

An Evidence-Based Tool for Regulatory Decision Making: The Regulatory Decision Pathway

Kathleen A. Russell, JD, MN, RN, and Beth K. Radtke, MS

In response to requests from boards of nursing, the National Council of State Boards of Nursing developed a model for disciplinary decisions that incorporates the systems approach and patient-safety principles and shifts the regulatory focus from outcomes and errors to system design and behavioral choices. This article describes the development of the Regulatory Decision Pathway, and explains how to use it. Included are two case studies that illustrate how the tool recommends different disciplinary actions based on the distinct behavioral choices of the nurses.

Boards of nursing (BONs), under the state's police power to protect the public, ensure safe patient care by establishing and implementing licensing requirements. When safety is breached through a violation of the state's practice act, regulators protect the public by stopping or limiting the practice of unsafe practitioners (Russell, 2012).

A landmark report, *To Err is Human*, by the Institute of Medicine (IOM, 1999), revealed that as many as 98,000 people die in hospitals from preventable medical errors each year. Despite more than 15 years since the IOM report brought patient safety to the forefront, recent evidence suggests that medical errors remain a major public concern (de Vries, Ramrattan, Smorenburg, Gouma, Boermeester, 2008; James, 2013). An important thesis of the IOM report is that the majority of medical errors were not the fault of people but resulted from faulty systems, processes, and conditions. Therefore, boards of nursing are becoming increasingly cognizant of the fact that the environment practitioners are working in is just as important to patient safety as the practice error.

Safety Culture Literature Review

Many in the health care profession have proposed that a cultural change is needed to achieve major improvements in patient safety. The risk to human life in clinical practice requires analysis and prevention. Analyzing errors using the "person approach" focuses on the cause aberrant act: forgetfulness, inattention, poor motivation, carelessness, negligence, or recklessness. The "system approach" analyzes the cause, rather than the consequence. Reason recommended that a *just culture*, one that draws a line between blameless and blameworthy actions, is an essential early step to creating a safe culture. As the science of safety develops, the emphasis is on interventions that minimize

the incidence and impact of adverse events through a systems approach (Emanuel et al., 2008). Consequently, patient safety must be concerned with the entire system.

David Marx (2001) proposed that discipline in response to honest mistakes does little to improve overall system safety. He defined a *just culture* paradigm that reflects a balance between justice and fairness on the one hand and the need to learn from a mistake and to take disciplinary action when appropriate on the other hand (Mayer & Cronin, 2008). A primary concept of a just culture is the systems approach to error accountability—accountability by the system and the individual regardless of whether harm resulted (Gorzeman, 2008; Griffith, 2009). Analysis of both the system and the individual actions can reveal the root of the problem, resulting in fewer errors (Gorzeman, 2008).

Individual accountability is measured by behavioral choices—human error, at-risk behavior, and reckless behavior (Marx, 2001). Human error includes unintentional and unpredictable behaviors; at-risk behavior involves unsafe habits, possibly negligence and carelessness; and reckless behavior is a conscious disregard with an understanding of the risk (Gorzeman, 2008; Griffith, 2009; Mayer & Cronin, 2008; Miller, Griffith, & Vogelsmeier, 2010).

Development of the RDP

The Regulatory Decision Pathway (RDP) was developed as a result of an expressed desire from BONs to have a tool for the evaluation of cases of nursing practice errors or unprofessional conduct that would promote disciplinary consistency and incorporate a systems approach.

After a systematic review of the patient-safety literature, the RDP framework was developed, which incorporates the

TABLE 1

Regulatory Decision Pathway Definitions

Mitigating factors: Extenuating, explanatory, or justifying facts, situations, or circumstances

Reasonably prudent nurse: A nurse who uses good judgment in providing care according to accepted standards

Remediation: Education or training to correct a knowledge or skill deficit

Substantial risk: A significant possibility that an adverse outcome may occur

System: An organization's operational methods, processes, or infrastructure/environment

systems approach and patient-safety principles and shifts the regulatory focus from outcomes and errors to system design and behavioral choices. Using four types of behavioral choices—human error, at-risk behavior, reckless behavior, and deliberate behavior—the RDP attempts to draw the disciplinary line. Definitions for terms in the RDP are presented in Table 1.

