

ONE INTENSIVE CARE NURSERY'S EXPERIENCE WITH ENHANCING PATIENT SAFETY

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ABSTRACT

Critically ill infants are among the most medically fragile patients in hospitals today. Given their size and gestational age, the tolerance for error within this population is extremely small. Medical errors that may seem inconsequential in adults can have disastrous consequences for infants. This article describes one unit's experience with adverse patient events, and the resulting safety program that was developed to enhance the unit's safety culture. Specific strategies for successfully implementing a staff-focused patient safety program are provided. These strategies include the development of a unit-based interdisciplinary safety team to identify and respond to areas of risk; tools and techniques utilized for the analysis and prioritization of risk; incorporation of safety rounds as a means improving the safety culture; and implementation of staff-driven solutions to address safety concerns. The important role that parents and families can play in risk assessment and mitigation is reviewed, and the concept of parent partnerships is presented. Finally, initial program outcomes are discussed, and implications for other providers are suggested.

KEY WORDS: patient safety, medical error, newborn, infant, newborn intensive care, newborn intensive care unit, root cause analysis.

In 2003 a tragic organ transplant mismatch occurred at this institution.¹ A 17-year-old girl received a heart and lung transplant with a set of organs incompatible with her blood type. Fifteen days after that transplant the patient died. This event received significant national media exposure and stimulated discussion regarding medical error and patient safety throughout the country.

This tragic incident also provided an impetus to evaluate the hospital's intensive care nursery (ICN) for patient safety risks. The ICN is a 48-bed Level III neonatal unit within an 800+ bed academic medical center.² It serves as a regional referral center, providing care for a wide variety of acute and convalescing

medical and surgical infants, with an admission rate >700 infants a year. The patient population consists primarily of premature infants, as well as full-term infants requiring the latest in intensive care technologies.

Critically ill infants in units such as this are among the most medically fragile patients in hospitals today.^{3,4} The inherent fragility of newborns, the challenges of performing high-frequency high-risk procedures on extremely low-birthweight infants, and the low tolerance for error with extremely small medication doses are but a few examples of the dangers. Providers who care for these patients on a routine basis understand the risks they face every day, and factor patient safety into their clinical decision-making processes.

Despite this increased awareness of risk, and actions taken on a daily basis to minimize it, the ICN team identified several areas of systems risk after a comprehensive safety evaluation. As each of these areas was addressed, the team felt increasingly confident in its ability to provide safe care to its vulnerable patient population. However, an event that occurred in the unit in the late summer of 2003 proved that despite formal review of all known patient safety issues, the unit and its patients remained vulnerable to adverse patient events.

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EVENT REVIEW

A 30-week gestation, 1500 g newborn infant male was stabilized, admitted to the ICN, and placed in an incubator. After intubation the infant was draped and prepped for umbilical catheter placement. During this procedure and while awaiting radiographs to confirm correct catheter placement, the infant's bedside monitor alarmed for an increasing axillary temperature. The drapes were initially kept in place to keep the field sterile for line adjustment after radiographic exam. However, based on the increasing temperature as well as a commensurate increase in heart rate, the drapes were removed before the radiographic exam took place. At this point, the infant had significant thermal injury, including erythema and blistering along the right side of the body. The unit staff administered initial treatment; the infant was then transferred to the regional burn center for further evaluation and treatment. The infant responded well to therapy and made a complete recovery.

An interdisciplinary team carried out an analysis of the event using the root cause methodology recommended by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).⁵⁻⁷ The team concluded that the placement of the sterile drapes in the incubator created a channel by which heated air was forced from the incubator's warming element directly to the infant's skin surface.

Although the convection of heated air was identified as the primary root cause, other contributing factors included: the design of the incubator; the infant's position within the incubator; the time spent under the drapes during the procedure; the caregiver's inability to visualize the infant or the temperature probe; and clinical demands of a critically ill infant diverting caregivers' focus away from basic principles of thermoregulation.

In response to these findings the unit implemented a number of new safety processes. These included a complete incubator and radiant warmer fleet replacement, as well as new unit policies and protocols related to: positioning during procedures; equipment utilization; patient monitoring; and performance of radiographic studies expediently to avoid prolonged draping after catheter insertion.

