Wound Care Essentials

Practice Principles

Fifth Edition

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Dedication

To my colleagues—Over the course of my nursing career, I've had the privilege of working with and interacting with the best and the brightest colleagues in wound care. It has been my honor to be involved in educating, influencing, and shaping the world of wound care. It is exciting that our book will debut in 2020 the "The Year of the Nurse."

To my family—Years have been very good to us. Our families have grown, dealt with sadness, and great change BUT we've had the strength to continue and always remember "family first."

To my much loved, children and grandchildren—You've been the best part of my life. The laughter, smiles, tears, and "out of the mouth of babes" will stay with me forever. Love you, Madison, Lexi, Brek, Lanie, Brooklyn, Morgan, Alia, Tyler, and Taryn. To Jim, Deborah, Jeffrey, JR, and Carissa, thank you for giving me my most beautiful gifts, my grandchildren. May your lives all be filled with new adventures and exciting new chapters.

To my granddaughter and future nurse, Madison—May your career bring you as much joy and happiness as mine did. May you always remember, there is a person attached to every wound.

To my husband, Jim—Thank you for accepting me and supporting my drive, ambition, and career: you are and always will be my perfect partner, husband, father, and grandfather.

With Love, Sharon/Mom and Gramma

"Family is everything, a la famiglia"

This is the motto of my parents, Phyllis and Tony; my brothers, Bob and Ron and their families; and of course me and my family. Now more than ever is this true especially as more and more of my loved ones become a blessed memory.

So, thank you to my families both biological, professional, friends, and patients who have shared their experiences, supported, and nurtured me through this incredible life and skin/wound care journey.

As 2020 is the international year of the nurse and the 200th anniversary of the birth of Florence Nightingale, I want to especially acknowledge all my colleagues from the professional organizations that have enriched my nursing career especially while serving in volunteer positions—National Pressure Injury Advisory Panel (NPIAP), American Professional Wound Care Association (APWCA), Wound Ostomy and Continence Society (WOCN), and the World Council of Enterostomal Therapists (WCET®). In the almost five decades of my nursing career, there are too many of you to mention individually; hopefully I have done a good job of expressing my gratitude and appreciation to you often.

To:

Mom, Dad, Bob, Ron, and their families for the food, laughs, and the smiles

Roberta, who mentored and taught this clinical nurse specialist the skill of writing and editing over 30 years ago

My **"Dream Team"** for having me as part of an extraordinary group of educators, authors, and researchers

Katie, the sister I never had, who taught me the real meaning of unconditional friendship

Sarah, whose joy of music taught me that when words fail, listen to the true meaning of healing

Wendy and Andrei, who give me hope for the future of health care and the promise of tomorrow. I am so proud of you

A. Scott, who brings the art through his paintings, guitar playing, and singing to balance my science. Thank you for your patience while I was busy with "the book." Now let's dance.

Love E.A.A.

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Preface

Tomorrow is the most important thing. … It's perfect when it arrives and it puts itself in our hands. It hopes we've learned something from yesterday." John Wayne, actor

We cannot believe that it is almost 20 years ago that we began writing our book "Wound Care Essentials: Practice Principles." It was a labor of love that we undertook in response to the many requests that our professional colleagues made to us to create a succinct book that combined the essential knowledge, synthesis of the current evidence with the expertise gained from clinical experience. We continue to be grateful to the many people who have let us know the role that our book has played in their initial and continuing professional education. It is always exciting when at a professional conference someone comes up to us showing us the well-used and dog-eared copy of their book. Using educational resources rather than having them sit on a shelf is so important. Many people have a 5-year plan, and while we were not sure back then that there would be future editions, here we are introducing you to this fifth edition.

As our book is publishing in the 200th anniversary of the birth of Florence Nightingale, a global visionary in the management of wounds, we thought it would be a good idea to use one of her important strategies which is reflection. Therefore, we have revisited a chapter we wrote in the first edition entitled "Wound care: Where we were, where we are, where we're going." Ms. Nightingale also strongly believed in evidence base practice and therefore you will find that all chapters have been thoroughly updated with the most current research available to our authors at the time of their chapter writing.

"Wound care: Where we were, where we are, where we're going."

Where we were: One obvious change is terminology. Pressure ulcers are now referred to as pressure injuries and the National Pressure Ulcer Advisory Panel (NPUAP) is now the National Pressure Injury Advisory Panel (NPIAP) along with the European Pressure Ulcer Advisory Panel (EPUAP) and Pan Pacific Pressure Injury Alliance (PPPIA) have released the third edition in November 2019 of the International Pressure Injury Clinical Practice Guideline. Documentation in the chart is now computer-based. Electric medical records are required in all healthcare settings in the United States. Gone are the days (thankfully) of attempting to read orders in cursive.

Where we are: Clinically, the exact turning interval for repositioning people to offload pressure is being researched to see if the old adage of "turn every 2 hours." Is really evidence base. National guidelines now support 4-hour intervals if on an appropriate mattress. The research team of Dr. Nancy Bergstrom continues to provide us new research and insights upon which to base prevention strategies. Some support surfaces/beds and even a wearable device can alert the staff that a patient is not moving and needs to be turned and repositioned. In this edition of our book, you will note that we have included extended information about device-related pressure injuries (MRPI) and mucosal injuries, etiologies of pressure injuries that were not emphasized back then. The newly updated and validated Braden QD risk assessment scale for pediatrics now includes medical devices as one of the factors to be assessed.

Wound care education has changed with shorter more frequent presentations and more and more online and distant education offerings available. Education has become more interactive, case based, global and interprofessional focused. Since many of our devoted readers have told us how much you like the "Show what you know questions," we have increased the number of questions in some chapters as well as the number of photos in our popular Wound Gallery.

Suggested in our original book that minimally invasive surgery would reduce the number of acute incision wounds—which is now true. Robots are part of the surgical team process as new techniques are implemented; some of which have resulted in getting patients out of patients sooner (within hours of surgery). It will be interesting

to see the impact (if any) on post-op patient care needs and/or complications. Truly new ways of thinking have to replace old practices.

Newer dressings continue to emerge and those with less aggressive adhesion have greatly reduced the pain of dressing removal and increased patient comfort. Who ever thought we could "peak" under a dressing to see the wound and then the dressing could be put back in place? Dressings are an important aspect of wound management, but we must also remember that other supportive measures like nutrition, antiseptics, and systemic antibiotics need to be given equal attention.

Technology has come a long way in the past 20 years. We predicted handheld scanning devices to detect stage 1 pressure injuries, and portable ultrasound equipment is now available for such assessments. A new device provides clinicians with visual pictures of the blood flow in the wound after HBOT treatments providing a reliable guide to assess the effectiveness of the treatment. Low cost infrared thermography is now used for early detection of Charcot foot and wound infection in persons with diabetic foot ulcers.

Where we're going: Research may support tissue engineering techniques like stem cells and gene therapy for achieving wound closure. Stem cell-based skin engineering and gene recombination represents an alternative tool we hope to see in our future. Of course, our hope is that with newer prevention options, there will be less wounds that occur and thus less need for newer and advanced treatment options.

Technology will continue to evolve with ever-changing new noninvasive devices to better our assessment skills. So that clinicians can have more time to care for patients rather than spending so much of their time writing care notes, we are still hoping that technology can streamline this process and be more time efficient. We are still wishing that what we asked for in the first edition will come true—that clinicians will speak into their work badge and that then this automatically sends their documentation notes to the patient's electronic medical record. Public policy and reimbursement have and will continue to impact practice. Health economics may govern how we practice, where we practice, and with whom we practice.

What has not changed is the caring for the whole person who has a skin or wound problem. We hope that never will. As Nightingale said, "*To our beginners, good courage, to our dear old workers, peace, fresh courage too, perseverance: for to persevere at the end is as difficult & needs yet better energy than to begin new work*."

To our new colleagues in skin and wound care, welcome, to our old colleagues, thank you for sharing your wisdom, research, and knowledge with us. We deeply appreciate your being part of our skin and wound care journey.

Sharon Baranoski and Elizabeth A. Ayello

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1 Quality of Life and Ethical Issues

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Objectives

After completing this chapter, you'll be able to:

- describe how wounds and those afflicted by wounds are viewed
- identify the impact of quality of life on patients with wounds and their caregivers
- describe the ethical dilemmas confronted in wound care
- identify issues and challenges faced by caregivers of patients with wounds
- describe the strategies aimed at meeting the needs of patients with wounds and their caregivers.

Introduction

Wound healing involves complex biochemical and cellular events. Chronic wounds do not follow a predictable or expected healing pathway, and they may persist for months or years.[1,2] The exact mechanisms that contribute to poor wound healing remain elusive; an intricate interplay of systemic and local factors is likely involved.[3] With an aging population and increased prevalence of chronic diseases, the majority of wounds are becoming recalcitrant to healing, placing a significant burden on the health system and individuals living with wounds and their caregivers. Although complete healing may seem to be the desirable objective for most patients and clinicians, some wounds do not have the potential to heal due to factors such as inadequate vasculature, coexisting medical conditions (terminal disease, end-stage organ failure, and other life-threatening health conditions), and medications that interfere with the healing process.[4] Whether healing is achievable or not, holistic wound care should always include measures that promote comfort and dignity, relieve suffering, and improve quality of life (QoL).

Case Study

Margaret is an 86-year-old woman who resides in a long-term care facility. With progressive dementia over the last 5 years, she has become incontinent and experienced significant weight loss due to poor oral intake. Margaret developed a stage 4 pressure injury (PI) in the sacral area after a recent hospitalization for exacerbation of heart failure. She continues to exhibit symptoms of dyspnea and prefers to sit in a high Fowler position (head of bed above 45 degrees) in bed to help breathing. She gets agitated when she is repositioned, especially

in a side-lying position. Her only daughter is distraught over her mother's agitation, and she wonders if the constant repositioning is necessary. During a family meeting, the daughter asked the following questions regarding her mother's care, "If this is not something she likes, are we doing the right thing for her? Is this quality of life?"

Quality of Life and Person-Centered Concerns

What is quality of life (QoL)? Generally, QoL is defined as a general perception of well-being by an individual. It is a subjective but dynamic construct that is influenced by emotions, beliefs and values, social contexts, and interpersonal relationships, which together account for its variability.[5–7] Health-related quality of life (HRQoL) is a measure intended to capture to the sense of well-being that is specifically affected by health and illness focusing on symptoms and functions, levels of impairment, disabilities, and handicaps,[8] along with other related efforts to promote health, manage disease, and prevent recurrence.[7] HRQoL refers to a subjective appraisal of life that is predicated on the meanings, purposes, expectations, demands, and priorities a person assigned to situations, taking into account of cultural norm, sociopolitical context, and value system. The concept is shaped by person–environment transactions; it is complex, fluid, dynamic involving multiple overlapping dimensions (e.g., biological and physiological factors, symptoms, functioning, general health perceptions, and overall QoL). Each component may carry more importance at a given time based on the context of health and illness. Among people with chronic wounds, there is very little dispute that their QoL is severely diminished.[8–12]

Quality of Life Instruments

There are a number of validated instruments to measure QoL. The generic instruments most commonly used are the Medical Outcomes Study Short Form-36 (SF-36) and adaptations,[13] Research and Development 36-Item Form, Sickness Impact Profile,[14] Quality of Life Ladder,[15] Barthel Index,[16] Nottingham Health Profile,[17] and EuroQol EQ-5D.[18] Specific instruments that are used to evaluate HRQoL for patients with diabetic foot ulcers (DFUs) include the Cardiff Wound Impact Schedule Diabetes,[19,20] Norfolk Quality of Life in Diabetes Peripheral Neuropathy Questionnaire,[21] Neuro-QoL,[22] Manchester–Oxford Foot Questionnaire,[23] Ferrans and Powers Quality of Life Index-Wound Version (FPQLI-WV),[24] and DFU Scale.[25] For the leg ulcer patient population, the Hyland Leg and Foot Ulcer Questionnaire,[26] Charing Cross Venous Leg Ulcer Questionnaire,[27] and Sheffield Preference-Based Venous Leg Ulcer 5D[28] could be considered.[29–31] Despite adequate psychometric properties, most of these instruments are designed for research purposes, and clinical utility for daily use may be questionable. HRQoL is a relative concept; personal perception of life may not reconcile with the measurement of demonstrable ability to complete certain tasks. Arguably, the preponderance of life choices may not be relevant to impoverished environments and certain cultures. In additional, lacking in most tools are items to capture and credit the impact of political economy, social justice, and equity on HRQoL. Lastly, the assumption that all subscales contribute equally to the quality of life can be misleading. It is possible that improvement in one subscale representing one aspect of HRQoL may compromise other domains of HRQoL. For instance, spending money on a new outfit may improve psychological well-being but put undue stress on marital relationship.

Quality of Life and Chronic Wounds

The three major chronic wound types are pressure injuries (PIs), DFUs, and venous leg ulcers. A PI is an area of skin breakdown due to prolonged exposure to pressure and shear leading to tissue ischemia and cell death. Despite intensive efforts to prevent their occurrence, PIs remain a significant problem across the continuum of healthcare services; prevalence and incidence estimates range from 0.32% to over 47.4% depending on the setting of care, geographical locations, and methods to collect data.[32–40] PIs are linked to a number of adverse patient outcomes including prolonged hospital stay, decline in physical functioning, and death. In fact, patients with a PI have been reported to have a 3.6-fold increased risk of dying within 21 months, as compared with those without a PI.[41]

Gorecki and colleagues[41] reviewed and summarized 31 studies (10 qualitative and 21 quantitative) that examined issues related to QoL in people with PIs. Common concerns and salient issues were synthesized and categorized into the following themes:

1. Physical restrictions resulting in lifestyle changes and the need for environmental adaptations
2. Social isolation and restricted social life
3. Negative emotions and psychological responses to changes in body image, self-concept, and loss of independence
4. PI symptoms: management of pain, odor, and wound exudate
5. Health deterioration caused by PI
6. Burden on others
7. Financial hardship
8. Wound dressings, treatment, and other interventions
9. Interaction with healthcare providers
10. Perception of the cause of PI
11. Need for education about PI development, treatment, and prevention

Diabetes is one of the leading chronic diseases worldwide.[42] Persons with diabetes have a 25% lifetime risk of developing foot ulcers that precede over 80% of lower extremity amputations in this patient population.[43–48] The 5-year mortality rates have been reported to be as high as 55% and 74% for new-onset DFUs and after amputation, respectively; the number of deaths surpasses that associated with prostate cancer, breast cancer, or Hodgkin's disease.[48–50] Individuals with unhealed DFUs share some unique challenges. Due to problems using the foot and ankle, patients with foot ulcers suffer from poor mobility limiting their ability to participate in physical activities.[51–53] Mobility issues may also interfere with their performance at work resulting in loss of employment and financial hardship. Increased dependence can lead to caregiver stress and unresolved family tension. High levels of anxiety, depression, and psychological maladjustment may affect patients' abilities to participate in self-management and foot care.[53,54]

Increasing attention is placed on stigma that is experienced and internalized by individuals through interactions with other people in the workplace, healthcare facilities, and educational institutions, even in close interpersonal relationships. Stigma is a complex social construct, and it refers to negative characteristics and stereotypes that are often experienced by individuals with diabetes.[31] Especially for people with foot ulcers, they are labeled as "noncompliant" and blamed for allowing ulcers to develop due to their lack of self-control, willpower, and competence to make healthy choices. Internalization of stigma may lead to feelings of failure, embarrassment, disempowerment, low self-efficacy, and fear of being judged and prevent people from seeking help, discussing their difficulties openly, and following treatment recommendations (such as using prescription footwear and orthotics). Yet, the impact of self-stigma on people with diabetes and their abilities to participate in self-management remains underrecognized and underexplored. It is crucial that self-stigma be addressed in this population to avoid the vicious cycle of self-stigma, demoralization, and disengagement from disease management.

