Policy impact: When policy fails

Judy E. Davidson DNP, RN, MCCM, FAAN1 | Mary Faith Marshall PhD, HEC-C, FCCM2 | Jonathan H. Watanabe PharmD, PhD, BCGP3

1Department of Psychiatry, University of California San Diego School of Medicine, University of California San Diego Health, La Jolla, California
2Center for Biomedical Ethics and Humanities, School of Medicine, School of Nursing, University of Virginia, Charlottesville, Virginia
3Division of Clinical Pharmacy, Skaggs School of Pharmacy and Pharmaceutical Sciences, University of California San Diego, San Diego, California

Correspondence
Judy E. Davidson, DNP, RN, FCCM, FAAN, Department of Psychiatry, University of California San Diego School of Medicine, University of California San Diego Health, MCM1 9425 Health Sciences Drive, MC 7691, La Jolla, CA 92037. Email: jdavidson@ucsd.edu

Abstract
The best policies are evidence-based, providing feasible solutions to healthcare issues to prevent unintended consequences. Nurse researchers need to generate evidence with which to create policy. The obligation to monitor the impact of policies and standards rests on nurse leaders who have the duty to advocate when policies fail. Nurses providing direct care are beholden to report failed policies. Advocacy in the situation of a failed policy often requires moral courage to prevent moral distress amongst the ranks of nurses who enact policies at the intersect of care. In this article, the impact of three healthcare policy issues on nursing end-users will be evaluated: aid in dying, titration of vasoactive medications, and the Center for Medicare and Medicaid Services 30-minute rule.

KEYWORDS
evaluation, healthcare policy, moral distress, regulatory, risk management, standards

1 | INTRODUCTION

Many agencies have responsibility for developing and overseeing health care. The Centers for Medicare and Medicaid Services (CMS) sets policy for the Department of Health and Human Services which consists of multiple agencies that regulate the delivery of healthcare. The Food and Drug Administration (FDA) ensures the safety of medications. The National Institutes of Health oversees health care research to generate new knowledge regarding health, disease, and treatments. The Centers for Disease Control and Prevention collects and monitors data related to infection, investigates outbreaks, and sets policy in response to outbreaks.

The 2010 Patient Protection and Affordable Care Act is designed to reconfigure health care policy to improve access to health insurance, to decrease health care costs and to optimize health care quality. Organizations such as the Institute of Medicine provide data to support legislation such as this one.

The policy may be made at the national, state or local government level. Healthcare policy sets goals and plans in place to optimize the health of society. At the state and local level clinicians and organizations are credentialed or licensed to optimize the delivery of care.

Accrediting agencies such as The Joint Commission do not set regulation, but instead, support the work of regulatory bodies in ensuring that healthcare policies are met through the development of a strict set of operational standards. Professional specialty organizations such as the American Nurses Association (ANA) and specialty organizations such as the American Association of Critical Care Nurses set professional standards that can be used to help shape future policy or to support existing policies. Local organizations set internal policy and standard to meet regulatory expectations.

Healthcare policies are evaluated at many points along the continuum of development. However, at the local level, the quality of a healthcare policy may be measured by whether it can be enacted with the available resources, achieves the preplanned outcomes, and does not result in unintended untoward consequences. A balance needs to exist between clarity of the policy or regulatory standard so that the intent is interpreted evenly by all users, and flexibility to provide individualized care or services based upon variation in societal health needs, resources and individual response to treatment or illness. (Figure 1). In this article, three healthcare policy issues and their impact on nursing end-users will be evaluated.
2 | AID IN DYING

2.1 | The problem

2.1.1 | State adoption

This healthcare policy issue reflects the tension between the incremental legalization of assisted dying and national professional norms that prohibit nurses or physicians from assisting, upon request, in a terminally ill and imminently dying patient’s death. At this writing Aid In Dying (AID), once known as physician-assisted suicide, is legal in California, Oregon, Vermont, Hawaii, Washington, Montana (through a court ruling), and Washington D.C. (through legislation). Criminal charges for performing AID in jurisdictions where it is not legal ranges from first to second-degree murder to manslaughter and a wide variety of felony charges. Nevada, North Carolina, Utah, and Wyoming either do not recognize common law, have no laws governing AID or do not address the legality of AID. In 2015 the New Mexico Court of Appeals struck down a lower court ruling in Morris et al v. Kari Brandenburg and Gary King; the lower court had found liberty, or constitutional, interest in AID.¹

