# clinical Management Extra

# Secondary Analysis of Office of Inspector General's Pressure Ulcer Data: Incidence, Avoidability, and Level of Harm





2.5 Contact Hours

Jeffrey M. Levine, MD, AGSF, CWSP • Attending Physician • Mount Sinai Beth Israel Medical Center and Icahn School of Medicine at Mount Sinai • New York, New York

Karen M. Zulkowski, DNS, RN • Associate Professor • Montana State University • Bozeman, Montana

All authors, staff, faculty, and planners, including spouses/partners (if any), in any position to control the content of this CME activity have disclosed that they have no financial relationships with, or financial interests in, any commercial companies pertaining to this educational activity.

To earn CME credit, you must read the CME article and complete the quiz and evaluation on the enclosed answer form, answering at least 13 of the 18 questions correctly.

This continuing educational activity will expire for physicians on September 30, 2016.

If you need CME or CE STAT, take the test online at http://cme.lww.com for physicians and www.nursingcenter.com for nurses. Complete CME/CE information is on the last page of this article.

#### **PURPOSE:**

To provide information about a secondary analysis of pressure ulcer data regarding incidence, avoidability, and level of harm.

#### TARGET AUDIENCE:

This continuing activity is intended for physicians and nurses with an interest in skin and wound care. OBJECTIVES:

After participating in this educational activity, the participant should be better able to:

1. Summarize the data provided in the Office of Inspector General (OIG) study regarding incidence of pressure ulcers (PrUs) found in hospitals and skilled nursing facilities (SNFs).

2. Identify the classification systems used that designate levels of harm to patients and the avoidability of PrUs.

#### ABSTRACT

**OBJECTIVE:** To investigate in greater detail the government data on pressure ulcer (PrU) incidence, avoidability, and level of harm.

**DESIGN:** The authors performed a secondary analysis of PrU data published in 2 studies by the Office of Inspector General (OIG) on adverse events in hospitals and skilled nursing facilities (SNFs).

**SETTING:** Acute care hospitals and Medicare-certified SNFs across the United States.

**PATIENTS:** The hospital sample included 780 Medicare beneficiaries randomly selected from 999,645 discharges during October 2008. The SNF population included 653 Medicare beneficiaries randomly selected from 100,771 patients whose stay began within 1 day of hospital discharge, who had a length of stay of 35 days or less, and whose stay ended in August 2011.

MAIN OUTCOME MEASURES: Pressure ulcer incidence with stage, location, avoidability, and level of harm using the Modified National Coordinating Council for Medication Errors Reporting and Prevention Index.

MAIN RESULTS: The PrU incidence in hospitals was 2.9%, and the incidence in SNFs was 3.4%. Most PrUs were Stages I and II, with 78.3% in hospitals and 54.5% in SNFs. The avoidability of PrUs was similar in both locations, with 39.1% unavoidable in hospitals and 40.9% unavoidable in SNFs. All hospital-acquired PrUs and 90.9% of SNF-acquired PrUs were designated level E on the National Coordinating Council for Medication Errors Reporting and Prevention Index, indicating a temporary harm event. **CONCLUSIONS:** The OIG studies captured few Stage III PrUs and no Stage IV PrUs, and they underestimate the level of harm generated from PrUs in hospitals and SNFs. The studies offer a structured algorithm for avoidability determination, but lack measures of reliability and validity. Nonetheless, the high rate of unavoidable ulcers leads to questions on the reliability of PrUs as a quality indicator. There are several weaknesses in OIG methodology with regard to PrUs; however, its structured algorithm can be viewed as a starting point for future studies of PrU avoidability.

**KEYWORDS:** pressure ulcers, wound care, healthcare costs, Medicare, quality measurement

ADV SKIN WOUND CARE 2015;28:420-8; quiz 429-30.

#### INTRODUCTION

The determination of avoidability of pressure ulcers (PrUs) has become an important issue from a quality, regulatory, and reimbursement standpoint.<sup>1</sup> Over the past 4 years, the Office

of Inspector General (OIG) released 2 studies on adverse events among Medicare beneficiaries in hospitals and skilled nursing facilities (SNFs).<sup>2,3</sup> These studies identified adverse events, determined harm levels, developed and utilized methodology to determine preventability, and measured the cost of adverse events to the Medicare program. The studies identified a heterogeneous group of adverse events, including those related to medication, such as bleeding and delirium; events related to ongoing patient care, such as aspiration, deep vein thrombosis, and PrUs; events related to surgery or other procedures, such as myocardial infarction and postoperative urinary retention; and events related to infection, such as catheter-associated urinary tract infection and sepsis. Within the OIG's published results were raw data on PrUs with information on incidence, stage, location, and preventability that are the subject of this secondary analysis.