It is estimated that approximately 1.5 to 3.0 per 1,000 adults in North America have active leg ulcers, and the prevalence continues to increase due to an aging population, sedentary lifestyle, and the growing prevalence of obesity.[55–58] Chronic leg ulcers involve an array of pathologies: 60% to 70% of all cases are related to venous disease, 10% due to arterial insufficiency, and 20% to 30% due to a combination of both.[59,60] Although venous leg ulcers are more common in the elderly, 22% of individuals develop their first ulcer by age 40 and 13% before age 30, hindering their ability to work and participate in social activities.[61] To understand the experience of living with leg ulceration, Briggs et al.[62] reviewed findings from 12 qualitative studies. Results were synthesized into five categories, similar to those identified above in individuals with PIs:

1. Physical effects including pain, odor, itch, leakage, and infection
2. Understanding and learning to provide care for leg ulcers
3. The benefits and disappointment in a patient–professional relationship
4. Social, physical, and financial cost of a leg ulcer
5. Psychological impact and difficult emotions (fear, anger, anxiety)

In two other reviews examining the impact of wounds on QoL, a total of 22[29] and 24 studies[63] were identified. Both qualitative and quantitative studies were included in the reviews. Pain was identified as the most common and disabling symptom leading to problems with mobility, sleep disorders, and loss of employment. Other symptoms associated with leg ulcers, including pruritus, swelling, discharge, and odor, are equally distressing but often overlooked by caregivers. In the studies, patients discussed the impact of leg ulcerations on their ability to work, carry out housework, perform personal hygiene, and participate in social/recreational activities. Patients report feeling depressed, powerless, being controlled by the ulcer, and ashamed of their body. Efforts were taken to conceal the bandages/dressings with clothing or shoes; however, the latter were often considered less attractive than what would normally be worn. Both reviews identified the need to address patient engagement and patient knowledge deficits to promote treatment adherence.[29,63–69] However, others are critical of this approach as the challenges of living with a chronic condition are increasingly recognized as constraining patients' ability to make informed decisions about their care. This is further compounded by the challenge patients face when expected to follow conflicting "best practice" advice from professionals dealing with different aspects of the patient's health. Approaches wherein solutions depend on educating patient to make behavior changes have been shown to increase the potential for patients to be labeled as disruptive/noncompliant and to receive suboptimal care.

Chronic Wound–Related Quality of Life (CW-QOL) Framework

Based on analysis of the interviews from a descriptive qualitative study that was designed to explore patients' and clinicians' perceptions and experiences of wound care, common themes were identified to create a conceptual framework for the concept of QoL as it relates to patients with chronic wounds (Fig. 1-1). Included in the framework are two concentric circles and a center representing the individual coping with a chronic wound. The outer circle represents the social, political, and healthcare systems within which QoL is realized and lived. The inner circle outlines six key stressors encountered by people living with chronic wounds:

1. Wound status and treatment
2. Pain and other wound-related symptoms
3. Function status and mobility
4. Emotions and psychological state
5. Financial resources and cost
6. Social relationships

Encumbered by increased disability and exacerbation of symptoms, patients identify a need to curtail regular recreational, social, and physical activities, and they struggle with becoming increasingly dependent on others for help. To improve patients' QoL, this paradigm places greater emphasis on the need to foster a climate that supports patient engagement as appropriate, accompanied by mindful scanning of the environment and health resource mapping. Collaborative care is the cornerstone of chronic disease self-management to help patients master problem-solving skills; the objective is for patients to experience the best possible quality of life. Individualized wound care plans that address specific patient-centered concerns are most likely to succeed and promote the best outcomes for the patient with a wound.

Person Coping with a Chronic Wound

People who are living with chronic wounds describe the experience as isolating, debilitating, depressing, and worrisome, all of which contribute to high levels of stress. Stress has a direct impact on QoL. Lazarus and Folkman[70] postulated that stress is derived from cognitive appraisals of whether a situation is perceived as a threat to one's well-being and whether coping resources that can be marshaled are sufficient to mitigate the stressor. Stress appraisal is constructed when the demands of a situation outstrip perceived coping resources.[70] While no one is immune to stress, the impact of a chronic wound on individual's perception of well-being and QoL depends on personal meanings and values that are assigned to the demands that arise from living with a chronic wound. Coping is less adaptive or effective if people lack self-esteem, motivation, and the conviction that they have the aptitude to solve a problem.[71] Woo[71] evaluated the relationship

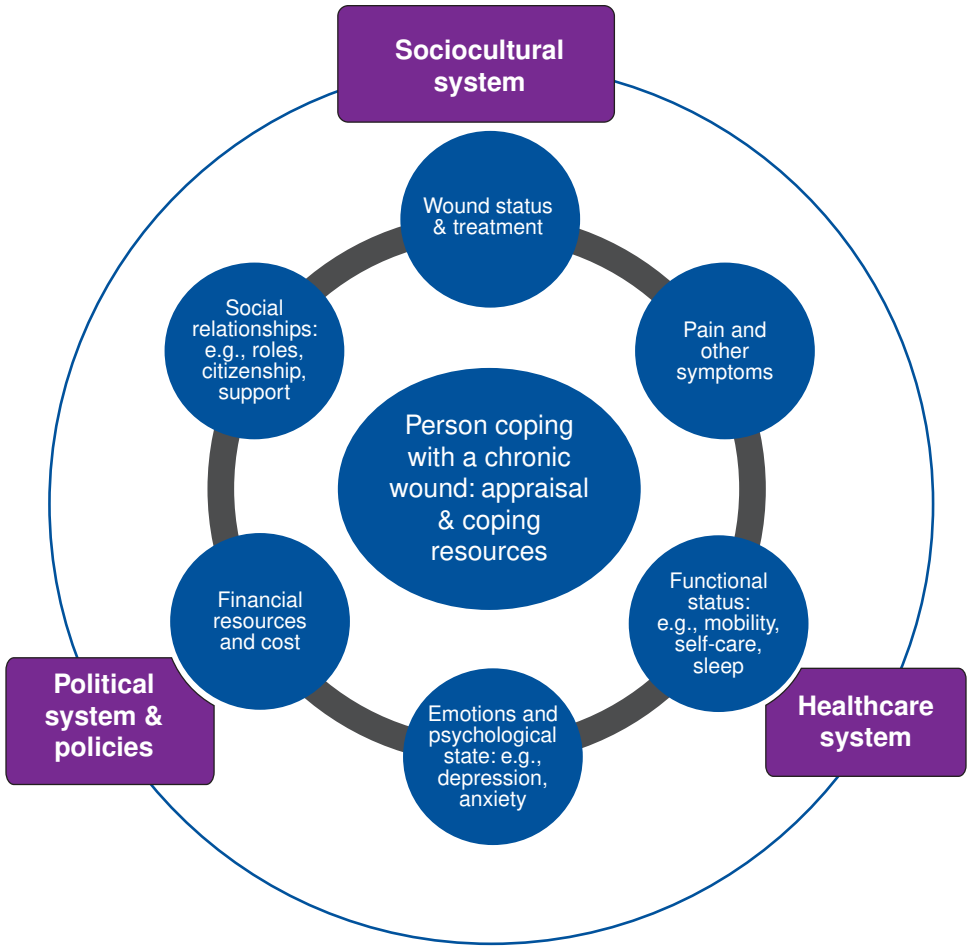

Figure 1-1 Chronic wound–related quality of life (CW-QoL) framework. (Copyright © 2014 KY Woo.)

between self-perception and emotional reaction to stress in a sample of chronic wound patients. Findings suggest that people who are insecure about themselves tend to anticipate more wound-related pain and anxiety.

Chronic Stress Is Not Innocuous

Stress triggers a cascade of physiological responses featured by the activation of the hypothalamic–pituitary–adrenal axis that produces vasopressin and glucocorticoid (cortisol).[72] Vasopressin is known for its property to induce vasoconstriction that could potentially be harmful to normal wound healing by compromising the delivery of oxygen and nutrients. Cortisol attenuates the immunoinflammatory response to stress. Excessive cortisol has been demonstrated to suppress cellular differentiation and proliferation, inhibit the regeneration of endothelial cells, and delay collagen synthesis. The body of scientific evidence that substantiates the deleterious impact of protracted stress on wound healing is convincing.[73–75] In one study, Ebrecht et al.[76] evaluated healing of acute wounds created by dermal biopsy among 24 healthy volunteers. Stress levels reported by the participants via the Perceived Stress Scale were negatively correlated to wound healing rates 7 days after the biopsy ($P < 0.05$). Subjects exhibiting slow healing (below median

healing rate) rated higher levels of stress during the study ($P < 0.05$) and presented higher cortisol levels 1 day after biopsy than did the fast-healing group ($P < 0.01$). Kiecolt-Glaser and colleagues[77] compared wound healing in 13 older women (mean age = 62.3 years) who were stressed from providing care for their relatives with Alzheimer disease, and 13 controls matched for age (mean age = 60.4 years). Time to achieve complete wound closure was increased by 24% or 9 days longer in the stressed caregiver versus control groups ($P < 0.05$).

Cognitive–behavioral strategies and similar psychosocial interventions are designed to help people reformulate their stress appraisal and regain a sense of control over their life's problem within an empathic and trusting milieu. Ismail et al.[78] identified 25 trials that utilized various psychological interventions (e.g., problem-solving, contract setting, goal setting, self-monitoring of behaviors) to improve diabetic self-management. Patients allocated to psychological therapies demonstrated improvement in hemoglobin A1c (12 trials, standardized effect size = −0.32; −0.57 to −0.07) and reduction of psychological distress including depression and anxiety (5 trials, standardized effect size = −0.5; −0.95 to −0.20).

Simple problem-solving technique is easy to execute and provides a step-by-step and logical approach to help patients identify their primary problem, generate solutions, and develop feasible solutions. The key sequential steps are[79]:

1. explanation of the treatment and its rationale
2. clarification and definition of the problems
3. choice of achievable goals
4. generation of alternative solutions
5. selection of a preferred solution
6. clarification of the necessary steps to implement the solution
7. evaluation of progress.

Wound Status and Management

The trajectory for wound healing is often tortuous and unpredictable, punctuated by wound deterioration, recurrence, and other complications. Despite appropriate management and exact adherence to instructions, there is no guarantee that healing will occur. The following quotes are some of the narratives that patients voiced to convey their worry, frustration, and feeling of powerlessness.

> "The wound doctor asked me to use this dressing, but the wound is not getting better. I don't know what else to do?"[80]
> "The wound is getting bigger, and now I am getting an infection; I don't know why this is happening to me?"[80]

Even when best practice is implemented, some treatment options are not feasible and they are not conducive to enhance patients' QoL, for example, a patient with foot ulcers who cannot use a total contact cast because he needs to wear protective footwear at work and he cannot maintain his balance walking on a cast, a patient with venous leg ulcer who likes to take a shower every day to maintain personal hygiene but cannot do so because she needs to wear compression bandages, or a patient with a PI who refused an air mattress because it generates too much noise that interferes with sleep. While turning patients every 2 to 4 hours has been recommended, repositioning can be painful, especially among patients who have significant contractures, increased muscle spasticity, and spasms. Among critically ill individuals, repositioning may precipitate vascular collapse or exacerbate shortness of breath (as with, e.g., advanced heart failure).[81] According to the study of hospitalized patients with PIs,[82] it was surprising for investigators to learn that even assuming a side-lying position could be uncomfortable. Briggs and Closs[83] indicated that only 56% of patients in their study were able to tolerate full compression bandaging, with pain being the most common reason for nonadherence. Similarly, patients' adherence to wearing compression stocking as a prophylactic measure to preempt ulceration is poor.[84] Patients should be informed of various treatment options and be empowered to be active participants in care decisions. Being an active participant involves taking part in the decision-making for the most appropriate treatment, monitoring response to treatment, and communicating concerns to healthcare providers.

When circulation is diverted from the skin to maintain hemodynamic stability and normal functioning of vital organs, skin damage is inevitable. For this reason, it is important that all

involved recognize that, despite the best efforts to mitigate skin damage, in certain situations wounds are not always avoidable. Much discussion in the qualitative literature has focused on patients' lack of knowledge about how chronic wounds develop as an issue to be resolved.[29,62] As a reminder, patients, especially those dealing with the challenges of chronic disease, may lack the cognitive ability to recognize factors contributing to their chronic wounds. As self-care practices become the new norm in health care, many in this population continue to rely heavily on healthcare practitioners (HCPs) for information, advice, and support related to treatment strategies to improve their conditions.[85] By providing information about how chronic wounds are largely preventable but not always avoidable, HCP can assist patients and their families to make informed choices and reduce feelings of guilt or blame that are often associated with wound development.