2.1.2 | Differences between methods of AID in adopted jurisdictions

Montana does not have a legal AID protocol for physicians, a patient request timeline or other constraints except that patients eligible for AID must be terminally ill and mentally competent adults. Patient eligibility for AID is similar in Oregon, Vermont, California, and Washington; patients must be at least 18 years of age, state residents, decisionally capable, and diagnosed with a terminal illness that will lead to death within 6 months. California requires that the patient be physically and mentally capable of self-administering the drug(s) or substances used for AID.

The patient request timelines are also similar. All five states require a 15-day waiting period after the patient’s first oral request to the physician. All six states also require a second oral request that is then followed by a written request. Oregon and Washington require a 48-hour waiting period before prescribed medications can be picked up from a pharmacy.

The physician protocols all require physician licensure in the same state as the patient; certification by a consulting physician of the diagnosis of terminal illness with death expected within 6 months, and attestation of the patient’s decisional capacity; as well as disclosure of alternatives such as palliative care, hospice, and pain management. Washington requires notification of next of kin of the prescription request.

2.1.3 | The solution

Legalized assisted dying in the United States

Oregon was the first state to legalize assisted dying. Oregon’s Death With Dignity Act, originally legislated in 1994, (with a 51% majority), was repealed in 1997, (with a 60% majority). In Gonzales v. State of Oregon, the Supreme Court of the United States ruled, via a majority opinion, that the Controlled Substances Act does not empower the Attorney General of the United States to prohibit physicians from prescribing regulated drugs for use in physician-assisted suicide under state law permitting the procedure. The Court’s ruling thus upheld the Death With Dignity Act.

The state of Washington passed ballot initiative 1000: Death With Dignity Act in November 2008 (with 54% of voters in favor). California’s End of Life Option Act was signed into law in October 2015. Vermont’s Act. No. 39: An Act Relating To Patient Choice and Control at End of Life was signed into law in May 2013. The Death With Dignity Act (Law 21-182) became effective in February 2017 in the District of Columbia. Baxter v. Montana was decided in favor of the physician plaintiffs (four Montana physicians, Compassion, and Choices, and Robert Baxter, a 76-year-old man dying of lymphocytic leukemia). The plaintiffs asked the Montana First Judicial District Court to establish a constitutional right “to receive and provide AID.” The Montana Supreme Court found that “we find no indication in Montana law that physician AID provided to terminally ill, mentally competent adult patients is against public policy” and therefore, the physician who assists is shielded from criminal liability by the patient’s consent.¹

2.1.4 | Position statements on AID

ANA. Official guidance of both the ANA and the American Medical Association (AMA) proscribe assisted suicide. The ANA Euthanasia, Assisted Suicide, and AID (24 April 2013) position states.

"The American Nurses’ Association (ANA) prohibits nurses’ participation in assisted suicide and euthanasia because these acts are in direct violation of Code of Ethics for Nurses with Interpretive Statements (ANA, 2001; herein referred to as The Code [note: most recent version 2015]), the ethical traditions and goals of the profession, and its covenant with society. Nurses have an obligation to provide humane, comprehensive, and compassionate care that respects the rights of patients but upholds the standards of the profession in the presence of chronic, debilitating illness, and at end-of-life.” [no page number]²

The AMA: opinion 2.211—physician-assisted suicide, the position is that:

"It is understandable, though tragic, that some patients in extreme duress—such as those suffering from a terminal, painful, debilitating illness—may come to decide that death is preferable to life. However, allowing physicians to participate in assisted suicide would cause more harm than good. Physician-assisted suicide is fundamentally incompatible with the physician's role as healer, would be difficult or impossible to control, and would pose serious societal risks." (no page number)3

