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Patient safety in Dutch hospitals

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Abstract

In various studies outside the Netherlands, it has been shown that a substantial number of patients suffer from some kind of harm during their treatment in hospital. The incidence of these so-called adverse events varies between 2.9% and 16.6%; it is estimated that between over a quarter and a half of these are considered to be avoidable.

Preventable adverse events can be considered to be a starting point for interventions to increase patient safety. In response to this, a study was initiated in Dutch hospitals investigating the nature and extent of adverse events and their causes. Lessons learnt will be discussed within the European Research Network on Quality in Health Care (ENQual), where researchers and policy makers come together to exchange knowledge and experiences.

Two important goals of the Dutch study are to reach a consensus on basic concepts and to improve research methodology. An unintended event resulting in harm caused by healthcare is called an adverse event in international literature. Preventable adverse events are especially important for prevention, in these cases the harm can be attributed to unintended events in the care process, caused by insufficient action according to professional standards and failures within the care system. Most adverse events, caused as they may seem by human action or failing to act at first sight, are often partly caused by a care process that has not been properly organized.

Uniform concepts are needed in order to facilitate European comparisons, which would allow, for example, the comparison of Dutch research results with those from other countries, and the identification of specific concepts. One of the six action areas of the WHO's World Alliance for Patient Safety is the development of a 'patient safety taxonomy'.

Key words: patient safety, research, adverse events, hospitals

Introduction

Patient safety is gaining more attention nationally as well as internationally. WHO has established a World Alliance for Patient Safety in order to enhance global patient safety[1]. During England's EU presidency, there was the desire to put patient safety on the European agenda. Additionally, a report, published in the Netherlands, advises that all hospitals in the near future should introduce a certified safety management system [2]. Also, improvement projects have started to investigate how and whether "safe incident reporting" can be arranged more securely and in accordance with the law [3-6].

Several overseas studies, for example, in the US, Canada, Australia, New-Zealand, France, United Kingdom and Denmark, show that many patients suffer harm during hospital treatment [7-16]. WHO encourages European countries to undertake comparable research in order to create the sense of urgency necessary to improve patient care. During the ISQua conference in Amsterdam in 2004, a WHO workshop showed that several European countries were planning to start epidemiological research, either on a large or small scale, in order to investigate the character and extent of adverse events in hospitals. Some countries, however, do not have the financial means necessary to undertake such research programmes.

For some time now, healthcare professionals in the Netherlands have felt the need to gain an insight into the extent to which patients suffer harm within the Dutch healthcare system. In 2005, an extensive study was started, initiated by the umbrella organization for medical specialist associations [de Orde van Medisch Specialisten] with the support of the Quality Institute for Health Care [Kwaliteitsinstituut voor de Gezondheidszorg CBO]. The objectives are a) to gain a more profound insight into the character, severity, extent and cost of adverse events and the resulting harm to patients in , ambulatory and extramural care in the Netherlands; b1) to gain a

more profound insight into the direct and indirect causes of adverse events and near misses, b2) to explore and describe the main safety culture in Dutch hospitals; c) to incorporate international best practices into the Dutch system and d) to evaluate safety improvement initiatives, such as those based on the discovered leverage points for prevention and international best practices.

This research is mainly financed by the Ministry of Health, Welfare and Sport and it is conducted by independent researchers.

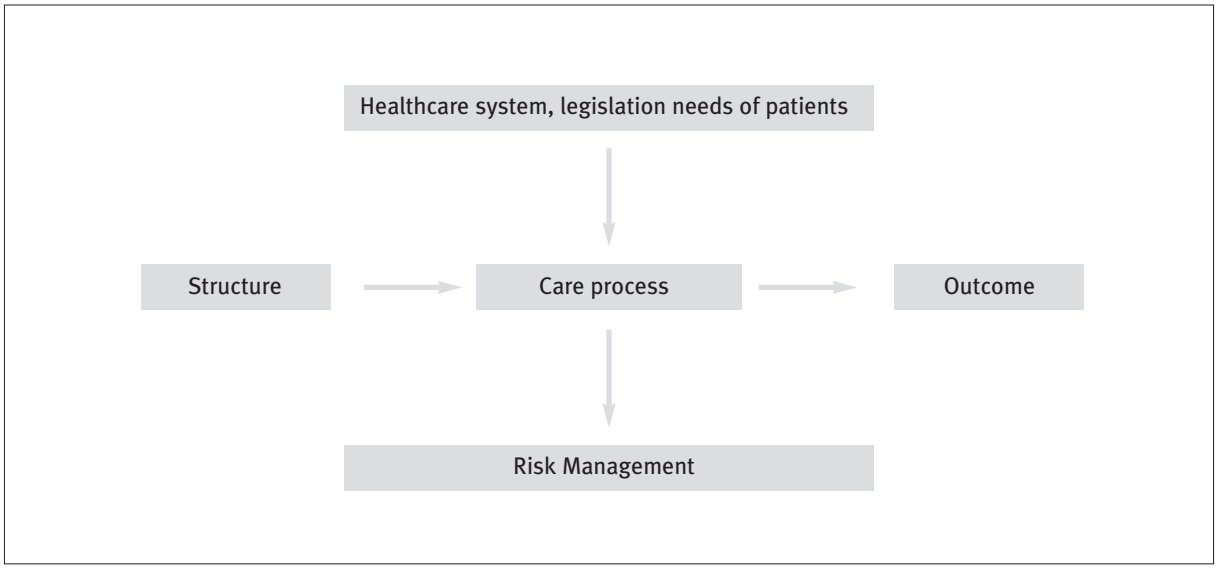
This article further examines some of the patient safety concepts; the main results of several foreign, and especially European studies; the design of the Dutch research program; as well as the possible roles of the European Research Network on Quality Management in Health Care (ENQual).

