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ORIGINAL ARTICLE

# The neonatal preventable harm index: a high reliability tool

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**OBJECTIVE:** The aim of this study is to identify, quantify and disseminate a novel set of safety indicators for monitoring the occurrence of preventable harm in the neonatal intensive care unit (NICU).
**STUDY DESIGN:** Literature review and experiences in an academic, level IV NICU identified prevalent, preventable safety events: hospital-acquired infections (catheter-associated bloodstream infection, ventilator-associated pneumonia), unscheduled extubations, intravenous infiltrates requiring intervention, first week readmissions, serious adverse drug events and miscellaneous events (unanticipated harm or serious near misses). Negative binominal regression evaluated the event incidence trends.
**RESULTS:** Of 226 preventable harm events occurring between March 2013 and January 2015, the most common were unscheduled extubations (98; 2/100 ventilator days) and intravenous infiltrates (62; 2.7/100 admissions). No trends were detected (rate ratio: 0.99; confidence limits: 0.96 to 1.01; $P = 0.38$).
**CONCLUSION:** The Neonatal Preventable Harm Index represents a novel and transparent means to monitor serious safety events and direct harm prevention strategies in the NICU.

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## INTRODUCTION

Nearly two decades of data highlight the persistence of preventable harm events in hospitals nationwide.[1–4] Enhanced recognition is a requisite first step towards improvement, yet standardized and consistent measures to evaluate our health-care system are lacking.[5,6] Although a small fraction of the biomedical research dollar is presently allocated to insure the provision of safe health care, legislative efforts, market forces and public demand are driving new expectations of quality and accountability.[7–10] High reliability organizations meet these expectations when they develop quantitative improvement tools that promote a culture of safety.[11]

Premature delivery remains a common and costly complication of pregnancy in the United States, estimated to affect 12% of pregnancies at a cost of over $20 billion annually.[12,13] The infants hospitalized in the neonatal intensive care unit (NICU) are particularly vulnerable to preventable harm compared with older children and adults.[14,15] Putative factors include the long length of hospital stays, reliance on central venous catheters, off-label use of medications and overall physiologic fragility.[16] The likelihood of experiencing preventable harm, and the severity of harm events, is inversely related to the gestational age.[17,18]

Many hospital-based safety events previously classified as inevitable are now widely considered preventable.[19] Efforts to define and quantify preventable harm events afford valuable opportunities for benchmarking. However, when the aggregate number of harm events is reported over time, with emphasis placed on the numerator (that is, the number of patients harmed), the resultant harm index carries a 'sense of urgency'.[20]

The pioneering Pediatric Preventable Harm Index described by Brilli in 2010 represents a valuable tool, as it provides a template by which to catalog potentially harmful events.[20] However, it does not specifically consider the unique health considerations of hospitalized neonates. Our objective was to identify, quantify and disseminate a novel set of safety indicators for monitoring the occurrence of preventable harm among infants in the NICU.

## METHODS

The Institutional Review Board at the Women and Infants Hospital of Rhode Island exempted this prospective quality assurance medical record surveillance.

### Setting

More than 8400 deliveries are performed per year at this academic, specialty hospital for women and infants. The 80-bed, single family room, level IV NICU is a regional referral center for Rhode Island, southeastern Massachusetts and eastern Connecticut that admits approximately 1200 infants annually, including more than 120 infants per year under 30 weeks gestational age.

### Index development process

A comprehensive literature review identified the three most prevalent preventable NICU safety events: hospital-acquired infections (central line-associated bloodstream infection, ventilator-associated pneumonia), respiratory events (unscheduled extubations) and cutaneous injuries (extravasation of intravenous fluid requiring hyaluronidase injection).[17,21] Medical and nursing leadership met and discussed the inclusion of additional categories with the proviso that such events must result in patient harm and be preventable. Collective experience identified readmission/emergency department visit within 1 week of discharge and serious adverse drug events as categories that were sufficiently common to warrant monthly surveillance. The group agreed that a sixth category, labeled 'miscellaneous events' was necessary. This category was intended to capture unanticipated harm events or serious near misses as defined by nursing and medical clinical leaders.

