BMJ

BMJ 2012;344:e832 doi: 10.1136/bmj.e832 (Published 13 March 2012)

RESEARCH

Patient safety in developing countries: retrospective estimation of scale and nature of harm to patients in hospital


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Abstract

Objective To assess the frequency and nature of adverse events to patients in selected hospitals in developing or transitional economies.

Design Retrospective medical record review of hospital admissions during 2005 in eight countries.

Setting Ministries of Health of Egypt, Jordan, Kenya, Morocco, Tunisia, Sudan, South Africa and Yemen; the World Health Organisation (WHO) Eastern Mediterranean and African Regions (EMRO and AFRO), and WHO Patient Safety.

Participants Convenience sample of 26 hospitals from which 15 548 patient records were randomly sampled.

Main outcome measures Two stage screening. Initial screening based on 18 explicit criteria. Records that screened positive were then reviewed by a senior physician for determination of adverse event, its preventability, and the resulting disability.

Results Of the 15 548 records reviewed, 8.2% showed at least one adverse event, with a range of 2.5% to 18.4% per country. Of these events, 83% were judged to be preventable, while about 30% were associated with death of the patient. About 34% adverse events were from therapeutic errors in relatively non-complex clinical situations. Inadequate training and supervision of clinical staff or the failure to follow policies or protocols contributed to most events.

Conclusions Unsafe patient care represents a serious and considerable danger to patients in the hospitals that were studied, and hence should be a high priority public health problem. Many other developing and transitional economies will probably share similar rates of harm and similar contributory factors. The convenience sampling of hospitals might limit the interpretation of results, but the identified adverse event rates show an estimate that should stimulate and facilitate the urgent institution of appropriate remedial action and also to trigger more research. Prevention of these adverse events will be complex and involves improving basic clinical processes and does not simply depend on the provision of more resources.

Introduction

Preventable harm to patients resulting from their healthcare is unacceptable at any time. Patient safety is first and foremost a clinical problem, but it is also an important cause of wasted resources. Keeping patients safe can also be viewed as a public health problem and a human rights issue.[1] Documentation of the scale of iatrogenic harm to patients has been accelerating

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Extra material supplied by the author (see http://www.bmj.com/content/344/bmj.e832?tab=related#webextra)

Appendix 1: Nurse review form (RF1)
Appendix 2: Medical review form (RF2)

since 1991, with one of the first hospital population studies by Brennan et al in New York state.[2] Studies progressed to national estimates,[3-5] and the focus moved from negligence to preventability. Results suggested that rates of adverse events in patients in hospital in the developed world were much higher than previously thought, with multiple studies showing rates of at least 8%.[6] Of these adverse events, more than 50% were judged to be preventable, and a worrying number of the patients experienced permanent disability or death as a result of the events. These reports suggest that the deaths of between 0.5% and 2% of patients in hospital are associated with an adverse event, which was often, but not always, preventable. These studies would rank harm from healthcare high on the list of all causes of death for the countries being studied. All published studies to date, however, have been from developed countries, with no reports from developing or transitional economies. This knowledge gap is a serious limitation to understanding the extent of the problem at the global level and, more importantly, in specific countries. The importance of this gap must not be underestimated. Health systems in developing and transitional countries face severe health threats and challenges in a context of scarce resources and weak infrastructure. Understanding whether, how much, why, and how patients are harmed through their respective healthcare systems is essential to inform the global health policy agenda in these countries and to adopt the most effective and efficient corrective actions.

The first global approach to dealing with patient safety came with the passing of resolution WHAA55.18 by the World Health Assembly in 2002 urging the World Health Organization and its member states to pay the closest possible attention to the problem of patient safety, with five specific topics for action. One of these was the encouragement of research into the size and nature of the problem of harm to patients. The WHO World Alliance for Patient Safety[7] (WHO Patient Safety) in conjunction with the Ministries of Health of Egypt, Jordan, Kenya, Morocco, Tunisia, South Africa, Sudan, and Yemen and the WHO Eastern Mediterranean and African Regions (EMRO and AFRO) took up the challenge of estimating the extent of harm that was caused by healthcare in a selection of hospitals in these countries. The research project started in 2006 with two objectives. The primary goal was to assess the frequency, cause, and preventability of adverse events in patients in hospital in the participating countries, all of which are either low income countries or countries in economic transition. Secondly, the study aimed to examine the feasibility of using the established methods of review of records in resource poor healthcare systems in which medical records might be less comprehensive. Notwithstanding the documented limitations of record review, it was chosen because it was the most commonly published method of measurement of rates of harm at a population level and also there was little alternative.

Methods

Design

This was a retrospective review of randomly selected medical records of patients in hospital in a convenience sample of 26 hospitals from eight developing and transitional countries.

Setting and population

The study was performed in hospitals from Egypt, Jordan, Kenya, Morocco, South Africa, Sudan, Tunisia, and Yemen. These countries have a cumulative population of nearly 265 million, about a third of whom live below the poverty line.[8] There is an average health expenditure of $133 (£84, €101) per head. The population sample was medical, surgical, paediatric, and obstetric inpatients in acute care public or private hospitals.

