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Reducing Medical Errors and Decreasing Risk

Clinical risk management in mental health: a qualitative study of main risks and related organizational management practices

Abstract

Background: A scientific understanding of clinical risk management (CRM) in mental health care is essential for building safer health systems and for improving patient safety. While evidence on patient safety and CRM in physical health care has increased, there is limited research on these issues in mental health care. This qualitative study provides an overview of the most important clinical risks in mental health and related organizational management practices.

Methods: We conducted in-depth expert interviews with professionals responsible for CRM in psychiatric hospitals. Interviews were transcribed and analyzed applying qualitative content analysis to thematically sort the identified risks.

Results: The main concerns for CRM in mental health are a) violence and self-destructive behavior (i.e. protecting patients and staff from other patients, and patients from themselves), b) treatment errors, especially in the process of therapy, and c) risks associated with mental illnesses (e.g. psychosis or depression). This study identified critical differences to CRM in hospitals for physical disorder and challenges specific to CRM in mental health. Firstly, many psychiatric patients do not believe that they are ill and are therefore in hospital against their will. Secondly, staff safety is a much more prominent theme for CRM in mental health care as it is directly related to the specifics of mental illnesses.

Conclusions: The current study contributes to the understanding of patient safety and raises awareness for CRM in mental health. The mental health specific overview of central risks and related organizational management practices offers a valuable basis for CRM development in mental health and an addition to CRM in general.

Keywords: Patient safety, Clinical risk management, Organizational risk management, Mental health care, Psychiatry, Qualitative analysis

Background

Understanding and improving patient safety is a growing concern, particularly following the publication of the Institute of Medicine reports "To err is human" [1], "Crossing the quality chasm" [2] and the NHS's "Organisation with a memory" [3]. These reports highlight that between 3.7-16.6% of patients admitted to hospitals suffer an adverse event, at least half of which are preventable. Such adverse events can result in unnecessary injury or death as well as enormous economic costs. Despite being ostensibly concerned with patient safety and minimizing risks in health care, a systematic approach to patient safety or a systematic organizational management of clinical risks is difficult to implement and therefore, seldom seen [4-6].

Nevertheless, research and knowledge on patient safety, have increased rapidly and improved many aspects in acute medical health care settings [7,8]. However, in mental health care, there is a "lack of awareness of the issues as well as a shortage of research and information on the topic" [9, p. 39]. A comprehensive literature review

highlights an inconsistency in basic patient safety concepts in mental health (e.g. defining and calculating adverse events), as well as a scarcity of high quality patient safety research in mental health [10]. Due to the resulting lack of patient safety principles specific to mental health care, concepts and strategies from acute medical health care settings are frequently adopted. This may be appropriate for some aspects, but mental health care differs from medical patient care in patient population and illnesses, as well as in historical and institutional contexts. There are also unique patient safety issues in mental health care that require further consideration [cf. 10-12], especially with regard to clinical risks. While medication related risks, such as medication mix-up or delivery of wrong dose, are found in acute medical care and mental health [e.g. 13], specific risks, such as suicide, violence and self-harm prevail in mental health [14]. To date, an overview of the spectrum of clinical risks found in mental health and the organizational risk management practices currently applied is lacking. Publications mostly discuss specific risks, such as violence, and do not offer an integrated view e.g. (for suicidal or violent patients, see [15,16]). Also, the traditional focus of the management of clinical risks in mental health care was located at the individual instead of the organizational level and was therefore narrowly "considered the business of predicting and preventing dangerousness" of patients [14, p. 3].

Furthermore, a systematic clinical risk management (CRM) can play a crucial role in enabling health care organizations to assess, manage, and contain risks related to patient safety and aims at reducing or eliminating harm to patients [8,17]. The more complex an organization, the greater the need for CRM. This is especially true for psychiatric hospitals, where the challenges to patient safety are varied and the connection between patient and staff safety is closer than in hospitals for medical complaints [e.g. 18,19].

To gain a systematic and comprehensive understanding of CRM in mental health, this study aims to provide an overview of clinical risks and related management practices in mental health. This is an important step in deepening our knowledge of patient safety and in supporting psychiatric hospitals to optimize their clinical risk management and to ultimately improve the health care system, for the mentally ill [13].

Methods

Sample, setting, and data collection

This study used semi-structured expert interviews to identify clinical risks in mental health care and organizational risk management practices. Expert interviews are a very useful instrument for innovative research taking into account the expert status of the interviewee; they allow for collecting the interviewees subjective experiences and interpretations regarding a predefined specialized topic [20]. The semi-structured form supports comparability between the interviews, yet allows for the inclusion of not anticipated, but important issues [21]. Interviewing persons with patient safety expertise in mental health care, therefore, is a valuable source of in-depth information that is urgently needed to expand research in this field where currently there is little research available [9].

