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# Medico-Legal Implications

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## Introduction

The medico-legal implications of pressure ulcer development are burgeoning throughout the world. Increasingly, pressure ulcers are being used as a quality indicator of care. Hence, the development of pressure ulcers can constitute a failure in the healthcare system. In the United States, the federal government believes that pressure ulcers are an excellent surrogate for how well the healthcare team is functioning. Thus, a high incidence of pressure ulcers usually can be correlated with high incidence of other care issues (e.g. falls, restraint usage, urinary incontinence). One aspect of the increasing view of pressure ulcer development as a marker for quality care has been the increasing level of pressure ulcer litigation against clinicians and their employers (hospitals, nursing homes, etc.).

This chapter will review various aspects of the medico-legal implications of pressure ulcer development. More specifically, it will review pressure ulcers as a political agenda; the legality of pressure ulcers; regulatory and reimbursement aspects of pressure ulcers; necessity of chart audits related to pressure ulcers; and pressure ulcers as a quality measure.

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## The Politics of Pressure Ulcers

In the past 10 years, there has been a fundamental paradigm shift in how governments and consumers of healthcare have thought about pressure ulcer development. In part, this has occurred because of a greater need of governments to control burgeoning healthcare costs associated with an ever-increasing older adult population. Although the true cost associated with pressure ulcer prevention and development remains unknown, these ulcers can significantly increase healthcare expenditures. For example, in the Netherlands pressure ulcer treatment is conservatively estimated from a low of \$362 million to a high of \$2.8 billion, 1% of the total Dutch healthcare budget [1]. In the UK, the costs of pressure ulcers have ranged annually from £180 million to £321 million, or 0.4–0.8% of healthcare spending [2] (see Chap. 2). The financial costs to the National Health Service (NHS) are also substantial. Preventing and treating pressure ulcers in a 600-bed general hospital costs between £600,000 and £3 million a year,

excluding litigation costs [3]. In the United States, it has been conservatively estimated that the treatment cost alone ranges anywhere between \$ 1.68 billion to \$ 6.8 billion or more than 1% of the total U.S. healthcare budget [4]. These estimates do not account for pain, suffering, or potential days of lost income. Thus, pressure ulcers are an expensive health problem.

The increasing accountability of healthcare clinicians to prevent and manage these wounds more effectively has led to an explosion of national guidelines on pressure ulcer. These national guidelines on prevention and treatment were developed by various healthcare providers and organizations as a method of streamlining and providing consistent pressure ulcer care. The earliest national guidelines were derived from the Netherlands and the United States [5]. Moreover, several governments have established national centres which have addressed quality pressure ulcer care. In the UK, the National Institute for Clinical Excellence released national guidelines on pressure ulcer risk management and prevention [6]. These guidelines were in part derived from the Royal College of Nursing. The NICE guidelines provide both a clinician and patient versions. The NICE guidelines are quite similar to the guidelines of the U.S. Agency for Health Care Policy and Research (now the U.S. Agency for Health Care and Quality) for pressure ulcer prevention in that both clinician and patient versions exist [4, 7].

Coupled with the growing needs for governments to manage their health expenditures more effectively, healthcare consumers have become increasingly aware through the media (internet, television) that pressure ulcers can be prevented and effectively treated. Thus, a more informed general public has led to the increasing need for healthcare providers to be educated on proper pressure ulcer care. One potentially negative consequence of an informed general public has been the increased scrutiny by the legal and/or government body to litigate or sanction penalties when care is not optimized.

## Litigation

There remains a steady increase in litigation related to either the development of pressure ulcers or failure to effectively manage them. This is fuelled by ever-increasing media attention to patients suffering from these ulcers. Moreover, in recent years there has been an effort by professional health organizations and ministries of health to educate the consumer on pressure ulcers. Although most cases may be settled through an inquiry by a health trust, there appears to be an increase of consumers seeking financial remedies.

A growing number of health professionals view the development of pressure ulcers as evidence of negligent care by a healthcare provider or health system. In one study by Tsokos et al. [8], 11.2% of 10,222 corpses in Germany were found to have a pressure ulcer. This study found that the ma-

jority of physicians did not associate the potential fatal outcome of pressure ulcers and fatalities (e.g. sepsis) related to the development of these ulcers. Moreover, the investigators stated that the prevalence of pressure ulcers is a good parameter of quality nursing and medical care, thus the field of legal medicine can contribute significantly to general quality control of standards of nursing and medical care.

