# Reporting Issues & Learning Approaches for Examining Medical Errors & Patient Safety

**National Summit on Medical Errors and Patient Safety Research**
**Presentation Made as Part of Panel 4: Reporting Issues and Learning Approaches**
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Good afternoon. I am Dr. Lucy Savitz, an Assistant Professor, in the Department of Health Policy and Administration in the School of Public Health and Obstetrics and Gynecology in the School of Medicine at the University of North Carolina at Chapel Hill. I am also an investigator in the UNC Program on Health Outcomes' Center for Education and Research on Therapeutics. The 7 federally funded CERTs at UNC, Duke, Vanderbilt, Georgetown, the University of Alabama at Birmingham, University of Pennsylvania, and Harvard Pilgrim Health Care, are designed to improve the quality of health care and reduce its costs by improving our understanding of the benefits and risks of therapeutic use. I appreciate having this opportunity to address several important reporting issues and learning approaches related to our efforts to examine medical errors and patient safety. I assure you that I am here solely as a UNC faculty member and have not received sponsorship from any proprietary interest.

To begin, it is important to recall that research has been conducted which documents both the under-reporting of *medical errors* and problems in the definition and scope of *medical errors*, making it difficult to incrementally build our understanding of complexities involved in learning about patient safety. Thus, we need to begin to address issues related to reporting and continued learning efforts by:

1. Establishing a common definition or set of definitions for what constitutes a preventable adverse medical event, or AME, that goes beyond individually attributed mortality, medication, and procedural errors to include technological failures and human errors;
2. Defining the appropriate scope within which to considers preventable AMEs; and


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3. Understanding the opportunities and limitations of comparative analyses, benchmarking, and reporting of this information.

Currently, research in the area of patient safety and medical errors is plagued by the pervasive problem commonly encountered by health services researchers whereby key outcomes are not consistently measured and/or modeled. For the incremental progression of learning through research to have the highest value, we should agree from the outset on a clinically relevant and meaningful definition or core set of definitions that will allow us to build a research base. The definition can be expanded as our ability to more precisely measure through enhanced data capture and reductions in measurement error increase over time. For example, health service organizations do not necessarily have processes in place to capture near misses and/or latent failures--those failures that are caught in time, contained, or remedied prior to the actual event that may or may not result in a negative patient outcome. This situation can already be seen from our expanded focus beyond medication errors to encompass a larger set of patient safety issues as the human engineering and related systems perspectives prevail in extending our enhanced understanding of these complex processes. The complex systems perspective suggests that system error or adverse events occur when errors at multiple levels—treatment/technology, patient characteristics, and work environment—coincide. This also implies that the scope of the definition will be incrementally expanding over time. Thus, it may be necessary to incorporate differential definitions in our analytic models as our information technology and measurement capabilities mature so that we can demonstrate the explanatory contribution of enhanced data quality.

In defining the appropriate scope for considering AMEs, it is critical that we acknowledge that adverse medical events are both preventable, including both individual "errors" and system failures, and non-preventable. It is often difficult to tell the difference. For example, some in-house deaths are preventable while others are a


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natural consequence of a patient's condition; and treating all inpatient deaths as "medical errors" compromises our understanding of these complex processes. Examples of the elements within the scope of medical events that should be appropriately considered when conducting such research include:

- Adverse drug events
- Iatronogenic infections
- Nosocomial infections
- Venous thromboembolism
- Decubitus ulcers
- Patient falls
- Poor management of patients in extremis—such as the unnecessary use of restraints and sedating medications
- Rare sentinel events—such as rape or kidnapping
- In-house death
- Unscheduled return to surgery
- Adverse device events and/or device malfunctions
- Overlooked patient preferences—such as do not resuscitate orders or wishes related to limitations on medical intervention

While these are important elements for discussion in defining AMEs, both preventable and non-preventable, our ability to adequately capture, measure, and distinguish the true nature of these events is limited at the present time. Some attention should be paid to improving our capabilities to reliably and validly capture this information.

Standardized definitions and appropriate scope of AMEs incorporated into our study designs will yield learning opportunities for valuable comparative analyses, benchmarking and reporting. Fragmentation within the health care industry presents a myriad of health services research problems, not the least of which includes a lack of definitional standards for even basic operational statistics, variation in information technology infrastructure, and lack of a national system for data reporting. Development of a set of common definitions to promote research and for health care facilities and integrated delivery systems to internally capture and monitor AME data will be an important beginning. Common definitional sets will pave the way for comparative analyses across facilities or systems of care, allow for benchmarking to ascertain


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industry standards and norms, and enable consistent reporting to meet the industry's needs for planned national data quality and regulatory reporting requirements for organizations like NCQA and JCAHO.

Establishing a common foundation for this research is critical to providing the incremental research base that will improve our understanding and yield practical and relevant solutions to the problem and prevention of AMEs and their respective patient consequences. Examples of key research questions that emanate from a systems perspective of AMEs include:

1. How can we use collected AME information to prevent future AMEs through the development of models that provide threshold alerts for patients and/or departments at risk?
2. What are the implications of financial cutbacks in staffing and resource allocation for patient safety (e.g., staffing mix substitutions of LPN/CNAs for RNs, staffing reductions that increase the patient/FTE ratios)?

It will be important to create a mechanism for pooling resources across the fragmented health care industry to address common research questions such as these. Focused task orders issued to recipients of the "Accelerating the Cycle of Research in Integrated Delivery Systems" awards or collaborating with established consortia such as the Center for Health Management Research/Center for Organized Delivery Systems may provide an important first step in pooling necessary resources to address the research and learning needs of the field. Given the information technology incompatibilities and variations in information capture (over time and in comprehensiveness), we will need to identify mature IDSs or facilities with sophisticated data warehouses to take a lead in the development of AME prevention models that can be used to generate the user-friendly tools that are critical to shared learning and


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ultimately the prevention of AMEs. Implementation of specific interventions should be evidence-based, much the same as we expect of clinical process innovations and medical practice, because the costs, risks, and administrative burden are likely to be significant. Along these lines, we will need to pilot developed interventions that promote patient safety and report on their effectiveness via soundly executed evaluation studies that can be published in the peer review literature so that best practices can be identified, shared, and adopted across the industry. Accumulated data from these trials in various types of health care settings can begin to yield necessary information for the adoption of national standards for reliable comparisons that don't unnecessarily burden a financially constrained industry. It is also important to devote some effort towards the development of a measure that can be used as a patient management tool to predict which patients are at greatest risk for system error and a companion management tool to support resource allocation decisions. This would be a valuable extension of focused research and learning in the area of patient safety, and development of such tools would permit the application of research in health care management and clinical practice. In order for this growing body of evidence to have a real influence on the adoption of interventions and ultimately improved patient safety, it will also be necessary to educate health care managers in the application and interpretation of such evidence.

I want to thank you again for this opportunity to share my views on these issues and would like to acknowledge the intellectual stimulation and support of my colleagues Diane Kelly, Arnold Kaluzny and Kerry Kilpatrick from UNC; Brent James and Stanley Pestotnik from Intermountain Health Care and the University of Utah; and Howard Zuckerman from the University of Washington and Director of the Center for Health Management Research. I welcome any questions during the comment period.


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