

WORLD ALLIANCE FOR PATIENT SAFETY

WHO DRAFT GUIDELINES FOR ADVERSE EVENT REPORTING AND LEARNING SYSTEMS

FROM INFORMATION TO ACTION



World Health
Organization

TABLE OF CONTENTS

1. INTRODUCTION.....	7
Purposes of reporting	7
Objectives.....	7
Definitions	8
Why should individuals or health-care organizations report adverse events and errors?.....	9
Core concepts.....	10
Organization of the Guidelines	10
2. THE ROLE OF REPORTING IN ENHANCING PATIENT SAFETY.....	12
The purpose of reporting adverse events and errors	12
Methods of learning from reporting.....	12
Accountability.....	15
3. COMPONENTS OF A REPORTING SYSTEM	16
Types of systems	16
Process	19
Classification.....	22
Analysis.....	26
4. ALTERNATIVE SOURCES OF INFORMATION FOR PATIENT SAFETY	30
Internal alternative sources of safety information	30
External alternative sources of safety information	34
5. NATIONAL REPORTING SYSTEMS.....	37
Types of patient safety reporting systems	38
Private and non-government initiated systems	44
6. CHARACTERISTICS OF SUCCESSFUL REPORTING SYSTEMS	49
7. REQUIREMENTS FOR A NATIONAL ADVERSE EVENT REPORTING AND LEARNING SYSTEM.....	53
Objectives.....	53
Capacity to respond	54
Security issues.....	56
8. RECOMMENDATIONS TO WHO MEMBER STATES.....	58
APPENDIX 1	
EXCERPT FROM INSTITUTE OF MEDICINE REPORT TO ERR IS HUMAN.....	59
APPENDIX 2	
CHECKLIST FOR DEVELOPING A REPORTING SYSTEM.....	75

6. CHARACTERISTICS OF SUCCESSFUL REPORTING SYSTEMS

Key messages

A successful reporting and learning system to enhance patient safety should have the following characteristics:

- **reporting is safe for the individuals who report;**
- **reporting leads to a constructive response;**
- **expertise and adequate financial resources are available to allow for meaningful analysis of reports;**
- **the reporting system must be capable of disseminating information on hazards and recommendations for changes.**

The ultimate measure of the success of a reporting system is whether the information it yields is used appropriately to improve patient safety. How that is done varies greatly according to the aims of its sponsor. While both learning and accountability systems seek to improve learning from mistakes, the fiduciary objectives of the latter impose an additional constraint: satisfying the public's interest in making sure that known mechanisms for injury prevention are being used (rules and safe practices) and that new hazards are promptly addressed when they are uncovered. This may require some departure from the following concepts, particularly regarding confidentiality and independence.

Successful patient safety reporting systems have the following characteristics:

- reporting must be safe for the individuals who report;
- reporting is only of value if it leads to a constructive response, and meaningful analysis;
- learning requires expertise and adequate financial resources. The agency that receives reports must be capable of disseminating information and making recommendations for changes, and informing the development of solutions.

Table One lists the characteristics that have been identified by various authors as essential to the success of any reporting systems concerned with patient safety (1-4). Many of these characteristics are derived from long experience both in health care (for example, the Institute for Safe Medication Practice) and in other industries, particularly aviation. These essential characteristics are discussed below.

Non-punitive. The most important characteristic for success of a patient safety reporting system is that it must be non-punitive. Neither reporters nor others involved in the incidents can be punished as a result of reporting. For public systems, this requirement is the most difficult to achieve, since the public often assumes an individual is to blame, and there can be strong pressure to punish the “culprit”. While perhaps temporarily emotionally satisfying, this approach is doomed to fail. People will not report any errors they can hide. It is important for national systems to protect reporters from blame. The best way to do this is by keeping the reports confidential.

Confidential. The identities of the patient and reporter must never be revealed to any third party. At the institutional level, confidentiality also refers to not making public specific information that can be used in litigation. Although, historically, breach of confidentiality has not been a problem in public or private systems, concern about disclosure is a major factor inhibiting reporting for many voluntary reporting programmes (5).