The assumption that pressure ulcers result from poor care by the medical and/or nursing staff has led to a flood of litigation. These lawsuits often lead to significant financial outlays by healthcare providers and/or healthcare institutions. In a retrospective study investigating the lawsuit judgment in cases of patients developing pressure ulcers on admission to hospitals, it was found that a significant number of medico-legal cases of pressure ulcer development could easily have been avoided at little expense to the healthcare institution. Thus, if the healthcare institution had provided systematic and comprehensive preventative measures it could have potentially avoided many lawsuits. The investigators found that the damages awarded varied from £ 3,500 to £ 12,500, although there have been cases with damages in excess of £ 100,000 [9].

In the U.S. pressure ulcer litigation has become rampant. In fact, it has become common for plaintiff attorneys to advertise on televisions and newspapers; they have even begun to advertise on roadside billboards. In a study investigating typical pressure ulcer awards in the U.S., sums ranging from \$ 5,000 to \$ 82,000,000, with a median award of approximately \$ 250,000, have been reported [10]. Most revealing in this study was that the average age of the plaintiff was 72 years. This indicates that an increasing number of older adults are bringing legal cases against healthcare providers and health institutions. The following case study highlights elements of how healthcare providers and healthcare institutions can be easily exposed to litigation.

*“83 y.o. male was admitted to hospital with history of congestive heart failure, right cerebral vascular accident, early stage dementia, urinary and faecal incontinence. A pressure ulcer risk assessment scale was completed indicating that the patient was at mild risk for pressure ulcers. The patient was placed on a standard mattress with a 4 inch solid foam overlay, turned every two hours while in bed and chair. On Day 2 of hospital admission, a nurse indicated an “erythematic” area on left hip and heel. She intervened by gently massaging the two erythematic areas with lotion and turned the patient on the right side. By Day 5, a Stage 2 pressure ulcer was noted on the left hip and a Stage 1 pressure ulcer was noted on the left heel. A hydrocolloid dressing was placed on the Stage II pressure ulcer, and nothing was ordered for the Stage I pressure ulcer. The charts noted that a tissue viability nurse would be consulted. By Day 8, a Stage III pressure ulcer was noted on left hip and heels. The Tissue Viability Nurse changed all of the wound care orders”.*

This case highlights some common errors made by the hospital staff. To identify a couple of areas of concern, the patient was at extreme high risk for pressure ulcers since he had multiple health conditions that rendered him immobile (congestive heart failure, right cerebral vascular accident,

early stage dementia, urinary and faecal incontinence). Moreover, the risk assessment tool showed only mild risk. This is an important factor, indicating that the tool may have been completed incorrectly. Further, no pressure ulcer risk assessment tool has 100% sensitivity and specificity [11] (see Chap. 2). The patient was only placed on a standard mattress with a foam overlay. Given the patient's risk level, a dynamic surface (alternating air mattress, etc.) might have been more appropriate. Further complicating this patient's condition was the massaging of the erythematous area on the patient's left hip and heel. Research indicates that massaging a red spot may actually deepen the devitalized area [12]. Further, although a hydro-colloid dressing was ordered for the stage 2 pressure ulcer, nothing was ordered for the stage 1 ulcer (e.g. removing load from the heel). In this case study, it was obvious that additional preventive measures were not instituted; thus these pressure ulcers could perhaps have been avoided.

The above case scenario could occur anywhere in the world. Thus, any healthcare provider could be exposed to litigation when caring for a patient with a pressure ulcer. It appears that several key factors must be met to bring a pressure ulcer case to court. Most cases involve negligence; in other words, the healthcare professional and/or healthcare institution failed in providing care. There are three major factors that must be fulfilled to prove negligence. These three factors are accountability, causation and breach of standard of care [13]. When all three are met, the verdict will be for the plaintiff.

The first key factor is accountability. Hence, the plaintiff was owed a duty of care, and this duty of care was breached. Moreover, the breach of care resulted in permanent damage or injury, and the plaintiff is owed compensation due to the injury. This factor is easily acknowledged since any patient that enters a hospital, nursing home or home care setting is owed a certain level of care by healthcare providers. Since pressure ulcers can develop when preventive measures are not implemented, it is very easy to meet this standard.