2.1.5 | Conflicts between regulatory and professional standards

The ANA guidance on assisted dying prohibits its members from participating in the process of AID, arguing that to do so would directly violate the Code of Ethics for Nurses with Interpretive Statements. However, providing comfort to patients during the AID process remains in the nurses' scope of practice.4 The paradox for many nurses, especially those practicing in the District of Columbia and the six states that allow AID, is that the norms of their national professional organization may predictably conflict with some nurses' own professional norms. However, there are no studies to date exploring nurses' values regarding their involvement in this process. Because administering medications is a normal part of a nurse's scope of practice, and patients often need support with this at end of life, it is plausible that some nurses would want to help the patient with the administration of medications. However, this is prohibited at this time by the scope of practice. For nurses in states where AID is legal who work with patients who may undergo AID, following the professional standard may cause moral distress; distress caused by being prevented from doing what one feels is the right action.5 Further, nurses who allow, endorse, or produce a situation that causes moral distress is in direct violation of the same ANA Code of Ethics and Interpretive Statements.6 Given that individual values related to AID predictably span a wide continuum, these two stipulations in the Code may be impossible for some nurses to adhere to simultaneously.

In Oregon, California, Vermont, California, Hawaii, Washington, Montana, and the District of Columbia, where AID is legal, nurses, those who work with the terminally ill may feel that part of their "obligation to provide humane, comprehensive, and compassionate care that respects the rights of patients" is to honor their patient's choice for assisted dying, to assist their patients in controlling the circumstances of their deaths, and directly support the dying process.8 Nurses could see forgoing this assistance as an abdication of their professional and moral responsibilities to their terminally ill and suffering patients and their loved ones.7

Guidance from the Oregon Nurses Association, "Assisted Suicide: The Debate Continues" clarifies actions for nurses who choose whether or not to be involved in assisted dying. Nurses who choose to be involved can "be present during the patient's self-administration of the medication and during the patient's death to console and counsel the family." They may not inject or administer the medication that will lead to the end of the patient's life: this is an act precluded by law.9 Those who choose not to be involved may "conscientiously object to being involved in delivering care. You are obligated to provide for the patient's safety, to avoid abandonment, and withdraw only when assured that alternative sources of care are available to the patient.8

The ANA's proscription against nurse participation in AID involves a logical fallacy. A representative of the ANA's Center for Ethics and Human Rights is quoted in The American Nurse as saying, "We acknowledge that the patient has a right to decide, but we don't support the action" (of AID). She pointed to language in Provision 1.4 in the revised Code that specifically states: "Nurses should provide interventions to relieve pain and symptoms in the dying patient consistent with palliative care practice standards, and may not act with the sole intent to end life...it's really about the intent." Clinicians who participate in AID could argue that their intent is to relieve a patient's current suffering, prevent future suffering, and honor that dying patient's voluntary and capable decision to exit life on his or her own terms. Patients who ask for assisted dying do so not because of a primary wish to exit this life, but because they see no alternative to ending their suffering.6

The moral dilemma described here clearly illuminates why nurses need to be actively involved in painting the legal landscape proactively to obviate the need for writing potentially conflicting professional standards later. The ANA Position Statement (04/24/13) Euthanasia, Assisted Suicide, and AID, was written to address the discord between policy and practice. This document provides recommendations that focus solely on educating nurses and the public as to why the organization prohibits this practice.7 We posit, however, that with potential ever-present conflict, the task at hand is to evaluate the moral landscape by conducting research to identify the actual values of nurses surrounding the practice of AID. Only then can we identify, and if needed, reconcile contradictions between values, professional standards, and the law. This is especially important as the growing movement towards acceptance of AID continues. Resolution of this divide by nurse leaders, as policy champions, individually and through their professional organizations, is necessary at the highest level to prevent the unintended consequence of moral distress amongst nurses. When policy results in unintended negative circumstances, advocacy is indicated (Figure 2). Further, this example points out the need to maintain our professional standards flexible enough to account for changing societal norms and the wide range of positions that nurses may have on controversial value-laden issues such as assisted dying (Figure 1).

2.2 | Vasoactive infusion titration

This healthcare policy issue reflects upon Title 22 Standards of Medication Administration in the State of California (Div5 Ch1Art3-70263 lg)(2). The regulation states:

"No drugs shall be administered except by licensed personnel authorized to administer drugs and upon the order of a person
lawfully authorized to prescribe or furnish...The order shall include the name of the drug, the dosage, and the frequency of administration, the route of administration, if other than oral, and the date, time and signature of the prescriber or furnisher. Orders for drugs should be written or transmitted by the prescriber or furnisher...Medications and treatment shall be administered as ordered”.