Complications such as wound infection are common but upsetting. According to an analysis of an extensive database comprising approximately 185,000 patients attending family medical practitioners in Wales, 60% of patients with chronic wounds had received at least one antibiotic in a 6-month period for the treatment of wound infection.[86] Bacteria compete for nutrients and oxygen that are essential for wound healing activities, and they stimulate the overproduction of proteases leading to degradation of extracellular matrix and growth factors.[87–89] Among patients with DFUs, wound infection is one of the major risk factors that precede amputations. Surgical site infection has been linked to prolonged hospitalization and high mortality.[90,91] In fact, the mortality rate has been reported to be over 50% in patients with bacteremia secondary to uncontrolled infection in PIs.[86,92] Receiving a diagnosis of an infection is anxiety provoking; patients often fear that infection is the beginning of a downward vicious cycle leading to hospitalization, limb amputation, and death. The need to align expectations and dispel misconceptions cannot be underestimated.

Pain and Other Symptoms

Wound-associated pain continues to be a common yet devastating symptom, often described as one of the worst aspects of living with chronic wounds.[93,94] Sleep disturbance, immobility, poor appetite, and depression are some of the consequences of unremitting pain. In an international survey of 2018 people with chronic wounds, over 60% of the respondents reported the experience of pain "quite often" and "all the time."[95] In a survey of 287 patients with PIs, McGinnis et al.[96] reported that 75.6% of patients with stage 1 PI experienced pain with the sacrum, buttocks, and heels being the most vulnerable and painful; the mean pain intensity was 6.4 (SD 2.53) and the median 7.0 on a 10-point pain scale. Of people with venous leg ulcers, the majority experienced moderate to severe levels of pain described as aching, stabbing, sharp, tender, and tiring.[94,97,98] Pain has been documented to persist up to at least 3 months after wound closure. Contrary to the commonly held belief that most patients with DFUs do not experience pain due to neuropathy, up to 50% of patients experience painful symptoms at rest, and approximately 40% experience moderate to extreme pain climbing stairs or walking on uneven surfaces.[99,100] Patients with diabetes who report pain most or all of the time had statistically and clinically significant poorer HRQoL than those who did not report pain.[52,101,102] However, pain in diabetes is often underestimated and undertreated. The need to improve pain assessment and management is incontestable. Pharmacotherapy continues to be the mainstay for pain management. Appropriate agents are selected based on severity and specific types of pain (see Chapter 12, Pain Management and Wounds).

Pruritus

Pruritus is another frequent complaint among people with chronic wounds. Of 199 people with chronic wounds who were surveyed, Paul et al.[103,104] documented that 28.1% complained of itch. Peripheral pruritus is often triggered by pruritogens (e.g., histamine, serotonin, cytokines, and opioids), giving rise to signals that are transmitted via pain-related neuronal pathways and terminated in somatosensory cortex where the sensation of itch is perceived.[105,106] In contrast, central pruritus is associated with psychiatric disorders or damages to the nervous system mediated through opioid and serotonin receptors. For patients with wounds, itch is commonly caused by peripheral stimulation of itch receptors

due to irritation of the skin and related dermatitis.[107] People with chronic wounds are exposed to a plethora of potential contact irritants accounting for approximately 80% of all cases of contact dermatitis and 20% of allergic dermatitis.[108] Excessive washing and bathing strip away surface lipid and induce dryness that can exacerbate pruritus.[109] To replenish skin moisture, humectants or lubricants should be used on a regular basis. Drug treatment with paroxetine, a selective serotonin reuptake inhibitor, and gabapentin has been shown to be beneficial in palliative care patients.[110]

Odor

Probst interviewed people with fungating breast wounds, and odor was highlighted as one of the most distressing symptoms that compromised their QoL.[111–114] Patients with DFU who were also working reported higher rates of odor, suggesting that the negative effects may be amplified in social situations.[115] Unpleasant odor and putrid discharge are associated with increased bacterial burden, particularly involving anaerobic and certain gram-negative (e.g., *Pseudomonas*) organisms. Metabolic by-products that produce this odor include volatile fatty acids (propionic, butyric, valeric, isobutyric, and isovaleric acids), volatile sulfur compounds, putrescine, and cadaverine.[105] To manage wound odor, topical charcoal-based dressings and antimicrobial and antiseptic agents are recommended.[116,117]

Exudate

Wound exudate contains endogenous protein-degrading enzymes, known as proteases or proteinases that are extremely corrosive and damaging to intact skin.[118,119] When drainage volume exceeds the fluid handling capacity of a dressing, enzyme-rich and caustic exudate may spill over the wound margins, causing maceration or tissue erosion (loss of part of the epidermis but maintaining an epidermal base) and pain.[120–122] Leakage of highly exudative wounds onto clothing, furniture, and bed linens can lead to feelings of embarrassment and inhibited sexuality and intimacy.[119,123,124] In conjunction with a thorough assessment to identify causes and remedies for excessive exudate, careful selection of discreet absorbent dressings (avoid bulky materials) will improve patients' QoL.[125,126]

Functional Status

According to the International Classification of Functioning, Disability and Health of the World Health Organization, disability refers to impairments, activity limitations, and participation restrictions because of the interaction between a health condition and other physical, social, mental, or emotional factors.[127] The majority of patients with chronic wounds suffer mobility problems, and their ability to perform activities of daily living is limited.[60,128] Activities often taken for granted by the general population, such as taking a shower, getting dressed, and even walking up the stairs, could become an enormous challenge for people with chronic wounds.[129] A study by Hyland et al.[26] revealed that of 50 patients with leg ulcers, 50% had problems getting on and off a bus and 30% had trouble climbing steps. Due to increased disability in the populations, the number of patients dependent on others for help is increasing. Requesting and receiving assistance could be a hassle and embarrassment, especially if the patient lives alone and needs regular help. Easy access to transportation and changes to living arrangements (such as widening doors for a wheelchair) will enhance individual's ability to function independently, but the effort to organize and execute the plan could be daunting.[81]

Emotional and Psychological State

People with chronic wounds tend to experience more emotional problems than people without wounds in the community and are less capable to cope with stressful events.[130] HCPs (n = 908), in responding to a Web-based survey, acknowledged that mental health issues are common in people with chronic wounds. Over 60% of the survey respondents indicated that between 25% and 50% of people with chronic wounds suffer from mental disorders.[131] Among all the symptoms, anxiety was rated the most common (81.5%). These results are consistent with findings from a pilot study in which over 60% of people living with chronic wounds expressed higher-than-average anxiety.[132]

Financial and Cost

Financial expenditures related to nonhealing wound care place a significant burden on the health system.[133] Patients with chronic wounds are often unemployed, marginalized, and isolated. In a study of 21 patients with DFUs by Ashford et al.[134] 79% of patients reported an inability to maintain employment secondary to decreased mobility and fear of someone inadvertently treading on their affected foot. In one study, 66 patients between 18 and 65 years old, with or at high risk to develop DFU, were asked about work-related issues. Over two-thirds (67.4%) of the respondents were not able to work due to disability, 63.6% expressed difficulty performing their duties at work that required prolonged standing or walking, and 21.2% reported leaving their jobs due to diabetic foot disease.[135]

Beyond occupational stressors and dilemmas, patients may incur additional out-of-pocket expenses for transportation, parking, telephone bills for medical follow-up, home health aide services, dressing supplies not covered by insurance, and drug costs if they have no prescription plan. Those who have no insurance but don't qualify for public assistance may be forced to tap into their savings or refinance their homes. Healthcare professionals, rather than simply dismissing patients as nonadherent, should show empathy, acknowledging access and financial hardships faced by patients, and partner with their patients in addressing these issues.[136,137]

Social Relationships and Role Function

Feeling embarrassed about the repugnant smell and fluid leakage from wounds and their bodies, people with chronic wounds may intentionally avoid social contacts and activities. Patients often feel detached and emotionally distant from their friends and families, rendering it difficult to maintain meaningful friendship and romantic relationships. Patients with chronic wounds are frequently isolated and lack social support. The concept of social support refers to an interactive process that entails perceived availability of help or support actually received. In a study of 67 patients with venous leg ulcers, Edwards and coinvestigators[138] evaluated the impact of a community model of care on QoL. Subjects were randomized to receive individual home visits from community nurses (the control group) or to pay a weekly visit to a nurse-managed leg club (the intervention group). Leg clubs offer a setting where the subjects can obtain advice/information to manage their ulcers through social interaction with expert nurses as well as with their peers. Subjects who attended the leg club expressed significant improvement in QoL ($P < 0.014$), morale ($P < 0.001$), self-esteem ($P = 0.006$), pain ($P = 0.003$), and functional ability ($P = 0.004$).

The notion that social media could be leveraged to provide virtual social support is gaining popularity. Social media encompasses a variety of platforms that provide opportunities for multiple users to exchange experiences and information and to provide support through multisensory communication. According to a 2011 survey, 80% of adult Internet users searched online and 62% used social media to obtain health information.[139] Of all the posted messages and dialogues that were abstracted from 15 Facebook groups focused on diabetes management, almost 30% of the content was related to the exchange of emotional support among members of a virtual community.[140] In one study that evaluated an online diabetes self-management program,[141] individuals randomized to the program exhibited a significant improvement in blood sugar control (A1c level), self-reported knowledge/skill, and self-efficacy compared with those who received usual care. However, the actual participation in household activities, recreation, and exercise was not different between the two study groups. Nicholas et al.[142] designed an online module to educate and provide support to adolescents with diabetes. Participants who were randomized to the treatment group received eight online information modules and participated in peer-to-peer online dialogue that was moderated by a social worker specialized in diabetes care. Perceived social support was rated higher in the treatment group compared to the control group, but the result was not significant given the small sample size ($n = 31$).

Healthcare System

Navigating through the healthcare system could be extremely confusing. A trusting and therapeutic relationship between patients and their healthcare providers may serve to buffer the effects of adversity and stress. However, patients sometimes criticize about feeling rushed and spending limited time during routine visits at wound care clinic. Patients discussed the importance of having healthcare providers who care and display a genuine interest in their well-being. In their description of the key attributes of someone who cares, patients use terms like "caring," "holistic," "friendly," being "vigilant," "cheerful," "gentle," and "knowledgeable." Healthcare providers should provide clear and consistent communication, to avoid confusion.

Sociocultural System

A recurring theme emerged from the literature that articulated the bleak feeling of isolation due to wound-related stigma. Given the negative image by which wounds are viewed (Table 1-1), it isn't surprising that patients with wounds are sometimes considered unattractive, imperfect, vulnerable, a nuisance to others, and, in some cases, even repulsive.[143,144]

Table 1-1 Emotional Impact of Wounds

In addition to the morbidity associated with wounds and the physical discomfort, wounds have an inherent emotional effect on the patient, caregivers, family, friends, and strangers the patient may encounter. Even healthcare professionals aren't immune to an emotional response to a patient's wound.
Wounds are typically perceived as: • a betrayal of one's own body • appalling, disgusting, and repulsive • haunting, scary, and associated with horror movies • nuisance, time-consuming, and costly • smelly, dirty, and disgusting • unpleasant and uncomfortable. • The patient's own perception of his/her wound may include such feelings as: • embarrassment and humiliation • guilt and shame • needing bandages to "hide the evidence" (i.e., of imperfection).

This can dramatically affect a patient's emotional response to their wound and their self-esteem. For patients who must endure the displeasing stares of others to their bandaged wounds, a wound clinic may be the only place where they can receive positive energy and reinforcement.[145,146]

Political System and Policies

Health policy refers to plans, processes/structures, and actions that are established to achieve specific healthcare goals within a society. Priority setting to optimize health service delivery should include easy access to resources, appropriate funding/reimbursement mechanisms, communication strategies, and sustainable training for staff. Pressure redistribution and downloading is critical for the management of foot ulcers by removing pressure and preventing recurrent injury to the affected areas. However, these devices are expensive and may require ongoing modification by a trained professional such as a podiatrist or chiropodist. Diabetic neurotrophic ulcers may have the potential to heal but fail because downloading is not optimized. Similarly, compression therapies are used to treat venous leg ulcers. However, in most countries, there is no additional funding or reimbursement program to cover the cost for podiatric/chiropody services and the purchase of therapeutic footwear/stockings.

Conclusion

Provision of wound care requires a systematized and holistic approach to address comorbid conditions and psychosocial issues and expertise that extends beyond local wound care and dressing selection. A well-coordinated and interprofessional team approach is integral to the delivery of high-performance and evidence-based wound care services. Management of these ulcers involves a detailed examination and discussion with patients to adequately address their concerns. Although traditional educational interventions to improve knowledge are necessary, they are rarely sufficient to change behaviors. Emerging evidence highlights a need to shift the chronic disease management paradigm to focus on patient engagement and self-management (Fig. 1-2).

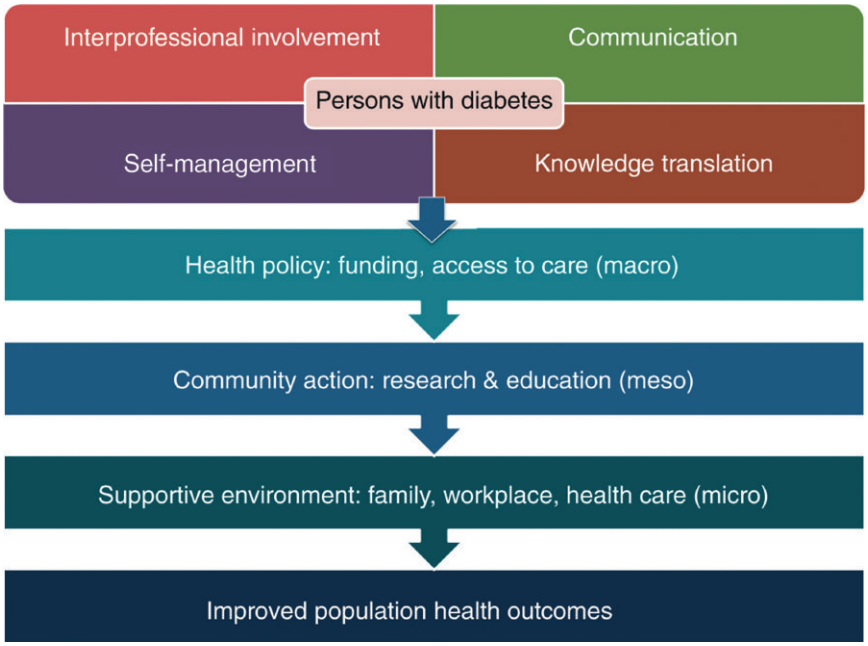

Figure 1-2 Multilevel chronic disease self-management model. (Copyright © 2014 KY Woo.)

