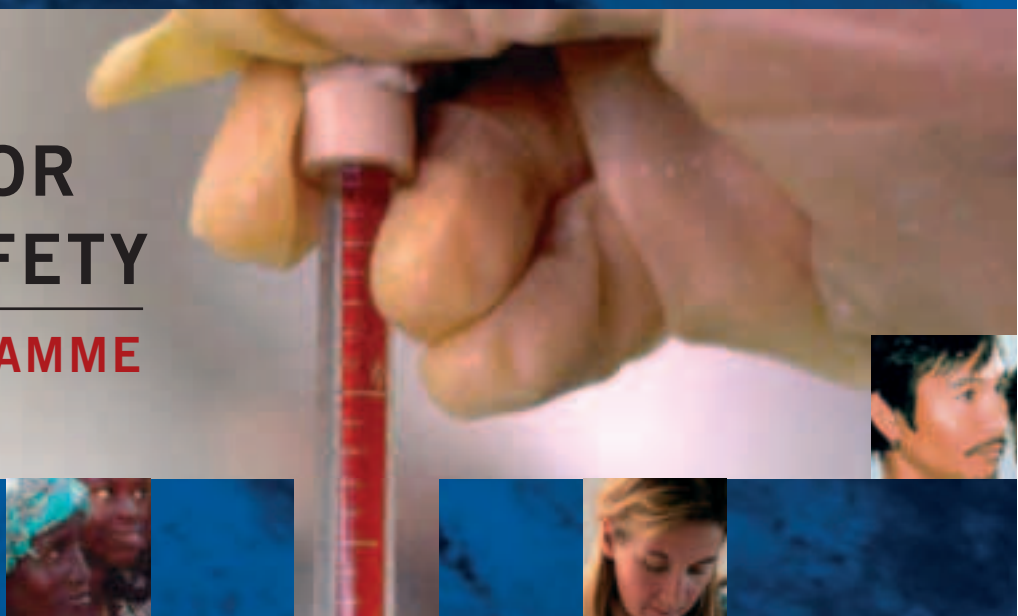
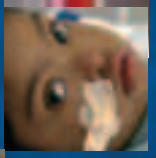
"First, do no harm..."
Attributed to Hippocrates circa 470-360 B.C.

WORLD ALLIANCE FOR PATIENT SAFETY

FORWARD PROGRAMME 2005





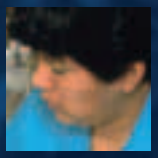
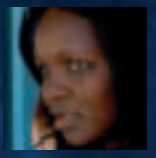
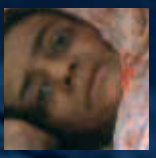





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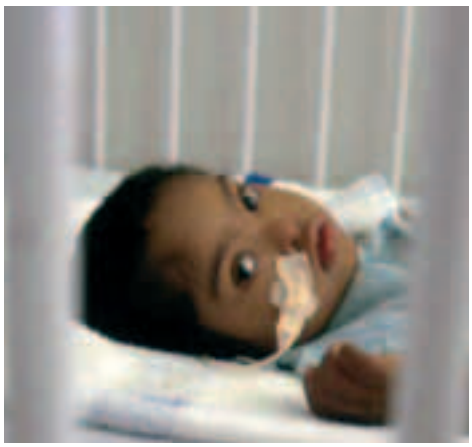
Table of contents



Introduction

Today's health-care context is highly complex. Care is often delivered in a pressurized and fast-moving environment, involving a vast array of technology and, daily, many individual decisions and judgements by health-care professional staff. In such circumstances things can and do go wrong. Sometimes unintentional harm comes to a patient during a clinical procedure or as a result of a clinical decision. Errors in the process of care can result in injury. Sometimes the harm that patients experience is serious and sometimes people die.

The problem of adverse events in health care is not new. Studies as early as the 1950s and 1960s reported on adverse events, but the subject remained largely neglected. A body of evidence started to emerge in the early 1990s with the publication of the results of the Harvard Medical Practice Study in 1991 (*1,2)*. Subsequent research in Australia (*3)*, the United Kingdom of Great Britain and Northern Ireland (UK) (*4)* and the United States of America (USA) and in particular the 1999 publication *To err is human: building a safer health system* by the Institute of Medicine (*5),* provided further data and brought the subject to the top of the policy agenda and the forefront of public debate worldwide. Today more countries, including Canada, Denmark, the Netherlands, Sweden and other member countries of OECD, are taking a serious look at the problem. New Zealand (*6,7)* and Canada (*8)* have recently published research into adverse events in public hospitals.