2.3 | The problem

On the first read, nothing about this healthcare issue sounds controversial or problematic. However, during one CMS inspection performed by the State Department of Health Service employees, who monitor adherence to Title 22, a problem was identified with titration of vasoactive agents in the intensive care unit (ICU). As standard local practice for many years and geographic standard in the community, the physician would order a vasoactive agent, write the desired end-goal (e.g., mean arterial pressure of 60 mmHg), and allow the nurse to titrate the medication to effect with a starting dose and maximum dose. On this occasion, regulatory agents found this unacceptable because it appeared as if nurses were creating their own unwritten orders by altering the frequency and increment of titration independently. If three nurses were asked how they would titrate the medications they would come up with different answers, all of which would meet the goal of obtaining the desired mean arterial pressure, yet achieving the goal in different ways. The nurses became quite concerned regarding the findings. To put their perspective in simple terms we present the analogy of baking. If three people were asked to bake a batch of brownies, and all three used a slightly different recipe, but all three batches of brownies were delicious, should there be a problem with the fact that they used different recipes?

Let’s think about how the titration of vasoactive agents works in clinical practice. Humans are all of the different size, volume status, blood pH, electrolyte balance, kidney and liver function, the number of protein stores for plasma protein binding, and tissue perfusion; all of which affect response to medications. Even within one human, the medication will respond differently from hour to hour depending on these same variables as they change in the body over time. Further, humans each have their own genetic make-up which we now know can affect the way medications are metabolized in the body and make the response to a new medication unpredictable. Differences in the cytochrome P450 liver enzymes responsible for drug metabolism can be powerfully affected by individual genetic polymorphisms.

It is important to remember that this phenomenon affects not only the elimination of drugs. Some drugs are administered as prodrugs that must first be metabolized to an active form by the cytochrome P450 liver enzymes; the ability to convert to an active drug may also vary from person to person. Examples of prodrugs that must be metabolized to an active drug are codeine and clopidogrel. Age also influences absorption, distribution, metabolism, and excretion of drugs affecting the time to a therapeutic range of active drugs after administration. Older adults have an increase in total body fat, reduced total body water, and reduced extracellular fluid. Due to differences in the lipophilic nature of drugs these physiologic changes in older adults will also influence the retention time of medications.

The physician orders the infusion of a vasoactive agent, communicating why the medication has been ordered and the goal to achieve with the titration. Then the nurse is left to achieve the goal. There is little scientific evidence about the best practice for titration for vasoactive medications and, therefore, historically orders have been written to titrate to physiologic endpoints. However, the regulatory agents expected that the physician would write discrete orders for incremental dosing (how much to titrate up or down by) and in what time intervals (how often this should happen). But is this pharmacologically sound? Consider a postoperative patient who comes out of surgery cold and hypovolemic. The medication will respond differently as the patient warms and becomes euvolemic. The frequency of need for titration may decrease, and the dose may decrease with these changes. Where once requiring 5 micrograms (mcg) of medication to effect an appreciable
improvement, may be now it is 3 mcg. However, discrete orders will only allow the nurse to do one or the other and the nurse is expected to call the physician if the existing order does not work. In critically ill patients, the changes can be very rapid, and fluctuate back and forth frequently.

In response to the regulatory finding, vasoactive medication titration order sets were developed, which prompt the physician to write all of the parameters requested by the CMS, limiting nurses from independently increasing or decreasing frequency or dose of titration. Except for possibly an infringement on the scope of practice of educated highly specialized nurses, this sounds like a reasonable solution. Pharmacists and physicians were satisfied with the initial response. All appeared fine until the clinicians caring for the patient at the point of service provided input.

Nurses describe two different responses to the edict: (a) titrate the drug as previously done, do not document anything until you find the patient’s ‘sweet spot’, and then call the physician for that order and document that dose or (b) follow the order with a resultant delay in the desired outcome as you wait with each call to the (frustrated) physician to adjust the order to meet the patients’ needs. In emergent clinical situations, it is clear that either option adds potentially fatal complexity. The nurses openly describe being in a no-win situation. They either need to “falsify” the charting, which is illegal and against their moral standards, or not meet the patient’s needs, which is again against personal moral standards, principles of human respect, and beneficence.

