DR. GOODMAN: No, no, no, because you could have 60 percent healed in both groups and one heals quicker than the other, or vice versa.
DR. BURKE: Okay.
DR. GOODMAN: They are both relevant.
DR. DAVIS: So we're on the computer and

we're going to delete the words healing velocity. All right, while we're waiting for that to be projected, you may proceed, please.

MS. JAMES: Sharon James, I'm an analyst on the staff of the Medicare Payment Advisory Commission. I was just wondering if anybody had considered and ruled out on the list of outcomes the avoidance of adverse outcomes, rehospitalization or AUCD for a wound complication.

(Inaudible colloquy.)

DR. DAVIS: Comments?

DR. BREM: I think the question was as part of the treatment of wounds in coming to the emergency room with a riproaring infection, and a secondary wound is an outcome, I think is what the question is, and I think it's a terrific idea.

DR. GOODMAN: But do we want to measure adverse events as a process measure or do we want to put in explicitly a complication rate?

DR. DAVIS: That's also getting into utilization, I suppose, along with length of hospital stay and all sorts of other things.

DR. GOODMAN: Maybe that would be part of complications, to add adverse events if that was going to be added to a specific case or not. I mean,

what's relevant is the adverse event, not whether the exact health care system dealt with it.

DR. DAVIS: Well, these utilization measures could reflect either lack of response or medical care, that would seem to be complex.

DR. GOODMAN: That's why adverse events, I'm not sure --

DR. DAVIS: Well, I don't think we're going to solve that one right now, but I think it's worth getting patient safety, if that's what your intent was, to get patient safety onto the agenda today, I think that's a good point. Yes.

DR. HORN: Speaking to both emergency department as well as hospitalization, one of the things in one of the papers that we studied that looked at multiple studies, we did examine the use of the factors of various surfaces, and not only associated with larger healing, but there were assessments that also showed significant decreases in hospitalization and emergency department use. And I think from our other discussion about whole continuum that we want to be thinking about, adding things like that here could be beneficial, if we showed specific interventions beyond the healing rates, had some of these other surrogate results.

DR. DAVIS: It seems like we're getting into Question B. We don't have to add these things to the bullets, but there is a question that says, are there other outcomes that should be considered? And without necessarily being definitive about it, if it's the sense of the committee, they do recognize that utilization of patient safety measures should be considered, people agree with that?

DR. MCBRYDE: Without getting into specifics.

DR. DAVE: Right. I see a lot of nodding of heads. Yes, Jonathan, did you want to add something?

DR. WEINER: I do think that these other measures are appropriate, and I hope we will have a chance to talk a little bit more about demonstration or care management in our population, and it's completely appropriate, as is recurrence, and I think more specific technology is not for this, but perhaps we can pick it up later.

DR. DAVIS: So we've talked about looking at utilization of patient safety under item 2.B, and then under 2.C, we've also discussed developing validated measures for the wound bed. Let me just see if anybody else would like to bring up other

thoughts before we move to item number three. If not, let's just move forward.
Item number three, based on evidence reviewed, how likely is it that the treatments discussed in Question 1 will positively affect the outcomes discussed in Question 2.
DR. GOODMAN: It seems to be reasking Question 1. I mean, that's what we already considered, right?
DR. DAVIS: There is a motion to move on. If we have time, we could come back to three as is, but let's jump ahead. Question 4, based on the evidence reviewed, do the treatments reviewed in Question 1, singly or in combination, produce clinically significant net health benefits in the treatments of chronic wounds? A lot of yeses. Any disagreements?
Question Number five -- speaking of velocity, we're picking up the pace. Number 5, based on the evidence reviewed, how likely is it that usual care used to treat chronic wounds can be generalized to, A, the Medicare population 65 and older, B, providers, facilities and physicians in community practice? We've already had some discussion about that. Comments? Let's start with A.

DR. MCNEIL: Well, a lot of the studies had older patients in them so it would seem to me that would help give an affirmative answer to A.
DR. DAVIS: A lot of yeses. Any nos? It looks like none. Let's go to B, generalizability to providers in community practice. A lot of yes, no, maybe.
DR. BURKE: (Inaudible.)
DR. DAVIS: Other comments? Dr. Horn?
DR. HORN: (Inaudible.)
DR. BURKE: (Inaudible) offices in the community and we are, when wound care as it's happening, so in certain situations we do have good evidence, but in many situations I didn't hear good evidence.
DR. DAVIS: I'm not clear I guess in this case about, for example, which physicians are we talking about, is it dermatologists, is it surgeons, is it family doctors?
DR. GOODMAN: We also heard a lot of evidence that compliance is very, very low, that it occurs in almost all settings, and I presume that's even maybe worse in community practice, so that was partially relevant to the question.
DR. DAVIS: Dr. Margolis.

