Never Events: Can The Congressional Mandate Be Met?

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Introduction

Pressure ulcers are serious health concerns, increasing mortality and morbidity, reducing quality of life, increasing the length of hospital stay, and the overall cost of care.4 The number of pressure ulcers reported has increased from 280,000 hospitalized patients in 1995 to 458,000 patients in 2004. CMS in 2007 calculated an average charge per stay of $43,180 for a patient with a Stage III or Stage IV pressure ulcer and stated that a total of 2,571,412 Stage III and IV ulcers require a payout of more than $14 billion.

Heel ulcers have become the second most frequently occurring type of pressure ulcer in the US7 with an incidence of up to 30% of all pressure ulcer patients.8 The numbers may even be underreported because of the nature of these ulcers, for example, in patients who are hospitalized for a short period the ulcer may only become apparent after the patient has been discharged. Extrapolating from CMS data, approximately $2,138 billion can be associated with hospital-acquired heel ulcers in the year 2007. Since pressure ulcers can largely be prevented by proper care, CMS declared many of them "Never Events."9

Off loading is crucial for the prevention of pressure ulcer development. In practice, for most body parts, this involves regularly turning the patient, in combination with specific pressure relieving materials (i.e., mattress), good skin care,10 proper nutrition, and a number of other measures.

Heel ulcer protocols and clinical outcomes:

Prevention of heel ulcers is based on the same principles as those utilized for other anatomical locations. However, in practice, off loading the heel is difficult. Several organizations have published guidelines for the prevention of heel pressure ulcers. In 1992 The Agency for Healthcare Research and Quality (AHRQ) and The Institute for Healthcare Improvement (IHI) recommended off loading the heel with pillows and cushions.11,12 More recently, the National GSI and European Pressure Ulcer Advisory Panel published their recommendations for the use of pillows specifically under the calves, to "clear" the heel.13

However, many claim that this is padding, rather than off loading. Figure 4 shows that true off loading can only be performed with specially designed devices.14 These heel protection devices assure that the heels are free of the surface of the bed and elevated while distributing the weight of the leg along the calf. The devices avoid putting pressure on the Achilles tendon, keep the foot in an anatomically correct position, and prevent damage to the neurovascular bundle. Indeed, the implementation of these devices dramatically helped reduce the incidence of pressure ulcers15-17 in orthopedic patients: from 13.8% to 9%,22 long-term care patients: reduction with 57%.19

In line with these published results, the optimal heel protector device needs to:

- elevate the heel off the underlying support surface
- prevent foot-drop and rotation of the leg
- maintain "rip" on the foot while in place as patient may be moving the leg
- decrease friction and/or shear, "ideally" allowing for the patient to be ambulated
- be easy to clean
- decrease heat to the heels
- be cost effective20,21

Because of the high risk of heel ulcer development, recently a new algorithm was introduced22 (Figure 1b) based on the expected period of immobility and the overall condition of the patient, the algorithm advises the use of pillows or dedicated, heel protecting off loading devices.

Economical aspects:

In October 2008, CMS stopped reimbursing healthcare providers for eleven so-called “never events” (reasonably preventable errors in healthcare) and hospital-acquired Stage III and IV pressure ulcers are among those events. According to federal law, hospital providers must provide pressure ulcer prevention and care for a patient. The hospital is no longer permitted to bill the government, or the patient, for such care unless the pressure ulcer was documented as “Present on Admission”5. Many state agencies and private insurers have followed CMS lead, hospitals can no longer charge for the treatment associated with hospital-acquired Stage III or IV pressure ulcers. These rulings offer an additional incentive for providing proper preventive care: an at-risk population the use of proper prevention devices was demonstrated to save $89,000 per 100 patients.23

While specific prevention devices are more expensive than pillows, these devices are economically effective, as illustrated by a simple economical model (Figure III). The model looks at a theoretical cohort of 100 patients, with 29% of patients developing a heel ulcer without the use of heel protectors. The use of heel protectors is assumed to reduce the incidence by 50%. The average (Internet) price for the reusable heel protectors is set at $100. Literature does not give an indication for the price of traditional heel pressure ulcers per se, however, $1,000 seems to be a reasonable estimate.20 All prices and numbers are on the very safe side of general information provided in the literature. The model illustrates a potential savings of $35,000 (46.7%), without even taking into account loss revenue to the patient (because of temporary immobility), cost to the hospital of litigation (the average compensation for pressure ulcer cases is almost $1 million24,25), or the impact on quality of life.

Conclusion:

Heel ulcers are among the most common type of pressure ulcers and are preventable with proper care; indeed, they should be prevented as mandated by legislation. For at-risk patients, proper care of the heel should include specialized devices as opposed to "foot pillows." The devices are designed to off load the heel, grip the limb to maintain heel floatation, and prevent contact with an underlying surface, while protecting the Achilles tendon and the neurovascular bundle. Research has shown that the use of heel protector devices is highly effective, while cost of care is significantly reduced. Thus, the Congressional Mandate on reducing the incidence and prevalence of heel pressure ulcers can largely be met, provided that proper methods and materials are routinely utilized.

This poster was supported by Sage Products, Inc.