Show What You Know

1. **Those afflicted with wounds are often viewed as:**
   A. pleasant and comfortable.
   B. pain-free.
   C. appalling and repulsive.
   D. attractive.

2. **Wound assessment is commonly lacking in the area of:**
   A. size.
   B. odor.
   C. drainage.
   D. pain.

3. **Quality-of-life treatment decisions should be based on the:**
   A. patient's perception of well-being.
   B. nurses' perceptions of well-being.
   C. family's perception of well-being.
   D. physicians' perceptions of well-being.

4. **Impact of chronic wound healing and the individual's perception of well-being includes:**
   A. stress appraisal.
   B. motivation.
   C. coping resources.
   D. all of the above.

Answers to these questions are found on page 681.

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2 Reimbursement Regulations Impacting Wound Care

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Objectives

After completing this chapter, you will be able to:

- discuss the significance of the U.S. Centers for Medicare and Medicaid Services
- discuss reimbursement issues related to hospitals, skilled nursing facilities, and home health agencies
- identify quality improvement efforts
- describe essential wound documentation required for reimbursement in the United States.

Chapter Overview

Reimbursement regulations in wound care as in any other sector of health care can be quite complex. This chapter is organized into five major sections, which are as follows: role of regulations in health care, government payers in wound care, principles of wound care reimbursement, wound care in different practice settings, and quality assessment and improvement issues.

Role of Regulation in Health Care

Regulations are a pervasive feature of the American healthcare system and, not surprisingly, significantly impact the delivery of wound care. Quite often, regulations and reimbursement determine who receives wound care and the level of wound care that is delivered. Thus, if clinicians are to provide optimum care, it is essential for them to have knowledge about the regulations that impact wound care in their specific practice setting.

Although many clinicians may view the current regulatory environment as burdensome and unnecessary, it's essential to recognize the important purpose that regulations fulfill. Healthcare regulations and standards are necessary to ensure compliance and to provide safe health care to every individual who accesses the system. The healthcare regulatory agencies in turn monitor practitioners and facilities, provide information about industry changes, promote safety, and ensure legal compliance and quality services.

Federal, state, and local regulatory agencies often establish rules and regulations for the healthcare industry, and their oversight is mandatory. Some other agencies, such as those for accreditation, require voluntary participation but

are still important because they provide rankings or certification of quality and serve as additional oversight, ensuring that healthcare organizations promote and provide quality care.

In the case of wound care, the goal of current regulations is to ensure access to high-quality wound care, particularly for vulnerable populations such as the elderly and nursing home residents. As healthcare expenses continue to grow, wound care regulations also increasingly focus on limiting costs. Balancing the need to ensure quality while limiting costs can often be challenging.

Regulations are promoted at all levels of the government including federal, state, and local agencies. Additionally, nongovernment organizations such as accrediting bodies are responsible for the regulatory environment in which clinicians practice.

There are many types of regulatory vehicles available to the government to help achieve this goal. Government regulations may involve entry restrictions such as licensure and accreditations that seek to limit the ability to offer a particular service; they could use different payment methodologies that determine reimbursements for care provided; or they could involve quality controls that seek to improve the care that is provided.

There are many payers that reimburse for wound care such as those who are private, health plans (i.e., UnitedHealthcare, Aetna, Blue Cross/Blue Shield), unions, and employers, and those who are public (i.e., the Department of Veterans Affairs, Tricare). However, in this chapter, our focus is on the government payers in wound care. The major regulatory agency involved in wound care in the United States is the Centers for Medicare and Medicaid Services (CMS). In addition, we include an overview of how wound care is covered, coded, and reimbursed by CMS and its contractors; the different reimbursement scenarios depending on the clinicians' practice settings; and a description of the agency's efforts in improving the quality of wound care. Through these efforts, CMS aims to improve health and health care while also making care more affordable.

General Information on Government Payers in Wound Care

Centers for Medicare and Medicaid Services

CMS is a federal agency within the U.S. Department of Health and Human Services. Prior to July 1, 2001, it was called the Health Care Financing Administration (HCFA). CMS administers the Medicare and Medicaid programs. Moreover, because CMS provides the states with at least 50% of their finances for healthcare costs, the states must comply with federal regulations.

The difference is that while both the Medicare and Medicaid programs are administered through federal statutes that determine beneficiary requirements, what is covered, payment fees and schedules, and survey processes of clinical settings (such as skilled nursing facilities [SNFs] or home health agencies [HHAs]) are determined by their respective programs. Both programs have a wide variance on coverage, eligibility, and payment fees and schedules. Therefore, it's important for the clinician to know what's covered and the level of reimbursement prior to developing a treatment plan with the patient. Because CMS remains the largest health insurance agency, many private insurance companies will provide coverage at similar levels.

Medicare

The Medicare program was developed in 1965 by the federal government.[1] In order to qualify for Medicare benefits, a person must be age 65 or older, have approved disabilities if under age 65, or have end-stage renal disease.

In 2017, Medicare provided coverage to more than 55.7 million people[2], spending $705.9 billion on benefits.[3] These benefit payments are funded from two trust funds—the Hospital Insurance (HI) Trust Fund and the Supplementary Medical Insurance (SMI) Trust Fund. Most often, these are referred to as Medicare Part A and Medicare Part B, respectively.[4]

The HI Trust Fund pays for a portion of the costs of inpatient hospital services and related care. Those services include critical access hospitals (small facilities that give limited outpatient and inpatient services to people in rural areas), SNFs, hospice care, and some home healthcare services. The HI Trust Fund is financed primarily through payroll taxes, plus a relatively small amount of interest, income taxes on Social Security benefits, and other revenues.

The SMI Trust Fund pays for a portion of the costs of physicians' services, outpatient hospital services, and other related medical and health services. As of 2019, the premium for Medicare Part B is $135.50 per month.[5] In some cases, this amount may be higher if the person doesn't choose Medicare Part B when he or she

first becomes eligible at age 65 or if the person files taxes greater than $85,000 as an individual or $170,000 as part of a couple. In addition, as of January 2006, the SMI Trust Fund pays for private prescription drug insurance plans to provide drug coverage under Part D of the program. The separate Part B and Part D accounts in the SMI Trust Fund are financed through general revenues, beneficiary premiums, interest income, and, in the case of Part D, special payments from the states.

The Medicare+Choice program was authorized by the Balanced Budget Act of 1997.[6] In this program, beneficiaries have the traditional Medicare Part A and Part B benefits, but they may also select Medicare managed care plans (such as health maintenance organizations [HMOs], preferred provider organizations [PPOs], or private fee-for-service [FFS] plans). Medicare+Choice plans provide care under contract to Medicare. They may provide benefits such as coordination of care or reducing out-of-pocket expenses. Some plans may also offer additional benefits, such as prescription drugs.

Prescription drug benefits are available for all Medicare beneficiaries regardless of income, health status, or prescription drug use[6] through Medicare Part D. A range of plans are available, so beneficiaries have multiple options for coverage. Moreover, persons can add drug coverage to the traditional Medicare plan through a "stand-alone" prescription drug plan or through a Medicare Advantage plan, which includes an HMO or PPO and typically provides more benefits at a significantly lower cost through a network of doctors and hospitals. Presently, no wound care products are covered under this benefit.

Medicaid

The Medicaid program was developed in 1965 as a jointly funded cooperative venture between the federal and state governments to assist states in the provision of adequate medical care to eligible people.[1] Medicaid is the largest program providing medical and health-related services to America's poorest people. Within broad national guidelines provided by the federal government, each of the states:

- administers its own program
- determines the type, amount, duration, and scope of services
- establishes its own eligibility standards
- sets the rate of payment for services
- determines what products are covered in that state.

Thus, the Medicaid program varies considerably from state to state as well as within each state over time. This wide variance also affects what is covered in wound care. For example, the number of times debridement of a wound is reimbursed differs by state, as do product treatment options.

Managed Care Organizations

Managed care organizations (MCOs) were developed to provide health services while controlling costs. They combine the responsibility for paying for a defined set of health services with an active program to control the costs associated with providing those services, while at the same time attempting to control the quality of and access to those services. The health benefits, which usually range from acute care services to dental and vision coverage, are usually clearly identified, as are the payment, copayment, and deductibles that are required for a specific health procedure (e.g., compression therapy for chronic venous insufficiency ulcer). Moreover, the MCO usually receives a fixed sum of money to pay for the benefits in the plans for the defined population of enrollees. Typically, this fixed sum is constructed through premiums paid by the enrollees, capitation payments made on behalf of the enrollees from a third party, or both. There are wide variations in MCOs and the services they provide for patients with wounds.

Economic Impact of Chronic Wounds in the Medicare Program

Chronic nonhealing wounds are a major contributor to the Medicare budget. A study, *An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds*,[7] published in the 2018 *Value in Health* journal demonstrates this impact in Medicare patients. The study analyzed the Medicare 5% Limited Data Set for calendar year 2014 and determined that chronic nonhealing wounds impact nearly 15% (8.2 million) of Medicare beneficiaries, far more than suggested by previous studies. Furthermore, conservative estimates for total Medicare annual spending for all wound types ranged from

$28.1 billion to $31.7 billion. Treatment and management of infected or reopened (dehisced) surgical wounds account for the highest per wound costs. Hospital outpatient care drove the highest site-of-service costs, demonstrating the shift from hospital inpatient to outpatient services in the wound care space.

Practice Point

Infected or dehisced surgical wounds treatment account for the highest per wound costs in the United States.

The findings highlight the need for federal research funding, quality measures, and reimbursement models that are relevant to wound care. Such measures are not currently included under the Centers for Medicare and Medicaid Services (CMS) payment policies, including the Medicare Access and CHIP Reauthorization Act (MACRA).

In addition, the documentation of the specific, significant burden of chronic wounds in the Medicare population illustrates the need for CMS and health policy makers to include wound-relevant quality measures in all care settings as well as develop episode of care measures, chronic care models, and reimbursement models to drive better health outcomes and smarter spending in the wound care space.

General Wound Care Reimbursement Principles

Reimbursement directly impacts how clinicians deliver care. Increasingly, payers (Medicare, Medicaid, HMOs) are examining where their money is going and whether they are getting the most from providers on behalf of their beneficiaries. Thus, payers are requiring more documentation regarding patient outcomes to justify payment. Clinicians who can document comprehensive and accurate assessments of wounds and the outcomes of their interventions are in a stronger position to obtain and maintain coverage and thus reimbursement.

Evidence-based wound care should always be the goal of clinicians. However, clinicians are increasingly being challenged to provide optimum wound care based on healthcare setting and payers.

Medicare reimbursement is more than just the payment for medical items and services. The key to understanding how Medicare reimburses providers, physicians, and suppliers for wound care involves a greater understanding of three main components that comprise the Medicare reimbursement system: coding, coverage, and payment. Each is a separate and distinct process. Just because a product is awarded a code does not mean it will be covered. Just because it is awarded a code and covered does not mean it will be reimbursed. Similarly, all procedures performed by clinicians have codes assigned to them and are reimbursed based on the payment system for the setting in which it was performed.

Since coding and coverage are universal to all settings, they will be discussed first. Then, we will discuss reimbursement in a setting-specific fashion.

Coding

In order for medical claims to be processed, billing codes are used by physicians, hospitals, and other providers to identify the diagnosis, product, service, and procedure that the clinician used in treating the patient in which they are billing a payer. Accurate coding is necessary in order for the claim to be properly and accurately processed.

The types of codes that are used include:

- Healthcare Common Procedure Coding System (HCPCS) Level I and Level II
- Diagnosis-related group (DRG)
- International Classification of Diseases (ICD-10)

HCPCS Level I

HCPCS Level I or Current Procedural Terminology (CPT®) codes are numbers assigned to a procedure that a clinician (e.g., physician, nurse practitioner, podiatrist) may perform on a patient, including medical, surgical, and diagnostic services. The codes are then used by insurers (Medicare, Medicaid, and private payers) to determine the amount of reimbursement for the clinician. Every clinician uses the same codes to ensure uniformity, but the amount of reimbursement may differ depending on their profession. An example of a CPT code for wound care is CPT 11042—debridement, subcutaneous tissue (includes the epidermis and dermis, if performed; first 20 sq. cm or less).

HCPCS Level II

HCPCS Level II code set is made up of five-character alphanumeric codes representing primarily medical supplies, durable medical goods, nonphysician services, and services not represented in the Level I code set (CPT). HCPCS Level II includes services and products such as ambulance, durable medical equipment (DME), prosthetics, orthotics, and supplies (DMEPOS) when used outside a physician's office. *Cellular and/or Tissue-Based Products for Skin Wounds* (CTPs), an updated and more clinically appropriate term for "skin substitutes," surgical dressings, support surfaces, and negative pressure wound therapy (NPWT), all have HCPCS Level II codes.

Diagnosis-Related Group

DRGs are used for inpatient hospital claims. DRGs are a means of classifying a patient under a particular group where those assigned are likely to need a similar level of hospital resources for their care. This allows hospital administrators to more accurately determine the type of resources needed to treat a particular group and to predict more closely the cost of that treatment.

International Classification of Diseases

ICD-10 is a set of codes used by physicians, hospitals, and allied health workers to indicate diagnosis for all patient encounters. The ICD-10-CM coding system contains over 68,000 codes and is much more specific than the ICD-9. For example, ICD-10-CM codes for pressure ulcers/injuries describe location, stage, and whether present on admission (POA).

Coverage

Coverage is the existence of a medical benefit category for a service, procedure, device, drug, or supply used in healthcare delivery. Coverage varies by the type of health plan (i.e., Medicare, Medicaid, private payers, etc.), the setting of care (i.e., hospital, home health, SNF, physician office, wound care clinic, etc.), and the condition of the patient. If coverage is permissible, payers may have a separate coverage policy that will dictate the specific criteria in which they will permit coverage of that product, service, or procedure. The coverage policy will set forth medical conditions, diagnosis, coding, and specific requirements and/or limitations for coverage of that particular service or product. This will dictate whether it will get paid.

The different settings by which coverage may be permitted for wound care includes hospitals (inpatient, outpatient, and long-term care hospitals) and outpatient clinics—including wound care clinics, SNFs, and physician offices and also home care.

