**Table 1. NPWT Peer Reviewer Comments**

| Name | Comments | ECRI Response |
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| Peer Reviewer 1 | This is a thoroughly researched, well written, and interesting report. I have two major and one minor concern.<br><br>1. The report is based on answering four key questions, which in general are based on exploring differences between the NPWT devices that are currently available. Due to the proliferation of these devices, these seemingly are very important questions. It would seem to me that first it would be important to demonstrate an advantage of using this class of device over standard care. Why would we care if one device is better than another, unless the class of devices offers an advantage over standard therapy? Certainly the authors have access to all of the important studies and could easily address this key issue. This issue was recently addressed by three reviews Gregor S et al Negative Pressure Wound Therapy *Arch Surgery* 2008 143: 189-196; Vikatmaa et al Negative Pressure Wound Therapy: a Systemic Review on Effectiveness and Safety *Er J Vasc Endovasc Su*rg 2008 36, 438-448; and Ubbink DT et al Topical negative pressure for treating chronic wounds, *Cochrane Database of Systemic Reviews* 2008 Issue 3. Art. No CD001898. In general these reviews acknowledge that NPWT might improve wound healing but overall there was insufficient evidence to clearly prove efficacy over standard therapies. This certainly does not mean that NPWT does not work but it does indicate that there is not enough evidence to reach a firm conclusion about efficacy or effectiveness for this class of therapy. Without beginning able to firmly reach this conclusion, it seems like it would be impossible or premature to demonstrate that one of many different forms of NPWT is superior to another.<br><br>2. As noted above, the overall theme of the key questions is to explore or demonstrate clinical advantages between the various devices that are currently marketed to provide NPWT. This a very difficult task because the market has been dominated by one device for many years. In fact, in comparison the additional devices that are currently marketed to provide NPWT have been available for a very short period of time. It would be very difficult for adequate studies of these newer devices to have been conducted and published. At this time, as you have shown, | In support of the upcoming coding review of NPWT devices, the Center for Medicare and Medicaid Services (CMS) requested that ECRI Institute perform an independent technology assessment of the various NPWT devices. The focus of this report was the comparative effectiveness of NPWT devices and the significant therapeutic distinction they may offer. We were not asked to address the effectiveness of this modality over standard care.<br><br>Reviews by Gregor S et al Negative Pressure Wound Therapy *Arch Surgery* 2008 143: 189-196; Vikatmaa et al Negative Pressure Wound Therapy: a Systemic Review on Effectiveness and Safety *Er J Vasc Endovasc Su*rg 2008 36, 438-448; and Ubbink DT et al. Topical negative pressure for treating chronic wounds, *Cochrane Database of Systemic Reviews* 2008 Issue 3. Art. No CD001898 are included in the review and may be referenced in the report by searching for the following reference numbers: (1-3).<br><br>Key questions were formulated for the report to test the hypothesis that one NPWT device or its components may provide significant therapeutic distinction compared to another NPWT device or its components. These questions were structured using the "PICO" framework: patients, intervention of interest, comparator, and outcomes.<br><br>For assistance in clarifying relevant outcomes, we looked for guidance from the U.S. Food and Drug Administration (FDA). According to the FDA, improved wound healing and improved wound care are important clinical outcomes with the use of a wound-treatment device. Specifically, the most important outcomes to consider under the category of improved wound healing are percent of patients with complete wound closure and time to complete healing (partial healing for facilitation of surgical wound closure). We therefore incorporated "time to complete wound closure" and "percent of wounds healed" as important patient-oriented outcomes. In addition, for cases that are not expected to result in complete wound closure but rather to advance the wound to a stage where healing is possible we |

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| | it is very unlikely that many of these newer devices were even available long enough to conduct comparative efficacy or effectiveness studies. As a result, the logistics of answering your key questions were not in your favor.<br><br>Finally, a minor comment about the ultimate outcome of a wound care trial. The FDA, perhaps wrongly, has been very resistant to accepting any outcome other than a healed wound as a proper outcome for a chronic wound healing study (Guidance for industry: Chronic cutaneous ulcer and burn wounds-developing products for treatment. Food and Drug Administration; 2006 Jun). The majority of your discussion evaluates outcomes that were not from studies that used this final study outcome. It is very important that you place your results in this perspective so that health care providers interested in wound care realize that your key questions may not be based on studies conducted with the goal of a "healed" outcome. This perspective is important especially if comparisons are to be made by a reader between NPWT and other wound care modalities. | incorporated "time to 50% reduction of wound initial volume", "percent change in wound volume", and "improved wound condition" as important outcomes of interest.<br><br>The analytic framework then drives the development of inclusion and exclusion criteria specific for each key question. Criteria may vary for each question, i.e., the inclusion of single arm studies for key question 3 only.<br><br>Next steps include an extensive search of the literature and in this case, a review of an additional 1,400 submissions. Items were evaluated for possible inclusion in the report based on their relevance to the key questions and the pre-determined inclusion exclusion criteria.<br><br>An obvious key component of this screening process is to affirm appropriate outcome measures are included in each study. This determination is addressed in the screening phase of our methods and does not drive this process.<br><br>Lastly, a very small number of studies were excluded in this report for "irrelevant outcomes". Of the 497 articles that remained at the article level only nine (2%) of the articles were excluded for this reason. Specifically these studies were focused on cellular and biochemistry measurements which were not suitable outcomes for this report. |
| Peer Reviewer 2 | 1. Strength – One particular strength of this Evidence Report is the inclusion of studies with both Intermediate and Patient-Oriented Outcomes (Pain, Bleeding, Mortality, Infection). Much of the chronic wound evidence base includes studies with only intermediate outcomes, following subjects for inadequate periods of time. A second strength is the inclusion of new information on unstageable wounds, and pressure ulcer development from the inside out. NQF is proposing a new two-stage classification of pressure ulcers – partial thickness and full-thickness, in addition to the unstageable category. This might make it easier for those assessing wounds, and allow for more accurate comparisons and outcomes analysis.<br><br>2. It is not clear what "wound volume" and "improved wound condition" refer to in the narrative. This is not typical wound care terminology. More familiar are the terms area or dimensions of the wound, or length, width, and depth. It is not | Very few wound measurements were reported in length, width and depth. Study authors equally reported wound size as a two-dimensional measurement of area or a three-dimensional measurement of volume. We have updated the Analytic Framework and table headings to reflect that both measurements may be reported.<br><br>Improved wound condition as presented in the Analytic Framework is defined as a reduction in wound exudate and infectious materials; the promotion of granulation tissue formation and perfusion; an improvement in graft appearance; a reduction in odor; and a greater rate of epithelialization. The Analytic Framework has been updated to read as such.<br><br>Remaining comments all pertain to discussion in our Background Section. This section of the report has been |

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| | clear what wound condition refers to – exudates, slough, necrotic tissue?<br>3. Infection/bacterial load may not be a very helpful measure. All chronic wounds have some degree of bacterial colonization. It is considered a wound infection if the colony count exceeds $10^5$ micro-organisms per gram of tissue or swab. Even if clinical infection is absent, however, wound healing may be impaired when the bacterial colonization counts exceed $10^5$ organisms per gram of tissue.<br>4. Are saline gauze and foam dressing sets the only two relevant dressings for the comparative analysis of components of NPWT systems? I have come across use of non-adherent porous wound dressings and antimicrobial dressings in conjunction with NPWT.<br>5. Diabetic foot ulcers are a major cause of amputations in diabetic patients – this should be emphasized.<br>6. Infection of chronic wounds occurs when host defenses are overwhelmed, and demonstrate erythema, edema, warmth, pain and purulent exudates. Fever, chills and leukocytosis suggest the development of bacteremia or septicemia. It is common for chronic wound infections to be polymicrobial, often with Staph aureus and anaerobes. These wounds should be cultured and micro-organism sensitivities determined. Systemic antibiotics are recommended for clinically infected ulcers. Patients may be treated with antimicrobial dressings or topical antibiotics to reduce wound bioburden, but their use remains controversial. Topical antiseptics are chemical agents that are broadly toxic to microbes. Antibiotics are narrow-spectrum antimicrobial agents. Microbial resistance may develop with the use of topical antibiotics, while antiseptics may cause damage to healthy tissue.<br>7. In the discussion of venous ulcers (and elsewhere), mechanical debridement is presented as one option or treatment choice. In almost all cases, mechanical debridement (wet-to-dry, whirlpool) is contraindicated – it is a nonselective form of debridement and very painful to the patient. Instead, sharp (use of lasers, forceps, scissors), enzymatic (exogenous) or autolytic (endogenous enzymes) debridement is preferred.<br>8. Dressings should be selected based on the principal of moisture | updated as per suggested. |

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| | management – absorptive if the wound is draining exudates, and hydrating if the wound is dry or has minimal drainage. The optimal dressing will change over time as wound goes through healing stages. Unfortunately, this is seldom acknowledged in RCTs and CPGs. Also, strong evidence supports the use of graduated compression during the healing process for venous leg ulcers, and continuous use of compression stocking to prevent recurrence once the ulcer has healed. Evidence also supports the use of multilayer compression bandages rather than single layer in promoting healing of chronic venous leg ulcers.<br>9. Page 48. I am not sure if the "cause" of many wounds can be eliminated or minimized. Instead, recommend the use of the term "contributing factors" to wound occurrence – which would include reducing friction or shear forces, improving nutritional status, and so on.<br>10. Later in evidence report, the discussion of debridement is again inadequate. Surgical debridement is performed less frequently for chronic wounds compared to other available approaches. It may be done initially to allow staging of the wound, and then be followed up with techniques requiring fewer resources and less expertise. Nurses can be trained to perform sharp debridement (using forceps or scissors), and enzymatic and autolytic debridement are more common in long-term care settings. Chemical debridement is a term not often used – enzymatic and autolytic debridement should be specified.<br>11. The evidence base for selection of dressings is inadequate. Studies have not been powered to find significant differences between different versions of the same type of dressing (hydrocolloid versus hydrocolloid). Dressings remain the same over the course of the study in spite of changing wound characteristics. Moist gauze dressings are not the same as wet-to-dry dressings. The use of moist gauze dressings, as pointed out, is time intensive, and may lead to skin maceration. Gauze is not as effective as "modern" dressings, but studies have been underpowered to find significant differences, intermediate outcomes have been used, limited comparisons made, and sample sizes have been small and highly selected (small wounds). The most important point is that dressings need to be selected to match the characteristics of the wound at that point in time. | |

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| | 12. A 3rd category of dressings is antimicrobial dressings (in addition to gauze and moisture management "modern"). Some antimicrobial dressings contain iodine or silver. These are different from use of topical antimicrobials (neomycin) and antiseptics (Dakin's solution). | |
| Peer Reviewer 3 | The WNDP 1109 NPWT Draft Report Document was read in detail. In my current full time faculty position at UCSD Medical Center, I am and have been extensively involved with the use of NPWT for patients with all wound etiologies. My major concern has been the misuse and extensive overuse (prolonged periods of time) with NPWT without evidence to support the prescribed indication.<br><br>I believe that the above document is a thorough and comprehensive review of the current data and information on NPWT and fully agree that evidence is lacking to support NPWT use over other standards of care to attain complete closure. I have not been able to find any evidence supporting one NPWT over the other.<br><br>There are errors in the document, in the description of venous ulcer etiologies and treatments. These wounds are primarily treated by compression, rarely develop severe infections and respond well in the majority of cases to chronic wounds. Also, the information on NPWT and its effect on matrix formation are not correct from a cellular biology or physiological standpoint. NPWT does promote granulation in a wound but does not do so my denaturing or destroying existing matrix. Also, NPWT removes exudate and does not necessarily promote a wound environment.<br><br>Not all dressing categories are listed in the dressing section. Collagen/combination and antimicrobial dressings are not discussed. Allografts and xenografts have been successfully used to treat chronic wounds and are also excluded.<br><br>Overall, this is an outstanding review that provides extensive evidence on the lack of well designed randomized controlled trials for NPWT. The review also supports that lack of evidence for use of NPWT to attain complete wound closure. NPWT tends to be used beyond its potential at a significant cost. Data is needed to support length and value of use. | Comments are all pertaining to discussion in our Background Section. This section of the report has been updated as per suggested. |
| Peer Reviewer 4 | I think that this is a very through and thoughtful review of the published data on negative pressure wound therapy. My only comment is that at least one major wound journal, Wounds: A | The journal Wounds: A Compendium of Clinical Research and Practice is indexed in the Embase and CINAHL databases which were included in our searches for this |

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| | Compendium of Clinical Research and Practice is not indexed through pub med and medline. They have articles published on negative pressure wound therapy. You may have reviewed the journal and I missed it in my review. However, I wanted to be sure that this journal was not overlooked. Thank you very much for giving me the opportunity to review the document. | report. |

Note: Peer reviewer comments are not presented in alphabetical order.

**Table 2. Response to Public Comments on Negative Pressure Wound Therapy Devices Report***

| Name(s) | Affiliation | Comments | Response |
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| Ahearn, Cindy | Prospera | Prospera finds the ECRI report highly commendable. The volume of information reviewed, distilled and summarized required a huge and disciplined undertaking. The conclusion, that no significant therapeutic distinction of one NPWT system or component over another can be drawn from well-controlled, head-to-head clinical comparisons, is consistent with the framework and criteria set forth and described in great detail by the reviewers. We admire the independence of ECRI, and the opportunity to comment on the report. Our brief comments fall into 4 general categories, all of which we consider interrelated. We've included a 5th Miscellaneous category to clarify a small number of report details to ensure the accuracy of the record.<br><br>Exclusion of Animal Studies<br><br>One, and perhaps the most-frequently cited study in the NPWT literature, is the 1997 porcine wound model study of Morykwas andArgenta[1] that became the early basis for the recommendation of negative pressure levels of -125 mmHg. Subsequent and recent work in more detailed models measuring microvascular blood flow in pig wound models have shown -125 mmHg to be unnecessarily high, and potentially harmful to tissue at the wound edge, aside from being a frequently painful level of negative pressure when used in patients. The same original Wake Forest study clearly showed the benefits of intermittent therapy over continuous therapy with respect to blood flow and in promoting granulation tissue formation. Studies of this type form the basis for both constructive questioning and confirmation.<br><br>We consider certain animal study findings to be invaluable for advancing NF'WT, guiding clinicians, and for evaluating currently available systems. For example, a recent study in pigs of lower and variable pressure therapy | Ms. Ahearn, thank you for your comments on the NPWT report. We would like to address the concerns presented in your letter.<br><br>First, while animal studies may lead to important discoveries that ultimately prove valuable in human applications, experts have cautioned that fewer than a third of highly-cited animal studies translate into human RCTs showing the same results of treatment.(9)<br><br>Animal studies also seldom use study design procedures such as randomization, concealment of allocation, and blinding of outcome assessment that would limit the potential for bias.(10) Publication bias, the preferential publication of studies with positive results, may be especially common with animal studies.(11) In addition, positive results in animal studies may not translate well to the clinical setting. Investigators can control the severity of the wound in animals to a greater extent than in human studies. Animal subjects are likely to be younger and healthier than humans with wounds. Animals in such studies may not have co-morbid health conditions or exposure to concurrent medical interventions, in contrast to human subjects with wounds.<br><br>An additional problem with animal studies of wound healing is determining which of the human wound etiologies (pressure ulcers, diabetic foot ulcers, venous leg ulcers, burns, sternal wound infections, or trauma-induced wounds) the animal model represents. Given the nature of the questions asked in our report and the outcomes of interest to the Center for Medicare Management at CMS, such evidence from animal models is not relevant. |

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| | | by Borgquist,[2] showed that 100% of maximum wound contraction was achieved at -75 mmHg, as well as 100% of maximum blood flow. The study clearly shows that significant biological effects of NPWT can be achieved at pressure levels well below those traditionally recommended.<br><br>Because well-designed animal models offer nearly the only means of evaluating effects of NPWT on inter-related mechanisms such as blood flow, granulation tissue formation and physical/mechanical effects on wound healing, we believe they need to be considered. As an extremely young company (formed in 2008), Prospera first drew upon the NPWT literature to guide product development. We have now completed and are in the process of publishing animal research that will directly compare our systems and components with competing systems, and based on the findings are considering an RCT which will include head-to-head system component comparisons and which we hope will be completed and published within two years.<br><br>Importance of Standardized Controls and Protocols<br><br>The ECRI report speaks to the importance of standardized controls and protocols in drawing valid conclusions in NPWT research. We think this cannot be over-emphasized. The ramifications of how foam and gauze are used under negative pressure are extremely important in quantifying the prevalence of pain and true costs associated with various NPWT systems. In addition, wound bed tissue properties differ when either foam or gauze is used under negative pressure, or when a non-adherent layer is used with foam placed between the wound bed and the foam to prevent granulation tissue in-growth. Clinicians need to know which dressing is most appropriate for the type of granulation tissue desired.<br><br>In past NPWT research, traditional wet-to-dry gauze dressings have sometimes been used as controls. These | We also agree on the importance of standardized control and protocols as well as the importance of examining underlying study assumptions in drawing valid conclusions and comparisons.<br><br>Thank you for the informative Willy publication "*The theory and practice of vacuum therapy. Scientific basis, indications for use, case reports, practical advice*"(7) and the articles on pain and pain management.(5,6) We have included relevant materials from the publication in the *Background* section of the report.<br><br>In keeping with the AHRQ methods guidance, we have captured important patient outcomes, such as quality of life, satisfaction with treatment (which would include mention of pain or discomfort during treatment), duration of treatment, and survival, for the report.(12) Outcomes such as improved compliance, convenience and personal preference (and patient-oriented outcomes such as quality of life or satisfaction with treatment) are considered by CMS to indicate significant distinctions only to the extent that they result in demonstrably improved clinical outcomes. Patient outcomes reported in 40 comparison studies, 103 single arm studies and 22 previous systematic reviews are included in Appendix C of the report. Key Question 3 specifically focuses on harms reported in studies comparing NPWT to comparator treatments. For reports of comparison studies, single arm studies and previous systematic reviews, we refer you to Tables 5, 38, and 42 respectively. Please also refer to the study inclusion criteria contained in the *Methods* section for an explanation as to why case reports were not included in this report.<br><br>Lastly, the report has been updated to reflect the requested changes described in Miscellaneous |

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| | | have no place in present-day studies where the benefits of moist wound healing are well-documented, such as with the use of moist gauze under negative pressure.<br><br>Importance of Examining Underlying Study Assumptions in Drawing Valid<br><br>Conclusions and Comparisons<br><br>NPWT has proved to be a valuable adjunctive therapy in wound care. Recommendations for achieving optimal results, however, differ between systems and because of their respective operating characteristics and components. Different negative pressure levels are often recommended, different treatment modes, different dressings, and different frequency of dressing changes, for example. Systems that use black polyurethane foam in direct contact with the wound often require dressing changes within 48 hours, to limit the negative effects of tissue in-growth and pain. Because the literature of the past has been dominated by VAC research, Prospera emphasizes the need to thoroughly examine the underlying assumptions for each study design treatment variable and endpoint, in evaluating past studies and in designing future trials. As an adjunctive therapy, NPWT is best used to help prepare the wound for closure, and not as a stand-alone approach in the overall treatment of difficult wounds to complete closure. Viewed in the correct context of use, we believe NPWT in general offers dramatic advantages over historical controls. Of all RCTs cited in the ECRI report, we take note that only one recently completed trial is to include a direct comparison of foam and gauze dressings (NCT00583141/NCT00590369 by Smith & Nephew, Inc.). We concur that at this point there is no RCT-based evidence on which to compare foam and gauze results under negative pressure in patients. We consider the lack of evidence unfortunate, especially in light of the number of years (over 6 years) where comparative trials could have been conducted by the market leader. During the same time period, four RCTs comparing foam with wet-to- | Corrections, Additions and Deletions. |

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| | | dry gauze dressings were conducted (inappropriate comparisons considering moist gauze under negative pressure is the relevant dressing for comparison), as well as a RCT using Redon bottles, an inappropriate system for comparison.<br><br>During a quarterly earnings conference call on the morning of April 21,2009, KC1 President and CEO, Cathy Burzik was asked by an analyst, "Do you think you need to do a head-to-head clinical trial in order to achieve some of your priorities in Washington?" Ms Burzik replied, "I think the answer to that is no. I think our biggest priority right now is around continued commercial success. As I just said, we are winning in the marketplace every day, so the marketplace is like an ongoing live clinical trial."<br><br>As mentioned earlier in this response, Prospera, in contrast, is already striving to play a leadership role in obtaining the directly comparable evidence, both through support of animal studies and anticipated RCTs.<br><br>Importance of Pain and Other Patient-focused Measures of Comparative Effectiveness<br><br>Prospera included in its original ECRI response, 10 references to pain and pain management associated with NPWT and the use of foam dressings. Although direct comparisons of pain and other complications across system platforms is lacking among the few available RCT examples, we consider other references, including the case reports and textbook examples we included in our submission, to be highly relevant in decision-making today and in the design of future trials.<br><br>References to high pain levels experienced by many patients as a result of foam adherence to the wound and unnecessarily high negative pressures, and the frequent need for opioid and other medications to address the pain, in our opinion form a consistent theme in the literature which we feel an obligation to firmly highlight. In addition to the original article by Krasner[3] we submitted, we | |

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<tr><td></td><td></td><td>submitted, we have enclosed a very recent (March/April 2009) WOCN article (Long and Blevins)[4] that shows through examples the current state of affairs and how different NPWT systems are used in today's clinical settings to treat different wounds and manage pain. We have also included and highlighted pages related to pain excerpted from the text of C. Wiily[5] which we submitted in full originally. Other quality-of-life issues also need to be considered, but we consider pain management a top priority.<br><br>Miscellaneous Corrections, Additions and Deletions<br><br>In Table 1 of the Executive Summary, the Prospera information needs to read as follows:<br><br><table><tr><td>Prospera<br>2831 Bledsoe Street<br>Fort Worth, TX 76107<br>(Prospera Technologies LLC owns the<br>Prospera NPWT systems and brand)</td><td>PRO-ITM (stationary and portable)<br>PRO-IITM (portable)<br>PRO-IFM (stationary and portable)</td></tr></table><br>In Table 2 of the Executive Summary, in the Prospera section, the PRO-III information (see above right) should be added. Reference to the SIMEX pump should be deleted. The Simex pump is a suction pump and not designed for NPWT. The Simex suction pump is analog-based, whereas the PRO series is digital and software operated.<br><br>References<br><br>Morykwas M, Argenta L, Shelton-Brown E. Vacuum-assisted closure: a new method for wound control and treatment: animal studies and basic foundation. Annals of</td><td></td></tr>
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| | | *Plastic Surgery*. 1997;38(6):553-562.(4)<br><br>Borgquist 0, Torbmd C, Ingemansson R, Malmsjo M. Biological effects of negative pressure wound therapy (NPWT) at low levels of negative pressure - intermittent and variable NPWT. (CONFIDENTIAL). Paper presented at: John A. Boswick Burn and Wound Care Symposium. Maui. Hawaii. Feb- 2009.<br><br>Krasner D. Feature: managing wound pain in patients with vacuum-assisted closure devices. *Ostomv/Wound Management*. 2002;48(5):38-43.(5)<br><br>Long, M.A.; Blevins, A: Options in Negative Pressure Wound Therapy, J Wound Ostomy Continence Nurs**.** 2009**,** 36**(**2**):**202-211.(6)<br><br>Excerpted pages from: Willy C ed. *The Theory and Practice of Vacuum Therapy: Scientific Basis, Indications for Use, Case Reports, Practical Advice*. Ulmfllonau, Germany: Lidqvist Book Publishing; 2006.(7)<br><br>Note: Prospera also submitted the following reference:<br><br>TriCenturion. Negative pressure wound therapy (NPWT) widespread probe results. Jurisdiction A--final report. Columbia (SC): TriCenturion; 2007 Feb. 2 p.(8) | |
| Akinyemi, Mosun | Haggai Healthcare | KCI is the best wound V.A.C. and the support is excellent. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |
| Anonymous Reviewer 1 | | In view of the fact that there is no current evidence from a direct comparison of the negative pressure systems and a total lack of research about gauze-based suction systems, there is insufficient evidence to support coding all negative pressure systems as if they were equivalent. Further, the evidence provided from research about foam-based, negative pressure systems (Vacuum Assisted Closure [VAC]) should not be the basis to assume equivalence of | Thank you for providing comments on the NPWT report. |

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| | | other alternative negative pressure systems (i.e., gauze-based or other). Further, well designed scientific investigations are necessary before this determination can be made. Without evidence to support the assumption that all methods are equivalent, they should not have equivalent coding. | |
| Anonymous Reviewer 2 | Acute Hospital/Out patient Wound Center | I have used NPWT since 2009, only recently have other NPWT devices been available for clinical use and trial. I feel there is not enough evidence or time as a clinician to truly identify pros or cons or differences of these devices. KCI VAC does distinguish itself so far with the following that you do not find with the other devices:<br><br>Tract Pad technology- the advancement of the Tract pad allows equal negative pressure at the site of the wound compared to the site of the machine which provides safety and efficacy for the patient. The sensor in addition assists the clinician with safe application for good seal and management.<br><br>Polyurethane porous foam- Smith and Nephew has a new foam but it seems denser that the KCI. KCI foam is porous with larger holes which allow microstrain and wound deformation allowing contraction of the wound bed to decrease size. In addition the microstrain demonstrates a stability which has proven worthy in trauma cases and in the military field during war times.<br><br>Multiple types of foam for different etiologies- silver foam for MRSA, etc. In addition white foam that can be utilized in tracts and deep undermining. Smith and Nephew do not have either of these capabilities.<br><br>With high exudating or draining wounds gauze seems to form a biofilm or sludge where with foam the porous material pulls that exudate into the canister. Gauze can be utilized for difficult to manage thicker drainage like fistulas that are problematic with foam.<br><br>The newer devices have just converted bedside suction | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| | | with gauze to a product to compare. KCI has brought us lite years ahead and now we are back to drain tubes and gauze like 9 years ago when I could attach someone to wall suction apply gauze to the wound bed cover with Opsite and stick my drain tube in with the same effect. KCI V.A.C. does represent a different type of system and modality that should stand out from the others. Maybe we should have a VAC code and NPWT code. The technologies are different and if there were more funding out there that could be shown. It is difficult and not fair to say due to the other NPWT devices having little research that they are compared equally. KCI has put out much literature related to many types of wounds and outcomes especially compared to other wound modalities. It is an obvious difference that these are two different systems. I believe future research will show that with time to compare. In addition the inability to do side by side studies is limited by the FDA due to risk of safety of the patient. So I am not sure how we should go about getting that information when we are not allowed to by the government. Please take much consideration when making a decision VAC has saved lives and limbs over the years. Not to say the other devices haven't or will not but we do not have that evidence to make that decision. Thank you for your time. | |
| Anonymous Reviewer 3 | | I have used the KCI Vac for over 15 years. I started using the original KCI Vac. Through the years they have improved the technology. I have used these updated Negative Pressure devices and dressings with a lot of success. KCI has done a great job at listening to their users and made improvements in their technology, equipment, and dressing kits.<br><br>As a CWOCN (Certified Wound, Ostomy, and Continence Nurse) specialist I have been exposed to the other Negative Pressure Products on the market. Over the last few years I have seen these devices at National and Regional Conferences. Also some Reps have come to my | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| | | office to in-service me and my staff. Each of these companies always talk about how less expensive their NP device and dressings are. However, when I ask for studies on their product there is none or very limited studies. As a Practioner I need this type of information to be assured their product is going to produce the same positive patient outcomes.<br><br>While I understand NP is used in a broad term my concern is the lack of creditable evidence that the other NP products lack. I have been in the Health Care Industry for over 30 years. I provide both hands on to patients and act as a Clinical Manager. In Home Care I have lived thru the years of changes and standards that Medicare has held our Industry accountable to. The current trend now is to use Evidence Based Practice in our care so we give the Best care and our patients have Positive Outcomes.<br><br>I would expect any product I use on my patient to have data reflective of quality and effectiveness with proven results.<br><br>For me to use any product in this category I need the assurance thru data that the product will give the same quality results me and my patients expect. | |
| Anonymous Reviewer 4 | | I have reviewed your report on NPWT. I find it disheartening that AHRQ would not accept 90% of the comments/feedback from clinicians and clinical evidence. I have applied both the Vista and the VAC on patients and it is my clinical opinion that the VAC is superior in application, functionality, and most importantly Results! NPWT should not be used on every patient; however, under the correct circumstances it heals my patient's wounds 2 to 3 times faster than conventional therapies. The KCI VAC is definitely superior, in my professional experience, to other NPWT therapies. Specifically, I have used the Vista system and my patients wound bed deteriorated to the point of considering weekly surgical debridements. After switching to the KCI VAC my | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS.<br><br>In response to your concern that we "did not accept 90% of the comments/feedback from clinicians and clinical evidence," we provide the following explanation:<br><br>The focus of this report was to evaluate the scientific evidence for a significant therapeutic distinction of any single NPWT system or its components compared to other NPWT systems or their components, based on specific outcomes of |

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| | | patients wound bed improved significantly, and costly weekly surgical debridements were not needed. | interest to the Center for Medicare Management at CMS. Key questions were prepared for the report using the "PICO" framework: patients, intervention of interest, comparator, and outcomes (see Figure 1). Inclusion and exclusion criteria were developed based on each key question prior to an examination of the evidence. Twelve inclusion criteria were established for this TA. In a TA, the inclusion criteria determine whether a study is "relevant" to the key questions. Studies that do not meet the inclusion criteria are excluded from the TA. Exclusion from the TA does not imply that the studies have no scientific merit, just that their findings are not applicable to answering a key question within the specific report. As explained below and in the report, most submissions from interested stakeholders were not relevant to the key questions posed in this particular report, the purpose of which was to determine whether there was evidence of a therapeutic distinction between different NPWT systems or components.<br><br>We undertook an extensive search of the literature from which we identified over 1,000 potential articles. In the interest of identifying all clinically relevant materials for this report, we also invited interested stakeholders to submit information regarding any published, unpublished, or currently registered studies for possible inclusion in the report. We received over 1,400 submissions by the February 6, 2009 deadline. Each submission was reviewed for possible inclusion in the report (see Appendix D).<br><br>During the evaluation of all stakeholder submissions, we excluded 638 (44%) of the 1,435 submissions due to duplication alone (see Figure 5 in Appendix D). Of the 797 (55% of original) unique submissions; 29 (4%) were |