Medicare is the federal health insurance program for more than 50 million older adults and disabled persons in the United States.<sup>4</sup> In 2012, US healthcare expenditures were \$2.8 trillion. Medicare alone had expenditures of \$536 billion in 2012, and this is projected to increase by 6.6% per year. In 2010, the average amount spent on healthcare per person was \$18,424 for persons older than 65 years: 5 times higher than what was spent per child (\$3628) and 3 times higher than that for working-age adults (\$6125).<sup>4</sup> Although this is overall healthcare spending, the numbers are just as striking when hospital and SNF costs are examined.

In 2009, Medicare spent \$137 billion for inpatient hospital services. This included \$4.4 billion that was spent on temporary or adverse harm events that were additional costs from the initial inpatient stay.<sup>2</sup> In addition, 1.5% of Medicare beneficiaries experienced an event that contributed to their death, which projects to approximately 15,000 persons in 1 month for acute care. Adverse or temporary harm was found to have been preventable 44% of the time.<sup>2</sup>

The OIG studies differentiate between an adverse event and a temporary harm event, based on severity level on the National Coordinating Council for Medication Errors Reporting and Prevention (NCC-MERP) Index discussed below. An adverse event resulted in prolonged hospital stay, permanent harm, lifesustaining intervention, or death. A temporary harm event designates an outcome that required medical intervention but did not result in lasting harm.

Post–acute stays (SNF stays that begin within 1 day of hospital discharge and last up to 35 days) constituted 70% of all Medicare patient stays in SNFs.<sup>3</sup> These SNF services, covering 1.8 million beneficiaries, cost Medicare \$28.4 billion in 2011. Residents in SNFs experienced adverse events in 22% of their stays, and 11% had temporary harm events, with 59% of these events being clearly or likely preventable.<sup>3</sup>

This article presents a secondary analysis of PrU data published in the OIG studies on adverse events among Medicare beneficiaries. To the authors' knowledge, these data have not been published elsewhere other than in these OIG reports. The authors discuss the data in light of assigned harm levels and avoidability algorithms. The authors address limitations of the OIG methodology, as well as its strengths and weaknesses, specific to PrUs. A closer look at the OIG studies yields insight into how PrUs are viewed within the quality debate, sheds light on tools for determining avoidability, and helps define a new direction for future PrU research.

The OIG defined preventable as "harm could have been avoided through improved assessment or alternative actions." Not preventable was defined as "harm could not have been avoided given the complexity of the patient's condition or care required." Neither the National Pressure Ulcer Advisory Panel definition nor Centers for Medicare & Medicaid Services' (CMS) Minimum Data Set 3.0 definition of avoidability for SNFs was used. The authors note that the OIG report used the term "preventable" and "not preventable," which the authors use interchangeably with "avoidable" and "unavoidable."

For greater detail on definitions and methodology, the reader is referred to the original OIG studies, which are available online.<sup>2,3</sup>

### MATERIALS AND METHODS

#### **Hospital Study Population**

The hospital study population included a random sample from the National Claims History database of 780 Medicare beneficiaries taken from 999,645 hospital discharges during October 2008. Sample beneficiaries had 838 hospital stays with discharges during that month, with an average length of stay of 5.2 days.

#### **SNF Study Population**

The SNF study population included all Medicare beneficiaries who had Medicare-paid SNF stays that began within 1 day of hospital discharge, who had a length of stay of 35 days or less, and whose hospitalization ended in August 2011. Using Medicare claims data from the National Claims History file, investigators selected a random sample of 653 patients from 100,771 individuals who met the selection criteria.

#### **Randomization Method**

Randomization was based on Medicare claims data, where beneficiaries are uniquely identified by their Medicare identification numbers. Many patients had multiple claims, so beneficiaries were assigned to a single entry in the sampling frame. At each beneficiary meeting, the selection timeframe parameters were assigned a random number using the RANUNI command in SAS, and beneficiaries were sorted by that random number. From the randomly ordered list, beneficiaries were selected from the top of the list, with sample size limitation based on funding considerations determined by a pilot study of cost for medical record review that considered record collection, chart abstraction, registered nurse screening, and physician review (personal communication with Ruth A. Dorrill, Deputy Regional Inspector General, Department of Health and Human Services/OIG/Office of Evaluation and Inspections).

#### **Classification of Level of Harm**

This study used an adapted version of the NCC-MERP Index to classify adverse events by level of harm.<sup>5,6</sup> This index was initially developed to categorize the effect of medication errors and includes 9 ascending levels of severity, each designated by a letter. This scale was found to be reliable based on substantial agreement between assessors.<sup>7</sup> Levels A through D are the least serious and do not represent harm to patient or resident. Level E represents an error that may have contributed to, or resulted in, temporary harm and required intervention. Levels F through I are more serious and correspond to prolonged facility stay or hospitalization, permanent patient harm, life-sustaining interventions, or death (Figure 1).