In the Medicare program, there are few national coverage policies (NCD) for the products that would be used to treat a patient with a chronic wound. Rather, coverage for most wound care products and procedures are made through local coverage determinations (LCDs) and policy articles by the Medicare Administrative Contractors (MACs). The Part A and B Medicare Administrative Contractors (A/B MACs) create coverage policies for CTPs, disposable NPWT, and debridement. The Durable Medical Equipment Medicare Administrative Contractors (DMEMACs) create coverage policies for DME prosthetics, orthotics, and supplies (DMEPOS). The policies they create in the wound care space include surgical dressings, NPWT, pneumatic compression devices, and support surfaces. Wound care–specific national coverage decisions issued by CMS include hyperbaric oxygen treatments, topical oxygen, and general coverage information for pneumatic compression devices. Both the national and local coverage policies and policy articles can be found on both the CMS and specific contractor's website: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.[8]

The following is additional information regarding the CMS contractors who create and implement the LCDs—the DMEMACs and the A/B MACs

Medicare Administrative Contractors

MACs are private healthcare insurers that have been awarded a geographic jurisdiction to process Medicare Part A and Part B (A/B) medical claims or DME claims for Medicare FFS beneficiaries. CMS relies on a network of MACs to serve as the primary operational contact between the Medicare FFS program and the healthcare providers enrolled in the program. MACs are multistate, regional contractors responsible for administering both Medicare Part A and Medicare Part B claims. MACs perform many activities including:

- Process Medicare FFS claims
- Make and account for Medicare FFS payments
- Enroll providers in the Medicare FFS program
- Handle provider reimbursement services and audit institutional provider cost reports
- Handle redetermination requests (first stage appeals process)
- Respond to provider inquiries
- Educate providers about Medicare FFS billing requirements
- Establish LCDs
- Review medical records for selected claims
- Coordinate with CMS and other FFS contractors

The MACs serve more than 1.5 million healthcare providers enrolled in the Medicare FFS program. Collectively, the MACs process more than 1.2 billion Medicare FFS claims annually, 218 million Part A claims, and more than 1 billion Part B claims and paid $386 billion in Medicare benefits.

Durable Medical Equipment Medicare Administrative Contractors

The DMEMACs are responsible for handling the administration of Medicare claims from DMEPOS suppliers. The DMEMACs serve as the point of contact for all Medicare suppliers, whereas beneficiaries can register their claims-related questions to Beneficiary Contact Centers. Currently, there are four DMEMACs (Table 2-1).

DMEMACs clearly define local medical coverage policies. The beneficiary usually pays a deductible for Medicare Part B, which in 2019 is the first $185.00 for covered medical services annually. Once that has been met, the beneficiary pays 20% of the Medicare-approved amount for services or supplies. If services weren't provided on assignment, then the beneficiary pays for more of the Medicare coinsurance plus certain charges above the Medicare-approved amount.

Examples of Coverage Policies for Certain Wound Care Products

Here are examples of coverage policies for certain wound care products:

- Negative pressure wound therapy—Medicare Part B provides coverage for NPWT pumps. In order for a NPWT pump and supplies to be covered, the patient must have a chronic stage 3 or 4 pressure injury, neuropathic ulcer, venous or arterial insufficiency ulcer, or a chronic (at least 30 days) ulcer of mixed etiology. Extensive documentation is required prior to a DMEMAC approving coverage for NPWT. Thus, it is important for the clinician to review the coverage policy and policy article to ensure that the product is covered under the Medicare program.[8]
- Support surfaces are also covered under Medicare Part B.[8] CMS has divided support surfaces into three categories for reimbursement purposes:
  - Group 1 devices include pads or mattresses that are comprised of air, gel, water, foam, or a powered pressure-reducing alternating mattress overlay/pad.
  - Group 2 devices include powered pressure-reducing mattress or overlay (alternating pressure, low air loss, or powered flotation without low air loss) and advanced nonpowered pressure-reducing mattress or overlay.
  - Group 3 devices comprise only air-fluidized beds.

Specific criteria must be met before Medicare will reimburse for support surfaces; therefore, it is essential for the clinician to review both the LCD and policy article.[8]

Table 2-1 The Four Durable Medical Equipment Medicare Administrative Contractors

- *JA—Noridian Healthcare Solutions LLC*, serving Connecticut, Delaware, the District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont
- JB—Cigna Government Services (CGS) Administrators, serving Illinois, Indiana, Kentucky, Michigan, Minnesota, Ohio, and Wisconsin
- JC—Cigna Government Services (CGS), serving Alabama, Arkansas, Colorado, Florida, Georgia, Louisiana, Mississippi, New Mexico, North Carolina, Oklahoma, Puerto Rico, South Carolina, Tennessee, Texas, U.S. Virgin Islands, Virginia, and West Virginia
- *JD—Noridian Healthcare Solutions LLC* serving Alaska, American Samoa, Arizona, California, Guam, Hawaii, Idaho, Iowa, Kansas, Missouri, Montana, Nebraska, Nevada, North Dakota, Northern Mariana Islands, Oregon, South Dakota, Utah, Washington, and Wyoming

Table 2-2 Coverage Under the Surgical Dressings Benefit

To have the dressings reimbursed under the Medicare/Medicaid surgical dressings benefit, the following criteria must be met:
- The dressings are medically necessary for the treatment of a wound caused by, or treated by, a surgical procedure.
- The dressings are medically necessary when debridement of a wound is medically necessary.

In certain situations, dressings aren't covered under the surgical dressings benefit, including those for:
- drainage from a cutaneous fistula that has not been caused by or treated by a surgical procedure
- first-degree burn
- stage 1 pressure injury
- wounds caused by trauma that don't require surgical closure or debridement (such as skin tears and abrasions)
- venipuncture or arterial puncture site other than the site of an indwelling catheter or needle.

Examples of dressing classifications that are covered under the surgical dressing benefit include but not limited to:
- foam dressings
- gauze
- nonimpregnated and impregnated dressings
- hydrocolloids
- alginates
- composites
- hydrogels
- collagen
- compression bandages and multilayer systems.

- Surgical dressings—The surgical dressing benefit covers primary and secondary dressings in outpatient care clinic settings (e.g., a hospital outpatient wound center) and physician offices (Table 2-2). This coverage policy is determined by the DMEMACs as well.
- Pneumatic compression devices are covered when treating a patient with chronic venous insufficiency with venous stasis ulcers or lymphedema. Reimbursement for these items is based upon the coverage criteria based in the LCD. The policy is very detailed and needs to be reviewed for specific coverage language when providing these devices to patients.

A/B Medicare Administrative Contractors

A/B MACs carry out the administrative responsibilities of traditional Medicare for Part A and B. They are responsible for claims processing or cutting checks to Medicare providers for their services; ensuring services are correctly coded and billed for, both before and after payment; deciding which healthcare services are medically necessary; and collecting overpayments. MACs follow the national coverage determinations set by the CMS, but in cases where there is no such determination or the rules are too vague regarding a specific procedure, a MAC may develop a LCD. The coverage policies for cellular and/or tissue products for skin wounds (CTPs) are administered through these A/B MAC contractors in their local jurisdictions within LCDs. In these policies, the coverage parameters can vary from one jurisdiction to another as can the title of the policy itself. The clinician would need to refer to each of the jurisdictions in order to understand whether CTPs are covered in their jurisdiction and their parameters for coverage. In addition to CTPs, LCDs related to disposable NPWT and debridement are also provided by the MACs in their wound care policies. Coverage policies for these areas are not consistent from one jurisdiction to another either and as such clinicians should review the coverage policies for their particular jurisdiction. There are currently 12 jurisdictions (Table 2-3).

Payment

Payment refers to the methodology used to determine reimbursement to a healthcare provider or supplier. Payment may take the form of a global or bundled payment for the combination of services needed to treat a particular condition, as is the case with many hospital inpatient and outpatient discharges, or may be made on an itemized basis, as is the case for many physician services such as office visits. In many cases, the payment method will be determined by the site of service rather than by the item or service itself.

As mentioned, since wound care is provided in multiple settings, a later section on "How Reimbursement Works in Clinicians' Practice Settings" is devoted to the various healthcare settings and how wound care products and services are reimbursed by CMS.

Important Shift in Clinician Payment

Historically, providers and healthcare organizations have been compensated for care provided based on FFS reimbursement models. When a

Table 2-3 The 12 AB Medicare Administrative Contractors

Jurisdiction E—Noridian Healthcare Solutions, serving American Samoa, California, Guam, Hawaii, Nevada, and the Northern Mariana Islands
Jurisdiction F—Noridian Healthcare Solutions serving Alaska, Arizona Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, and Wyoming
Jurisdiction H—Novitas Solutions serving Arkansas, Colorado, Louisiana, Mississippi, New Mexico, Oklahoma, and Texas
Jurisdiction J—Palmetto Government Benefits Administrators serving Alabama, Georgia, and Tennessee
Jurisdiction K—National Government Services serving Connecticut, Maine, Massachusetts, New Hampshire, New York, Rhode Island, and Vermont
Jurisdiction L—Novitas Solutions serving Delaware, the District of Columbia, Maryland, New Jersey, and Pennsylvania
Jurisdiction M—Palmetto Government Benefits Administrators serving North Carolina, South Carolina, Virginia, and West Virginia
Jurisdiction N—First Coast Service Options serving Florida, Puerto Rico, the U.S. Virgin Islands
Jurisdiction 5—Wisconsin Physicians Service Iowa, Kansas, Missouri, and Nebraska
Jurisdiction 6—National Government Services serving Illinois, Minnesota, Wisconsin
Jurisdiction 8—Wisconsin Physicians Service serving Indiana and Michigan
Jurisdiction 15—Cigna Government Services Kentucky, Ohio

provider is reimbursed based on a FFS model, they are compensated for each procedure, test, treatment, etc. they perform, regardless of whether that procedure, test, or treatment results in a better outcome for the patient.

Essentially, with the FFS model, providers are financially rewarded for quantity over quality. With this payment model, it's easy to see how patients can sometimes undergo unnecessary tests or treatments when perhaps less invasive, lower-cost, and just-as-effective options are available.

When congress enacted the Medicare Access and CHIP Reauthorization Act (MACRA) in 2015, it changed the way physicians got paid by repealing the unpopular sustainable growth rate (SGR) formula and created a shift from a fee-for-service reimbursement model to one that is value-based.

Medicare will allow physicians to choose between two payment tracks starting in 2019. The first track, the Merit-Based Incentive Payment System (MIPS), more closely resembles previous Medicare payment methods. Physicians are reimbursed primarily via FFS, with relative payment rates for each service determined by the resource-based relative value scale. Physicians will also receive bonuses or penalties related to their performance. Performance-based payments will be based on quality of care, resource use, meaningful use of electronic health records (EHRs), and clinical practice improvement, replacing several previous Medicare physician incentive programs.

The second payment track includes physicians with significant participation in certain alternative payment models (APMs). In contrast to FFS, value-based APMs compensate providers not for the quantity of procedures performed but rather for the quality of the care they provide, measured by patient health outcomes as well as quality care, improved health, and lower costs. In a value-based reimbursement model, providers are rewarded for effectively managing the health of individuals and populations.[9]

In 2017, 34% of total U.S. healthcare payments were tied to these APMs, which have these categories:[10]

- 41% of healthcare dollars in Category 1 (FFS—No Link to Quality & Value)
- 25% of healthcare dollars in Category 2 (FFS—Link to Quality & Value)
- 34% of healthcare dollars in Categories 3 (APMs Built on FFS Architecture) and 4 (Population-Based Payment)

Value-based care requires providers to take a more team-oriented approach to patient care, coordinating care across the continuum and collaborating with a patient's other care providers to deliver the best health outcomes possible.

Correct Documentation Is Key for Payment

Comprehensive documentation (see Table 2-4) is the critical foundation for successful reimbursement of services and products. Physician documentation of debridement as well as the application of CTPs is important to ensure coverage and payment. Moreover, physician

Table 2-4 Essential Wound Documentation

For essential wound care documentation, include the following:

- Change in clinical status or wound healing progress
- Characteristics of the wound, including:
  - Location
  - Length, width, and depth
  - Staging/category/classification
  - Exudate amount
  - Tissue type
  - Pain
- Local wound care and dressing selection
- Nutritional status
- Pressure redistribution/support surfaces (both bed and chair)
- Outcome and Assessment Information Set (OASIS-C2) per schedule in home health care
- Minimum Data Set (MDS 3.0) per schedule in SNF
- Regular assessment and reassessment of the wound (such as daily or weekly)
- Repositioning schedule
- Routine daily skin assessment and care

documentation of pressure ulcers/injuries at the time of hospitalization is particularly important for identifying POA status. Regulatory agencies, independent of their healthcare settings, set forth the requisite documentation for reimbursement, and their requirements for documentation should always be carefully reviewed prior to applying for coverage. Thorough documentation justifies the medical necessity of services and products and should reflect the care required in the prevention or treatment of wounds. Without adequate documentation, providers run the risk that the product or service being provided will be denied or reimbursement withheld. In order to promote better documentation for pressure ulcers/injuries as well as the availability of data necessary for quality measurement, CMS is also promoting the use of EHRs.[11] Specific financial incentives are available to providers using EHRs and reporting data on quality of care.

For other areas in wound care that are governed by the A/B MACs such as debridement and CTPs, it is imperative to be aware of and review the coverage policies that impact your practice as they do set forward documentation requirements that need to be strictly adhered to. Finally, as of July 24, 2017, the DMEMACs issued a specific LCD, which specifically addresses documentation for all DMEPOS claims submitted to them—for wound care, this would include surgical dressings, NPWT, pneumatic compression, etc. The documentation requirements must be followed in order to gain coverage and ultimately reimbursement for those products provide to your patients.[12]

How Reimbursement Works in Clinicians' Practice Settings

Hospital Inpatient

Hospital reimbursement is part of the inpatient prospective payment system (IPPS). Payments made under the IPPS totaled $112 billion in 2015.[13] The inpatient benefit covers beneficiaries for 90 days of care per episode of illness. There is a 60-day lifetime reserve. The episode of care begins when the Medicare beneficiary is admitted to the hospital and ends when he or she has been out of the hospital or an SNF for 60 consecutive days.