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| | | | included in our *Background* section and 269 (33%) items were excluded; 147 (56%) of the excluded items were case reports, abstracts or poster presentations given at conferences.<br><br>Of the 499 (35%) remaining articles, 354 (71%) were excluded at the article level. Based on the a priori inclusion/exclusion criteria, narrative reviews (k = 152 [43%]); animal studies (k = 39 [11%]); and studies with fewer than five patients in each arm (k = 30 [8%]) were excluded.<br><br>Of the 144 (10%) original submissions that met inclusion criteria, 117 (81%) were previously identified by the ECRI Institute literature searches. We subsequently included 28 studies not previously identified in our searches in the final report. Please see Appendix D for additional details on individual submissions and subsequent disposition in the report.<br><br>For a clearer understanding of our evaluation process, we have included documentation of all 1,435 submissions in Appendix D of the report. This section of the report, alphabetized by submitter, includes an attrition diagram and accompanying table that describes the disposition of each individual submission therein. The attrition diagram provides a visual representation of the disposition of materials as they go through the evaluation process. The accompanying table in the report includes a citation for each submission and lists either the placement in the report or reason for exclusion. |
| Anonymous Reviewer 5 | | I find it interesting that there have not been any trials by other companies that they wish to share on their NPWT. It was interesting seeing the quality of those trials that had been done. I feel that the companies coming out with their NPWT use all the studies already done by KCI. Yes we | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| | | know that NPWT works that is not the question, the question is what mechanisms of action are effective. I have not used another NPWT other than KIC and really have no intention to do so. I personally had a VAC used on a wound myself and truly the foam was the key to the therapy. I have looked and read as much as I can find on the other systems and have yet to find a system I feel I would trust. The other reason for not using another system is not to "muddy the waters" with another system for the staff. We have been getting great results with the VAC and plan on continuing to use it until data supports another system being as effective. Cost is not the only drive to therapy. | |
| Anonymous Reviewer 6 | | NPWT is a vital modality in the realm of wound care. I have used the NPWT from Smith and Nephew whereas a saline soaked gauze is utilized and I have used the "sponge" from the KCI wound VAC. The Granufoam has superior outcomes in all aspects and in surgical wound dehiscence the rate of closure is much greater using a wound VAC with sponge. Pain levels are significantly lower with the saline soaked gauze NPWT but with adjustments of nonadherent mesh gauze and pain medication the response to therapy is similar. Any modality that uses gauze should be looked at in a different light as the foam utilizes macro strain and micro stain technology and the saline soaked gauze is utilizing principles of moist wound healing. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |
| Anonymous Reviewer 7 | | I have had the opportunity to work with several negative pressure systems and feel that the KCI Vac therapy system is much better and more comfortable for the patient. I have used the Smith and Nephew system which in my experience seems to have more problems with air leaks causing it not to function oe exert the negative pressure it needs to. Because of the leaks the patient then removes it defeating the purpose. I also work in a center which used hyperbaric oxygen and the KCI wound vac has been pressure tested and the tubing is safe to go into the | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| | | chamber which we found is not the case with other negative pressure systems. If the negative pressure had to be removed each day for treatment then the purpose of this treatment is also defeated. | |
| Anonymous Reviewer 8 | | I have used the KCI wound management system since it was approved. I care for many complex wounds both in trauma and at in a rehab setting. I have also used other negative pressure wound management systems in the past. I have found that the KCI system is far superior to the others and have abandoned them in favor of the former. I feel that this system is unique and offers a distinct advantage in wound management over the other systems that are currently on the market. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |
| Anonymous Reviewer 9 | | I have had the opportunity to try different negative pressure devices on various patients and none work the same as KCI VAC therapy with the type of dressings they provide. Theirs is the only one that provides equal pressures throughout the wound base whereas others have varying pressures. They may not seem significant to the average person, but often times the perimeter of the wound bed has to much drainage and often causes maceration of the wound edge which slows the healing process and if to much pressure is offered where their catheter site is, it can cause trauma to the tissue. The VAC also provides more safety features for the patient as to maintaining therapy between dressing changes. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |
| Anonymous Reviewer 10 | | I would like to respond to the current review of NPWT devices. I work in a 700bed acute care hospital. On average we have 5 patients with NPWT in use. In the past 6 years I have predominantly used the VAC therapy from KCI for the following reasons:<br>It is a well researched product with multiple studies to guide and support the use of NPWT.<br>The application of the dressing is safe, user friendly and adaptable to a multitude of wounds. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| | | It is easy for the nursing staff to maintain and correct if leakage occurs. This is made possible through the detailed troubleshooting guidelines and product information available on the VAC's touch screen.<br><br>The results of the VAC application have been consistent with the researched application guidelines and facilitated decreased hospital-stays for patients. Especially the formation of granulation tissue allowed for much sooner wound closure than would be possible without NPWT.<br><br>Due to cost issues and the arrival of other NPWT products I have had the opportunity to use the original and updated BlueSky NPWT, as well as the Engenex NPWT. Both of these products proved to be inferior to the KCI VAC for the following reasons:<br><br>Blue Sky and Engenex NPWT application was not as versatile and easy to use for complex wounds.<br><br>The dressings did not stay in place; trouble shooting per nursing staff was much more skill dependent on the individual nurse as no guidance was easily available on the NPWT unit.<br><br>The Engenex system was also perceived as "painful" by several of my patients.<br><br>The material used to fill the wound bed was difficult to remove, and reported as feeling like a "foreign body" that was painful in the undermined areas or tracts of the wound bed.<br><br>Most discouraging however was the diminished formation of granulation tissue and the poor quality of it. When I compared the healing potential of different patients based on their nutritional status and disease process etc. Blue Sky and Engenex did not facilitate healing of the wound to the same degree as the KCI VAC.<br><br>One pt. was actually switched from the Engenex NPWT to | |

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| | | the KCI VAC due to lack of progress after two weeks of NPWT use. Within three days of KCI VAC use the quality and quantity of the granulation tissue had markedly improved. This development was also reported by several of my colleagues in the quarterly WOC symposium meetings.<br><br>Needless to say that quality of patient care and outcome monitoring dictated a return to the NPWT provided by KCI. | |
| Anonymous Reviewer 11 | | Good afternoon! I am writing regarding concerns with the conclusions reached in the draft NPWT report from AHRQ. My facility has used the KCI V.A.C. Therapy system for 10 years with excellent clinical and economic outcomes.<br><br>Although there are other forms of NPWT, evidence is very limited on their product outcomes and scientific foundations. I believe there is a significant therapeutic difference in the various types of NPWT. We have used the Blue Sky product on an inpatient basis as well as an outpatient basis through our Wound Center. It was very difficult to maintain a dressing seal using the normal saline moistened gauze, especially if the patient was active. Rarely, do we have difficulty maintaining a seal with the KCI product. The alarm system to alert you to a problem is superior with the KCI V.A.C. Therapy system. It is very specific about the type of problem and assists you with troubleshooting. The wound appearance is dramatically improved after the first or second dressing change with KCI?s NPWT. A longer time period was required to see wound improvement when using the Blue Sky product. The KCI NPWT system allows us to store a photograph of the wound being treated so that everyone involved in the wound care is able to view the wound without actually being present at the dressing change. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS.<br><br>We appreciate your concern with the findings of the report. Due to the lack of published or unpublished studies that evaluated other NPWT systems we were unable to perform direct or indirect comparisons. In the absence of such comparisons, ECRI Institute was unable to draw conclusions about the superiority or equivalence of any NPWT system or its components compared to other NPWT systems or components. |

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| | | Published studies are important to me in considering the use of a product at our hospital. It appears the vast majority of all published NPWT literature is V.A.C. Therapy specific. I am concerned that decisions were made stating there is no difference in the NPWT products on the market when there are very few studies by the other companies regarding their products performance. Clinical evidence and clinical outcomes cannot be represented then as the same for all NPWT systems. I believe the KCI V.A.C. Therapy system has unique features that improve wound healing and are not available in other product lines. KCI has the scientific foundation to support their product. I cannot say the same for the other NPWT companies. I would ask your consideration of these facts when determining future coding decisions for NPWT. Thank you. | |
| Anonymous Reviewer 12 | | I have used both the Blue Sky now Smith and Nephew and KCI NPWT systems. The KCI system is much more effective that the Smith and Nephew in speed of wound healing. In my opinion, speed of recovery should be one of the most important issues in any part of healthcare, even more today with a burden of economic decline. I have used the KCI system on my patients for years and have had no pain or infection control problems. The Smith and Nephew system just does not do the job the KCI system does and it should NOT be considered for insurance coverage. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |
| Anonymous Reviewer 13 | | As users of the KCI negative pressure therapy since it's' introduction to the wound care arena we can wholeheartedly state that the efficacy of the KCI negative pressure therapy is far superior when compared to other negative pressure therapies. In our outpatient wound care setting we have patients that come from long term settings and home settings with the other negative pressure therapies already in place. The gauze shreds and becomes impregnated into the wound bed and then an inflammatory | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| | | response is noted thus delayed healing. We have noted increase in local reaction, increase in maceration and decrease in granulation tissue growth. Our preference is for the KCI negative pressure therapy as noted in our faster healing rates. Thank you. | |
| Anonymous Reviewer 14 | | I am pleased to comment on negative pressure wound management. This concept is one that arose from such devices made from inexpensive materials commonly found in all hospitals.<br><br>Although suction dressings are helpful, they are simply an alternative of convenience. I would challenge whether there is any good data that shows that these appliances show greater wound healing than cheaper dressings (e.g. saline and guaze). Furthermore, the devices are given almost mystical all by some practitioners. They are often used as reasons to delay the only proper wound closure which is surgery. As such, negative pressure dressings extend length of stay and delay recovery. The costs are astronomical. There is also no evidence that any particular dressing is superior; I am astounded that KCI has now solicited me twice via email to explain why we should use only their product.<br><br>If the government/CMS is really interested in evidence based medicine, it should not pay for any such device unless there is Class I evidence to support faster wound healing. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |
| Anonymous Reviewer 15 | | I have used three different negative pressure wound therapy products and by far, the KCI wound V.A.C. has been noted to be superior to the other two I have used. I have used the Prospera Pump and also the ITI pump. The Prospera pump/product uses a gauze type dressing while the ITI product does use a similar sponge type dressing to KCI. Our wound program director (a physician) did try the Prospera pump but felt that it was not beneficial to patients with any type of Stage II-IV pressure ulcers. Even | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| | | though official studies and comparisons were not done at our facility, clinicians know when something just does not work well as a treatment. When using the KCI Wound V.A.C., wounds just appeared healthier as well as healed more quickly as evidenced by decreased sizes/measurements of the wounds. There were just noticeable changes when using the KCI wound V.A.C. compared with the Prospera pump in which a lot of wounds deteriorated with this pump (Prospera) in place. The ITI pump, although better than the Prospera pump/product still has not shown the same progress on wounds that the KCI pump has shown in our facility. The seal of the dressing and overall pump don't keep the negative pressure in place at times and the pump has failed to alarm on numerous occasions. Although the company is working to fix this problem, we have still not seen the results of wound healing that we have noted when using the KCI wound V.A.C. Although the other two have similar technology in regards to "negative pressure" they do not have the "whole package" that KCI provides. The pump design, the track pad, the sponge product and drape all go together to provide a superior treatment plan for patients that have wounds that need negative pressure therapy. | |
| Arrey, Sally, RN, WCC | NR | I am a certified wound care nurse in a nursing home in Lee's Summit, MO. I have used the Negative Pressure Wound Therapy Device for several years now. This is a very advanced and beneficial device made both for the patients and for the insurance companies and also for the government financially. These devices assist the wound healing time, which reduces the patient's time of stay in the hospitals or going to the wound centers. These devices also decrease the times that nurses see the patients for wound care to three times a week as to five times a week; this in turn reduces the cost for all those involved. I do this is a very good device and these companies are constantly making improvement so that the patients | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| | | wounds heal in a short amount of time. Thanks. | |
| Beltz, William R., MD | Susquehanna Health | I am commenting about the negative pressure wound therapy report. I have had considerable experience using the KCI Vac. I have not used other devices and, unless convincing evidence of their effectiveness, do not plan to do so. The KCI device is easy for patients to use, effective, and has excellent clinical service. The clinical experience reported to date for the KCI device is extensive. The literature for other devices is limited. That limitation is due to the fact that the studies have not been done and not that no difference exists. It is worth remembering that "the most expensive treatment is the one that doesn't work." | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |
| Best, Ellie, LPN | Glade Valley Nursing and Rehab/ Adventist Health Care | I have used the KCI negative pressure wound pump on many patients over the past 6 years and have had great success with it. I do not use this product on most patients due to the price but when I have had difficult wounds or stalled wounds this has done the trick. I feel this product has decreased the amount of time the patients have taken to heal. It is a very easy product to use and my patients have had no problems with it. This would be very cost effective if paid for by MEDICARE and there would be 90% reduction in nurse time and healing time. If you need any proof I can give you some measurements and time it took to heal some of my difficult wounds. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |
| Breece, Shirley | Southern Hills Advanced Wound Care | The KCI wound V.A.C. has been so beneficial to our patients in healing their wounds. It is easy for them to use and they receive great support from the company anytime questions or concerns arise.<br>As a clinician, I have found the wv to be easier to use, the sponge is better when packing tunnels and undermining and the supplies and support needed has always been outstanding. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |
| Brooks, Theresa, | Bayada | I am an RN, BSN, WCC. I am very concerned over the | Thank you for providing us with information |

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| RN, BSN, WCC | Nurses | study that was conducted involving NPWT. I have used V.A.C. Therapy on many of my home care patients. I have greatly appreciated the benefits of the KCI V.A.C. vs. other NPWT. Since you do not have research that proves that all NPWT are equally effective I do not believe it is beneficial to patient care when you do not differentiate between KCI and other companies. It has been my experience that wounds that were VAC appropriate do heal considerably quicker with the VAC than with other treatment modalities. I have used other NPWT devices and have actually seen an increase in tunneling of the wound in question rather than a healing process. I can only attribute this to the pressure differences as well as that fact that the foam dressing is a key ingredient in the healing process. As you well know only the VAC has the patent for the foam dressing. Because wounds heal faster with the VAC there is a definite cost benefit both to the insurer as well as the medical facilities involved in providing the care. Faster healing time means patients can return to their lives quicker and there is a decrease risk of infection. There is also a decrease in harm to the surrounding tissue because the VAC keeps drainage from irritating the peri-wound area. I would choose the VAC over any other NPWT product not only because it is more effective but because I strongly believe that it is more user friendly to the patient. It does not simply alarm when there is a problem it tells you exactly what the problem is. My experience is that KCI is extremely receptive to input from their clients as noted by the fact that they are continually creating better equipment... Equipment that is light weight for patient safety and ease of use, pre cut foam to make it easier and less time restrictive to provide wound care, better drape for increase comfort to the patient during care. The reps at KCI are readily available to the consumer to help troubleshoot any difficulties not to mention the fact that they provide excellent in-servicing as well as one on one training as needed to all of their customers. | regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS.<br><br>In regards to your comment "if you would only take the time to be thorough and do your homework completely," we provide the following response:<br><br>We undertook an extensive search of the literature from which we identified over 1,000 potential articles. In the interest of identifying all clinically relevant materials for this report, we also invited interested stakeholders to submit information regarding any published, unpublished, or currently registered studies for possible inclusion in the report. We received over 1,400 submissions by the February 6, 2009 deadline. Each submission was reviewed for possible inclusion in the report (see Appendix D). Diagrams and tables illustrating the disposition of submissions are provided in the report. During the evaluation of all stakeholder submissions, we excluded 638 (44%) of the 1,435 submissions due to duplication alone (see Figure 5 in Appendix D). Of the 797 (55% of original) unique submissions; 29 (4%) were included in our *Background* section and 269 (33%) items were excluded; 147 (56%) of the excluded items were case reports, abstracts or poster presentations given at conferences.<br><br>Of the 499 (35%) remaining articles, 354 (71%) were excluded at the article level. Based on the a priori inclusion/exclusion criteria, narrative reviews (k = 152 [43%]); animal studies (k = 39 [11%]); and studies with fewer than five patients in each arm (k = 30 [8%]) were excluded.<br><br>Of the 144 (10%) original submissions that met inclusion criteria, 117 (81%) were previously identified by the ECRI Institute literature searches. |

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| | | A huge problem, for me personally, with the AHRQ report is that such a report will encourage insurance companies to only utilize substandard equipment resulting in prolonged healing time and other complications for the patient. All of which can be avoided if you would only take the time to be thorough and do your homework completely.<br>While you may think you are saving money on a less expensive version of the VAC ultimately it will cost much more for not only insurance companies but the patient as well as the healthcare agency. I urge you to think carefully about what you are promoting by cutting corners with research. If other companies want to join KCI in the arena of NPWT they should be required to show research of their own which proves they are as effective as the competition. If their product is as good as the VAC research will prove that out. If not, then for the sake of patient care they should go back to the drawing board until they can get it right. As an agency that should be obligated to be an advocate for the patient, not requiring thorough research means you are letting the patient down. | We subsequently included 28 studies not previously identified in our searches in the final report. Please see Appendix D for additional details on individual submissions and subsequent disposition in the report.<br>For a clearer understanding of our evaluation process, we have included documentation of all 1,435 submissions in Appendix D of the report. This section of the report, alphabetized by submitter, includes an attrition diagram and accompanying table that describes the disposition of each individual submission therein. The attrition diagram provides a visual representation of the disposition of materials as they go through the evaluation process. The accompanying table in the report includes a citation for each submission and lists either the placement in the report or reason for exclusion. |
| Brown, Karen, R.N. | Healthback Home Health and Faith Hospice | I am the supervisor for our Wound Care Team and have been affiliated with KCI and the Wound V.A.C. for the last 5 years. The Wound V.A.C. has allowed our patients to have great outcomes in wound healing. We have seen amazing results in decreasing the time to close a pressure ulcer. In today's economy with our Medicare payment we have to look for the most effective, efficient and economical method to treat our patients and the V.A.C. provides us with that. The V.A.C. has been simple for our staff to learn and use. The nurses are able to document the time the patient was compliant with the V.A.C. and the patient lockout keeps patient compliant. I believe the V.A.C. is one of the most important tools we have as an agency in our challenges with wounds. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |
| Carson, Randall R., Manager, | Wound Management, | Smith & Nephew respectfully submits these comments in response to the ECRI Institute Evidence-based Practice | Thank you for your comments on the NPWT report. We note that due to the lack of published or |

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| Health Policy & Reimbursement | Smith & Nephew, Inc. | Center's draft Technology Assessment, Negative Pressure Wound Therapy Devices, released Friday, April 10, 2009 for public comment.<br><br>In the report, ECRI found that there was insufficient evidence to identify a significant therapeutic distinction of one Negative Pressure Wound Therapy (NPWT) system or component over another. In other words, there is no clinical basis for distinguishing among NPWT systems. Smith & Nephew supports ECRI and their findings, actively contributed to their body of evidence during the writing of this report as requested by the sponsors, and plans on continuing to work with the sponsors during the final writing of this report. ECRI conducted a very robust review of all applicable data, looking at both clinical literature and adjusted indirect comparisons. The criteria for the inclusion of studies in the assessment and the types and kinds of evidence used consist of a sufficient body of evidence to support and justify ECRI's findings.<br><br>The lack of evidence distinguishing among NPWT devices supports the conclusion that all NPWT devices should continue to be classified into the same Healthcare Common Procedure Coding System (HCPCS) code. Additionally, the lack of differentiation between the products in the NPWT space clearly indicates that the Medicare program and patients could benefit from competitive bidding among the relevant vendors. Smith & Nephew supports the Medicare Durable Medical Equipment (DME) Competitive Bidding Program and based on the findings in the Technology Assessment, Smith & Nephew encourages CMS to include all NPWT devices in the Competitive Bidding program for Round II.<br><br>Smith & Nephew has reached out to the AHRQ Center for Outcomes and Evidence and plans to work collaboratively with Agency staff to develop minimum standards of evidence for comparative effectiveness in the NPWT product category. Smith & Nephew also welcomes the | unpublished studies that evaluated other NPWT systems we were unable to perform direct or indirect comparisons. In the absence of such comparisons, ECRI Institute was unable to draw conclusions about the superiority or equivalence of any NPWT system or its components compared to another NPWT system or its components. |

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| | | opportunity to provide data in line with these standards.<br><br>Smith & Nephew is devoted to providing value to its patients and does so by providing a continuum of care associated with NPWT, including the pump and dressing, clinical support, quality assurances for both the manufacturing of NPWT devices and their re-use, logistics support, discharge planning and care coordination support, and documentation/billing support.<br><br>Smith & Nephew will continue to pursue opportunities to work collaboratively with all relevant agencies to educate key stakeholder and maintain product access to beneficiaries through the enforcement of internal quality standards throughout the supply chain process.<br><br>Please contact myself or Randall R. Carson, Manager, Health Policy & Reimbursement, North America, at 401-241-9043 with any questions or additional comments.<br><br>Sincerely,<br><br>Professor John Posnett, DPhil<br>Vice President, Health Economics<br>Smith & Nephew | |
| Charles, Allison | Caldwell Memorial Hospital | I am writing in support of Negative Pressure Wound Therapy as a valid treatment tool in the field of wound care and in response to the evaluation by the Secretary of Health and Human Services to determine proper reporting and billing for these services. I am a Physical Therapist and Certified Wound Specialist through the American Academy of Wound Management and have been practicing wound care for 11 years. I have seen many treatment products and procedures come and go through the years and in my professional and clinical opinion none have been more clinically effective than Negative Pressure Wound Therapy.<br><br>I have seen numerous patients that have benefitted dramatically from VAC Therapy with the KCI device. We | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| | | have had patients with trans-metatarsal amputations as a complication from Diabetes that has bone exposed and within a matter of 1-2 weeks the bone is covered by healthy granulation tissue. If wet-dry dressing changes were done with these patients instead of VAC Therapy the patient would have been coming to see us for months and have been exposed and at risk for osteomyelitis and further amputation and loss of limb. I have seen VAC therapy close a 30 cm long and 20 cm wide abdominal wound with bowel exposed in a couple months instead of 6 months to 1 year with normal wet to dry dressings. Before we had VAC Therapy as an option patients did not granulate as quickly and wounds stayed open significantly longer.<br><br>The clinical expertise needed in applying the VAC dressings and operating the VAC should not be underestimated. The clinician needs to learn the anatomy of the wound bed to ensure that there are no exposed arteries or tendons. Should those structures be present you have to know what secondary dressing to put over them before applying the VAC dressing or they will be damaged. Tunnels and Sinus tracts in a wound should be properly packed and the clinician has to know how to pack those tunnels and what kind of foam to use. The Clinician has to determine with the Physician what setting of pressure to set the dressing. Sometimes the clinician has to know whether to bridge the dressing in order for the patient to achieve optimal function. This truly is a skilled treatment that should continue to have a CPT code attached to it with reimbursement. A complicated VAC dressing change can take an hour for a skilled clinician to apply. This is NOT for a family member or non-skilled clinical staff. Also because this dressing and device demand commitment and effort from the patient this modality is not abused and over utilized in the field. If anything reimbursement should be increased for these codes.<br><br>Clinical benefits from VAC Therapy should not be | |

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| | | underestimated also. VAC patients have decreased healing time, increased granulation tissue formation, and the ability to control drainage from their wounds. I know I would rather have a VAC dressing control my drainage from a heavily draining wound than have to change a drainage laden gauze dressing several times a day. That is if I could reach my wound. If I could not a family member would have to do it and if I did not have any family to help I would be left to bear a foul smelling dressing.<br><br>I have not actually used other NPWT devices however did meet with a Representative of one of those products and I can tell you that the VAC Therapy products should not be put in the same category as those devices that use gauze or other types of dressing material in the wound bed. I found the products inferior in quality and design to the VAC Therapy and for that reason did not decide to utilize them in the clinic in which I am a Director.<br><br>Please do not dismiss comments like mine from clinicians. We have worked with patients with horrific wounds and if you or a loved one were suffering from one would you not want the best treatment available? Or would you want to have to deal with that wound for a much longer time than necessary? The research and done on the VAC Therapy clearly upholds therapeutic efficacy. If the other NPWT devices do not show clinical relevance it is up to the clinician to decide on the evidence which device to use. Please take the time to read and consider these comments. | |
| Chartrand, Carol, PT, CWS | Greater Lowell VNA | I have been using KCI's VAC system for 4 years. In our agency we have seen tremendous results, especially with the closure of abdominal wounds. Over the past 2-3 years there has been an increase in the number of surgical dehiscence wounds that are left to heal by secondary intention. Typically, these abdominal wounds drain copious amounts of fluid and require dressing changes 2-3 x/day, which is extremely expensive and a scheduling burden to nursing staff. The KCI NPWT system allows us | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| | | less visits, proper containment of drainage and improved healing time. I have noticed the use of NPWT closes wounds at least twice as fast as standard dressings, when used properly. Our agency has trialed Smith and Nephew's NPWT device and do not find that it seals well and it is more difficult to apply. I do not feel that KCI's NPWT systems and other NPWT systems are the same and should not be reviewed in that way. The foam that is used in KCI system makes a significant difference in the healing times and their research must be taken into consideration. Thank you for your time. | |
| Chihara, Tyler, DPM, FACFAS | Kauai Medical Clinic | I have used the sponge system and the gauze system for negative pressure wound therapy over the past several years in dealing with deep diabetic foot ulcerations. I have seen improved granulation with a healthier base using the Granufoam versus the alternative gauze technique. Because the wound is kept occluded for several days at a time, the gauze tends to absorb and retain some of the drainage directly in the wound bed, rather than being passed through into the drainage canister. I tend to be more concerned about infection related to the amount of unhealthy fibrinous tissue and odor related to the gauze left in the wound bed. In my experience, the foam system is superior. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |
| Clark, Sonya, RN, CWOCN | Henry County Medical Center | I am a CWOCN with 10 years of experience with wound care including using KCI's VAC system in a hospital and outpatient setting. I believe NPWT does an excellent job in helping different types of wounds heal. Although I support the KCI VAC I also believe that it is important for us as health care professionals to be able to utilize different brands and types of products. There is such a range of patients with complicated issues that one product cannot meet every need.<br><br>I fully support the use of different types of NPWT and the use of the same coding for these different types. I feel that the lack of studies supporting different forms of NPWT is | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| | | a drawback but should not limit health care professionals from being able to utilize these products.<br><br>I also believe that through the years KCI has made it difficult for other companies to develop similar products and therefore has had a monopoly in this area which has driven the pricing to an extreme. With more companies now being involved I believe that we have more opportunities to heal patients and meet the multiple complicated needs that exist with these patients. Thank you for your efforts in this area. I am not and have never been affiliated with any company who sells NPWT. | |
| Cojocnean, Felicia, FNP | Care More | I have been working as a Nurse Practitioner for Care More in Southern California for the last two. During this time I have had the opportunity to see and treat a wide variety of wounds using both products: V.A.C Therapy as well as other NPWT.<br><br>Unfortunately, my experience with other NPWT was negative every time. Two to three weeks after beginning of treatment the wounds got worse. There were problems with drainage from under the drape despite every effort to maintain a tight seal. Leaking drainage lead to further maceration of the peri-wound and the wound itself got worse and bigger. In other instances the wound got infected after beginning treatment with other NPWT therefore prolonging the healing time. I have never seen a wound which healed or closed with the use of the other NPWT.<br><br>On the other hand, I experienced great success with the V.A.C therapy. When patients failed treatment with the other NPWT, I have changed to V.A.C therapy and the wounds were successfully closed. I have witnessed many wounds closed/healed within a very short period of time without any complications such as infection as a result of V.A.C therapy.<br><br>Furthermore, due to advance antimicrobial dressings used | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| | | with V.A.C therapy, I was able to successfully treat and closed wounds which were infected at the time of initiation of treatment. Worth mentioning is the fact that V.A.C therapy is backed up by valid clinical trial, which I have yet to see from the other NPWT.<br><br>Experiencing great success with the V.A.C therapy, it had actually secured a contract between Care More and KCI. I am very happy to be able to offer this superior V.A.C therapy to our wound patients, and I wish that every patient would benefit from it before having to fail the other NPWT. | |
| Conrad, John | NR | We have had very positive outcomes from using the KCI wound VAC. Many wounds are very difficult to address due to the severity of the disease process and due to patients underlying co-morbidities. The KCI wound VAC stands alone in being able to address issues involved with these wounds. There foam allows for stimulation of granulation tissue and other changes in the "micro" environment of the wound to help it close, the overall "macro" environment changes of suctioning of the fluids and grossly approximating the wound are also very important in helping to heal the wounds. Overall, the KCI wound VAC is a great tool in our ability to help patients care for their wounds.<br><br>My biggest concern that I would like to convey to you is that there are a number of KCI VAC "look-a-likes" on the market today. I want to express my displeasure with these negative pressure therapies. These therapies, of which the Smith and Nephew negative pressure therapy is one of the leading "look-a-likes" on the market, are NOT the same as the KCI VAC. The KCI VAC works completely differently than the "look-a-likes". It is my firm belief that not only do these "look alike" negative pressure therapies waste money, but they are detrimental to the healing of the wounds. I have seen these "look alike" therapies used in the Nursing Home due to lower costs of the therapy, and | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| | | we have seen significant deterioration of wounds. This not only wastes money at the initial use of a machine that doesn't work, but delays the healing of the wounds, sets the wounds back, and incurs far higher costs in healing of the wounds. | |
| Crist, Brett, MD | NR | KCI VAC therapy (NPWT) has revolutionized wound care through the mechanisms that were discussed in the assessment. Over the last 9 years as an orthopaedic resident, orthopaedic trauma fellow, and an orthopaedic trauma surgeon, VAC therapy has significantly improved outcomes in my practice for skin grafts, soft tissue wounds with defects, open fracture wounds, soft tissue edema resolution with lower rates of wound dehiscence or wound problems in high risk injuries that were treated surgically, managing infected wounds with dead space, and has decreased the need for potential soft tissue coverage procedures in open fracture wounds. This is with regards to both acute and chronic management. My patients have required fewer dressing changes that can be associated with significant pain. It has decreased the burden on nursing or physician staff that would be changing the dressing and it keeps the wound isolated from the potential contamination associated with frequent dressing changes or saturated standard dressings. With the availability of home VAC therapy, it has also decreased the cost of keeping a patient in the hospital solely for dressing changes for complicated wounds or skin grafts. What used to mean 5 days in the hospital post skin grafting, now means home in 1-2 days which saves 3 inpatient hospital days.<br><br>Admittedly, I have not formally used the other NPWT devices available but have had a chance to see and handle some of them. I have chosen to use KCI VAC therapy over different devices for the following reasons:<br><br>They were the first commercially available product. Prior to this system, we would have to make crude NPWT with | Thank you for providing us with information regarding your experience with NPWT systems.<br><br>We wish to respond to the following comments in your posting: "The problem that I have with the current assessment is that it set out to see if there was a difference between devices, but wasn't able to answer key questions because there's only data available for the KCI VAC. Could you not say that KCI VAC is the only device that has data to support its use? And that all of the other devices are being lumped in because they are in the same category. How does that prove that they're as effective or effective at all?"<br><br>The purpose of this report was not to provide evidence of the effectiveness of NPWT in comparison to other types of wound care treatments such as specialized dressings or topical products. The *Methods* section of this report specifically states "this report does not address whether NPWT systems provide a better wound care alternative compared to non-NPWT wound care therapies." Instead, the focus of this report was to evaluate the scientific evidence for a significant therapeutic distinction of any single NPWT system or its components compared to other NPWT systems or their components, based on specific outcomes of interest to the Center for Medicare Management at CMS. Key questions were prepared for the report using the "PICO" framework: patients, intervention of interest, comparator, and outcomes (see Figure 1). Inclusion and exclusion criteria were developed |

