Near misses and research subjects

H J Murff, R S Dittus

Near miss reporting used in clinical care should be extended to include clinical research

As in clinical care, the highest priority of clinical research is to protect participants from any undue harm. There are inherent risks involved in any human experiment, but careful analysis of several research related fatalities has clearly shown that human error and system failures contributed to these events.[1 2] While clinical medicine has embraced organizational based approaches to patient safety, much of the clinical research safety process remains narrowly focused. This focus has resulted from the traditional ''protocol-centric'' approach for managing clinical research risk. Both Institutional Review Boards and Data Safety Monitoring Boards predominately review safety problems on a study by study basis. While these traditional approaches have been remarkably successful, their narrow scope may limit their ability to identify and manage clinical research risks comprehensibly.

Clinical research and clinical care share many similar risks. Both involve analogous procedures, many of which are invasive, and both use pharmacological agents with known and unknown toxicities. Patient safety research has identified system failures as important contributors to adverse drug events, nosocomial infections, and procedural mishaps. These same latent failures may also contribute towards adverse events within clinical research. For instance, environmental factors such as the lack of conveniently placed antiseptic solutions can contribute to poor sterile technique and nosocomial infections.[3] Hospital infection surveillance programs seek to identify these environmental factors by reviewing rates of events within the context of the expected rates of infections across an organization. In the ''protocol-centric'' model for safety monitoring, the organizational context in which an adverse event occurs becomes lost. Thus, in a single clinical trial an intravenous line infection would be treated as an anticipated adverse event and managed by including this risk within the informed consent document. If an unexpectedly high rate of intravenous line infections were occurring, this pattern would be unlikely to be identified unless all of these events occurred within a single protocol. This amounts to a hospital infection control program following a single employee to determine their rates of nosocomial infections. While this approach may identify problematic individuals, it is unlikely to contribute to overall patient safety.

In order to correct latent failures, organizations must actively seek to identify them. One proposed method to identify these system flaws within clinical medicine is through ''near miss'' reporting.[4] A near miss is an error that does not result in any harm. Because these errors often result from the same system failures which can also lead to patient injuries, routing out these latent failures before any harm occurs is an appealing strategy. In addition, because no injury is associated with the error, it is believed that individuals will be more inclined to report near misses because they are less inclined to fear any disciplinary action. Several non-medical industries have incorporated near miss reporting systems into their safety plans. Within clinical care, transfusion medicine has been a pioneer in this respect.

But near miss reporting should not be limited to clinical care. It may also be able to identify potential latent system failures which may threaten the safety of research volunteers. As such, we have been developing a near miss reporting system for use within a General Clinical Research Center (GCRC).[5] GCRCs are research centers funded through the National Institute of Health in the USA which conduct clinical research on human participants. The primary targeted users of this near miss reporting system were the GCRC staff nurses. GCRCs employ staff nurses who are typically involved in multiple study protocols involving different human subjects simultaneously. The system allows for both web based and paper based reporting, and reports are anonymous. Some examples of reported research related near misses include medication errors resulting from lack of access to study protocol documents and delays in obtaining appropriate equipment due to a lack of standardization regarding equipment placement. Once identified, as in clinical care, standard operating protocols can be devised and these failures addressed.

Near miss reporting could have an important role in any comprehensive human subject protection program. Although any stakeholder in clinical research would be encouraged to participate, near miss reporting systems would particularly benefit from the input of individuals who work across multiple study protocols. Research nurses and pharmacists would represent an ideal source.

Unfortunately, the success of reporting systems can be greatly hindered by the organizational culture. In clinical medicine several barriers have been described which may hinder reporting, such as fear of reprisals or concerns about going against the ''authority gradient''. Whether and how organizational culture might impact safety in clinical research remains poorly evaluated. In a survey we conducted of over 400 GCRC staff nurses we found that 11% reported being made to feel uncomfortable for reporting a protocol violation and 12% suggested they would get into trouble if they refused to carry out a protocol because they thought a subject did not fully understand the study.[6] This suggests that reporting barriers similar to those reported within clinical medicine may exist within clinical research.

Clinical research shares many of the same risks to patient safety as clinical care. Clinical care has begun to adopt systems based approaches to manage these risks, while clinical research has remained more narrowly focused, managing safety issues on a study by study basis. While this method does successfully address many of the research related risks a study volunteer may experience, we would argue that it is not sufficiently comprehensive to identify and manage all of the potential risks to research subjects. System failures can contribute to research related injuries and must be managed from an organizational perspective. To help facilitate the reporting of events, we propose extending the near miss reporting model to clinical research. Just as in clinical medicine, similar barriers exist which provide a disincentive to report errors and will have to be mitigated. It is time that the same ''culture of safety'' emphasized in clinical care be brought into clinical research.

