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Medical Device–Related Hospital-Acquired Pressure Ulcers

Development of an Evidence-Based Position Statement

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■ ABSTRACT

Hospital-acquired pressure ulcers (HAPUs) are a problem in the acute care setting causing pain, loss of function, infection, extended hospital stay, and increased costs. In spite of best practice strategies, occurrences of pressure ulcers continue. Many of these HAPUs are related to a medical device. Correct assessment and reporting of device-related HAPUs were identified as an important issue in our organization. Following the Iowa Model for Evidence-Based Practice to Promote Quality Care, a task force was created, a thorough review of current evidence and clinical practice recommendations was performed, and a definition for medical device-related HAPU and an evidence-based position statement were developed. Content of the statement was reviewed by experts and appropriate revisions were made. This position statement provides guidance and structure to accurately identify and report device-related HAPU across our 18 healthcare facilities. Through the intentional focus on pressure ulcer prevention and evidence-based practice in our organization and the use of this position statement, identification and reporting of device-related HAPUs have improved with a decrease in overall HAPU rates of 33% from 2011 and 2012. This article describes the development and implementation of this device-related HAPU position statement within our organization.

KEY WORDS: Evidence-based, Iowa Model, Medical device-related pressure ulcers, Position statement

Patient safety and prevention of harm are foundational principles of healthcare, and nursing in particular, yet patients continue to develop pressure ulcers while under our care. Hospital-acquired pressure ulcers (HAPUs) cause pain, loss of function, and infection, extend hospital stays, and increase costs. The cost of treating these wounds is approximately $11 billion a year. In spite of progress in wound care products, support surfaces, and prevention methods, occurrences of pressure ulcers persist.[1] Medical device-related HAPUs are common in both adults and children in the acute care setting.

A pressure ulcer can occur wherever external pressure impairs circulation to the skin. Pressure ulcers have been defined by the National Pressure Ulcer Advisory Panel (NPUAP) as "a localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear."[2(p6)] This definition is helpful but many pressure ulcers occur as a result of external pressure from medical devices that do not completely fit this definition. The NPUAP addressed device-related HAPUs, which develop on mucosal membranes by issuing a statement describing the inappropriate use of staging/category classification due to anatomical differences between mucosal membrane with skin structures. The National Database of Nursing Quality Indicators recommends using the term "indeterminate" when classifying HAPUs over mucosal membranes when reporting HAPU.[3,4] However, neither of these recommendations provides a clear and concise definition for all device-related HAPUs.

Hospital-acquired pressure ulcer development is considered a quality indicator across healthcare systems.[5] Healthcare facilities are required to track and report HAPU rates. In our large academic healthcare system, prevention and accurate identification and classification of HAPUs are a high priority. Monthly skin audits within our facility found that a high percentage, often more than 50%, of HAPUs are device related. In addition, the identification,

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definition, and reporting of these types of HAPU are inconsistent with high variation across this organization's acute care facilities. Therefore, a task force was created and given the directive to explore this issue. The purpose of this article is to describe the process this task force used to address this important issue.

■ Development of the Project

When examining a practice issue or problem, it is helpful to use a model that provides a guide to identify areas of clinical inquiry through synthesis and application of research findings.[6] One such model is the Iowa Model of Evidence-based Practice to Promote Quality Care (Figure 1). It provides guidance for nurses to use research findings for improvement of patient care. Using this model, we first created a task force that included members of our Pressure Ulcer Prevention systemwide committee. Task force members represented 4 of our adult acute care facilities and our childrens' hospital. Four of the task force members were certified WOC nurses, 3 were also masters prepared and/or a clinical nurse specialist, and 1 member was doctorally prepared. Using the Iowa Model of Evidence-based Practice to Promote Quality Care, the task force identified medical device-related pressure ulcers as a problem-focused trigger, a clinical problem, and a priority of the healthcare organization. This was an important first step because a topic that is aligned with the strategic goals of the organization and embraced by staff has a high likelihood of being adopted by those providing care.[6] In addition, connecting the knowledge gained from research to an organizational initiative that has relevance to both the organization and the WOC nurse creates an opportunity and environment for support that might not be available if the topic were chosen to fulfill local interests alone.[7]

Developing a well-formulated purpose statement is beneficial once the topic or problem is identified. The purpose statement directs the evidence search, helps focus reading, and defines the boundaries and limits around the work to be accomplished. Finally, we advocate formulating a clear and concise purpose statement to assist with developing an appropriate implementation and evaluation plan. The task force was charged with developing a standardized, evidence-based definition for device-related HAPU, which would support appropriate identification and reporting of these pressure ulcers.