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| | | sponges/dressings and drains to create NPWT. Currently when people talk about NPWT, most people assume you're talking about VAC therapy.<br><br>They have a consistent product that has been dependable. KCI has been responsive to suggested improvements to make their product better. Each generation of pump unit, dressing, TRAC pad, etc. has been better than its previous version. The current pump device allows one to identify and manage leaks and store information such as wound photos which is very helpful in managing these often times complicated patients. KCI continues to push the envelope with developing unique products such as the Instill.<br><br>Granulofoam is a more consistent dressing than the other products I've seen. I've not seen any evidence that the newer foam dressings or the standard gauze dressings that are being marketed work.<br><br>I continue to use KCI VAC therapy because it's been successful in my practice. I can see granulation tissue forming, wounds gradually closing, edema resolving, etc. That is the only reason why I recently became an advisory panel member. If I am going to be a part of developing a product, I only want to be associated with one that I think works.<br><br>KCI has been the only one to date, that I know of, that has evidence behind their device. This was validated in the tech assessment.<br><br>Although there are other NPWT devices on the market, KCI VAC therapy has been the pioneer and primary developer of this treatment on a commercial scale. Their commitment to developing the product is evident in their research support. They have committed substantial financial and personnel resources to prove that this therapy works. As with all evaluation of research, financial disclosure is important. However, as an investigator, it is difficult to do large scale trials without industry support due to lack of grant availability. Although there is a | based on each key question prior to an examination of the evidence.<br><br>No studies directly comparing one NPWT system or its components to another NPWT system or its components were identified in ECRI Institute internal searches or from submissions from interested parties. Due to the lack of published or unpublished studies that evaluated other NPWT systems we were unable to perform direct or indirect comparisons. In the absence of such comparisons, ECRI Institute was unable to draw conclusions about the superiority or equivalence of any NPWT system or its components compared to another NPWT system or its components. |

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| | | potential for bias with industry funding, it doesn't guarantee it and shouldn't necessarily be assumed. It's difficult to compete for large grants for this topic versus someone investigating cancer or cardiovascular disease that impacts more people. To expect specific devices or therapies to only be evaluated through independent financial support in order to validate the use of them is unrealistic in today's climate.<br><br>The problem that I have with the current assessment is that it set out to see if there was a difference between devices, but wasn't able to answer key questions because there's only data available for the KCI VAC. Could you not say that KCI VAC is the only device that has data to support its use? And that all of the other devices are being lumped in because they are in the same category. How does that prove that they're as effective or effective at all? By grouping them together, these other commercial entities, whose goal is profit, are benefiting from the research KCI did. Unless there is consistent data that proves the other devices are as effective as KCI VAC, I will continue to use KCI VAC exclusively. If this assessment is supposed to be based upon evidence, that's the only conclusion one can come to.<br><br>Thank you for the opportunity to review this assessment. | |
| Currier, Deb, RN WCC | Peace Harbor Hospital | I have used the KCI VAC therapy since the early 1990's. I have found this to be an evolving technology that does in fact change the lives of our patients. This is a specialized product, and should not be applied by those who are not trained and or certified to do such. Neither is the KCI VAC therapy to be confused with other NPWT products and systems on the market. I have witnessed firsthand the amazing results in granulating and closing a previously stalled or difficult wound. Its application ranges from plastic surgery to trauma and on to pressure ulcers and other chronic wounds. This Negative Pressure Wound Therapy should not be confused with other products. I | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| | | have had occasion through the years to use the products of competitors. And while the products have ranged from the complex to the simple, there has been nothing that provided the same results as the KCI VAC therapy. The gauze packing and suction tubing used by the Blue Sky system has minimal value to an immobile patient for containing drainage. The new generation Renasys by Smith and Nephew (which is an evolution of the Blue Sky product) unfortunately does not provide the same result. These products also require a specific technique of application which requires specialized education and training to produce a positive result, but it is a poor imitation at best to the KCI VAC therapy.<br><br>Again, let me state that these therapies are specialized and should be initiated and completed by trained, certified, licensed medical professionals. The coding of the therapy should reflect that this is indeed a complex therapy. This is not a product that is safe in the hands of Nurse Assistants, Medical Office Assistants, Physical Therapy Assistants, etc. Incorrect or improper application of the dressing can in fact create a larger wound or cause injury to surrounding tissues. Often KCI VAC therapy is used deep within the body adjacent to bones, tendons, and visceral organs. Again, specialized training is required to use the product safely. In short, this product and therapy is a one of a kind item. Coding and payment and or reimbursement should reflect such. Thank you for your time. | |
| Davidson, David M., DPM | NR | I am writing to express my concern about the AHRQ NWPT Assessment that has recently been made public. As a podiatrist in private practice for more than thirty years and as a clinician and current medical director of a wound care center in a hospital setting for more than three years, I have had a great deal of experience in treating chronic wounds. The V.A.C. Therapy System, developed by KCI has become an important part of my treatment of patients with chronic wounds. I have also had the opportunity to evaluate competing products and continue to feel the KCI | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS.<br><br>In regards to your concern that the research literature was not fully evaluated, we provide the following response:<br><br>The focus of this report was to evaluate the scientific evidence for a significant therapeutic |

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| | | product is, by far, superior for the following reasons:<br><br>The VAC unit transmits controlled negative pressure to the wound.<br><br>The foam, not only draws drainage away from the wound, but also draws the edges together reducing the wound area, but also increases granulation tissue formation at the cellular level. This is far away, different than any other product on the market.<br><br>The T.R.A.C. pad technology gives us accurate monitoring and the ability to adjust the negative pressure when necessary<br><br>Before using this device, I actually did a good deal of research on negative wound pressure therapy. The truth is that, to date, the literature is filled with studies showing the effectiveness of this system and very little, if anything, has been written about other devices.<br><br>Since our Center for Wound Care began at a local hospital in Buffalo, New York, dozens of patients with chronic wounds have had the benefit of using the KCI V.A.C System. Our healing rate of these wounds is 95% and this success is due not only to the care of our medical staff but to the use of the V.A.C.<br><br>I have several concerns about the AHRQ Assessment as I do not feel the research literature was fully evaluated. If it had been, the report would have had to elevate the V.A.C System to the top of the list. In my opinion there is no competitor that compares to the others in efficacy.<br><br>Thank you for taking the time to read my opinion. | distinction of any single NPWT system or its components compared to other NPWT systems or their components, based on specific outcomes of interest to the Center for Medicare Management at CMS. Key questions were prepared for the report using the "PICO" framework: patients, intervention of interest, comparator, and outcomes (see Figure 1). Inclusion and exclusion criteria were developed based on each key question prior to an examination of the evidence. Twelve inclusion criteria were established for this TA. In a TA, the inclusion criteria determine whether a study is "relevant" to the key questions. Studies that do not meet the inclusion criteria are excluded from the TA. Exclusion from the TA does not imply that the studies have no scientific merit, just that their findings are not applicable to answering a key question within the specific report. As explained below and in the report, most submissions from interested stakeholders were not relevant to the key questions posed in this particular report, the purpose of which was to determine whether there was evidence of a therapeutic distinction between different NPWT systems or components.<br><br>We undertook an extensive search of the literature from which we identified over 1,000 potential articles. In the interest of identifying all clinically relevant materials for this report, we also invited interested stakeholders to submit information regarding any published, unpublished, or currently registered studies for possible inclusion in the report. We received over 1,400 submissions by the February 6, 2009 deadline. Each submission was reviewed for possible inclusion in the report (see Appendix D).<br><br>During the evaluation of all stakeholder submissions, we excluded 638 (44%) of the |

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| | | | 1,435 submissions due to duplication alone (see Figure 5 in Appendix D). Of the 797 (55% of original) unique submissions; 29 (4%) were included in our *Background* section and 269 (33%) items were excluded; 147 (56%) of the excluded items were case reports, abstracts or poster presentations given at conferences.<br><br>Of the 499 (35%) remaining articles, 354 (71%) were excluded at the article level. Based on the a priori inclusion/exclusion criteria, narrative reviews (k = 152 [43%]); animal studies (k = 39 [11%]); and studies with fewer than five patients in each arm (k = 30 [8%]) were excluded.<br><br>Of the 144 (10%) original submissions that met inclusion criteria, 117 (81%) were previously identified by the ECRI Institute literature searches. We subsequently included 28 studies not previously identified in our searches in the final report. Please see Appendix D for additional details on individual submissions and subsequent disposition in the report.<br><br>For a clearer understanding of our evaluation process, we have included documentation of all 1,435 submissions in Appendix D of the report. This section of the report, alphabetized by submitter, includes an attrition diagram and accompanying table that describes the disposition of each individual submission therein. The attrition diagram provides a visual representation of the disposition of materials as they go through the evaluation process. The accompanying table in the report includes a citation for each submission and lists either the placement in the report or reason for exclusion.<br><br>After thorough review of the materials described above, ECRI Institute was unable to draw |

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| | | | conclusions about the superiority or equivalence of any NPWT system or its components compared to another NPWT system or its components. There were no studies that directly compared different systems and there were no RCTs of systems other than the KCI V.A.C.® system, which might have allowed us to make indirect comparisons. |
| DeJohn, Terri, M. | NR | I have been doing wound care for the past 6 years, full time in a hospital based out-patient clinic. I have had the opportunity to use the Blue Sky, and Engenex device in addition to the KCI VAC. These are very different products although they all fall under the umbrella of NPWT. It is akin to saying "They are all motorized vehicles" when you are evaluating the safety of motorcycles and luxury cars. We have had excellent results with the KCI VAC and very inconsistent results with the other products. I believe this is because of the difficulty patients have using the other products; heavy, shorter battery life, very difficult to get and maintain a good seal. The dressings used with the KCI product are very functional as compared to the much less effective dressing especially that of the blue sky. Foam is very different from gauze! The clinical expertise of the KCI personnel is invaluable and certainly adds to the effectiveness of the therapy.<br><br>To suggest that because there are no studies of the other products they should be considered to be as effective as the KCI products is ridiculous. Consider this; if you did well in school and got all A's but your brother skipped school, was kicked out and got no grades - would your parents consider the two of you the same?<br><br>The pressure used in these devices is not the same, the interface layer is not the same, the results in our clinic are not the same and there is no research to prove they are the same. (The bad brother might claim to be as smart as you are, but any reasonable parent would say, "Prove it") | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| Driesel, Terri, P.T. | Texas County Memorial Hospital | My name is Terri Driesel and I am a physical therapist at Texas County Memorial Hospital in Houston, Missouri. I have been a practicing physical therapist for 21 years. Our facility does a large amount of wound care and due to our rural status and lack of a wound care nurse, the physical therapy department provides the majority of our wound care services. We have been utilizing NPWT for approximately 5 years and our system of choice is the KCI Wound VAC. We have gone through presentations from other companies concerning the benefits of their systems and have seen the results of the use of other systems in local long term care facilities. From a clinical standpoint, there is a vast difference in the application, operation, and end results of these systems when compared to the KCI Wound VAC system. The other systems are bulky, difficult to apply, and rely on hard plastic inserted into the wound and layered between gauze, which in itself can create problems with wound healing. Although they may assist with removing fluids from the wound, they do little or nothing to encourage proliferation of tissue growth when compared to the KCI VAC. They also lack the needed ability to easily control and vary the amount of pressure applied to the wound site; there is no direct feedback mechanism in place as there is with the KCI system.<br><br>The KCI system allows for easy application with a sterile packaged dressing made of foam which allows for proper fluid movement and facilitates proliferation of granular tissue. The foam is superior to the other company's dressings in fluid movement and prevention of maceration. The system allows you to vary the pressure applied based on clinical need and patient comfort and has a feedback mechanism to alarm when pressures fall below prescribed level due to dressing leaks, tubing or canister blockage or electricity/battery failure. The connection for providing NWPT is on the outside of the dressing where as the other devices require insertion of a tube directly into the wound. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| | | The insertion of the suction device into the wound can create additional problems with wound healing due to more frequent blockages resulting in loss of vaccuum pressure, direct point pressure on healing tissues, and difficulty maintaining appropriate pressure due to dressing seal leakage.<br><br>As a clinician, I encourage you to carefully evaluate these issues when making your decision. I, for one, feel there is a night and day difference in usage and results between the KCI Wound VAC system and other systems on the market. This facility will continue to exclusively use the KCI Wound VAC because of its superior results. | |
| Drummond-Dye, Roshunda | American Physical Therapy Association | On behalf of the American Physical Therapy Association (APTA), I would like to submit the following comments in response to ECRI Institute's draft report on Negative Pressure Wound Therapy (NPWT) commissioned by the AHRQ. APTA represents over 74,000 physical therapists, physical therapist assistants, and students of physical therapy. The practice of physical therapy is integral in the management and treatment of wounds, therefore APTA is very interested in the Agency's work on this subject.<br><br>As we mentioned in our previous comments to AHRQ's Request for Information (RFI), we believe that negative pressure wound therapy is a beneficial and proven method of treating wounds. NPWT is a procedure that manages wound exudates and promotes wound closure. The vacuum cleanses the wound and stimulates the wound bed, reduces localized edema and improves local oxygen supply. It places mechanical stress on the tissue that increases the rates of cellular proliferation, granular tissue formation and new vessel growth. NPWT requires work and practice expense that is different than any other procedures considered to be selective debridement in current CPT coding.<br><br>When treating patients with chronic wounds, a physical therapist reviews the reason for referral and any relevant | Thank you for your comments on the NPWT report. Please allow us to address a few of the concerns presented in your posting.<br><br>In regards to your concern that "the draft report largely ignores all clinical evidence outside of the realm of RCTs," we provide the following responses:<br><br>Inclusion criteria #5 on page 46 of the draft report states: "*For Key Question 1, 2, and 4, study must have been a controlled study comparing one NPWT system or components of a system to another NPWT system or components. Randomization to a NPWT system group was not required."* The report actually included more non-RCTs than RCTs. The Executive Summary states that "*Of 38 studies comparing a NPWT system to another wound care therapy, all were studies of the Kinetics Concepts Inc. (KCI) VAC® system and only nine were RCTs."* Current EPC Methods Guidance does specify that <u>indirect</u> comparisons should only utilize data from RCTs in which the treatments of interest have been evaluated against a common control intervention. Had there been RCTs available of different NPWT systems compared to the same |

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| | | medical records. The patient's medical history is taken, and an examination is performed that includes assessment of the wound. The wound assessment involves the evaluation of the wound characteristics, including location, size, shape, depth, necrotic and viable tissue characteristics, peripheral tissue edema, peri-wound characteristics (e.g. erythema, edema, and maceration), and pulses. In addition, physical therapists will look for signs of infection or inflammation and examine wound characteristics for bleeding, drainage, necrosis, undermining, contraction, tunneling and odor. Based on the examination and evaluation of the findings, the therapist will develop a plan of care and determine the patient's prognosis and the anticipated outcomes of treatment. The physical therapist will establish goals, including the expected outcome of treatment and its impact on the patient's function in daily life.<br><br>Within the initial RFI request, ECRI Institute requested that randomized controlled trials (RCTs), observational studies, or other compelling clinical evidence that uses NPWT devices to impact relevant clinical outcomes be submitted for consideration. As instructed APTA submitted a list of studies other than RCTs that met the established criteria. Unfortunately, the draft report largely ignores all clinical evidence outside of the realm of RCTs. We contend that by omitting this clinical information, ECRI Institute has drafted a report that is incomplete and flawed in nature**.** APTA strongly believes that the totality of compelling and published clinical evidence should be analyzed before ECRI Institute finalizes this draft report and AHRQ utilizes said findings to effect HCPCS coding changes and other payment polices related to negative pressure wound therapy.<br><br>In conclusion, APTA fully understands the importance of evidence based practice as a critical element of negative pressure wound therapy and other rehabilitation interventions. Therefore, we are very supportive of | control treatment, we would have attempted to use the data to perform indirect statistical comparisons. This is the only situation for which we would have required RCTs.<br><br>In regards to your concern that "the totality of compelling and published clinical evidence should be analyzed before ECRI Institute finalizes this draft report," we provide the following comments:<br><br>The purpose of this report was not to provide evidence of the effectiveness of NPWT in comparison to other types of wound care treatments such as specialized dressings or topical products. The *Methods* section of this report specifically states "this report does not address whether NPWT systems provide a better wound care alternative compared to non-NPWT wound care therapies." Instead, the focus of this report was to evaluate the scientific evidence for a significant therapeutic distinction of any single NPWT system or its components compared to other NPWT systems or their components, based on specific outcomes of interest to the Center for Medicare Management at CMS. Key questions were prepared for the report using the "PICO" framework: patients, intervention of interest, comparator, and outcomes (see Figure 1). Inclusion and exclusion criteria were developed based on each key question prior to an examination of the evidence. Twelve inclusion criteria were established for this TA. In a TA, the inclusion criteria determine whether a study is "relevant" to the key questions. Studies that do not meet the inclusion criteria are excluded from the TA. Exclusion from the TA does not imply that the studies have no scientific merit, just that their findings are not applicable to answering a key question within the specific report. As explained below and in the report, most submissions from |

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| | | AHRQ?s efforts to not only examine the variations in techniques for negative pressure wound therapy devices, but also the differences in efficacy and outcomes. We believe that the discussion being developed within this report is critical to accurately formulating appropriate coding and coverage policies under Medicare (Medicaid and other federal healthcare programs). Therefore, it is imperative that all valid clinical information be considered at this critical juncture in the process.<br><br>Thank you for your time and consideration, and we look forward to our continued interactions on this subject matter and future studies. | interested stakeholders were not relevant to the key questions posed in this particular report, the purpose of which was to determine whether there was evidence of a therapeutic distinction between different NPWT systems or components.<br><br>Next, we undertook an extensive search of the literature from which we identified over 1,000 potential articles. In the interest of identifying all clinically relevant materials for this report, we also invited interested stakeholders to submit information regarding any published, unpublished, or currently registered studies for possible inclusion in the report. We received over 1,400 submissions by the February 6, 2009 deadline. Each submission was reviewed for possible inclusion in the report (see Appendix D).<br><br>The screening of all identified materials is a two-step process. An initial evaluation is done at the abstract level at which items may be excluded, used in our *Background* section or passed to the next level of evaluation. During the evaluation of all stakeholder submissions, we excluded 638 (44%) of the 1,435 submissions due to duplication alone (see Figure 5 in Appendix D). Of the 797 (55% of original) unique submissions; 29 (4%) were included in our *Background* section and 269 (33%) items were excluded; 147 (56%) of the excluded items were case reports, abstracts or poster presentations given at conferences.<br><br>Of the 499 (35%) remaining articles, 354 (71%) were excluded at the article level. Based on the a priori inclusion/exclusion criteria, narrative reviews (k = 152 [43%]); animal studies (k = 39 [11%]); and studies with fewer than five patients in each arm (k = 30 [8%]) were excluded.<br><br>Of the 144 (10%) original submissions that met |

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| | | | inclusion criteria, 117 (81%) were previously identified by the ECRI Institute literature searches. We subsequently included 28 studies not previously identified in our searches in the final report. Please see Appendix D for additional details on individual submissions and subsequent disposition in the report.<br><br>For a clearer understanding of our evaluation process, we have included documentation of all 1,435 submissions in Appendix D of the report. This section of the report, alphabetized by submitter, includes an attrition diagram and accompanying table that describes the disposition of each individual submission therein. The attrition diagram provides a visual representation of the disposition of materials as they go through the evaluation process. The accompanying table in the report includes a citation for each submission and lists either the placement in the report or reason for exclusion. |
| Evangelist, J., RN, MSN, APN, CWOCN | NorthCrest Medical Center Wound Healing & Hyperbaric Center | My comments on NPWT include extensive use of the KCI VAC system, moderate use of the Renasys system by Smith & Nephew, and the Blue Sky system. NPWT delivered with the KCI system is far superior in terms of clinical evidence, outcomes in healing, and service/ease of use for the patient.<br><br>The clinical outcomes with the patients I have seen since 2000 with the KCI VAC are far superior compared with the other systems I have tried to use in the last 2 years. Gauze is in no way able to be compared to the polyurethane foam effect on cells (according to science). The other NPWT set ups available other than KCI are nothing more than mini Gomco suction pumps set up with bubble tubing and Christmas tree adapters to a dressing. Suction is wildly variable with no effective safety alarms. It's like driving a model T today instead of the Ford F350 | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| | | for the patient in terms of equipment. I would encourage you to acknowledge the lack of science for the equipment/outcomes of the other systems. Suction is not the only variable. I would encourage you to be assertive in requesting the other systems to have head to head studies to further the science, not to make assumptions based on the science of only one product. They are NOT the same in the most important variable of patient heal times which in turn effects quality of life, return to work, and the ability to contribute to society as an end result. Refer to practicing clinicians if you want to know the facts. | |
| Fife, Carolyn E., MD | The University of Texas Health Science Center, Houston | The following information is from a paper entitled, "A Longitudinal Study of the Adverse Events Associated with the Use of Negative Pressure Wound Therapy in a Large Outpatient Wound-care Population," by Caroline E. Fife and colleagues, submitted to the International Journal of Wound Care, where it is currently under final review.(13)<br><br>The objective of this study was to determine the rate of adverse events with NPWT as delivered by V.A.C.® Therapy System when compared to standard moist wound care. This study was undertaken by KCI when the FDA required KCI to demonstrate that negative pressure wound therapy using reticulated open-cell foam (NPWT/ROCF) was no less safe than standard wound care. In other words, the safety of the VAC was not compared with other negative pressure devices, but to NO negative pressure. Thus, randomized, controlled trial data were of no use for this study. Information had to be obtained from "real world" clinical practice. Therefore, we performed a retrospective review of a large wound dataset using electronic medical records obtained over a 5-year period comprising 9119 outpatients who had 20,371 wounds (traumatic and surgical wounds, flaps and grafts, and pressure and diabetic foot ulcers) in 151,913 outpatient visits. The parameters of drainage rate, culture rate, peri-wound complication rate, and prescription rates for antibiotics and pain medications for NPWT/ROCF wounds | Thank you for your comments on the NPWT report. Please allow us to address a few of the concerns presented in your posting.<br><br>On January 9, 2009, we received your e-mail and attached paper, which you stated was "currently under review *by Ostomy and Wound Management*."(13) You further stated that "We have been asked to make changes prior to publication and are in the process of addressing the reviewer comments. However, since this represents the largest study of the safety of NPWT of which we are aware, we thought the AHRQ should have access to these data. As soon as the revised manuscript is accepted, we will forward the final copy to you." We did not receive a final version of your paper. On further review of the draft you supplied in January, we note that hyperbaric oxygen therapy is listed as a concomitant therapy, presumably for a subset of the patients. For this report, we have only included adverse events associated with NPWT when it is the primary wound management, and would need to see the adverse events listed separately for those who did not receive concomitant therapies such as hyperbaric oxygen. |

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| | | were compared to non-NPWT/ROCF wounds using general linear (GLM) model analysis. NPWT/ROCF was used in 931 patients.<br><br>Our results showed no significant increase in infection surrogates among NPWT/ROCF-treated patients versus non-NPWT/ROCF-treated patients. In traumatic wounds, pressure ulcers, and diabetic foot ulcers, NPWT/ROCF significantly reduced infection surrogates (drainage, culture, and peri-wound rates) compared to patients treated by other means (except for drainage rate in diabetic foot ulcers). Rates of antibiotic usage were significantly reduced in traumatic wounds, pressure ulcers, and diabetic foot ulcers treated with NPWT/ROCF compared to non-NPWT/ROCF-treated patients, similar to decreases in drainage and culture rates. There were no bleeding complications that could be solely ascribed to usage of the NPWT/ROCF even though 8% of patients were on heparin or other anticoagulants.<br><br>This study showed that NPWT as delivered by V.A.C.® Therapy System is safe. It demonstrated that the V.A.C. does not result in an increase in signs or symptoms associated with infection or pain when compared with most wound care, that is, when compared to not using any form of negative pressure. It showed that the V.A.C. is even safe among patients receiving anticoagulation.<br><br>This was the largest safety study of negative pressure ever performed, evaluating over 20,000 wounds of which 10% had negative pressure. I provided this information to the AHRQ within days of the call for information, and these data are not referenced in the final report.<br><br>There are two overarching issues of great concern. The first is that the FDA required KCI ALONE to demonstrate the safety of its product. The bar which was set was to show that the V.A.C. was as safe as moist wound care. The second issue is that the AHRQ has performed an analysis for which the only safety data available pertains to the | In regards to your comment that "AHRQ has performed an analysis for which the only safety data available pertains to the V.A.C. since no other company has safety data," we have the following comments. The focus of this report was to determine if a significant therapeutic distinction was clinically apparent among any NPWT system or its components compared to other NPWT systems or their components. Key questions were formulated for the report to test the hypothesis that a NPWT system or its components provided a significant therapeutic distinction compared to other NPWT systems or their components. These questions were structured using the "PICO" framework: patients, intervention of interest, comparator, and outcomes (see Figure 1). Inclusion and exclusion criteria were methodically developed based on each key question prior to an examination of the evidence.<br><br>Key Question 3 addresses the reported occurrences of pain, bleeding, infection, other complications, and mortality for NPWT systems. Key Question 4 addresses the hypothesis that patients being treated with one NPWT system have a significant therapeutic distinction in terms of less pain, bleeding, infection, other complications, or mortality than other NPWT systems. As mentioned, these key questions were developed prior to the identification of the evidence that subsequently evaluated only one NPWT system, KCI's V.A.C.®.<br><br>While we were able to capture the severity of harms reported by case series and comparison studies evaluating NPWT to comparator treatments, due to the lack of studies comparing one NPWT system to another NPWT system, we were unable to determine the severity of adverse events for one |

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| | | V.A.C. since no other company has safety data. The AHRQ has concluded that there is no therapeutic distinction among products when no safety data were available for comparison.<br><br>What the evidence allows you to say is that the V.A.C. is as safe as moist wound care, and no other negative pressure device has demonstrated its equivalence to the V.A.C. from the standpoint of safety. | NPWT system compared to another. |
| Fleming, Cindy | HealthBack Homecare | I have had the pleasure of using the KCI V.A.C. for many years. The simplicity of the unit and the use of the dressing change components make it much easier for any nurse to perform a dressing change. I am very happy to be able to track the progress of the client's therapy by looking at the therapy hours and looking for compliance.<br><br>The other NPWT devices have many dressings that are difficult to use for NPWT.<br><br>I have a concern in regard to the pressures that all the different machines seem to operate at, this should be based on the wound type and the measurements should be a factor when deciding on the appropriate NPWT device.<br><br>There is a lack of evidence and studies to be able to put all the NPWT devices in the same category and to assume the results will be the same. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |
| Fortner, Terri, LPNWCC | Healthback Home Health, Oklahoma | I have had the privilege of using V.A.C. therapy with my patients for over 10 years and have seen its many benefits. I have witnessed almost miraculous healing rates on wounds that doctors and patients thought would never heal. I have not used any other type/brand of NPWT other than the KCI V.A.C. and prefer to continue using this brand. Over the years, KCI has worked to improve their V.A.C. product resulting in better, faster outcomes for the patient and a more user friendly device for the clinician. My only concern is that some patients never benefit from this incredible machine because they are on state funded | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| | | Medicaid and do not have the funds to afford this treatment when, in fact, V.A.C. therapy is more cost effective than other treatments due to the fast heal rate. | |
| Foster, James E., II, MD, FACS | Medical Director, Carilion Wound Care Center, Clinic | I have been actively involved in the care of multiply injured and chronic wound care patients for 30 years. My surgical career has paralleled the development of negative pressure wound therapy. I have been prescribing the use of Wound Vac systems for several years. As Medical Director of our wound care center, I have had the opportunity to see patients treated with products other than the KCI V.A.C family of devices. It is clear from my personal experiences that the KCI system is unique and currently is the most effective wound healing system available in the NPWT environment. I have had several patients in the last year show significant wound deterioration when treated with systems other than the KCI product. Other products may serve as equivalent wound drainage collection devices but the KCI V.A.C system has demonstrated a significant improvement in wound closure and is more effective in stimulating granulation formation than any other product I have experienced. Therefore, I believe the KCI Wound V.A.C. system warrants a unique designation as an adjunct to complicated wound care. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |
| Francis, Kenneth R., MD, FACS | The New York Presbyterian Hospital | To all concerned entities,<br>A matter of great concern has been brought to my attention by KCI, the manufacturer of the VAC negative pressure wound therapy system. I am a board certified plastic surgeon, licensed in the states of New York and Florida and have been practicing for fifteen years. Wound care and wound management have been an integral part of my plastic surgery practice for those fifteen years, with ten years served as medical director of one or another wound care center. I currently hold medical directorships at the Wound Care Centers at both Flushing Hospital and St. Vincent's Hospital Medical Centers in New York City. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS.<br>We appreciate your concern with the findings of the report. Due to the lack of published or unpublished studies that evaluated other NPWT systems we were unable to perform direct or indirect comparisons. In the absence of such comparisons, ECRI Institute was unable to draw conclusions about the superiority or equivalence of any NPWT system or its components compared to other NPWT systems or components. |

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| | | I have always taken great pride in my efforts to practice "evidence based medicine" even before the terminology existed as such. For this reason, 10 or 12 years ago I made an educated "evidence based" decision to incorporate VAC NPWT into my practice. The “evidence” at that time was mainly scientific in nature with support from animal studies. Since that decision was made countless hundreds, if not thousands of patients under my care have benefitted from the superior, what I consider to be, standard of care offered only by the KCI VAC. The level 1 evidence that has since graced the plastic surgery and wound care literature parallels my practice experience in confirming the safety and efficacy of the KCI devices.<br><br>At no time have I ever considered using any of the competing negative pressure wound therapy devices. All devices within a technology are not equal. If it were just a matter of applying negative pressure to a wound perhaps this would be the case. However, the VAC technology incorporates a proprietary foam technology and pressure sensing system that actually provides the mechanism of action and ensures consistency of negative pressure delivery. These properties set the KCI VAC as the gold standard in NPWT, well beyond any other device currently available.<br><br>Perhaps my greatest concern is the assumption by AHRQ that lack of evidence (as provided by the competitors to the KCI VAC) implies that no therapeutic distinction can be made between VAC NPWT and its competing devices. This assumption is just that, and you know what happens when we assume. All kidding aside, CMS has set the standard for the field of medicine in its initiatives to foster "evidence based medicine". The acceptance of substandard devices as equivalent, without any supporting evidence is simply and sadly contrary to these initiatives. | |
| Franklin, Richard, M.D., F.A.C.S. | Northwest Hospital | I am a surgeon and have been involved in advanced wound care for many years. I have been using the KCI Wound | Thank you for providing us with information regarding your experience with NPWT devices. We |