Reliable data sources were identified for each subgroup. A literature review of each topic sought to identify comparative rates for the purpose of benchmarking where available.

### Index components

1. Hospital-acquired infections: blood cultures positive for bacterial growth obtained from NICU patients with central venous access or an endotracheal tube triggered a team huddle. This huddle was

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attended by the bedside nurse, nurse manager, medical provider and infection control manager. Clinical information was recorded and all suspected cases of hospital-acquired infection were presented monthly to the NICU Sepsis Task Force. This group utilized National Safety Healthcare Network definitions for central line-associated bloodstream infection and ventilator-associated pneumonia to confirm diagnoses.[22,23] Our data were compared with national estimates from level III NICUs.[24] Considering our historically low rates of indwelling bladder catheters and catheter-associated urinary tract infection, this type of hospital-acquired infection was not reported monthly in the Preventable Harm Index.

2. Respiratory events: respiratory therapists historically maintained a daily workflow sheet with patient information on mode and level of pulmonary support. A new section was added to the sheet to capture unscheduled extubation events, contributing circumstances and patient outcome (for example, immediate reintubation). Respiratory therapists were taught how to complete the new section and each respiratory therapist subsequently entered required information during their work shifts. Compliance was assessed with random spot checks performed by the principal investigator. A team of two designated respiratory therapists reviewed the daily flow sheets monthly to capture the extubation events and the total ventilator days, and these findings were compared with the published unscheduled extubation rates.[25–27]
3. Cutaneous injuries: a hospital pharmacist with advanced training in medication safety queried the electronic medication ordering system to identify those NICU patients for whom hyaluronidase was ordered. The pharmacist then cross-referenced the data with information from the electronic medication administration system to confirm that hyaluronidase was administered. Each confirmed case was reviewed by the NICU Medication Task Force. This group reviewed the medical record to assure the timeliness and appropriateness of the intervention. The findings were compared with the published estimates.[28] Considering our historically low incidence of pressure ulcers (no events reported in the electronic medical event reporting system during the period 2013 to 2015), this form of cutaneous injury was not included in the monthly Preventable Harm Index report.
4. Readmission or emergency room visit within 1 week of discharge: all the patients admitted to the NICU with a length of stay greater than 5 days were eligible for inclusion in a federally funded study aimed at improving discharge readiness and transition to home. The study participants received home visits and telephone calls from medical providers at regular intervals after discharge. The data from the 1 week post-discharge visit pertaining to readmission or emergency room visits was provided to the principal investigators.
5. Serious adverse drug events: a hospital pharmacist with advanced training in medication safety queried the pharmacy's electronic medication safety system to identify serious drug safety events resulting in patient harm recorded by the staff pharmacists. In addition, the pharmacist received notification of all NICU medication-related events entered into the hospital's anonymous medical event reporting system. The pharmacist also received data from the electronic ordering/administration systems regarding NICU doses prescribed/delivered. Each suspected case identified by the medication safety specialist was subsequently reviewed by the NICU Medication Task Force. This group studied the medical record to confirm the facts of the event and that harm or need for increased monitoring ensued.
6. Miscellaneous events: the NICU Nurse Manager and Medical Director received notice from the hospital Patient Safety Steering Committee of all the NICU-related safety events entered into the hospital's anonymous medical event reporting system. The leadership team reviewed each case, along with other cases identified during leadership rounds, and collaboratively considered whether events warranted inclusion in the monthly Neonatal Preventable Harm Index. Inclusion in this category was limited to unanticipated harm events or serious near misses.