Selection of hospital and sampling of records

The individual national teams invited hospitals to participate in the study. Because of the logistical and other challenges of conducting multicentre research in developing countries, we resolved a priori to use a convenience, though non-representative, sample of hospitals. This resulted in over-representation of large teaching and urban hospitals in each national sample. In total 26 hospitals were selected from the eight countries (two to six hospitals per country): 13 teaching hospitals, 23 general public hospitals (includes the 13 teaching hospitals), one obstetric hospital (>15 000 admissions), one paediatric hospital (10 000 admissions), and one private hospital. The selected hospitals had 13 722 beds and admitted about 560 000 patients in 2005.

At each selected hospital, a list of all admissions for 2005 was generated. From this list a random sample of over 600 patient records was obtained, as we estimated that up to 500 completed records were required. At least 450 records per site were useable for the study and sometimes many in excess of that figure. The excess was allowed to cater for records that could not be tracked or were too incomplete to be evaluated. Same day admissions were not eligible for inclusion.

Definitions

An adverse event was defined as an unintended injury that resulted in temporary or permanent disability or death (including increased length of stay or readmission) and that was associated with healthcare management rather than the underlying disease process. If more than one adverse event was identified within the index admission, only the most serious one was described and counted. Thus the total number of admissions associated with an adverse event is being estimated. An index admission is associated with an adverse event, regardless of whether it occurred before and contributing to or during the index admission.[2 3]

Preventability implied that the adverse event could have been averted with different management or treatment. Generally, for an adverse event to be judged as preventable, the reviewer needed to establish that there was a process failure because of non-compliance with accepted practices. This failure could include system and clinical processes. The appropriate standard for the reviewer to apply in this context was the current expected level of performance for the average practitioner who treats this type of problem in the country in question. Reviewers used a judgment scale (see below).

Organisation of data collection

Country research teams were multidisciplinary and comprised epidemiologists, medical record specialists, healthcare professionals, and, in most cases, representatives from the Ministry of Health, who provided the necessary links with the health policy environment. Teams were responsible for selection and training of local reviewers, data collection, and web based data entry. They received technical support from the principal investigators and logistic support from the WHO regional office.

Review staff were selected in each country on the basis of relevant clinical experience, interest and availability to participate, fluency in English, and familiarity with the local language. Review teams were largely made up of experienced nurses and senior doctors with internal medicine, surgical, or anaesthetic backgrounds; all underwent training. Training was

performed at "learning sessions" of all teams combined, then continued with international and local research team leaders in the respective countries.

The central project office supported web based data entry. Data were exported from data entry in Excel files and then cleaned and analysed centrally in SAS. In addition to this paper, technical reports have been provided to WHO and the participating countries.

Process of review of medical records

Traditional two stage methods were used. The primary review was an initial screening stage in which nurses, or, in some countries, junior doctors, were trained to review the selected medical records for the presence of one or more of 18 explicit criteria (form RF1). A senior physician then reviewed records that screened positive for one or more of the 18 criteria to determine the presence of an adverse event and its preventability (secondary review, form RF2) (see appendix 1 and 2 on bmj.com for the RF1 and RF2 forms). Because of available resources and on the basis of previous publications,[6] a single physician reviewed the records, rather than duplicate review, which has been used in some large studies.[2 3] A more recent publication supports this approach.[9] The record review tools used in this study were adapted from those used in the Australian study.[3] For use in the French speaking countries one of the authors translated the review tools and instruction guide into French. An injury or complication was judged to be an adverse event if it was associated with death, disability at discharge, or prolonged stay in hospital and received a causation rating of at least 2 on a 1-6 point causation scale (see box 1). This is the same threshold that has been previously used[3] but is different from the causation threshold in the initial publication that used these methods,[2] which used at least 4, rather than 2. The adverse event was preventable if rated higher than 3, on a 1-6 point preventability scale.

Reliability study

Assessment of reliability was built into the initial design of the study with the intention of independent double blind review of a random 10% sample of all records at both the primary and secondary review stages.

Results

The conduct of this study was challenging logistically for many reasons, including distance and communication. These challenges account in large part for the duration of the study, the need for a convenience sample of hospitals within each country, and the absence of reliability testing of the secondary review. Identification of hospitals, records for review, and recruitment of reviewers started in 2006 and training of teams continued until 2008. Data collection occurred mostly during 2007 and analysis was completed in 2008, with reports being provided to WHO and discussed with participating countries.

Of the 18 146 records that were initially selected for review, in 605 (3.3%) there were insufficient data to positively identify the patient, and 1443 (7.9%) records could not be located. It is unclear where there was a systematic reason for the unavailability of these records, but we believe that it is more likely to be a random effect reflecting the management of medical records and, given the large sample size, should not significantly affect the findings on adverse event rate. There was no way to further elucidate this issue. Therefore nearly 89% of all selected records were available for review, of which 3% were duplicates. The review data from the 15 548 remaining records forms the basis for the subsequent results.

