

# CHALLENGING PRECEDENT: CRITICAL CARE NURSING AND MEDICAL PRODUCT INNOVATION

By Karen K. Giuliano, PhD, MBA, RN

In this presentation, I will share my unconventional journey, starting from my first job as a critical care staff nurse to my current role as tenure-track faculty at the University of Massachusetts Amherst, where I hold a joint position with the Institute for Applied Life Sciences and the College of Nursing. Throughout this journey, I have had many opportunities to participate in interdisciplinary clinical outcomes research and medical product development as a staff nurse, clinical nurse specialist, and project lead from the clinical, industry, and academic perspectives. While passionate about my central clinical research interests in technology innovation and its responsible use in critical and acute care, the foundation of my approach is dedicated to the values and lessons of my earliest experiences in critical care bedside nursing: supporting and preserving the dignity and humanity of person-centered patient care. Early in my career as a critical care nurse, I realized how vitally important a critical care nursing perspective could be in the design of technology for meeting the critical care needs of patients, nurses, and other professionals who provide this care. As the nation's largest group of health care professionals, nurses use more products than any other health care professional, and thus nurses have a uniquely practical and care-sensitive perspective on the development and design of medical products. Nurses, especially critical care nurses, are in a unique position to identify and address everyday health care issues, challenge assumptions and the status quo, address unrecognized and unarticulated needs, and ensure that clinical outcomes research serves as the foundation for validating the effectiveness of medical product innovation. My goal is to share lessons learned and to help participants to see the many different ways that critical care nursing knowledge can be used to improve patient care (*American Journal of Critical Care*. 2020;29:253-261)

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**O**ne of Clara Barton's most outstanding qualities was her almost complete disregard of precedent. The fact that a thing had always been done in a given way was evidence to her that it could be done again in that fashion but was of almost no value to her as proving that was the best way. She always had faith in the possibility of something better. It irritated her to be told how things had always been done. Having once decided upon a course that defied the tyranny of precedent, she held true to her declaration of independence."<sup>1</sup>

My practice and clinical research interests are largely driven by a passionate desire to improve the *delivery of care* for nurses and the *experience of care* for patients and their families.

As far back as I can remember, I have been driven by a deep curiosity about how things work. My father was a tireless tinkerer who could transform any object into a tool, always looked for better ways of doing

things, and had a special knack for making work seem like play. These early experiences provided me with a determined "can-do" attitude, a habit of questioning the status quo, a tolerance for failure, and a restless impatience when told that things "have always been done this way." My nursing practice has always included a propensity to play with ideas and do things differently, and my practice and clinical research interests are largely driven by a passionate desire

to improve the *delivery of care* for nurses and the *experience of care* for patients and their families.

I began my professional career as a critical care nurse in 1985 at Miriam Hospital, a Brown University-affiliated teaching and research hospital. In the following 30-plus years, I have held a diverse set of professional roles in which my critical care nursing knowledge has provided a foundation for clinical care, teaching, and clinical research. These included roles as a critical care staff nurse and a critical care clinical nurse specialist (Miriam Hospital, University of Virginia, and Baystate Medical Center), an industry-based nurse professional in medical device design and research (Philips Healthcare, Fluidnet, and Sage/

#### About the Author

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Stryker), a nursing doctoral student (Boston College), a postdoctoral research fellow (Yale University), as an associate tenure-track professor of nursing and executive director of Healthcare Innovation & EntrepreneurNURSEship at Northeastern University. In September 2019, I transitioned to the University of Massachusetts-Amherst, where I hold a joint position in the Institute for Applied Life Sciences and the College of Nursing and lead a product development laboratory.

While I am passionate about my central clinical research interests in technology innovation and responsible use of technology in critical and acute care, the foundation of my approach is dedicated to the values and lessons of my earliest critical care bedside nursing experiences: supporting and preserving the dignity and humanity of person-centered patient care. These core values found expression in some of my earliest publications focused on the bedside nurse-patient relationship in "The Little Things," "When Technology Fails," "Organ Transplants, Tackling the Tough Ethical Issues", "What Does a DNR Order Really Mean" and several others.<sup>2-12</sup> Technology is and will always be a tool that, at its best, facilitates humanistic, evidence-based clinical care.