The next step in the Iowa Model is to appraise the evidence related to the question or purpose statement. In order to find the most current new knowledge related to device-related pressure ulcers, a search was conducted of the current relevant literature. We searched the MEDLINE electronic database. Key search strategies were: (1) time frame: 1996 to September 2012; (2) exp *"Equipment and Supplies"/ (312834); (3) exp *Pressure Ulcer/ep, et [Epidemiology, Etiology] (851); (4) 1 and 2 (84); (5) limit 3 to (English language and humans) (78); and (6) from 4 keep 2–4, 6, 13, 16–17, 20, 23–24, 26–31, 35–39, 53–54, 64, 69–71, 76–78 (30). This search identified 30 references, which were reviewed by our team.

The task force identified the definition of medical devices by the Food Drug & Cosmetic Act as integral to developing a definition of device-related HAPUs. The US Food and Drug Administration defines a medical device as "…an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."[8(p1)]

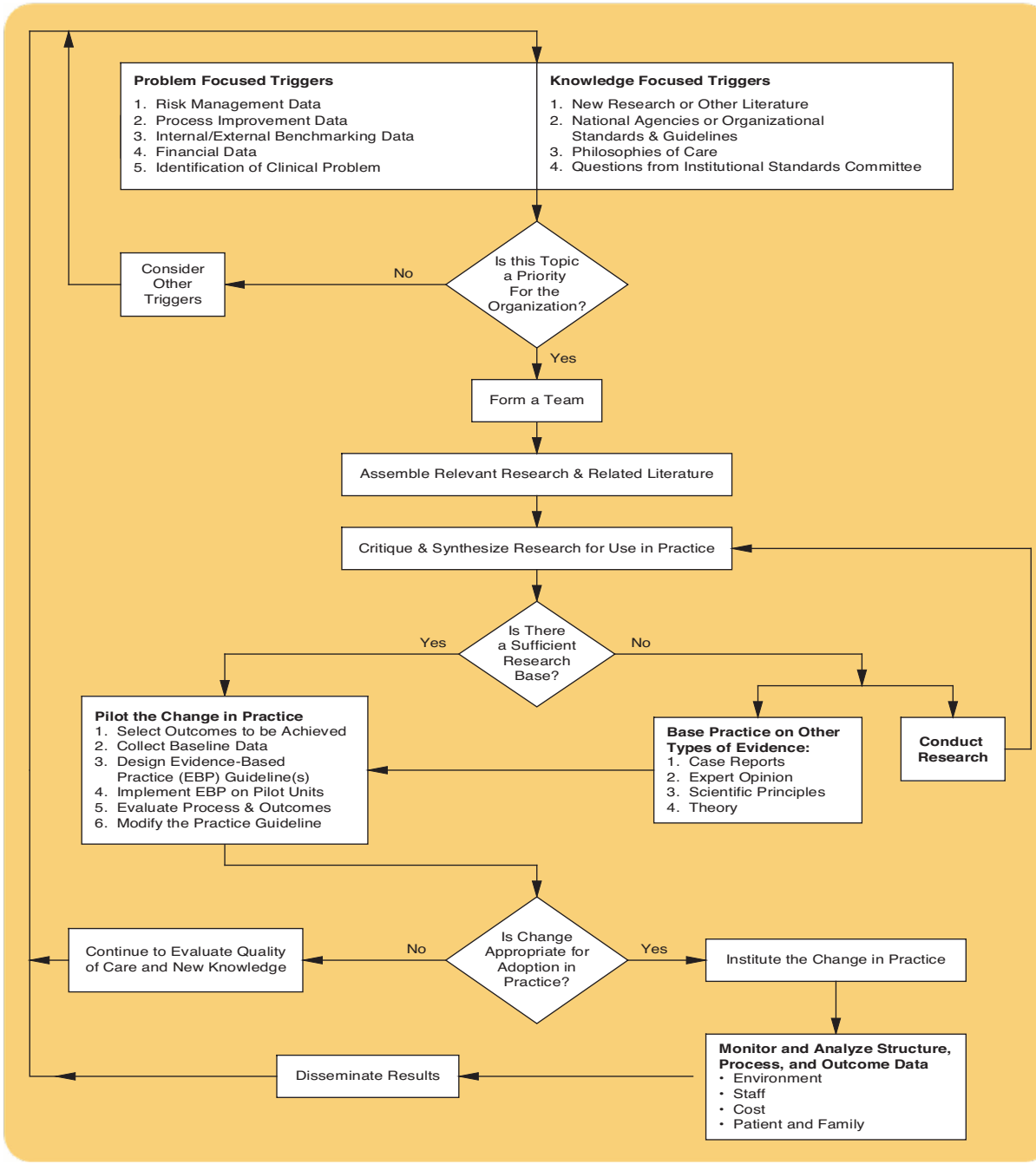
Another important piece of evidence was that of the NPUAP and its work surrounding pressure ulcers. The NPUAP hosted a consensus conference in 2010 and again in 2014 to discuss the complexities of avoidable versus unavoidable HAPUs. As a result of this work, NPUAP has led efforts of the wound and pressure ulcer expert community in identifying key components related to pressure ulcer development and the complexities surrounding these wounds. This work is in its initial stages, but a state of the science article was published recently describing unavoidable pressure ulcer incidence and the key risk factors that influence them.[9] One of these key risk factors identified is that of medical devices. Medical device-related pressure ulcers are difficult to prevent as they are necessary for treatment. They are also challenging to assess due to the inability to remove them in certain instances, and they may produce compromise of underlying tissue due to moisture or edema.