Interestingly, even in retrospect, the root cause analysis (RCA) team was unable to identify previous clinical scenarios that would have warned staff and faculty that such an event was possible (Sidebar 1). In general, root cause analyses are effective at identification of corrective action for individual incidents; however, they do not necessarily provide the tools for anticipating future events that differ from the original incident. Thus, avoiding rare events that cannot be anticipated is best managed by the infusion of a culture of safety into every aspect of care. This culture should include every member of the healthcare team and all ancillary staff.⁸

SIDEBAR 1. A NURSE'S GUIDE TO USING ROOT CAUSE ANALYSIS^{5,6}

Root cause analysis (RCA) is a process that health-care teams can use to identify the basic or causal factor(s) that underlie variations in performance, including the occurrence or possible occurrence of a sentinel event. In general, RCAs:

- Are interdisciplinary in nature and include those closest to the process;
- Focus primarily on systems and processes rather than individuals;
- Ask *what* and *why* until the entire process is reviewed and all contributing factors are identified;
- Identify systems and process changes to improve performance and reduce the potential for future events or near misses.

To be thorough, an RCA must include:

- Evaluation of the human and other factors most directly associated with the event or near miss, and the processes and systems related to its occurrence;
- Analysis of the underlying systems and processes through a series of "why" questions to determine where system redesign might reduce risk;
- Identification of risks and their potential contributions to the event or near miss;
- Determination of potential improvement in processes or systems that would tend to decrease the likelihood of such events in the future, or a determination, after analysis, that no such improvement opportunities exist.

To be credible, an RCA must:

- Include participation by the leadership of the organization and by individuals most closely involved in the processes and systems under review;
- Be internally consistent (i.e., not contradict itself or leave obvious questions unanswered);
- Include consideration of relevant literature.

SAFETY PROGRAM IMPLEMENTATION

The serious burn of an infant in our NICU, combined with a concurrent system-wide increased focus on patient safety, led to the development of the ICN safety program. The safety structure put in place has resulted in a much stronger patient care environment where patient safety is the driving force behind all aspects of caregiving.

At the program's outset, the ICN leadership team recognized that, although they were able to recognize vulnerabilities in their environment, their knowledge of the actual science of safety was limited. To address this shortcoming, they requested assistance from the Children's Services Chief Medical Officer and other patient safety experts within the medical center. In response, the team was provided with focused educa-

tion, which included presentations at various unit meetings as well as essential safety reading material.

Once this education was complete, the ICN team began examining the unit's baseline safety culture, starting with the question "where does patient safety fit within our current provision of care?" Although from an academic perspective safety should always be the priority, in reality there are complexities associated with the delivery of care that force providers to balance competing factors to get the work done. Factors such as unit census and acuity, staffing levels, and clinical practicalities must be constantly balanced in an effort to provide the highest quality care. Because of these realities it is critical to have predetermined principles and priorities to guide decision-making in the heat of the moment. These principles can then become the foundation for a true patient safety vision that helps further guide decisions and ensures that providers never lose sight of the need to include safety as a critical aspect of patient care.

As a way to begin building this foundation the team then asked the question, "where do we want patient safety to fit in our ideal model?" It is easy to say that safety should be the highest priority; however, the intent of this process was to determine the actual desired state, to develop a value proposition based on the group's goals that would drive medical and nursing practice into the future. If the unit was to instill a true culture of safety within each team member it was essential that each of those members knew what "that" meant and were in agreement about exactly how "that" would be achieved.⁹ A mission statement hanging on the wall in the waiting room would not suffice—a vision not just accepted but truly embraced by all staff was essential to guide practice.⁸

To achieve this goal the unit's leadership team held numerous interdisciplinary meetings with staff and faculty. During these meetings all of the participants were encouraged to express their views of patient safety. This allowed the team to consider each individual provider's perspective and resulted in a much richer safety vision. The ultimate result of these open forums was the establishment of a culture in which each and every individual was empowered to raise concerns related to patient safety.

These initial steps were accomplished through the unit's highly active interdisciplinary executive committee. This committee included frontline caregivers as well as representatives from medical and nursing leadership, advanced practice nurses, pharmacy, and respiratory therapy. During this same time period, one of the recommendations of the broader Children's Services patient safety initiative was for each of the units in the Children's Hospital to form a safety team to champion patient safety initiatives at the local level. To ensure that safety efforts were well integrated into the overall unit structure, the ICN made the decision to utilize its existing Executive Committee to fulfill this role. This proved to be an effective model for several

reasons. First, the membership of the existing committee already included the formal leaders from the unit's administrative team. Their involvement ensured that safety received the highest level of attention possible.^{8,10} Second, given the broad scope of the existing executive committee's work, safety could be considered in every decision that the executive committee made, rather than as a secondary topic for later isolated discussion within a new safety team (Table 1).