Under the IPPS, each hospital discharge is assigned to 1 of 335 different DRGs based on the ICD-10 diagnostic code and procedure codes. Each DRG may be further divided into two or three Medicare Severity DRGs (MS-DRG) based on the presence of specific comorbidities or complications. Hospitals are reimbursed on a predetermined, lump-sum fixed rate for each MS-DRG. For hospitals, this payment would also include all medical care, procedures, surgeries, wound care products, devices, and support surfaces. Because the IPPS is based on an adjusted average payment rate, some cases will receive payments in excess of cost (less than the billed charges), whereas others will receive payment that's less than cost. The system is designed to give hospitals the incentive to manage operations more efficiently by evaluating those areas in which increased efficiencies can be instituted without affecting the quality of care and by treating a mix of patients to balance cost and payments. CMS does revise annually the rules for its IPPS.

Increasingly, CMS is emphasizing value-based purchasing, and there are at least three different programs that will modify the amount that a hospital receives for any given case.[13] Under the Hospital Readmissions Reduction Program, hospitals with risk-adjusted readmission rates above the national average will have their IPPS reduced by as much as 3%. The Hospital Value-Based Purchasing Program looks at a broad number of

quality, safety, and satisfaction measures in awarding an incentive to high-performing hospitals.[14] Under the Hospital-Acquired Condition (HAC) Reduction Program, 25% of hospitals with the highest rates of avoidable complications, such as falls and catheter-associated urinary tract infections, receive a 1% reduction in payments.

Wounds are considered in these different quality programs. Both stage 3 and 4 pressure ulcers/injuries and surgical site infections are considered as HACs that are used in both the Value-Based Purchasing Program and the HAC Reduction Program. Rates are calculated from the Patient Safety Indicators (PSIs) software, which uses a highly selective algorithm to determine which wounds are counted.[15,16] The pressure injury rates in the PSIs consider only stage 3 and 4 pressure injuries and excludes wounds occurring in certain high-risk populations such as nursing home residents and people with spinal cord injuries. The impact of these reimbursement programs on pressure ulcer/injury rates remains uncertain.[16] In 2008, as part of the HACs Initiative, CMS eliminated comorbidity payments to hospitals for stage 1 and 2 pressure injuries that were POA. The financial impact on hospitals of this change was 200 times greater than the impact of removing payments for hospital-acquired stage 3 or 4 pressure injuries.[17] These different programs emphasize the importance of clinicians identifying and subsequently documenting the pressure injuries or specific surgical site infection that are POA.

Hospital Outpatient Centers

The Balanced Budget Act of 1997 provided authority for CMS to develop a prospective payment system (PPS) under Medicare for hospital outpatient services. The new outpatient PPS took effect in August 2000.[18] All services paid under this PPS are placed into ambulatory payment classifications (APCs). A payment rate is established for each APC, depending on the services/procedures provided. CPT codes and modifiers identify clinic visits and services/procedures. The CPT codes track to an APC group based on the cost and the level of resources required to perform the service or procedure. Services or procedures in each APC are similar in cost. Since hospital outpatient claims are submitted to the Part B MAC, the MAC pays a predetermined amount for the APC group—which includes all supplies including, but not limited to, wound care dressings. Beginning in 2013, CMS determined that cellular- and tissue-based products for skin wounds (CTPs) should be bundled. As a result, these products are now packaged into the facility fee for the procedure. At time of publication, CMS is considering other payment methodologies for CTPs. They are seriously considering an episode of care method of payment. Whatever methodology CMS decides to adopt, they are targeting 2020 for implementation.

Hospitals may be paid for more than one APC per encounter. Medicare beneficiaries also can pay a coinsurance, which is the amount they will have to pay for services furnished in the hospital outpatient department after they have met the Medicare Part B deductible. A coinsurance amount is initially calculated for each APC based on 20% of the national median charge for services in the APCs. The coinsurance amount for an APC doesn't change until the amount becomes 20% of the total APC payment. It should be noted that the total APC payment and the portion paid as coinsurance amounts are adjusted to reflect geographic wage variations using the hospital wage index and assuming that the portion of the payment/coinsurance that's attributable to labor is 60%.

Skilled Nursing Facilities

A patient who is eligible for Medicare may receive Medicare Part A for up to 100 days per benefit period in an SNF.[19] The patient must satisfy specific rules in order to qualify for this benefit. These rules include the following:

- Beneficiary is admitted to SNF within 30 days after the date of hospital discharge.
- Beneficiary must have been in a hospital receiving inpatient hospital services for at least 3 consecutive days.
- A physician determines that the beneficiary requires skilled nursing care by or under the supervision of a registered nurse or requires physical, occupational, or speech therapy that can only be provided in an inpatient setting.
- Services are needed on a daily basis.
- Skilled services are required for the same or related health problem that resulted in the hospitalization.

Since 1998, SNFs have been paid on the basis of a PPS. The PPS payment rates are adjusted

for case mix and geographic variation (urban vs. rural) in wages. The PPS also covers all costs of furnishing covered SNF services. Thus, wound care supplies, therapies, and support surfaces are included in the PPS per diem rate, which could limit the incentive to provide more expensive wound care therapies.[20] The SNF isn't permitted to bill under Medicare Part B until the 100 days are in effect.

Long-term care is among the most heavily regulated industries. All SNFs participating in Medicare and Medicaid must comply with these federal and state regulations, commonly referred to as federal (or F)-Tags.[21] In November 2017, CMS released its revised interpretative guidelines to clarify requirements and assist with the survey process. Requirements for chronic wounds emphasize the proper identification of the type of wound and development and implementation of a comprehensive plan of care. Requirements for pressure ulcers/injuries are particularly extensive and are specified in F-Tag 686 (before 2017 it was F-Tag 314). This emphasizes that:

- A resident receives care, consistent with professional standards of practice, to prevent pressure ulcers/injuries and does not develop pressure ulcers/injuries unless the individual's clinical condition demonstrates that they were unavoidable.
- A resident with pressure ulcers/injuries receives necessary treatment and services, consistent with professional standards of practice, to promote healing, prevent infection, and prevent new ulcers from developing.

SNFs that are found to be noncompliant with these regulations can receive civil money penalties of several thousand dollars per day, or CMS and the state can withhold payments and close the facility because of system-wide imminent danger to residents.

Resident Assessment Instrument

In order to improve care, CMS requires that a standardized assessment consisting of the resident assessment instrument (RAI) be completed on all SNF residents. Central to the assessment process is the Minimum Data Set (MDS), a 400-item form that attempts to identify the functional capacity of residents in SNFs. Among the different dimensions captured during the assessment are functional status, cognition, continence, active medical conditions, and skin condition. Based on these assessments, further evaluations are triggered and care plans developed. The MDS is completed on admission, quarterly, and with significant changes in health status.[22]

The current MDS version 3.0 has been in use since 2010. This revised version was intended to improve reliability, accuracy, and usefulness when compared to earlier versions. Significant changes were made, in particular, to Section M on skin conditions.[23,24] Two subsections describe number of venous and arterial ulcers as well as the presence of other skin conditions such as burns, skin tears, surgical wounds, and moisture associated skin damage. The remaining nine subsections are dedicated to pressure ulcers/injuries. Information is collected on risk of pressure ulcers/injuries, the number of ulcers at various stages, the most severe tissue type, and whether there is worsening of pressure injury status. With MDS 3.0, CMS also adapted the National Pressure Injury Advisory Panel's staging categories with the inclusion of deep tissue injuries and unstageable pressure injuries. Healing of pressure injuries is better described so that there is no need for reverse staging. Since implementation of MDS 3.0, there have been ongoing updates. Specific directions in 2016 helped clarify under what conditions a pressure injury is classified as POA to the nursing home.[24] Staging of blistering pressure injuries has also undergone revisions.[25]

Based on the responses in Section M, specific actions may be triggered that address pressure injuries, nutritional status, or dehydration/fluid maintenance. The net result of these changes is closer linkage of the resident assessment to quality of life, incorporation of updated guidelines for ulcer staging, and broadening of the care planning process to include current clinical protocols and evidence-based standards.

Resource Utilization Groups

The RAI is also linked to Medicare SNF payment using a case-mix classification system. This PPS creates a per diem rate that covers most SNF services including wound care. Based on the MDS, each resident is assigned to 1 of 66 Resource Utilization Groups (RUGs).[26,27] RUGs is a classification system that assigns nursing home residents to different groups depending on resident

characteristics and specific therapies being received. Each RUG category is considered to be relatively homogeneous with regard to expected resource utilization. The classification system includes 14 rehabilitation groups, 9 groups for days with rehabilitation and extensive services, 3 groups for extensive services, 16 groups for special care, and 10 groups for clinically complex care. Wound care is typically within the special care group. RUG rates are computed separately for urban and rural areas, and a portion of the total rate is adjusted to reflect labor market conditions in each SNF's location. Because of RUGs, it is essential for the SNF to complete the MDS correctly. The SNF must pay close attention to all health problems of the resident because the more intensive the care required, the higher the daily rate will be. Moreover, completing the MDS accurately and in a timely manner will help to ensure correct payments. If a SNF doesn't complete the MDS in a timely manner, it receives a default payment, which is usually significantly lower, or it may not receive payment at all.

Beginning in late 2019, CMS is updating its PPS for SNFs. There is an increased emphasis on value-based purchasing so that facilities receive a positive or negative financial incentive based on how well they prevent hospital readmissions.[28] Additionally, rather than relying on RUGs, there is a new case-mix–based PPS called the Patient-Driven Payment Model, which aims to base payments more on resident clinical characteristics than on specific services being received.

Home Health Agencies

Home health services, including skilled nursing and home health aide services, physical therapy, occupational therapy, and speech therapy, are also covered by Medicare. The Balanced Budget Act of 1997 called for the development of a PPS for Medicare home health services, which was implemented on October 1, 2000.[29] Beneficiaries receiving home health care are typically restricted to their homes, need skilled care on a part-time or intermittent basis, and are not required to make any copayments for these services.

Medicare currently purchases home health services in units of 60 days—or episodes of care. To capture the differences in expected resource use, patients are assigned to 1 of 153 home health resource groups (HHRGs) based on their clinical and functional status and service use as measured by the Outcome and Assessment Information Set (OASIS). There is a base rate for the HHRGs, which is then adjusted based on geographic factors. Reimbursements for routine and nonroutine medical supplies are included in this base rate for every Medicare home health patient. However, the HHRG payment does not include drugs, biologics, or DME—including but not limited to NPWT and pressure-relieving devices. Since 2017, a separate payment is made to HHAs for NPWT using a disposable device for a patient under the home health benefit. This was included in the Consolidated Appropriations Act, 2016 (Pub. L 114-113), which requires a separate payment to be made to HHAs for disposable NPWT devices when furnished, on or after January 1, 2017, to an individual who receives home health services for which payment is made under the Medicare home health benefit.

Disposable NPWT services are billed using the following CPT® codes:

- 97607—NPWT (e.g., vacuum-assisted drainage collection), utilizing disposable, nonDME including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 sq. cm.
- 97608—NPWT (e.g., vacuum-assisted drainage collection), utilizing disposable, nonDME including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 sq. cm.

These codes include both performing the service and the disposable NPWT device. Payment for disposable would be made under the Hospital Outpatient Prospective Payment System (HOPPS); therefore, the payment amount will also be subject to the area wage adjustment policies in place under the OPPS in a given year.

CMS created an educational article called MedLearn (MLN) Matters to inform home health agencies how to bill for these products.[30]

Furthermore, in July 2018, CMS proposed a revision to the PPS for Medicare home health care that is intended to be implemented in 2020.[31] The Patient-Driven Groups Model would remove the current incentive to overprovide therapy and,

instead, is designed to rely more heavily on clinical characteristics and other patient information to allow payments to more closely coincide with patients' needs. The unit of payment would also be changed to a 30-day episode of care.

OASIS-C2

When it is determined that a Medicare patient can receive home health services, an OASIS form must be completed. OASIS is a group of comprehensive assessments that are the basis for delivering patient care, systematically measuring patient outcomes with appropriate adjustment for risk factors affecting those outcomes, and, since 2000, assisting in the PPS.[32] OASIS-C2 is the current version of the OASIS data set and was implemented in 2017 in order to comply with requirements for standardized, cross setting measures for postacute care under the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. Major items on the OASIS-C2 include sociodemographic, environmental, support system, health, and functional status. Based on these assessments, a care plan can be generated. The OASIS-C2 document collects detailed information on all pressure injuries as well as more limited information on stasis ulcers and surgical wounds. OASIS-C2 assessments are completed on admission to home health, at 60 days, on discharge, and with any hospitalization.

Data from OASIS-C2 are used as part of the Home Health Quality Reporting Program.[33] Both process and outcome measures are calculated. Process measures focus on the use of specific evidence-based activities such as routine immunizations and use of risk assessment tools. Outcome measures are all risk-adjusted and focus on rates of improvement in important areas such as activities of daily living, potentially avoidable events such as falls with injury, and utilization measures.

Accurate assessment of OASIS-C2 items by clinicians is essential. A number of studies have evaluated the reliability and validity of OASIS-C2 and have reported values in the low to moderate range, depending on the specific items.[34] These include assessments of interrater reliability in which the assessments of two different people are compared. Proper training of staff may help improve reliability and validity. Home health agencies are required to transmit OASIS-C2 data electronically to their state system. Improper completion of OASIS-C2 can also lead to significantly lower payments or no payments at all. Thus, accurate assessments and charting are essential for recouping payments.

Physician Offices/Qualified Health Practitioners

The Medicare program pays for physician and other qualified healthcare practitioner services based on the Medicare Part B Physician Fee Schedule. Under this schedule, physicians and other qualified healthcare practitioners are paid for each medically necessary (and documented) service and procedure they perform. This includes office visits, surgical procedures, and a broad range of other diagnostic and therapeutic services. The Physician Fee Schedule is a list of 7,400 unique covered services and their payment rates. All services—surgical and nonsurgical—are classified and reported to CMS on claims according to the HCPCS code. When determining rates for each service, CMS considers such factors as the amount of work required to provide the service, practice expenses (the expenses related to maintaining a practice), and liability insurance. Through a calculation taking into account geographic variations, etc., Medicare pays the provider 80% of the fee schedule amount, and the Medicare beneficiary is liable for the remaining 20%.