### Data analysis

The monthly reports from each subgroup listed above were sent to the principal investigators for review and aggregation. Baseline information on NICU admission and patient days were obtained from an administrative, departmental database. The aggregate monthly rate of harm occurrences was calculated per 100 patient days. The overall mean rate of occurrences per 100 patient days and s.d. were calculated for the entire study period. The upper and lower control limits were defined, respectively, as rates 3 s.d. above and below the mean. To account for the dispersed nature of the rates, a negative binomial regression model was used regressing events per 100 days over a year to calculate a rate ratio and assess for trends in the incidence of harm over time.[29]

The event-specific harm rates were calculated for unscheduled extubations (per 100 ventilator days), intravenous infiltrates requiring intervention (per 100 patient admissions), hospital-acquired infections (central line-associated bloodstream infections per 1000 central line days and ventilator-associated pneumonia per 1000 ventilator days), readmissions/emergency room visits within 7 days of discharge (per 100 discharges), and serious adverse drug events (per 1000 doses dispensed).

The data collection began in April 2013 and is ongoing. The data reported here were collected from March 2013 through January 2015. After 1 year of data collection, the findings were broadly disseminated to the frontline staff through a concentrated educational program. The presentations were made by the principal investigators to the NICU nurses and medical providers and to senior hospital administrators.

## RESULTS

In the 22 months between 1 April 2013 and 31 January 2015, there were 2274 admissions (365 patients $< 1500$ g) to the NICU resulting in a total of 44 262 patient days. During that time interval, there were 226 preventable harm events (monthly median: 13, range: 5 to 24) for an overall rate of 0.51/100 patient days. Table 1 lists the total and monthly breakdown of patients harmed, as well as the relative contribution of each subcategory. No trends were detected using the negative binomial regression (rate ratio: 0.99; confidence limits: 0.96 to 1.01; $P = 0.38$).

Figure 1 displays the overall rate of preventable harm and rate by month per 100 patient days (Mean 0.5/100 patient days; s.d. 0.22). The upper control limit was 1.18 and the lower control limit was 0. There were no data points above the upper control limit.

The most common safety events observed during the study period were: unscheduled extubations (98; 2/100 ventilator days) and intravenous infiltrates requiring intervention (62; 2.7/100 patient admissions). The remainder of harm events comprised the following: hospital-acquired infections (central line-associated bloodstream infections: seven; 0.99/1000 central line days and ventilator-associated pneumonia: eight; 1.6/1000 ventilator days), readmissions/emergency room visits within 7 days of discharge (37; 3.3/100 discharges) and serious adverse drug events (two, both related to emergent epinephrine dosing; 0.006/1000 doses dispensed). There were 12 'miscellaneous events' (3 discharges without collection of a newborn screen for inborn errors of metabolism, 2 discharges without adequate communication of critical information to the primary care physician, 5 discharge without a hearing screen, 1 infant fall resulting in skull fracture, 1 occurrence of excessive bleeding following umbilical venous catheter removal).

Figure 2 displays the overall and monthly rate for each harm event for which comparative benchmarks are available.

After 1 year of data collection, concepts and findings were broadly introduced to frontline care givers and hospital leadership during a concentrated education initiative that ran from April to June 2014. The Neonatal Preventable Harm Index and associated data were presented at a series of six, 30-min-long 'dine-and-learn' lectures (staff nurses), a monthly staff meeting (nurse managers), departmental morbidity and mortality conference (pediatric residents, fellows, nurse practitioners and attending neonatologists), a semi-annual Quality and Safety lecture (multi-disciplinary, cross-departmental attendance) and hospital quality board meetings (senior hospital administrators).