Table 1⇓ gives the number of primary and secondary reviews and the proportion of positive findings. A total of 15 548 admissions underwent primary review, and the number in each country varied from nearly 1000 in three countries to more than 3500 in two countries. Overall 21.6% primary reviews were found to be positive for one or more criteria. Three countries had positive primary review rates of about 15%, four with rates of about 20-25%, and one with a rate of 39%.

Perceived adequacy of medical records

Of the selected medical records, 86% were available for review. Table 2⇓ shows the completeness of the medical records. The lack of availability of nursing notes, pathology reports, and procedure notes in some countries must have an effect on both stages of review. In addition, the low rate of positive results to the primary review criteria on readmission (average 7.5%, range 1.3-19.9%) reflects that many hospitals started a new record each time a patient presented and hence earlier clinical information was unavailable to reviewers and possibly to treating clinicians. This low rate compares with published rates up to 23.5% for this criterion.[3 4] Given that the readmission questions were the most common trigger for second stage review in all of the published studies that used these methods, this failure to identify readmissions led to an important reduction in the number of records being considered for determination of adverse events.

Patients' demographics and length of stay

The mean age of patients ranged from 26 to 44 across all countries. The percentage of patients aged under 1 ranged from 2% to 13%, and the percentage of females varied from 47% to 66%, reflecting that some countries selected hospitals with a preponderance of obstetric and paediatric patients. Figure 1⇓ shows that the adverse event rate increased with patients' age.

The median length of stay ranged from 2 to 7 days, and the mean varied from 3.3 to 13.4, reflecting variation in local practice and case mix. The adverse event rate increased with length of hospital stay, starting at 4% increasing to 25% for stays of 30 days (fig 2⇓). Contrary to the study protocol, 2215 cases in which the patients stayed for one day were inadvertently included in the study population and are included in the length of stay figures above. If the adverse event rate is recalculated with these cases excluded it increases to 8.8%.

Reliability

The reliability at screening level compared well with that reported for previous studies, which have reported κ of 0.67-0.70. Data on reliability of the primary review were available from six of the eight countries. In four of these the κ score was very good (0.85-0.88), in one good (0.77), and in one poor (0.33). Reliability testing at the secondary review level for determination of adverse events was not completed.

Frequency and preventability of adverse events

Table 3⇓ shows the adverse event rate by country, which varied from 2.5% to 18.4%, the percentage of adverse events that were judged as preventable, and the percentage of hospital admissions that were associated with an adverse event that resulted in the death of the patient. These adverse events could have occurred

Box 1 Scales for physicians to judge causation and preventability of adverse events

Causation

After due consideration of the clinical details of the patient's management, irrespective of preventability, what level of confidence do you have that the healthcare management caused the injury?

- Virtually no evidence of management causation
- Slight to modest evidence of management causation
- Management causation not likely (less than 50/50, but "close call")
- Management causation more likely (more than 50/50, but "close call")
- Moderate to strong evidence of management causation
- Virtually certain evidence of management causation

Preventability

Rate, on a 6 point scale, your confidence in the evidence for preventability of the adverse event:

- Virtually no evidence of preventability
- Slight to modest evidence of preventability
- Preventability not quite likely (less than 50/50, but "close call")
- Preventability more than likely (more than 50/50, but "close call")
- Strong evidence of preventability
- Virtually certain evidence of preventability

before and caused the admission to hospital or occurred during the admission.

There were 17 general public hospitals with fewer than 20% of admissions being for obstetrics. These hospitals had a higher adverse event rate of 11.6%, rather than 8.2%. This shows the impact of case mix on adverse event rates. Detailed data (such as international classification of diseases (ICD) codes or diagnosis related group (DRG)) were not available from the study hospitals, so more detailed adjustment for case mix was not possible.

When we increased the adverse event causation threshold from at least 2 to at least 4, the number of adverse events fell from 1277 to 949 and the overall adverse event rate from 8.2% to 6.1%.

Up to 83% (range 55-93%) of adverse events were judged to be highly preventable, with the remainder considered non-preventable or as having insufficient data to make a determination. About 30% of adverse events were associated with the death of the patient, which equates to nearly 2% of patients in hospital across the eight countries sustaining an adverse event that was associated with their death.

Disability resulting from adverse events

Table 4 shows the outcomes attributed to the 958 adverse events coded for disability⇓. Of these, 305 (32%) patients recovered fully within 30 days, 154 (16%) recovered fully in six to 12 months, 111 (14%) sustained permanent disability, and 288 (30%) died from causes associated with the adverse event. Each adverse event caused an average of 9.1 additional days in hospital for the records reviewed in this study.