Various studies have investigated the extent of adverse events (see Table 1). The Harvard study found that 4% of patients suffer some kind of harm in hospital; 70% of the adverse events result in short-lived disability, but 14% of the incidents lead to death (*1,2)*. The Institute of Medicine (IOM) report estimated that "medical errors" cause between 44 000 and 98 000 deaths annually in hospitals in the USA — more than car accidents, breast cancer or AIDS (*5)*. The UK Department of Health, in its 2000 report, *An organisation with a memory*, estimated that adverse events occur in around 10% of hospital admissions or about 850 000 adverse events a year (*13)*. The Quality in Australian Health Care Study (QAHCS), released in 1995, found an adverse-event rate of 16.6% among hospital patients (*3)*. The Hospitals for Europe's Working Party on Quality Care in Hospitals estimated, in 2000, that every tenth patient in hospitals in Europe suffers from preventable harm and adverse effects related to his or her care (*14)*. The New Zealand and Canadian studies have also suggested relatively high rates of adverse events: around 10% (*6,7,8)*.

Table 1. Data on adverse events in health care from several countries

Study	Study focus (date of admissions)	Number of hospital admissions	Number of adverse events	Adverse event rate (%)
USA (New York State) (Harvard Medical Practice Study) (*1,2*)	Acute care hospitals (1984)	30 195	1 133	3.8
USA (Utah-Colorado Study (UTCOS)) (*10*)	Acute care hospitals (1992)	14 565	475	3.2
USA (UTCOS)[1] (*10*)	Acute care hospitals (1992)	14 565	787	5.4
Australia (Quality in Australian Health Care Study (QAHCS)) (*3*)	Acute care hospitals (1992)	14 179	2 353	16.6
Australia (QAHCS)[2] (*10*)	Acute care hospitals (1992)	14 179	1 499	10.6
UK (*4*)	Acute care hospitals (1999-2000)	1 014	119	11.7
Denmark (*12*)	Acute care hospitals (1998)	1 097	176	9.0
New Zealand (*6,7*)	Acute care (1998)	6 579	849	12.9
Canada (*8*)	Acute and community hospitals (2001)	3 720	279	7.5

1. UTCOS revised using the same methodology as the Quality in Australia Health Care Study (harmonizing the four methodological discrepancies between the two studies).

2. QAHCS revised using the same methodology as UTCOS (harmonizing the four methodological discrepancies between the two studies).

Adverse events exact a high toll in financial loss as well. In the UK consequent additional hospital stays alone cost about £ 2000 million a year *(13)*, and paid litigation claims cost the National Health Service around £ 400 million annually, in addition to an estimated potential liability of £ 2400 million for existing and expected claims *(13)*. The total national cost of preventable adverse medical events in the USA, including lost income, disability and medical expenses, is estimated at between US$ 17 000 million and US$ 29 000 million annually *(5)*. Added to these costs is the erosion of trust, confidence and satisfaction among the public and health-care providers.

The situation in developing countries and countries in economic transition merits particular attention. The poor state of infrastructure and equipment, unreliable supply and quality of drugs, shortcomings in waste management and infection control, poor performance of personnel because of low motivation or insufficient technical skills, and severe under financing

of essential operating costs of health services make the probability of adverse events much higher than in industrialized nations. World Health Organization (WHO) figures suggest that developing countries account for around 77% of all reported cases of counterfeit and substandard drugs (*15)*. It is also reported that at least half of all medical equipment in most of these countries is unusable or only partly usable, at any given time, resulting in neglect of patients or increased risk of harm to them and to health workers (*16)*. In the European countries that have achieved independence in recent years, about 40% of hospital beds are reported to be located in structures originally built for other purposes (*17)*. This makes facilities for radiation protection and infection control extremely difficult to incorporate, with the result that such facilities are often either substandard or absent.

Most of the current evidence on adverse events comes from hospitals, because the risks associated with hospital care are high, strategies for improvement are better documented, and the importance of patient trust is paramount. But many adverse events occur in other health-care settings, such as physicians' offices, nursing homes, pharmacies and patients' homes. Recent literature highlights concerns about outpatients as well, but there are few data on the extent of the problem outside hospitals.

Every point in the process of care giving contains a certain inherent lack of safety: side-effects of drugs or drug combinations, hazards posed by a medical device, substandard or faulty products entering the health service, human shortcomings, or system (latent) failures. Adverse events may therefore result from problems in practice, products, procedures or systems. Immunization, which is given to healthy individuals, poses a particular challenge. With the decline in prevalence of vaccine-preventable diseases, concern about potential adverse events following immunization may have a negative impact on national immunization programmes and preventive health care in general.