Janet (not her real name) was a beautiful and energetic 19-year-old woman before becoming a patient in our intensive care unit (ICU). The picture-and card-laden bulletin board behind her bed gave painful witness to her prior health and active lifestyle. Amidst the overflow, one picture stood out. There was Janet smiling in the group embrace of her 3 best friends. That one picture made it impossible to ignore the harsh reality of how much her life had changed in the past 2 months.

Before her admission, Janet complained of general malaise and aching joints. When medication and rest did not relieve her symptoms and they began to worsen, her mother took her to the hospital. Because findings on her neurological exam were abnormal, she was admitted for further evaluation.

Janet's symptoms and neurologic status only continued to worsen, and after she had spent a week

in the general medical care area, the health care team remained puzzled. One afternoon when her mother was present, Janet's neurological and respiratory status decompensated so rapidly that intubation and an emergency transfer to our ICU became necessary.

When I admitted Janet to the ICU that afternoon, she was edematous and having difficulty tolerating the ventilator. Sedation was necessary to prepare her for yet another brain scan, which again revealed nothing. For me, this was a particularly heart-wrenching experience from the very start. I worked in an adult ICU, and with no pediatric experience, taking care of a 19-year-old patient was a new experience for me. In addition to attending to her serious physical problems, a significant part of our care included supporting the emotional and coping needs of her family, especially her mom, who was desperately worried.

Day after day, Janet's mom and aunt would sit by her bedside, watching her condition continue to deteriorate. Over the course of a few weeks, Janet became completely unresponsive. There was not an inch of Janet's beautiful body that was left untouched by the sometimes useless wonders of modern critical care. Monitoring and intravenous (IV) lines cluttered and bruised her arms and neck. Several chest tubes were crowded into different areas of her chest. Her groin was scarred and bandaged from blood drawing and central lines. But the most disturbing thing for her family to look at was her face. Janet had always prided herself on impeccable grooming. But now half her head was shaved, an intracranial pressure monitor jutted out the side, her lips were scabbed, sputum drained from her mouth and nose, and endless rolls of tape anchored this labyrinth of tubes in place.

It was becoming increasingly obvious that Janet was not likely to survive. A mysteriously pernicious disease was taking away her beautiful young life, bit by bit, day by day. It was particularly painful to watch her mother and aunt talk to her by the hour and continue to build hope on the infrequent, spastic twitches of her swollen body.

Soon after Janet was admitted to our ICU, I began to wash and French braid her hair every day. I realized that our expert critical care was not going to save her life, or even protect the integrity of her body. As her primary nurse, I needed something comforting and normalizing to offer to her family and to help me feel something other than utterly helpless.

After 6 painful weeks in our ICU, Janet died. It was very difficult for her family and the entire health care team. Perhaps the worst part was that an autopsy failed to reveal the root cause of her death. However,

several weeks after she died, I received a card from her mom. It read simply, "God Bless you, Karen. Thank you for doing Janet's hair."

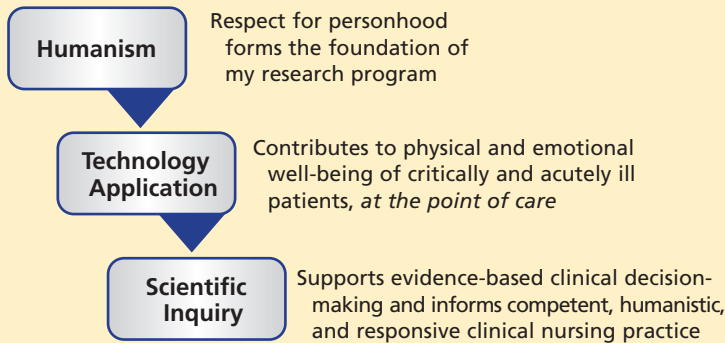
That card instantly filled me with incredible emotion. It served as a powerful reminder that sometimes it is the little things in life that mean the most. There is so much comfort in simply caring for those in pain, even when all else fails. As an ICU nurse, I have never forgotten this lesson.<sup>7,8</sup>

This early experience shaped the foundation of my nursing practice, one rooted in humanism and a respect for personhood. It has sustained me during the past 30 years while caring for so many critically ill patients and their families and has driven my development as a nurse scientist and innovator.

