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Patient safety in hospitals

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ABSTRACT.

In various studies outside the Netherlands, it has been shown that a substantial number of patients suffer some kind of injury during their treatment in a hospital. The incidence of these so-called adverse events varies between 2.9% and 16.6%; of these, estimates between more than a quarter and up to half are considered to have been avoidable. Preventable adverse events can offer a starting point for interventions to increase patient safety. Therefore, a study has been initiated in Dutch hospitals investigating the nature and extent of adverse events and their causes. Important goals of the study are to reach a consensus on basic concepts and to improve the research methodology.

1. INTRODUCTION

Attention for the safety of patients is on the increase, internationally and also in the Netherlands. To enhance patient safety worldwide the World Health Organisation (WHO) has initiated in October 2004 a World Alliance for Patient Safety). In the Netherlands, within the frame work of a program under the name "Sneller beter" ("more rapid improvement"), a report from the president director of Shell Holland appeared at the end of the year 2004 with the recommendation to implement in the short term in all hospitals a certified safety management system [6]. In addition, small scale improvement projects have been started and whether and how "blame free reporting" can be regulated, respectively better regulated, by law, is under investigation [10–12,14]. In several studies from foreign countries, like the United States, Canada, Australia, New Zealand, France, United Kingdom and Denmark, it became clear that a large number of patients suffer injury during their treatment in hospitals [1,3–5,9,13,15,16,18,21]. Data from foreign studies, especially studies from the US, are with a certain degree of regularity extrapolated towards the Dutch situation. However, to what extent patients in the Dutch health care system experience injury has never been examined systematically.

1.1. Dutch study

In 2005, as an initiative of the Dutch Order of Medical Specialists and with support of the Dutch Institute for Healthcare Improvement (CBO) and the Dutch Association of Hospitals a far-reaching investigation was started. Aim is (a) to provide more insight in the nature, seriousness, extend and costs of unintentional harm for patients within the intramural and related ambulatory and extramural health care in the Netherlands, (b) to provide more

insight in the direct and indirect causes of adverse events and near-accidents, (c) to map out the dominating safety culture in Dutch hospitals, (d) to translate international standard procedures for the Dutch situation and (e) to evaluate specific improvement initiatives, keeping in mind the found pretexts and the international standard procedures. The study is mainly financed by the Ministry of Health, Welfare and Sport. It is carried out by the Department of Public and Occupational Medicine and the EMGO Institute,VU University Medical Centre in Amsterdam, together with the Dutch Institute for Research in Primary Health Care (NIVEL) in Utrecht. In this article we will discuss some terms and concepts concerning patient safety, the most important findings from a number of foreign studies and the set-up of the research programme that has now been started in the Netherlands.

2. CONCEPTS AND DEFINITIONS

In an unknown, but probably not so small number of health care situations something goes wrong, which means that an unintended event takes place during the care process, with the possibility of injury for the patient. Such events are generally called “incident”. An incident without injury is a “near accident”: in that case the unintentional event which has surfaced by the act or the omitted act of a care provider or of the care system does not reach the patient because the impact of the event has been recognised in time and has been corrected. An unintentional outcome with injury which is caused by the health care system is called an “adverse event” in the international literature. The word “complication”, as used in the Dutch language, has a somewhat broader meaning than “adverse event”. Both can be the consequence of an incident during the care process, as for example a misjudgement, but also of an unforeseen response of the patient, such as an allergic reaction, or of a calculated risk or an to be expected side effect. Moreover the term “complication” also includes the unintentional outcome resulting from the primary disorder or from co-morbidity of the patient; such outcomes are not counted as adverse events. The term “complication” returns in the complication recordings of some medical-scientific societies. Possible injury may encompass for example an increase of the duration or an intensification of the treatment, temporary or permanent health injury and in extreme instances premature death. From a viewpoint of prevention especially the avoidable adverse events respectively complications are important, where injury can be shown to be related to unintentional events in the process of care, caused by inadequate acting according to the professional standard or shortcomings of the care system. Although at first sight most of the incidents arise from human acts or failure to act, a not proper functioning care process is often also responsible. That process of care is on its turn influenced by the organisation of the health care system, the applicable laws and regulations and the demands of parties such as health care insurers and patient organisations (Fig. 1).