Concepts

Things can go wrong in healthcare, situations for which little is known, but which are presumably not rare. During the care process an unintentional event occurs resulting in possible damage to the patient; this is generally called an incident. An incident without damage is called a near-miss or a near-accident. The unintentional event is the result of an action or non-action of the medical doctor, other healthcare professionals or the care system which does not reach the patient, because the consequences have been recognized in time and corrected. In international literature an unintended result resulting in harm caused by the care given is called an adverse event. In the Netherlands, an unintended result which has resulted in harm is often referred to as a "complication", as in the complication registrations of some medical and scientific associations. The term "complication" is a slightly wider concept than adverse event: both can be the result of an incident during the care process, such as an assessment failure, but they can also be the result of an unexpected reaction of the patient, such as an allergic reaction, or a weighted risk or calculated risk. Additionally, a complication contains the unintended result from the patient's primary illness or co-morbidity; this is not covered by the adverse event. Possible harm may consist of continuing or intensifying treatment, temporary or permanent health damage and, in extreme cases, premature death. Preventable *adverse events* are especially important for prevention, in these cases the damage can be blamed on unintended events in the care process, caused by insufficient action according to professional standards and healthcare system failures. Most adverse events, caused seemingly caused by human action or failing to act at first sight, are often partly caused by a care process that has not been properly organized. This care process, in turn, is influenced by the organization of the health care system, the existing laws and regulations and the demands of the parties, such as health care insurers and patients (Figure 1). In these cases, patient safety can be defined as "a situation in which the patient will not suffer, or has only a slight risk of suffering any damage caused by health care professionals who are not acting in accordance with the professional standards or by failures in the care system".

Uniform concepts are needed in order to facilitate European comparisons; including

Figure 1. Structure and process model for patient safety based on Donabedian



comparing Dutch research results with those from other countries and to recognize the specific concepts involved. One of the six action areas of the WHO's World Alliance for Patient Safety is the development of a 'patient safety taxonomy' [1]. In a pre-study, a Dutch framework for patient safety was developed; beginning the process of uniformity. In order to reach a consensus the framework has been further developed in cooperation with representatives of organizations, such as the health care inspectorate, the umbrella organizations of hospitals, medical specialists and nurses, and the national quality institute [17].

Foreign studies into patient safety

The number of adverse events. The report 'To err is human: building a safer health system', published in the United States by the Institute of Medicine at the end of 1999, caused quite a stir [18]. '*Medical errors'* were said to cause the death of 44 000 to 98 000 patients a year, which is more than the number of deaths from traffic accidents, breast cancer or AIDS. Several foreign studies show that the percentage of adverse events varies from 2.9% of the hospital admissions in Utah and Colorado to 16.6% of those in Australia [7-16]. Of these adverse events, more than a quarter (France) to half (Australia) were said to be avoidable(27.7-51.2%) [9-16].

Studies concerning adverse events looking particularly into the differences between men and women show no differences between the two sexes; adverse events more frequently occurred in older patients [7, 10-12, 15].

Character of adverse events. Studies looking into the character of adverse events showed that most adverse events were connected with surgery, for example technical complications, bleeding and wound infections. Regarding treatment without surgery, adverse events occurred mainly in prescriptions, administering and giving medication, for example, a known or unknown allergic reaction, wrong medicine or dose [8-11,13].

Locating adverse events. Some studies try to locate the adverse events. Around 80% of the adverse events took place in hospitals. Some 40% of the adverse events took place in operating theatres and a quarter in the patients' rooms. Adverse events outside the hospital most frequently occurred in general practice (6.4-8.7% of the adverse events) [8,9,11,12].

Kind of harm. Greater than one third to two thirds of the patients who suffered from an adverse events incurred minimal damage and the patients recovered within one month (34.2-66.4%). Permanent harm occurred in 5.2-20.2% of adverse events, 2.3-7.9% of which caused more than 50% disability. In 4.5-15.9% of the patients the adverse event resulted in death [7,9-12,15,16]. Patients with adverse events stayed on average 6.0-9.3 days longer in hospital than patients without adverse events [10-12, 15,16].