Classification of the level of harm was determined by a panel of physician reviewers. For purposes of understanding the level of harm classification, it is important to reiterate the definition of "temporary harm." A temporary harm event is level E on the NCC-MERP Index and designates an outcome that has required medical intervention but did not result in lasting harm. Other examples of temporary harm events include conditions such as headache, episodes of vomiting, and hypoglycemia due to medication.

#### **Definition of Adverse Events**

For the hospital population, investigators identified adverse events if they met at least 1 of the following criteria: (1) event was on the National Quality Forum list of serious reportable events (SREs); (2) event was on the Medicare list of hospital-acquired conditions (HACs); or (3) event resulted in 1 of the 4 most serious categories on the NCC-MERP Index (F through I). These criteria captured PrUs of Stage III or IV. Investigators classified PrUs of Stages I and II within NCC-MERP Index level E, which designated outcomes resulting in temporary harm.

For the SNF population, investigators used an SNF trigger tool that was a modified version of the Institute of Healthcare Improvement's Global Trigger Tool. This trigger tool captured PrUs of any stage.

#### Figure 1. NCC-MERP INDEX FOR CATEGORIZING ERRORS

	Circumstances or events that have the capacity to	
Category A	cause error	
	An error occurred but the error did not reach the	
Category B	patient (An "error of omission" does reach the patient)	Harm does not
	An error occurred that reached the patient but did not	reach patient
Category C	cause patient harm	
	An error occurred that reached the patient and required	
	monitoring to confirm that it resulted in no harm to the	
Category D	patient and/or required intervention to preclude harm	
	An error occurred that may have contributed to or	
1	resulted in temporary harm to the patient and required	
Category E	intervention	
	An error occurred that may have contributed to or	
	resulted in temporary harm to the patient and required	
Category F	initial or prolonged hospitalization	Harm reaches
	An error occurred that may have contributed to or	patient
Category G	resulted in permanent patient harm	
	An error occurred that required intervention necessary	
Category H	to sustain life	
	An error occurred that may have contributed to or	
Category I	resulted in the patient's death	

## **Identifying Adverse Events**

A 2-phase review was used to identify adverse events for both hospital and SNF, with different criteria for each group. The hospital study screened 780 randomly chosen patient records for adverse events in the following manner: (1) certified medical coders identified codes in Medicare claims data that were not present on admission; (2) nurse reviewers found potential adverse events; or (3) patient had hospital readmission within 30 days of discharge. In the second phase, 420 cases were flagged, and the chart was reviewed by a group of physicians. Subspecialties of physician reviewers were not identified for the hospital study.

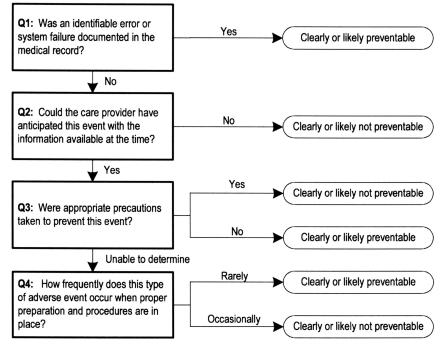
For the SNF study, 1 nurse practitioner and 4 nurses performed the initial screen of 653 randomly chosen patient records, reviewing the record for evidence of harm using an OIGdeveloped trigger tool to standardize reviews. This trigger tool had a category indicated as "pressure ulcer" that did not discriminate among stages. A total of 262 charts flagged in the initial screen underwent a second review by 5 contracted physicians. The physicians included a cardiologist, infectious disease specialist, internist, orthopedist, and geriatrician with experience as an SNF medical director.

## **Determination of Preventability**

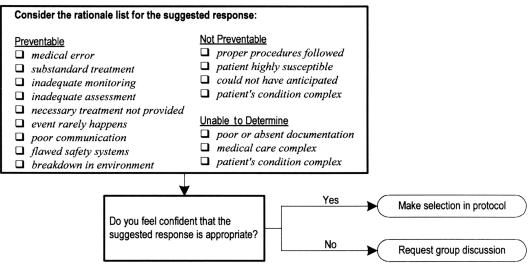
Determination of preventability used a decision algorithm reproduced in Figure 2. This decision algorithm was developed by OIG for the study of adverse events in hospitals. Preventability was determined by identification of errors and system failures, whether the outcome was an anticipated event, and whether appropriate precautions were taken. The decision algorithm incorporated a 2-part process, including a flow chart and a rationale list to evaluate and determine the final response. Reviewers judged preventability on the basis of information in the medical records, clinical experience with similar cases, research literature, and group discussion. The

### Figure 2. PHYSICIAN REVIEW PROCESS FOR DETERMINING AVOIDABILITY

# Part I – Decision Algorithm to Determine Suggested Response



# Part II – Rationale List to Evaluate Suggested Response



OIG report did not cite specific literature on which this model was based.

