

MEASURING AND PREVENTING ADVERSE EVENTS IN THE NICU

by John Salyer RRT-NPS, MBA, FAARC



If you have not made a serious clinical error in your practice in the neonatal intensive care unit, then several explanations come to mind, including: 1) you really have made a serious error, you just don't know it (yet), 2) you just haven't been practicing long enough, or 3) you have supernatural powers. Not too long ago I wrote a column for *Focus* in which I made a plea for clinicians to report their errors and mishaps. Health services researchers have known for some time that most adverse events (AE) don't get reported into hospital measurement systems. There are a number of traditional methods that have been used to measure the rates of adverse events in hospitalized populations, including 1) voluntary and verbally solicited reports from hospital staff, retrospective review of medication administration records, non-focused retrospective review of the entire medical record, and review of medical malpractice claims. Using these methods to study adverse drug events (ADE's), rates of ADE's have been reported to occur in between 2.3 % and 6.5% of all patients.

However, it has been known for some times that these methods under represent the actual rates of adverse events. Classen et al reported in 1991 that 112 AE's occurred in every 100 patients (112%) in a study of adults using a computerized method of identifying these events.

More recently, a new methodology has been reported that yields AE rates that may be 50 times higher than those discovered

using traditional methods. This technique is referred to as trigger methodology. A trigger is defined as an "occurrence, prompt, or flag found on review of the medical record that 'triggers' further investigation to determine the presence or absence of an adverse event". An example might be a dose of Naloxone given to a patient. This finding in a chart would then prompt a more detailed review of the medical record and clinical staff, looking for the possibility of opioid induced respiratory depression.

Using this methodology, Sharek and colleagues studied the rate of AE's in a neonatal population. This fascinating and disturbing study was done in 15 NICU's (14 in the U.S. and 1 in Canada). A panel of 6 practicing neonatologists with expertise in patient safety science developed a list of 17 adverse event triggers that were used to further identify the occurrence of AE's in the medical records of 749 neonatal patients that represented 17,106 patient days. These triggers are as follows: Nosocomial infection, Antibiotic use, Unplanned extubations, Hypotension, Respiratory arrest, Death, Catheter infiltration/burn, Naloxone, Anticoagulant, Rising serum creatinine, NEC, Seizures, Phenobarbital, Electrolyte abnormality, Abnormal cranial imaging, Hyperglycemia and Return to surgery.

Remember, these were not necessarily the AE's that were found, these were just the triggers or flags to stimulate the chart reviewers to dig deeper. Anyone who has hoisted around a few neonatal charts can see why the trigger methodology could be so useful. With a mean length of stay of 22 days, ranging from 2 to 250 days, you can easily get low back pain from trying to lug one of these medical records around. Of course, this could lead to a protracted paid medical leave, so it might not be all bad. Looking for triggers simplifies the process of screening and makes this kind of review more feasible and sustainable.

The researchers discovered 74 AE's per 100 patients. The range was from 0 to 11 AE's per patient. Remember, other researchers have been reporting AE rates of between 2 and 7 per 100 patients. The 4 most frequent findings were nosocomial infections (28%), catheter infiltrates (16%) abnormal cranial imaging (11%), and unplanned extubations requiring reintubation (8%). Said another way, 75% of patients had an adverse event. Of course it can be argued that not all AE's of this type are preventable, nor do they all harm the patient. While this is true, it is mighty thin ice to be skating on.

It turns out that 40% of the AE's contributed to or resulted in temporary harm to the patient and required intervention, 23% resulted in permanent harm 7% required intervention to save the patient's life and 10% contributed to or resulted in the patient's death.

And if your fire is not yet lit, they report that 56% of AE's were preventable, 16% could have been identified earlier, and 6% could have been dealt with more effectively. You might ask how well the hospitals existing voluntary reporting system worked at identifying these events. Not so hot, since only 8% of these events were found in the hospitals incident reporting system.