Quality Improvement Efforts

Regulations related to reimbursements are tightly integrated with efforts in quality assessment and improvement. Indeed, care that is found not to meet quality standards may not be reimbursed. Even appropriate care may not be reimbursed if the condition being treated is the result of a medical error. Moreover, claims for reimbursements for substandard care could be viewed as fraudulent and result in criminal penalties. CMS does not rely solely on such punitive methods and various other initiatives exist. Most of these efforts center on pressure injuries, which may serve as a future model for other wounds. There are at least four ways in which quality measurement can be used to improve care, and different healthcare settings employ different approaches.

First, quality measurement is being used to empower consumers of health care. The

assumption is that patients and their families, if given information about quality of care, will select those providers offering the best care. Such information then needs to be made available to patients in a timely fashion. Further, providers need to proactively improve their care in order to attract patients. This approach is exemplified by the Home Health Compare and Nursing Home Compare websites maintained by CMS. These sites contain not only facility rates of performance but also national and statewide rates to permit comparisons. To further facilitate use of this information by consumers, Nursing Home Compare employs a five-star rating system that combines information on these quality measures with results from state surveys and staffing levels. Whether this approach will indeed be successful in improving care, however, remains unknown.[35]

Second, quality measures are being used in quality improvement activities (IAs). The systematic use of such data can aid in the identification of quality-of-care problems and help determine the nature of these problems.[36] Nearly all healthcare provider organizations are involved in continuous quality IAs, with varying levels of implementation into clinical practice. A central component of such activities is feedback on performance. Indeed, demonstration projects have suggested that providing home care agencies with performance feedback does result in reduced rates of hospitalization.[35]

Third, quality measures may help to focus more detailed analyses of the care provided to individual patients. Patients flagged by the Hospital Compare indicator may undergo a more detailed review of the care processes associated with the development and treatment of a pressure ulcer/injury. In nursing homes, state survey agencies are required to conduct annual unannounced surveys at SNFs to determine compliance with federal regulations regarding quality of care. A major focus of these surveys is an evaluation of pressure ulcer/injury prevention and treatment practices and whether the SNF is compliant with care.[37] Cases reviewed are often identified based on the MDS quality indicators.

Finally, CMS is increasingly relying on pay for performance and value-based purchasing as an important way of using reimbursements to improve care. Providers delivering the best care will be reimbursed more than providers delivering poor-quality care. While in theory this should be a highly effective mechanism for quality improvement, the data to date, which do not involve wound care, have not been convincing.[38] Basic issues such as the appropriate dollar amount to incentivize care, whether pay for performance represents a reward or an agent of change, and how best to measure care have not been completely resolved. While a number of projects have evaluated pay for performance in hospital and ambulatory care settings, demonstration projects involving nursing homes are in early stages. The extent to which pay for performance will focus on wound care is uncertain.

Role of Quality Measurement

Measuring quality is central to ensuring quality care. If you don't measure quality, you can't improve it. Facilitating such quality measurement is the wealth of data available in existing CMS databases, such as MDS 3.0 and OASIS-C, which provide patient-specific information on processes and outcomes of care. ICD-10 codes from hospital stays are also now much more informative. These changes may address some of the problems that have been identified in the past when using ICD-9-CM codes to measure rates of pressure injuries in hospitals.[39] Undercoding and misstaging of pressure injuries seem to remain a concern.[40,41]

Using these data sources, CMS is disseminating quality measures specific to different healthcare settings. In nursing homes, CMS reports two measures on its Nursing Home Compare website: the percent of short-stay residents with pressure ulcers/injuries that are new or worsened and the percent of long-stay high-risk residents with pressure injuries. Measures are being standardized across settings. Nursing Home Compare, Long-Term Care Hospital Compare, and Inpatient Rehabilitation Facility Compare all report on percent of pressure injuries that are new or worsened. The Hospital Compare website includes pressure ulcer/injury rates among its complications of care. While these measures of quality of care are widely available on CMS websites, their use has not been free of criticism. One issue has been the quality of the data, particularly ICD codes. Pressure injury rates calculated from clinical data are 10-fold higher than rates based on ICD-9-CM codes.[16,42] Not surprisingly, the positive predictive value of the hospital pressure injury rate based on these ICD-9-CM code is limited, although this may be

less of an issue since the implementation of the POA code and ICD-10 CM.[15] A second issue is whether these rates should be adjusted for residents' risk of developing a new or worsening pressure injury. Studies have shown that differences in facility performance mostly represent differences in resident/patient mix rather than in facility performance.[43] Finally, these rates may not capture true differences in performance. Nursing homes that performed well and poorly on the pressure injury measure were found to have few differences in how care was actually delivered.[44] Another study in 52 nursing homes found that a successful quality improvement effort was not associated with an improvement in the publicly reported CMS quality measure, but there was a decline in the incidence of stage 3 or 4 pressure injuries.[45] This again suggests that the CMS quality measures may not always capture differences in care performance.

Many other measures of wound care quality exist. Organizations such as the National Quality Forum will review these measures and determine whether they meet specific standards for reliability and validity. Those measures meeting these standards can be found on their website. One example is the Assessing Care of Vulnerable Elders (ACOVE) indicators for pressure injuries, which consist of a set of 11 indicators that capture different aspects of pressure injury care.[46] Each indicator is structured as an *if–then* statement, where the *if* component specifies a specific situation and the *then* component indicates what should be done in that situation.

Quality Measures and Qualified Health Professionals

On January 1, 2017, CMS began a new method for determining Medicare payments to qualified health professionals (QHPs) like physicians and nurse practitioners. Most QHPs are subject to the MIPS, which assigns a score from 0 to 100 for each QHP based on four performance categories, which include the reporting of quality measure data (QMs), clinical practice IAs, promoting interoperability of electronic health data, and cost. The composite score of these four weighted categories determines whether the QHP simply retains their Medicare Part B billing or experiences a bonus or penalty. MIPS is a zero-sum game, so bonus money is taken from the contributions of physicians who experienced penalties. The goal, over time, is to gradually increase the importance of the cost component. Because so many practitioners were exempted for various reasons during Year 1, the maximum bonus for a perfect score of 100 was less than 2%, which significantly reduced the willingness of practitioners to maximize their participation for a bonus. In 2019, a -7% penalty is possible, so practitioners are motivated to achieve at least the minimum points to avoid that.

The likelihood of succeeding at MIPS is significantly increased if QHPs participate through a Qualified Clinical Data Registry (QCDR). CMS has approved the U.S. Wound Registry (USWR) as a MIPS registry. A complete list of the USWR quality measures[47] can be found on the USWR website.[48] The barrier to reporting wound care–relevant QMs has been the reluctance of EHR vendors to incorporate the programmatic language for the QMs. The absence of significant bonus money has made this an insurmountable barrier although data are accumulating that practitioners who report even basic measures like diabetic foot ulcer (DFU), off-loading, venous leg ulcer (VLU) compression, and arterial screening have at least a 10% improvement in the healing rate of those respective ulcers. Benchmark rates have been set for DFU and VLU healing using the Wound Healing Index, which levels the playing field so that practitioners caring for more severe ulcers are not penalized by making their outcomes look worse than their peers. The WHI allows the impact of quality improvements to be evident. The USWR has developed clinical practice IAs relevant to wound care. The USWR IAs may provide a way for practitioners unable to report wound care quality measures to still participate in wound care–related activities and achieve the minimum MIPS score to avoid a penalty.

Managing and Improving Care

Beyond these nonspecific approaches, CMS also actively promotes quality IAs directed toward Medicare beneficiaries. The primary mechanism for this is through quality improvement organizations (QIOs). QIOs are nongovernmental organizations, usually working under contracts, that aim to implement evidence-based practices through structured learning and collaborative efforts. They frequently focus on targeted medical conditions and priority populations in their efforts to improve patient safety and clinical outcomes.

In wound care, most of these efforts have again centered on pressure injuries. In New York, toolkits have been developed with which hospitals can assess and improve their pressure injury prevention and treatment practices. In nursing homes, QIOs from three states developed a strategy to train nursing home teams in quality improvement methods and proper pressure injury care. This training was reinforced through the use of outside mentors who regularly met with the teams. As a result of these initiatives and interventions, key processes of care improved dramatically.[49] A particularly impressive quality improvement collaboration within the New Jersey Hospital Association that involved over 150 hospitals and nursing homes resulted in reduction of more than 70% in pressure injury rates statewide.[50]

Government agencies other than CMS are also promoting initiatives to improve skin care, although in a nonregulatory manner. The Agency for Healthcare Research and Quality (AHRQ) has developed a toolkit for preventing pressure injuries among hospital patients.[51] This toolkit is unique in the strong emphasis it places on evaluating organizational readiness for implementing changes in practice. For nursing homes, AHRQ has recently promoted a clinical decision support instrument that has been shown to lead to significant reductions in pressure injury incidence.[52]

Results of Improvement Efforts

Evidence is demonstrating that these efforts spearheaded by CMS and other healthcare organizations are having an impact on improving pressure injury preventive care. Many hospitals have significantly reduced their rates of pressure injury occurrence. As one example, the Collaborative Alliance for Nursing Outcomes (CALNOC), a registry of 78 hospitals mostly in California, demonstrated a decline in hospital-acquired pressure injuries from 10.4% to 1.8% between 2003 and 2010.[53]

Summary

Regulatory agencies play a major role in wound care. With the increasing need to evaluate the cost-effectiveness of wound care, regulatory agencies will likely impose further regulations, which will lead to greater complexity in obtaining and maintaining reimbursements. Thus, the key to providing optimum wound care will depend on good documentation that clearly articulates the need for services and products and clearly identifies assessment of the patient, interventions instituted, and outcomes achieved. When this is accomplished, the patient, the provider, and the regulatory agency all benefit.

PATIENT SCENARIO

Clinical Data

Mr. Y, a 72-year-old resident from a long-term care facility, is admitted to the hospital for treatment of pneumonia. He was receiving treatment for a stage 3 pressure injury on his sacrum at the long-term care facility. There is no documentation about the injury by the physician in the hospital admission medical record. The nursing admission record documents the presence of a stage 3 pressure injury on the sacrum. Mr. Y is treated successfully for his pneumonia and is returned to the long-term care facility.

Case Discussion

The financial implications regarding use of POA coding have been in effect since October 1, 2008. Under CMS ruling, the practitioner responsible for establishing the medical diagnosis needs to document the diagnosis on admission. In this case, the POA pressure injury was not documented by the physician; therefore, the hospital was poised to lose a higher amount of reimbursement for the DRG of a stage 3 pressure injury as a secondary diagnosis. The hospital coder noticed the difference between the physician and nursing documentation and queried the physician. Once it was established that the pressure injury was indeed POA, the physician completed his progress note and documented the location and stage of the pressure injury. The coder could then submit this secondary diagnosis for billing.

Show What You Know

1. **Medicare Part B is a federal program that:**
   A. supports state programs to provide services and products to the poor.
   B. reimburses hospitals for wound care services.
   C. reimburses for selected wound services and products in SNFs and home health agencies.
   D. doesn't require copayment from the beneficiary.

2. **For which one of the following healthcare settings is completion of OASIS-C2 required?**
   A. Hospitals
   B. Home health agencies
   C. Hospital outpatient centers
   D. SNFs

3. **Which one of the following criteria must a patient with a wound meet in order to qualify for SNF care?**
   A. Skilled services must be required for the same or related health problem that resulted in the hospitalization.
   B. The beneficiary must be in the hospital for 2 consecutive days.
   C. Services are needed once per week.
   D. The beneficiary must be admitted to the SNF within 90 days of admission to the hospital.

4. **Which of the following approaches *is not* being used by CMS to improve the quality of care?**
   A. Empower consumers to select high-quality providers through the provision of information on performance.
   B. Increase payments to providers of better care.
   C. Develop computer reminders on when to turn patients.
   D. Work with providers through regional QIOs.

Answers to these questions are found on page 681.

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3

Legal Aspects of Wound Care

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Objectives

After completing this chapter, you'll be able to:

- explain the major litigation players and their roles in a lawsuit
- define the four elements of a malpractice claim
- describe the general rules for proper wound care charting
- indicate ways the medical record, standards, and guidelines can be used in a malpractice case
- describe documentation practices that predispose the medical record to legal risks
- describe strategies to improve consistency and accuracy of medical record documentation that minimize potential litigation risk.

The Current Climate

In recent years, the concept of patients as "consumers of health care" has risen to the forefront. Rather than blindly trusting clinicians, the consumer–patients of today are better educated, more aware of healthcare issues, and more willing to make use of legal resources when treatment goes awry. Easy access to the Internet has provided yet another information portal for consumer–patients to review writings about health care and disease states (including treatments that may or may not be evidence based) that can affect their views of the care they have received. Social media sites such as Facebook provide access to "pages" devoted to the experiences, many negative, of patients who underwent or are currently undergoing treatment that may also influence consumer–patients. Although wound care generates no more litigation than many areas of healthcare practice, and arguably less than some others, the threat of litigation may affect the way clinicians approach the delivery of care. A wound is "visible" to the patient and/or family, whereas failure of other organs is less or not at all "visible."

Clinicians need to protect themselves while ensuring evidence-based, high-quality care to their consumer–patients. This chapter sets forth basic legal principles and suggests practice strategies that advance patient care *and* protect clinicians.

Litigation

During the course of human history, it became apparent that nonviolent means of settling disputes

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must be developed. The law and the legal process, including litigation, continue to be one of civilized society's experiments at achieving nonviolent resolutions to disputes. The success of this experiment is itself the source of much dispute, to which no resolution (nonviolent or otherwise) is currently in sight.

Contrary to television and film portrayals, the real-life litigation process is arduous and time-consuming. While fictitious television and film lawsuits resolve in a matter of weeks or months, usually ending with a dramatic trial resulting in a stunning jury verdict, most real-life cases take years to get through the legal system. In some jurisdictions with crowded dockets, and due to their complexity, medical negligence/malpractice lawsuits can take as long as 5 years to resolve. Those that require appeals can take considerably more time before all issues are finally put to rest. Trials (dramatic or not) are few and far between, as nearly all lawsuits are settled before trial. When trials do happen, they are usually slow-moving, uninteresting events that tax the patience and attention of jurors. Litigants expecting "Perry Mason" moments from their attorneys are sure to be disappointed, and, as anyone who has ever served on a jury knows, closing arguments by attorneys is never, ever over in the 5 minutes before the final commercial.