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| | Wound Center | V.A.C. as part of the treatment for appropriate patients as well. I have reviewed the new guidelines and feel that they are based on flawed evaluations of the data available. The V.A.C. system is unique because of the foam used in its design, the pore size of the foam, and the ability of the unit itself to provide a constant and reliable amount of negative pressure at all times. In addition, the safety features regarding leaks or high pressure are extremely important regarding patient safety. Other systems are based on inferior foams or gauze that do not have the ability to have a uniform negative pressure over the entire wound being treated. In addition, the suction units are not reliable as to the exact amount of pressure applied or the ability to detect a leak, which can cause the wound to worsen. I have seen other products used, and uniformly, across the board the wound has worsened. When that wound is then treated with KCI's product, it improved at a rapid rate. Lastly, the studies referred to are almost all based on the KCI Wound V.A.C. and it is unfair to extrapolate these results to other therapeutic modalities that may be similar. The KCI product should be treated as a separate and unique treatment modality. Thank you very much. | will share this information with the Center for Medicare Management at CMS.<br><br>We would like to respond to your comment that "it is unfair to extrapolate these results to other therapeutic modalities that are similar." Due to the lack of published or unpublished studies that evaluated other NPWT systems we were unable to perform direct or indirect comparisons. In the absence of such comparisons, ECRI Institute was unable to draw conclusions about the superiority or equivalence of any NPWT system or its components compared to another NPWT system or its components. |
| Gonzalez, Karen, DON | AMNA Healthcare Services | I have been working with negative pressure wound therapy for some time now. I as the DON of an agency have been extremely impressed with the patients wound healing because of the negative pressure. The outcome is what every patient wants to achieve after a surgery, traumatic injury, diabetic ulcer, and I as the nurse and happy to have been part of their exceptional healing experience. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |
| Grove, Carolyn | RN CWOCN Hospital wound care nurse | In review of a draft report on NPWT I would like to comment. I have used several different forms of NPWT and there is a significant difference in the response to the wound using the KCI VAC vs NPWT using gauze. From my 26 years of experience as a RN and last five as a Certified Wound Care Nurse I have seen the VAC work more rapidly to promote granulation tissue formation and | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| | | closure of wound sooner because of this. I will use other forms of NPWT but only when forced to because of reimbursement source. I believe there is a significant difference in how the NPWT is provided and should be coded and reimbursed differently. | |
| Hajimirsadeghi, Amir, DPM | Group Practice | I believe the negative pressure wound therapy with sponge is absolutely superior and have saved thousands of limbs and have closed multiple hard to tackle wounds. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |
| Hertling, Jennie, RN, CWS, CHRN | Lee Wound Care | In response to your request regarding NPWT in our wound clinic we have used the KCI wound V.A.C. for years and have been very satisfied with the results. Wounds heal in a much shorter period of time when compared to other dressing options by promoting granulation within the wound beds and keeping the drainage away from the pt. The pt does not have to deal with the problems of excessive drainage along with its complications. Wound healing is progressive with few complications associated with using the vac. The KCI staff demonstrates excessive knowledge and is always available for trouble shooting. If our specific rep is not available, KCI will find someone to cover. We are never left without assistance. Our reps give us frequent updates and in services regarding any changes. In the past, in our clinic, we have used the Blue Sky which was totally unacceptable. The patient's wounds quickly became worse with maceration and necrotic tissue. The product was difficult to use. The representatives demonstrated very little knowledge of their product and were unable to answer questions asked by our staff. They were seldom available for trouble shooting assistance. As for your report, I apologize, but I am a clinician and do not have the time to read 474 pages at this time. I am reporting what I know from using the KCI product and feel it is the one to use as it has proven itself over and over by the rapid granulation that occurs. Most patients tolerate it very well and feel they get excellent support from the KCI reps as well as our clinicians. This | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| | | may not be the detailed pathophysiology report you are looking for, it is simply a clinician's opinion on a great product that has helped our pts tremendously. Thanks for asking for my input. | |
| Higginbotham, Debra, RN, BSN, CWOCN | Palestine Regional Medical Center, Palestine, TX | We have used the KCI Wound V.A.C. and the Invia Liberty by Medela. The foam based Wound V.A.C., is more difficult to apply but I feel the results are better. We had trouble with the seal over the gauze based dressing on the Invia Liberty, and I'm not sure if it is because of the location of the wounds that we applied it to which was underneath the folds of the abdomen all 3 of the patients. The skin became irritated and rashy as well as moist most of the time. I did like that the Invia Liberty had the tube that could be placed in the tunnels and that we were not losing small pieces of the foam in those tunnels, also the dressing was easier to apply, but it's difficult to say if it was better for the patient because we had to take it off after a few visits due to skin irritation. I feel that the Wound V.A.C. by KCI is a step above the other gauze based NPWT. Both NPWT systems that we used were pretty good about keeping the patient from having frequent dressing changes and containing the drainage (if used appropriately). In a perfect world we would have a body part that had no cracks or crevices and could place the dressing on a flat surface, and not experience any rashes. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |
| Hill, Georgiana T., COWN | NR | I am a CWOCN that has worked with the KCI Wound V.A.C. for many years. In the past several months, I have also had an opportunity to trial some of the other NPWT systems that are now on the market. Where I work, I am given the directive to use evidence-based products that are in the best interest of the individual patients that I work with. Over the years, I have read the many clinical trials and case studies that KCI has performed on the Wound V.A.C. In my own practice, I have positive evidence every time I have take off a Wound V.A.C. dressing of the excellent granulation and forward progression in the wound bed. To me, it is exciting to take off the V.A.C. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| | | dressing and see that beefy red granulation and the significant improvements in the wound since the last dressing change. The foams created and used by KCI are one of the key factors in the success of their product and therefore, the success of wounds to heal in a positive, timely manner.<br><br>In using the other NPWT systems, I did get some new granulation and there was some improvement in the wounds, but at maybe half the rate of the Wound Vac. The new granulation was not of as high a quality as with the Wound V.A.C. also. I have not been able to find any clinical trials for these other NPWT systems, only case studies. What I want to see are well thought out and planned clinical studies that show me a comparison of the Wound V.A.C. and these other systems.<br><br>From my own experience, they are not in the same and are not even in the same category. The Wound V.A.C. is more superior in every way and the granulation and progression of the wound is the key factor when I am choosing the V.A.C. for one of my patients. In the long run, I believe the KCI Wound V.A.C. is more cost effective because of the decreased time involved in efficiently and successfully healing of wounds. | |
| Hodge, Robert, MD | NR | As a user of NPWT in treating acute and chronic wounds including open abdomens, burns, ulcers, fistulas, etc. I can say that the VAC system provided by KCI has been the only NPWT system that has been supported by its manufacturer in such a way as to make it usable in any kind of environment, in the hospital or at home. It is versatile, easily deployed and maintained, with consistent reproducible results and beneficial patient outcomes. My only comparison to the KCI VAC system is the Blue Sky product which I have found difficult to use and maintain, and ineffective relative to the KCI product.<br><br>In my opinion, in the absence of valid scientific evidence to support such a conclusion, it would be a mistake to | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS.<br><br>No studies directly comparing one NPWT system or its components to another NPWT system or its components were identified in ECRI Institute internal searches or from submissions from interested parties. Due to the lack of published or unpublished studies that evaluated other NPWT systems we were unable to perform either direct or indirect comparisons. In the absence of such comparisons, ECRI Institute was unable to draw |

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| | | conclude that there is therapeutic equivalence among the NPWT products currently available. Until then CMS should leave the HCPCS for NPWT alone and not discourage NPWT's use. | conclusions about the superiority or equivalence of any NPWT system or its components compared to another NPWT system or its components. |
| Hodges, Linda | NR | I have used the KCI wound vac for numerous years and have seen wonderful results. The following are some of the ways the VAC is used in our facility:<br>The VAC prevents skin grafts from lifting/floating off.<br>The VAC is used with open chest wounds, pressure ulcers, incisions, fistulas, and traumatic wounds to control drainage and many more.<br>I explain to patients that the VAC helps pull drainage and infection out and the foam applies pressure to the cells which make them split and multiply which is one of the most important factors that the KCI VAC has that other negative pressure devices do not. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |
| Horch, Raymund E., Prof. Dr. | Department of Plastic and Hand Surgery, University H ospital, Erlanger, Germany | Dear Ladies and Gentlemen, on your Draft Report titled: Negative Pressure Wound Therapy Devices Draft Project ID: WNDT1108 I found my name several times cited as an author of papers relevant to this subject.<br>I can understand that your systematic review needs to be strictly formalized. But I want to comment on the categorization and conclusions drawn from papers stemming from my group. While for instance one paper is cited as a case report, for other reports there is a categorization of "not relevant" for unknown reason for other publications. Seemingly, in such surveys as the one you have prepared, reviewers do not estimate completely new developments, because they are on the search for great numbers. Although it has become very popular to collect as many numbers as possible assuming that the height of the numbers correlates with scientific evidence treatment of complex wounds and tumor defects is not easily reflected with numbers collected from various | Thank you for providing comments on the report. We would like to respond to several concerns presented in your posting.<br>First we would like to clarify the inclusion criteria for the report. We required a minimum of five patients per treatment group to improve the generalizability of the findings. Individual case reports and very small (< 5 patients in this case) may reflect atypical circumstances either in terms of the patients or the application of the technology. Obviously, as experience with an application grows, more patients would be available for inclusion in a study. This is not to say that very early reports are unimportant, simply that we are hesitant to generalize their findings.<br>The purpose of this report was not to provide evidence of the effectiveness of NPWT in comparison to other types of wound care treatments |

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| | | reports.<br><br>When for instance we can prefabricate a new trachea, as in one such "irrelevant" paper, this is a major breakthrough in reconstructive medicine for patients who have lost their trachea and cannot speak. Prefabrications of such very complex tissues that are developed within the patient itself have become possible with the help of a foam interface between the diverse tissues to exert even pressure to the newly created tissue compounds while at the same time assuring that such tissue surfaces are not allowed to occlude at any place and any time during such procedures. There is no chance to achieve any similar effect with gauze or other materials as an interface between newly generated tissues. Our own experiences as well as other reports have revealed that gauze as an interface does not work sufficiently when compared to a PU foam. In the opposite when we tried the same system with a gauze we experienced tremendous failures with serious negative effects that were only due to the gauze interface (adhesion of tissues, integration of gauze into growing tissue, sloughing of grafts when removing gauze etc.). This did not happen, when PU foam was used to achieve consistent negative pressure in complex 3D tissue generation.<br><br>It lies in the nature of such complex newly developed procedures that there is only a small number of cases initially. As so often, unfortunately clear advantages of new techniques fail to impress reviewers who are not familiar with the seriousness of such medical conditions and who may not realize the true value of publications (papers from my group in this context are only an example for this effect) dealing with new achievement in a naturally smaller number of patients.<br><br>It is clear that decreasing inflammation positively affects wound healing. It has been shown clinically and experimentally that using a PU foam on wounds to exert NPWT leads to a reduction in bacterial counts. This was not shown for any other type of interface (such as gauze | such as specialized dressings or topical products. The *Methods* section of this report specifically states "this report does not address whether NPWT systems provide a better wound care alternative compared to non-NPWT wound care therapies." Instead, the focus of this report was to evaluate the scientific evidence for a significant therapeutic distinction of any single NPWT system or its components compared to other NPWT systems or their components, based on specific outcomes of interest to the Center for Medicare Management at CMS. Key questions were prepared for the report using the "PICO" framework: patients, intervention of interest, comparator, and outcomes (see Figure 1). Inclusion and exclusion criteria were developed based on each key question prior to an examination of the evidence. Twelve inclusion criteria were established for this TA. In a TA, the inclusion criteria determine whether a study is "relevant" to the key questions. Studies that do not meet the inclusion criteria are excluded from the TA. Exclusion from the TA does not imply that the studies have no scientific merit, just that their findings are not applicable to answering a key question within the specific report. As explained below and in the report, most submissions from interested stakeholders were not relevant to the key questions posed in this particular report, the purpose of which was to determine whether there was evidence of a therapeutic distinction between different NPWT systems or components.<br><br>Studies documenting comparisons of different components while utilizing the same NPWT system would facilitate understanding of the importance of those components. Studies employing different NPWT systems utilizing the same components (dressings, drainage methods) would further expand |

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| | | etc.) Experimental data also show that the positive and negative imprints of compressible foam deliver alternating physical strain to cells in a wound on a microlevel. It is common sense that physical stimulation of cells offers an impulse to cells that induces proliferation. While there is evidence that a foam type interface induces such forces there is hint that other media such as gauzes etc. will be equally compressible or will deliver such forces to the wound surface.<br><br>From our own experiences and including all scientific and pre-clinical research, opinions from wound care experts, clinical experience, and feature, function, and operational experience it is clearly discernible that the use of a foam as an interface to deliver NPWT is a prerequisite for most types of wounds. Especially in cavities gauze may collapse, even in particular areas, may cause exudate retainment, may get stuck with debris due to the nonsufficient interconnectivity of gauzes and thus may deteriorate local tissue, leading to serious complications.<br><br>I agree with the authors of this survey that certainly more prospective randomized controlled studies are desirable to evaluate the impact of technical details as here in negative pressure therapy.<br><br>However, it seems very strange, that despite a considerable body of literature and of numerous evidences collected worldwide over many years, one has the impression that in this report the reviewers did not acknowledge the fact, that obviously all significant research published to date on NPWT relates only to V.A.C.? Therapy. Reviewing the corpse of literature it becomes clear that there is a lack of medical evidence on other NPWT products. Therefore if anything, this finding fully supports V.A.C.® Therapy's clinical superiority and differentiation from the data available today and the data cited in this AHRQ draft.<br><br>The fact that AHRQ equates the absence of evidence on other NPWT products as evidence of therapeutic | our understanding.<br><br>In response to your comment "The fact that AHRQ equates the absence of evidence on other NPWT products as evidence of therapeutic equivalence of all NPWT products seems alarmingly frail and should be corrected in the sense of good scientific practice," we reply that we were unable to draw conclusions about the superiority or equivalence of any NPWT system or its components compared to another NPWT system or its components. There were no studies that directly compared different systems and there were no RCTs of systems other than the KCI V.A.C.® system, which might have allowed us to make indirect comparisons. |

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| | | equivalence of all NPWT products seems alarmingly frail and should be corrected in the sense of good scientific practice. | |
| Houchens, Linda, RN/CWS | Shore Health System | As the Educator of Shore Home Care & Hospice of Easton, Md. and formerly of Southern MD Home Health Services and also as a Certified Wound Specialist with the American Academy of Wound Management (AAWM), I have had a great deal of experience with and opportunities to use the KCI Wound VAC on patients with wounds of all kinds. Once educated on the use of the VAC on a wide variety of wounds and having determined its effectiveness, I was able to recommend its use to our physicians and nursing staff. This therapy has proven to have an amazing ability to more rapidly move wounds through the healing process than other more traditional wound therapies. KCI has continued to listen to clinicians and improve this product on the basis of their collective recommendations. KCI has continually provided us with clinical studies proving the therapeutic value of VAC therapy to assist us in providing evidence based wound care in our practice. Although I have given our clinicians the opportunity to try other negative pressure wound therapy products and compare them to the VAC, they have expressed very little interest in doing so. They are pleased with our wound outcomes using the VAC and see no reason to change to another similar product. I would encourage the AHRQ to re-evaluate and reconsider the full spectrum of scientific evidence and pre-clinical research submitted by KCI and considers the lack of evidence on other NPWT products. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |
| Houston, Michael | Piedmont Surgical Clinic | The KCI wound V.A.C. is the superior NPWT product. The other products in this category are far inferior in assisting patients. While cost is always a relevant and necessary consideration in choosing products, my first and foremost concern is what is best for patients. In the realm of NPWT, the KCI product is the best product for patient care. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| Hurlow, Jennifer, GNP, CWOCN | NR | I am writing to express my concern about the risk of bundling all negative pressure wound therapy (NPWT) systems. I am a clinician. I am a Certified Wound, Ostomy, Continence Nurse (CWOCN), Geriatric Nurse Practitioner (GNP). I am currently working with wounds in the acute care and outpatient settings. I have worked also in the nursing home setting. Clinically, I have seen that outcomes vary significantly with different NPWT systems.<br><br>The external track pad on the KCI VAC supports consistent and trouble free suction. I have used a NPWT system that places the suction device within the wound packing. I have found that this method is more likely to lead to peri-ulcer pressure damage related to the tubing, which exits from the edge of the wound dressing. I have also experienced difficulty monitoring system suction. I have found that when the suction device is placed within the wound packing, the system is more likely to register dressing suction as intact when, in fact, the suction over the wound bed is lost and the sensor is simply registering negative pressure resulting from suction on the packing alone.<br><br>The below link is to a January 2007 article that compares VAC foam to gauze. The authors of this article are some of our nation's finest wound experts. Their case studies reveal a significant difference in outcome between the VAC foam and gauze; this difference leading to very significant differences in healing time and complications. I have seen that the gauze system is more likely to lead to peri-ulcer maceration. http://www.woundsresearch.com/files/docs/LomaLinda.pdf<br><br>The VAC suction computer device is much easier for the support staff to use and provides much more accurate therapy monitoring. This sophisticated equipment drives the function of the VAC NPWT. Other suction systems do | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| | | not match the sophistication of the KCI device. In my opinion, it is therefore not possible to infer that other systems will provide equal healing outcome. It is my understanding that one of the newer foam systems has no way to alert staff to a full canister. For many reasons this is a crucial short coming. The risk for costly complications, in my opinion, is much higher with the less sophisticated suction equipment. At the very least, support staff (especially in nursing homes); tend to have more difficulty initiating and maintaining the less sophisticated suction systems. This leads to more cost-abusive rather than cost-effective outcomes.<br><br>I am concerned that perhaps our government has not yet learned all of the lessons offered by our current financial crisis, especially as this relates to our healthcare system. Current guidelines allow devices to gain credibility by jumping on the back of research provided by other device companies. Perhaps the government believes that our free market system will support best outcome. But, we have now begun to see that money and greed tend to drive our markets. Based on this realization, CMS is beginning the Quality Purchasing initiative. The collective we need to be enticed to focus on cost effective outcomes. To facilitate this goal, I think that it would be quite prudent to reevaluate this device policy. Device manufacturers should be not be able to make claims unless specifically supported by their own research with their own devices. Currently, the other NPWT systems are using KCI research to support their devices. Yet none of these other systems are using the patented KCI sponge system, which is reported to be key to the KCI study outcomes. Tell me; is it logical to assume that if you can drive a car that you can drive a truck? No, this is a different vehicle system. Is it logical to assume that cotton gauze will provide that same negative pressure to a wound surface as patented foam? I do not believe it is. I am all for cost effective care. But if our government is changing focus to quality outcomes then they should not blur the lines between | |

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| | | lesser quality and the higher quality devices that may be required to deliver positive outcomes in more challenging cases. In my opinion, CMS should commit to consistently highlighting quality; from quality outcomes to quality providers to quality pharmaceuticals, to quality DME supplies, and quality devices. Various devices need to stand on their own research so that we practitioners can make well informed choices. Patients deserve the chance for best possible outcomes and, as our population ages, better quality devices will be required to meet the challenges of the elderly.<br><br>I had a patient with a 26cm x 32cm x 6cm sacral pressure ulcer. While in acute care, her wound was progressing with the VAC. But, the sub-acute facility chose to use a less costly gauze NPWT system (I wonder what thought process drove this decision). This NPWT system did not stay on; the staff assumed that it was continuing to function because they did not hear alarms alerting them otherwise, the large amount of wet gauze in the wound bed led to site infection and costly complication ensued. All NPWT is NOT equal.<br><br>I appreciate your willingness to listen to the concerns of us frontline clinicians. I have no financial relationships with any of the involved companies. My only goal is; always has been; and always will be; to deliver the best, most cost effective care to my patients. | |
| Husain, Zeeshan, DPM | DMC and Crittenton Hospitals | I have been using various wound VACs over the past several years and have found a clear distinct advantage when using the KCI Wound VAC versus some of the other competitor products. These thoughts and observations have also been echoed by nurses who also assist with wound care. The main difference I find is the effectiveness of the products in terms of wound healing.<br><br>The amount of negative pressure generated by the KCI Wound VAC is more than the others which helps to drain more and promote more granulation tissue. I see fewer | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| | | maceration problems with the KCI Wound VAC than the others.<br><br>The KCI Wound VAC has more specialized dressings and drains that are specific to the needs of certain types of ulcerations. The other products have standard equipment which may not be flexible enough for particular types of wounds. I have more issues with leaks with the other products.<br><br>The KCI VAC unit and carriers are more patient-friendly. The ease of use and mobility are some positive feedback that we have gotten. In addition, the patient support network has been better with KCI. When there have been issues with faulty equipment or need of more supplies, KCI has always responded quickly.<br><br>In terms of outcomes, I have only had positive outcomes with the KCI Wound VAC with fewer complications. The other products, which also have shown the ability to help with healing, do not demonstrate as quick of a response. To minimize complications, it is vital to use something that will get the quickest results. It has been shown that the longer wounds stay open, the greater the chance of re-infection and complications. As a physician, who advocates the best treatment options for patients, I would strongly recommend the KCI Wound VAC over all the other products available currently. Unfortunately, some insurance companies and facilities have contracts with various companies that prevents using the KCI Wound VAC. When patient care is compromised, I do not think using a less-expensive product is justified. | |
| Kamepalli, Ravi K., MD, CWS | Regional Infectious Diseases and Infusion Center, Lima OH | I have been a long term user of NPWT. My observation has been that the interphase between the wound and the V.A.C. machine is the key for granulation. I am not sure about the pore size issue but KCI V.A.C. device has worked wonders for my patients. I do think there is a lot of difference between the V.A.C. devices out there and the each has it qualities that are being touted. A V.A.C. device | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| | | needs to not only help with drainage but also needs to improve blood flow to the wound bed and improve granulation. It is my clinical judgment that KCI V.A.C. has far outperformed its competitors. That said it has its own problems with cost, that hopefully will be worked out and there needs to be clinical trials proving its competence beyond further questions. | |
| Kirkland, Jennifer | Mercy Wound Center, Redding, CA | KCI Wound Therapy Closure Device has all Scientific and clinical data for KCI Device-that uses specialized foam and not gauze dressing. The Smith and Nephew Product use KCI data and say it is the same, when it is not.<br><br>I have been a Certified Wound Nurse for 19 years and have used the KCI VAC for 15 years with great success. It promotes healing by 50% or more percent. Encourages chronic non-healing wounds to heal. It reduces edema, promotes perfusion and removes exudate and infectious material. I have used the VAC in the acute, home health and wound clinic settings. The consumer service is outstanding. We have 4 Clinicians locally and they provide us with up to date information and provide many in-services for our staff. They also make home visits to assist patient or caregiver in learning VAC care. The clinicians are always available by phone at any time. We can order the product on line and they deliver and process in a timely manner. The other wound therapy device, has not been used locally. They have no clinicians available. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |
| Kobylus, Brian J., D.P.M. | Private Practice | I have been using KCI V.A.C. therapy for the past approximately 9 years for multiple types of wounds/ulcers to the lower extremities. The therapy has yet to show any negative results when used correctly on compliant patients. It has decreased healing time in many patients and improved the clinical appearance of many wounds due to its debridement of unhealthy tissue with dressing changes and ne angiogenesis secondary to mechanism of action.<br>I have discussed other negative wound pressure products with some of my colleagues, and after hearing some of | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| | | their experiences, I would not use any of these products on my patients. I feel that if I were going to use any other product than KCI V.A.C. therapy it would be detrimental to my patients and beneath my standard of care. | |
| Kravitz, Steven, DPM, FAPWCA | American Professional Wound Care Association | The American Professional Wound Care Association (APWCA) a multi disciplinary organization representing 2,700 health care professionals providing wound care; 80% are physicians, 20% are nurses and other wound care professionals. This correspondence is written to address the concerns of competitive bidding with reference given to negative pressure wound therapy (NPWT) and the solicited information and commentary pertaining thereto. This commentary is provided in response to the draft published by the Agency Health Care Research and Quality (AHRQ).<br><br>Our review of the AHRQ draft and discussion with members of the Association suggests several concerns as follows.<br><br>There is an apparent limit as to the type of evidence that was considered in that only randomized clinical trials (RCT) were used in the assessment. Why were other resources of data not utilized in the review process for the draft? Other evidence may have provided vital information and there is no method indicated to assess the quality of the RCTs utilized.<br><br>Total wound closure was used as a primary end point in the studies reviewed. This appears inconsistent with wound care therapy. It is rare that one form of therapy would be used through the entire treatment regimen. Closure of wounds most often requires multiple forms of treatment which are initiated and then discontinued as the wound progresses. Additionally, negative pressure wound therapy which was the regimen investigated here is not used for full closure. Therefore, total closure as a primary end point is inconsistent with the realities of practice and does not reflect a real life experience. | Thank you for providing comments on the report. We would like to take this time to respond to the concerns presented in your posting.<br><br>First we would like to address your concern that the report evaluated "only randomized controlled trials."<br><br>Inclusion criteria #5 on page 46 of the draft report states: "*For Key Question 1, 2, and 4, study must have been a controlled study comparing one NPWT system or components of a system to another NPWT system or components. Randomization to a NPWT system group was not required."* The report actually included more non-RCTs than RCTs. The Executive Summary states that "*Of 38 studies comparing a NPWT system to another wound care therapy, all were studies of the Kinetics Concepts Inc. (KCI) VAC® system and only nine were RCTs."* Current EPC Methods Guidance does specify that indirect comparisons should only utilize data from RCTs in which the treatments of interest have been evaluated against a common control intervention. Had there been RCTs available of different NPWT systems compared to the same control treatment, we would have attempted to use the data to perform indirect statistical comparisons. This is the only situation for which we would have required RCTs.<br><br>Next, we provide the following comments in regards to your concern about the use of total wound closure as an endpoint.<br><br>The *Methods* section includes an analytical |

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| | | The draft presented by AHRQ implies evidence based on the V.A.C., a specific form of NPWT and its mechanism of action was applied to other products. There are significant differences between various NPWT products so that using data that was derived from V.A.C. research should not automatically be assumed to establish equivalency with other products on the market.<br><br>In summary, the APWCA believes there should be a broader consideration of other forms of evidence aside from the RCT. We further believe that end points used in studies should reflect the realities of practice. Not doing so can establish protocols which might be inconsistent with realities of real life situations. Finally we also address concern that products that provide a similar form of therapy may do so with very forms of applications. This is especially of concern when the forms of therapy are used on very compromised patients so that misjudgment of a type of therapy applied has a greater risk of leading to failure and morbidity.<br><br>While this correspondence deals with concerns regarding the HCPCS coding review of NPWT, the issues it raises also indirectly relate to the review process that is to be utilized for all competitive bidding. This can have significant impact on the quality of our healthcare delivery system. We hope that these comments regarding the AHRQ NPWT draft are helpful and will open a dialogue for further consideration on these issues.<br><br>Respectfully submitted,<br><br>Laura Jacobs, MD, PhD, FAPWCA<br>Chair APWCA Insurance Committee<br><br>Sharon Baranoski, RN, CWOCN, DAPWCA<br>Member APWCA Board of Directors and APWCA Insurance Committee | framework (Figure 3 in the report) that lists outcomes that were considered in this report. For assistance in clarifying relevant outcomes, we looked for guidance from the U.S. Food and Drug Administration (FDA).(14) According to the FDA, improved wound healing and improved wound care are important clinical outcomes with the use of a wound-treatment device. Specifically, the most important outcomes to consider under the category of improved wound healing are percent of patients with complete wound closure and time to complete healing (partial healing for facilitation of surgical wound closure). We therefore incorporated "time to complete wound closure" and "percent of wounds healed" as important patient-oriented outcomes. In addition, for cases that are not expected to result in complete wound closure but rather to advance the wound to a stage where healing is possible we incorporated "time to 50% reduction of wound initial volume," "percent change in wound volume," and "improved wound condition" as important outcomes of interest. In keeping with the AHRQ methods guidance, we have captured important patient outcomes, such as quality of life, satisfaction with treatment (which would include mention of pain or discomfort during treatment), duration of treatment, and survival.(12) Outcomes such as improved compliance, convenience and personal preference (and patient-oriented outcomes such as quality of life or satisfaction with treatment) are considered by CMS to indicate significant distinctions only to the extent that they result in demonstrably improved clinical outcomes. Patient outcomes reported in 40 comparison studies, 103 single arm studies and 22 previous systematic reviews are included in Appendix C of the report. Key Question 3 specifically focuses on harms reported in studies comparing NPWT to comparator |

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| | | | treatments. For reports of comparison studies, single arm studies and previous systematic reviews, we refer you to Tables 5, 38, and 42 respectively.<br><br>Lastly, in response to your comment that the draft report "implies evidence based on the V.A.C., a specific form of NPWT and its mechanism of action was applied to other products," we note that due to the lack of published or unpublished studies that evaluated other NPWT systems we were unable to perform direct or indirect comparisons. In the absence of such comparisons, ECRI Institute was unable to draw conclusions about the superiority or equivalence of any NPWT system or its components compared to another NPWT system or its components. |
| Lind, Richard A., D.P.M. | Private Practice | As a practicing Podiatric Physician, I can relate with first-hand experience, the life and limb saving ability of the VAC system as pioneered by KCI. Essential to negative pressure wound therapy is the transport system and the creation and maintenance of the wound seal. The unique sponges created and used in the VAC system work with minimal maceration and allow continued transport of drainage. The analogy of a cotton sock verses the modern synthetic materials which are able to wick the perspiration while keeping the foot dry. Specialized sponges have also been created to fit the human heel and to combat on-going wound infection. The continued negative pressure accomplished through a durable drape and the adhesive which maintains skin contact allows patient comfort, compliance and peace of mind for the wound health care team.<br><br>For these reasons, I feel the VAC system by KCI is unique and other similar systems which lack these features should not be considered as equals. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |
| Lucas, Nancy, | NR | In my Wound/Ostomy RN practice, I ONLY use KCI | Thank you for providing us with information |

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| RN, CWON | | Wound VAC for negative pressure. In my acute care setting, I do see other "negative pressure" devices, but I typically see poor results with them. In patients that are re-admitted to our facility, wounds that have been treated with other devices are macerated, filled with slough and biofilm and generally declined since we DC'd them to facilities that utilize non-KCI negative pressure. It has become our practice to specify "KCI Wound VAC only-No substitution". Thank you. | regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |
| Mangel, Eugenia | NR | I am writing in regards to the review of the current Negative Pressure Wound Therapy (NPWT) Healthcare Common Procedural Coding Set (HCPCS) regarding ensuring accurate reporting and billing for all NPWT items and services under these codes as shown below in the legislation.<br><br>It was brought to my attention that the review done by ERCI:<br><br>Used the lack of evidence on other NPWT products as the basis to find no significant therapeutic distinction in this category, and that this rationale is contrary to the stated purpose of the evaluation. If anything, this finding fully supports V.A.C. Therapy's clinical superiority and differentiation.<br><br>Dismissed almost 90% of the evidence and information submitted, including all scientific & pre-clinical research, clinical opinion, best practice guidelines, clinical experience and feature, function and operational information.<br><br>Equated the absence of evidence on other NPWT products as therapeutic equivalence.<br><br>As a wound care professional who works with all types of wounds including very complex wounds with fistulae, multiple traumas, orthopedics, pressure ulcers, reconstructions, I do not believe that all of the NPWT treatments are equal. I have had the opportunity to trial the | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS.<br><br>In regards to your first point, we provide the following response:<br><br>Due to the lack of published or unpublished studies that evaluated other NPWT systems we were unable to perform either direct or indirect comparisons. In the absence of such comparisons, ECRI Institute was unable to draw conclusions about the superiority or equivalence of any NPWT system or its components compared to another NPWT system or its components.<br><br>Next in response to your concern that we "dismissed almost 90% of the evidence," we provide the following explanation:<br><br>The focus of this report was to evaluate the scientific evidence for a significant therapeutic distinction of any single NPWT system or its components compared to other NPWT systems or their components, based on specific outcomes of interest to the Center for Medicare Management at CMS. Key questions were prepared for the report using the "PICO" framework: patients, intervention of interest, comparator, and outcomes (see Figure |

