（資料2－2－3）

WORLD ALLIANCE FOR PATIENT SAFETY

WHO DRAFT GUIDELINES FOR ADVERSE EVENT REPORTING AND LEARNING SYSTEMS

FROM INFORMATION TO ACTION

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FOREWORD

Imagine a jet aircraft which contains an orange coloured wire essential for its safe functioning. An airline engineer in one part of the world doing a pre-flight inspection spots that the wire is frayed in a way that suggests a critical fault rather than routine wear and tear. What would happen next? I think we know the answer. It is likely that – probably within days – most similar jet engines in the world would be inspected and the orange wire, if faulty, would be renewed.

When will health-care pass the orange-wire test?

The belief that one day it may be possible for the bad experience suffered by a patient in one part of the world to be a source of transmitted learning that benefits future patients in many countries is a powerful element of the vision behind the WHO World Alliance for Patient Safety.

The most important knowledge in the field of patient safety is how to prevent harm to patients during treatment and care. The fundamental role of patient safety reporting systems is to enhance patient safety by learning from failures of the health care system. We know that most problems are not just a series of random, unconnected one-off events. We know that health-care errors are provoked by weak systems and often have common root causes which can be generalized and corrected. Although each event is unique, there are likely to be similarities and patterns in sources of risk which may otherwise go unnoticed if incidents are not reported and analysed.

These draft guidelines are a contribution to the Forward Programme 2005 of the World Alliance for Patient Safety. The guidelines introduce patient safety reporting with a view to helping countries develop or improve reporting and learning systems in order to improve the safety of patient care. Ultimately, it is the action we take in response to reporting – not reporting itself – that leads to change.

Reporting is fundamental to detecting patient safety problems. However, on its own it can never give a complete picture of all sources of risk and patient harm. The guidelines also suggest other sources of patient safety information that can be used both by health services and nationally.

The currency of patient safety can only be measured in terms of harm prevented and lives saved. It is the vision of the World Alliance that effective patient safety reporting systems will help to make this a reality for future patients worldwide.

Sir Liam Donaldson

Chair
World Alliance for Patient Safety

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1. INTRODUCTION

Reducing medical errors has become an international concern. Population-based studies from a number of nations around the world have consistently demonstrated unacceptably high rates of medical injury and preventable deaths. In response, a global effort, the World Alliance for Patient Safety, has been launched by WHO to galvanize and facilitate efforts by all Member States to make health care safer.

These draft guidelines are a contribution to the Forward Programme 2005 of the World Alliance for Patient Safety (1). The guidelines introduce adverse event reporting and focus on reporting and learning to improve the safety of patient care.

Purposes of reporting

In seeking to improve safety, one of the most frustrating aspects for patients and professionals alike is the apparent failure of health-care systems to learn from their mistakes. Too often neither health-care providers nor health-care organizations advise others when a mishap occurs, nor do they share what they have learned when an investigation has been carried out. As a consequence, the same mistakes occur repeatedly in many settings and patients continue to be harmed by preventable errors.

One solution to this problem is reporting: by the doctor, nurse, or other provider within the hospital or health-care organization, and by the organization to a broader audience through a system-wide, regional, or national reporting system. Some believe that an effective reporting system is the cornerstone of safe practice and, within a hospital or other health-care organization, a measure of progress towards achieving a safety culture. At a minimum, reporting can help identify hazards and risks, and provide information as to where the system is breaking down. This can help target improvement efforts and systems changes to reduce the likelihood of injury to future patients.

Objectives

The objective of these draft guidelines is to facilitate the improvement or development of reporting systems that receive information that can be used to improve patient safety. The target audience is countries, which may select, adapt or otherwise modify the recommendations to enhance reporting in their specific environments and for their specific purposes. The guidelines are not meant to be an international regulation and will undergo modification over time as experience accumulates.

The guidelines draw on a review of the literature about reporting systems, a survey of countries about existing national reporting systems, and the experience of the authors.

Reporting may capture errors, injuries, non-harmful errors, equipment malfunctions, process failures or other hazards (see definitions below). While an individual report may contain important information about a specific incident or event, the notion of a reporting system refers to the processes and technology involved in the standardization, formatting, communication, feedback, analysis, learning, response, and dissemination of lessons learned from reported events.

Reports are generally initiated by health-care workers such as care providers or administrators from hospitals, ambulatory sites, or communities. Reporting systems may also be designed to receive reports from patients, families, or consumer advocates.

Definitions

Safety: Freedom from accidental injuries (2).

Error: The failure of a planned action to be completed as intended (i.e. error of execution) or the use of a wrong plan to achieve an aim (i.e. error of planning) (3). Errors may be errors of commission or omission, and usually reflect deficiencies in the systems of care.

Adverse event: An injury related to medical management, in contrast to complications of disease (4). Medical management includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. Adverse events may be preventable or non-preventable.

Preventable adverse event: An adverse event caused by an error or other type of systems or equipment failure (5).

"Near-miss" or "close call": Serious error or mishap that has the potential to cause an adverse event but fails to do so because of chance or because it is intercepted. Also called potential adverse event.

Adverse drug event: A medication-related adverse event.

Hazard: Any threat to safety, e.g. unsafe practices, conduct, equipment, labels, names.