Types of error causing adverse events

Figure 3⇓ shows that the most common type of adverse event was caused by therapeutic error (34.2%, range 4-49%), followed by diagnostic error (19.1%, 12-41%) and operative (18.4%, 7-47%). Therapeutic error indicates that a diagnosis has been made but an appropriate therapeutic response was either not ordered or not delivered. Diagnostic error indicates either failure to make a diagnosis or to do so in a timely manner or the failure to make a correct diagnosis from provided information. Operative adverse events occurred more in the peri-operative period but this also includes those occurring during the actual procedure.

Impact of comorbidity on rate of adverse events

Table 5⇓ shows that patients with chronic illnesses were at a higher risk of adverse events when in hospital. Among patients taking any regular drugs, the adverse event rate goes up to 11.9% compared with 12.4% for patients with diabetes mellitus and 15.3% for those with malaria.

Clinical context for the adverse event

As part of the secondary review, the complexity and urgency of cases with adverse events and also the degree of deviation from the accepted norm for care were assessed in a structured fashion. Adverse events predominantly occurred when there was general consensus on diagnosis and treatment and in relatively non-complex settings. Figure 4⇓ shows that deviation from the accepted clinical norms of management was judged as inappropriate in many cases.

Contributory factors to adverse events

Reviewers were asked to code contributory factors to the adverse event (fig 5⇓). Inadequate training or supervision of clinical staff was the single largest category, followed by absence of or the failure to implement a relevant protocol or policy. Hence failures in clinical process rather than the absence of essential resources accounted for most contributory factors to the adverse events in this study. This table might provide a skewed picture because the nature of review of medical records means it is more likely to provide a focus on individual performance and not easily identify the system based failures that often lie behind the mistakes of individuals.

Discussion

This large scale review of records of patient safety in developing and transitional countries indicates that the scale of preventable disability and death from healthcare in the Middle East and Africa is a serious public health problem with major implications for health policy, planning, and resource allocation. Though we were able to review medical records and detect adverse events, the reported rate of just over 8% probably represents an underestimate of the true rate. This underestimate might be quite large but is more likely to affect less serious events. Retrospective review of medical records was selected as an

already established method and was shown to have limitations, which contribute to this underestimation, but none the less was able to generate the information in this report.

Potential underestimate of adverse event rate

The average adverse event rate of 8.2% across the eight countries, ranging from 2.5% to 18.4%, is similar to that reported in other studies using these methods, in which the rate is about 10%.[4 10] The proportion of preventable adverse events, however, is significantly higher at 83% compared with about 50% found in previous studies. The high preventability rate could imply that some reviewers might have confused causation and preventability and hence excluded less preventable adverse events from being considered in the overall pool. This would lead to an erroneous lowering of adverse event rate. It is important to note that the physician reviewers were from the participating countries and used a definition of preventability based on the standard practice in the country. The high rate of preventability can therefore not be explained by the reviewers expecting local care to meet international standards, if they differ. In addition the percentage of adverse events associated with deaths is also much higher at 30% than the 4-15% reported previously.[3-5] This could be because of under-reporting of adverse events resulting in minimal disability compared with published studies from more developed economies or could reflect that patients in hospital are sicker in these countries. This again might suggest a further underestimate of the adverse event rate compared with published literature.

Contributors to variation in adverse event rates between hospitals

There are several possible reasons for the variability between adverse event rates in the participating countries. In addition to possible variation in the quality of healthcare actually provided to patients, there are also methodological reasons that might account for some of the reported variation. The variable completeness of the medical record, and hence the ability of reviewers to detect clinical events, must have an effect that would lead to under-reporting in less adequate records. Particularly noteworthy is the low rate of positive screening at the primary review, which would preclude the record from further review. The rate in this study of nearly 22% is lower than in the studies from the United States (26%),[2] Australia (44%),[3] Canada (41%),[4] and England (40%).[11] The criteria indicating readmission were the most frequent triggers for further review in these four published studies but were not found in most of the records in this report. This could mean that readmissions had not occurred and might not be as useful a trigger in developing countries or that readmissions did occur but were not detectable from the medical record for reasons mentioned earlier. Given that the reliability scores for the first screen were good, it is unlikely that this difference is totally accounted for by reviewer performance. The limitations inherent to the methods of retrospective record review are well understood and reported elsewhere.[12 13] Additionally in this study, the language in the medical record varied and within some countries a single medical record could have documentation in three different languages, not all readily understood by some reviewers or all care givers.

The performance of the reviewers can also lead to variation in reported adverse event rates. Selection and training of reviewers was standardised within budget and logistic constraints. The country leaders were trained by the international faculty who also oversaw some of the data collection in most countries. The country leaders would then train reviewers in the individual countries with standardised manuals and data collection tools. The time for training was about four days for the country leaders and in most countries at least two days for the reviewers, who then had further supervision from the country leaders during the record review period.

Data entry was standardised for local data entry teams in their countries, uploading data with a specifically designed web based program. This resulted in unification of the presentation and analysis of data, but there were problems with the interface. Failure of internet connections led to problems with missing data and duplication of records. Although this had a major impact on data entry and cleaning, it affected a maximum of 3% of the selected records and hence could contribute only a small amount to the adverse event variation or under-reporting.