The second factor is causation. Thus, the harm suffered by the patient was a foreseeable consequence of the breach of the duty of care. Although the majority of patients that develop pressure ulcers do not die due to the pressure ulcer, pressure ulcers (especially stage 3 and 4 ulcers) can increase the potential for infections (sepsis, cellulites). Pressure ulcers may also be quite painful. Proving causation can be quite easy, especially when the medical record is void of good documentation of the type and quality of care provided. The absence of good documentation on the preventative services provided or treatments carried out can make it easy for a plaintiff attorney to show that lack of care caused the formation of the pressure ulcer.

The final factor is the standard of care by staff. It is important to note that the standard of care is not at the level of an expert, but rather that of an average healthcare professional. Most often, expert practitioners are used to determine the expected skill mix of the average healthcare provider related to wound care. A physician expert would be used to determine the physician skill mix and a nurse expert would be used to determine a nurse

skill mix. When the expert resides in a country that has developed national guidelines on the prevention and treatment of pressure ulcers, quite often these will be used to determine the appropriateness of pressure ulcer care. One study investigating the impact of implementation and subsequent compliance with practice guidelines in mitigating exposure to litigation found that of 49 plaintiff cases with compensations worth \$ 14,418,770, use of guidelines could have saved the defendant \$ 11,389,989 [14].

It appears that national guideline recommendations can be costly to implement for many healthcare institutions. One study found that the cost of implementing support surface equipment varies widely, from over £ 30,000 for some bed replacements to less than £ 100 for some foam overlays [15]. According to the UK National Health Service many clinical areas will already have access to equipment, but this is not always the case – especially for the pressure-redistributing overlays/mattresses on operating tables, which are supported by relatively recent and convincing evidence for use in high-risk individuals. Local decisions need to be made about the access and purchase of equipment in the light of available resources [15]. Consideration also needs to be given to the ongoing costs of equipment maintenance and replacement, given that the average daily cost of managing a pressure ulcer ranges from £ 38 to £ 196 with little variation by stage of ulcer [16].

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## Documentation

One major factor in decreasing the exposure to litigation appears to be the adequacy of documentation. Comprehensive documentation is also requisite for reimbursement of services and products in some countries. Moreover, good documentation justifies the medical necessity of services and products. Regulatory agencies, independent of healthcare setting, provide requisite documentation to justify continuation of pressure ulcer care. Good documentation should reflect the care required in the prevention and/or treatment of pressure ulcers [17]. Essential documentation should include the following, independent of healthcare setting:

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### Prevention of Pressure Ulcers

1. Risk assessment tool (e.g., Waterlow, Norton, Braden tools)
2. Daily skin assessment
3. Repositioning (off loading) and turning schedules
4. Use of support surfaces to address pressure redistribution (both bed and chair)
5. Control of moisture from perspiration and urinary and faecal incontinence
6. Nutritional assessment and supplementation when appropriate
7. Education of patient and/or family

### **Treatment of Pressure Ulcers**

1. Regular assessment/reassessment of the wound (daily, weekly, etc.)
2. Characteristics of the ulcer
  - a) length
  - b) width
  - c) depth
  - d) exudate amount
  - e) tissue type
  - f) pain
3. Local wound care
4. Wound-bed preparation
5. Repositioning (off loading) and turning schedules
6. Use of support surfaces to address pressure redistribution (both bed and chair)
7. Control of moisture control from perspiration and urinary and faecal incontinence
8. Nutritional assessment and supplementation when appropriate
9. Use of adjunctive therapies (negative-pressure wound therapy, electrical stimulation, etc.)
10. Education of patient and/or family

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### **Regulation and Reimbursement**

It is universally accepted that patients receiving care in hospitals, nursing homes or the community should be free of pressure ulcers or, if ulcers exist, care should be provided to treat them effectively. The majority of healthcare settings are under the auspices of the national ministry of health, which has broad parameters for operating the various trusts (usually determined by geographical locations) within a specified country. With the socialized healthcare still prevalent in European and South American countries, quality pressure ulcer care is most dependent on the resource allocation by the specific healthcare trust. To this end, the quality of pressure ulcer care (as measured by support surfaces, types of dressings, adjunctive therapies used) may vary greatly dependent on the trust. The Canadian and Mexican models for pressure ulcer care are quite similar to the European model. Thus, pressure ulcer regulation and resource allocation for the acquisition of dressings, support surfaces, and adjunctive therapies (e.g. negative-pressure wound therapy) are dependent on the provincial trusts. In these systems, one trust may provide superior wound care based on the amount of resources that are allocated to pressure ulcer care. It should be noted that complaints by a health consumer or family are usually addressed by the individual trusts.