Taking Safety to the "Streets" (or Bedside)

This formalized committee serves to prioritize safety concerns identified by individual caregivers. Once these issues have been raised the committee provides oversight to ensure the involvement of all appropriate stakeholders, a thorough exploration of all potential solutions to the problem, adequate resource allocation for projects (both human and financial resources), and accountability for project completion.

Given the critical role that the executive committee plays in patient safety, the team's membership was reevaluated to explore potential gaps in the team's safety perspective. To capitalize on the knowledge and experience of bedside caregivers, the committee actively sought the participation of nurses who were in key staff leadership positions. The chairs of the ICN Clinical Practice Committee, Performance Improvement Committee, and Staff Education Committee were appointed because of the important roles they played in the unit's shared governance structure. Additionally, 2 bedside caregivers, representing both day and night shifts, were elected by their peers to serve on the committee.

With increased frontline participation, and a renewed focus on safety given the recent clinical event, the entire nursing staff became critical links in the safety process by pointing out specific cases where individual infants and the unit were potentially vulnerable. Staff representatives validated the practicality of proposed safety initiatives. When new practices were adopted, the chairs of the Clinical Practice Committee and Staff Education were present to facilitate implementation. In short, the bedside caregiver played a key role in turning rhetoric into reality.

Discussions in a conference room, although helpful, can only take a safety program so far. The real effectiveness of safety efforts is determined at the bedside, when safety considerations are automatically integrated into practice and are a topic of discussion at every ICN team meeting.

As the team literally moved out of the conference room and began addressing issues at the bedside, more and more staff nurses became engaged in conversations about the impact each individual caregiver could have on patient safety. The old culture was to express concerns to the nursing delegates for discussion at Executive Committee meetings—in other words—identify, report, and expect someone else to fix it. The new culture became one of increased responsibility and urgency—sharing concerns directly with the team and

Table 1. Composition of the Unit-Based ICN Safety Team

Team Member	Team Role/Representation
Neonatologist	Co-Safety Team Chair
Neonatal Clinical Nurse Specialist	Co-Safety Team Chair and Six Sigma Green Belt
Nurse Managers	Unit nursing leadership
Chief of Neonatology	Unit medical leadership
Neonatal and Pediatric Critical Care Clinical Operations Director	Pediatric Core Safety Team and Six Sigma Black Belt
Bedside nurses	Clinical Practice Council Chair Staff Education Committee Chair Performance Improvement Committee Chair Representatives from day and night shifts
Neonatal pharmacist	Pharmacy
Neonatal respiratory therapy supervisor	Pediatric respiratory therapy
Lead NNP	NNP team
Neonatal Infection Control Nurse	Hospital infection control
Neonatal Nurse Educator	Staff education
Neonatal Fellow	Neonatal fellows and residents
Clinical Quality Manager	Accreditation and patient safety

Abbreviations: ICN, intensive care nursery; NNP, neonatal nurse practitioner.

developing solutions together, often in real-time (Fig 1).

This new culture allowed for the identification of issues using multiple routes and encouraged shared ownership of those issues at both administrative and front-line staff levels. Once an issue was identified, the safety team evaluated and prioritized it and assigned team members to explore potential solutions. The proposed solutions were then brought back to the safety team for further analysis and discussion. If the team agreed that the solution(s) would be effective in addressing the initial concern, then the change(s) would be implemented. The impact of these changes was continually evaluated through feedback received via staff meetings, e-mail communications, and educational offerings. This “cycle of safety” helped staff to see that concerns being raised through safety rounds and other forums were indeed being addressed.

ROLE OF PARENTS AND FAMILIES IN PATIENT SAFETY

One aspect of the ICN safety culture that is often overlooked is the inclusion of parents and families in safety initiatives. This gap was addressed by involving parents in safety rounds. These rounds routinely take place at the bedside and include staff and faculty members as well as members

of the safety team. Safety rounds have proven to be one of the most valuable tools in the safety program’s repertoire.^{11,12} Their primary focus is to engage staff and faculty at the bedside to identify and address safety concerns directly at the point-of-care. Formal rounds are scheduled with Executive Committee members at least monthly and more informal safety rounds are conducted on a more frequent basis with the unit’s nursing leadership and individual staff members.