DR. MARGOLIS: Certainly most of the larger cohort studies and the RCTs were conducted in specialty centers, the RCT center either started out as a specialty center or became a specialty because of the training that was required to enroll in the RCT. Many of the large cohorts and many of the large databases that were mentioned, they were specifically from large wound care centers. So I guess most of what we talked about was from larger centers. I guess part of the question is the question that, can people in the community be trained to do these things and because I think they're all relatively simple, I would assume that they could be, but most of what we reviewed isn't from the community.

DR. DAVIS: You know, I think the question is, trying to read between the lines here as well as reading prior Medicare coverage decisions, there have been limitations towards centers of excellence, so I think that might be a question.

DR. PHURROUGH: Well, this relates to the question I brought up earlier. The question I brought up earlier is, all the evidence we have is around, in the RCTs, is in specialized treatment facilities. Dr. Horn mentioned the facilities she has looked at, but can you take that evidence and

make an assumption and generalize that evidence to other practitioners, or is this kind of care such that you need to see the evidence itself before you know the community practitioners can provide this care. That's the question, do you think that this kind of care, the kind of care provided in these trials is such that anyone could provide that care in their practice or do you need evidence before you think that that could happen.

DR. DAVIS: I'm not sure I caught them, Dr. Brem was second, there was something in the middle, Dr. Weiner. Go ahead, Dr. Weiner.

DR. WEINER: I think this is about, can we take the scientific evidence from the university centers and apply it, and I think the answer is mixed. And you raised, David, the issue of general community practice/centers of excellence, and I think that too is mixed. I'm concerned that when this is put out on a population basis that we cannot apply it, so I would vote no. And to assume that without centers of excellence or some sensitivity to the health care, it will work in a rural location, I'm not sure, and I'm a little concerned. But I think that will take special focus, special consideration, it's not really scientific, that's really more a

policy, and I'm seeing some nods.
DR. DAVIS: Dr. Brem? Oh, sorry.
MS. KUEBLER: Anecdotally in rural Michigan, I can tell you that home care nurses and primary care community-based physicians are using (inaudible) or hydrogen peroxide on a routine basis. So it may sound great to educate them, but we're having problems with other areas, like they diagnose COPD for asthma, so I think having specialists and having referral bases is important for those communities.
DR. DAVIS: Dr. Brem, did you also want to speak to this?
DR. BREM: Again, I defer to you, but if we could focus on the outcome just like we do with a melanoma or hypertension, we know what the expectations are, then that answer will answer itself. If we focus on a healing wound and we say this patient has diabetic foot ulcer, or this patient has pressure ulcer, I believe the data, as do most of my colleagues, believe that if we have a diabetic foot ulcer anywhere in the foot for a person who has diabetes, it doesn't have to progress to osteomyelitis, we would expect not to have a digit or limb amputation. We've done over 100,000 limb

amputations. Most of my colleagues agree that if we get to Stage I, II, III pressure ulcers, we can keep them from getting to Stage IV. So if we could just educate that one concept, the cost of both human life and dollars would be significantly diminished, and that's what our education program needs to be. Then if it turns out that there's a terrific set of nurses in Wisconsin that could do that, that's great, we provide the resources, but we focus on cost savings and good health outcomes.

DR. DAVIS: Yes.

DR. GOODMAN: Again, I think the phrasing of the question makes its answer difficult. It says based on this evidence, how likely is it that this could be used, you know, generalized to providers in the community? This is phrased as, do we have sufficient evidence to be confident that this treatment if applied to either current providers, that would answer the question, or you know, with certain training could be applied effectively, which is a different question. But in either case, we don't actually have that evidence at the moment. So saying on the basis of the evidence, how likely is it, is a very different question than do you have sufficient evidence to conclude blank. I

think it's very, very clear that we don't have the evidence. The issue of how likely it is, given that we have very, very little evidence is we don't have enough evidence. It's a little bit moot, and that's frank speculation and opinion.

DR. DAVIS: Right. And I think the idea is we have some experts around the table and we have some knowledge about the complexity of the treatment, and that is what we're asked to judge on.