The case mix and age differences could account for some of the variation seen in the adverse event rates. This study bears out previous reports that the rate of adverse events increases with age and also that it is relatively lower in obstetric and paediatric populations than in other diagnostic categories. Hence, with 11 of the 26 hospitals having 20-90% of their admissions being for obstetric care, the adverse event rate would be expected to be lower for this population and contribute to variation between hospitals and countries. Many of the previously published studies on adverse events excluded obstetric and psychiatry patients.

The potential difficulty of engaging a larger number of hospitals in each country, both politically and logistically, and also the considerable cost increase that would be required to study a representative sample from each country, precluded systematic selection of hospitals that would have provided a nationally representative sample for each country. The country research teams have informally commented that the hospitals chosen in each of their countries included hospitals that would be considered anecdotally as providing some of the best care in that country. Hence this report provides data on the hospitals studied but does not give an adverse event rate for each country because of the method of hospital sampling. Nevertheless, our objective was not to produce nationally representative figures but to produce valid data from a selection of hospitals that would be indicative of the extent of the problem in these hospitals as well as being useful for raising awareness at the national and international level. The fact that many of the selected hospitals were considered as among the best providers in their respective countries would give a powerful message regarding the importance of patient safety.

In summary, the data obtained in this study from 26 hospitals admitting more than 500 000 patients a year across eight developing and transitional countries give the best view to date of adverse events by using previously tested methods. It does not allow the comparison of adverse event rates between the countries in the study.

Limitations on generalising the results

Despite these limitations, these data raise several important points. Firstly, the problem of patient safety is not confined to the developed economies of the world. These data, although almost certainly an underestimate, show that patient safety is a much bigger problem in these developing and transitional countries, when judged by the number of preventable deaths from adverse events, compared with reports from developed economies. Extrapolating these figures to the activity of the study hospitals yields a calculation that suggests that nearly 2% of their annual about 550 000 admissions, or more than 10 000 patients, would die from adverse events in those 26 hospitals

each year. This amounts to more than one death a day in each of these hospitals, with most of these deaths being potentially preventable. When compared with the cause of death data for Egypt, these data would rank "unsafe healthcare" as the fifth most common cause of death after cardiovascular disease, digestive disease, infectious and parasitic disease, and cancer.

Understanding the nature and causes of harm to patients is vital to developing strategies for improvement. The classification of adverse events in the review form is similar to that of previous studies. Interestingly the proportion of "therapeutic errors," where a diagnosis has been made but an appropriate therapeutic response is not ordered or delivered, is much higher, at 34% compared with around 7% in western studies.[3] Conversely drug errors usually account for 15% of adverse events but in this study account for only 4%. In addition to the likelihood that fewer drugs were being routinely used, attention to basic clinical processes is needed to ensure that fundamental diagnostic and therapeutic steps are taken in the care of patients. Further useful information might be contained in the narrative section of the reviews and is the subject of further study. Box 2 provides a series of vignettes to assist understanding of the cases coded as adverse events.

In addition to the coding of contributory factors to the adverse events, reviewers were asked to make comments on strategies for prevention of the adverse event occurring again (fig 6⇓). For some it was not possible to identify contributory factors or methods of prevention from the medical record, but important observations were made. Clear priority is given to improving the training and supervision of clinicians, improving the availability and implementation of standardised best practice protocols, and improving record keeping. The reviewers gave a relatively low priority to lack of clinical staffing or the availability of necessary equipment or supplies. This is not to contradict the healthcare workforce studies[14] but to underscore that we need improved clinical processes and supervision for them to be effective in efforts at patient safety. Given that the medical record is the source, it is not surprising that factors focused on individual rather than system failures predominate in this analysis. This does not take away from what is presented but should drive the need for further study of the context and systems in which the care is being provided.

Conclusions

This study provides evidence on the extent and nature of patient harm in 26 hospitals in eight developing or transitional economies in the Middle East and Africa. Our results, despite the study's necessary limitations, place patient safety as one of the major concerns for the health policy agenda in these countries. The rates of preventable harm and death are higher than previously reported in other studies, raising important concerns for policy makers and practitioners. Further confirmatory studies are required, as well as renewed efforts to identify the underlying causes and to find solutions to patient harm that could be feasible and able to be implemented in highly resource constrained health systems. Importantly, this will not be solved only by providing more staff and equipment, even if that were immediately possible. Basic clinical processes of diagnosis and treatment need broad attention, aided by the provision of clinical policies and protocols standardised on best practice and supervised in their implementation

Our study also shows that retrospective review of records can be used in transitional and developing countries to gain important information on occurrence of adverse events and that the extent of preventable mortality from healthcare in patients in these countries is higher than any published reports from developed countries.