I have always loved working directly with patients and families, and even now as a nurse scientist, I continue to spend considerable time at the bedside. The pace, necessity of teamwork, and acuity of the critical care environment are a match for my personality and interests. I was always intensely interested in the fundamental importance of technology in the care of critically ill patients, but once I began to practice, I quickly realized that it was just as important to know when to set aside technology as it was to know when to initiate its use. That realization led to the inception of my early program of research, which I generally refer to as the "responsible use and development of technology" (Figure 1).

When someone is a patient in the ICU, it is a time of considerable stress and anxiety for the patient and their loved ones. With all the technology required to support patients during critical illness, I know firsthand how easy it can be to forget that there is a person at the center of everything. In both my critical care practice and my technology research, I remain committed to the notion that every critically ill patient is first, a person (often with a family), and second, a critically ill patient.

My career-long research interest in medical device design and innovation reflects my desire to use technology to respond to evolving patient clinical needs rapidly, effectively, and ethically. My first experience in technology innovation and design was in the 1990s, when I was a critical care staff nurse at Miriam Hospital in Providence, Rhode Island. I worked with the ICU intensivist/director, Dr William Kaye, and Laerdal to help develop the first semiautomated defibrillator (which was soon followed by a fully automated one)<sup>13</sup> and the first computerized training mannequin for advanced cardiac life support (ACLS; Figure 2). It was then that I realized how vitally important my critical care nursing



**Figure 1** Research program: the responsible use of technology.



**Figure 2** Karen Giuliano with William Kaye, MD, director of the intensive care unit at Miriam Hospital and our adult cardiac life support (ACLS) team.

perspective could be in the design of technology for meeting the critical care needs of patients, nurses, and other professionals who provide that care. A medical product must work for its intended purpose and be designed so that it is easy to use in the care environment. The best product designs are those in which end users are included as an integral and reciprocal part of the product development process. As the nation's largest group of health care professionals, nurses use more products than any other health care professional, and thus nurses have a uniquely practical and care-sensitive perspective on medical product development and design.

### Challenging Precedent: The Critical Care Environment

In 1994, I became the critical care clinical nurse specialist in a 24-bed medical-surgical-trauma ICU at Baystate Medical Center in Springfield, Massachusetts, and quickly learned that it was a very special place

that provided excellent care to critically ill patients. At that time, open visitation was not common and Baystate, with its restrictive visitation rules, was no exception.

Shortly after arriving, I began talking with ICU staff about implementing an open visitation policy and found a tremendous amount of support for the idea. In short order and with a great deal of leadership from the entire health care team, we challenged precedent to expand the definition of family from "immediate family only" to include anyone the patient identified as significant, changed the visiting "restrictions" to a virtually open policy (except for during change of shift; Figure 3), and supported family presence during resuscitation. We also thought, "Why can't families help turn their critically ill loved ones? Why can't they help brush their teeth? Why can't they learn how to suction?" So we began to teach families and significant others to participate in the care of their critically ill loved ones.<sup>11,14</sup> Through these experiences, we found that patients and nurses felt more supported and family members felt less distressed and more useful and satisfied with the care being provided to their loved ones.

Our unit included an adult trauma service, where we cared for many patients who were part of families with small children. There was additional trauma to the family when suddenly and without warning mom or dad or a sibling simply stopped coming home. We all knew how important it was for our patients to see their young family members and for these children to see their loved ones, but as adult nurses we were fearful about how to go about this and needed help to make sure these visits would be therapeutic and not cause additional distress or trauma. Fortunately, we had a pediatric ICU right down the hall, complete with a caring and skilled group of child life specialists. These incredibly talented health care professionals used all kinds of developmentally appropriate strategies and tools to prepare children to visit their critically ill family members. We challenged precedent to develop a successful child visitation program in our adult trauma ICU that provided our staff with countless opportunities to witness joy in the faces of our patients and their families during these challenging phases of life and deeply meaningful and impactful visits. I was so often struck with the seemingly uncomplicated ability of these children to look past all the tubes and lines and right into the eyes and heart of their loved ones. These children taught us a great deal about what it means to take care of the whole person in the face of critical illness.