Avoidable cost of adverse events. In England the cost of staying longer in hospital as a result of avoidable adverse event were an estimated to be £1 000 million per year [15]. The total cost of avoidable adverse events in the United States were an estimated $17 000-29 000 million per year, including lost revenue, productivity loss resulting from absenteeism, and direct cost in health care; more than half of these are direct costs [18].

Limitations in comparing foreign studies

The results of foreign studies are based on retrospective file studies of patients, or a sample of patients, hospitalized during a specific time period. The selected files were assessed in two phases for the occurrence of adverse event "triggers", following a fixed screening list. The first assessment was done by a nurse or a medical coder, the second by a medical practitioner, most often by a specialist. They assessed only files that had scored positively on at least one of the triggers as assessed by the nurse.

Comparing foreign studies is limited by the fact that the methodologies used vary slightly. For example, the definitions are not always the same, the percentage of adverse events has not always been calculated in the same way and the kind of assessor sometimes varies. Australian data analyzed according the Utah and Colorado method, for example, will result in a decrease in the percentage of adverse events from 16.6% to 10.6%. In contrast, the percentage of adverse events from Utah and Colorado will increase from 2.9% to 5.4% if the study is done following the Australian methodology [19]. An added limitation is the fact that only files have been used to gain insight into the prevention of adverse events and therefore, the quality of the files determines the percentage of the adverse events [20]. A final problem is the reliability between assessors: two internists will not analyze a disease history in the same way, and an internist will do this differently from a surgeon. Therefore, important points for improvement are: clear definitions, for example, what an adverse event is and what it is not; proper training for the assessors, the use of only very experienced assessors with the appropriate expertise; assessors with the

appropriate background should assess the disease history; more than one assessor should examine each file and there should be a procedure to reach consensus.

Extrapolation

Adaptation of foreign results to the Netherlands shows that the avoidable death rate in the Netherlands is 1500 to 6000 patients a year. However, the extent of adverse events in the Netherlands in intramural care and the character and extent of the harm incurred by the patients has never been looked into systematically, partly due to the cost of such a study. This can also be said for ambulatory care and extramural care. The number of events reported to the Health Care Inspectorate is very low compared to what could be expected based on foreign studies [21]. Current registration of incidents and complications in hospitals are based on voluntary reports and thus their completion depends on the willingness of the professionals involved. It is believed that many ward incidents and complications are not recognized or if so only with some difficulty, or they are interpreted incorrectly, or they cannot be reported safely because of the culture; therefore the real number of incidents and complications will undoubtedly be higher than the registered number. Which incidents are reported and which are not in the current registration systems is not known. Further insight into the causes of adverse events and possible prevention is needed in order to limit patient harm. A research program on patient safety was introduced in 2005 to gain insight into the situation in the Netherlands.

Research program in 22 Dutch hospitals

The research program consists of different projects that are carried out during a four year period, running both consecutively and parallel; a pilot study was undertaken in 2004 [22]. The main projects are: (1a) a retrospective epidemiological study (file study comparable with foreign studies) in 22 hospitals examining the character, severity, extent and cost of adverse events during hospitalization and the resulting harm to patients, (1b) a prospective epidemiological study (file study and interviews with patients) of adverse events during day-care in these hospitals, and (1c) a comparison between the adverse events of the file study, the incidents reported and the registration of complaints. Project 2 concerns a prospective study undertaken in surgical departments, ER's and departments of internal medicine; it examines the causes of adverse events and near misses, and how to prevent these. In these wards, the roles relating to the occurrence of the adverse events and near misses, such as those relating to the organization, the human factors, as well as technical and patient-related factors are investigated. The study into near misses will especially focus on the human recovery factors thus preventing the incident from causing harm.

Future Directions

Other countries embarking on similar plans are able to build on the recent experiences of the Netherlands, however, a platform is needed to facilitate the exchange of knowledge, instruments and experience within Europe. ENQual, the European research Network on Quality Management in Health Care, which was set up with financial support from the EU, could be this very platform (www.enqual.info). In the last two years, representatives of ten European countries have met three times to exchange knowledge and experience on national quality policy, quality activities and instruments, patient safety issues as well as evaluation methods.

Important issues for future research on patient safety are:

1) Research into the most appropriate way to analyse adverse events and to translate these to structural improvements.
2) Monitoring the incidence of adverse events during the years and with regard to safety improvement initiatives.
3) Research into the integration of quality management systems and safety management systems in European countries.
4) Research into the causes of the differences in adverse events in foreign studies.

The European research network ENQual can be utilised to explore some of these issues, enabling them to work cooperatively with other existing European policy networks, such as the European Society for Quality in Health care (ESQH), and participants from existing European projects, such as the SYMPathie en Marquis.

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