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We thank all the country teams that participated in the study and Nittita-Prasopa Plaizier from WHO Patient Safety and Hoda El Sabbahy from EMRO for technical and administrative support. We also thank Jean Bosco Ndihokubwayo and WHO colleagues for support and encouragement; Martin Fletcher, G Ross Baker, and David Bates for their advice; and Liam Donaldson for his vision.

Contributors: RW, PM, SO, and CV designed and oversaw the conduct of the study, trained the country leads, and drafted the manuscript. RG advised on design and oversaw data collection and performed data analysis. OR, SQ, WM, AS, SW, MA, ML, and NA lead the conduct of the project in each of their countries and reviewed and contributed to the final version of the manuscript. AA was the executive sponsor for the project at the EMRO of WHO and instrumental in establishing the necessary collaborations to conduct the study. IL was the WHO executive sponsor in Geneva, provided advice on the conduct of the study and on the final manuscript. RW is guarantor.

Funding: This study was sponsored and funded by WHO. The Northern Centre for Healthcare Improvement of NSW Health was contracted by WHO to conduct the study. RW was the director of the centre, and RG was subcontracted for advice on statistical methods and analysis. Most other authors received support for travel related expenses for the study. The authors employed by WHO received salaries from WHO and travel expenses related to the study.

Competing interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Ethical approval: The study went through appropriate ethics review managed by WHO ethics review committee for the Eastern Mediterranean region. Where participating hospitals also have a specific ethics review committee, the study received the local specific approval.

Data sharing: French translations of the review forms (RF1 and RF2) are available on request from the corresponding author.

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Box 2 Anonymised vignettes of adverse events

- A 20 year old woman who was four months pregnant and had had recent outpatient treatment for malaria was admitted to hospital with symptomatic anaemia and palpable splenomegaly. There was a delay in reporting of her low haemoglobin concentration and her condition deteriorated, requiring urgent transfusion. This was performed without blood grouping or cross matching. The patient died soon after from transfusion reaction
- A 2 year old was seen in the emergency department for fever associated with convulsion. Child was sent home without specific diagnosis or treatment and died at home from further convulsions with progressive fever
- A 34 year old patient developed tetanus after a previous admission to a local hospital with traumatic frontal head injury, without assessment of tetanus status or immunisation. The patient died from tetanus and its complications
- One day after a normal vaginal delivery the baby was noted to have head swelling and oozing. Computed tomography showed a skull fracture with haematoma. After clinical deterioration and transfer to intensive care unit, the baby died from the head injury
- A 50 year old woman with diabetes was readmitted two days after discharge after laparoscopic cholecystectomy. Biliary peritonitis was diagnosed and she was transferred to intensive care. She died some days later
- An 18 year old man was admitted with fever and irritability; malaria and typhoid fever were diagnosed. He became more sleepy and irritable, leading to transfer to psychiatric hospital, where he subsequently died without adequate treatment for malaria and typhoid
- A 15 year old girl was discharged from emergency department after presenting after a fall from second floor of a building, complaining of back pain and absent lower limb movement. Paraplegia was subsequently diagnosed
- A 30 year old woman was admitted twice for drainage of liquor during pregnancy. On previous admission, she complained of labour-like pain. On the index admission, a breech presentation noted and caesarean section was performed. At surgery the uterus was noted to be ruptured, presumably from liquor drainage, and subsequently repaired
- A 35 year old woman complained of amenorrhea for seven months. Diabetes with pregnancy was diagnosed. She was given insulin to control her blood glucose concentration. She refused to stay in hospital and discharged herself
- An 85 year old man was admitted through the emergency department with difficulty with micturition. The diagnosis was benign prostatic hypertrophy. He underwent surgery, from which he died 24 hours later
- An 18 year old girl was admitted through the emergency department with complaint of headache, fever, and convulsion. She received drug treatment and was referred to the psychiatric department
- A patient was readmitted a week after laparotomy for intussusception and bowel obstruction. On representation the wound had broken down and stool was discharging from it. At a second laparotomy, three perforations of the ileum with resulting fistulas were found. Ileal resection and re-anastomosis was done. After few days patient was discharged without any documentation
- An obese 30 year old women (gravida 7, para 3) with uncertain dates was delivered by emergency caesarean section under general anaesthesia because of large baby, a girl who weighed 4400 g. The woman arrested and died in the operating theatre
- A 23 year old pregnant woman, uncertain about dates, delivered vaginally. She developed postpartum haemorrhage but without close observation or treatment. Later laparotomy and hysterectomy were performed but she died during surgery
- A 23 year old woman presented to the emergency room with severe headache and vomiting and was treated and discharged. She returned a few hours later with deterioration of level of consciousness and was found to have a brain haemorrhage. Deterioration continued and she died a few days later
- A 60 year old man with history of ischaemic heart disease with atrial fibrillation was admitted with acute pulmonary oedema. He arrested after bolus intravenous injection of morphine 10 mg and hydrocortisone 200 mg, and died the same day

What is already known on this topic

With regard to healthcare of patients in hospital, several studies from developed economies show that about 10% of patients experience harm (an adverse event) and at least half of these are preventable

