

Near Miss Registry Project – Concept Paper

THE NEED:

In the 1999 Institute of Medicine's report *To Err is Human*, it was estimated that 44,000 to 98,000 patient deaths were attributable to medical errors with total costs of preventable medical errors from \$17 billion to \$29 billion per year. In this groundbreaking report, the Institute of Medicine put forth recommendations for building a safer health system. The Institute recommended mandatory reporting for all adverse events and encouraged the development of a voluntary reporting system for near misses. Near misses are events that might have resulted in severe consequences for patients but were corrected before harm was done. While true medical errors require mandatory reporting in New York State, it is suspected that they are relatively uncommon. Near miss events on the other hand, probably occur at a much higher frequency and currently there is no way to capture and analyze this data. The report posited that these near miss events could be powerful indicators of systemic weakness and voluntary reporting would allow these events to be tabulated and analyzed. This analysis could then be used to create a safer health system that maximized patient safety.

Key to understanding these recommendations is also appreciating that truly safe systems are those which have become robust enough to withstand inevitable human factor related errors. While in the medical culture individual responsibility and accountability remain the cornerstone of professionalism, it is imperative, in order to build a safe system of care that the system be robustly safe, despite errors that might occur. . The Institute of Medicine's report found that the majority of medical errors are not the result of individual recklessness but more commonly are the result of "faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them." It is believed that designing a system that avoids hazards, has more redundant barriers to errors or has smaller defects in each layer of barriers can prevent many medical errors.

In 1976 the Aviation Safety Reporting System (ASRS) at NASA was established to collect data on near miss incidents. The ASRS is a voluntary, confidential incident reporting system and currently receives over 30,000 reports annually. The ASRS was designed to be a risk free and anonymous reporting system. The very fact that the data is housed at NASA rather than the FAA is meant to reinforce the fact that there is no risk to those who report errors. These incidents were then analyzed and systems were designed to prevent similar events in the future. It is important to note that in Australia, where a similar system was constructed, a pilot's identity was accidentally revealed. After that no further reports came in to the registry. This helps to illustrate the importance of anonymity in a risk free reporting system.

In 1999, the Department of Veterans Affairs developed the National Center for Patient Safety with the goal of reducing and preventing unintended harm to patients secondary to their care. In an effort to meet these goals, a confidential, non-punitive system was developed to allow individuals to report near miss events. These events are then analyzed to determine how and why an event occurred and what can be done to prevent similar events from occurring in the future. The stated goal is to "design systems that are "fault tolerant" so that when an individual error occurs, it does not result in harm to a patient." With the data collected, system changes have been implemented and protocols developed to increase patient safety.

Despite little evidence, medical errors have been attributed to the sleep deprivation of physicians and house staff typical in traditional medical training. In an effort to reduce these errors, New York State instituted regulations in 1988 that limited the number of hours residents were able to work each week. The Accreditation Council for Graduate Medical Education (ACGME), which sets standards for residency

training, has adopted similar regulations. While regulation compliance is increasing, to date there is no data to support that regulation compliance decreases near-miss events or that these regulations maintain or increase the quality of care to patients. In fact, many have questioned the safety of the multiple hand offs that now occur in response to the duty hour restrictions.

By constructing an easy to use, internet-based confidential reporting system to collect and analyze near miss events, the New York Chapter in conjunction with the New York Special Interest Group of the Association of Program Directors in Internal Medicine (APDIM NYSIG) is promoting quality improvement efforts. This project supports a more open and honest dialogue about near miss events with the goal of creating systems that prevent events in the future in an effort to improve patient care.

PROPOSAL:

Utilizing an internet-based survey tool, the project director, Ethan Fried, MD and NYACP staff created a near-miss tracking instrument with input from Internal Medicine residency program directors from across the state. Five institutions participated in the program's pilot phase and communication began at four of the institutions in January 2005 with a power point presentation at Grand Rounds or house staff conference. The fifth institution was added in April 2005. With permission from the Institutional Review Boards of each of the pilot hospitals, near miss data was collected in an anonymous, non-patient specific, de-identified manner using a web-based, user-friendly reporting tool that stored the data confidentially and securely. Data collected include patient gender, age range, type of institution, primary diagnosis, time the event occurred, the role of the person reporting the event, etc. (see attached survey tool). Also collected was the relationship of the event to duty hours, rest, and coverage strategies. Finally, details of the near miss event itself were collected in free text.