Independent. The reporting system must be independent of any authority with the power to punish the reporter or organization with a stake in the outcome. Maintaining a “firewall” between the reporting agency and the disciplinary agency in a governmental system can be difficult, but it is essential if trust in reporting is to be maintained.

Expert analysis. Reports must be evaluated by experts who understand the clinical circumstances under which the incidents occur and who are trained to recognize underlying systems causes. While it seems obvious that collecting data and not analysing it is of little value, the most common failure of governmentally run reporting systems is to require reporting but not to provide the resources needed to analyse the reports. Huge numbers of reports are collected only to sit in boxes or on computers. Expertise is a major, and essential, resource requirement for any reporting system.

Credible. The combination of independence and the use of content experts for analysis is necessary if recommendations are to be accepted and acted upon.

Timely. Reports must be analysed without delay, and recommendations must be promptly disseminated to those who need to know. When serious hazards are identified, notification should take place rapidly. For example, the Institute for Safe Medication Practice issues prompt alerts through its regular publication when new hazards in drugs are discovered.

Systems-oriented. Recommendations should focus on changes in systems, processes or products, rather than being targeted at individual performance. This is a cardinal principle of safety that must be reinforced by the nature of recommendations that come from any reporting system. It is based on the concept that even an apparently egregious individual error results from systems defects, and will recur with another person at another time if those systems defects are not remedied.

Responsive. For recommendations to result in widespread systems changes, the organization receiving reports must be capable of making and disseminating effective recommendations, and target organizations must make a commitment to implement recommendations. A good example is the National Reporting and Learning System in England and Wales which allows the National Patient Safety Agency to develop new solutions that are disseminated throughout the system.

Table 1 Characteristics of Successful Reporting Systems (7)

Non-punitive	Reporters are free from fear of retaliation against themselves or punishment of others as a result of reporting.
Confidential	The identities of the patient, reporter, and institution are never revealed.
Independent	The reporting system is independent of any authority with power to punish the reporter or the organization.
Expert analysis	Reports are evaluated by experts who understand the clinical circumstances and are trained to recognize underlying systems causes.
Timely	Reports are analysed promptly and recommendations are rapidly disseminated to those who need to know, especially when serious hazards are identified.
Systems-oriented	Recommendations focus on changes in systems, processes, or products, rather than being targeted at individual performance.
Responsive	The agency that receives reports is capable of disseminating recommendations. Participating organizations commit to implementing recommendations whenever possible.

Several of these characteristics are included among the attributes that Runciman has proposed for national reporting and learning systems (6):

- an independent organization to coordinate patient safety surveillance;
- agreed frameworks for patient safety and surveillance systems;
- common, agreed standards and terminology;
- a single, clinically useful classification for things that go wrong in health care;
- a national repository for information covering all of health care from all available sources;
- mechanisms for setting priorities at local, national and international levels;
- a just system which caters for the rights of patients, society,

and health-care practitioners and facilities;

- separate processes for accountability and “systems learnings”;
- the right to anonymity and legal privilege for reporters;
- systems for rapid feedback and evidence of action;
- mechanisms for involving and informing all stakeholders.

References

1. Cohen M. *Discussion paper on adverse event and error reporting in healthcare*. Institute for Safe Medication Practices, 2000.
2. Cohen M. Why error reporting systems should be voluntary. *British Medical Journal*, 2000, 320:728-729.
3. Gaynes R et al. Feeding back surveillance data to prevent hospital-acquired infections. *Emerging infectious diseases*, 2001, 7:295-298.
4. Billings CE. The NASA aviation safety reporting system: lessons learned from voluntary incident reporting. 1998. *Enhancing Patient Safety and Reducing Errors in Health Care*. Annenberg Conference, Rancho Mirage, CA.
5. O'Leary D. Testimony before the House Committee on Ways and Means. *House Committee on Ways and Means*, 106th Congress, 2000.
6. Runciman WB. Lessons from the Australian Patient Safety Foundation: setting up a national patient safety surveillance system - is this the right model? *Quality and Safety in Health Care*, 2002, 11:246-251.
7. Leape, L.L. Reporting adverse event. *New England Journal of Medicine*, 2002, 347 (20): 1633-8