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| | | Smith and Nephew NPWT in both foam and gauze as well as the Svedman system. From patient outcomes reflective on wound improvement, I feel that the KCI VAC is much superior to the other two systems. There may be some basic wounds that can be managed with other NPWT's, the KCI VAC is the easiest to manage and has shown positive wound outcomes.<br><br>I have never had a wound being managed by VAC become infected. But when using the Smith and Nephew system I had a wound with serosanguinous drainage turn to a blue /green drainage indicative of pseudomonas.<br><br>I am a skilled technician with NPWT, and can place NPWT on most of the most difficult wounds, but the materials used in the KCI competition made dressing application more difficult for me, more time consuming, which caused more discomfort for my patients.<br><br>When our hospital nursing staff worked with the KCI competitor VACs (Smith and Nephew and Svedman) several nurses asked if they were older or cheaper systems since they were harder to apply and were more similar to the early KCI dressings, drapes and machines. The numerous steps using paste strips, IV dressing covers and extra pink Hytape made the dressings more cumbersome, left more room for error and typically resulted in RN frustration.<br><br>A patient with bilateral lower extremity surgical wounds who had been managed with Smith and Nephew at an outside facility reported an ease in dressing changes and the husband felt that the wounds were healing more quickly once she started the KCI VAC at our facility.<br><br>These are just a few instances that I can remember at this time. I am very concerned for the best interest of our patients with wounds who benefit from NPWT.<br>I appreciate your attention to this matter. Please do not hesitate to contact me with any further questions. | 1). Inclusion and exclusion criteria were developed based on each key question prior to an examination of the evidence. Twelve inclusion criteria were established for this TA. In a TA, the inclusion criteria determine whether a study is "relevant" to the key questions. Studies that do not meet the inclusion criteria are excluded from the TA. Exclusion from the TA does not imply that the studies have no scientific merit, just that their findings are not applicable to answering a key question within the specific report. As explained below and in the report, most submissions from interested stakeholders were not relevant to the key questions posed in this particular report, the purpose of which was to determine whether there was evidence of a therapeutic distinction between different NPWT systems or components.<br><br>We undertook an extensive search of the literature from which we identified over 1,000 potential articles. In the interest of identifying all clinically relevant materials for this report, we also invited interested stakeholders to submit information regarding any published, unpublished, or currently registered studies for possible inclusion in the report. We received over 1,400 submissions by the February 6, 2009 deadline. Each submission was reviewed for possible inclusion in the report (see Appendix D).<br><br>During the evaluation of all stakeholder submissions, we excluded 638 (44%) of the 1,435 submissions due to duplication alone (see Figure 5 in Appendix D). Of the 797 (55% of original) unique submissions; 29 (4%) were included in our *Background* section and 269 (33%) items were excluded; 147 (56%) of the excluded items were case reports, abstracts or poster presentations given at conferences. |

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| | | | Of the 499 (35%) remaining articles, 354 (71%) were excluded at the article level. Based on the a priori inclusion/exclusion criteria, narrative reviews (k = 152 [43%]); animal studies (k = 39 [11%]); and studies with fewer than five patients in each arm (k = 30 [8%]) were excluded.<br><br>Of the 144 (10%) original submissions that met inclusion criteria, 117 (81%) were previously identified by the ECRI Institute literature searches. We subsequently included 28 studies not previously identified in our searches in the final report. Please see Appendix D for additional details on individual submissions and subsequent disposition in the report.<br><br>For a clearer understanding of our evaluation process, we have included documentation of all 1,435 submissions in Appendix D of the report. This section of the report, alphabetized by submitter, includes an attrition diagram and accompanying table that describes the disposition of each individual submission therein. The attrition diagram provides a visual representation of the disposition of materials as they go through the evaluation process. The accompanying table in the report includes a citation for each submission and lists either the placement in the report or reason for exclusion.<br><br>Finally, in response to your third point, we point out that ECRI Institute was unable to draw conclusions about the superiority or equivalence of any NPWT system or its components compared to another NPWT system or its components. There were no studies that directly compared different systems and there were no RCTs of systems other than the KCI V.A.C.® system, which might have allowed us to make indirect comparisons. |

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| McReynolds, Shirley, RN CWS | Covenant Health System | While working as a wound specialist for the past 8 years, I have seen many different devices emerge with the declaration of being comparable to the KCI NPWT system. In my opinion, the KCI system is superior to any gauze system due to the fact that there is a more rapid development of granulation tissue and wound closure. The system offers more safety factors and applications for a more definitive individualized care. I truly believe in the KCI system as the best choice should negative pressure wound therapy be needed. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |
| Mendez-Eastman, Susan | NR | I am a registered nurse and practice in Nebraska. I am also on the Speakers Bureau for KCI and therefore feel it is appropriate to disclose that information. I take the responsibility of speaking to peers very seriously and therefore attempt to remain informed on research, new products and the clinical application of negative pressure wound therapy. I attended the national release of the Smith and Nephew product and have had multiple companies present their products to our wound care department. As a magnet certified hospital we utilize evidence based products and procedures. It my opinion and the opinion of my colleagues that the wound VAC by KCI is the only product that has any evidence.<br>The multiple companies that have presented their products to our department are using evidence on the wound VAC by KCI to market their products despite the fact that multiple factors of these systems are not comparable. The most notable differences are in the interface products however the delivery and maintenance of the negative pressure are also important aspects of the therapy that are being bundled as "like therapies". I think the most basic analogy would be that you cannot take a Dyson Vacuum, garden hose and kitchen sponge and call it negative pressure wound therapy. It is a system that encompasses multiple factors and the entire system must be considered and proven effective rather than being bundled into a "like" category. The opinion of this technology report was | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| | | that there was a lack of comparison of products. I completely agree but feel as though the opinion did not go far enough and should include the fact that the various companies marketing their products under the research umbrella of the KCI wound VAC research and clinical experience have an obligation to provide research and evidence on their particular product prior to being compared or considered the equivalent to the one product that does have and evidence base - the KCI Wound VAC. | |
| Menendez, Moises, MD, FACS | Baylor University Medical Center | My only experience with a non KCI product regarding negative pressure therapy was in El Dorado, Arkansas, about two years ago. I was the Medical director of the Wound Care Center & Hyperbaric Medicine and I had two elderly patients who required negative pressure for pressure ulcers. The product the nursing home used was Blue Sky. After a few weeks of therapy the wounds became worse, so the therapy had to be discontinued. I was told that this product was cheaper than the KCI wound VAC. Since then, the wound Center did not use this product again.<br><br>However, we had a vast experience with the KCI wound VAC with much success.<br><br>Currently I work at the Baylor Specialty Hospital in Dallas, Texas. In fact, there is no comparison between these two products. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |
| Michael, Kristell, RN, FNP-C, CWS, FACCWS, WOCN, CHRNC | NR | I have 10 years experience with KCI's Wound V.A.C. NPWT. There is no comparison clinically with regard to patient outcomes (and comfort) in using competitor's suction dressings-which I have, unfortunately, become familiar with over the past 5 years. KCI's system is unique and I am sure that if all the supporting evidence is taken into account, as well as the lack of independent research from the counterparts, AHRQ would see the difference. Please do not allow imposters of NPWT to ride along on KCI's research. I have personally seen limb salvage and | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| | | lives saved, with restored quality of life in the duration, simply because of having access to KCI's Wound Vac. Have a look at the support and outcomes that KCI has provided to our wounded soldier's with the Wound Vac. Please take time to investigate the differences as it matters to patients. Ask them. Thank you for your attention. | |
| Morris, Susan Vice President Health Policy KCI and Fruchterman, Todd Sr Vice President Research & Development Chief Technology Officer Chief Medical Officer KCI | KCI | Kinetic Concepts, Inc. (KCI) respectfully submits these comments to the Technology Assessment (TA) for Negative Pressure Wound Therapy (NPWT) Devices conducted by the ECRI Institute which was posted by the Agency for Healthcare Research and Quality (AHRQ) on April 10, 2009. KCI is the manufacturer and distributor of the V.A.C. Therapy System (V.A.C. Therapy). In our comments, which include this letter and several attachments, we discuss concerns related to:<br>The ECRI review process<br>Review of V.A.C. Therapy evidence<br>Application of evidence to other NPWT products<br>Unique aspects of wound care evidence review<br>Conclusions reached in the four key questions<br><u>Section I. The ECRI Review Process</u><br>On behalf of the Evidence Based Practice Center (EPC) at AHRQ, the ECRI Institute, on December 30, 2008, issued a broad request for information to be considered for this TA. Given the complexity of patients treated with NPWT, we agreed that the request soliciting a wide range of data types and sources was both appropriate and necessary.<br>This approach was also in keeping with the EPC's practice of evaluating all relevant scientific literature on clinical, behavioral, and organizational and financing topics to produce technology assessments. It also follows David Sackett & W. Scott Richardson's expert opinion | <u>Section 1. The ECRI Review Process</u><br><u>Response to KCI points #1, #2, #3, #4, #5, and #6:</u><br>The focus of this report was to evaluate the scientific evidence for a significant therapeutic distinction of any single NPWT system or its components compared to other NPWT systems or their components, based on specific outcomes of interest to the Center for Medicare Management at CMS. Key questions were prepared for the report using the "PICO" framework: patients, intervention of interest, comparator, and outcomes (see Figure 1). Inclusion and exclusion criteria were developed based on each key question prior to an examination |

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| | | that, evidence based medicine is not restricted to randomised trials and meta-analyses. And sometimes the evidence we need will come from the basic sciences, such as genetics and immunology.<br><br>Additionally, we believe that such a broad review of information and evidence was intended by Congress in the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) which directed HHS to consider all relevant studies and information pursuant to such a process when it conducted a review of NPWT HCPCS coding. Given the fact that this TA was commissioned specifically for the purpose of informing the legislatively-mandated HCPCS coding review now being undertaken by the Centers for Medicare & Medicaid Services (CMS), it was not only appropriate but necessary for ECRI to consider all information and evidence which should be assessed as part of any coding review.<br><br>In keeping with the public request for information, on February 4, 2009, KCI submitted a large body of scientific, pre-clinical and clinical research and published clinical guidelines on V.A.C. Therapy. Additionally, we submitted information on product labeling, clinical use guidelines, and FDA 510(k) clearances, and over 580 research articles and documents. Due to the volume and complexity of this material, we also included an evidence summary. (See Attachment A V.A.C. Therapy Overview of Scientific, Clinical and Cost Effectiveness Evidence and Attachment B Annotated Bibliography and Original Table of Contents for KCI Submission to ECRI)<br><br>When the draft report was released on April 10, 2009, we were surprised to learn that almost 95% of published literature was excluded when answering the seminal question, including valid scientific and pre-clinical evidence which was clearly relevant to any review of comparative effectiveness of NPWT products and would have conformed to EPC guidelines for evidence review and provisions of MIPPA legislation. (See Attachment B | of the evidence. Twelve inclusion criteria were established for this TA. In a TA, the inclusion criteria determine whether a study is "relevant" to the key questions. Studies that do not meet the inclusion criteria are excluded from the TA. Exclusion from the TA does not imply that the studies have no scientific merit, just that their findings are not applicable to answering a key question within the specific report. As explained below and in the report, most submissions from interested stakeholders were not relevant to the key questions posed in this particular report, the purpose of which was to determine whether there was evidence of a therapeutic distinction between different NPWT systems or components.<br><br>Next, we undertook an extensive search of the literature from which we identified over 1,000 potential articles. In the interest of identifying all clinically relevant materials for this report, we also invited interested stakeholders to submit information regarding any published, unpublished, or currently registered studies for possible inclusion in the report. We received over 1,400 submissions by the February 6, 2009 deadline. Each submission was reviewed for possible inclusion in the report (see Appendix D).<br><br>The screening of all identified materials is a two-step process. An initial evaluation is done at the abstract level at which items may be excluded, used in our *Background* section or passed to the next level of evaluation. During the evaluation of all stakeholder submissions, we excluded 638 (44%) of the 1,435 submissions due to duplication alone (see Figure 5 in Appendix D). Of the 797 (55% of original) unique submissions; 29 (4%) were included in our *Background* section and 269 (33%) items were excluded; 147 (56%) of the excluded |

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| | | Annotated Bibliography and Original Table of Contents KCI ECRI Submission)<br><br>Additionally, ECRI did not follow the normal procedure of conducting a review of the report with outside specialists in the specific area of medicine prior to the release of the draft report to the public. Had the normal peer review procedure been followed, it is very likely that the evidence review process would have been appropriately expanded prior to publication for public comment.<br><br>Given these facts, we believe that the ECRI report does not accurately nor completely fulfill the charge given to them by CMS through MIPPA. | items were case reports, abstracts or poster presentations given at conferences.<br><br>Of the 499 (35%) remaining articles, 354 (71%) were excluded at the article level. Based on the a priori inclusion/exclusion criteria, narrative reviews (k = 152 [43%]); animal studies (k = 39 [11%]); and studies with fewer than five patients in each arm (k = 30 [8%]) were excluded.<br><br>Of the 144 (10%) original submissions that met inclusion criteria, 117 (81%) were previously identified by the ECRI Institute literature searches. We subsequently included 28 studies not previously identified in our searches in the final report. Please see Appendix D for additional details on individual submissions and subsequent disposition in the report.<br><br>For a clearer understanding of our evaluation process, we have included documentation of all 1,435 submissions in Appendix D of the report. This section of the report, alphabetized by submitter, includes an attrition diagram and accompanying table that describes the disposition of each individual submission therein. The attrition diagram provides a visual representation of the disposition of materials as they go through the evaluation process. The accompanying table in the report includes a citation for each submission and lists either the placement in the report or reason for exclusion.<br><br>While we agree with the 1996 editorial by Sackett et al.(15) that "evidence based medicine is not restricted to randomised trials and meta-analyses…and sometimes the evidence we need will come from the basic sciences such as genetics or immunology," the context of this particular report necessitates restriction to human studies |

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| | | | reporting clinically relevant outcomes. While the available evidence did not allow us to make direct or indirect comparisons of NPWT devices or their components, we have tabled data from 40 studies comparing NPWT to other types of wound treatments, 103 non-comparative studies and 22 previous systematic reviews.<br><br>Evidence-based reports, for the purpose of policy or clinical decision making, rarely rely on non-clinical evidence (studies using animals, cell culture, cadavers, etc.) to address the effectiveness of treatments. While animal studies may lead to important discoveries that ultimately prove valuable in human applications, experts have cautioned that fewer than a third of highly-cited animal studies translate into human RCTs showing the same results of treatment.(9)<br><br>Animal studies also seldom use study design procedures such as randomization, concealment of allocation, and blinding of outcome assessment that would limit the potential for bias.(10) Publication bias, the preferential publication of studies with positive results, may be especially common with animal studies.(11) In addition, positive results in animal studies may not translate well to the clinical setting. Investigators can control the severity of the wound in animals to a greater extent than in human studies. Animal subjects are likely to be younger and healthier than humans with wounds. Animals in such studies may not have co-morbid health conditions or exposure to concurrent medical interventions, in contrast to human subjects with wounds.<br><br>An additional problem with animal studies of wound healing is determining which of the human wound etiologies (pressure ulcers, diabetic foot ulcers, venous leg ulcers, burns, sternal wound |

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| | | | infections, or trauma-induced wounds) the animal model represents. Given the nature of the questions asked in our report and the outcomes of interest to the Center for Medicare Management at CMS, such evidence from animal models is not relevant.<br><br>The submitted clinical opinions and descriptions of personal experience did not meet inclusion criteria for our review but they have been provided to CMS.<br><br>Our pre-determined inclusion/exclusion criteria specified that studies must include a minimum of five or more patients per treatment group. Case reports and very small studies may represent unusual patients or circumstances and may not be applicable to more typical patient populations. "Morris S. Additional V1 failures/VAC rescues. 2006. 2 p. Case reports submitted by KCI to CMS"(16) cited in Table 48 (page 456) was excluded for this reason.<br><br>The exclusion of studies identified as "scientific" or "pre-clinical" has also been questioned. A key component to our screening process is to affirm that appropriate outcome measures are reported in each study. We excluded ten (2%) studies because they did not measure relevant outcomes. Specifically these studies were focused on cellular and biochemical measurements which were not suitable outcomes for this report.<br><br>The draft report has been reviewed by four wound care specialists who were identified by AHRQ.<br><br>Finally, in response to the comment that the EPC did not accurately nor completely fulfill the requirements of MIPPA, we want to confirm our understanding of the importance of the commissioning of this report and strongly believe that we have adequately fulfilled our charges as |

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| | | | instructed. We did consider all information and evidence presented to us, categorized that information as to its relevance to the key questions in this report, and provided CMS with an assessment of the merits and quality of the evidence as it pertains to the coding review. |
| | | Section II. Review of V.A.C. Therapy Evidence<br><br>The TA suggests that the primary benefit of NPWT is wound drainage. This statement demonstrates a fundamental misunderstanding of the V.A.C. Therapy System and its benefits. While V.A.C. Therapy does remove excess fluid and infectious materials; it also has unique performance characteristics that produce the significant clinical benefits. For example:<br><br>Micro-deformation: This stretch of the cells lining the wound bed is an important part of the tissue response which promotes the development of granulation tissue. This effect was confirmed by a small clinical study which demonstrated increased angiogenesis ($p = 0.03$). In silico analyses showed that when a GranuFoam Dressing (as compared to gauze dressing) is used as the manifolding material 23% more tensile strain and 23% more compressive strain is imparted to tissue.<br><br>Increased perfusion: An early preclinical study demonstrated that intermittent therapy resulted in a 4-fold increase in perfusion ($p < 0.001$). Subsequent studies confirm that V.A.C. Therapy results in an increase in perfusion. Another small, but compelling study on burns showed the use of V.A.C. Therapy to be associated with hyper-perfusion of the burns and potentially a reason why 5 out of 7 patients healed without skin grafts. V.A.C. Therapy showed increased perfusion on day 2 ($p = 0.001$) and on day 3 ($p = 0.006$).<br><br>Decreased inflammation: An 8-patient Stage 3-4 pressure | Section II. Review of V.A.C.® Therapy Evidence<br><br>Response to KCI point #1:<br><br>As to KCI's comment that the TA suggests that the primary benefit of NWPT is wound drainage, the information provided in the *Background* section of the report states that "the development of negative pressure techniques for wound healing is based on two theories: 1) the removal of excess interstitial fluid decreases edema and concentrations of inhibitory factors, and increases local blood flow; and 2) stretching and deformation of the tissue by the negative pressure is believed to disturb the extracellular matrix and introduce biochemical responses that promote wound healing." Nowhere in the report did we suggest that the "primary benefit of NPWT is wound drainage" and we believe that the peer reviewers would have alerted us if at any time we demonstrated a "fundamental misunderstanding of the V.A.C.® Therapy System and its benefits." However, we have expanded this section with additional references to potential mechanisms of action. |

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| | | ulcer study showed a significant decrease in TNF ($p < 0.05$), a pro-inflammatory cytokine, after 24 hours of treatment. A separate study on stage III-IV pressure ulcers showed that levels of MMP-3 and MMP-3/TIMP-1 decreased significantly over baseline values in response to V.A.C. Therapy ($p < 0.05$). These findings of decreased inflammation are also supported by Greene2 and Moues. Additionally comparative evidence of decreased inflammation when using V.A.C. Therapy compared to gauze under negative pressure suggests that decrease in monocytes ($p < 0.05$) and neutrophils ($p < 0.05$).<br><br>Cellular Energetics: An in vitro study12 indicates that V.A.C. Therapy increases fibroblast proliferation when compared to gauze under negative pressure ($p < 0.05$). Compared to gauze under negative pressure, V.A.C. Therapy shows evidence of increase mitochondrial metabolism ($p < 0.05$) and increased synthesis of Transforming Growth Factor and Platelet Derived Growth Factor ($p < 0.05$).<br><br>Granulation tissue formation: Two preclinical studies 4, 14 reported higher rates of granulation tissue formation with V.A.C. Therapy compared to controls when using -125 mmHg. In an animal study comparing V.A.C. Therapy to gauze under negative pressure, wound area was significantly decreased at 48 hours ($p < 0.05$). 15<br><br>Pressure Monitoring and Adjusting Technology: A recently displayed poster presentation demonstrated that under difficult simulated wound environments, while there were no significant differences between the pump display and pressure delivered to the wound site by the V.A.C. Therapy system, the Versatile 1 pumps with gauze were unable to deliver requested negative pressure to the wound site ($p < 0.05$).16<br><br>V.A.C. Therapy's ability to deliver consistent negative pressure to the wound bed have been observed even in extreme atmospheric conditions as demonstrated by its | |

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| | | approval for medical transport for the US military.17 These consistent negative pressures delivered to the wound site were critical in the positive wound outcomes demonstrated by Wild, et al. 18 | |
| | | <u>Section II. Review of V.A.C. Therapy Evidence (continued)</u><br><br>The TA relies upon only a small portion of the evidence requested and submitted. While the request for information was quite broad and extensive evidence was submitted, the evidence reviewed or at least relied upon was very limited in scope. To answer the seminal question (Q1), ECRI included only 5% of the submitted published literature, limiting their ability to assess comparative evidence and efficacy.<br><br>The most common reasons cited for exclusion were: case report (~27% of exclusions), narrative (~25%) and animal study (~6%). The following exclusion codes accounted for approximately another 5% of excluded material: not relevant, not relevant to report, or not a clinical study. 100% of scientific and pre-clinical research was excluded from the TA. This is about 11% of excluded material.<br><br>Additionally, ECRI excluded information from CMS on ineffective treatment using other NPWT products (page 442, AHRQ Draft Report, Ref 749)<br><br>This narrow review focus led ECRI to miss evidence of | Response to KCI point #2:<br><br>All materials were reviewed and evaluated for relevance to the key questions based on the study inclusion criteria developed for this report. Clear distinctions between V.A.C.® Therapy and other NPWT products could not be determined from the available clinical studies that were relevant to this report.<br><br>In response to the statement that ECRI "misinterpreted the importance of Dr. Wilds' 2008 RCT"(17) we present the following:<br><br>Our searches did not identify any studies comparing one NPWT system component to another NPWT system component (with both groups receiving negative pressure treatment) that addressed Key Question 2. This question was designed to examine studies that compared different dressing sets, tubing, or pumps while maintaining identical components for the other parts of an NPWT system. We did identify the Wild et al. study that compared an electrical pump to a Redon set as non-powered |

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| | | the comparative effects of NPWT devices. (See Attachment D - Comparative Evidence Not Evaluated) Had this evidence been reviewed, in keeping with the EPC's stated practice, MIPPA and the general practice of evidence based medicine (EBM), clear distinctions between V.A.C. Therapy and other NPWT products would be evident. Additionally, clinical opinion was not reviewed; personal communication not reviewed accounted for ~4% of excluded material.<br><br>Having not evaluated the scientific and pre-clinical research, ECRI misinterpreted the importance of Dr. Wild's 2008 RCT. Used to answer Question 2, Wild, et al found that V.A.C. Therapy was more effective than Redon vacuum bottles (a source of uncontrolled negative pressure) using GranuFoam Dressings in terms of change in surface granulation tissue ($p = 0.001$), presence of necrotic tissue and change in fibrin tissue ($p = 0.035$). The study was terminated at day 9 due to large disparity in outcomes and the added care need for the Redon group (p 55, AHRQ Draft NPWT Report).<br><br>Unfortunately, ECRI did not attribute the controlled delivery of negative pressure to the differential healing outcomes described in this study. Controlled delivery of negative pressure is a feature that only V.A.C. Therapy provides through the proprietary T.R.A.C. Pad Technology (T.R.A.C.) system; this is a component difference leading to therapeutic distinction. (See Attachment C - Scientific and Pre-Clinical Evidence)<br><br>Other review errors are listed in:<br><br>Attachment E: Misrepresented and Omitted Evidence from Evaluated Studies | method of delivering negative pressure. The authors of this paper concluded that the non-powered vacuum bottle approach to applying negative pressure to a pressure ulcer was not appropriate. To demonstrate that the T.R.A.C. Pad has a significant therapeutic distinction over other pump and drain components from other NPWT systems would require comparison studies with such systems.<br><br>In response to items KCI submitted in Addendum D titled "Relevant Comparative Data (Evaluating NPWT Comparative Evidence Not Evaluated)" and the comment that these studies were not reviewed, we present the following:<br><br>Jones SM, Banwell PE, Shakespeare PG. Interface dressings influence the delivery of topical negative-pressure therapy. Plast Reconstr Surg 2005 Sep 15;116(4):1023-8(18) was excluded due to the inclusion of healthy volunteers. According to our pre-determined methodology and depicted in our "PICO" framework the patient population of interest includes only patients with acute or chronic wounds.<br><br>Argenta A, Webb K, Simpson J, Gordon S, Kortesis B, Wanner M, Kremers L, Morykwas M. Deformation of superficial and deep abdominal tissues with application of a controlled vacuum. In: European Tissue Repair Society, Focus group meeting Topical Negative Pressure (TNP) Therapy; 4-6 December 2003; London.(19) Although evaluated as an original submission, this item was inadvertently not labeled as such. This item however was excluded because it focused on cellular and biochemical measurements which were not suitable outcomes for this report. The report has been updated accordingly.<br><br>Derrick KL, Norbury K, Kieswetter K, Skaf J, |

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| | | | McNulty AK. Comparative analysis of global gene expression profiles between diabetic rat wounds treated with vacuum-assisted closure therapy, moist wound healing or gauze under suction. Int Wound J 2008 Dec;5(5):615-24.(20) This item was excluded in our draft report for being an animal study.<br><br>McNulty AK, Schmidt M, Feeley T, Kieswetter K. Effects of negative pressure wound therapy on fibroblast viability, chemotactic signaling, and proliferation in a provisional wound (fibrin) matrix. Wound Repair Regen 2007 Nov-Dec;15(6):838-46.(21) This item was excluded from the report for being an in vitro study, which could not be used to address the questions in this report.<br><br>McNulty A.K., Schmidt, M., Feeley, Teri, Villaneuva, P., Kieswetter, K. 2009. Effects of negative pressure wound therapy on cellular energetics in fibroblasts grown in a provisional wound (fibrin) matrix [In Press]. Wound Repair Regen. 2009 Mar-Apr;17(2):192-9.(22) This item was excluded from the report for being an in vitro study, which could not be used to address the questions in this report.<br><br>McNulty A., Spranger, I., Green, J., Courage, J., Rycerz, A. The Ability of the V.A.C. Therapy System to Compensate for Pressure Drop While Imparting Macrostrain. Presented at the Diabetic Foot Global Conference. March 19-21, 2009.<br><br>As noted, this item was presented in March 2009. Interested stakeholders were notified on December 30, 2008 of the February 6, 2009 deadline for submissions. ECRI Institute also sent out a letter to stakeholders on January 29, 2009 that served as a reminder of the impending deadline for submissions. Although the submission was not |

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| | | | provided before the deadline this item would have been excluded for its focus on cellular and biochemical measurements which were not suitable outcomes for this report and not a full article publication.<br><br>Timmers MS, Le Cessie S, Banwell P, Jukema GN. The effects of varying degrees of pressure delivered by negative-pressure wound therapy on skin perfusion. Ann Plast Surg 2005 Dec;55(6):665-71.(23) This article was excluded because it did not include relevant outcomes. This study also included healthy volunteers which is another exclusion criterion.<br><br>Wild T, Stremitzer S, Budzanowski A, Hoelzenbein T, Ludwig C,Ohrenberger G. Definition of efficiency in vacuum therapy – A randomised controlled trial comparing Redon drains with V.A.C. Therapy™. Int Wound J 2008 Dec;5(5):641-7.(17) Although KCI includes this in the "comparative evidence not evaluated," this item was described in our report.<br><br>Wilkes R, Zhao Y, Kieswetter K, Haridas B. Effects of Dressing Type on 3D Tissue Microdeformations During Negative Pressure Wound Therapy: A Computational Study. J Biomech Eng 2009 Mar;131(3):031012.(24) This item was a "computational study" and excluded because it was not a clinical study.<br><br>In response to items KCI submitted in Addendum C titled "Scientific and Pre-Clinical Evidence" we present the following: These items all focused on cellular and biochemical measurements which were not suitable outcomes for this report.<br><br>In response to items KCI submitted in Addendum E "Analysis of Evidence Reviewed or Omitted", we |

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| | | | present the following:<br><br>Andrews BT, Smith RB, Chang KE, Scharpf J, Goldstein DP, Funk GF. Management of the radial forearm free flap donor site with the vacuum-assisted closure (VAC) system. Laryngoscope 2006 Oct;116(10):1918-22.(25) This item was identified only in the KCI submission. As a chart review, this study would only be eligible for inclusion in Key Question 3 regarding adverse events. No adverse events were reported in the publication.<br><br>Armstrong DG, Lavery LA, Boulton AJ. Negative pressure wound therapy via vacuum-assisted closure following partial foot amputation: what is the role of wound chronicity? Int Wound J 2007 Mar;4(1):79-86.(26) We chose to include this report as it is a more recent publication of this study (2007 versus 2005.(27) During the quality assessment of this study, the earlier publication(27)was used for reference.<br><br>Armstrong DG, Lavery LA, Diabetic Foot Study Consortium. Negative pressure wound therapy after partial diabetic foot amputation: a multi-centre, randomised controlled trial. Lancet 2005 Nov 12;366(9498):1704-10.(27) After further review, the quality assessment score for the publication of the study included in our report(16) will be adjusted to reflect that allocation was concealed. The method of randomization was not reported.<br><br>Armstrong DG, Kunze K, Martin BR, Kimbriel HR, Nixon BP, Boulton AJ. Plantar pressure changes using a novel negative pressure wound therapy technique. J Am Podiatr Med Assoc 2004 Sep-Oct;94(5):456-60.(28) This study was inadvertently excluded for including a “homemade device” however this study reports on a method of |

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| | | | relieving pressure on the bottom of the foot during NPWT. As such this study will be excluded for the following reason: "not a NPWT study." The report has been updated to read as such.<br><br>Baharestani MM, Houliston-Otto DB, Barnes S. Early versus late initiation of negative pressure wound therapy: examining the impact on home care length of stay. Ostomy Wound Manage 2008 Nov;54(11):48-53.(29) The reason for exclusion in Table 13 incorrectly read "duplicate study". After further review of this study, this retrospective analysis will be excluded in the final report for not including relevant outcomes.<br><br>Blume PA, Walters J, Payne W, Ayala J, Lantis J. Comparison of negative pressure wound therapy using vacuum-assisted closure with advanced moist wound therapy in the treatment of diabetic foot ulcers: a multicenter randomized controlled trial. Diabetes Care 2008 Apr;31(4):631-6.(30) In our discussion of Key Question 1, we stated that Blume et al. reported a 30% attrition rate. Attrition rates were similar for NPWT (32%) compared to advanced moist wound therapy (28%). We still believe, however, that an attrition rate this high is a limitation of the study.<br><br>In Key Question 3, we reported that along with 18 other controlled studies, Blume et al. reported fewer complications in the NPWT-treated patients than in those receiving other wound therapies. Although it is true that "there were no significant differences in adverse event rates between the VAC® Therapy Group and the control group," this finding was not relevant to the focus of our report. Key Question 3 asks, "*What are the reported occurrences of pain, bleeding, infection, other complications, and mortality for NPWT systems*?" We listed reports of pain, bleeding, infection, mortality, and other |