DR. GOODMAN: Right, and I guess usually these questions are on the strength of the evidence, not on the basis of asking someone, what's your opinion? That's a very, very different question that's no longer asking us what the strength of the evidence is, and that's why it's a difficult question.

DR. MCNEIL: I think this is a very difficult question, asking us to conclude that the centers in these RCTs that it would apply across the communities. I think on this one we could talk all we want and the bottom line is that we don't have the evidence and therefore, I don't see how we could answer it yes.

DR. DAVIS: Well, we could split this into whether the evidence exists, and then have a separate

question on how likely do you think this generalizability would be. So the first instance is tied to the evidence and the second is how do we feel, so how do we want to do that? Let's just clarify, we'll start with the, what I think is the easy question first, and that is, what is the evidence, how would we phrase this?

(Dr. Phurrough and Dr. Davis conferred off record.)

DR. DAVIS: Steve feels he can sense where the committee is at without voting.

DR. PHURROUGH: We are comfortable.

DR. BURKE: We'll happily move on.

DR. DAVIS: Okay. Any further comments on Question 5? If not, Question 6, what are the knowledge gaps in current evidence pertaining to the usual care of chronic wounds? Yes, Dr. Greenough.

DR. GREENOUGH: I've been holding back on this all day, but I think the gold standard of any new technology, including the high cost bed, would be against adequate nursing time at the bedside. From Dr. Horn's presentation, that's a very important variable, and if you take the lower cost bed, the gold standard study would have been increased by an equivalent amount of money for nursing time at the

bedside in comparison to the new bed. That's a study that has never been done, but I think it's very important to have a non-technologic intervention front and center involving nursing as compared to any other gizmo that might be said to improve wound care. That came out loud and clear, but I would be interested in hearing Dr. Horn comment further on the nursing ratio to the results in wound care. I think this is something we need to look at. I remember not seeing a pressure sore going through my entire five years of post-graduate training and so forth, although there were some, but there has been a radical change in what we're seeing. I note that something like 70 to 80 percent of the pressure ulcers is coming out of acute care instead of long-term, so I think we need to have a fresh look at the importance of bedside nursing in this area because we are in an area of epidemic depression.

DR. DAVIS: Thank you for that. Barbara.

DR. MCNEIL: Well, couldn't we just wrap up this question by saying that the knowledge gaps include the training of appropriate staff, the educational level of the staff, and the role of all the new modalities that were listed in 1.B as gaps in our knowledge base?

DR. GOODMAN: Does that include education of the patients?
DR. MCNEIL: I'm sorry, I left out education of the patients, I'm sorry, Steve. So just lumping these things in a general way as opposed to trying to parse things out and talk about each one.
DR. DAVIS: Yes, Dr. Brem.
DR. BREM: I think the deal, when I was trying to learn the field years ago, I heard that there would never be a randomized trial, one thing will never make a difference, and that turned out to be totally not true. Consistently in medicine, people want to do the proper trials. I heard you say today we have to, we can, and I want to emphasize there are huge gaps in knowledge and we absolutely must insist that we fill those gaps with good clinical science. They do it in the rest of medicine and there is no reason in the world why they can't do it in wound healing. That's been said over and over again and it has always been disproven.
The areas where we have large gaps in knowledge are in almost every single wound healing product. There are a lot of things that we don't know. However, we do need to get those answers and we can design the proper trials to do that.

DR. DAVIS: We have had some discussion throughout relating to gaps in knowledge, such as generalizability to providers in community practice, quality of life measures, we talked about that, so if somebody went back to the transcript, there would probably be a lot of other issues that would touch on Question Number 6. Yes.

SPEAKER: The one thing about lumping this back together with the adjunctive modalities is there were a few things that had level A evidence, electrical stimulation (inaudible) some support services, so those are some of the few areas that we actually do have a number of RCTs, and we're putting them in the area of knowledge gaps versus some of the other areas where we truly do have obvious knowledge gaps or lack of evidence, so I just wanted to bring that up with you.

DR. DAVIS: Thank you. Other comments on gaps in the knowledge? Yeah, Dr. Horn, or others at the table?