While most patients recover from these events, a small percentage experience permanent disability or die; the older the patient and the longer the stay in hospital, the higher the rate of adverse events

What this study adds

Patients admitted to hospital in developing or transitional economies experience important harms associated with healthcare

Despite methodological limitations of this study, the risk of mortality from adverse events in these patients is even higher than previously reported

Prevention strategies must go further than the provision of more resources if they are to succeed

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Accepted: 25 November 2011

Cite this as: *BMJ* 2012;344:e832

Tables

Table 1| Number of records that underwent primary (RF1) and secondary (RF2) review, number positive for potential adverse event, and number of adverse events in eight developing countries

	Primary screen (RF1)*		Secondary screen (RF2)†		
Country	No in sample	No (%) positive	No in sample	No (%) of adverse events	Adverse event rate/admission
A	1358	342 (25)	342	81 (24)	6.0
B	3769	550 (15)	546	93 (17)	2.5
C	1938	422 (22)	422	281 (67)	14.5
D	984	383 (39)	383	146 (38)	14.8
E	931	149 (16)	149	76 (51)	8.2
F	3977	946 (24)	946	218 (23)	5.5
G	930	136 (15)	136	77 (57)	8.3
H	1661	423 (26)	418	305 (73)	18.4
Total	15 548	3351 (22)	3345	1277 (38)	8.2

*Initial screening stage by nurse or junior doctor for presence of one or more of 18 specific criteria indicating potential adverse event.

†Review by senior physician of positive records from primary review to determine presence of adverse event and preventability.

Table 2| Proportion of records that had evidence for variables shown from total number assessed for quality of medical record in eight developing countries

Country	No of records available*	Proportion (%) with evidence for elements shown†					
		Initial medical assessment	Medical progress notes	Nursing progress notes	Procedure documentation	Pathology reports	Discharge summary
A	1358	96	89	66	90	24	66
B	3769	96	90	98	90	45	97
C	1938	100	100	47	99	52	86
D	984	91	90	82	92	52	37
E	931	98	97	95	93	75	64
F	3977	99	95	46	69	86	20
G	930	100	100	47	99	52	86
H	1661	93	80	43	80	22	85
Total	15 548	97	92	72	85	68	67

*Indicates number of completed first review forms (RF1).

†Does not indicate completeness or accuracy of those elements.

Table 3| Frequency of adverse events, percentage of preventable adverse events, and percentage of admissions associated with adverse events that resulted in death* in eight developing countries

Country	No of hospitals	No of records reviewed	Adverse event rate/100 admissions*	% preventability†	% admissions resulting in death
A	3	1358	6.0 (4.7 to 7.3)	72.5 (62.8 to 82.2)	1.25
B	5	3769	2.5 (2.0 to 2.9)	83.3 (75.7 to 90.9)	0.61
C	2	1938	14.5 (12.9 to 16.1)	76.6 (71.6 to 81.6)	3.2
D	2	984	14.8 (12.6 to 17.0)	85.6 (79.9 to 91.3)	3.58
E	2	931	8.2 (6.4 to 10.0)	55.1 (43.9 to 66.3)	0.75
F	6	3977	5.5 (4.8 to 6.2)	84.0 (79.1 to 88.9)	1.62
G	2	930	8.3 (6.5 to 10.1)	85.7 (77.9 to 93.5)	1.29
H	4	1661	18.4 (16.5 to 20.3)	92.8 (89.9 to 95.7)	4.28
Total	26	15 548	8.2	83.0	1.85

*Score ≥2 on 6 point scale (see text), as well as injury and disability, required for determination of adverse event.
†Score ≥4 on 6 point scale (see text) required for adverse event to be considered as preventable.

Table 4| **Frequencies (percentage) for disability from adverse events associated with healthcare in eight developing countries**

Disability/outcome	A	B	C	D	E	F	G	H	Total
Minimal impairment	5 (10)	35 (41)	34 (32)	43 (301)	27 (41)	57 (32)	39 (53)	65 (25)	305 (32)
Moderate impairment:									
1-6 months	8 (16)	12 (14)	6 (6)	14 (10)	13 (20)	28 (16)	14 (19)	24 (9)	119 (12)
6-12 months	1 (2)	5 (6)	0	13 (9)	3 (5)	3 (2)	1 (1)	9 (4)	35 (4)
Permanent disability:									
<50%*	4 (8)	2 (2)	1 (1)	18 (13)	8 (12)	3 (2)	6 (8)	12 (5)	54 (6)
>50%*	4 (8)	1 (1)	1 (1)	14 (10)	1 (2)	6 (3)	0	30 (12)	57 (6)
Permanent nursing	1 (2)	0	0	1 (1)	0	12 (7)	0	5 (2)	19 (2)
Institutional care	0	0	0	0	0	1 (1)	0	4 (2)	5 (1)
Death	17 (34)	23 (27)	61 (58)	35 (25)	7 (11)	62 (35)	12 (16)	71 (28)	288 (30)
Unknown	10 (20)	7 (8)	2 (2)	3 (2)	7 (11)	7 (4)	2 (2)	38 (15)	76 (8)
Total	50	85	105	141	66	179	74	258	958

*=50% was not an option for reviewer.