Many states are recognizing the importance of HAPUs and are requiring the reporting of prevalence of HAPUs as a quality measure. Minnesota used data collected through mandatory statewide adverse health events reporting system to identify trends in causative factors for device-related pressure ulcers. An interdisciplinary team convened to develop best practices for prevention of pressure ulcers related to the use of medical devices.[10] Although the findings from this report are helpful, no definitive definition for device-related HAPUs was described.

■ Implementation of the Project

Using the US Food and Drug Administration definition for medical devices, evidence-based guidelines, and position statements from various organizations, and results of an expert review, the task force defined device-related skin injury to those devices that were medical and external. The task force identified 2 critical elements to be included in the

The Iowa Model of Evidence-Based Practice to Promote Quality Care



◇ = a decision point

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FIGURE 1. The Iowa Model of Evidence-Based Practice to Promote Quality Care. Reprinted with permission from the University of Iowa Hospitals and Clinics and Marita G. Titler, PhD, RN, FAAN, Copyright 1998. For permission to use or reproduce the model, please contact the University of Iowa Hospitals and Clinics at 319-384-9098 or uihcnursingresearchandebp@uiowa.edu

definition of device-related HAPUs: (1) NPUAP definition of pressure ulcers provides the basis of the definition and (2) device-related HAPUs will be limited to external medical devices. After a thorough review of the evidence and using clinical practice expertise, an evidence-based device-related HAPU definition for adults and pediatrics was developed. A device-related HAPU is defined as a localized injury to the skin and/or underlying tissue including mucous membranes, as a result of pressure, with a history of an external medical device at the location of the ulcer, and mirrors the shape of the device. This definition provides needed guidance, structure, and process to assist with prevention, identification, reporting, and treatment of medical device-related HAPU.

The task force used this evidence-based definition to develop the Medical Device-Related Pressure Ulcer Position Statement. Following the format example of the Wound, Ostomy and Continence Nursing Society and other organizations, a position statement was developed. In order to improve the content validity of the position statement, experts in wound management and pressure ulcers were asked to review the content. Based on their recommendations, appropriate revisions were incorporated into the document.

The next step in the Iowa Model is to move the evidence into practice. Effective dissemination of evidence includes mindful communication among opinion leaders, change champions, core groups of influence, and academic detailing. Opinion leaders were defined as those colleagues who are viewed as important and respected sources of influence among their peers. Change champions embrace and demonstrate the persistence necessary to promote the adoption of evidence.

The task force disseminated the position statement by informing various systemwide leadership groups involved in patient quality/safety, systemwide pressure ulcer prevention committee, facility-specific WOC nurse experts, and facility-specific direct-care nurse wound teams. Dissemination continues as the use of the Medical Device-Related Pressure Ulcer Position Statement is integrated into the process of conducting our monthly facility-wide pressure ulcer prevalence surveys.

Conclusion

A pressure ulcer may occur wherever external pressure impairs circulation to the skin. Pressure ulcers cause pain, loss of function, and infection, extend hospital stays, and increase cost. In addition, pressure ulcer development is considered a quality indicator across healthcare systems.[5] Increased scrutiny and reduced payment or nonpayment for HAPU by the Centers for Medicare & Medicaid Services has made the prevention and early detection of pressure ulcers a prominent quality improvement initiative of healthcare systems across the country. A key component in prevention and detection of pressure-related injury is an accurate skin assessment. In order to perform an accurate skin assessment, an evidence-based definition for device-related pressure ulcers is crucial. Our Device-Related Pressure Ulcer Position Statement guides practice, education, and research within this healthcare organization. This definition is used when identifying, reporting, treating, and developing prevention strategies for device-related HAPU. It has proven useful for distinguishing between pressure ulcers resulting from an external medical device versus nonmedical device. Through the intentional focus on pressure ulcer prevention and evidence-based practice in our organization and the use of this position statement, identification and reporting of medical device-related HAPUs have improved with a decrease in overall HAPU rates of 33% from 2011 and 2012. This concise and evidence-based position statement supports appropriate and consistent identification and reporting of medical device–related pressure ulcers. Staging of these ulcers continues to follow the staging recommendations of NPUAP and National Database for Nursing Quality Indicators reporting instructions.

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