Although discipline can be effective under the right circumstances, the RDP concentrates on remediation, counseling, and supervision of the nurse to prevent future errors and protect the public.

Another major focus of the RDP is collaboration with the health care facility when a system error is revealed. These communications bring attention to the system's influence in or responsibility for the error. Collaboration between the nurse and the health care facility is encouraged when an action plan is essential to prevent future errors. Communication creates and strengthens collaboration between health care facilities and BONs, providing a consistent model of evaluation and BON action.

After the initial development of the RDP, thirteen BONs reviewed the tool, using more than 180 disciplinary cases (National Council of State Boards of Nursing, 2014). The tool was evaluated for clarity, usefulness, missing issues, and ability to impact decision-making consensus. The RDP was identified as clear, useful for disciplinary discussions, effective in leading to consensus in decisions, and in alignment with BON conclusions regarding disciplinary outcome. (See Figure 1.)

RDP Evaluation

In the RDP, a *system* is defined as an organization's operational methods, processes, infrastructure, or environment. An evaluation of the system may include questions for the organization's leaders to explore underlying system issues. Specific inquiries and evaluation should include the facility's policies or procedures, whether other providers in the health care system were

partially or solely responsible, or whether other institutional factors contributed to the error.

The RDP focuses its evaluation of the practice error or unprofessional conduct by considering the behavioral choices of the nurse. Specifically, the evaluation addresses whether or not the nurse's behavioral choices included any of the following: deliberate harm, concealment of the error, or substantial or unjustifiable risk (which is associated with a significant possibility that an adverse outcome may occur). Also, the evaluation addresses whether or not the nurse's history includes similar or serious errors and whether the nurse received remediation or counseling for a similar error.

Next, the BON considers mitigating factors that could influence its decision, including extenuating, explanatory, or justifying facts, situations, or circumstances. Finally, the BON reviews the nurse's actions in the context of the likely actions of a reasonably prudent nurse in similar circumstances. The *reasonably prudent nurse* is a nurse who uses good judgment while providing care according to accepted standards.

Disciplinary Decisions and Follow-Up

Following the RDP through the behavioral choices of the nurse and an evaluation of mitigating and aggravating factors leads to conclusions regarding the type of behavior the nurse exhibited: human error, at-risk behavior, reckless behavior, or deliberate behavior. The RDP concludes with suggestions for BON action. The suggestions primarily reflect the error education approach; however, discipline is suggested if the nurse has exhibited conscious disregard of risk or there were aggravating factors that lead to a conclusion of reckless behavior.

When a deliberate action by the nurse or a system issue is revealed, the BON communicates its findings to the health care facility via correspondence. Further communication between the nurse and the facility or employer also helps convey any practice restrictions, remediation, supervision, mentoring, counseling, or coaching necessary for the nurse to practice safely.

Case Studies

The following two case studies involve a nurse's failure to perform routine nursing procedures when administering a blood component: 1) bedside verification of the patient and blood component (bedside verification), and 2) verification of the transfusion record attached to the unit with the label on the unit by two individuals (transfusion record verification). However, each case study has a slightly different set of facts.