DR. HORN: I was waiting to make these comments until we got to number seven, because I think the two actually go together. With regard to what kinds of studies you can do to fill gaps, as Dr. (inaudible) just said, I think there is a problem

when we try to look at just one thing at a time, that is never going to really translate into practice. We need to look at the combination of RN staffing, other kinds of staffing, various kinds of interventions done in various combinations, various specific types of ulcers and patients to really see what's happening. And I really think your question is an excellent one, I've always kind of wondered if once we figured out from these data what are the optimal things to do for particular types of patients, do we need as much RN staffing, or was it the fact that we didn't have things standardized. It could have been that a more educated person like an RN spending more time with the resident that's able to see problems come up more quickly, and consequently preventing them from getting worse, seeing the skin getting bad and preventing it from an ulcer, and helping in terms of the healing process, seeing other complications occurring, preventing the hospitalization as a result of those interventions, and I do think we can design studies to look at these things.

DR. DAVIS: So, we're bringing Question 7 onto the agenda so we can talk about 6 and 7 together. Thank you for that comment. Other comments?

DR. BREM: I think the question is often, the first area is to focus perhaps on treatment, and I think there are practically clinically such a massive fear of punitive action in reporting an ulcer, that it won't progress to horrific states, but had it been reported earlier, it wouldn't have progressed, so that's a problem in preventing progression.

So what type of studies could be done is Question 7. So if we were to take out the individual wounds, diabetic ulcers, venous ulcers, pressure ulcers, sickle cell ulcer, and non-healing surgical wounds, and we used optimal standard care and practices, would (inaudible) HIV and others, medications, anticoagulants and others, or would you use an antibiotic prior to treatment. All of these are addressed in standard clinical practice and so we have the methodology to do that currently.

If we do it, I would predict that you would find that our amputation rate would dramatically decrease in the elderly, that the incidence of pressure ulcers would dramatically decrease, and our next series of meetings perhaps would be now, how could we do it better. But we might be able to take off, save tens of thousands of

lives and improve the quality on several millions of lives, and certainly save millions of dollars.

DR. DAVIS: Steve.

DR. GOODMAN: I just want to point out, if we are doing RCTs, one answer to what's important to be considered, the answer could be none, and that's an important answer to have on the table because that's what enables the design of simple large and practical RCTs. Now putting in all these variables, it can be very valuable to understanding the why of what you found, perhaps even designing the next study, but it may make some of these studies unwieldy. And if we're hearing that funding is a major problem and that Medicare will support most of the care costs but not any of the administrate costs, the more feasible trials might be ones where a well designed modification of some aspect of intervention is done, and very few of these things are measured, and they are the ones that generate the administrative costs.

The other thing I want to point out is that advances in understanding are never made by a gigantic leap but by a large number of study pieces of care, and this is how it has occurred in every other specialty. So every one of these, it is

absolutely true that many of these trials only modify one piece of the complex care network and may or may not show large differences, but the whole constellation of them, I mean, what's important is getting many, many more done, looking at many of these elements, and those pieces will fit together as part of a large puzzle.

So there is no one problem that is going to settle things, but the trials can be designed with various intensity of care, because I think even if you decide for every one of those, they can give you more intensivity or less intensivity, but those studies can also be designed. But the important thing is to get these studies started, that's the problem, and not necessarily view them as not being done for a variety of reasons.

DR. DAVIS: Dr. Horn.

DR. HORN: The gentleman is no longer here, but in terms of funding of studies that are not randomized trials, NIH to my knowledge, no matter how many proposals they get, they are not looking in that direction, they only want randomized trials. So, to be able to do something that to me would allow us to address all of the doubters, because what happens if you do a small study, you don't minimize the

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patients, you allow a larger group of patients to come in and you see what happens in terms of the outcomes, and then you get people who are doubters who will say well, I see that you have something slightly better here, but my patients are different and I'm not sure I needed to do that (inaudible) haven't measured all of those other confounders. Usually the conversation ends and nobody changes. What we have found has been very successful in getting people to change in the actual practice of care is when we have these comprehensive data studies of patient treatments and the outcomes, and although the doubters can say I don't believe it, I think it's something else, and then we can always come back to that subset that has had a confluence of patient signs and symptoms and we can see whether the (inaudible) things like that. It really makes a difference, no matter what kind of study you're looking at.

So I would advocate in these circumstances putting together large comprehensive databases that will allow us to be able to address these things that we're talking about today, and determine for very specific types of patients, what treatment combinations are associated with best outcomes. It's

getting more to this sort of personalized care but I think we're at the point now that we can do this and we can do this because we've got better information, we've got better computers that allow us to put together these kinds of analyses that we couldn't do in the old days when we were doing randomized trials and when they first came into existence, because we didn't have computers and the level of sophistication that we have today.

DR. DAVIS: Dr. Burke.