With the transformation of our visitation program from restrictive to virtually open, we knew that for some patients their four-legged furry friend was a very significant loved one. In collaboration with our colleagues from infection control, we challenged precedent to develop a program that included hospital pet therapy dogs and the patient's own cats or dogs<sup>6</sup> (Figure 4). I once had a patient who was going into cardiac surgery, knew she was not likely to survive, and her last wish was to see her cat. Fortunately, and with help from her daughter, we were able to make that happen. I will never forget the image of the cat being placed on the hospital bed and immediately running up to the head of the bed to cuddle with her owner. Just like the children, that cat easily looked right past all the sounds, smells, and equipment to engage the humanity of the person she loved.

### Challenging Precedent: Clinical Practice and Critical Care Technology

At Baystate Medical Center, the first technology evaluation project we initiated was to compare the accuracy of tympanic and electronic oral thermometers in intubated patients. The hospital purchasing department began a clinical trial of tympanic thermometers without input from clinicians. In the absence of effectiveness data, the plan was to implement the tympanic thermometers and remove the electronic oral thermometers in current clinical use. When the nursing staff tried the tympanic thermometers, their impression was that they were not as accurate or as easy to use as the electronic oral thermometers. They described how they "just knew in their gut" that this was not the right decision. Although I thought they were probably right, my response was "the gut's not going to tell administration not to buy those thermometers!" We quickly formed a project team, asked for a hold on the purchase, wrote a research proposal designed to measure the clinical effectiveness of tympanic thermometers against the gold standard of pulmonary artery core temperature, obtained approval from the institutional review board and funding, and completed our first research study together. This study was quickly followed by a second study addressing the same issue. Both studies were published in highly regarded journals, remain some of our most frequently cited articles, and, most significantly, no tympanic thermometers were ever purchased.<sup>15,16</sup> End-user experience matters, although it is too often relegated to an afterthought or anecdote in the absence of credible empirical evidence. In this

**ICU**

**Visiting Regulations:  
Immediate Family Only.  
2 visitors, 10 minutes  
every hour on 1/2 hour.**

**CALL BEFORE ENTERING  
POD A-4800 RMS. 1-8  
POD B-4820 RMS. 9-16  
POD C-4840 RMS. 17-24**

**– STOP –**

**AUTHORIZED PERSONNEL ONLY**  
Visitors Dial 4800 from Waiting Room Phone  
for Admittance to I.C.U.

**VISITING HOURS  
ARE BASED ON  
THE PATIENT'S  
NEEDS. PLEASE  
CALL THE NURSE.  
CALL BEFORE ENTERING  
POD A-4800 RMS. 1-8  
POD B-4820 RMS. 9-16  
POD C-4840 RMS. 17-24**

**Figure 3** Visitation signs on the doors of the intensive care unit from before and after open visitation was implemented.



**Figure 4** Zachary visiting the intensive care unit. Photo courtesy of Zachary's Paws for Healing. Used with permission.

case, we challenged the precedent of administration decision-making without nursing end-user input.

During and since my tenure at Baystate Medical Center, I have worked on numerous technology development projects. As reflected in my publications and presentations, I have dedicated myself to clinical research designed to answer practical questions on the use and performance of a variety of critical

care practices and technologies. Examples include “How can we improve accuracy in medication infusion calculations?” “What is the best practice for central venous pressure measurement accuracy?” “Can we use oral thermometry with intubated patients?” “Can the use of point-of-care blood analyses improve patient care and be cost-effective?” “Can continuous cardiac output measurement be done accurately without placing the patient flat in bed?” “Can a program of continuous venovenous hemofiltration be safely

developed and implemented by critical care nurses?” “What are best practices for 12-lead electrocardiography (ECG) and cardiac monitoring?” “Do clinical differences exist among different pulse oximetry (SpO<sub>2</sub>) technologies?” “What is the best method for early detection of sepsis? and most recently, “Can the use of improved oral care reduce the incidence of