The interim result to the situation is a distrust of the system at a regulatory level, temptation to practice against the scope of practice, and erosion of faith in organizational leadership. In the absence of advocacy at the organizational level, nurses turn silently to “doing the right thing” and “knowing what to do when agents come back to check on their work”.

2.4 | The solution

In this situation, it should be noted that all hospitals in this region practice in the manner that the CMS found unacceptable. The practice had been in place for over 30 years. The regulation had not changed but was interpreted differently than previously be a particular set of regulatory agents. This speaks to the need for writing regulatory standards with enough clarity so that they can be enforced uniformly across similar locations.

What could or should happen next? The problem, here, is the need to advocate against authority gradient. The CMS is a federal agency with great power and reach. If an organization challenged the CMS with a poor result to the challenge, the organization could lose licensure. The risk of resisting the request of the CMS can be deemed internally greater than the common good. It is not known how many other organizations have been faced with the same issue. For obvious and good reasons, organizations do not eagerly share their deficiencies with others, so the breadth of the problem is poorly understood. It can be predicted that the request for practice change by the CMS will spread, and so will the moral distress amongst ICU nurses; knowing the right thing to do and being prevented from doing it. Further, nurse leaders will also be challenged with what is seemingly on the surface a situation with no reasonable solution; again stimulating moral distress.

For this situation, no single organization feels that they can assume the risk of agency, even though challenging this practice standard is the real “right thing to do.” According to the ANA Code of Ethics, it is the responsibility of nursing leadership, to advocate for ethical practice and prevent moral distress amongst our ranks. It is also the responsibility of nurses to advocate on their own behalf and leave organizations that do not support ethical practice. This case demonstrates how difficult it is to actually advocate when the group stimulating the moral dilemma has the power to shut down the health system. The reality of this particular situation is that momentum for change should build when organizations can band together to challenge the practice without incurring individual risk.

In the meantime, it would behoove nurse scientists and quality improvement specialists to collect data to demonstrate why the existing requirements are ineffective in meeting patient needs. Also, efforts to automate titration response using artificial intelligence could make the problem obsolete. Armed with evidence and/or new approaches to care, the regulatory standard can be modified, as we see in the next case report. Open dialogue amongst nurse leaders across organizations exposing the issue at hand is important to move past the inertia caused by fear of retribution to challenge the status quo. For complete resolution, an evaluation and action plan undertaken at the national level such as the one described in the case to follow is needed.

3 | CMS 30-MINUTE MEDICATION REGULATION

3.1 | The problem

This healthcare issue reports on the successful advocacy to change a CMS regulatory standard. The CMS 30-minute medication regulation was developed to assure that patients received medications in a timely manner. Timely medication is a laudable goal. The regulation dictated that inpatients were to receive medications within 30 minutes on either side of the administration due time. So, if the medication was due at 0900, the medication should be administered between 0830 and 0930. Again, at face value, this sounds reasonable until the voice of the clinician administering medications is taken into account. The rule had been in place so long it would be difficult to trace its origin. Because it was written, as a rule, failure to comply could generate a citation, fines, and threaten the organization’s ability to bill to Medicare and Medicaid. However, this threat was minimized because the rule was not actively enforced.