Working in collaboration with the New York State Department of Health, organizations such as the Healthcare Association of New York State, Greater New York Hospital Association, and Committee of Interns and Residents, this project will be expanded to include all Internal Medicine Programs in New York State. We propose a 36-month study that anonymously gathers information on near miss events in New York State. Outreach and data collection will occur for the initial 30 months and data analysis will take place in the final 6-months. The goal of reporting is to identify and analyze the causes of "near miss" events. We also will be able to identify patterns of near miss events that will improve our ability to anticipate and prevent hazards to patients and close some the defects in the barriers that help to protect patients from these hazards.

The expanded project would need a greatly expanded educational component. Introduction to the program will occur through a power point presentation given at each participating hospital's Grand Rounds or house staff conference. This presentation will include a description of the program's goals and objectives and instruction on the use of the web based reporting tool. Discussed at length would be the anonymous nature of the data collection and the protection from discoverability afforded by a State sanctioned research waiver. It would be stressed that the system is a voluntary, anonymous, risk-free and confidential reporting system.

Data analysis, report preparation and assistance with the development of the survey tool (to enhance clarity, response rate and accuracy), along with training and working with those involved in data entry and management, assistance with project oversight and evaluation/measurement activities will be subcontracted to two research specialists, one connected with the SUNY School of Public Health and another with the Foundation for Healthy Living

Working with the DOH, SPARCS and NYPORTS representatives and other organizations involved in the current adverse events reporting database, we will modify the current web based instrument. The goals of this modification will include pull down menus to ease and quantify the description and correct tabulation of the actual event. Another modification will be a utility that rejects the report if a patient was actually harmed thus making the report no longer a near-miss but a fully committed medical error. The user, in that case will be directed to more a more appropriate venue to disclose the error as is required. More importantly modification will also standardize reporting to ease in the statistical analysis of the data at the completion of the study. Consultants will review the data throughout the study but will conduct its final analysis of the data in the last 6-months of the study.

AUTHENTICATION/OUTCOMES:

Forty-seven (47) near miss events have been reported within a three-month period and preliminary data analysis begun. More than a third of these have been related in some way to communications issues around a hospital. Early indications are positive that this project will be effective in gathering data to improve health care systems and specifically patient care.

As we move to expand the pilot project, an approach to ensure anonymity and authentication that data is coming from duly authorized health care providers will be based on two levels: hospital and resident. The two levels are independent where it may be decided that both should be implemented or only one is needed.

Level One – Hospitals

- 1) Ticket boxes (the concept is similar to movies ticket roles) will be designed/bought
- 2) The number of ticket boxes will equal the total number of hospitals participating in the Near-Miss project
- 3) Each of the ticket boxes will contain uniquely numbered tickets that correspond to the maximum number of residents and others available per hospital in the group
- 4) The number of the ticket box as well as the individual ticket numbers have no unique identifiers (to track tickets)
- 5) Hospitals will select any ticket box of their choosing. The selection process will be double-blinded, i.e. neither party would know which hospital selected what ticket box.

This approach will result in a blind assignment of ticket boxes to hospitals. There will be no mechanism/way to track reporting to an individual hospital.

Level Two – Residents

- 1) Each of the ticket boxes will contain uniquely numbered tickets that correspond to the maximum number of residents available per hospital in the group
- 2) The number of the ticket box as well as the individual ticket numbers have no unique identifiers (to track numbers)
- 3) Hospitals/Residency program directors will ask residents and others to select a ticket
- 4) Neither the hospital/program director nor participants will know what number was selected by potential reporters
- 5) If the number of tickets available in the ticket box are more than the number of participants, the remaining tickets will either be stored or discarded by the hospital/program director
- 6) When reporting a near-miss incident, the reporter will have to enter his/her number to gain access to the reporting site
- 7) The last sheet in the reporting will require that the reporters re-enter his/her number to finalize submission (this would allow for verification and detection of errors in entering the ticket number)

This level will allow verification that reporting was done by an authorized person and at the same time ensure anonymity of reporting by that person.

CONCLUSION

As discussed above, these two levels may be used simultaneously or individually. The main aim of this approach would be to ensure anonymity of reporting – a factor which is probably associated with better reporting-, and authentication of reporting, a critical element in evaluating the near-miss project and ensuring validation of results. This process may also allow for feedback of de-identified data to individual institutions collected by the project for purposes of institutional assessment to improve patient safety.