The interviewees were selected following a national study on CRM in Switzerland in 2007/08 [see 4,17]. The sampling technique was purposive: all 11 experts were responsible for the coordination of CRM in their psychiatric hospital and had considerable knowledge and experience in the field of patient safety in mental health care. Eight of these experts had worked for more than five years in their respective institutions; six hospitals were public, five were private. Four hospitals had fewer than 100 beds (all private hospitals), two had 100–200 beds (all public), and five had over 200 beds (four public, one private). Participation was voluntary and did not affect respondents physically or mentally. All responses were de-identified. The research did not include any patients and is in line with the WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects. Such research does not require ethics approval in Switzerland, as mere surveys in the sense of opinion surveys or interviews are not counted as research on humans (see http://www.vpf.ethz.ch/about/commissions/EK).

Interviews were carried out by an experienced researcher (in most cases accompanied by an assistant) between June and September 2008 in the interviewees' offices in the respective psychiatric hospital. In three interviews, additional personnel participated (nursing resp. medical head, responsible person for work safety). Interviews lasted between 80 and 160 minutes and were audio recorded.

The interview manual was developed as part of the project, "Clinical risk management in Swiss hospitals" [17]. It was based upon results from a literature review on CRM and was critically examined by an expert panel consisting of 11 patient safety experts (comprised of the persons in charge of patient safety and/or quality of five main Swiss healthcare institutions, the president of the Swiss Society for Quality Management in Health Care, the head of quality of a major reinsurance company, and four clinical experts with a proven record of accomplishment in patient safety. For details see [17]). The manual included exploratory questions on tasks, content and organization of CRM (e.g. "What is the meaning of CRM and patient safety in a psychiatric hospital?"), and questions on future developments pertaining to CRM (e.g. "What activities are planned in the next 12 months in the area of CRM/patient safety in your psychiatric hospital?"). It also comprised a structured review of the

results of a 2007/2008 survey of CRM that is not part of the current study. The results from the survey are published in Briner, Manser and Kessler [4].

Data analysis

Interviews were transcribed verbatim and in their entirety, which is crucial for an explorative study, as protocols from memory or summaries reduce information in a methodologically uncontrolled way [22]. To achieve uniformity, the same researcher transcribed all the interviews. The transcripts were analyzed applying qualitative content analysis [23]. This method qualifies for semi-structured expert interviews as it is used for coding text with a predefined coding system which can be refined and completed with new themes emerging in the interviews [22,23]. Our initial coding system used categories which were defined following the literature review of CRM. It allows for organizing, sorting and retrieving the coded text passages. This technique for guiding the analysis of qualitative data relying on prior research had proven valuable in previous studies, for example, identifying and categorizing errors in mental health [13].

The coding was performed using the program MAX QDA2010 that was developed particularly for computer-assisted analysis of qualitative data. To begin the qualitative content analysis, two primary coders (MB and an assistant) coded the transcripts. The specific risks and related organizational risk management practices were assigned to the appropriate categories. Meaningful units (whole or part sentences) were defined as units of analysis. Results were compared between coders to deepen the understanding of the categories and to achieve consensus. The primary coders then reviewed all interviews a second time to refine, expand, bridge or eliminate categories for the purpose of fully describing risks and their organizational management. Inter-rater agreement was calculated to measure the extent different coders agreed upon which text passages were assigned to which categories [23]. Therefore, the spontaneously mentioned risks (risks that, at the beginning of each interview, were spontaneously mentioned to the question, "What is the meaning of CRM in a psychiatric hospital?", were assigned to the respective categories by the three coders (MB and two assistants) independently. These spontaneously mentioned risks offer a heuristic [fast and frugal judgment, cf. 24] of frequent or obvious risks in mental health. Overall, an inter-rater agreement of 81% was reached. The remaining disagreements were discussed between the three coders until a consensus was reached. Where there was ambiguity, the coding system was adapted and refined accordingly. The two primary coders coded all interviews a third time using this refined coding system in order to reach a final assignment of text passages to categories. The results were further processed independently from the original text and codes were summarized thematically. The frequencies of risks mentioned across all interviews, as well as the spontaneously mentioned risks, were counted to indicate the relative importance of individual risk categories (see results and Table 1). Similar methods were also used by Brickell and McLean [9] for their qualitative analysis of expert perspectives on patient safety in mental health. As management of specific risks was often mentioned at the same time as the risk, it was coded simultaneously.