DR. BURKE: While I think Dr. Horn and Dr. Goodman both make excellent points about how to do studies, and I think both have their pros and cons. I think Dr. Goodman's proposal to have randomized trials is very nice and as he points out, you don't have to control for covariates or it isn't randomized. On the other hand, if you have a heterogeneity of patients and heterogeneity of treatments, that implies you're going to have to do a lot of randomized controlled trials, so that presents a problem.

Dr. Horn's approach, if I could characterize her approach, and I'm a fan of her approach, you know, doing large prospective randomized populations, I mean representative

populations to a large prospective representative population, what that means is the representative is really going to capture what you need to know, which is whether the intervention will work. You're also going to capture the heterogeneity of patients, the heterogeneity of treatments, but CMS would have to get rid of the payment bias.

DR. PHURROUGH: You're talking money so I'm going to leave.

(Laughter.)

DR. BURKE: The bias is the treatment that the patient gets, and then of course you have to make sure there is no unmeasured covariates, so in other words, there is no covariates dictating what treatment a patient gets that she doesn't measure. So that, I mean, that is a nice approach that could also work.

DR. DAVIS: A time check, a few people on the panel need to leave around four, so we'll try to finish by around four. So we have about ten more minutes if people are willing to wrap things up. Dr. Margolis.

DR. MARGOLIS: I can certainly talk faster if you want me to. I think we just need to reiterate what level of evidence is such that it's going to be

accepted by CMS. Generally this would tend to be randomized clinical trials. I think the large simple randomized trials that Dr. Goodman talks about are also very adequate and nice. You get a cluster of randomized trials and they answer some of the questions.

And Number 6, if they were willing to accept cohort studies, it certainly would make my life that much easier. So you know, we have case studies and everything else, they're all included in the level of evidence.

DR. DAVIS: This is a semi-digression. I guess in a couple of other areas in which I have worked, people have analyzed how many research dollars have gone into a particular field, especially from government where we can easily get the information. Would anybody be able to answer the question, how much has the federal government spent on research having to do with wound care and how have those research dollars been allocated? Has anybody collected that information?

DR. BREM: There are 17 institutions at the NIH to do research in wound care at some level. It might be, if you add everything together, it would be up to $10 million a year, up to, it's about 90

percent purely basic.
DR. DAVIS: But we're talking about a lot of research needs and it would seem to be helpful to collect that information to make the point that the federal government can ramp up its support of this area of research.
DR. BREM: Who would be the audience for that? I would certainly be willing to do the preparation.
DR. DAVIS: Well, I have seen a lot of papers that are published on what the federal government is spending on research in areas A, B and C, in some areas of biomedical research. So I think that somebody ought to do this work, publish it in the appropriate journal and it would then become part of the advocacy agenda, I would think. And if it turns out you get the total dollar figure, but let's say hypothetically it's impressive but 85 percent of it is going to basic animal research and hardly anything to randomized controlled trials, there's an important message there. Yes, Dr. Weiner.
DR. WEINER: Two ideas. It is true that CMS doesn't fund randomized trials, I think it's a great idea, but they do have papers, an MO project that they can waive current payment structure, say

poof, as long as you're collecting data and it's new information, we will pay for it, there is a waiver. They also have what is called quality improvement programs funded by PRO, CYO, a project where they have a lot of expertise going into offices and collecting data. They also have, as several people mentioned, initiatives and pay for performance, and the HR, (inaudible) records, and all of those would lend themselves to some real world practical trials. And since a lot of variability is already in place out there, those are things to consider, again, outside of this forum.

DR. DAVIS: I mean, Dr. Brem, if the research investment at NIH for wound care is as low as you surmise that it is, there is nothing to keep this committee from making a recommendation to CMS that it encourage NIH to ratchet up its investment in this area. I recall many MCAC meetings ago we made a recommendation that CMS communicate that point to NIH, and although we're not dealing with a specific question, there is general agreement here, and we can indicate a consensus that if this is the amount, we can indicate that there is consensus here that CMS communicate to NIH to ramp up its investment in research having to do with wound care.