System: A set of interdependent elements (people, processes, equipment) that interact to achieve a common aim.

Other commonly used terms:

Event: Any deviation from usual medical care that causes an injury to the patient or poses a risk of harm. Includes errors, preventable adverse events, and hazards (see also incident).

Incident (or adverse incident): Any deviation from usual medical care that causes an injury to the patient or poses a risk of harm. Includes errors, preventable adverse events, and hazards.

Potential adverse event: A serious error or mishap that has the potential to cause an adverse event but fails to do so because of chance or because it is intercepted (also called "near miss" or "close call") (6).

Latent error (or latent failure): A defect in the design, organization, training or maintenance in a system that leads to operator errors and whose effects are typically delayed (3).

Many other terms have been used: adverse outcomes, mishaps, untoward or unanticipated events, etc. WHO has commissioned the development of an international taxonomy for patient safety in order to promote greater standardization of terminology and classification. Meanwhile, for these guidelines we will use the simpler terms: errors, hazards, adverse events and incidents.

Why should individuals or health-care organizations report adverse events and errors?

Health-care organizations or individuals benefit from reporting incidents if they receive back useful information gained by generalizing and analysing similar cases from other institutions. Consider the following case: In an intensive care unit at a hospital, the oxygen tubing is inadvertently connected to an intravenous line and causes an air embolism. Investigation reveals that the tubing connectors are similar, the oxygen tubing had been left disconnected from a prior respiratory treatment, and the lights in the unit were dim. The hospital's response might include implementing a new policy requiring that all tubing be labelled, a weak and cumbersome solution.

If the event and the results of the analysis are not reported to an external authority, the lessons learned are trapped within the walls of that hospital. The opportunity to generalize the problem is lost and the opportunity to develop more powerful and generalizable solutions is missed.

In contrast, if the event is reported and the findings from the investigation are entered into a database, the event can be aggregated with similar incidents to elucidate common underlying causes. A variety of solutions could emerge, ranging from

nursing practice standards to label and trace all tubing, to a requirement for medical device manufacturers to develop incompatible connectors for all medical tubing.

Appendix 1 contains an excerpt from the landmark Institute of Medicine report To Err is Human, which provides an overview of the systems approach to human error within health-care and other industries.

Core concepts

The four core principles underlying the guidelines are:

- The fundamental role of patient safety reporting systems is to enhance patient safety by learning from failures of the health-care system.
- Reporting must be safe. Individuals who report incidents must not be punished or suffer other ill-effects from reporting.
- Reporting is only of value if it leads to a constructive response. At a minimum, this entails feedback of findings from data analysis. Ideally, it also includes recommendations for changes in processes and systems of health care.
- Meaningful analysis, learning, and dissemination of lessons learned requires expertise and other human and financial resources. The agency that receives reports must be capable of disseminating information, making recommendations for changes, and informing the development of solutions.

Organization of the Guidelines

Section 2 describes the role of reporting in enhancing patient safety, its purposes and the ways in which reporting can enhance safety.

Section 3 discusses the essential components of a patient safety reporting system, considering the types of systems, the process of reporting (what is reported, by whom, and how), analysis of reports, response and dissemination, and application of results.

Section 4 examines alternative sources of information for safety. Reporting is but one method of obtaining such information, not necessarily the best. Other sources of useful data are briefly described.

Section 5 provides information about several existing national reporting systems, both governmentally sponsored and those implemented by non-governmental agencies or groups. This illustrates the broad variation in how Member States have dealt with these issues.

Section 6 describes the characteristics of successful reporting systems. While experience is limited in health care, successful existing systems have common features in purpose, design and operation, that have general applicability.

Section 7 outlines the requirements for a national adverse event reporting system, including the mechanism for collecting reports, the capacity to perform investigations, the expertise required, the technical infrastructure, and the capacity to disseminate findings.

Section 8 concludes with recommendations to WHO Member States.

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2. THE ROLE OF REPORTING IN ENHANCING PATIENT SAFETY

Key messages

- **The primary purpose of patient safety reporting systems is to learn from experience.**
- **A reporting system must produce a visible, useful response to justify the resources expended and to stimulate reporting.**
- **The most important function of a reporting system is to use the results of data analysis and investigation to formulate and disseminate recommendations for systems change.**

The purpose of reporting adverse events and errors

The primary purpose of patient safety reporting systems is to learn from experience. It is important to note that reporting in itself does not improve safety. It is the response to reports that leads to change. Within a health-care institution, reporting of a serious event or serious "near-miss" should trigger an in-depth investigation to identify underlying systems failures and lead to efforts to redesign the systems to prevent recurrence.

In a state or national system, expert analyses of reports and dissemination of lessons learned are required if reports are to influence safety. Merely collecting data contributes little to patient safety advancement. Even monitoring for trends requires considerable expert analysis and oversight of the reported data.

The important point is that a reporting system must produce a visible, useful response by the receiver to justify the resources expended in reporting, or, for that matter, to stimulate individuals or institutions to report. The response system is more important than the reporting system.

Methods of learning from reporting

There are several ways in which reporting can lead to learning and improved safety. First, it can generate alerts regarding significant new hazards, for example, complications of a new drug. Second, lessons learned by health-care organizations from