**End-user experience matters, although it is too often relegated to an afterthought in the absence of credible empirical evidence. In this case, we challenged the precedent of administration decision-making without nursing end-user input.**

nonventilator hospital-acquired pneumonia?” and “Can we improve the safety of IV medication infusion with IV smart pumps?”<sup>17-45</sup> Since my first publication in 1990, I have remained active in disseminating our collaborative work through peer-reviewed publication and national and international conference presentations with nursing and interdisciplinary colleagues, with the hope of helping to narrow the research to practice gap.

### Challenging Precedent: Current Areas of Technology Research Focus

More recently, my clinical research focus has evolved into understanding and addressing usability and safety issues of multiple infusions using IV smart pumps. Since nurses are the primary end users of IV smart pumps, the nursing experience and perspective is vitally important to informing development and innovation of future IV smart pumps. During my 2-year postdoctoral research fellowship (2014-2016) with Dr Marjorie Funk at Yale University, I began to study and publish in this area.<sup>18,46-51</sup> Intravenous smart pumps with integrated dose-error reduction systems (DERS) are among the most frequently used technologies in health care, particularly in critical care. Though the use of IV smart pumps has been associated with reductions in medication errors, they have not eliminated error, including serious adverse drug events. Currently available IV smart pumps have numerous, well-known usability issues that often result in user error, include overriding dose error alerts and manually bypassing the DERS. Critical care nurses routinely cite the complexity of the device user interface, the time required to program the DERS, and incomplete drug libraries as some of the most common reasons that they bypass the safety features of IV smart pumps. My program of research in this area is, in part, intended to ensure that critical care nurses' role demands inform IV smart pump innovation. By working closely with clinical engineers, manufacturers, and patient safety organizations to understand smart pump functionality, critical care nurses are uniquely positioned to drive innovation in this very important area of patient safety.

A second area of research interest is nonventilator hospital-acquired pneumonia (NV-HAP), now recognized as the No. 1 hospital-acquired infection in the United States, with a mortality rate up to 30%.<sup>52</sup> During acute care hospitalization, disruption of the oral microbiome places patients at increased risk for pneumonia owing to changes within the oral flora that harbor pathogenic organisms.<sup>53-55</sup> During the past several years, I have collaborated with an

interdisciplinary research team on our “Hospital-Acquired Pneumonia Prevention: Intervention, Evaluation, and Research ” (HAPPIER) initiative. Our goals are to characterize the epidemiology of NV-HAP and study the impact of improved oral care and other strategies on NV-HAP prevention. This work began as a quality improvement initiative at Sutter Medical Center in Sacramento, California.<sup>56</sup> The HAPPIER initiative requires team building and broad interprofessional collaboration among nurses, physicians, speech pathologists, infection preventionists, the dental community, hospital administrators and support systems, and most importantly, patients and their families. Our productive collaboration has already yielded several publications,<sup>56-61</sup> resulting in interest from numerous hospitals in the United States and abroad. One of our HAPPIER partners, Dr Shannon Munro, is leading more than 50 Veterans Affairs (VA) hospital units with her Hospital-Acquired Pneumonia Prevention by Engaging Nurses (HAPPEN) program. The HAPPEN program has saved hundreds of veterans’ lives and millions of dollars for the VA.<sup>62,63</sup> Working closely with the Orlando Health nursing research team, which includes Dr Daleen Penoyer and Dr Dian Baker, we have just completed a small cluster-randomized HAPPIER study that looked at the impact of improved oral care on NV-HAP prevention. Preliminary data analyses showed a significant reduction in NV-HAP for the medical patients in the experimental group who received our HAPPIER intervention, and preparation of the full manuscript is currently in process. Nonventilated critically ill patients are one of the highest risk groups for NV-HAP, making this area of clinical research a natural progression of the past decade’s success in critical care practice in reducing ventilator-associated pneumonia.

