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

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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.