Preventability was indicated on a 5-point response scale: • Clearly preventable—harm could definitely have been avoided through improved assessment or alternative actions. • Likely preventable—harm could have been avoided through improved assessment or alternative actions.

• Likely not preventable—harm could not have been avoided given the complexity of the resident's condition or the care required.

· Clearly not preventable-harm could definitely not have been avoided given the complexity of the resident's condition or the care required.

• Unable to determine—unable to determine preventability because of incomplete documentation or case complexity.

#### RESULTS

#### **Hospital Data**

In the hospital sample, 23 patients with PrUs were identified, yielding an incidence rate of 2.9%. Distribution of stages was as follows: 8 (34.8%) Stage I, 10 (43.5%) Stage II, 3 (13.0%) Stage III, 1 was suspected deep tissue injury (sDTI) (4.3%), and 1 was not staged (4.3%). There were no Stage IV PrUs documented in the hospital sample.

Some patients had more than 1 wound; 27 new PrUs were identified, and 2 of these did not indicate a location. Of the 25 PrUs with identified location, 8 (32%) were on the buttocks, 12 (48%) on sacrum or coccyx, 4 (16%) on the heel, and 1 (4%) on the ankle. See Table 1 for a summary of hospital PrU stages.

Avoidability was determined on a per-patient rather than a per-ulcer basis. Regarding avoidability determination, no hospitalacquired PrUs (HAPUs) were designated clearly preventable, 13 (56.5%) were found likely preventable, 7 (30.4%) were likely not preventable, 2 (8.7%) were clearly not preventable, and 1 (4.3%) was designated unable to determine preventability. Thus, 39.1% of HAC PrUs were determined not preventable. See Table 2 for a summary of preventability determination for PrU. There were 3 Stage III PrUs designated as adverse events, but all were designated level E harm, or temporary harm events, even though they fulfilled CMS criteria for HAC and/or the National Quality Foundation criteria for an SRE. The remaining 20 Stage I, Stage II, or sDTI PrUs were designated level E, temporary harm events.

#### Table 1.

STAGE DISTRIBUTION OI	NEW PRESSURE ULCERS
-----------------------	---------------------

	Hospital	l	SNF	
Stage 1	8	34.8%	9	40.9%
Stage 2	10	43.5%	3	13.6%
Stage 3	3	13.0%	8	36.4%
Stage 4	0	0.0%	0	0.0%
Unstageable	0	0.0%	2	9.1%
DTI	1	4.3%	0	0.0%
Not staged	1	4.3%	0	0.0%
Total	23	100.0%	22	100.0%

#### Table 2. PREVENTABILITY OF NEW PRESSURE ULCERS<sup>a</sup>

	Hospital		SNF	
Clearly preventable	0	0.0%	2	9.1%
Likely preventable	13	56.5%	9	40.9%
Likely not preventable	7	30.4%	8	36.4%
Clearly not preventable	2	8.7%	1	4.5%
Unable to determine	1	4.3%	2	9.1%
Total	23	100.0%	22	100.0%
<sup>a</sup> Reported on a per-patient basi	s.			

Of 23 patients with HAPUs, there was only 1 patient with a Stage III PrU that was classified as hospital acquired. It is unclear from OIG data why the remaining 2 Stage III PrUs were not in the HAC classification. All HAPUs including Stage III were designated level E, or temporary harm events.

#### SNF Data

There were 22 patients with PrUs noted in the OIG study sample, yielding an incidence rate of 3.4%. Of these, 9 (40.9%) were Stage I, 8 (36.4%) Stage II, 3 (13.6%) Stage III, and 2 (9.1%) were unstageable. There was no Stage IV or sDTI PrU documented in this sample. See Table 1 for a summary of SNF PrU stages.

Several patients had more than 1 wound, and a total of 30 PrUs were identified in the OIG sample. Five wound locations were not designated. Of the remainder, 5 (20%) were on the buttocks, 5 (20%) were on the coccyx, 10 (40%) were on the heels, and 5 (20%) were on other areas including the hand, thigh, elbow, scapula, and toe. There was no clarification as to why a PrU occurred on a patient's hand.