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| | | | complications in Tables 5-9 in the *Results* section of the report.<br><br>Blume PA, Walters J, Payne W, Ayala J, Lantis J. Comparison of negative pressure wound therapy using vacuum-assisted closure with advanced moist wound therapy in the treatment of diabetic foot ulcers: a multicenter randomized controlled trial. Diabetes Care 2008 Apr;31(4):631-6.(30) Blume et al. did not report utilizing a digital planimetry with photographic validation as a wound assessment tool in this publication. They did report wound assessment by examination and tracings (see page 632 of the study) which would be an acceptable instrument used to measure "change in wound area/volume." Question 18 in the quality assessment of this study has been changed to read "Yes". The overall score of this study has now been upgraded to 6.59.<br><br>Gabriel A, Heinrich C, Shores JT, Baqui WK, Rogers FR, Gupta S. Reducing bacterial bioburden in infected wounds with vacuum assisted closure and a new silver dressing - a pilot study. Wounds 2006 Sep;18(9):245-55.(31) The reason for exclusion for this study has been changed to read "duplicate study population.(32) Gabriel A, Heinrich C, Shores J, Cho D, Baqai W, Moores D, Miles D, Gupta S. Outcomes of vacuum-assisted for the treatment of wounds in a paediatric population: case series of 58 patients. J Plast Reconstr Aesthet Surg 2008 Oct 2;Epub ahead of print.(32), also submitted by KCI, is a more recent publication included in Key Question 3 which includes the pediatric patients reported in the earlier publication.(31)<br><br>Moisidis E, Heath T, Boorer C, Ho K, Deva AK. A prospective, blinded, randomized, controlled clinical trial of topical negative pressure use in |

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| | | | skin grafting. Plast Reconstr Surg 2004 Sep 15;114(4):917-22.(33) Moisidis et al. reported on 22 adult patients who had wounds requiring skin grafting. (Patients were used as their own controls by randomizing half of each wound to a bolster dressing and the other half of the wound to NPWT). Graft outcome was assessed at two weeks by a clinician blinded to the randomization of wound halves. Graft take was recorded both quantitatively (expressed as a percentage of epithelialization recorded by gross inspection) and qualitatively (rated as poor, satisfactory, good, or excellent). The authors state "although the quantitative graft take was not significant, the qualitative graft take was found to be significantly better with the use of topical negative pressure therapy." Due to the extremely short follow-up time reported for this assessment and the absence of information about the success of blinding, we reported only on the quantitative measures of percent of epithelialization rather than the more subjective qualitative assessment. Perhaps the discordance between the quantitative measurements and the clinical impressions could be explored further in future studies.<br><br>Moues CM, Vos MC, van den Bemd GJ, Stijnen T, Hovius SE. Bacterial load in relation to vacuum-assisted closure wound therapy: a prospective randomized trial. Wound Repair Regen 2004 Jan-Feb;12(1):11-7.(34) For the purposes of this review, we chose to include the more recently published study by Moues et al.(35) and felt that the information provided sufficient data on this study population.<br><br>Philbeck TE Jr, Whittington KT, Millsap MH, Briones RB, Wight DG, Schroeder WJ. The clinical and cost effectiveness of externally applied |

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| | | | negative pressure wound therapy in the treatment of wounds in home healthcare Medicare patients. Ostomy Wound Manage 1999 Nov;45(11):41-50.(36) We are aware that many patients who receive negative pressure wound therapy have failed to respond to previous interventions. This article was excluded at the abstract level due to the reporting on "Stage III and IV trochanteric and trunk wounds treated with low-air-loss and negative pressure wound therapy." Since no concurrent group received a single therapy we cannot distinguish between the effect of the low-air-loss mattress and NPWT on wound healing.<br><br>Wanner MB, Schwarzl F, Strub B, Zaech GA, Pierer G. Vacuum-assisted wound closure for cheaper and more comfortable healing of pressure sores: a prospective study. Scand J Plast Reconstr Surg Hand Surg 2003;37(1):28-33. Wanner et al. evaluated pressure ulcers of 22 paraplegics or tetraplegic patients. The authors concluded that gauze soaked with Ringer's solution when compared to NPWT was "equally effective in forming granulation tissue." In Table 25 titled Treatment-Related Characteristics in Comparison Studies of NPWT Devices Used to Treat Diabetic Foot and Pressure Ulcers we reported the V.A.C.® treatment change for the study was "every 2-7 days." In the *Background* section, under Principles of NPWT we do state "manufacturers recommend initially changing the dressing at 48 hours then two to three times per week as indicated."<br><br>Response to KCI point #3:<br><br>KCI is incorrect in stating that "the TA only included complete wound closure and time to |
| | | <u>Section II. Review of V.A.C. Therapy Evidence (continued)</u><br><br>The TA only included complete wound closure and time to complete wound healing as acceptable endpoints. | |

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| | | ECRI noted that some wound healing technologies are not intended to bring wounds to complete closure (pg 44, AHRQ Draft NPWT Report); this is the case for NPWT products. It is generally recognized that there are four stages of wound healing: hemostasis, inflammation, proliferation and maturation. V.A.C. Therapy is intended for use in the management of edema and exudate as well as the promotion of granulation tissue formation (i.e., the inflammation and proliferation stages). The amount of granulation tissue development required to meet a specific NPWT goal of therapy may vary depending on whether that goal is partial granulation, complete granulation or preparation of the wound bed for surgical closure. Effective use of NPWT is frequently measured by the time and total treatment cost required to meet the goal of therapy.<br><br>As a result of this narrow endpoint requirement, ECRI missed evidence of V.A.C. Therapy's efficacy including the effect on: amputations, secondary amputations, step-down to less complex surgeries, and promotion of flap and graft take. V.A.C. Therapy health economics data, which is linked to positive clinical outcomes, and the comparative rate at which outcomes were achieved were not evaluated. (See Attachment F - Cost Effectiveness Evidence Not Evaluated) Inclusion of this data would have affected the overall review of V.A.C. Therapy's efficacy. | complete wound healing as acceptable endpoints." The *Methods* section includes an analytical framework (Figure 3 in the report) that lists additional outcomes that were considered in this report.<br><br>For assistance in clarifying relevant outcomes, we looked for guidance from the U.S. Food and Drug Administration (FDA).(14) According to the FDA, improved wound healing and improved wound care are important clinical outcomes with the use of a wound-treatment device. Specifically, the most important outcomes to consider under the category of improved wound healing are percent of patients with complete wound closure and time to complete healing (partial healing for facilitation of surgical wound closure). We therefore incorporated "time to complete wound closure" and "percent of wounds healed" as important patient-oriented outcomes. In addition, for cases that are not expected to result in complete wound closure but rather to advance the wound to a stage where healing is possible we incorporated "time to 50% reduction of wound initial volume," "percent change in wound volume," and "improved wound condition" as important outcomes of interest.<br><br>As previously mentioned we relied on guidance from AHRQ and CMS in the determination of appropriate outcomes. Later in the process we sought feedback from four experts in wound healing.<br><br>ECRI Institute evaluated and reviewed all of the information submitted by interested parties for this report. However, all of the studies compared V.A.C.® Therapy to therapies that are not other NPWT systems or their components. In the economic studies, the efficacy data reflects the comparison of V.A.C. ® Therapy to gauze, not to |

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| | | | other NPWT systems. Therefore the economic studies do not address the key questions of this report.<br><br>Although we did not include economic data as a suitable outcome measure in this report, we do believe that responding to each item included in Addendum F titled "Exclusion of Relevant NPWT Economic Data" is important.<br><br>Therefore, in response to items submitted in Addendum F we present the following:<br><br>Apelqvist J, Armstrong DG, Lavery LA, Boulton AJ. Resource utilization and economic costs of care based on a randomized trial of vacuum-assisted closure therapy in the treatment of diabetic foot wounds. Am J Surg 2008 Jun;195(6):782-8.(37) We did not describe this study as "being used to answer KQ1 and KQ3." Apelqvist et al. is listed as an excluded study because it did not address the comparisons and outcomes of interest for the purposes of this report. The study is listed as an excluded study three times in the report; in Table 13 titled "Excluded Studies, in Table 43 titled "Status of Submissions by American Association for the Advancement of Wound Care", and in Table 44 titled "Status of Submissions by Kinetic Concepts Inc."<br><br>Baharestani MM. Negative pressure wound therapy: an examination of cost-effectiveness. Ostomy Wound Manage 2004 Nov;50(11A Suppl):29S-33S.(38) This study was excluded because it was a cost analysis without outcomes of relevance for this report. Upon further analysis of the abstract, we agree that this submission is a review article. This study will now be excluded for the following reason: "narrative review."<br><br>Armstrong DG, Lavery LA, Diabetic Foot Study |

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| | | | Consortium. Negative pressure wound therapy after partial diabetic foot amputation: a multi-centre, randomised controlled trial. Lancet 2005 Nov 12;366(9498):1704-10.(27) We chose to include Armstrong et al. 2007(26) which is a more recent publication of this study.<br><br>Scherer LA, Shiver S, Chang M, Meredith JW, Owings JT, Tominaga GT, Schecter WP, Parks SN, Peck J, Mayberry J. The vacuum assisted closure device: a method of securing skin grafts and improving graft survival. Arch Surg 2002;137(8):930-4.(39) As we reported in our discussion of Key Question 1, "improved graft survival was reported by Scherer et al.(39) in an assessment of graft take placed for burn (52%), soft tissue loss (44%) and fasciotomy-site coverage (3%). Repeated split-thickness skin grafting (STSG) to same site was significantly higher in controls compared to V.A.C. (5 [19%] versus 1 [3%]). Although grafts were significantly larger in the control group (984 ±996 $cm^2$ versus 387 ±573 $cm^2$) the 6 repeated grafts were of small or moderate size." However, this study does not directly address the key questions regarding a significant therapeutic distinction versus other NPWT systems.<br><br>Braakenburg A, Obdeijn MC, Feitz R, van Rooij IA, van Griethuysen AJ, Klinkenbijl JH. The clinical efficacy and cost effectiveness of the vacuum-assisted closure technique in the management of acute and chronic wounds: a randomized controlled trial. Plast Reconstr Surg 2006 Aug;118(2):390-7; discussion 398-400.(40) This study was included in our discussion of Key Question 1. Braakenburg et al. reported that "Vacuum-assisted closure therapy did not result in significantly faster granulation or wound surface |

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| | | | reduction or better bacterial clearance, but patient comfort was an important advantage." Although the data KCI has presented on total nursing hours and nursing minutes per day are accurate, the authors concluded, however, that "overall costs were similar for both groups." However, the study did not address the comparison of one NPWT system or its components to another system or its components.<br><br>Blume PA, Walters J, Payne W, Ayala J, Lantis J. Comparison of negative pressure wound therapy using vacuum-assisted closure with advanced moist wound therapy in the treatment of diabetic foot ulcers: a multicenter randomized controlled trial. Diabetes Care 2008 Apr;31 (4):631-6.(30) This study was described in our discussion of Key Question 1 and included in answering Key Question 3. The authors did conclude that "V.A.C.® Therapy appears to be as safe and more efficacious than AMWT for the treatment of diabetic foot ulcers." However, the study does not directly address the key questions regarding a significant therapeutic distinction versus other NPWT systems.<br><br>Schwien T, Gilbert J, Lang C. Pressure ulcer prevalence and the role of negative pressure wound therapy in home health quality outcomes. Ostomy Wound Manag 2005;51: 47-60.(41) As mentioned, this study was described in our discussion of Key Question 1 and included in answering Key Question 3. However, the study does not directly address the key questions regarding a significant therapeutic distinction versus other NPWT systems.<br><br>Page JC, Newswander B, Schwenke DC, Hansen M, Ferguson J. Retrospective analysis of negative pressure wound therapy in open foot wounds with significant soft tissue defects. Adv Skin Wound Care 2004 Sep;17(7):354-64.(42) As mentioned, |

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| | | | this study was described in the discussion of Key Question 1 and included in answering Key Question 3. However, the study does not directly address the key questions regarding the comparison to other NPWT systems.<br><br>Lavery LA, Boulton AJ, Niezgoda JA, Sheehan P. A comparison of diabetic foot ulcer outcomes using negative pressure wound therapy versus historical standard of care. Int Wound J 2007 Jun;4(2):103-13.(43) We agree with your comment that as noted in Lavery et al.(43) the "V.A.C.® Therapy group reached successful wound treatment endpoints more rapidly and the benefit was more apparent in all wound sizes." Although we did not include cost information in our report, we note that your statement that "expected treatment costs $16,733 V.A.C.® Therapy vs. $28,691 WTM" is true only when comparing NPWT to wet-to-moist therapy based on two nursing visits per day. The 20-week expected cost for wet-to-moist therapy for one nursing visit per day was $15,258. Therefore, Lavery et al. concluded that "the expected 20-week costs associated with NPWT are similar to those of wet-to-moist therapy for one nursing visit per day and 42% less than those of wet-to-moist therapy for two nursing visits per day."<br><br>Flack S, Apelqvist J, Keith M, Trueman P, Williams D. An economic evaluation of VAC therapy compared with wound dressings in the treatment of diabetic foot ulcers. J Wound Care 2008 Feb;17(2):71-8.(44) As stated, this article was excluded as a cost analysis not including comparisons and outcomes of relevance for this report.<br><br>Gabriel A, Shores J, Heinrich C, Baqai W, Kalina S, Sogioka N, Gupta S. Negative pressure wound therapy with instillation: A pilot study describing a |

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| | | | new method for treating infected wounds. Int Wound J 2008 Jun;5(3):399-413.(45) As stated, patients in the NPWT-instillation group had fewer in hospital days: 14.7 ±9.2 days vs. 39.2 ±12.1 ($p < 0.001$) than the control group. The authors however only concluded that "the use of NPWT instillation may reduce cost" and do not state "estimated treatment costs savings 50% less due to less nursing time" in this publication.<br><br>Kaplan M. Negative pressure wound therapy in the management of abdominal compartment syndrome. Ostomy Wound Manage 2004 Nov;50(11A Suppl):20S-25S.(46) This article was excluded as a case report with fewer than 5 patients.<br><br>Vuerstaek JD, Vainas T, Wuite J, Nelemans P, Neumann MH, Veraart JC. State-of-the-art treatment of chronic leg ulcers: A randomized controlled trial comparing vacuum-assisted closure (V.A.C.) with modern wound dressings. J Vasc Surg 2006 Nov;44(5):1029-37; discussion 1038.(47) As stated, this study was described in our discussion of Key Question 1 and included in the response to Key Question 3. The authors did state that the time to complete healing was significantly reduced in the V.A.C.® group compared to controls (29 days versus 45 days). However, there was a greater relapse at one year follow-up (52% of all healed V.A.C.® ulcers relapsed compared with 42% in the control group).<br><br>Niezgoda JA. The economic value of negative pressure wound therapy. Ostomy Wound Manage 2005 Feb;51(2A Suppl):44-7.(48) This article was excluded as a narrative article.<br><br>Siegel HJ, Long JL, Watson KM, Fiveash JB. Vacuum-assisted closure for radiation-associated wound complications. J Surg Oncol 2007 Dec |

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| | | | 1;96(7):575-82.(49) As stated, this study was described in the discussion of Key Question 1 and included in the results for Key Question 3. We agree with the statement that the "hospital length of stay was statistically shorter in the V.A.C.® Therapy Group, ($p$ <0.025)" in comparison to a historical control group managed with other unspecified "dressing changes" and wound coverage procedures.<br><br>Moues CM, van den Bemd GJ, Meerding WJ, Hovius SE. An economic evaluation of the use of TNP on full-thickness wounds. J Wound Care 2005 May;14(5):224-7.(50) We excluded this study due to its focus on cost rather than the outcomes of interest for this report. The authors did state "TNP *[total negative pressure]* had higher material costs…these were compensated by the lower number of time-consuming dressing changes and the shorter duration until they were 'ready for surgical therapy'." However, the study authors also state that "there was no significant difference in total costs per patients between the two therapies" and concluded that TNP was "equally as expensive as conventional moist gauze."<br><br>Philbeck TE Jr, Whittington KT, Millsap MH, Briones RB, Wight DG, Schroeder WJ. The clinical and cost effectiveness of externally applied negative pressure wound therapy in the treatment of wounds in home healthcare Medicare patients. Ostomy Wound Manage 1999 Nov;45(11):41-50.(36) As previously mentioned this article was excluded at the abstract level due to the treatment of Stage III and IV trochanteric and trunk wounds treated by dual therapies. Since no concurrent group received a single therapy we cannot distinguish between the effect of the low-air mattress and NPWT on wound healing. |

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| | | | Song DH, Wu LC, Lohman RF, Gottlieb LJ, Franczyk M. Vacuum assisted closure for the treatment of sternal wounds: the bridge between debridement and definitive closure. Plast Reconstr Surg 2003 Jan;111(1):92-7.(51) As noted, this study was described in the discussion of Key Question 1 and included in the response to Key Question 3. We noted that there were "no significant differences for average days between debridement and definitive closure of the sternal wound (6 ±1.3 d vs 8 ±2.9 d, control)" as we considered this to be the most important clinical outcome in this study. The additional clinical data on the mean dressing changes and average soft-tissue flaps per patient are also reported in the study as noted by KCI.<br><br>Frykberg RG, Williams DV. Negative-pressure wound therapy and diabetic foot amputations: a retrospective study of payer claims data. J Am Podiatr Med Assoc 2007 Sep-Oct;97(5):351-9.(52) As stated previously, this article was excluded as a cost analysis without additional outcomes relevant to this report. |
| | | <u>Section II. Review of V.A.C. Therapy Evidence (continued)</u><br><br>The TA did not review the unique FDA-cleared Indications for Use for V.A.C. Therapy<br><br>V.A.C. Therapy is the only NPWT product intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material which are all necessary for the effective outcomes documented in the V.A.C. Therapy evidence.<br><br>V.A.C. Therapy is also the only NPWT product with | Response to KCI point #4:<br><br>We understand that NPWT systems are considered Class II devices by the FDA. Class II devices receive clearance for marketing through the 510(k) process. While the FDA-cleared indications for medical devices are important for marketing purposes, they may not reflect the type of evidence important for a technology assessment.<br><br>In response to KCI's comments that we did not review the unique FDA-cleared indications for use for V.A.C.® Therapy, we present the following:<br><br>As previously mentioned, information provided in the *Background* section of the report was |

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| | | cleared indications for use in acute, extended and home care settings. This home care indication for use clearance was achieved by providing significant evidence to the FDA that V.A.C. Therapy works both effectively and safely in the home care setting where clinical caregivers are not present around the clock.<br><br>The TA did not address the fact V.A.C. Therapy is cleared by the FDA as an integrated wound management system. The scientifically documented outcomes of V.A.C. Therapy are linked to the mechanisms of action and performance characteristics of the individual V.A.C. Therapy components used together as a system. V.A.C. Therapy components cannot be used interchangeably with components of other NPWT systems.<br><br>(See Attachment G Differences in NPWT 510(k) Cleared Indications for Use) | provided as general information on negative pressure wound therapy (NPWT) devices and the potentially therapeutic benefits for the treatment of acute and chronic wounds. Also, Table 2, "Negative Pressure Wound Therapy Systems: Indications and Contraindications" lists products, manufacturers, U.S. Food and Drug Administration Indications for Use (510k database), Indications Presented on Company Web Site and Contraindications Presented on Company Web Site.<br><br>The FDA cleared indications for NPWT systems are provided in Table 2. That the FDA has given clearance for use of the NPWT systems for these indications does not provide evidence that helps to answer the key questions addressed in this report.<br><br>While there are differences between devices in the language used in the indications as presented in Attachment G titled "Differences in FDA 510(k) Cleared Indications for Use for NPWT Products," they do not provide evidence that helps to answer the key questions addressed in this report. |
| | | <u>Section III. Application of V.A.C. Therapy Evidence to Other NPWT Products</u><br><br>The TA correctly noted that the only evidence of effectiveness applies to V.A.C. Therapy (Pg 7, AHRQ Draft NPWT Report). The TA then inappropriately applies that evidence to the entire NPWT category. Without evidence establishing scientific equivalence, it cannot be assumed that the other products provide microstrain, macrostrain, increased perfusion, decreased inflammation, fibroblast proliferation and granulation tissue formation.<br><br>Without evidence establishing equivalent performance characteristics, mechanisms of action, and evidence of clinical effectiveness of the other NPWT products, V.A.C. | <u>Section III. Application of V.A.C.® Therapy Evidence to Other NPWT Products</u><br><br>The purpose of this report was not to provide evidence of the effectiveness of NPWT in comparison to other types of wound care treatments such as specialized dressings or topical products. The *Methods* section of this report specifically states "this report does not address whether NPWT systems provide a better wound care alternative compared to non-NPWT wound care therapies." We did provide an overview of the clinical research on NPWT and assessed 40 studies comparing a NPWT system to another wound care therapy, all of which were studies of the Kinetic Concepts Inc. |

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| | | Therapy evidence should not be assumed to be applicable to the other NPWT products.<br><br>The absence of evidence of clinical effectiveness of the other NPWT products should not be assumed to establish equivalence of those products with V.A.C. Therapy. Instead, this should demonstrate a therapeutic distinction for V.A.C. Therapy. | (KCI) V.A.C.® System. ECRI Institute did not apply this "evidence to the entire NPWT category" or assume that it was applicable to the other NPWT systems.<br><br>The report mentions in several places that the available "evidence was limited to the evaluation of V.A.C.® Therapy." This appears in the Executive Summary and in the *Results*, *Previous Systematic Reviews* and *Discussion* sections of the report.<br><br>Due to the lack of published or unpublished studies that evaluated other NPWT systems we were unable to perform direct or indirect comparisons. In the absence of such comparisons, ECRI Institute was unable to draw conclusions about the superiority or equivalence of any NPWT system or its components compared to another NPWT system or its components.<br><br>Lastly, KCI comments that "the absence of evidence of clinical effectiveness of the other NPWT products should not be assumed to establish equivalence of those products with V.A.C.® Therapy. Instead, this should demonstrate a therapeutic distinction for V.A.C.® Therapy." Since we were unable to compare V.A.C.® Therapy to another NPWT system we cannot conclude whether KCI's product provides a significant therapeutic distinction over another NPWT system or its components. At the same time, we cannot conclude that the lack of evidence from other manufacturers implies less effectiveness. |
| | | <u>Section IV. Unique Aspects of Wound Care Evidence Review</u><br><br>The TA does not acknowledge the importance of applying all elements of evidence-based medicine (EBM) to any review of wound care evidence. Evidence of effectiveness | <u>Section IV. Unique Aspects of Wound Care Evidence Review</u><br><br>Response to KCI point #1:<br><br>This same comment was made by KCI under Section I above. Please see our response there. |

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| | | for wound care products and services is not limited to clinical research. It can be established through a combination of scientific evidence, expert knowledge and patient preference. This approach is consistent with the widely-accepted definition of EBM: "Evidence-based medicine (EBM) is the integration of best research evidence with clinical expertise and patient values."<br><br>Perfect medical device RCTs are difficult to conduct. In order to achieve appropriate levels of patient matching, most wound care RCTs are required to adopt narrow inclusion criteria which limit the number and/or severity of co-morbidities, thereby excluding complex patients. Despite this fact, 17 RCTs have been conducted on V.A.C. Therapy, contributing to evidence based decision making.<br><br>Reasonably conducted wound care RCTs should be considered in any wound care evidence review. These should be confirmed by retrospective evidence, scientific evidence, expert opinion, as expressed in published clinical practice guidelines, medical society positions and leading researcher positions.<br><br><u>Section V. Conclusions Reached in the Four Key Questions Based on the presence of other types of sources of relevant evidence and information which distinguish V.A.C. Therapy from other NPWT products, KCI recommends that the following amended answers be included in the final TA</u>:<br><br>Question #1:<br><br>Given that all evidence of effectiveness is applicable only to V.A.C. Therapy and given that the positive outcomes associated with that evidence are tied to specific mechanisms of action and performance characteristics found only in V.A.C. Therapy, it must be assumed that V.A.C. Therapy has a significant therapeutic distinction from other NPWT products. | Response to KCI point #2:<br><br>We understand the difficulties faced by investigators due to the nature of this treatment and this patient population.<br><br>Response to KCI point #3:<br><br>The available RCTs were assessed for this review. No studies were available that addressed the question of whether one NPWT system or its components had demonstrated a significant therapeutic distinction over any other NPWT system or its components.<br><br><u>Section V. Conclusions Reached in the Four Key Questions</u>.<br><br>Key Question 1<br><br>Due to the lack of published or unpublished studies that evaluated other NPWT systems we were unable to perform either direct or indirect comparisons. In the absence of making such comparisons ECRI Institute was unable to draw a conclusion about the superiority or equivalence of any NPWT system or its components compared to another NPWT system or its components. |

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| | | Question #2:<br><br>Given that the Wild RCT found evidence that V.A.C. Therapy's controlled delivery of negative pressure to the wound bed is a critical component for positive wound outcomes, the controlled delivery of negative pressure, as provided through T.R.A.C. Pad Technology, should be identified as a component of V.A.C. Therapy providing significant therapeutic distinction over other NPWT systems.<br><br>Additionally, because all evidence evaluated was V.A.C. Therapy evidence and conducted on GranuFoam Dressings, this interface material should be identified as a significant therapeutic distinction over other NPWT systems.<br><br>Questions #3 & #4:<br><br>Given that 133 of 137 articles evaluated for question 3 were on V.A.C. Therapy and no comparative evidence was established for question 4, it cannot be assumed that other NPWT products have the same safety profile as V.A.C. Therapy.<br><br>SUMMARY:<br><br>KCI believes that the TA published on April 10, 2009, incompletely and inaccurately answers the questions posed by CMS. In order to comply with the MIPPA evidence review requirements, the final TA should review all relevant studies and information. Based on the totality of the evidence, the final report should then stipulate the following:<br><br>All evidence of effectiveness is applicable only to V.A.C. Therapy and cannot be applied to other NPWT products.<br><br>Given the unique mechanisms of action and | Key Question 2<br><br>The conclusion expressed in the Wild et al study was that the non-powered vacuum bottle approach to applying negative pressure to a pressure ulcer is not appropriate.(7) None of the NPWT systems considered in this review make use of a non-powered vacuum bottle.<br><br>Key Questions 3 and 4<br><br>While a majority of the evidence included in Key Question 3 captured the severity of harms of V.A.C.® Therapy, we were unable to determine the severity of adverse events for one NPWT systems compared to another. Therefore, we did not draw conclusions about the relative safety of different NPWT systems or products.<br><br>We believe that we have reviewed all relevant studies and assessed them against the Key Questions, and inclusion and exclusion criteria for this report. We thank KCI for their comments on the NPWT report and hope that we have provided a comprehensive response to all the issues they have raised. |

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| | | performance characteristics of V.A.C. Therapy, the absence of evidence of effectiveness for all other NPWT products cannot be assumed to establish equivalency of those products to V.A.C. Therapy.<br><br>Given the unique mechanisms of action, performance characteristics and evidence of effectiveness applicable only to V.A.C. Therapy, it can be assumed that V.A.C. Therapy has both therapeutic and functional distinctions from other NPWT products.<br><br>Given the lack of research on gauze based NPWT products, GranuFoam Dressings should be noted as a component of NPWT providing a significant therapeutic distinction.<br><br>Given the differences in outcomes noted in the Wild RCT based on the ability to monitor and adjust pressure, wound site pressure monitoring and adjusting technology (T.R.A.C. Pad Technology) provided by V.A.C. Therapy's a significant therapeutic distinction.<br><br>We appreciate the opportunity to comment on this important Technology Assessment.<br><br>Best regards,<br><br>Susan Morris<br>Vice President Health Policy<br>KCI<br><br>Todd Fruchterman<br>Sr Vice President Research & Development Chief Technology Officer Chief Medical Officer KCI<br><br>Reference List<br><br>(1) Saxena V, Hwang CW, Huang S, Eichbaum Q, Ingber | |

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| | | D, Orgill DP. Vacuum-assisted closure: microdeformations of wounds and cell proliferation. Plast Reconstr Surg 2004 October 1;114(5):1086-96.<br><br>(2) Greene AK, Puder M, Roy R et al. Microdeformational Wound Therapy: Effects on Angiogenesis and Matrix Metalloproteinases in Chronic Wounds of 3 Debilitated Patients. Ann Plast Surg 2006 April 1;56(4):418-22.<br><br>(3) Wilkes R, Zhao Y, Kieswetter K, Haridas B. Effects of Dressing Type on 3D Tissue Microdeformations During Negative Pressure Wound Therapy: A Computational Study. J Biomech Eng 2009 March 1;131(3):031012-1-031012-12.<br><br>(4) Argenta LC, Morykwas MJ. Vacuum-assisted closure: a new method for wound control and treatment: clinical experience. Ann Plast Surg 1997 June 1;38(6):563-76.<br><br>(5) Timmers MS, Le CS, Banwell P, Jukema GN. The effects of varying degrees of pressure delivered by negative-pressure wound therapy on skin perfusion. Ann Plast Surg 2005 December 1;55(6):665-71.<br><br>(6) Wackenfors A, Gustafsson R, Sjogren J, Algotsson L, Ingemansson R, Malmsjo M. Blood flow responses in the peristernal thoracic wall during vacuum-assisted closure therapy. Ann Thorac Surg 2005 May 1;79(5):1724-31.<br><br>(7) Kamolz LP, Andel H, Haslik W, Meissl G, Frey M. Use of subatmospheric pressure (VAC) to prevent the progression of partial thickness burns: first experiences. Presented at the European Tissue Repair Society, Focus Group Meeting, Topical Negative Pressure (TN) Therapy, Museum of London 4-6 December 2003. 12-4-2003. Ref Type: Abstract<br><br>(8) Stechmiller JK, Kilpadi DV, Childress B, Schultz GS. Effect of Vacuum-Assisted Closure Therapy on the expression of cytokines and proteases in wound fluid of adults with pressure ulcers. Wound Repair Regen 2006 | |