[FIGURE 1]

2.1. Notions framework for patient safety

Patient safety can be defined as “the (virtual) lack of (any risk of) injury to the patient as a result of actions of health care workers which are not according to the professional standard and/or by shortcomings of the care system”. In order to create the possibility to make a good comparison between the results of Dutch research with those from foreign studies it is necessarily to use a uniform terminology or to know what is implied by specific terms. One of the six fields of action of the World Alliance for Patient Safety of the WHO is the development of a classification of patient safety (“patient safety taxonomy”; www.who.int/ patientsafety/en/brochure_final.pdf). We have developed in a preliminary analysis a proposal for a Dutch notions framework for patient safety. For this purpose we have looked at the definitions which are used internationally and those that are in use in the

Netherlands. To reach consensus and to create general support the proposal has been further explored with representatives of among others the Dutch Health Care Inspectorate (IGZ), the Royal Dutch Medical Association (KNMG), the Dutch Order of Medical Specialists (OMS), the Netherlands Centre for Excellence in Nursing (LEVV), The Dutch Institute for Healthcare Improvement (CBO) and the Platform for Patient Safety which is under development [19].

3. Foreign studies of patient safety

3.1. Number of adverse of events

At the end of 1999 much commotion was created in the United States by the report "To err is human: building a safer health system" that was published by the Institute of Medicine [8]. It was claimed that in hospitals annually 44,000–98,000 patients died as a result of medical errors, which is more than the mortality caused by traffic accidents, breast cancer or AIDS. It appears from the different foreign studies that the percentage of adverse events varies from 2.9% of the hospital admissions in the North American states Utah and Colorado to 16.6% of the hospitalisations in Australia [6–15]. Over a quarter (in France) to half (in Australia), to be exact respectively 27.7% and 51.2%, of these events was considered to be avoidable [1,4,5,13,15,16,18,21]. In those studies that had looked at gender the number of adverse events in men and women were approximately the same; these events occurred more often in elderly patients [1,3,4,21,18].

3.2. Nature of the incidents

In the studies in which the investigators had looked at the nature of the adverse events, it was always so that most of them had been related to surgical interventions and these events included, among other things, technical complications, haemorrhage and wound infections. With respect to non-operative interventions events occurred preponderantly during prescribing, delivering and administering of medications; included were, among others, the occurrence of previously known or unknown allergic reactions, the administration of the wrong drug or of the wrong dose [1,5,9,16,21].

3.3. Location of the incidents

In a number of studies also the location where the adverse events took place was looked at. Approximately 80% took place in the hospital. About 40% of these in-hospital events occurred in the operation room and approximately a quarter in the room of the patient. Of the adverse events outside the hospital the majority took place in the practice of a doctor: i.e. 6.4–8.7% of the adverse events [9,4,16,21].

3.4. Nature of injury

In more than one-third to two-thirds of the (patients with) adverse events there was only minimal injury or the patient recovered within 1 month (34.2–66.4%). Of the events 5.2–20.2% resulted in permanent injury, and 2.3–7.9% in invalidation of more than 50%. In 4.5% to 15.9% of the cases the patient died [1,3,4,15,16,18,21]. Patients who suffered from adverse events were on average 6.0–9.3 days longer in the hospital then patients who had not experienced such an event [1,4,21,15,18].

3.5. Costs of avoidable adverse events

The costs of increased hospital stay attributable to avoidable adverse events were approximated in the UK at £ 1000 millions per year [14]. The total costs of avoidable adverse events in the United States were estimated at $ 17,000–29,000 millions per year, including loss of income, production loss as a result of the absence of staff, incapacity for work and the direct health care costs. The direct costs of health care were more than half of the total costs [8].