Avoidability was determined on a per-patient rather than a per-ulcer basis. Regarding avoidability determination, 2 (9.1%) were designated clearly preventable, 9 (40.9%) were likely preventable, 8 (36.4%) were likely not preventable, 1 (4.5%) was clearly not preventable, and 2 (9%) were designated as unable to determine preventability. Thus, 41% of all SNF-acquired PrUs were determined not preventable. See Table 2 for a summary of hospital and SNF preventability determinations.

There were 20 of 22 (90.9%) PrUs designated level E on the modified NCC-MERP Index (temporary harm events), which were therefore excluded from overall rates of adverse events. This group was almost entirely Stage I or II, but included 1 Stage III of the hand. Level E determination was made because, in consultation with physician reviewers, the effect of these events was not comparable with those of more serious events and did not result in transfer to the hospital or prolong SNF stays. Of the remainder,

1 case of PrU (Stage III of the sacrum and Stage II of the buttocks) was designated level F, and 1 (Stage III of the heel) was level G.

#### DISCUSSION

The Patient Protection and Affordable Care Act mandates the Department of Health and Human Services to establish a national strategy for quality improvement in healthcare, including patient safety and a search for best practices.<sup>2</sup> The OIG's mission is to protect the integrity of the Department of Health and Human Services programs and the health and welfare of beneficiaries served by those programs. This mission is conducted through a network of audits, investigations, and inspections. Over the past 4 years, OIG released studies assessing the extent to which adverse events in hospitals and post–acute SNF stays were preventable and calculates the cost of these events to Medicare.<sup>2,3</sup> These studies contained raw data on PrUs that formed the basis for the authors' secondary analysis.

The incidence of PrUs was 2.9% in hospitals and 3.4% in SNFs. Most PrUs were early stages, with 78.3% Stages I and II in the hospital and 54.5% of similar stages in the SNFs. The OIG studies captured few Stage III and no Stage IV PrUs, which may suggest that facilities were either efficient at detecting earlier-stage lesions or underreporting higher stages of wounds. In comparison, the 2009 international prevalence data found 7% of PrUs were Stage III, 7% Stage IV, 15% unstageable, and 9% were sDTI.<sup>8</sup> Lyder et al<sup>9</sup> performed a retrospective secondary analysis of the national Medicare Patient Safety Monitoring System study and found an incidence of 4.5% during hospitalization.

When placed on the NCC-MERP Index harm level, nearly all new ulcers in both hospitals and SNFs were designated level E, indicating a temporary harm event. Given the known mortality and morbidity related to PrU, this classification might not be accurate. In addition, some harm levels related to PrUs may have been misclassified. Three PrUs were either Stage III or unstageable and designated as level E, whereas 2 other Stage III ulcers were designated either level F or G. There was no explanation or rationale to explain this disparity. According to guidelines from the National Quality Forum, any PrU of Stage III or Stage IV or that is unstageable should be designated as an SRE.<sup>10</sup> Lyder et al<sup>9</sup> found that patients with HAPUs in the national Medicare Patient Safety Monitoring System study had an odds ratio of in-hospital mortality of 2.81 (95% confidence interval, 2.44–3.23). Thus, the OIG analysis underestimates the level of harm incurred by facility-acquired PrUs.

The OIG studies found that 39.1% of PrUs in hospitals, and 40.9% of PrUs in SNFs, were unavoidable. The authors are unaware of studies that provide preventability rates, which can be compared with these results. Nonetheless, the high rate of unavoidable ulcers leads to questions on the reliability and validity of PrUs as a quality indicator, particularly in light of recognition

that many PrUs are unavoidable.<sup>1</sup> A quality indicator is a quantitative measure used to monitor and evaluate clinical systems that affect patient outcomes.<sup>11</sup> Use of a quality indicator with such high percentage of unavoidability may cast a negative shadow on what is otherwise adequate care. Considering the importance of this high preventability determination, it is necessary to critically examine OIG preventability determination methodology.

Examination of OIG methodology reveals both strengths and weaknesses that can be applied to future studies of avoidability of PrUs. The preventability determination algorithm used in OIG studies is similar to previously published models, with a 2-stage review beginning with initial screen followed by structured event analysis with a multilevel scoring scale (Figure 2).<sup>12</sup> The OIG studies did not cite a specific model on which the algorithm was based, but the algorithm was constructed after extensive discussion and review of the literature (personal communication with Ruth A. Dorrill, Deputy Regional Inspector General, Department of Health and Human Services/OIG/Office of Evaluation and Inspections). A major strength is the structured process to assess preventability, with a scale that designates the level of preventability. However, the authors identify several areas of potential unreliability specifically regarding PrU findings. The PrUs were 1 of a heterogeneous group of adverse outcomes identified in an initial medical record screening process. The complexity of PrU prevention and documentation might have been lost with this broad approach that was not disease specific. Medical record reviews are known to be unreliable for identifying substandard quality, and PrUs are often poorly documented.<sup>13</sup>