DR. BREM: That would be a tremendous accomplishment. I think that with the wound care discipline, hearing that from a different branch of government would help them a great deal.
Steve, I have a question to ask you.
Would it be possible to possibly look at some statistics that would help all of us keep a focus on the early treatment of these patients? For example, could you match reporting on length of stay of pressure ulcers, forget where they came from, just 707.0, the code for pressure ulcer, and how that increases, let's say, common diagnoses for the elderly population, let's say for pneumonia and urinary tract infections? When we've looked it up, we found it's significantly up, and I don't think that's available on a national basis. Do we have a way of watching that?
DR. PHURROUGH: We paid some folks lots of money to look at our database and unfortunately, searching for chronic wounds is extremely poor and commonly is not listed as the reason for admission, either to the nursing home or to another facility, so we don't have access to it, it's a lower level diagnosis, the reason for admission is sepsis or they have cardiovascular disease, so that's the first

diagnosis and not wounds. So determining our patient population that is receiving wound care from our database is extremely difficult if not impossible.

DR. BREM: If you took pneumonia or UTI with or without 707.0 pressure ulcer, length of stay, that (inaudible) the early treatment, wouldn't it?

DR. HORN: We did a study several years similar to the one you're describing in a hospital setting, we actually took groups of DRGs for those without pressure ulcers and those who had pressure ulcers within the same DRG clusters. We also controlled for the admission severity of the patient, so we had these structured. And on average, it cost $4,200 more per case at that time, which was back in the early 1990s, to treat the patient who developed a pressure ulcer in the hospital compared to one who didn't with the same diagnosis and the same DRG.

SPEAKER: Could I add one thing? As we looked at data, one of the difficulties we encountered was not only the lack of standardized usual care practices, but the lack of standardization in the documentation process itself. We find that people don't describe wounds the same way. Even in one facility you might get very poor interrelated

documentation tools (inaudible) common nomenclature and common practice affect how we are able to compare the effectiveness of technology in a large sample population that may have a broader base, but the documentation is going to be a problem.
DR. DAVIS: Which speaks to the issue of research needs and evaluative measures.
I just want to return and finish with the point that I brought up a few moments ago, and that is urging CMS to encourage NIH to increase its funding for research pertaining to wound care. Is there agreement that the committee would like to do that, by showing a nodding of the heads? Is there any disagreement with that? Let the record show that the committee supports that recommendation.
So, I've got a few minutes before four, time to wrap up. Yes, please.
SPEAKER: One other comment. When you're talking about the incidence of wounds, what Curative has done over the past seven years is we have purchased every acute care hospital data, and we got a group of physicians' and nurses' claims data, and were able to identify to your point, the pressure ulcers as well as venous and diabetes ulcers in every acute care hospital for the last seven years. That

is something that we can give you, if you really need that data, but we were able to take your data and do that, so it's also in the packet.

DR. GREENOUGH: And the letter to NIH should say not only randomized controlled trial, since it can't be blinded anyway, so that simply destroys its status.

DR. AYELLO: And when we look at it, we've heard about inconsistencies in documentation, but I also think we need to clearly define minimal documentation, and I would urge you to look at the newly revised 314 rule in an effort to define minimally documentation for pressure ulcers, and then to look at the commonalities for different kinds of wounds.

DR. DAVIS: Final comments on Questions 6 and 7? If not, I think we're ready to close. I just want to thank all the presenters for the great information they presented to us, all the panel members for their outstanding contributions, CMS staff who helped plan the meeting, and I'm going to pass it over to Dr. Phurrough to make final comments.

DR. PHURROUGH: Before we adjourn, just a couple comments. Again, thank you very much to the

panel. I know this is always a challenge to get through all the stuff that we send you, to show up and be ready to make your comments. I think this was a very helpful meeting. As I mentioned earlier the next step is that we will review the information, we will publish the minutes and the transcript of this particular meeting for the public to review, and then in the near future we will publicize what our next steps are, how we plan to use this meeting to advance with the care of wounds in our patient population.

One last issue before we leave.

Membership in the MCAC is by nomination approved by the Secretary and it's for a two-year membership with the option of renewing for a second two years, but a maximum of four years, and then you have to take a year break. Until a couple of years ago, we had roving chairmen of each of our MCAC panels and a couple years ago we got smart and decided that perhaps the more intelligent thing to do is have some consistency in the chairmanship.

Ron Davis has been our chairman for the last several meetings and has done a superb job, and this is his last meeting before his four years are up and he has to rotate off. I want to publicly thank Ron for his superb work as chairman of our last

several meetings. They have gone extremely well, I think have been examples of how the public can assist federal agencies in providing advice and recommendations. So Ron, thank you very much from all of us.

(Applause.)

DR. PHURROUGH: And with that, then, thank you for your input and we look forward to future discussions.

(Whereupon, the committee adjourned at 4:05 p.m.)