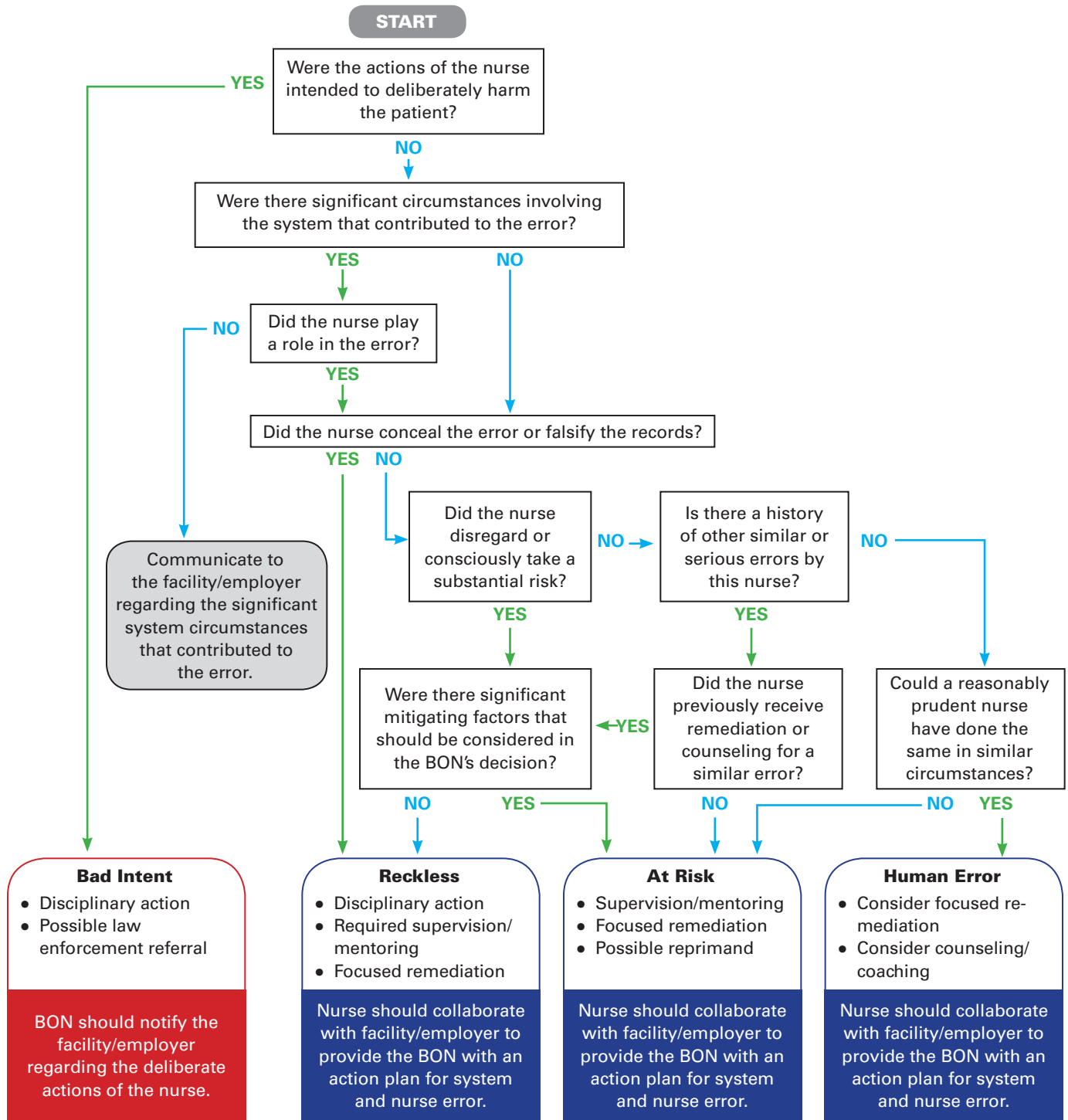
Case Study 1

Avery, a registered nurse (RN), was working in a busy emergency department (ED) when a trauma patient was admitted.

FIGURE 1

Regulatory Decision Pathway

The Regulatory Decision Pathway (RDP) is designed for board of nursing (BON) discipline decisions in cases of **practice errors** or **unprofessional conduct**. With the use of the RDP, the BON's discussion is focused on whether system failure and/or behavioral choices by the nurse contributed to the error. Through the use of the RDP, the BON will determine the type of behavior exhibited and whether disciplinary action or other action would assist in protecting the public.