The OIG methodology incorporated a 2-tiered review with nurses performing the initial medical record screen and a panel of physicians making the final preventability determination, which may have resulted in inaccurate results regarding PrUs. Most day-to-day PrU care is performed by nurses, and physicians often do not examine or document them. Physicians are known to have poor knowledge base regarding PrUs.<sup>14</sup> When compared with previously published Medicare data on the incidence of Stages III and IV PrUs, the OIG studies likely underrepresent these wounds.<sup>15</sup>

Many methods have been developed for assessing preventability of adverse events, such as drug-related incidents and outcomes due to medical malpractice.<sup>12,16,17</sup> However, to date, no comparable methodology has been applied explicitly to PrUs, rendering this a potential new frontier for PrU research. Implicit review relies on the practitioner's expert opinion and global impressions of care, whereas explicit review uses well-defined criteria. Implicit reviews can be structured and directed toward specific parts of the medical record.<sup>18</sup> Assessment of avoidability can incorporate both implicit and explicit methodologies.<sup>18</sup> The methodology used by OIG was structured implicit review that was not disease specific (Figure 2).

Several potential pitfalls require consideration if preventability algorithms are applied to PrUs. It is sometimes difficult to distinguish outcomes related to errors in medical care from outcomes attributable to underlying illness.19 Determination of adverse events due to medical error can be biased by reviewers' experience, attention to detail, background of the reviewer, and characteristics of the population studied.<sup>19</sup> Consideration of the patient's prognosis can affect avoidability determination.<sup>20</sup> Incorporation of a consensus discussion may improve accuracy of results.<sup>21</sup> Conclusions on avoidability can be compromised by failure to assess reliability and validity.<sup>19</sup> Reliability refers to the consistency of ratings or the ability of raters to reach the same conclusion about a specific case, where validity refers to accuracy or to the extent to which a measurement by a rater approaches the true value.<sup>18,19</sup> The OIG studies provided neither reliability nor validity data for their findings.

A recent literature review mentions numerous medical conditions that may lead to unavoidable PrUs, but does not address methodology for unavoidability determination.<sup>1</sup> Caring for PrUs is multidisciplinary and involves complex hospital systems, which must be taken into consideration when developing tools for analyzing avoidability. Future studies on PrU avoidability should consider formal tools, such as that presented in the OIG studies, to improve accuracy and reproducibility of results. The authors recommend a disease-specific structured implicit review that captures the complexity of clinical care using objective criteria, with interdisciplinary reviewers trained in PrU prevention and treatment. The tool should incorporate a multiplicity of underlying illnesses known to contribute to unavoidable PrUs.<sup>1,22</sup> Graded levels of preventability are recommended, similar to OIG studies, with accountability as to how conflicting assessments are managed.<sup>12</sup> When possible, it is best to rely on accurate staging performed by trained clinicians. The authors also recommend incorporation of standardized definitions of unavoidability that were derived specifically for this outcome.

A major objective of the OIG studies was to determine the cost of adverse events to the Medicare program; however, it seems that costs related to PrUs were underestimated. For hospitals, because cost determination included only events that satisfied the HAC criteria, Stages I and II PrUs were excluded. Of 23 patients with HAPUs, there was only 1 patient with a Stage III PrU that was classified as HAC. The OIG data are at variance with previously published Medicare cost data that showed that PrUs were the most common and most expensive HAC.<sup>15</sup> For SNFs, cost data incorporated only events resulting in hospitalization or an emergency department visit, which excluded all NCC-MERP level E events—the level at which 90.9% of PrUs were classified. Because the cost estimates of adverse events in the OIG studies considered only lesions of advanced stage and higher harm level, Medicare expenditures related to PrUs were certainly underestimated. Future studies of costs related to PrUs need to accurately capture advanced stages to reflect the reality of this disease.

#### CONCLUSIONS

Avoidability of PrUs has been a topic of controversy since Jean Martin Charcot developed his neurotrophic theory in the 19th century.<sup>23</sup> This theory, since disproven, stated that all PrUs were unavoidable when nutritive fibers connecting the central nervous system to the skin were interrupted. Charcot's theory prompted the neurophysiologist Edouard Brown-Sequard to experimentally demonstrate that PrUs can be avoided by eliminating environmental factors such as pressure and body waste.<sup>23</sup> In the present day, as PrUs have become identified as a quality indicator, the controversy over avoidability has become increasingly important from a regulatory, risk-management, and reimbursement standpoint.<sup>1</sup>

The CMS requires SNFs to report PrUs through the Minimum Data Set, and PrU rates are publicly reported as Quality Measures on the Nursing Home Compare website.<sup>24,25</sup> Since 2008, the CMS denies payment for increased medical complexity incurred by Stages III and IV HAPUs, deeming them "reasonably preventable through the application of evidence-based guidelines."<sup>15</sup> Recent decades have seen a dramatic rise in lawsuits against caregivers regarding PrUs with the explicit assumption that these wounds demonstrate poor-quality care.<sup>26</sup> Given this backdrop, it is imperative that methodology is developed to verify the reliability of PrUs as a quality indicator, measure their avoidability in an accurate and reproducible manner, and quantify their cost to the healthcare system.