Recently the team began including parents in these safety discussions. After an introduction and explanation of safety rounds by one of the safety team members, parents are asked questions such as “What do you worry about when you leave your baby?,” “Are there aspects of your baby’s care that you find concerning?,” “Do you feel comfortable sharing concerns with your baby’s care providers? For example, if a nurse or doctor did not wash their hands before they touched your baby would you feel like you could tell them?” (Table 2). This open dialogue provides a unique perspective that helps the team identify safety concerns that otherwise may go unnoticed.¹³ The unit has built on this parent partnership by developing and providing written parent-focused safety information in an effort to actively engage all parents and not just those who are present for safety rounds.

As a result of this bedside initiative, parents as well

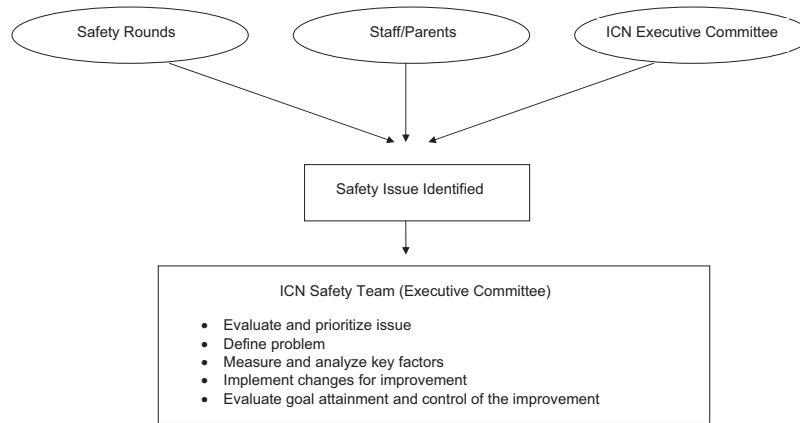


Figure 1. Identification and decision-making process to improve patient safety.

as unit team members have expressed more support of the unit's safety program. Staff and faculty feel more invested in the program and have noted an increase in the number of concerns resolved by the unit's leadership team. Parents have also reported feeling more involved in their infants' care.

SYSTEM-WIDE SUPPORT—THE PEDIATRIC CORE SAFETY TEAM

Even with this effective unit-based structure, additional support is sometimes needed to accomplish the team's objectives. The Pediatric Core Safety Team provides the local ICN team with support and access to

resources and information from across Children's Hospital. It also serves as an organization-wide champion for ICN issues that need to be addressed at the medical center level.

As part of this support the Core Team structure provides an additional level of confidentiality for the topics discussed by the team. Both core and local teams are included under both the hospital's Performance Improvement Oversight Committee and the Executive Committee of the medical staff as a mechanism for ensuring confidentiality under peer review statutes. In addition to the medico-legal protection provided by this model it also encourages the honest and open communication considered essential for understanding and resolving sensitive safety concerns.¹⁴

Finally, the core team is able to serve as an objective sounding board or arbiter for complex issues that the ICN team is unable to resolve internally. Although the vast majority of unit-specific issues are addressed at the local level, the ICN team has found the objectivity of the core team beneficial in helping to identify the most appropriate course of action on several occasions.

SUCCESSFUL PROJECTS TO DATE

Since its inception, the ICN's safety team's efforts have resulted in a number of successes that contribute to a safer environment for patients (Table 3). For instance, one of the team's earliest successes was the development of a nursing care delivery model that provided not just a free-standing charge nurse, but also allowed for a stabilization nurse to respond to all high-risk deliveries and unit emergencies. This updated staffing standard increased the charge nurses' ability to focus on the details of minute-to-minute unit operations and ensuring the safest possible patient environment.