4. Limitations of the comparison with foreign studies

The findings of the foreign studies were based on retrospective case record review of a sample of patients admitted in hospitals in a certain period. The selected files were assessed in 2 phases for the presence of indications (triggers) for adverse events with a screening list that was prepared in advance. The first appraisal was generally done by a nurse or a medical coder, the second by a doctor, in most cases a medical specialist. The doctor only assessed those files which were given a positive score by the nurse for one or more triggers. Limitations for the comparison of the foreign studies are that there are small differences in the methods that were used. Not always the same definitions were used, the percentage of adverse events was not always determined in the same way and the same type of evaluator was not always used. If for example the Australian data are analysed with the method of Utah and Colorado, then the percentage of adverse events of 16.6% is reduced to 10.6%. On the other hand, the percentage adverse events seen in Utah and Colorado of 2.9% increases to 5.4% if the study had been done in the Australian way [17]. Another limitation is that only case records were used to get insight in the occurrence of adverse events and that therefore the percentage of adverse events is determined by the quality of these records [2]. Finally, also the inter-assessor reliability has to be mentioned as a problem. One internist can have another opinion about a case history than another internist, and again, an internist might evaluate differently compared to a surgeon. Thus important points of interest for improvement are: make clear agreements, for example over what we will consider to be an adverse incident and what not, provide adequate training for the observers, use only very experienced assessors with well recognised expertise, have case histories evaluated by assessors of a matching discipline, employ more than one assessor per case record and come to an agreement on an adequate procedure to reach consensus.

5. Extrapolation of the foreign findings to the Dutch situation

If the findings of foreign studies are translated to the Netherlands, then the avoidable mortality in the Netherlands will be 1500–6000 patients per year. However, to what extent adverse events can be prevented in the intramural health care in the Netherlands and what the nature and scope of the injury for patients are, as well as the costs, were never systematically investigated. The same is true for the ambulatory and extramural care. The number of calamities reported to the Dutch Health Care Inspectorate (IGZ) is very low in comparison with what can possibly be expected on the basis of foreign studies [7]. The existing registers of incidents and complications in hospitals which exist at the moment are based on voluntary reports and depend on the willingness to report of the professionals involved. Because it may be assumed that in many hospital departments incidents and complications are recognised with difficulty or not at all, that they are incorrectly interpreted or that there is not a culture which creates the possibility for safe notification, there is no doubt that the real number of incidents and complications is higher than the number that is registered. Which incidents are reported in the current reporting systems and which incidents mostly not, is unknown. Also more insight in the causes of adverse events and in the possibilities for their prevention is necessary to limit the harm for patients. To get insight in the Dutch situation, a research programme concerning patient safety has been started in 2005.

6. Research program on patient security in Dutch hospitals

The current research program on patient safety is made up of several projects which are partly implemented after each other over a period of 4 years and partly parallel. A pilot study was carried out in 2004 [20]. The first project includes: (a) a retrospective epidemiological study in 22 hospitals of the nature, the seriousness, the scope and the costs of adverse events during hospitalisation and the attributable harm for patients, consisting of case record reviews similar to the studies abroad, (b) a prospective epidemiological study consisting of

case record reviews and interviews with patients during ambulatory care in these hospitals, and (c) in the same hospitals an inventory study of the degree in which adverse events, found with the case record reviews, can also be retrieved in the current reporting- and complaint recording systems. The second project concerns a prospective epidemiological study of the causes of adverse events and near-accidents and the possibilities for prevention in a number of surgical departments and operation rooms, emergency care units and departments of internal medicine. In these departments it is investigated to what extent factors of an organisatorial, human, technical and patient-related nature play a role for the occurrence of adverse events and near-accidents. In the study of near-accidents extra attention will be given to the human correction factors such as extra controls which could prevent incident induced injury. The research program is supervised by a by a broad-based commission of experts from various disciplines. It is the intention to publish the results in the Dutch and international professional literature.

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FIGURES

Fig. 1. Structure and process model for patient security [2].