#### PRACTICE PEARLS

- The OIG studies captured few Stage III PrUs and no Stage IV
- PrUs, which is not comparable to previously published data.
- The OIG studies underestimate the level of harm and costs generated from PrUs in hospitals and SNFs.
- The OIG presents a structured algorithm for determining PrU avoidability. This algorithm can serve as a starting point for future studies of PrU avoidability, but needs measures of reliability and validity.

• The high rate of unavoidable ulcers leads to questions on the reliability of PrUs as a quality indicator.

#### REFERENCES

- Edsberg LE, Langemo D, Baharestani MM, Posthauer ME, Goldberg M. Unavoidable pressure injury: state of the science and consensus outcomes. J Wound Ostomy Continence Nurs 2014;41:313-34.
- Department of Health and Human Services, Office of Inspector General. Adverse events in hospitals: national incidence among Medicare beneficiaries. November 2010. OEI-06-0900090. https://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf. Last accessed July 7, 2015.

- Department of Health and Human Services, Office of Inspector General. Adverse events in skilled nursing facilities: national incidence among Medicare beneficiaries. February 2014. https://oig.hhs.gov/oei/reports/oei-06-11-00370.pdf. Last accessed July 7, 2015.
- CMS (2014 NHE Fact Sheet). http://www.cms.gov/Research-Statistics-Data-and-Systems/ Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheethtml. Last accessed July 9, 2015.
- National Coordinating Council for Medication Error Reporting and Prevention. http:// www.nccmerp.org. Last accessed July 7, 2015.
- Griffin FA, Resar RK. IHI Global Trigger Tool for Measuring Adverse Events (Second Edition). IHI Innovation Series White Paper. Cambridge, MA: Institute for Healthcare Improvement; 2009. http://www.ihi.org/resources/Pages/IHIWhitePapers/IHIGlobalTrigger ToolWhitePaper.aspx. Last accessed July 7, 2015.
- Forrey RA, Pederson CA, Schneider PJ. Interrater agreement with a standard scheme for classifying medication errors. Am J Health Syst Pharm 2007;64:175-81.
- VanGilder C, MacFarlane G, Harrison P, et al. The demographics of suspected deep tissue injury in the United States: an analysis of the International Pressure Ulcer Prevalence Survey 2006-2009. Adv Skin Wound Care 2010;23:254-61.
- Lyder CH, Wang Y, Metersky M, et al. Hospital-acquired pressure ulcers: results from the national Medicare Patient Safety Monitoring System study. J Am Geriatr Soc 2012;60: 1603-8.
- List of Serious Reportable Events, National Quality Forum. Last updated July 13, 2012. http://www.qualityforum.org/Topics/SREs/List\_of\_SREs.aspx. Last accessed July 7, 2015.
- 11. JCAHO. Characteristics of clinical indicators. Qual Rev Bull 1989;11:330-9.
- Hakkarainen MK, Anderson Sundell K, Petzold M, Hägg S. Methods for assessing the preventability of adverse drug events: a systematic review. Drug Saf 2012;35:105-26.
- Weingart SN, Davis RB, Palmer RH, et al. Discrepancies between explicit and implicit review: physician and nurse assessments of complications and quality. Health Serv Res 2002;37:483-98.
- 14. Levine JM, Ayello EA, Zulkowski KM, Fogel J. Pressure ulcer knowledge in medical residents: an opportunity for improvement. Adv Skin Wound Care 2012;25:115-7.