As a complement to my research in medical product innovation and development, I enjoy working with medical device companies to help with product design, prototyping, clinical testing, and clinical outcomes research. Recovery Force (RF) Health is working on a next-generation system to enhance patient mobility and provide mechanical prophylaxis of deep vein thrombosis (DVT). Their Movement and Compressions (MAC) system is absent of tubes and pumps, stays in place during ambulation, is lightweight and comfortable for continuous wear, and is designed to improve compliance with recommended use. Working in close collaboration with RF Health, we submitted and were awarded a \$1.8 million National Institutes of Health Small Business Innovation Research (SBIR) phase II grant. This funding will allow us to complete the development of the

device and conduct a clinical outcomes study at 2 sites, Tufts Medical Center (Boston, MA) and Eskenazi Hospital (Indianapolis, IN).

### Challenging Precedent: Academia

The synergies between my critical care nursing practice experiences and networks and industry-based medical device development experience have provided me with a unique perspective for innovating, testing, and improving medical devices using human factors design principles and will continue to drive my clinical research. Moreover, my transition into full-time academia at this point in my career allows me to focus on my own research interests and facilitates more easy navigation of the conflicts associated with commercial influence. The goal of my joint faculty position at the Institute for Applied Life Sciences (IALS) and the College of Nursing at the University of Massachusetts Amherst is to expand capacity for nurse-driven medical product innovation through interdisciplinary collaboration and the development of 2 laboratories.

First, we will create a product prototyping lab in IALS, where design-thinking, human-factors principles, and rapid iterative prototyping can be used for product creation. Second, the plan is to build a product usability lab at the University of Massachusetts Mount Ida campus that can be used for product testing with nurse/clinician end users. These 2 labs will also provide the infrastructure needed for additional clinical, academic, and industry collaborations outside of the university to further enrich our product innovation capabilities. My hope is to cultivate productive and fun interdisciplinary collaborations, especially with business and engineering colleagues, deepen and share my passion and ability to contribute to person-centered, humanistic patient care, and expand my capacity to develop and mentor the next generation of nurses.

Be interdisciplinary and collaborative; take every chance you can to mentor and be mentored; never miss an opportunity to celebrate the success of others; never take no for an answer (well, almost never... 😊).

### Challenging Precedent: Final Thoughts

Throughout my unconventional journey as a nurse researcher and medical product innovator, I have learned some important lessons along the way: make patient care and end-user needs a centerpoint of your

work; be passionate and follow your passion; take advantage of the opportunities you are given—do not let fear or uncertainty stop you; work with groups, be interdisciplinary and collaborative; take every chance you can to mentor and be mentored; share success and never miss an opportunity to celebrate the success of others; be persistent—never take no for an answer (well, almost never... 😊); and have FUN!

Nurses are in a unique position as frontline clinicians to identify and address everyday health care issues, challenge assumptions and the status quo, and address unrecognized and unarticulated needs. As a result of role differences, most other health care professionals do not understand the full scope of these everyday issues and their impact on workflow and patient care. At the same time, nurses are part of a team where every discipline and every job is important. That is why the best and most cost-effective outcomes for patients are most likely to be achieved when all members of the health care team partner collaboratively and where the expertise and role of the nurse is recognized, empowered, and becomes a driver of innovation and a reality check on pro-innovation biases that often miss or ignore unintended and unanticipated negative consequences. My own experience in medical product development and working with our business and engineering colleagues over the years has served to highlight the vital importance of having a nursing perspective built into the product development process from idea to commercial release. My wish is to see that same opportunity be available for all nurses.

#### ACKNOWLEDGMENTS

While my unconventional journey has been more rewarding than I could have ever imagined, it would not have been possible without the support of so many along the way, including

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My late mother-in-law, Kaye Giuliano, who loved and supported me unconditionally for 38 years. She remains dearly beloved, deeply missed, and forever my reliable cheerleader. My children, Marissa and Chris, whose curiosity about my work helps make for a fun and integrated home-work life, and who delight in helping to spend down my frequent traveler points.

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#### FINANCIAL DISCLOSURES

None reported.

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