**Table 1.** Total and monthly breakdown of patients harmed

| *Month* | *ADE* | *HAI* | *IV infiltrates* | *Extubations* | *Readmission or ER visit* | *Miscellaneous events* | *Total* |
|---|---|---|---|---|---|---|---|
| April 2013 | 0 | 0 | 4 | 7 | 1 | 0 | 12 |
| May 2013 | 1 | 0 | 3 | 6 | 1 | 0 | 11 |
| June 2013 | 0 | 0 | 0 | 5 | 2 | 1 | 8 |
| July 2013 | 0 | 0 | 4 | 17 | 2 | 1 | 24 |
| August 2013 | 0 | 2 | 4 | 3 | 1 | 1 | 11 |
| September 2013 | 0 | 0 | 2 | 4 | 0 | 2 | 8 |
| October 2013 | 0 | 0 | 6 | 4 | 1 | 1 | 12 |
| November 2013 | 0 | 2 | 5 | 4 | 1 | 1 | 13 |
| December 2013 | 0 | 1 | 1 | 4 | 0 | 0 | 6 |
| January 2014 | 0 | 0 | 3 | 2 | 2 | 0 | 7 |
| February 2014 | 0 | 1 | 1 | 5 | 3 | 0 | 10 |
| March 2014 | 0 | 0 | 0 | 3 | 2 | 0 | 5 |
| April 2014 | 0 | 0 | 1 | 1 | 3 | 0 | 5 |
| May 2014 | 1 | 2 | 4 | 7 | 3 | 0 | 17 |
| June 2014 | 0 | 2 | 8 | 5 | 2 | 0 | 17 |
| July 2014 | 0 | 1 | 1 | 3 | 0 | 1 | 6 |
| August 2014 | 0 | 1 | 2 | 4 | 1 | 1 | 9 |
| September 2014 | 0 | 2 | 0 | 2 | 1 | 1 | 6 |
| October 2014 | 0 | 0 | 1 | 3 | 3 | 0 | 7 |
| November 2014 | 0 | 0 | 2 | 3 | 0 | 1 | 6 |
| December 2014 | 0 | 0 | 3 | 2 | 6 | 1 | 12 |
| January 2015 | 0 | 1 | 7 | 4 | 2 | 0 | 14 |
| Total | 2 | 15 | 62 | 98 | 37 | 12 | 226 |

Abbreviations: ADE, adverse drug events; ER, emergency room; HAI, hospital-acquired infections; IV, intravenous.

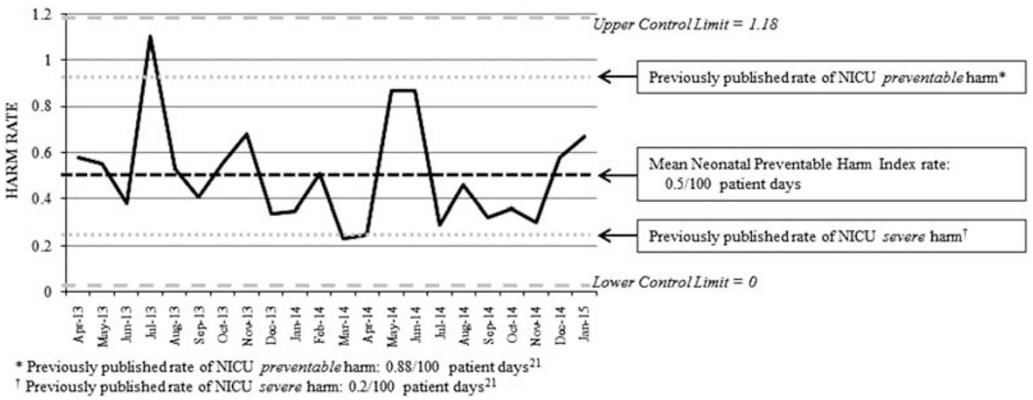


**Figure 1.** Overall and monthly rates of preventable harm per 100 patient day. NICU, neonatal intensive care unit.

## DISCUSSION

In this paper, we propose a novel approach to monitoring patient safety events in the NICU. We provide overall and event-specific rates over a 22-month time period. The concept of a pediatric preventable harm index was originally proposed by Brilli in 2010, and our work extends the original index to capture the unique health risks faced by critically ill neonates.

In building and disseminating the Neonatal Preventable Harm Index, raw incidences were highlighted to focus equal attention on each patient harmed, thus personalizing events. Proponents of this approach report a focus on actual patients harmed, rather than rates, inspires staff and leaders to make necessary changes.[30] In addition, predefining a list of specific events supports the development of a shared mental model, a key feature of high-functioning teams.[31]