- Medicare program: changes to the hospital inpatient prospective payment systems and fiscal year 2009 rates. Fed Regist 2008;73(161):43434. http://www.gpo.gov/fdsys/pkg/ FR-2008-08-19/html/E8-17914.htm. Last accessed July 7, 2015.
- Localio AR, Weaver SL, Landis R, et al. Identifying adverse events caused by medical care: degree of physician agreement in a retrospective chart review. Ann Intern Med 1996; 125:457-63.
- 17. Hiatt HH, Barnes BA, Brennan TA, et al. A study of medical injury and medical malpractice. N Engl J Med 1989;321:480-4.
- Rubenstein LV, Kahn KL, Harrison E, Sherwood WJ, Rogers WH, Brook RH. Structured implicit review of the medical record: a method for measuring the quality of inhospital medical care and a summary of quality changes following implementation of the Medicare prospective payment system. Rand Corporation N-3033-HCFA 1991.
- Brennan TA, Localio RJ, Laird NL. Reliability and validity of judgments concerning adverse events suffered by hospitalized patients. Med Care 1989;27:1148-58.
- Hayward RA, Hofer TP. Estimating hospital deaths due to medical errors: preventability is in the eye of the reviewer. JAMA 2001;286:415-20.
- van Doormaal JE, Mol PG, van den Bemt PM, et al. Reliability of the assessment of preventable adverse drug events in daily clinical practice. Pharmacoepidemiol Drug Saf 2008;17:645-54.
- Levine JM, Humphrey S, Lebovits S, Fogel J. The unavoidable pressure ulcer: a retrospective case series. J Clin Outcomes Manage 2009;16:359-63.
- Levine JM. Historical perspective: the neurotrophic theory of skin ulceration. J Am Geriatr Soc 1992;12:1281-3.
- Levine JM, Roberson S, Ayello EA. Essentials of MDS 3.0 section M: skin conditions. Adv Skin Wound Care 2010;23:273-83.
- Centers for Medicare & Medicaid Services. Fact sheet: nursing home compare five-star quality rating system December 2008. http://www.cms.gov/Medicare/Provider-EnrollmentandCertification/CertificationandComplianc/Downloads/consumerfactsheet.pdf. Last accessed July 7, 2015.
- Voss AC, Bender SA, Ferguson ML, Sauer AC, Bennett RG, Hahn PW. Long-term care liability for pressure ulcers. J Am Geriatr Soc 2005;53:1587-92.

For more than 128 additional continuing education articles related to skin and wound care topics, go to NursingCenter.com/CE.

# **CE** CONNECTION

#### CONTINUING MEDICAL EDUCATION INFORMATION FOR PHYSICIANS

Lippincott Continuing Medical Education Institute, Inc. is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

Lippincott Continuing Medical Education Institute, Inc. designates this journal-based CME activity for a maximum of 1 *AMA PRA Category 1 Credit<sup>TM</sup>*. Physicians should only claim credit commensurate with the extent of their participation in the activity.

#### PROVIDER ACCREDITATION INFORMATION FOR NURSES

Lippincott Williams & Wilkins, publisher of the Advances in Skin & Wound Care journal, will award 2.5 contact hours for this continuing nursing education activity.

LWW is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

This activity is also provider approved by the California Board of Registered Nursing, Provider Number CEP 11749 for 2.5 contact hours. LWW is also an approved provider by the District of Columbia and Florida CE Broker #50-1223. Your certificate is valid in all states.

#### **OTHER HEALTH PROFESSIONALS**

This activity provides ANCC credit for nurses and *AMA PRA Category 1 Credit*<sup>™</sup> for MDs and DOs only. All other healthcare professionals participating in this activity will receive a certificate of participation that may be useful to your individual profession's CE requirements.

#### CONTINUING EDUCATION INSTRUCTIONS

Read the article beginning on page 420.

• Take the test, recording your answers in the test answers section (Section B) of the CE enrollment form. Each question has only one correct answer.

- Complete registration information (Section A) and course evaluation (Section C).
- Mail completed test with registration fee to: Lippincott Williams & Wilkins, CE Group, 74 Brick Blvd, Bldg 4 Suite 206, Brick, NJ 08723.
- Within 3 to 4 weeks after your CE enrollment form is received, you will be notified of your test results.
- If you pass, you will receive a certificate of earned contact hours and an answer key. Nurses who fail
  have the option of taking the test again at no additional cost. Only the first entry sent by
  physicians will be accepted for credit.

• A passing score for this test is 13 correct answers.

- NURSES: NEED CE STAT? Visit www.nursingcenter.com for immediate results, other CE activities, and your personalized CE planner tool. No Internet access? Call 1-800-787-8985 for other rush service options.
- PHYSICIANS: NEED CME STAT? Visit http://cme.lww.com for immediate results, other CME activities, and your personalized CME planner tool.

Questions? Contact Lippincott Williams & Wilkins: 1-800-787-8985.

Registration Deadline: September 30, 2017 (nurses); September 30, 2016 (physicians).

#### **PAYMENT AND DISCOUNTS**

- The registration fee for this test is \$24.95 for nurses; \$22 for physicians.
- Nurses: If you take two or more tests in any nursing journal published by LWW and send in your CE enrollment forms together by mail, you may deduct \$0.95 from the price of each test. We offer special discounts for as few as six tests and institutional bulk discounts for multiple tests.
   Call 1-800-787-8985 for more information.