Despite the difficulties and drawbacks, the litigation process does afford citizens an impartial forum for dispute resolution grounded in the law. And the law, as Plato stated, is "a pledge that citizens of a state will do justice to one another."

The discussion in this chapter is limited to *civil litigation*, that is, litigation in which citizens have a dispute with each other—rather than *criminal litigation*, in which the state or a government seeks to prosecute a party for the violation of law. There are significant differences between the two forms of litigation (e.g., standards of proof). The remedy sought in civil litigation is monetary damages. In contrast, only the prosecuting state or government may seek to deprive the alleged lawbreaker of his or her liberty by incarceration.

How Is a Medical Malpractice Lawsuit Born?

Litigation begins the moment a person believes he or she has been wronged by another and seeks the advice and counsel of an attorney in an effort to "right the wrong" or "get justice." During the initial interview between the prospective client and the attorney, the attorney makes a number of preliminary judgments usually based solely on the client's presentation:

- Is this the type of case the attorney is capable of handling? Does it fall within his or her expertise and practice experience? Does the attorney have the time to handle the matter?
- Is the client's story credible?
- Will the client make a good witness?
- Are the damages, if proven, sufficient to warrant entering into the litigation process?
- Is there a party responsible (liable) for the client's injuries?
- How likely it is that both liability and damages can be proven?
- Are there any glaring problems or difficulties with the case?

If the answers to these questions are satisfactory and the client wishes to retain the attorney, a lawsuit has then been conceived.

Before filing the legal documents that start the litigation process in a medical malpractice case, most attorneys perform an intensive investigation in order to definitively answer questions concerning liability and damages. Medical records and other information must be obtained and examined by an expert to determine whether a malpractice claim can be made. Information related to the identities of potential defendants must be analyzed, and strategic legal issues related to jurisdiction (which court can the case be brought in) must be thought through. If after this investigation the attorney still believes the case has merit, legal papers starting the actual lawsuit will be filed, and a lawsuit will be born (Box 3-1).

The Pretrial Litigation Process

The pretrial litigation process consists of several steps: complaint and answer, discovery, and motion practice.

Complaint and Answer

The initial legal paper that gives rise to a lawsuit is called the *complaint*. While procedural requirements vary between jurisdictions, generally the complaint is a document that sets out the claims made by the plaintiff against the defendant, the

Box 3-1 Players in the Litigation Process

The litigation process is initiated and enacted by people with a dispute to resolve and those whose task it is to aid in resolving that dispute.

The Parties

The principal parties involved in litigation are the *litigants*—the individuals on either side of the dispute. The *plaintiff* is the person who initiates the lawsuit and who claims he or she has suffered injury due to the actions of another. A lawsuit may be filed by multiple plaintiffs.

The plaintiff sues the *defendant*—the person(s) or organization(s) alleged to have injured the plaintiff by his/her or its actions. In most cases, the parties are individuals, but parties can be corporations, companies, partnerships, government agencies, or, in some cases, governments themselves.

The Judge

The *judge* is an individual, usually an attorney, who has been appointed or elected to oversee lawsuits on behalf of the state or government under whose jurisdiction the lawsuit is brought. The judge acts as referee during the pretrial phase of the case and decides legal issues that arise as the lawsuit progresses toward trial. In a trial, the judge's responsibility is *to interpret the law*.

The Jury

The *jury* is a panel of citizens chosen by the attorneys for the litigants to hear evidence in the case and render a decision or verdict. The jury's responsibility is *to determine the facts* in a trial. It's up to the jury to decide whether the plaintiff and his or her attorney proved their case, thereby rendering a decision about the defendant's liability and the amount of damages the defendant should pay to the plaintiff.

basis of the jurisdiction of the court, the legal theories under which the plaintiff is making the claims, and, in some jurisdictions, the amount of damages claimed. The complaint must allege sufficient facts to establish a *prima facie* (based on the first impression or true until proven otherwise) case. Defendants may and often do file an application to the court before answering the complaint, seeking to have the case dismissed by the court before it starts based on insufficient factual detail in the complaint.

If the case is not dismissed at the outset, or if the defendants choose not to make that application, the defendant must then file an *answer* within the permitted time that responds on a count-by-count basis to the plaintiff's complaint and that, depending again on jurisdictional rules, may also include claims against the plaintiff. These two basic *pleadings* initiate the formal lawsuit.

Discovery

Discovery is the process by which the parties find out the facts about each other, about the incidents that have given rise to the claims of malpractice alleged by the plaintiff, and the defenses to those claims asserted by the defendant. The law has provided discovery devices—procedural mechanisms by which the parties ask for and receive information. Demands are routinely made for documents and other tangible items related to the lawsuit's claims, for statements made by the parties to others, and for the identification of witnesses to the incidents. Then, pretrial testimony (*deposition or examination before trial [EBT]*) is taken of the parties and fact witnesses to the lawsuit. This testimony, while out of court, is sworn testimony transcribed by a certified court reporter and can be used for any purpose in the lawsuit, including for purposes of *impeachment*—the demonstration of prior untruthful or inaccurate testimony, or a challenge to the credibility of a witness—at trial.

Finally, *expert discovery*—information about the opinions of experts retained by the parties—is usually permitted. Experts are individuals accepted by the court to assist the finder of fact—the jury—in understanding issues that commonly fall outside of the experience of the typical juror. In medical malpractice cases, the plaintiff must

prove that there was a deviation from the standard of care that resulted in an injury. Expert testimony related to the field of medicine, treatments, and standards of care at issue in the case is essential to successfully meet proof requirements for each element of a malpractice claim brought by a plaintiff. Likewise, the defense of such claims requires opposing expert testimony—in essence, an explanation by a credentialed individual supporting the actions taken by the defendant from which the claim of malpractice stems.

Motion Practice

Disputes over discovery often arise in the context of a lawsuit, and those disputes that can't be resolved by the parties require court intervention. Formal resolution of these disputes usually requires an application to the court—a *motion*—setting forth the dispute and the position of the party making the application (the moving party or *movant*) and requesting certain *relief* or results to be *ordered* by the court. Naturally, this requires a response from the other party—the *opposition*—that sets out the reasons why the court shouldn't grant the relief requested.

Some motions can be decided by the court *on the papers*, that is, without a formal oral presentation (*oral argument*) by the parties before the judge is assigned. More complicated motions, especially those seeking to eliminate or modify legal claims, almost always require argument before the presiding judge or court.

The Trial

While the vast majority of lawsuits settle before trial ("out-of-court settlements"), some cases do proceed to trial. Medical malpractice trials are almost without exception jury trials. Once it's determined that settlement isn't an option, a trial date is set and the attorneys begin to prepare. In federal jurisdictions and many state courts, litigants are required to prepare pretrial statements and submissions. They also disclose exhibit lists (materials and documents the attorneys anticipate they will use at trial). They may also designate deposition testimony to be read or, if the testimony was videotaped, to be shown at trial. The pretrial submission and disclosure process helps to ensure that the trial is as fair as possible and eliminates the possibility of "trial by ambush." Thus, the "Perry Mason" moments of television and film renown are relatively few and far between.

On the day of the trial, the attorneys for the parties proceed with jury selection. Each attorney tries to select jurors that he or she believes will decide in favor of (*find for*) his or her client. Procedurally, the jury selection process varies widely by jurisdiction. In some courts, the trial judge will take an active role by questioning the jurors. Other jurisdictions permit the attorneys to question jurors directly without court supervision, and the trial judge becomes involved only when a significant dispute arises. The fight over selection is then left to the attorneys. As you can imagine, jury selection in a jurisdiction with strong judicial control is a much briefer process than in those jurisdictions where the attorneys are left to their own devices. No matter what the individual procedure, once the jury is chosen (*empanelled*), the trial begins.

At trial, the parties each give an opening statement, one of the two times in the entire trial that the attorneys are permitted to speak directly to the jurors. After the opening statements, the plaintiff's attorney presents the plaintiff's case. As the burden of proof is on the plaintiff, the plaintiff's attorney goes first. After the plaintiff's direct case is finished, the plaintiff "rests," and the defendant's attorney presents the defendant's case. The *direct case* consists of evidence (testimony, documents, etc.) presented by the attorney for a party. The party has the right to cross-examine each witness after the direct examination, and then additional examination may follow ("redirect" and "recross") as necessary. After all the evidence has been presented by both sides, the parties make closing statements (*summations*), which is the last time the attorneys are permitted to speak directly to the jurors.

Once summations are completed, the judge then instructs the jurors on the appropriate law that they're to apply to the facts of the case. Remember that the jury is the *finder of fact*—it determines what happened, when it happened, who did it, where it happened, and how it happened—and the judge is the *interpreter of the law*. After the jurors receive the judge's instructions, they leave the courtroom and begin deliberations (Fig. 3-1).

Every trial attorney hopes to be lucky enough to serve on a jury that goes to deliberations. For trial lawyers, understanding what happens inside

Figure 3-1 Courtroom.

the jury room during deliberations is the Holy Grail of trial practice. In jurisdictions that permit attorneys to interview jurors after verdict, attorneys often spend many hours with the jurors who are willing to discuss the case in order to determine what did—and what didn't—work during the trial. It's often surprising to find that what the lawyer thought was of prime importance wasn't so important to the jury. The jury room in our legal system is sacrosanct, and, no matter how it happens, the jury will arrive at a verdict that will be delivered to the parties in open court. Once the verdict is read and the jury excused, the trial is over.

Appeals

Each jurisdiction has an appellate process, of which the litigants may take advantage. Depending on the jurisdiction, appeals may add years (and many dollars) to the resolution of claims and lawsuits.

Legal Elements of a Malpractice Claim

A medical malpractice claim is made up of four distinct elements, each of which must be proven to the applicable standard of proof in the jurisdiction of the case. The usual standard of proof for civil cases is a *preponderance of the evidence*. The preponderance standard can be best described as a set of scales that represent the plaintiff on one side and the defendant on the other, which are evenly balanced at the start. The party that wins is the one on the side of the scale that dips lower at the end of the trial. In other words, in order to prevail, plaintiffs need to show by only 50.0000001%—just a bit more than one-half—that they've proven each of the elements that make up a malpractice claim.

The four general elements that make up a malpractice claim are:

- existence of a duty owed to the plaintiff by the defendant
- breach of that duty
- an injury that is causally related to that breach of duty
- damages flowing from that injury that are recognized by law.

Duty

In general, there is no duty to protect a person endangered by the actions or omissions of another if there is no special relationship between the two persons. The patient–physician relationship is the basis for the claim of duty between the plaintiff–patient and the defendant–healthcare professional in medical malpractice cases because that relationship requires the patient to rely on the physician's knowledge, expertise, and skill in treatment. Thus, the allegations of medical negligence arise within the course of that professional relationship. Translating that definition into healthcare terms, some examples of a duty may be the obligation of a healthcare practitioner to give patients care that is:

- consistent with the level of his or her experience, education, and training
- permitted under the applicable state practice act
- authorized or permitted under the policies and procedures of the institution that are applicable to the position.

Practice Point

Duty: In negligence cases, *duty* may be defined as obligation, to which the law will give recognition and effect, to conform to a particular standard of conduct toward another. The word *duty* is used in the law to denote the fact that the actor is required to conduct himself in a particular manner at the risk that if he doesn't do so, he becomes liable to another to whom the duty is owed for any injury sustained by such person, of which that actor's conduct is a legal cause (Restatement, Second, Torts, Section 4).[1]

Breach of Duty

In addition to proving the existence of a duty, the plaintiff must also prove the defendant breached that duty. Breach of duty can result from commission, omission, or both. Most often, to establish this element of the claim, the plaintiff in a medical malpractice case must also show that the defendant healthcare practitioner deviated from an accepted standard of care or treatment. In defense of the claim, the practitioner isn't required to provide the highest degree of care but only the level and type of care rendered by the *average practitioner*. What the standard of care is, and whether and how it was deviated from, must be established for the jury, and this is most often the province of expert testimony.

Breach of duty in the healthcare setting may be illustrated in the following ways:

- Failure to give care within the applicable practice act
- Failure to perform professional duties with the degree of skill mandated by the applicable practice act
- Failure to provide care for which the circumstance of the patient's condition warrants

Practice Point

Breach: The failure to meet an obligation to another person that's owed to that person; the breaking or violating of a law, right, obligation, engagement, or duty by commission, omission, or both.[1]

Injury Causally Related to a Breach of Duty

In a medical malpractice case, proof of an injury isn't enough to carry the day unless that injury can be causally linked to a breach of duty by a healthcare practitioner. That breach of duty is then considered the proximate cause. Without the breach of duty, the injury wouldn't have occurred (Box 3-2).

Proximate cause in the healthcare setting can be illustrated by the following examples:

- Fractured hip due to a fall because of failure to raise the side rails of the bed
- Decreased total protein due to failure to provide nutrition (either failure to provide actual nourishment or failure to order/call a consult)
- Osteomyelitis resulting in limb amputation following failure to attain/call an infectious disease consult and provide antibiotic therapy

Box 3-2 Proving Proximate Cause

While standards of proof related to proximate cause may vary among jurisdictions, one of two questions is almost always used to determine this issue:

- Was the healthcare practitioner's negligent conduct a "substantial factor" in causing the injury?
- Would the injury not have happened if the healthcare practitioner hadn't been negligent?

Practice Point

Proximate cause: That which, in a natural and continuous sequence, unbroken by any efficient intervening cause, produces injury, and without which the result wouldn't have occurred and without which the accident couldn't have happened, if the injury be one that might be reasonably anticipated or foreseen as a natural consequence of the wrongful act.[1]

Damages

Finally, the fourth element that makes up a malpractice claim is damages. A healthcare practitioner may be held liable for damages when the jury finds that the practitioner deviated from the applicable standard of care in treating the plaintiff–patient and, as a result, caused injury resulting in legally recognized damages. In most jurisdictions, a plaintiff may recover for proven monetary losses (lost wages and unreimbursed medical expenses) and for pain and suffering that result from the proven injury. As noted previously, it's the jury—the finder of fact—that sets the monetary award to the plaintiff.

Practice Point

Damage: Loss, injury, or deterioration caused by the negligence, design, or accident of one person or another, with respect to the latter's person or property.

Damages: A pecuniary compensation or indemnity that may be recovered in the courts by any person who has suffered loss, detriment, or injury, whether to his or her person, property, or rights, through the unlawful act or omission or negligence of another.[1]