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Let's pause and reflect on these numbers for a minute. OK, now that I have reflected, I am shocked and not shocked. I knew that the issue of adverse events and errors was serious, but this research seems to indicate that it is much more serious than we might have imagined in the NICU. Of course not all the adverse events identified by this study were the result of errors. 40% or so were not really preventable. Well I sure feel better. But my good feelings are short lived, since, during the brief period of reflection at the start of this paragraph I realized that all of this is still based mostly on the medical record and a lot of what happens to patients does not get entered into the medical record, especially paper records, and especially unhappy things.

One thing on the horizon that might help us better measure (and hopefully improve) the safety of our clinical practice is the advent of the electronic medical record. First, having all information about the patient coded into an electronic record makes mining of these data much more feasible and would help create more credible measurement systems. Second, if data were acquired automatically, e.g. if monitoring systems were hard wired into the electronic data gathering system, then there would be less chance of adverse events not being recorded in the medical record.

Finally, but really first, hospitals must create a just culture. This is one in which clinicians are not afraid to report their errors, which then allows the hospital to become a learning culture. All the clinical disciplines should collaborate to create a set of agreed upon principles for drawing the line between acceptable and unacceptable actions with regard to making errors. This does not mean there are never consequences to making errors, but it means that careful consideration will be given to intentions of the practitioners, and the degree to which poorly designed systems helped contribute to mishaps. We may, and sometimes do have little help to offer our patients, but we must remember that our very first duty to do no harm.

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requiring that at least one vehicle be towed from the accident scene. This database was created in 1989 and the information is gathered from police accident reports by state agencies which are then transferred electronically to the FMCSA for inclusion in the MCMIS. On average approximately 100,000 accidents are recorded to the MCMIS each year and published in the annual Large Truck Crash Overview.

The National Highway Traffic Safety Administration estimates that 100,000 automobile crashes per year are fatigue related. These sleepiness related accidents contribute to an estimated 71,000 injuries and 1,500 deaths per year. Moreover, in a report from 1990 the National Traffic Safety Board found that one third of fatal to driver heavy truck crashes in the commercial driving industry were fatigue related. The mean cost of a crash involving a single large vehicle has been calculated to be \$51,000 but when fatalities are involved the cost per crash increases to \$2.7 million. Despite these impressive numbers there is a sense in the field of sleep medicine that these numbers are a gross under estimation of sleep related motor vehicle accidents. Society has been very successful in decreasing the number of drunk driving fatalities which in the United States have declined by more than 50% since receiving national and local interest more than 25 years ago. However, there has been a major lag in recognizing the dangers of drowsy driving, especially the dangers of chronic partial sleep deprivation which seems to be prevalent in certain occupations such as long haul truck drivers. It is well known that performance consistently begins to decline after 16 hours of continuous wakefulness regardless of how long the nightly sleep duration was. Furthermore, this cumulative partial sleep deprivation is more problematic than acute sleep deprivation since it can be very difficult to identify and many individuals may misperceive their level of impairment. Of dire significance is the scientific data showing that a person who has been awake for 24 consecutive hours demonstrates the same impairment in judgment and reaction time as an adult with a blood alcohol concentration of 0.10%, which in years past was the definition of legal intoxication. However, as of August 2005, all states in the United States by Federal mandate have lowered the definition of legal intoxication to a blood alcohol concentration of 0.08%.

As reported by The National Sleep Foundation, the Federal Motor Carrier Safety Administration (FMCSA) has indicated that it will issue a notice of proposed rule making related to trucking safety. This notice essentially starts the discussion on whether or not the United States will require mandatory or voluntary use of electronic onboard recorders (EOBR) and the conditions that should be in place when using EOBRs. Additionally, as reported by the National Sleep Foundation, this rule making would evaluate alternatives for encouraging or providing incentives for EOBRs to ensure that hours of service record keeping and compliance are met by American commercial drivers. EOBRs would essentially serve the same function as the black boxes in airplanes and record the movement, data, and activity of trucks and drivers independent from manual daily logs that are kept by the actual truckers.

Noteworthy on 8/10/06 President George W. Bush signed into law the new Federal Transportation Bill which includes a mandate that driver fatigue be added to the list of safety factors that must be included in all state highway programs. This involves adding more rumble strips to roads, providing information on driver fatigue in driver education programs as well as educating

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