Table 5| **Comorbidity and rate of adverse events in review of medical records in eight developing countries**

Comorbidity	% of study population	Adverse event %
Receiving regular drug treatment	14.8	11.9
Hypertension	7.2	11.8
Diabetes mellitus	5.6	12.4
Malaria	2.3	15.3

Figures

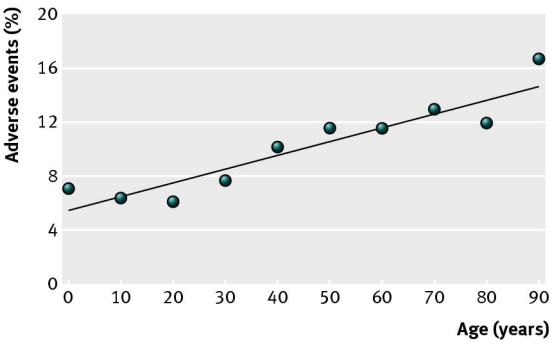

Fig 1 Rates of adverse events with age in patients in hospital in developing countries

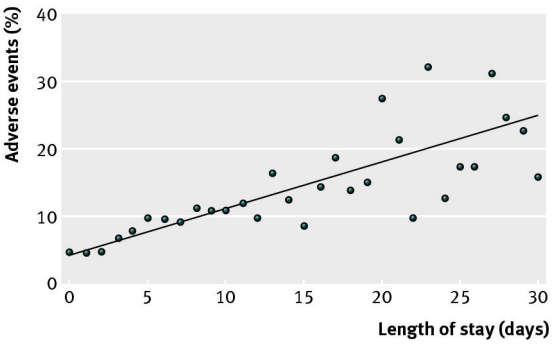

Fig 2 Rate of adverse events by length of stay, indicated as average for index admission in sampled records, per hospital. Rates increases with length of stay, starting at 4% and increasing to 25% for stays of 30 days. Length of stay is shown as average for index admission in sample record per hospital

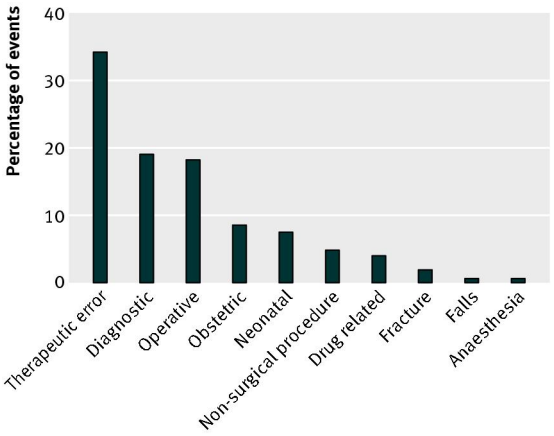

Fig 3 Type of error related to occurrence of adverse event shown as percentage of 890 adverse events with codes for this classification (multiple coding possible)

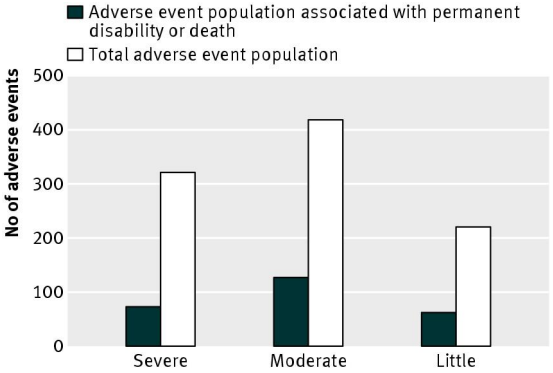

Fig 4 Degree of deviation of management from accepted norm in patients who experienced adverse event in hospital

Fig 5 Factors contributing to the adverse events. Coding was not possible for all adverse events and multiple codes could be used for same event

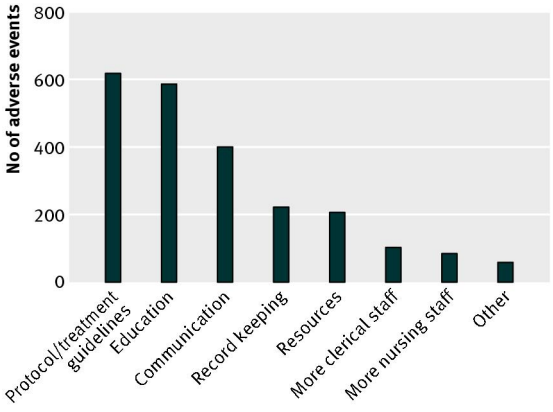

Fig 6 Strategies for preventing recurrence of 1277 adverse events from eight countries in adverse event study. Coding was not possible for all adverse events and multiple codes could be used for same event