

ASHP Statement on Reporting Medical Errors

Position

The incidence of death and serious harm caused by mistakes and accidents in health care is unacceptable.¹ This serious public health problem merits top-priority national attention. Addressing this issue will require major reforms and sizable investment of resources throughout the health care system, including the medication use process, which is a particular focus of the American Society of Health-System Pharmacists (ASHP).

ASHP believes that the following steps should be taken as part of a comprehensive national solution to the problem: (1) The establishment of a standardized, uniform nationwide system (with the characteristics noted below) of mandatory reporting of adverse medical events that cause death or serious harm, (2) continued development and strengthening of systems for voluntary reporting of medical errors, and (3) strengthening efforts to implement process changes that reduce the risk of future errors and improve patient care.

The fundamental purpose of reporting systems for medical errors is to learn how to improve the health care delivery process to prevent these errors. Reporting of medical errors must become culturally accepted throughout health care. A major investment of resources will be required in the health care system to apply the lessons derived from the reporting of medical errors. Marshaling those resources is an urgent issue for the governing boards of health care institutions, health care administrators, health professionals, purchasers of health care (including federal and state governments), third party payers, public policy makers, credentialing organizations, the legal profession, and consumers.

Requirements

The primary goal of *mandatory reporting* of adverse medical events that cause death or serious harm should be to foster accountability for health care delivery process changes to prevent errors or adverse medical events. If a patient dies or is seriously harmed because of a mistake or accident in the health care system, the practitioner or institution responsible for the patient's care should report the incident to a designated state health body. Further, states should be obligated to share information based on these reports promptly with a national coordinating body and with national programs that are designed to improve the quality and enhance the safety of patient care.

ASHP's support of a mandatory reporting system is contingent upon the system having the following characteristics:

1. An overall focus on improving the processes used in health care, with the proper application of technical expertise to analyze and learn from reports,
2. Legal protection of confidentiality of patients, health care workers, and the information submitted to the extent feasible while preserving the interest of public accountability,
3. Nonpunitive in the sense that the submission of a report, per se, does not engender a penalty on the reporting institution or practitioner or others involved in the incident,
4. A definition of "serious harm" that concentrates on long-term or irreversible patient harm, so as not to overburden the reporting system,
5. National coordination and strong federal efforts to ensure compliance with standardized methods of reporting, analysis, and follow up, that emphasize process improvement and avoid a culture of blame,
6. Adequate resources devoted to report analysis, timely dissemination of advisories based on report analysis, and development of appropriate quality improvement efforts, and
7. Periodic assessment of the system to ensure that it is meeting its intent and not having serious undesired consequences.

Experience associated with current mandatory state reporting of adverse medical events and mandatory public health reporting of certain infectious diseases should be assessed, and the best practices of such programs should be applied to the new system of mandatory reporting of adverse medical events that cause death or serious harm.

The primary goals of *voluntary reporting* of medical errors should be quality improvement and enhancement of patient safety. Reports by frontline practitioners of errors and "near misses" are a strength of such programs when report analysis and communication lead to prevention of similar occurrences. The public interest will be served if protection is granted to individuals who submit reports to voluntary reporting programs. The Medication Errors Reporting Program operated by the United States Pharmacopeia in cooperation with the Institute for Safe Medication Practices is an important initiative that merits strengthening; this program may be a model for voluntary reporting of other types of medical error.

Reference

1. Institute of Medicine Division of Health Care Services Committee on Quality of Health Care in America. *To err is human: building a safer health system*. Washington, DC: National Academy Press; 1999.

This statement was reviewed in 2005 by the Council on Professional Affairs and by the Board of Directors and was found to still be appropriate.

Approved by the ASHP House of Delegates, June 5, 2000.

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