The successful adoption of this safety monitoring framework at our institution is predicated jointly on the assumptions that the events in question are both harmful and preventable. Some physicians and nurses were initially reluctant to grant these assumptions and discussion during the educational series often focused on these issues. The relatively common occurrence of unscheduled extubations and intravenous infiltrates, for example, may prevent clinicians from sufficiently appreciating the attendant harm. Unscheduled extubations can result in rapid clinical deterioration and if emergent reintubation is required, airway trauma may ensue.[26,27,32] Extravasation of intravenous fluid into the surrounding tissue may result in pain, infection and disfigurement.[33] With regard to preventability, significant decreases in the rates of hospital-acquired infections, unscheduled extubations and serious adverse drug events after the implementation of NICU improvement measures or care bundles have been reported.[26,27,34–37] Studies of newborn readmission characterize many such events as preventable, particularly those readmissions that occur for feeding issues and jaundice.[38,39] Though unmeasured, the presentation of data regarding preventability and associated harm led to a greater conceptual acceptance of the index as a whole.

We acknowledge that comparative benchmarking must be done with caution. The most similar project to date was performed at a single center NICU in France.[21] Direct comparison with our data is challenging, as the list of qualifying harm events in the French experience was broader than those captured by our neonatal preventable harm index and the composite rate of

