

INFORMATIONAL REGULATION TO PREVENT MEDICAL MISTAKES:  
A STUDY OF MEDICAL ADVERSE EVENT REPORTING IN THE U.S.

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## *Abstract*

*Although medical injury is inflicted in the course of medical treatment by individual health care practitioners, many errors in hospitals go back to systemic causes such as lack of communication among physician teams, inadequate staffing, or insufficient protocols. A study found that as many as 80% of medication errors are associated with systemic rather than individual causes. Lawmakers and regulators, however, focus their error prevention efforts on individual provider performance and increase reporting of medical mistakes or malpractice information, arguing that, by increasing information flow on medical errors, health care providers will strive to present good performance data and thus improve the quality of care. To this end, various federal and state data banks collect information on medical adverse events, malpractice payments, and licensure actions against physicians. This thesis addresses the question of whether the expectations associated with reporting systems are justified. If the targeted social goal is prevention of medical errors, what regulatory strategy, if any, would be most effective in achieving it? Is reporting of medical adverse events an effective regulatory tool that helps reduce the risk in question?*

*The thesis follows the steps of a regulatory policy analysis and presents the first application of regulatory instrument choice theory to the problem of medical error prevention. After discussing the main barriers to medical error reporting, I will argue that there is an incoherency between medicine's growing recognition of the systemic nature of medical mistakes and administrative agencies' reliance on outcome-based regulation to prevent them. In order to be more effective, regulation should also intervene at the planning stage (before error occurs) rather than only at the output stage (after error occurs). In other words, regulation should be concerned with both individual performance and error management.*

*The concluding policy recommendation borrows from food safety regulation and suggests exploring the merits of management-based regulation for medical adverse events. Secondly and finally, I will argue that reports of adverse events and "near misses" constitute valuable information that is essential for the detection of patterns and trends in medical errors and, therefore, crucial for improving patient safety. To encourage openness about medical error confidentiality concerns need to be addressed by shielding reports from subsequent discovery in malpractice litigation.*

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