Probably the most regulated country with regard to pressure ulcer care is the United States. With the federal government being the largest health

insurer (through Medicare), regulations exist for all settings related to reimbursement and survey process for ensuring quality pressure ulcer care. Although a given state may have additional regulations, all states must follow the federal regulations. For example, in nursing homes, the quality for pressure ulcers is ensured by the federal survey process guidelines [18].

These guidelines state that:

1. A resident who enters the facility without a pressure ulcer does not develop pressure ulcers unless the individual's clinical condition is such that they were demonstrably unavoidable.
2. A resident having pressure ulcers receives necessary treatment and services to promote healing, prevent infection and prevent new ulcers from developing.

Federal and/or state surveyors visit all 19,000 nursing homes in the U.S. to ensure compliance with the federal mandate. The inspections are unannounced and may occur at any time of the day (10% of visits must occur in the evening or night time). To assist the surveyors in evaluating whether a nursing home is compliant with the federal mandate, an investigative protocol is followed that covers all areas of pressure ulcer care (assessments, prevention, documentation, treatment, etc.). If the nursing home has been found to be non-compliant, then monetary penalties are calculated based on the seriousness of the violation. The maximum penalty for non-compliance is \$ 10,000 per day [18]. If the violation is serious enough, the nursing home can be closed immediately. For example, if a survey team finds more than one resident with Stage 3 or 4 ulcers that they believe were avoidable, then the nursing home can lose all financial support from the federal and/or state governments.

Some have argued that the survey team only has to prove that the pressure ulcer developed after admission to the nursing home, whereas the nursing home must prove that the pressure ulcer was unavoidable [19]. Given that all aspects of care are usually not documented, proving unavailability is difficult. It should be noted that all nursing home survey results are in the public domain and can be accessed on the government website. This places more pressure on nursing homes to reduce their pressure ulcer rates, since it may affect the decision by families to place their loved ones in a particular home.

In an attempt to understand the magnitude of adverse events in U.S. hospitals, the federal government has developed a monitoring program to track multiple patient safety issues. One of the first clinical indicators under study is pressure ulcers. In this program, the development of pressure ulcers in a hospital could be classified as a medical error. Presently, the data are being collected; however, this initiative will have potentially significant regulatory and legal implications for U.S. hospitals.

Until December 2002, Japan used the universal health coverage paradigm, similar to Europe and Canada. However, in January 2003 Japan introduced a modified prospective payment system on a select group of health conditions for hospitalized patients [20]. The new system is consid-

ered a hybrid between the European universal coverage and the American prospective payment system. Pressure ulcers were selected as one of the health conditions to be pilot tested. Hospitals will need to begin to track pressure ulcer incidence and outcomes of interventions. Moreover, hospitals are now required to have an interdisciplinary wound team (comprising at least physicians and nurses). All patients with pressure ulcers must be evaluated and a plan of care instituted. Although the defined acceptable rate of pressure ulcers has not been released, hospitals exceeding this incidence rate will incur monetary penalties [20].

## Benchmarking

The ability to benchmark incidence or prevalence rates for any disease condition is critical to assess the health status from a national, regional, local or institutional level. Without obtaining incidence or prevalence data, it is difficult to ascertain the effectiveness of preventative or treatment interventions (also see chapter 2). Thus, chart audits have become extremely popular throughout the world. In the past 10 years, numerous studies have published incidence and prevalence data on pressure ulcers. Both measure disease frequency. Incidence measures the proportion of people at risk for the disease (pressure ulcer) who eventually acquire the disease (pressure ulcer) over a specific period of time [21]; it conveys the likelihood that an individual in that population will be affected by the condition. Prevalence is the proportion of people who have the disease (pressure ulcer) in a specified population at risk [22, 23]. Studies usually report point prevalence, which is the prevalence rate for a specific point in time (what is the prevalence of pressure ulcers for today?). Period prevalence refers to a prevalence rate over a given time (what is the prevalence of pressure ulcers over a 3-month period?) [24]. The National Pressure Ulcer Advisory Panel has published a comprehensive monograph on the prevalence and incidence of pressure ulcers in the U.S. This document also presents step-by-step guidance on how to conduct studies on both incidence and prevalence of pressure ulcers [25].