A second team success demonstrates the need for support of safety initiatives at multiple levels within the organization. The ICN had historically allowed

Table 2. Safety Rounds Questions for Parents

1. Have you had any safety concerns during your baby's hospitalization?
2. Have you heard any other parents express concerns about the safety of their baby?
3. Do you feel comfortable leaving your baby to take breaks?
4. If there was one thing we could change to improve safety, what would it be?
5. Do you have a good understanding of your baby's condition?
6. Do the nurses and doctors keep you well informed about your baby's progress?
7. Do you have a good understanding of all the medicines your baby is receiving?
8. Do you know why each medication is being given, and what each drug does?
9. If you felt something was wrong with the care of your baby, would you feel comfortable asking questions?
10. If you didn't understand some aspect of your baby's care, would you feel comfortable asking for more information?

Table 3. Intensive Care Nursery Safety Initiatives

Initiative	Practice/Process Change	Outcome
Infant name changes	<ul style="list-style-type: none"> • Computerized information system no longer allows infant name changes after admission • Exceptions require administrative approval 	Decreased potential for patient identification errors
Staffing model	<ul style="list-style-type: none"> • Addition of dedicated stabilization nurse 	Increased staff coverage for admissions, procedures, staff breaks Improved staff satisfaction
Nosocomial infection	<ul style="list-style-type: none"> • Back-to-basics handwashing campaign targeted at providers 	Decreased blood stream infection rates
TPN administration	<ul style="list-style-type: none"> • Dedicated staff to write TPN orders • Prioritization of ICN TPN preparation by the compounding pharmacy • Added delivery times • Standardization of hang time of day 	Improved efficiency and effectiveness of TPN administration
Bar coding breast milk	<ul style="list-style-type: none"> • Development of bar coding software to interface with current patient data and institution technology • Preprinted labels for all breast milk with unique bar code 	Decreased potential for a wrong match between a mother's breast milk and her baby

Abbreviations: ICN, intensive care nursery; TPN, total parenteral nutrition.

parents to change infants' names at the parents' request (to address paternity issues, for example). With the increased focus on patient safety the ICN team identified a trend in which infants who experienced name changes during their inpatient stay were at increased risk for patient identification errors. Initial attempts to address this concern by policy development and staff education were unsuccessful. After discussion with the unit's Parent Advisory Board to review the issue and discuss the impact of planned changes on parent satisfaction (another example of parent involvement in the unit's safety culture), the team requested the hospital's Information Technology (IT) department's assistance in developing a technical solution to the issue. This collaboration led to the development of a system-solution in which no inpatient name changes can be accepted by the hospital's computerized information system without approval by the unit's leadership team. As a result, the unit has experienced only 1 inadvertent name change since the new system was implemented. That name change occurred through a previously unidentified programming interface and was immediately resolved by the IT staff when brought to their attention.

In addition to these larger projects the ICN team has become more responsive to safety challenges that occur as part of routine unit operations. For example, the team rapidly implemented a multifaceted plan including cohorting of patients and a back-to-basics infection control campaign in response to an insidious MRSA

outbreak that severely compromised the unit's ability to admit and care for patients.

CHALLENGES

Despite the success of initiatives such as these a number of challenges remain. Sustaining high performance safety efforts and quality improvement initiatives requires time and energy. The leadership team's efforts must remain focused on the bedside and not be isolated within the confines of a conference room, nor become the sole purview of a core team. Defining issues, measuring their impact, analyzing what is critical to quality and implementing meaningful solutions is a continuous process. Further, these solutions must be communicated to and operationalized by a very large team that includes all frontline care staff.

The ever-present challenge of balancing safety efforts with increasing patient volume and acuity levels continues. Admitting volumes continue to increase and the patients are smaller and sicker. These challenges are complicated by the nature of neonatal admissions, which are unpredictable and require split-second decision-making to ensure the best patient outcomes. This dynamic environment is one in which all providers must constantly be aware of the operational flow of the unit and be able to respond quickly and accurately to clinical needs.

Finally, there is always a challenge of communicating the special needs of the ICN patient population to the larger medical center. The ICN makes up <5% of

the hospital's bed capacity, yet contains perhaps its most vulnerable patient population. Decisions made at an institutional level on behalf of the majority of patients may carry unanticipated consequences for highly specialized populations, such as infants, if focused consideration is not given to the needs of those populations. Both core and local teams provide mechanisms for addressing this concern by ensuring prospective ICN team participation in institutional decisions that have the potential to influence care.