3.2 | The solution

In 2010 the Institute for Safe Medication Practices issued a survey to solicit feedback about the rule. A resounding 17 500 nurses responded to the request with universally negative feedback. They
declared the rule impossible to follow, unnecessary, and potentially harmful to patients. Of the survey participants, 70% stated that their organizations endorsed the rule, and only 5% stated that they could comply with it. Attempting to follow the rule had many unintended consequences. Consider morning medications. Since most morning medications are ordered at 0900, nurses would cluster in line at the medication dispensing unit all at the same time. It is a safe medication practice to pull one patient's medications at a time so that they are not mixed up inadvertently resulting in medications being given to the wrong patient. However, to meet the time standards, nurses were tempted to shortcut the process and pull all of their patients' medications at the same time so that they did not need to line up 3 to 5 times. Multiplying out the number of nurses and number of patients with medications at the frequently ordered administered medication times, it was mathematically impossible for nurses to pull the medications for one patient at a time and administer them all within 30 minutes of each side of the administration time. Nurses reported that they did not have time to check doses carefully or to answer patient questions about the medications, so attempting to meet one standard resulted in not meeting others. Because of electronic recording with the electronic health record and bar-coding, nurses knew they could be tracked and would take shortcuts in bar-coding by using duplicate patient armbands. All of these shortcuts decreased resultant patient safety. Practice does not exist in a vacuum. Situations also often arise when clinical pharmacists recommend to nurses medication administration should be delayed based on new clinical information that will affect the medication dosing. Increased serum creatinine levels, reduced antibiotic serum levels, or changes in dialysis timing are just a few examples of scenarios that will all result in additional cognitive time for the care team that may delay medication administration for the express purpose of optimizing safety and efficacy.

This healthcare issue demonstrates another example where a rule was created without evidence to support the fact that it is necessary, feasible or reasonable to carry out (Figure 2). Both this scenario and that of the vasoactive agents could have been prevented if regulatory agents had walked the process with clinicians before crafting the rule. By engaging with frontline staff and watching the workflow a more reasonable process would have been developed.

In this case, for many years, nurses violated their own moral standards by breaking a rule to provide care in the best interest of the patient. In the process, they often increased the risk to their patients by taking shortcuts in medication administration to meet the time standard. Being prevented from doing what you know is right results in moral distress and associated long term consequences. This distress was needlessly imposed on staff by a poorly constructed policy executed without thought to workflow or feasibility.

In 2010, the 30-minute rule was reversed. Instead, hospitals were to create their own internal policies for how to administer medications in a timely manner. Organizations were encouraged to consider the different classifications of medications. For example, urgent replacement of sodium in a hyponatremic patient should have a different time urgency than routine daily aspirin for heart attack prevention.

4 | DISCUSSION

4.1 | A process for policy formation

The following process map (Figure 2) is offered to demonstrate a model high-level process for policy formation. First, evidence exists identifying a best practice. This evidence is grounded in research. When enough evidence exists to support the best practice, professional specialty organizations (e.g. American Association of Critical Care Nurses, ANA, American Association of Operating Room Nurses) develop national practice standards. Once the practice standard or guideline is developed and issued, each organization at the local level reviews the standard and considers adopting. The Chief Nurse Officer is ultimately responsible for adopting appropriate standards into the workplace. Clinical Nurse Specialists and other nurse leaders often lead the review of new national standards for potential adoption in the workplace. The Chief Nurse Officer may elect not to adopt a given standard, due, for instance, to lack of resources. This decision also incurs a risk if it has become a geographic standard to adopt the standards. In this situation, the Chief Nurse Officer consults with Risk Management to determine the risk/benefit ratio to the organization and make a final decision. Widespread adoption coupled with advocacy at a high level may result in policy formation. Regulatory agencies write policy and regulatory standard with the intent that if the policy is not followed the practice is wrong. Not following policies issued by regulatory agencies may result in sanctions, fines, loss of revenue, loss of accreditation, or loss of license. Finally, in a perfect world, if a policy generates untoward unintended consequences, constituents would advocate for change and a revision to the policy would be written.

4.1.1 | Policy as regulation of the best practice.

It should be noted that policy should be written only when there is clear evidence that the absence of this best practice could cause harm. There are risks to over-regulating the work environment. Over-regulation could stimulate the development of an oppressed workforce, moral distress, depression, burnout, and even suicide amongst the staff. When regulation is made in response to direct response to adverse events without evidence to support the action, the risk of unintended consequences increases (Figure 2).

4.1.2 | Policy evaluation: reflective inquiry

Policies at all levels should be evaluated for outcomes and effect on workflow so that unintended consequences can be evaluated and reported back to policy-makers. Internal breeches of nonconformance
to policy should be evaluated using reflective inquiry without the assumption of blame. Reflective practice questions can be divided into cognitive, moral, socio-political, affective, and behavioral categories. Sample questions are provided:

- Cognitive: What do you think contributed to this event?
- Moral (ethical): Did anything or anyone prevents you from doing what you felt was the right thing to do in this case?
- Socio-political: Are the policies/guidelines/equipment set up for successful avoidance of this situation?
- Do you have the equipment you need? □ Yes □ No
- Are there any bureaucratic (hierarchical) issues or tensions that we need to discuss to avoid this in future cases?
- Affective: What are your feelings about this issue/this case?
- Behavioral: What could we do differently to avoid this from happening in the future?