Many staff members were attending to the patient during the first 20 minutes. Avery was administering I.V. fluids and medications and documenting their administration. Vital signs and other assessment findings indicated that the patient was losing blood and deteriorating quickly. Units of packed cells were ordered as soon as the patient was admitted. With the patient already intubated, two physicians were in the process of inserting a chest tube. The trauma room was crowded. Someone handed the first unit of packed cells to Avery and said, "Here's the blood for your patient." Avery administered the packed cells.

Later, it was determined that the unit of packed cells was not intended for Avery's patient. Avery assumed the nurse who handed her the unit of packed cells had performed the bedside verification and transfusion record verification. Therefore, Avery administered the unit of packed cells without performing the bedside verification and transfusion verification or ensuring that they had been performed. Avery reported the error to the charge nurse and documented the error in the patient's record.

Avery had been working at the hospital since graduation 2 years ago; for the past 6 months, she had been working in the ED. Avery had not reported an error of any kind during her employment, and her nursing license was unencumbered. Avery was responsive during the BON disciplinary review process and appreciated the risk of her actions.

The RDP review found the following:

- Avery did not intend to harm the patient.
- The system in the ED may have contributed to the error.
- Avery did play a role in the error.
- Avery did not conceal the error or falsify the record.
- Avery did not consciously take a substantial risk.
- Avery does not have a history of similar or serious errors.
- A reasonably prudent nurse could have taken the same action as Avery in similar circumstances.

The RDP conclusion: Avery committed a human error. The experience of the disciplinary process may stay with her for a period of time and may influence her future behavioral choices. The BON could suggest counseling and coaching from her employer. The hospital should be informed of the findings regarding the investigation of the system error via correspondence.

Case Study 2

Sam, an RN, was working the night shift on a surgical floor, caring for a patient who had undergone abdominal surgery for a rare cancer. Two units of packed cells were ordered for the patient. When the first unit was available, the patient-care unit was quiet. One nurse had accompanied a patient to radiology. Other nurses were caring for their patients, and the charge nurse was off the unit on break. No staff members were at the nursing station or visible in the hallway. In the past, Sam had

checked many units of blood using two-person transfusion record verification. But on this night he could not locate another staff member, and he wanted to start the unit so he could go on break when the charge nurse returned. Sam performed a one-person verification of the transfusion record and the bedside verification. He then began the transfusion. Sam signed the transfusion record and left the cosigner signature area blank.

Sam, a nurse of 15 years, had been working at the hospital for 1 year. He had been reported for several minor medication errors and once for not following proper procedures regarding documentation. His nursing license was unencumbered.

The RDP review found the following:

- Sam did not intend to harm the patient.
- There were no known system influences that may have contributed to the error.
- Sam did play a role in the error.
- Sam did not conceal the error or falsify the record.
- Sam disregarded and consciously took a substantial risk.
- There were no mitigating factors. The patient was stable. However, there were several aggravating factors. Sam wanted to get to his break; he did not complete the medical record as required; and he had a history of medication and documentation errors.

The RDP conclusion: Sam committed reckless behavior by violating the policy for verification of blood products and should receive discipline from the BON. At a minimum, discipline should include focused remediation and required supervision and mentoring. Additionally, he should collaborate with his employer regarding the required supervision and mentoring.

Disciplinary Decisions

Even if the patient outcome in these two cases were identical, the RDP recommends treating Avery and Sam differently. The BON's decisions should be tailored to each nurse and the actual violation. Frequently, harm to the patient is what gets organizational leaders' attention that an error has occurred, but with the RDP, harm is not the determining factor as to whether or not disciplinary action takes place. A near miss at one point in time could result in a catastrophic outcome at a future point in time.