Qual Saf Health Care 2006;**15**:228–229.
doi: 10.1136/qshc.2006.018176

Authors' affiliations
H J Murff, R S Dittus, Division of General Internal Medicine and Public Health, Vanderbilt University Medical Center and the Department of Veterans Affairs, Tennessee Valley Healthcare System, GRECC, Nashville, TN, USA

Correspondence to: Dr H J Murff, Department of Veterans Affairs, VA Tennessee Valley Healthcare System, GRECC, 1310 24th Avenue South, Nashville, TN 37212-5381, USA; Harvey.murff@med.va.gov

Competing interests: none.

REFERENCES

1 **Cassel C**, Stock MC, Wood AJ, *et al. Report of Johns Hopkins University External Review Committee*, 8 August, 2001.
2 **Steinbrook R**. Improving protection for research subjects. *N Engl J Med* 2002;**346**:1425–30.
3 **Burke JP**. Infection control – a problem for patient safety. *N Engl J Med* 2003;**348**:651–6.
4 **Shaw R**, Drever F, Hughes H, *et al*. Adverse events and near miss reporting in the NHS. *Qual Saf Health Care* 2005;**14**:279–83.
5 **Murff HJ**, Byrne DW, Harris PA, *et al*. ''Near-miss'' reporting system development and implications for human subjects protection. In: Henriksen K, Battles JB, Marks ES, Lewin DI, eds. *Advances in patient safety:from research to implementation. Volume 3. Implementation issues*. AHRQ Publication No 05-0021-3. Rockville, MD: Agency for Healthcare Research and Quality (AHRQ), 2005.
6 **Murff HJ**, Pichet JW, Byrne DW, *et al*. Research participant safety and system factors in general clinical research centers. *IRB: Ethics and Human Research* 2006 (in press).

Hierarchies and patient safety

Hierarchies: the Berlin Wall of patient safety

M M Walton

To maximise patient safety considerations the medical hierarchy needs to be balanced in favour of teaching and learning rather than the exercise of power

Reporting and preventing adverse events is the theme in two papers in this issue. In their commentary, Murff and Dittus[1] suggest that nurses and pharmacists could report medication errors and equipment failures during clinical research, and Seiden *et al*[2] identify a role for medical students in recognising and preventing errors during their clinical attachments.

While I agree with their recommendations for improved reporting, enhanced communication and acting ethically, I remain sceptical that change will occur without significant examination and understanding of the role of hierarchies in our healthcare system.

UNDERSTANDING WHERE WE HAVE COME FROM

The word ''hierarchy'', first found in 1380 in the Oxford English Dictionary, referred to priests in relation to God. Today the term has broader application and refers to a group of individuals ranked according to authority, capacity, or position. At the turn of the 20th century hospitals were organised into hierarchical structures with the medical hierarchy at the pinnacle.[3] Typically, this involved ever increasing power with each rank subject to the authority of the next level up. This arrangement has endured despite increased complexity and costs and significant changes in technology. Hospital patient populations, clinical pathways, and workforce have radically changed over the last three decades, yet the organisational structure for doctors remains substantially unchanged since the 19th century.[4] New areas (specialties and subspecialties) have been accommodated by adding to existing structures, creating departments and hierarchies often without reference to the needs of patients.

Nineteenth century medical apprentices were legally bound to their surgeon (master) for 7 years, during which time they worked as a servant in return for the acquisition of skills to enable them to practice.[5] Surgeons had no more than two apprentices at any one time, thus allowing them an intimate knowledge of their trainees. Today interns, residents, and registrars work with many health professionals and seniors on a day to day basis and are required to understand and implement instructions from doctors above them. Registrars work for five or more consultants. They are expected to follow the usually unwritten rules of each of their ''bosses'' and to take instructions. This results in inadequate communication, fragmented supervision, inadequate instructions, and more frequent suboptimal patient outcomes.[6]

The medical hierarchy, a natural derivative of the apprenticeship model, is today best characterised by the power relationship between a superior and a subordinate rather than the relationship between teacher and learner. The good ingredients of the apprenticeship model—mentoring, coordination, and constant observation—only survive in temporary situations such as a teaching session between a clinician and trainee. Instead, what has survived is the unhealthy obsequiousness shown by a substantial portion of health professionals, medical students, and junior doctors to senior clinicians.

HOW THIS IMPACTS ON CAREER PROGRESSION

Medical students, interns, and residents are low in the hospital and medical hierarchies and remain dependent upon clinical supervisors for their instructions and learning. Their progress up the hierarchy depends on favourable reports from supervisors about their competence, performance, and professional development. Maintaining a good relationship with those higher up the ladder understandably becomes a prime focus, often at the expense of other priorities such as reporting on errors or on poor patient care. Calling attention to a supervisor's mistakes or potential mistakes may have repercussions for the junior. Medical students, interns, residents and registrars tell me about their fears (real or imagined) that disclosing mistakes—even reminding a senior about a protocol—may lead to an unfavourable report, decreased employment opportunity, reduced chance of access to training programs, or all three.

The unequal power relationship means that novices will be silent when they should speak up. This is not because we are training unethical or bad doctors. They do what they do because they have no option. Raising a potential problem or error with a senior or contradicting their decisions becomes still more problematical if the clinician practices in the area of medicine which interests the junior.