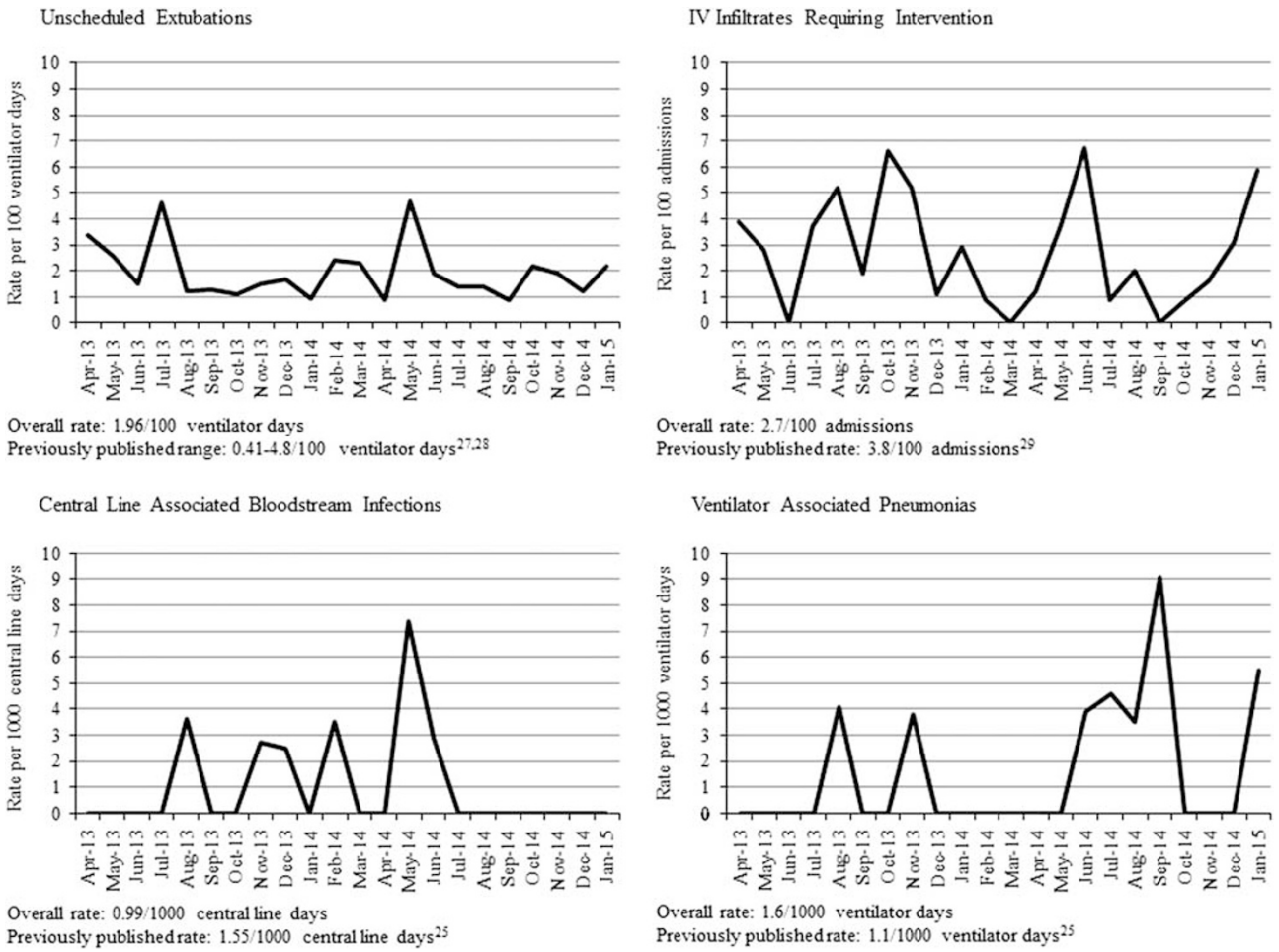


**Figure 2.** Overall and monthly rates of preventable harm by type. IV, intravenous.

severe, preventable harm events was not reported. We chose to focus attention on the composite outcome of severe, preventable harm.

Comparison of specific safety events rates for the purposes of benchmarking is equally challenging. To highlight this point, previously published rates of adverse drug events vary based on error classification and denominator: ranging from an administration error rate of 15 per 100 dosages dispensed to a preventable adverse drug event rate of 2.8 per 100 medication orders.[14,40] Much of these data were published before the advent of electronic order entry systems, like the one present in our institution, which have dramatically decreased the incidence of adverse drug events across the hospital.[41]

The great strength, and added value, of the Neonatal Preventable Harm Index is the attention brought by disseminating the numerator: each patient harmed. The merits of this conceptual framework must not be lost in our eagerness to explain where, how and why we measure up. Any attempts to compare data between institutions should be informed by the consistent application of definitions and methodology.

The six components of the Neonatal Preventable Harm Index sufficiently capture preventable safety issues commonly seen at our institution and potentially, other similar units. We expect units caring for different types of patients (for example, postoperative cardiothoracic procedures) may wish to modify one or more elements of the index to that unique subset of patients.

The undefined component of the Neonatal Preventable Harm Index, labeled 'Miscellaneous Events,' provides necessary flexibility. After 18 months of data collection, we observed a modest increase in the number of newborn hearing screenings being missed. This set off a process improvement project using failure mode event analysis, which is currently ongoing and will result in corrective measures. We acknowledge that as new safety challenges emerge, we must be prepared to identify and willing to include them in subsequent iterations of the harm index.

The potential applications of this ongoing data monitoring approach are evident. The staff at our institution began to utilize Neonatal Preventable Harm Index to inform daily practice. Following a cluster of post-discharge emergency room visits for hypothermia last winter, the nurses tailored discharge instructions to focus on heat safety for the remainder of the season. After data monitoring began, serious adverse drug events were observed related to epinephrine overdose during code situations. New colored labels were subsequently purchased for the code carts to distinguish the route of epinephrine administration (intravenous vs endotracheal tube). A 'stop and double check' procedure immediately before the delivery of epinephrine was advocated within the code team. These improvements developed directly from the identification of the process problem rising from the index. Further attention, using rigorous quality improvement methodology, must now be directed to the most common harm events identified.

In the future, demographic information will be collected about each patient harmed. This information will identify uniquely at-risk patient subpopulations and direct improvement efforts in an informed manner. Additional future efforts may explore the impact of factors such as nursing staffing ratios and unit census/acuity on the occurrence of harm events.

In summary, the Neonatal Preventable Harm Index represents a novel and transparent means to monitor serious safety events and direct harm prevention and mitigation strategies in the NICU. Transparency boosts awareness among frontline health-care providers. Dissemination may help NICUs progress towards an ultimate goal of zero harm. This tool informs a practical, evidence-based, patient safety dashboard unique to the neonate. The patient is kept at the forefront in keeping with our most basic commitment to non-maleficence.

## CONFLICT OF INTEREST

The authors declare no conflict of interest.

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