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| | | May 1;14(3):371-3.<br><br>(9) Kilpadi DV, Stechmiller JK, Childress B et al. Composition of wound fluid from pressure ulcers treated with negative pressure wound thereapy using VAC therapy in home health or extend care patients: a pilot study. Wounds 2006 May 1;18(5):119-26.<br><br>(10) Moues CM, van Toorenenbergen AW, Heule F, Hop WC, Hovius SE. The role of topical negative pressure in wound repair: expression of biochemical markers in wound fluid during wound healing. Wound Repair Regen 2008 July 1;16(4):488-94.<br><br>(11) Norbury K, Kieswetter K. Vacuum-assisted closure therapy attenuates the inflammatory response in a porcine acute wound healing model. Wounds 2007 April 1;19(4):97-106.<br><br>(12) McNulty AK, Schmidt M, Feeley T, Kieswetter K. Effects of negative pressure wound therapy on fibroblast viability, chemotactic signaling, and proliferation in a provisional wound (fibrin) matrix. Wound Repair Regen 2007 November 1;15(6):838-46.<br><br>(13) McNulty AK, Schmidt M, Feeley T, Villaneuva P, Kieswetter K. Effects of negative pressure wound therapy on cellular energetics in fibroblasts grown in a provisional wound (fibrin) matrix. Wound Repair Regen 2009 March 1;17(3):192-9.<br><br>(14) Morykwas MJ, Faler BJ, Pearce DJ, Argenta LC. Effects of varying levels of subatmospheric pressure on the rate of granulation tissue formation in experimental wounds in swine. Ann Plast Surg 2001 November 1;47(5):547-51.<br><br>(15) Derrick KL, Norbury K, Kieswetter K, Skaf J, McNulty AK. Comparative analysis of global gene expression profiles between diabetic rat wounds treated | |

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| | | with vacuum-assisted closure therapy, moist wound healing or gauze under suction. Int Wound J 2008 December 1;5(5):615-24.<br><br>(16) McNulty AK, Spranger I, Green J, Courage J, Rycerz A. The ability of the V.A.C. Therapy System to compensate for pressure drop while imparting macrostrain. Presented at the DFCon 2009 (March 19-21, 2009 Los Angeles CA) . 3-19-2009. Ref Type: Abstract<br><br>(17) Leininger BE, Rasmussen TE, Smith DL, Jenkins DH, Coppola C. Experience With Wound VAC and Delayed Primary Closure of Contaminated Soft Tissue Injuries in Iraq. J Trauma 2006 November 1;61(5):1207-11.<br><br>(18) Wild T, Stremitzer S, budzanowski A, Hoelzenbein T, Ludwig C, Ohrenberger G. Definition of efficiency in vacuum therapy-a randomized controlled trial comparing Redon drains with V.A.C. Therapy. Int Wound J 2008 December 1;5(5):641-7. | |
| Mullaney, Mary Ann | Greenville Memorial University Medical Center | I am an advanced practice nurse whose clinical focus is Wound Care. I am employed in a teaching facility, level 1, 600 bed facility.<br><br>I am writing in response to the comparison of NPWT modalities. I have worked with the NPWT from KCI since its inception. I have also worked with other forms of NPWT. The outcomes desired are reached with the KCI NPWT and not with the competitors.<br><br>Ex: 28 year old with diagnosis of Familia Ossificans Progressiva. First use of the VAC in world population, 4 stage 4 ulcers which healed in less than 2 months.<br><br>I have applied the VAC to patients across the age spectrum and rarely have been unable to achieve the desired outcomes. My experience is across a 20 year time frame | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| | | and the positive outcomes are not achieved by the competitors. | |
| Nelson, Gloriajean, RN, MBA, WOCN | Rogue Valley Medical Center | I am a WOCN in Medford Oregon and would like to voice my concerns about negative pressure therapy. I have seen many different types of wounds during the last 3 years and some that I thought would never heal. These wounds have exposed organs, bone and or tendons that with the use of negative pressure therapy saved a limb or life.<br><br>I realize in today's economy we MUST look at all cost saving possibilities and I appreciate you looking at this cost. Unfortunately, I do not believe that all negative pressure therapies are the same and I am quite concerned with the trend that we are moving with these products.<br><br>The technology and process is quite different between the systems. With the gauze system under negative pressure it does stimulate and encourage wound healing but so does a wet to dry dressing. This system utilizes both wet to dry dressing with a negative pressure drain to remove the excess moisture. The gauze does not do anything to encourage healing to the wound bed itself. The foam of the KCI wound V.A.C. places microstrain to the wound bed and encourages rapid cellular growth among other things. Additionally, we have been able to apply the foam to the outside of the skin over undermined or tunneled areas to graft the layers together and decrease the length of time required to heal wounds. This type of grafting is NOT possible with gauze negative pressure systems.<br><br>I have two cases studies I would like to bring up. The first is a patient with 2 small openings that that communicated to each other with a large undermined cavity below. She had a ventral hernia repair with mesh and is a diabetic. Since the openings were so small, and the wounds had copious amounts of drainage we thought that the gauze system would be a better option for this patient.<br>The system was applied; during the first 2 weeks we did not get any improvement in the wound. The second 2 | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| | | weeks the drainage improved and the wound was slightly smaller. The patient then developed a bowel obstruction and was hospitalized. At that time we applied a KCI wound vac. The amount of growth and improvement in her wound was tremendous over that one week. We discharged her from the hospital on this system and were able to place her wound V.A.C. on hold last week due to the significant amount of healing. She continues to heal quickly and without any further issues.<br><br>The second case is a patient that had a bilaterally modified radical mastectomy that developed bilaterally wound infections. She required debridement along her entire chest wall anteriorly and laterally. Initially we applied the KCI Granufoam wound V.A.C. into the wound bed to generate good granulation tissue. We were then able to apply the foam to outer skin with a small wick at the opening of the wound bed. Utilizing this combination of negative pressure over the top and the edge of the wound bed the two areas were grafted together. This worked beautifully and we only had two very small opening to heal instead of 2 extremely extensive undermined wounds. This type of grafting is not possible with gauze negative pressure systems.<br><br>Thank you very much for taking the time to investigate completely before making a decision. I realize that the gauze companies feel that their product is comparable to the KCI product but there is not ONE product that will meet ALL patient needs effectively. I believe switching to just one system will prevent us from healing patients.<br>It will be limit the flexibility needed to meet changing patient's needs. | |
| NR | American Society of Plastic Surgeons | Thank you for the opportunity to comment on the ECRI's draft report on negative pressure wound therapy (NPWT). Given the lack of available evidence, the American Society of Plastic Surgeons encourages CMS and AHRQ to fund head-to-head comparison studies in order to | Thank you for your comments regarding the report. |

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| | | determine if there is any distinction among the various NPWT products. | |
| Nusgart, Marcia | Executive Director, Coalition of Wound Care Manufacturers | On behalf of the Coalition of Wound Care Manufacturers, I am submitting the following comments on the AHRQ draft report entitled, A Review of Negative Pressure Wound Therapy Devices. The Coalition represents medical device companies who manufacture a wide range of wound care technology including negative pressure wound therapy devices. We would like to commend AHRQ and ECRI on the quick time frame in which this draft report was released.<br><br>The Coalition agrees with the conclusions reached in this report, including the inability of AHRQ to utilize studies that by design were biased as well as the fact that there are no head to head human studies that currently compare the two types of NPWT devices gauze and foam. However, we disagree that there are NO head to head studies comparing the two devices. In fact there are animal studies that do show that gauze and foam based NPWT therapies are the same and/or that the clinical benefits are the same. Moreover, is has been shown through clinical use and individual studies that when NPWT is used appropriately whether gauze or foam based the clinical results are the same. In fact, based on the literature, NPWT is an effective therapy in an arsenal of wound care treatments to help heal patients with chronic wounds.<br><br>The Coalition has several concerns with the report which we will address in greater detail in these comments:<br><br>Ensuring that the release and utilization of the final report will be in enough time so that it can be used by the CMS HCPCS Workgroup in making their preliminary coding decisions.<br><br>Using solely RCTs to reach conclusions in this draft report<br><br>Utilizing wound closure as the only measurement | Ms. Nusgart, thank you for your comments on the NPWT report. Thank you for your concerns that the HCPCS Workgroup work with the most up-to-date information. We can assure you that CMS will be utilizing the final draft of the report, which has also been peer reviewed, to help in their decision making process.<br><br>We provide the following information in response to your concerns about the inclusion and exclusion criteria utilized in the report :<br><br>The focus of this report was to evaluate the scientific evidence for a significant therapeutic distinction of any single NPWT system or its components compared to other NPWT systems or their components, based on specific outcomes of interest to the Center for Medicare Management at CMS. Key questions were prepared for the report using the "PICO" framework: patients, intervention of interest, comparator, and outcomes (see Figure 1). Inclusion and exclusion criteria were developed based on each key question prior to an examination of the evidence. Twelve inclusion criteria were established for this TA. In a TA, the inclusion criteria determine whether a study is "relevant" to the key questions. Studies that do not meet the inclusion criteria are excluded from the TA. Exclusion from the TA does not imply that the studies have no scientific merit, just that their findings are not applicable to answering a key question within the specific report. As explained below and in the report, most submissions from interested stakeholders were not relevant to the key questions posed in this particular report, the |

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| | | for NPWT<br><br>Not utilizing or reviewing all of the studies/information submitted to the Agency.<br><br>First, the Coalition is concerned about the timeframe for the use of this report in the decision-making process for HCPCS coding of NPWT. The Coalition would like to ensure that the process and timeline to perform an evaluation of the HCPCS codes is fair and appropriate. We are interested to know whether the CMS HCPCS Workgroup will be using the AHRQ draft or final report to base their preliminary coding decisions. We have concerns that if the Workgroup uses the draft instead of the final report on which to base their preliminary coding decisions, it may contain inaccuracies since it has not yet been peer reviewed. We would recommend that the CMS HCPCS Workgroup only use a final version of the AHRQ report to make both their preliminary and final coding decisions. As we understand it, the HCPCS Coding Public Meeting will be taking place on July 9 and as such the preliminary information has to be released 30 days before this date. In order for the HCPCS Workgroup to have enough time to review this before making a preliminary decision, one would estimate that the final report would need to be issued by mid-May. While there was a quick turnaround for the draft report, we hope that the AHRQ/ECRI Institute staff also thoughtfully reviews the comments and writes the final report to be published in the appropriate timeframe.<br><br>It is our understanding that AHRQ (through the ECRI Institute) will be providing CMS with relevant studies and information for use in consideration of coding changes as required by the MIPPA legislation. The CMS HCPCS Workgroup will be utilizing certain thresholds in determining what studies are appropriate as they determine whether existing HCPCS codes adequately represent the technology and comparative benefits of NPWT devices. The Coalition would be interested in discussing the | purpose of which was to determine whether there was evidence of a therapeutic distinction between different NPWT systems or components.<br><br>We undertook an extensive search of the literature from which we identified over 1,000 potential articles. In the interest of identifying all clinically relevant materials for this report, we also invited interested stakeholders to submit information regarding any published, unpublished, or currently registered studies for possible inclusion in the report. We received over 1,400 submissions by the February 6, 2009 deadline. Each submission was reviewed for possible inclusion in the report (see Appendix D).<br><br>During the evaluation of all stakeholder submissions, we excluded 638 (44%) of the 1,435 submissions due to duplication alone (see Figure 5 in Appendix D). Of the 797 (55% of original) unique submissions; 29 (4%) were included in our *Background* section and 269 (33%) items were excluded; 147 (56%) of the excluded items were case reports, abstracts or poster presentations given at conferences.<br><br>Of the 499 (35%) remaining articles, 354 (71%) were excluded at the article level. Based on the a priori inclusion/exclusion criteria, narrative reviews (k = 152 [43%]); animal studies (k = 39 [11%]); and studies with fewer than five patients in each arm (k = 30 [8%]) were excluded.<br><br>Of the 144 (10%) original submissions that met inclusion criteria, 117 (81%) were previously identified by the ECRI Institute literature searches. We subsequently included 28 studies not previously identified in our searches in the final report. Please see Appendix D for additional details on individual submissions and subsequent disposition in the |

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| | | specifics of the thresholds and whether they are in fact appropriate for NPWT.<br><br>Second, the Coalition's main concern in the draft report is that AHRQ/ECRI Institute based its conclusions in the NPWT draft report solely utilizing randomized controlled trials (RCTs) almost to the exclusion of all other types of evidence. While we agree that RCTs are the gold standard, there is other relevant evidence that should and must be considered. We question why the ECRI Institute requested interested stakeholders to submit not only published and unpublished RCTs but also observational studies or other compelling clinical evidence that uses NPWT devices to impact relevant clinical outcomes if it was not going to be considered or published for this report. We would like to emphasize the importance of utilizing all evidence and not just RCTs.<br><br>Patients in the wound care community present with a variety of wound etiologies as well as multiple co-morbidities and often have a poor nutrition history. As such, wound care research is very different than other areas of medical research; and thus, different levels of evidence should to be utilized when assessing any wound care product. The Coalition believes that complete wound healing outcomes in RCTs may no longer be appropriate and other types of evidence need to be considered. We submit that AHRQ should be including in its final report the wide range of scientific evidence (i.e. published and unpublished randomized controlled trials (RCTs), observational studies, and other compelling clinical evidence) that was submitted to the Agency that was not in its draft report. In addition, while expert opinion has traditionally not been viewed by CMS or its contractors - as high on levels of evidence, we would request that the Agency seriously consider it as the standard of care for the patient population in wound care.<br><br>This thinking of using other levels of evidence along with the recommendations of using surrogate endpoints (noted | report.<br><br>For a clearer understanding of our evaluation process, we have included documentation of all 1,435 submissions in Appendix D of the report. This section of the report, alphabetized by submitter, includes an attrition diagram and accompanying table that describes the disposition of each individual submission therein. The attrition diagram provides a visual representation of the disposition of materials as they go through the evaluation process. The accompanying table in the report includes a citation for each submission and lists either the placement in the report or reason for exclusion.<br><br>In regard to your concerns about the exclusion of animal studies, we provide the following explanation:<br><br>Evidence-based reports, for the purpose of policy or clinical decision making, rarely rely on non-clinical evidence (studies using animals, cell culture, cadavers, etc.) to address the effectiveness of treatments. While animal studies may lead to important discoveries that ultimately prove valuable in human applications, experts have cautioned that fewer than a third of highly-cited animal studies translate into human RCTs showing the same results of treatment.(9)<br><br>Animal studies also seldom use study design procedures such as randomization, concealment of allocation, and blinding of outcome assessment that would limit the potential for bias.(10) Publication bias, the preferential publication of studies with positive results, may be especially common with animal studies.(11) In addition, positive results in animal studies may not translate well to the clinical setting. Investigators can control the severity of the |

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| | | below) is contained in the current wound care literature. One current article which we will enclose as an attachment is Evidenced-Based Medicine in Wound Care- Time for a New Paradigm by Drs Marissa Carter and Robert Warriner in the January 2009 Advances in Skin & Wound Care, a peer-reviewed journal.(53)<br><br>Third, we disagree with this statement in the AHRQ draft report, "The most important outcomes to consider under the category of improved wound healing are percent of patients with complete wound closure and time to complete healing (partial healing for facilitation of surgical wound closure)." While current FDA requirements of efficacy and safety for wound care technology approval consider complete wound healing as the only acceptable outcome, this may not be totally realistic for wound care research today. Most wound care trials last 4-8 weeks, and show little difference between complete wound healing of the treatment versus control arms because few patients in total have achieved complete wound healing. This has led to trial protocols that employ a variety of primary outcomes, such as changes in wound size area or volume, time required for wound bed preparation, wound granulation fill, or infection parameters if relevant to the product. Rarely, if ever, do clinicians utilize NPWT simply for wound closure. While wound closure is the ultimate goal in treating any wound care patient, there are other surrogate endpoints for the use of NPWT including, but not limited to complete granulation of tissue, preparation for skin grafts, to be able to utilize bioengineered skin tissue, and to achieve epithelialization. If AHRQ is utilizing the FDA definition, then it should be noted that NPWT devices were not approved for wound closure they were approved for wound drainage. This is an important distinction to be made.<br><br>Given the challenges of conducting prospective comparative research in complex subpopulations of wound care patients, we believe that mechanisms of action, | wound in animals to a greater extent than in human studies. Animal subjects are likely to be younger and healthier than humans with wounds. Animals in such studies may not have co-morbid health conditions or exposure to concurrent medical interventions, in contrast to human subjects with wounds.<br><br>An additional problem with animal studies of wound healing is determining which of the human wound etiologies (pressure ulcers, diabetic foot ulcers, venous leg ulcers, burns, sternal wound infections, or trauma-induced wounds) the animal model represents. Given the nature of the questions asked in our report and the outcomes of interest to the Center for Medicare Management at CMS, such evidence from animal models is not relevant.<br><br>In response to your comment that only RCTs were considered, we offer this reply:<br><br>Inclusion criteria #5 on page 46 of the draft report states: "*For Key Question 1, 2, and 4, study must have been a controlled study comparing one NPWT system or components of a system to another NPWT system or components. Randomization to a NPWT system group was not required."* The report actually included more non-RCTs than RCTs. The Executive Summary states that "*Of 38 studies comparing a NPWT system to another wound care therapy, all were studies of the Kinetics Concepts Inc. (KCI) VAC® system and only nine were RCTs."* Current EPC Methods Guidance does specify that indirect comparisons should only utilize data from RCTs in which the treatments of interest have been evaluated against a common control intervention. Had there been RCTs available of different NPWT systems compared to the same control treatment, we would have attempted to use the data to perform indirect statistical comparisons. |

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| | | cellular science, pre-clinical research and expert clinical opinion must also be considered in this or any review of advanced wound care interventions. Limiting a review to pristine randomized controlled trials with total wound closure as the only endpoint, overlooks evidence that appropriately addresses effectiveness in patients with serious co-morbidities who are routinely excluded from RCTs.<br><br>Finally, The Coalition has concerns that AHRQ did not publish or consider all of the comments that organizations and individuals had submitted. The Agency had requested all interested stakeholders to submit information regarding additional studies of relevance to NPWT. The Coalition submitted information to AHRQ for review. However, in reviewing the draft report, specifically appendix A and D, AHRQ only identifies 15 professional organizations in Appendix A**,** and only 2 in Appendix D in which information was utilized for review and the Coalition comments were not identified at all. In addition, we know of several clinicians that submitted individual information that also does not appear to be included in this review. As such, the Coalition is concerned about the information that AHRQ did utilize and questions how complete was the review of the literature.<br><br>The Coalition believes it is clear from the literature that NPWT is beneficial to the patients that receive this type of therapy. While earlier technology assessments have been critical of the NPWT technology because of small sample sizes, vague clinical endpoints and the majority of studies funded by a single manufacturer, the Coalition believes that this is just a reflection of the wound care population and the difficulties this population presents when trying to conduct studies.<br><br>We appreciate the opportunity to provide you with our comments and look forward to working with you as you finalize the report on NPWT devices. If you would like further information or have any questions, please feel free | This is the only situation for which we would have required RCTs.<br><br>Next, you stated that the report only utilized wound closure as the only measurement for NPWT. We wish to correct this misunderstanding and refer you to Figures 1 and 3 of the report, which list nine additional outcomes that were considered in this report.<br><br>For assistance in clarifying relevant outcomes, we looked for guidance from the U.S. Food and Drug Administration (FDA).(14) According to the FDA, improved wound healing and improved wound care are important clinical outcomes with the use of a wound-treatment device. Specifically, the most important outcomes to consider under the category of improved wound healing are percent of patients with complete wound closure and time to complete healing (partial healing for facilitation of surgical wound closure). We therefore incorporated "time to complete wound closure" and "percent of wounds healed" as important patient-oriented outcomes. In addition, for cases that are not expected to result in complete wound closure but rather to advance the wound to a stage where healing is possible we incorporated "time to 50% reduction of wound initial volume," "percent change in wound volume," and "improved wound condition" as important outcomes of interest.<br><br>In keeping with the AHRQ methods guidance, we have captured important patient outcomes, such as quality of life, satisfaction with treatment (which would include mention of pain or discomfort during treatment), duration of treatment, and survival.(12) Outcomes such as improved compliance, convenience and personal preference (and patient-oriented outcomes such as quality of life or satisfaction with treatment) are considered by CMS |

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| | | to contact me. | to indicate significant distinctions only to the extent that they result in demonstrably improved clinical outcomes. Patient outcomes reported in 40 comparison studies, 103 single arm studies and 22 previous systematic reviews are included in Appendix C of the report. Key Question 3 specifically focuses on harms reported in studies comparing NPWT to comparator treatments. For descriptions of comparison studies, single arm studies and previous systematic reviews, we refer you to Tables 5, 38, and 42 respectively.<br><br>Lastly, we would like to address the issue that submissions were missing from the report. We can confirm the receipt of your submission dated February 6, 2009. At that time, we can assure you that we thoroughly reviewed the listing of studies provided. The relevant materials were previously identified in our literature searches or were also submitted by Prospera or Smith and Nephew (who you identify as providing input into your submission). |
| Perry, Karen | NR | I have used KCI NPWT for years with positive results. Most of the MDs in Northern Ky only use NPWT from KCI. I trust the VAC and my patient have loved it for its remarkable healing results. Thank you. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |
| Peterson, Alan | NASL | The National Association for the Support of Long Term Care (NASL) submits the following comments in response to the Technology Assessment report entitled, "Negative Pressure Wound Therapy Devices." Since the Agency for Healthcare Research and Quality (AHRQ) report will influence the Centers for Medicare and Medicaid Services (CMS) in making coding decisions regarding negative pressure wound therapy (NPWT) devices, it is important that the report reflect a thorough and accurate review of "all relevant studies and information furnished pursuant to such process," as required by the Medicare Improvements | Thank you for providing comments on the report. We would like to respond to the concerns presented in your posting.<br><br>First, we would like to reply to your comment that "It appears that the review did not follow generally accepted principles of evidence-based medicine, excluding mechanisms of action, cellular science, pre-clinical research and expert clinical opinion.<br><br>We have followed the methods guidance for the Evidence-based Practice Center (EPC) Program. |

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| | | for Patients and Providers Act (MIPPA).<br><br>NASL is a trade association representing providers of ancillary services and products to the long-term care industry. Our member companies provide speech language pathology, physical, occupational and respiratory therapy; portable x-ray/EKG and ultrasound; pharmacy; long-term care software systems; and other ancillary services. NASL members also provide products such as complex medical equipment, parenteral and enteral equipment, supplies and nutrients, and other specialized supplies for post-acute care settings.<br><br>Our primary concern about the report relates to process. It appears that the review did not follow generally accepted principles of evidence-based medicine, excluding mechanisms of action, cellular science, pre-clinical research and expert clinical opinion. By limiting the review to controlled trials with total wound closure as the only endpoint, the report overlooked evidence that appropriately addressed effectiveness in patients with serious co-morbidities who are excluded routinely from randomized clinical trials. If the report had been expanded to include the other evidence, it likely would have found significant therapeutic distinctions between the mechanisms of action, performance characteristics and therapeutic benefits of the NPWT products.<br><br>Based on an absence of comparative head-to-head evidence, the report's conclusion that there are no therapeutic distinctions between NPWT products or components of NPWT products is flawed. The narrow review of evidence used to arrive at this conclusion is not the review standard mandated by the by MIPPA, which directed CMS to "consider all relevant studies and information furnished pursuant to such process" in a code review for NPWT products.<br><br>NASL recommends that the report be amended to note which NPWT products have clear evidence of clinical | The purpose of this report was not to provide evidence of the effectiveness of NPWT in comparison to other types of wound care treatments such as specialized dressings or topical products. The *Methods* section of this report specifically states "this report does not address whether NPWT systems provide a better wound care alternative compared to non-NPWT wound care therapies." Instead, the focus of this report was to evaluate the scientific evidence for a significant therapeutic distinction of any single NPWT system or its components compared to other NPWT systems or their components, based on specific outcomes of interest to the Center for Medicare Management at CMS. Key questions were prepared for the report using the "PICO" framework: patients, intervention of interest, comparator, and outcomes (see Figure 1). Inclusion and exclusion criteria were developed based on each key question prior to an examination of the evidence. Twelve inclusion criteria were established for this TA. In a TA, the inclusion criteria determine whether a study is "relevant" to the key questions. Studies that do not meet the inclusion criteria are excluded from the TA. Exclusion from the TA does not imply that the studies have no scientific merit, just that their findings are not applicable to answering a key question within the specific report. As explained below and in the report, most submissions from interested stakeholders were not relevant to the key questions posed in this particular report, the purpose of which was to determine whether there was evidence of a therapeutic distinction between different NPWT systems or components.<br><br>We did not restrict our evaluation to head-to-head comparisons. Had there been RCTs of different NPWT systems evaluated against a common comparator, we may have been able to perform |

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| | | effectiveness. It should not be assumed that evidence regarding one product can be applied to the other products currently assigned to the NPWT category, and it should not be assumed that the lack of evidence for other NPWT products be used to establish their clinical equivalence. Each product ought to stand on its own record of clinical effectiveness. Thank you for your consideration of these comments. | indirect comparisons, in keeping with the EPC Methods Guidance. However, there were no RCTs of any systems other than the KCI V.A.C.® system, so this was not possible.<br><br>Next, you stated that the report only utilized "total wound closure as the only endpoint." The *Methods* section includes an analytical framework (Figure 3 in the report) that lists additional outcomes that were considered in this report. For assistance in clarifying relevant outcomes, we looked for guidance from the U.S. Food and Drug Administration (FDA).(14) According to the FDA, improved wound healing and improved wound care are important clinical outcomes with the use of a wound-treatment device. Specifically, the most important outcomes to consider under the category of improved wound healing are percent of patients with complete wound closure and time to complete healing (partial healing for facilitation of surgical wound closure). We therefore incorporated "time to complete wound closure" and "percent of wounds healed" as important patient-oriented outcomes. In addition, for cases that are not expected to result in complete wound closure but rather to advance the wound to a stage where healing is possible we incorporated "time to 50% reduction of wound initial volume," "percent change in wound volume," and "improved wound condition" as important outcomes of interest. we have captured important patient outcomes, such as quality of life, satisfaction with treatment (which would include mention of pain or discomfort during treatment), duration of treatment, and survival.(12) Outcomes such as improved compliance, convenience and personal preference (and patient-oriented outcomes such as quality of life or satisfaction with treatment) are considered by CMS to indicate significant distinctions only to the extent that they result in |

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| | | | demonstrably improved clinical outcomes. Patient outcomes reported in 40 comparison studies, 103 single arm studies and 22 previous systematic reviews are included in Appendix C of the report. Key Question 3 specifically focuses on harms reported in studies comparing NPWT to comparator treatments. For reports of comparison studies, single arm studies and previous systematic reviews, we refer you to Tables 5, 38, and 42 respectively.<br><br>In response to your comment that "The narrow review of evidence used to arrive at this conclusion is not the review standard mandated by the by MIPPA, which directed CMS to 'consider all relevant studies and information furnished pursuant to such process' in a code review for NPWT products," we have the following reply:<br><br>We did consider all information and evidence presented to us, categorized that information as to its relevance to the key questions in this report, and provided CMS with an assessment of the merits and quality of the evidence as it pertains to the coding review. We carefully evaluated over 1000 articles identified in our literature searches and the 1435 items submitted by stakeholders for consideration. Our literature search methodologies are provided in Appendix A, along with a list of excluded studies with reasons for exclusion. In addition, we have included documentation of all 1,435 submissions in Appendix D of the report. This section of the report, alphabetized by submitter, includes an attrition diagram and accompanying table that describes the disposition of each individual submission therein. The attrition diagram provides a visual representation of the disposition of materials as they go through the evaluation process. The accompanying table in the report includes a citation for each submission and lists either the placement |

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| | | | in the report or reason for exclusion.<br><br>In regards to your comments that "It should not be assumed that evidence regarding one product can be applied to the other products currently assigned to the NPWT category, and it should not be assumed that the lack of evidence for other NPWT products be used to establish their clinical equivalence," we point out that due to the lack of published or unpublished studies that evaluated other NPWT systems we were unable to perform direct or indirect comparisons. In the absence of such comparisons, ECRI Institute was unable to draw conclusions about the superiority or equivalence of any NPWT system or its components compared to another NPWT system or its components. |
| Phillips, Charles, HH Director | Community Home Care | We have had the opportunity to use negative pressure wound devices in the past and come to find that KCI's Wound VAC therapy is in my opinion that best. The pump is easy to use, has enough options to tailors its use to the patients needs, is light so they are still mobile. In terms of healing I have found that while all negative pressure therapy speed wound healing time KCI's works the quickest to generate granulation and tissue formation. The patients heal in about 1/2 to 1/3 the time it would generally take without therapy. The other difference I see is the product i.e., black and white foam, types available, etc., stimulates granulation, with other manufacturers. As for support, I couldn't ask for better, the reps are always available for questions, advice and on more than one occasion has made visits to the patient's home with staff to help with difficult location placement. KCI's wound VAC is great can't say enough. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |
| Polley, Arja, BSN, RN, CWON | Accolade Home Care | It is my opinion from over 40 years of experience in wound care and over 10 years of experience with negative pressure wound therapy that a system incorporating the use of a porous open-cell foam does indeed actively induce | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| | | macrostrain and microstrain of the tissues pulling wound edges together and helping tissues to replicate and the wound to exhibit much more rapid healing than the gauze based negative pressure wound healing systems. | |
| Postlewaite, Cheryl, MSN, RN, CWOCN | Mission Hospitals | Not all NPWT is the same. That's like saying that an apple and a radish are the same because they're both red and round. They are each unique and provide different nutrients. The same is true of different NPWT products. I have seen some pretty bad outcomes after patients were transitioned to a gauze based system. I have seen wounds stall and deteriorate. Additionally, if you look at the contraindications and warnings, most of the gauze based products warn and caution against use when organs and other vital structures are present in the wound bed. We have the ability to use the VAC safely in those situations. The bottom line is: it's more cost effective to use the best product for the patient the first time around, even if that product appears more expensive at first. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |
| Progar, Monica | Amedisys | My clinical practice is in Home Health care. What I can say I consistently see is our elderly, frail, debilitated patients with multiple co-morbidities have better outcomes on the KCI VAC for wound healing. The gauze NWPT seems to work best on those who are younger with little co-morbidity. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |
| Puglisi, Janet | Homecare | The negative wound V.A.C. is a cost saver and entirely needed. | Thank you for providing your comment. |
| Randilph, Ronald W., PA | Cincinnati Jewish Hospital, Cincinnati, OH | I like using wound V.A.C. for management of surgical or chronic wounds. I hope they continue to be funded and used for patient management throughout the U.S. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |
| Ranger, Janice | Travelers Rest SC | I have tried the British NPWT device and I placed it on a patient that had 5 wounds. I placed the KCI wound V.A.C. on the right trochanter and Ischeum as well as the sacrum. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for |

