Special Study Summary

Survey Topic: Negative Pressure Wound Therapy (NPWT)

Year Conducted: 2009-2010

Reference OMB No. 0910-0500

Background

The effort was to learn about device issues faced by professional home care providers, as well as those issues potentially encountered by lay caregivers who use NPWT in the home setting or in other non-hospital environments. While the FDA has received reports of problems with the use of NPWT, feedback from providers can help to promote a better understanding of why these adverse events occur and also inform FDA if other types of events have occurred.

Participants were recruited from the Medical Product Safety Network (MedSun) facilities and from professional organizations that represent home care providers or advocate on behalf of wound care patients. Instruments included: a Web survey questionnaire; a semi-structured questionnaire for telephone interviews; and a self-administration questionnaire (SAQ). Three-hundred and forty two respondents completed the Web survey questionnaire, which ran for two months. Fifteen one-hour telephone interviews were conducted with seventeen participants using the semi-structured questionnaire; five participants completed the SAQ. Questions were based on the following topics: Device Performance and Experience, Prescription and Discharge Planning, Training and Labeling, Issues Associated with Dressings, Patient Outcome.

Summary

The most common NPWT systems used by respondents include the KCI Wound V.A.C. product line, mainly the ActiV.A.C. and V.A.C. Freedom[1]. Other commonly used systems were the Smith and Nephew (formerly Blue Sky) models.

A model mentioned often by the phone/SAQ respondents was the ConvaTec Engenex. Phone/SAQ respondents were more likely to indicate complications, notably bleeding, infection, pain, retained foam and tissue adherence, whereas Web respondents primarily cited infection and bleeding issues. According to phone/SAQ respondents, prescription (patient selection, wound type, length of use), discharge planning and training tend to vary as a function of the facility type (hospital, outpatient clinic, Home Health Agency [HHA]) procedures[2]. These respondents felt that issues arise when there is a poor transition from the hospital to home and when the devices are not initially ordered, prescribed, set up or applied by a certified wound specialist or an experienced professional. Other problems were attributed to the prescriber's lack of specific education about wound management therapy.

Respondents indicated that lay caregivers and patients are largely trained on the meaning of alarms, how to troubleshoot, how to change drainage canisters, how to identify an emergency and what to do in an emergency situation. Respondents were generally happy with the lay-caregiver/patient educational materials, training and support provided by the manufacturer. Although most Web respondents thought all or some of these device labels and instructions were written for a lay audience, nearly two-thirds indicated they observed challenges with caregivers' and patients' ability to follow device instructions. Of those who observed challenges, the majority attributed them to patients' or caregivers' distractibility, whether because of their illness, altered consciousness, or other medical situation. A few phone/SAQ respondents suggested condensing the materials for the patient or be written at a 5^{th} or 6^{th} grade reading level. Some had even written their own instructions to make them more understandable to the patient.

Respondents stated patients or lay caregivers should not be administering the therapy because they aren't trained to understand the complexities and intricacies of wound care, and also because clinical professionals are needed to monitor and assess the wound in addition to changing the dressing.

Dressings were changed often, 2-3x per week, as indicated in the instructions. However, phone respondents stated that problems can arise when the dressing is changed too often, or not frequently enough.

Overall, respondents felt that there is a definite benefit to NPWT therapy, regardless of the care setting and that it is a safe therapy when prescribed and administered appropriately. Safety and effectiveness in neonatal and pediatric patients has not been determined at this time, necessitating future study – a recommendation provided by phone respondents. Users generally are happy with the systems they use and the company support they and their patients receive.

Respondents said there should be more prescriber education about when therapy can and should be used and, equally important, when it should be stopped. Some expressed the opinion that NPWT is overprescribed mainly because of aggressive marketing tactics. Phone/SAQ respondents, especially directors of wound care centers, said that home care providers need to be more experienced when it comes to administering wound care and changing dressings. Opportunities to gain more experience and expertise should be afforded to those who provide care. They also felt there needs to be more consistent patient and wound monitoring, especially in the home setting.

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Special Studies and Surveys are two of many tools the Agency is using to evaluate the public health impact of the potential problems associated with the use of medical devices. Additionally, FDA continues to receive adverse event reports from its Medical Device Reporting program. FDA will also continue to make use of the literature and other published information. FDA scientific, medical, nursing and engineering staff are made aware of the survey results as needed. If FDA believes there is a significant risk of adverse events as noted from the survey, it will combine those results with data gained from the other sources. FDA will work with the manufacturers and health care professional organizations to make important information known to the clinical community. Additionally, FDA continues to work with manufacturers to ensure the development, testing and promulgation of methods for reducing the risk associated with these devices and to minimize the complications from adverse events that may occur in the course of normal usage. If the results of any survey raise serious concerns about the safety of these devices, FDA may convene an Ad Hoc group of clinical and manufacturing representatives to discuss further actions.

[1]Note: of all the respondents surveyed, KCI was the most common system used and is why majority of the findings refer to this particular manufacturer's product line.

[2] Web respondents were not asked about discharge planning because respondents are primarily home care providers, who provide patient care regardless of how the therapy migrates into the home.
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