The prevalence and incidence rates appear to differ greatly depending on the healthcare setting studied and within countries. In Canada, researchers noted a point prevalence rate of 25.7% for pressure ulcers in hospital, nursing home and community care settings [26], while in Japan a point prevalence rate of 6% is common in hospital and nursing homes [27]. In the United Kingdom, point prevalence rates have ranged from 8.5 to 32.1% for hospitals and 2.5 to 6.1% in the community [28–30]. A study investigating period prevalence of pressure ulcers in 11 German hospitals found a range of 12–53.5%, with an average of 28.3% [31].

In the United States more studies exist that report the incidence of pressure ulcers. In attempting to understand whether or not there has been an overall decrease in the incidence of pressure ulcers in the United States, the



National Pressure Ulcer Advisory Panel collected data from the published research literature over a 10-year period (1990 to 2000). They found incidence rates of 0.4–38% for hospitals, 2.2–23.9% for nursing homes and 0–17% for home care [25].

When benchmarking published data on either incidence or prevalence of pressure ulcer it is imperative to ensure that you are comparing similar data points as well as patient or unit populations. For example, an incidence rate of 20% for a hospital may be significant or not, depending on what particular medical units were involved. If this information is not available, comparisons among hospitals, nursing homes, etc. will be very difficult to make and should be avoided.

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## Pressure Ulcers as a Quality Measure

There has been little discourse on whether or not pressure ulcers should be used as an indicator of quality care. In fact, some have noted that the development of pressure ulcers results from a breakdown in the institutional system of care delivery because the prevention of pressure ulcers requires the cooperation and skill of the entire medical team. There is abundant literature that suggests that a large proportion of pressure ulcers can be prevented through systematic risk factor identification, skin assessments, use of effective support surfaces, and education of patients and staff. Implementation of a pressure ulcer prevention program is effective in decreasing the incidence of pressure ulcers in hospitals. However, few studies have been published that demonstrate the implementation prevention guidelines in their entirety, which is most likely due to the complex and interdisciplinary nature of pressure ulcer prevention. Several studies have reported the implementation of components of recommendations from the AHCPR guidelines. Gunningberg et al. [32], investigating the incidence of pressure ulcers in 1997 and 1999 among patients with hip fractures, attributed the significant reduction in incidence (from 55% in 1997 to 29% in 1999) to performance of systematic risk assessment on admission, accurate staging of pressure ulcers, use of pressure-reducing mattresses, and continuing education of staff. Another study, involving implementation of a comprehensive prevention program consisting of a risk assessment tool, uniform skin care, pressure-reducing support surfaces, repositioning schedules, standardized nutritional assessment and support, and staff education, found significant reductions in pressure ulcer incidence during a 5-month period [33]. Similar results have been noted elsewhere [34, 35]. Although these studies support the benefit of a comprehensive approach, no study could be found that has implemented all recommendations of the AHCPR prevention guidelines or any other national guidelines. Moreover, the sustainability of pressure ulcer reductions has not been studied for long periods.

Pressure ulcers may indicate a potential problem within the healthcare organization, but some ulcers may be unavoidable. There is a paucity of lit-

erature that suggests an acceptable rate for pressure ulcer development. Lyder suggested that a rate of 5% should be allowed, since not all risk factors have been identified nor has any study been published that consistently implemented a respective country's pressure ulcer prevention guidelines [11]. The discourse on avoidability versus unavoidable remains heated; however, little guidance can be found in the world literature beyond the assumption that the pressure ulcer may be deemed unavoidable if all preventative guidelines have been implemented and the ulcers develops.

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## Conclusion

There remain numerous medico-legal issues related to pressure ulcers. Given the burgeoning world of electronic information technology, cutting-edge information on pressure ulcer care can readily be transmitted throughout the world. The ever-increasing knowledge level of the general public, primarily conveyed by the mass media, will most likely lead to increasing legal claims against healthcare providers and healthcare institutions. Healthcare providers will need to educate themselves on currently acceptable practices related to pressure ulcer prevention and treatment. This will also lead to more accountability within the healthcare community and in turn to increased documentation of care provided. The key to providing optimum pressure ulcer care will be good documentation that clearly articulates the needs for services and products implemented. Moreover, good documentation will clearly identify assessment of the patient, interventions instituted and outcomes achieved.

As governments continue to quantify health expenditures related to pressure ulcers, there will be increased pressure on healthcare systems to address this costly problem. Many experts believe that the healthcare team has some capacity to thwart the development of pressure ulcers. Therefore, many countries may experience increased regulations related to pressure ulcer care, as already seen in Japan and the United States.

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