NEXT STEPS

Although progress to date is encouraging, the ICN's journey of patient safety has just begun. Developing a culture of safety demands a mindset that continuously seeks out vulnerabilities and prospectively addresses them through systems-based rather than individual-based solutions.¹⁵⁻¹⁷ To meet this goal the unit has adopted a mindset that focuses on system solutions, rather than the more typical approach that focuses on individual performance.

For example, the ICN is actively involved in the hospital's Six Sigma process improvement model (Sidebar 2). Six Sigma is widely considered the next phase in the evolution of performance improvement (PI) strategies.^{18,19} It is based on the scientific method, and utilizes a problem solving approach known as DMAIC (define, measure, analyze, improve, and control) to systematically analyze and improve performance. Individuals critical to the unit's process improvement efforts have received specialized training in Six Sigma techniques and statistical analysis tools. The use of these tools and methodologies has contributed to a number of process improvements, including safe system design and comprehensive solutions to safety concerns.

IMPLICATIONS FOR PRACTICE

Patient safety concerns are not unique to any single organization and neither are solutions to those concerns. The importance of sharing lessons learned across units, across disciplines, and across organizations cannot be overstated. Sharing is critical to the collective success of enhanced patient safety and reduction of medical error in neonatal care. The information in this article can be used by others to develop or refine safety programs and in turn, share valuable new lessons.

Everyone involved in providing care to critically ill infants provides that care in an environment of risk. Although the complexities of clinical care and the intricacies of human behavior may prevent us from totally negating that risk, caregivers are certainly in a position to develop a culture of safety that can minimize the risk of an adverse event occurring in their unit.

SIDEBAR 2: WHAT IS SIX SIGMA?

Six Sigma is a process improvement methodology in which the goal is performance excellence and the achievement of near perfection. The name refers to the Greek letter sigma, which is the symbol for standard deviation. Six Sigma targets an error rate of 3.4 mistakes per million opportunities, which is 6 standard deviations (or six sigma) from the mean of that population.

Several core principles of Six Sigma within the healthcare environment include the following:

- A focus on the customer (patient, family, staff members);
- The use of data and facts rather than assumptions and perceptions;
- Utilization of the scientific method to analyze processes;
- A focus on results; and
- A focus on long term improvement, the need to "hold the gains"

Through the use of a performance improvement approach known as DMAIC (define, measure, analyze, improve, and control), Six Sigma teams strive for breakthrough improvement in clinical processes.

Most Six Sigma projects are overseen by "Black Belts." These are individuals who have received advanced training in Six Sigma tools and techniques, and they serve to spearhead the improvement process. In many cases they are assisted by "Green Belts," individuals who have received Six Sigma training, but do not have the same degree of training and proficiency as the Black Belts.

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A NATIONAL NURSE FOR AMERICA

We have a Surgeon General. Why not a National Nurse? In March of this year, California Representative Lois Capps introduced House Resolution 4903, a bill that would amend the Public Health Service Act to create an Office of the National Nurse.

The idea of a National Nurse came from Teri Mills, an Oregon nurse who wrote an editorial last year for the New York Times. She pointed out that nurses, the most trusted health professionals, are in the best position to take action to improve the nation's health through education. A National Nurse could involve all Americans in preventive health care practices, as well as focus national attention on the nursing shortage and promote the profession of nursing.

HR 4903 lists the following duties of the National Nurse:

- 1) Carry out activities to encourage individuals to enter the nursing profession, including providing education on the distinct role of nurses in the health professions and examining nursing issues that would increase public safety, such as issues relating to staff levels, working conditions, and patient input;
- 2) Carry out activities to encourage nurses to become educators in schools of nursing;
- 3) Carry out activities to promote the public health, including encouraging nurses to be volunteers to projects that educate the public on achieving better health; and
- 4) Conduct media campaigns and make personal appearances for purposes of 1 through 3.

The bill further states that each fiscal year, the National Nurse will designate 4 annual health priorities, or methods of achieving better health that will be given priority by the National Nurse. Community-based projects for the purpose of educating the public on annual health priorities will take place in settings such as schools, senior centers, and libraries, and will be carried out by teams of nurse volunteers in individual states and communities.

To learn about the history or progress of HR 4903 and ways to help, please go to <http://www.nationalnurse.blogspot.com>. There you will find information about how to contact elected representatives to voice your support for HR 4903, to request their co-sponsorship of the bill, sign a petition in support of the Office of the National Nurse, or sign up to receive the National Nurse newsletter.

—LS