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| | | I placed the other one on the Left Trochanter and Ischeum. After one week the three wounds with the KCI vac were retracting and had granulation tissue. The left side was larger and clean, but no granulation tissue. I, of course, did not continue with the other NPWT. I cannot see how a gauze and drain can do the same job as the foam. I only use KCI. If there were an alternative that did a better job, I would definitely use it. The patient is what is important here, not the company. | Medicare Management at CMS. |
| Roady, Sharon, LPN | NR | I have been a clinician in CONNECTICUT for the last 9 years; 4 years as a staff LPN in the hospital setting and the last 5 years in the home care setting. In my time working in a hospital for rehabilitation specifically spinal cord injury I was involved in pressure ulcers to stage 4 in which various wound treatments were used namely the KCI V.A.C. system and continued to use this system of NPWT in the home care setting for a variety of surgical pressure ulcers and diabetic ulcer patients. I have found that KCI VAC system to be easy to utilize and the newer portable system to be of lighter weight and easily managed by patients. Overall patient healing times were cut in half and patients seemed to have less pain and infection related to less need for dressing changes; on average VAC dressings were changed 3 times weekly verses daily or every other day with convention dressings; the VAC system was also able to be used until 100 percent granulation/healing was completed.<br><br>During the last 5 years I was fortunate to have the opportunity to utilize 2 other NWPT systems; Smith & Nephew, Vista versatile 1 portable and Talley Group, Ltd., Venturi Negative Pressure Wound Therapy (portable). The Vista versatile 1 portable system was used for a surgical lower abdominal wound r/t to c -section a diabetic heel ulcer that was surgically debrided. I found that the normal saline wet antimicrobial gauze caused more maceration to the wound edges especially the diabetic heel wound. I also found that the NWPT set at 80mmHg even with a well | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| | | sealed dressing did not seem to be strong enough suction and less absorbance of the antimicrobial gauze seemed to cause drainage to stay longer at the wound site. This system also had a higher potential for infection from drainage related to the system not having a back flow valve to prevent leakage and isolyzer packet to solidify fluid waste. During use of this system both patients had experienced infections and neither patient continued the system after being treated for the infection.<br><br>I also had the opportunity to use The Talley Group ltd, Venturi Negative Pressure wound therapy portable for a patient which had a right upper quad surgical abdomen wound. During my time with a representative from the company to review the system with me, the representative in disconnecting the tubing from the patient to the machine had actually gotten splattered with drainage from the system. This system was the worse device I have ever used. The machine was very heavy and had no protective filters or mechanisms to prevent drainage from either leaving the canister if tipped or and risked the patient and clinician from splattering drainage. Needless to say the patient was unable to tolerate the system and ultimately was treated for infection and MD had discontinued the system.<br><br>In conclusion, overall the preference of NWPT systems wound be the KCI VAC system. The KCI VAC system was far superior than the others. Most patients found it is easy to manage and as a clinician it was easier to use. There was no risk of drainage from the system coming in contact with patient or clinician when removing system during wound care and because of its closed system design patients did not have to worry about how they handled the machine.<br><br>I also found more granulation faster utilizing the GRANUfoam verses the antibacterial gauze dressing and most patients that used the KCI VAC system were able to use it until wound was fully granulated and experienced | |

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| | | less infection during use of the system. I also found that there was a higher risk of gauze fibers to be left in the wound bed especially if the wound had tunnelling the GRANUfoam did not break apart easily and had less chance of foam particles being left in wound bed during healing.<br><br>I would strongly suggest that the KCI V.A.C. system should be made the Benchmark NWPT system. Most literature and studies using NWPT quote clinical trials and studies done by KCI or clinicians who use the KCI products. The other systems have limited study base materials to base their products as better than KCI product and use a lesser sub-atmospheric pressure 60- 80mmHG based on testing utilizing a rabbit, whereas most surgical models and devices that are developed such as surgical staples are tested with pigs which have closed organ and tissue consistency to human. The KCI VAC system is based on many more clinical studies utilizing pig tissues which determine that optimal sub atmospheric pressure to be 125mmHG which increases levels granulation tissue at a micro and macro cellular levels and overall healing time is faster in the end saving cost and allows patients to get back to their optimal health faster.<br><br>The KCI VAC system has also met the high standards of the FDA for more specialized wound types than the others. | |
| Rolley, Joseph | Convatec Inc. | ConvaTec Inc. is a leading global developer and marketer of advanced wound dressings, negative pressure wound therapy devices and clinical decision support tools. ConvaTec is the exclusive distributor of the Engenex(R) Advanced NPWT System manufactured by Boehringer Technologies, L.P. As a wound care industry stakeholder, we would like to express our support for the conclusions drawn by AHRQ in its study of Negative Pressure Wound Therapy devices (Draft Project ID: WNDT1108). As such, we believe the existing HCPCS code set for NPWT adequately describes the devices included in this category | Thank you for providing comments on the report. |

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| | | at this time. We would discourage the Centers for Medicare and Medicaid Services from requesting the National HCPCS Panel split the NPWT category by creating new HCPCS codes for these devices in the current coding cycle.<br><br>The Engenex NPWT System has been in the US market for a relatively short period of time and evidence of its clinical performance continues to build. Our medical research team would welcome dialog and engagement with AHRQ and CMS in future research projects in this area. | |
| Ruberto D., B.S.N., R.N. | NR | As a Wound Care nurse who has used N.P.W.T. products from different companies, I would like to address the unique value of K.C.I. negative pressure wound therapy. A patient with a pressure ulcer on the elbow was debrided and placed on the Smith & Nephew Blue Sky V.A.C. This product advertised as N.P.W.T. utilizes saline gauze under the V.A.C. drape. Recommended setting was 78 - 80 mmHg continuous. The Blue Sky V.A.C. was a trial therapy to last several months. The patient stated he wanted a quieter V.A.C. motor and his insurance case manager had agreed with the lower price for the trial period. I found the Blue Sky adhesive V.A.C. drape tore easily and more was needed for an effective seal. The canister was full of drainage every other day, yet there was no leaking noted or rash observed. At the proximal end of the wound 3 cms healed into a thick, strong skin scar.<br><br>However, with the Blue Sky V.A.C., there was no increase in granulation despite serial debridements in the clinic. Instead, the wound base remained pale and polypoid looking. The Blue Sky V.A.C. only seemed to serve as a collection unit to suction copious drainage. Due to the absence of granulation tissue, Clinic decision was made to switch therapy to K.C.I. Wound V.A.C. when the Blue Sky trial period ended. Resumption of the K.C.I. Wound V.A.C. resulted in bright red granulation tissue in the wound base after just three days. Although bone had been | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| | | felt in the wound base in the last few weeks, it is now firmly covered with tissue. The wound continues to resolve length and width dimensions about 1 cm. each week.<br><br>My conclusion was that although the N.S. gauze V.A.C. removed copious drainage, it was not in firm contact with the wound base promoting granulation tissue to reduce the size of the wound. The firm contact of the K.C.I. V.A.C. sponge to the wound base has led to the continuing resolution of this pressure ulcer. | |
| Smith, Barbara E. | WOCN | I have found VAC therapy is far superior to other NPWT. I have been using VAC therapy for more than 8 years and have used it on PU, grafts and surgical, diabetic and dehisced wounds. The VAC company is always improving on their technology by listening to people out in the field dealing with the wounds. I have seen a dramatic improvement on chronic and sub-acute wounds and complete closure on traumatic and acute wounds. My experience is in long-term, sub-acute and acute care hospitals.<br><br>I have also tried another NPWT system which did have a sponge. The equipment was not self contained for patient mobility and safety. Even though it had a larger canister which could be reused, when canister was full it was extra weight to system which decreased mobility of patient and canister could possibly spill wound fluids. Our wound team experienced problems with this system on keeping seal and there were no intermittent settings.<br><br>I have not experienced any major problems as described in the AHRQ assessment with the VAC system. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |
| Steffensmeier, Donna, L.P.N. C.W.S. | MD Wound Healing Center | Hello, I am a C.W.S., L.P.N. That currently works in Waldorf, MD. at an outpatient wound center. My previous experience was with a V.A.C. system named "Blue Sky" back in 2003 at a local hospital. At that time, I was the in-house wound care nurse, and was already using the KCI | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| | | wound V.A.C. for our hospitalized patients, but the comptroller of the hospital did not want to "rent" the KCI system, so I trialed the “Blue Sky” system with hopes to purchase this unit for the hospital to use.<br><br>I was extremely unhappy with the outcome. At that time, there were no safety features on the blue sky unit. The suction was not to exceed a certain amount for the type of surgical wound I was using it for. The suction set-up dial could be manually increased or decreased, whereas KCI's suction had a cut-off valve so that if a practitioner mistakenly would increase a suction setting, they were unable to do so using the KCI set-up. So, as best I could, I set the patient's suction properly using their blue sky machine, informed the floor nurses of the ordered suction to be delivered to the patient, made signs above the pt's bed, on the actual machine itself, and at his bedside stand as well, communicating not to alter the suction past the ordered amount. Well, when I made rounds on this patient the next day, the suction had been altered to the highest amount of suction possible, this (in my opinion, I believe) created an abdominal fistula, the patient developed an electrolyte imbalance and expired the next day!! I have never used it since!<br><br>I am the nurse manager for the wound center I practice in now, and never encourage the doctors I work with to order anything other than the KCI wound V.A.C. system. we do have some patients that see us from various local nursing homes, who do use the "vista" system (as required by their institutions), and it does seem like that system is not as efficient with delivering a quality negative pressure suction to the patient's wound beds as compared to KCI.<br><br>I hope Medicare does not allow other faulty negative pressure systems to share the same billing codes as the KCI system. KCI truly is in a league of their own, and we do see great things using their product. Feel free to contact me if necessary. | |

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| Tashjian, Paula | Accent Care Home Health | KCI is the only NPWT which has foam that shows increase granulation r/t the interaction of sponge and wound bed. I have used other NPWT without the KCI foam and did not get equal results. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |
| Thurs, Kathy | Aspirus Hospital Wound Clinic | I would like to comment on the recommendation that all negative therapy devices be placed in one category. I have worked in wound care for over 10 years. I have worked with KCI VAC extensively in that time period. I have also trialed Blue Sky in a comparative trial with the VAC during the last 5 years. I have also used the newer devices on the market because of the nursing home contracts with those companies. In my professional opinion there is no comparison with KCI as far as effectiveness. The other devices do well with suctioning the fluid away from the wound but do little to promote granulation and healing. Most recently the Exsudex from MacMed was proposed for a sternal wound but I could not in good conscious order it regardless of payer source. The cost for these suction devices with gauze is simply not effective.<br><br>I work in a wound clinic and see 15-20 patients a day. The need for the VAC is extensive. Please consider my comments. | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |
| Wells, Jay Lynne | NR | I have used more than one NPWT device. In my opinion, the KCI VAC is the first and the superior product. My reasons are based on proven results on all types of wounds. There are studies for NPWT but everyone seems to not understand that these studies are all based on KCI VAC not their own products. I have various reasons for my trust in KCI VAC:<br><br>It is a safer product…. less chance of contamination of the wound and the home of the patient. The fact that is uses foam not gauze and instruction to keep the system connected to the wound others teach they can leave it off for several hours. Settings of intermittent and continuous | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| | | make the VAC work well and give the physician choices.<br><br>I feel that KCI VAC is in a class by itself and others should not be classified the same because they are not. The truth is in the use and results of this proven therapy. | |
| Willis, Ellen K. | Texas County Memorial Hospital | My name is Ellen K. Willis, MPT, CLT-LANA. I am a staff physical therapist at Texas County Memorial Hospital in Houston, Missouri. Traditionally physical therapists aren't as involved in wound care as I am, but our facility does not have a wound ostomy continence nurse so the physical therapy department provides this niche.<br><br>We have been using the KCI Wound VAC exclusively for the last 5 years. Wound care is one of my specialty areas and I have been very impressed with the KCI VAC, including the research that the company has conducted, their customer service, and ease of ordering the KCI VAC. VAC therapy has been a great addition to my wound care practice and I have personally seen how beneficial it can be for my patients/clients.<br><br>As a facility we have been approached by other companies regarding other vacuum assisted closure devices. In my opinion, these devices are not as advanced for the following reasons. First, the KCI VAC is very user friendly with touch screen controls with many options as far as the amount of negative pressure provided to the wound, the intensity of the therapy, and then a continuous versus intermittent option for the therapy. Many of the other units run off of wall suction and do not have these options to control the therapy that you are providing to the patient's wound.<br><br>Second, the dressings differ greatly between the different companies. I find that KCI's system is very easy to manage, it comes pre-packaged with the appropriate foam and drape to complete an entire dressing change, all you need is scissors. The other systems involve various foams, gauzes, transparent adhesive dressings, and surgical drains | Thank you for providing us with information regarding your experience with NPWT devices. We will share this information with the Center for Medicare Management at CMS. |

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| | | to complete the dressing. Other dressing supply companies provide kits of dressings but I have found that they include unneccesary components and are wasteful. The use of surgical drains (ie. JP drain) for the suction is not as effective due to the fact that it is difficult to monitor the continuous pressure which is a benefit to the KCI VAC which provides continuous monitoring through their T.R.A.C. pad system. The other drains can become clogged and there is no alarm system to alert the clinician. KCI provides a variety of dressing types including dressings with silver for antimicrobial properties and dressings that work well in the abdomen or on the heel.<br><br>Third, the foam that is provided with the KCI VAC differs greatly from the hydrophilic foam that is used with the other negative pressure systems. KCI Granufoam has open cells that allow for the transfer of fluid to the VAC unit. In my experience, the other foam holds the fluid in the wound becoming very moist, which delays wound healing.<br><br>Finally, the KCI VAC system allows for input of pictures and measurement information that can be stored in the devices memory to allow for comparison of volumetric measurements as the wound heals. This allows for more accurate measurements.<br><br>Please consider these comments as a decision is being made concerning Negative Pressure Wound Therapy. There is an astounding difference between the KCI VAC and other systems on the market. As a clinician, I can attest to the improvement in wounds that had been treated with another system at another facility when they were transferred to this facility and then switched to KCI VAC therapy. I plan to continue using the KCI VAC exclusively in my practice when NPWT is selected as the wound healing modality of choice. | |
| Wright, Susan | NR | I am a seasoned wound care nurse. I have used the KCI NPWT for years with very good results. In the last 12 | Thank you for providing us with information regarding your experience with NPWT devices. We |

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| | | months I have observed the use of the Renasys-G on two different patients, both with poor results.<br><br>There is a distinction between the types of NPWT and I believe the proof is in the pudding. This distinction should be reflected in the coding. | will share this information with the Center for Medicare Management at CMS. |

* Reviewers accepted public disclosure

NR: Not reported.

## Summary of Other Comments

A total of 46 individuals did not use the mechanism established by AHRQ to submit their reviews and thus did not sign the disclosure statement. Their comments and our responses are presented in summary form.

Of these 46 reviewers, 35 reported having used more than one NPWT system, seven reported experience only with V.A.C.® Therapy while four made no report. A majority of the anonymous reviewers (n = 44 [96%]) specifically expressed support for V.A.C.® Therapy.

Most reviewers did not express concern with the NPWT report but did report their day-to-day experience with NPWT systems (n = 38 [83%]). Of the reviewers that expressed concern with the report; three reviewers only reported concern that the inclusion criteria were too restrictive. Two reviewers expressed support for the competitive bidding process. One reviewer only expressed concern that the lack of evidence on other NPWT systems did not extrapolate to superiority by V.A.C.® Therapy. One reviewer expressed concern with both the inclusion criteria and lack of superiority reported for V.A.C.® Therapy. Lastly, one reviewer provided attachments for possible inclusion in the report however did not provide comments regarding the report or experience with NPWT. Of the two submissions provided for possible inclusion in the report, one comparison study(54) was subsequently included in the discussion of Key Question 1 of the final report.

For those reviewers that reported anecdotal experience with NPWT systems, we would like to express our thanks for providing us with this important information. We will share this information with the Center for Medicare Management at CMS.

Some reviewers expressed concern that the inclusion/exclusion criteria for the report were too restrictive. Key questions were formulated for the report to test the hypothesis that a NPWT system or its components provided a significant therapeutic distinction compared to other NPWT systems or their components. These questions were structured using the "PICO" framework: patients, intervention of interest, comparator, and outcomes (see Figure 1 of the report). Inclusion and exclusion criteria were methodically developed based on each key question prior to an examination of the evidence. Twelve inclusion criteria were established for this technology assessment (TA). In a TA, the inclusion criteria determine whether a study is "relevant" to the key questions. Studies that do not meet the inclusion criteria are excluded from the TA. Exclusion from the TA does not imply that the studies have no scientific merit, just that their findings are not applicable to answering a key question within the specific report. Next, we undertook an extensive search of the literature from which we identified over 1,000 potential articles. In the interest of identifying all clinically relevant materials for this report, we also invited interested stakeholders to submit information regarding any published, unpublished, or currently registered studies for possible inclusion in the report. We received over 1,400 submissions by the February 6, 2009 deadline. Each submission was reviewed for possible inclusion in the report (see Appendix D).

The screening of all identified materials is a two-step process. An initial evaluation is done at the abstract level at which items may be excluded, used in our *Background* section or passed to the next level of evaluation. During the evaluation of all stakeholder submissions, we excluded 638 (44%) of the 1,435 submissions due to duplication alone (see Figure 5 in Appendix D). Of the 797 (55% of original) unique submissions; 29 (4%) were included in our *Background* section and 269 (33%) items were excluded; 147 (56%) were case reports, abstracts or poster presentations given at conferences.

Of the 499 (35%) remaining articles, 354 (71%) were excluded at the article level. Based on the a priori inclusion/exclusion criteria, narrative reviews (k = 152 [43%]); animal studies (k = 39 [11%]); and studies with fewer than five patients in each arm (k = 30 [8%]) were excluded.

Of the 144 (10%) original submissions that met inclusion criteria, 117 (81%) were previously identified by the ECRI Institute literature searches. We subsequently included 28 studies not previously identified in our searches in the final report. Please see Appendix D for additional details on individual submissions and subsequent disposition in the report.

The draft report has been thoroughly reviewed by four outside specialists in wound care. They have concurred that the report provides a thorough evaluation of the current evidence for NPWT systems.

Lastly, reviewers were concerned that the lack of evidence from other NPWT systems should demonstrate the superiority of V.A.C.® Therapy. It is important to note that due to the lack of published or unpublished studies that evaluated other NPWT systems we were unable to perform either direct or indirect comparisons. In the absence of such comparisons, ECRI Institute was unable to draw conclusions about the superiority or equivalence of any NPWT system or its components compared to another NPWT system or its components.

# References


1. Gregor S, Maegele M, Sauerland S, Krahn JF, Peinemann F, Lange S. Negative pressure wound therapy: a vacuum of evidence? Arch Surg 2008 Feb;143(2):189-96. PMID:18283145

2. Vikatmaa P, Juutilainen V, Kuukasjarvi P, Malmivaara A. Negative Pressure Wound Therapy: a Systematic Review on Effectiveness and Safety. Eur J Vasc Endovasc Surg 2008 Oct;36(4):438-48. PMID:18675559

3. Ubbink DT, Westerbos SJ, Evans D, Land L, Vermeulen H. Topical negative pressure for treating chronic wounds (Review). In: Cochrane Database of Systematic Reviews [internet]. Issue 3. Hoboken (NJ): John Wiley & Sons, Ltd.; 2008 [Art. No.: CD001898]. PMID:18646080

4. Morykwas MJ, Argenta LC, Shelton-Brown EI, McGuirt W. Vacuum-assisted closure: a new method for wound control and treatment: animal studies and basic foundation. Ann Plast Surg 1997 Jun;38(6):553-62. PMID:9188970

5. Krasner DL. Managing wound pain in patients with vacuum-assisted closure devices. Ostomy Wound Manage 2002 May;48(5):38-43. PMID:12046489

6. Long MA, Blevins A. Options in negative pressure wound therapy: five case studies. J Wound Ostomy Continence Nurs 2009 Mar-Apr;36(2):202-11. PMID:19287271

7. Willy C, editor. The theory and practice of vacuum therapy. Scientific basis, indications for use, case reports, practical advice. Ulm,Germany: Lindqvist book publishing; 2006. 405 p.

8. TriCenturion. Negative pressure wound therapy (NPWT) widespread probe results. Jurisdiction A - final report. Columbia (SC): TriCenturion; 2007 Feb. 2 p.

9. Hackam DG, Redelmeier DA. Translation of research evidence from animals to humans. JAMA 2006 Oct 11;296(14):1731-2. PMID:17032985

10. Hackam DG. Translating animal research into clinical benefit. BMJ 2007 Jan 27;334(7586):163-4. PMID:17255568

11. Perel P, Roberts I, Sena E, Wheble P, Briscoe C, Sandercock P, Macleod M, Mignini LE, Jayaram P, Khan KS. Comparison of treatment effects between animal experiments and clinical trials: systematic review. BMJ 2007 Jan 27;334(7586):197-200. PMID:17175568

12. Agency for Healthcare Research and Quality (AHRQ). Methods reference guide for effectiveness and comparative effectiveness reviews, Version 1.0. [Draft posted Oct. 2007]. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 128 p. Also available: http://effectivehealthcare.ahrq.gov/repFiles/2007_10DraftMethodsGuide.pdf.

13. Fife CE, Otto G, Walker D, Thomson B, Carter MJ. A retrospective longitudinal study of the adverse events associated with the use of the VAC in a large wound-care population [unpublished]. 28 p.

14. Center for Biologics Evaluation and Research (CBER). Guidance for industry: chronic cutaneous ulcer and burn wounds — developing products for treatment. Rockville (MD): U.S. Food and Drug Administration, Center for Drug Evaluation and Research; 2006 Jun. 22 p. Also available: http://www.fda.gov/cder/guidance/index.htm#clinical%20medicine.

15. Sackett DL, Rosenberg WM, Gray JA, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't [editorial]. BMJ 1996 Jan 13;312(7023):71-2. PMID:8555924

16. Morris S. Additional V1 failures/VAC rescues. 2006. 2 p.

17. Wild T, Stremitzer S, Budzanowski A, Hoelzenbein T, Ludwig C, Ohrenberger G. Definition of efficiency in vacuum therapy--a randomised controlled trial comparing with V.A.C. Therapy. Int Wound J 2008 Dec;5(5):641-7. PMID:19134065

18. Jones SM, Banwell PE, Shakespeare PG. Interface dressings influence the delivery of topical negative-pressure therapy. Plast Reconstr Surg 2005 Sep 15;116(4):1023-8. PMID:16163089

19. Argenta A, Webb K, Simpson J, Gordon S, Kortesis B, Wanner M, Kremers L, Morykwas M. Deformation of superficial and deep abdominal tissues with application of a controlled vacuum. In: European Tissue Repair Society, Focus group meeting Topical Negative Pressure (TNP) Therapy; 4–6 December 2003; London.

20. Derrick KL, Norbury K, Kieswetter K, Skaf J, McNulty AK. Comparative analysis of global gene expression profiles between diabetic rat wounds treated with vacuum-assisted closure therapy, moist wound healing or gauze under suction. Int Wound J 2008 Dec;5(5):615-24. PMID:19134062

21. McNulty AK, Schmidt M, Feeley T, Kieswetter K. Effects of negative pressure wound therapy on fibroblast viability, chemotactic signaling, and proliferation in a provisional wound (fibrin) matrix. Wound Repair Regen 2007 Nov-Dec;15(6):838-46. PMID:18028132

22. McNulty AK, Schmidt M, Feeley T, Villanueva P, Kieswetter K. Effects of negative pressure wound therapy on cellular energetics in fibroblasts grown in a provisional wound (fibrin) matrix. Wound Repair Regen 2009 Mar-Apr;17(2):192-9.

23. Timmers MS, Le Cessie S, Banwell P, Jukema GN. The effects of varying degrees of pressure delivered by negative-pressure wound therapy on skin perfusion. Ann Plast Surg 2005 Dec;55(6):665-71. PMID:16327472

24. Wilkes R, Zhao Y, Kieswetter K, Haridas B. Effects of Dressing Type on 3D Tissue Microdeformations During Negative Pressure Wound Therapy: A Computational Study. J Biomech Eng 2009 Mar;131(3):031012. PMID:19154071

25. Andrews BT, Smith RB, Chang KE, Scharpf J, Goldstein DP, Funk GF. Management of the radial forearm free flap donor site with the vacuum-assisted closure (VAC) system. Laryngoscope 2006 Oct;116(10):1918-22. PMID:17003705

26. Armstrong DG, Lavery LA, Boulton AJ. Negative pressure wound therapy via vacuum-assisted closure following partial foot amputation: what is the role of wound chronicity? Int Wound J 2007 Mar;4(1):79-86. PMID:17425550

27. Armstrong DG, Lavery LA, Diabetic Foot Study Consortium. Negative pressure wound therapy after partial diabetic foot amputation: a multicentre, randomised controlled trial. Lancet 2005 Nov 12;366(9498):1704-10. PMID:16291063

28. Armstrong DG, Kunze K, Martin BR, Kimbriel HR, Nixon BP, Boulton AJ. Plantar pressure changes using a novel negative pressure wound therapy technique. J Am Podiatr Med Assoc 2004 Sep-Oct;94(5):456-60. PMID:15377721

29. Baharestani MM, Houliston-Otto DB, Barnes S. Early versus late initiation of negative pressure wound therapy: examining the impact on home care length of stay. Ostomy Wound Manage 2008 Nov;54(11):48-53. PMID:19037137

30. Blume PA, Walters J, Payne W, Ayala J, Lantis J. Comparison of negative pressure wound therapy using vacuum-assisted closure with advanced moist wound therapy in the treatment of diabetic foot ulcers: a multicenter randomized controlled trial. Diabetes Care 2008 Apr;31(4):631-6. PMID:18162494

31. Gabriel A, Heinrich C, Shores JT, Baqui WK, Rogers FR, Gupta S. Reducing bacterial bioburden in infected wounds with vacuum assisted closure and a new silver dressing - a pilot study. Wounds 2006 Sep;18(9):245-55.

32. Gabriel A, Heinrich C, Shores J, Cho D, Baqai W, Moores D, Miles D, Gupta S. Outcomes of vacuum-assisted closure for the treatment of wounds in a paediatric population: case series of 58 patients. J Plast Reconstr Aesthet Surg 2008 Oct 2;Epub ahead of print. PMID:18835547

33. Moisidis E, Heath T, Boorer C, Ho K, Deva AK. A prospective, blinded, randomized, controlled clinical trial of topical negative pressure use in skin grafting. Plast Reconstr Surg 2004 Sep 15;114(4):917-22. PMID:15468399

34. Moues CM, Vos MC, van den Bemd GJ, Stijnen T, Hovius SE. Bacterial load in relation to vacuum-assisted closure wound therapy: a prospective randomized trial. Wound Repair Regen 2004 Jan-Feb;12(1):11-7. PMID:14974959

35. Moues CM, van den Bemd GJ, Heule F, Hovius SE. Comparing conventional gauze therapy to vacuum-assisted closure wound therapy: a prospective randomised trial. J Plast Reconstr Aesthet Surg 2007;60(6):672-81. PMID:17485058

36. Philbeck TE Jr, Whittington KT, Millsap MH, Briones RB, Wight DG, Schroeder WJ. The clinical and cost effectiveness of externally applied negative pressure wound therapy in the treatment of wounds in home healthcare Medicare patients. Ostomy Wound Manage 1999 Nov;45(11):41-50. PMID:10687657

37. Apelqvist J, Armstrong DG, Lavery LA, Boulton AJ. Resource utilization and economic costs of care based on a randomized trial of vacuum-assisted closure therapy in the treatment of diabetic foot wounds. Am J Surg 2008 Jun;195(6):782-8. PMID:18355797

38. Baharestani MM. Negative pressure wound therapy: an examination of cost-effectiveness. Ostomy Wound Manage 2004 Nov;50(11A Suppl):29S-33S. PMID:15632465

39. Scherer LA, Shiver S, Chang M, Meredith JW, Owings JT, Tominaga GT, Schecter WP, Parks SN, Peck J, Mayberry J. The vacuum assisted closure device: a method of securing skin grafts and improving graft survival. Arch Surg 2002;137(8):930-4. PMID:12146992

40. Braakenburg A, Obdeijn MC, Feitz R, van Rooij IA, van Griethuysen AJ, Klinkenbijl JH. The clinical efficacy and cost effectiveness of the vacuum-assisted closure technique in the management of acute and chronic wounds: a randomized controlled trial. Plast Reconstr Surg 2006 Aug;118(2):390-7; discussion 398-400. PMID:16874208

41. Schwien T, Gilbert J, Lang C. Pressure ulcer prevalence and the role of negative pressure wound therapy in home health quality outcomes. Ostomy Wound Manag 2005;51:47-60. PMID:16230764

42. Page JC, Newswander B, Schwenke DC, Hansen M, Ferguson J. Retrospective analysis of negative pressure wound therapy in open foot wounds with significant soft tissue defects. Adv Skin Wound Care 2004 Sep;17(7):354-64. PMID:15343085

43. Lavery LA, Boulton AJ, Niezgoda JA, Sheehan P. A comparison of diabetic foot ulcer outcomes using negative pressure wound therapy versus historical standard of care. Int Wound J 2007 Jun;4(2):103-13. PMID:17651226

44. Flack S, Apelqvist J, Keith M, Trueman P, Williams D. An economic evaluation of VAC therapy compared with wound dressings in the treatment of diabetic foot ulcers. J Wound Care 2008 Feb;17(2):71-8. PMID:18389832

45. Gabriel A, Shores J, Heinrich C, Baqai W, Kalina S, Sogioka N, Gupta S. Negative pressure wound therapy with instillation: A pilot study describing a new method for treating infected wounds. Int Wound J 2008 Jun;5(3):399-413. PMID:18593390

46. Kaplan M. Negative pressure wound therapy in the management of abdominal compartment syndrome. Ostomy Wound Manage 2004 Nov;50(11A Suppl):20S-5S.

47. Vuerstaek JD, Vainas T, Wuite J, Nelemans P, Neumann MH, Veraart JC. State-of-the-art treatment of chronic leg ulcers: A randomized controlled trial comparing vacuum-assisted closure (V.A.C.) with modern wound dressings. J Vasc Surg 2006 Nov;44(5):1029-37; discussion 1038. PMID:17000077

48. Niezgoda JA. The economic value of negative pressure wound therapy. Ostomy Wound Manage 2005 Feb;51(2A Suppl):44-7. PMID:15699565

49. Siegel HJ, Long JL, Watson KM, Fiveash JB. Vacuum-assisted closure for radiation-associated wound complications. J Surg Oncol 2007 Dec 1;96(7):575-82. PMID:17999398

50. Moues CM, van den Bemd GJ, Meerding WJ, Hovius SE. An economic evaluation of the use of TNP on full-thickness wounds. J Wound Care 2005 May;14(5):224-7. PMID:15909439

51. Song DH, Wu LC, Lohman RF, Gottlieb LJ, Franczyk M. Vacuum assisted closure for the treatment of sternal wounds: the bridge between debridement and definitive closure. Plast Reconstr Surg 2003 Jan;111(1):92-7. PMID:12496568

52. Frykberg RG, Williams DV. Negative-pressure wound therapy and diabetic foot amputations: a retrospective study of payer claims data. J Am Podiatr Med Assoc 2007 Sep-Oct;97(5):351-9. PMID:17901338

53. Carter MJ, Warriner RA 3rd. Evidence-based medicine in wound care: time for a new paradigm. Adv Skin Wound Care 2009 Jan;22(1):12-6. PMID:19096278

54. Timmers MS, Graafland N, Bernards AT, Nelissen RGHH, Van Dissel JT, Jukema GN. Negative pressure wound treatment with polyvinyl alcohol foam and polyhexanide antiseptic solution instillation in posttraumatic osteomyelitis. Wound Repair Regen 2009 Mar-Apr;17(2):278-86.