Notice that the language is not ‘what did you do wrong?’ but instead ‘what can we do differently?’ During an evaluation framed as reflective inquiry, it is often found that noncompliance stems from operational root causes. Structural inadequacies such as outdated fields in electronic health records to record the new expectations can result in false negatives (the policy is being followed, but it does not appear so from the documentation). At all costs, the blame should be avoided unless it is definitively found that the people involved intentionally did not follow the policy and had everything they needed to do so. Blame can cause symptoms similar to that of moral distress (sleep disorders, stress disorders, intention to leave the position and leaving the profession). Moral distress in the workplace affects both the health of the workforce and patient outcomes.

5 | FILTERS AFFECTING POLICY FAILURE

5.1 | Ethical filters

According to the ANA Code of Ethics, it is the responsibility of nursing leadership, to advocate for ethical policies to prevent moral distress in nursing practice. When confronting morally controversial medical practices, the obligation to monitor the impact of policies and standards rests on nurse leaders who have the duty to advocate when policies fail. Nurses providing direct care are beholden to report failed policies. Advocacy in the situation of a failed policy often requires moral courage to prevent moral distress amongst the ranks of nurses who enact policies at the intersect of care.

5.2 | Communication filters

The rationale for the policy involving the controversial medical practice must be communicated to all stakeholders. The rationale must be provided to current and future providers, users, and the public, to hold the provider accountable for correctly treating the use according to policy.

5.3 | Collaboration filters

All of the stakeholders must be represented and involved in the development of policies involving controversial medical practices. These stakeholders must represent the expertise necessary to design and implement the policy. Winkler noted that "Giving those directed by the policy (stakeholders) a voice in its creation recognizes them as moral agents." "Channels for constructive criticism" (p. 563).

5.4 | Conflict filters

Once developed and implemented, a mechanism must be provided for evaluating and criticizing the controversial medical practice. Criticism and objection may result in conflicts, creating barriers to implementation that must be addressed, e.g., conscientious objection. Mechanisms may then be anticipated and designed for modifying the policy, e.g., "channels for constructive criticism" (p. 565).

6 | SUMMARY

In summary, the best policies are evidence-based providing feasible solutions to healthcare issues to prevent unintended consequences. Nurse researchers need to generate evidence with which to create policy. The obligation to monitor the impact of policies and standards rests on nurse leaders who have the duty to advocate when policies fail. Nurses providing direct care are beholden to report failed policies. Advocacy in the situation of a failed policy often requires moral courage to prevent moral distress amongst the ranks of nurses who enact policies at the intersect of care.

ORCID

Judy E. Davidson http://orcid.org/0000-0003-1459-181X
Jonathan H. Watanabe http://orcid.org/0000-0002-2543-5305

REFERENCES

11. Smith BS, Yogaratnam D, Levasseur BA. Rational drug therapy. druginformation.org/viewarticle/772501_3

AUTHOR BIOGRAPHIES

Dr. Judy Davidson is a nurse scientist for the University of California, San Diego Health. Her background includes serving as Chair of the Ethics committee for the Society of Critical Care Medicine and current research centers on workplace wellness.

Dr. Mary Faith Marshall is a Bioethicist and member of the ethics consult team for the University of Virginia, Charlottesville. She also served as the Chair of the Ethics Committee for the Society of Critical Care Medicine.

Dr. Jonathan Watanabe is an Associate Clinical Professor for the Skaggs School of Pharmacy and Pharmaceutical Sciences in San Diego. He was a contributor to the National Academy of Sciences, Engineering, and Medicine Ensuring Patient Access to Affordable Medications study and the Making Medicines Affordable: A National Imperative report that we reviewed by the US Senate and the White House Council of Economic Advisers. Dr. Watanabe examines large, real world databases with the goal of developing policy solutions to improve patient care, augment population health, and reduce medical costs.