These case studies demonstrate that error events fall on a continuum from a human error or mistake to a deviation or drift from the standard of care to deliberate violation of policy, as previously proposed in the literature (Etchells, Lester, Morgan, & Johnson, 2005; Ring & Moody Fairchild, 2013). System design and mitigating factors contribute to the BON's evaluation of organizational versus individual nurse accountability for an error. BONs and employers know that disciplining nurses for a human error does little to improve overall public safety, but holding a nurse responsible for mak-

ing reckless choices is clearly necessary (Burhans, Chastain, & George, 2012).

Model of Safety

Safety is a shared value achieved by creating an environment that includes consistent communication and values learning, nonpunitive error reporting, and fairness (Ring & Moody Fairchild, 2013). BONs who create a values supportive model with a balance in accountability between individuals and systems contribute to learning and a safety culture (Ring & Moody Fairchild, 2013). BONs fully aware of their charge to protect the public through evaluation and investigation of errors contribute to the culture of safety.

Following a consistent model of evaluation of violations of the nurse practice act that considers the system and the nurse's behavioral choices leads BONs to adapt their response to the cause of the violation. Seeking to uncover the rationale that led to the violation causes the BON to provide an individualized plan for remediation, counseling, coaching, or disciplinary action.

References

- Burhans, L. D., Chastain, K., & George, J. L. (2012). Just culture and nursing regulation: Learning to improve patient safety. *Journal of Nursing Regulation*, 2(4), 43–49.
- de Vries E. N., Ramrattan M. A., Smorenburg S. M., Gouma D. J., & Boormeester M. A (2008). The incidence and nature of in-hospital adverse events: A systematic review. *Quality & Safety in Health Care*, 17, 216–233. doi:10.1136/qshc.2007.023622
- Emanuel, L., Berwick, D., Conway, J., Combes, J., Hatlie, M., Leape, L., ... Walton, M. (2008). What exactly is patient safety? In K. Henriksen, J. B. Battles, M. A. Keyes, et al. (Eds.), *Advances in patient safety: New directions and alternative approaches* (Vol. 1). Rockville, MD: Agency for Healthcare Research and Quality; 2008. Retrieved from www.ncbi.nlm.nih.gov/books/NBK43629/
- Etchells, E., Lester, R., Morgan, B., & Johnson, B. (2005). Striking a balance: Who is accountable for patient safety [Special issue]. *Healthcare Quarterly*, 8, 146–150.
- Gorzeman, J. (2008). Balancing just culture with regulatory standards. *Nursing Administration Quarterly*, 32(4), 308–311.
- Griffith, K. S. (2009). Column: The growth of a just culture. *Joint Commission Perspectives on Patient Safety*, 9(12), 8–9. Retrieved from http://legacy.justculture.org/media/Joint_Commission-Just_Culture.pdf
- Institute of Medicine. (1999). *To err is human: Building a safer health system*. Washington, DC: National Academies Press.
- James, J.T. (2013). A new, evidence-based estimate of patient harms associated with hospital care. *Journal of Patient Safety*, 9(3), 122–128.
- Marx, D. (2001). *Patient safety and the "just culture": A primer for health care executives*. New York, NY: Columbia University.
- Mayer, C. M., & Cronin, D. (2008). Organizational accountability in a just culture. *Urologic Nursing*, 28(6), 427–430.
- Miller, R., Griffith, S., & Vogelsmeier, A. (2010). A statewide approach to a just culture for patient safety: The Missouri story. *Journal of Nursing Regulation*, 1(1), 52–57.
- National Council of State Boards of Nursing. (2014). *Regulatory decision pathway*. Retrieved from www.ncsbn.org/4833.htm

Russell, K. A. (2012). Nurse practice acts guide and govern nursing practice. *Journal of Nursing Regulation*, 3(3), 36–42.

Kathleen A. Russell, JD, MN, RN, and Beth K. Radtke, MS, are Associates, Nursing Regulation, National Council of State Boards of Nursing.