Focus group for reflecting interview results

Focus groups offer the possibility to deepen the understanding of results from qualitative studies [cf. 25]. Experts appraise, discuss and reflect upon the findings and thereby add content validity to a study [for the importance of content validity, see 26]. In our case, a focus group took place in August 2011. This comprised four renowned Swiss patient safety experts in mental health care. Each focus group participant was briefed on the study in advance and received a thematically organized tabular overview of the spontaneously mentioned risks found in all interviews (integrated in Table 1, details see above) to prepare for the two-hour focus group session. Three experts were able to participate in the focus group (one was ill and gave written feedback). The three interview coders guided the discussion on the overview of risks in mental health. The discussion was recorded in writing and used to refine the overview of the main risk themes of CRM in mental health (Table 1).

Results

Our results highlight specifics of CRM in mental health care and give an overview of risks in mental health. The most important organizational CRM practices are presented in conjunction with the corresponding risks, since the experts frequently mentioned them at the same time as the risk. Quotes were translated verbatim into English. The index number (e.g. I1, P3) indicates the interview and the paragraph where the quote was taken from.

Specifics of CRM in mental health care

It was highlighted throughout the interviews that CRM in mental health differs from CRM in medical health care in important aspects. A major difference lies in the characteristics of psychiatric patients, whose mental illnesses, such as psychosis or depression, entail specific clinical risks. Repeat admission patients are significant as they are characteristic to some kind of diagnoses. In addition, some patients do not believe that they are ill and therefore refuse treatment, whereas patients with an obvious physical injury, such as a broken leg, would not behave in that way. On the other hand, high-risk

Table 1 Detailed overview of the main risk themes of clinical risk management in mental health care

Risks	Main- / subcategories	Risk description	Number spont.	Number total	Total spont.	Total overall	Mentioned organizational CRM practices (selection)
A	Clinical risks	General statements about clinical risks without the mention of a specific risk	1 of 11	1 of 11	1	2	
A1	Clinical risks specific to mental health care	Clinical risks specific to mental health care, i.e. risks that occur only (or predominantly), or are typical, in mental health care	1 of 11	3 of 11	1	5	• Admission interview generally considered important
A1.1*	*Violence / aggression*	General statements about risk themes regarding violence or aggression (physical/psychological). Specific risks are listed in the sub-categories	8 of 11	*10 of 11*	12	*42*	• Aggression management training • Violence risk assessment (e.g. Brøset -Checklist) • Compulsory measures, sensory deprivation, seclusion • Structural preventive measures • When too dangerous: prison and external supervision
A1.1.1	*Self-destructive behavior*	Self-destructive behavior of a patient (e.g. suicide, suicide attempts, self-injury and self-harm: cutting.)	9 of 11	*11 of 11*	11	*51*	• Good anamnesis, pre-admission interview • Clarify during admission interview and other consultations • Intensive support/monitoring • No-suicide contract • Closing of the ward • Good follow-up care and debriefing
A1.1.2*	*Compulsory measures*	Seclusion, restraint, etc. when mentioned as a risk or as a measure against a risk	4 of 11	*9 of 11*	4	*31*	• Training • Standardized procedures • Inform beforehand • Observation and/or seclusion room • Debriefing
A1.1.3*	Next of kin, risks from the outside	Assault/threats from next of kin or from outside	1 of 11	2 of 11	1	4	
A1.1.4*	Violence with or towards objects	Any form of violence with objects (e.g. weapons, lighters); also violence towards objects (e.g. to destroy furniture)	0	2 of 11	0	5	• No dangerous objects and infrastructure • Nonflammable material in the rooms
A1.1.5*	Physical vs. verbal abuse	General statements specific to verbal abuse (threats) or physical abuse	0	2 of 11	0	3	

Table 1 Detailed overview of the main risk themes of clinical risk management in mental health care *(Continued)*

A1.2	*Treatment errors*	Treatment errors / treatment risks during treatment procedure, psychotherapy	4 of 11	*11 of 11*	6	*33*	• Standard procedures for consultations • Interdisciplinarity • Avoid one-to-one consultations • Anamnesis with pro-active risk assessment • Sufficient staff • An ombudsman service that a patient can turn to
A1.2.1	Assaults by staff on patients during the therapeutic process	Assault by a staff member on a patient, especially during the therapeutic setting, that also include, for example, consensual sexual contacts or abuse of power by the therapist	2 of 11	3 of 11	2	6	• Special training • Inform patients specifically about this issue • Intervision (peer consulting) and supervision see also A1.2
A1.2.2	Diagnostic errors	Establishing a diagnosis of a mental illness instead of an underlying physical illness or the misdiagnosis of psychiatric illness, which could result in incorrect treatment	1 of 11	2 of 11	2	3	• Differential diagnosis • Additional tools to evaluate physical risks.
A1.2.3	Specific medication risks occurring mainly in psychiatry	All risks related to medication that are (mainly) psychiatric specific, especially: 1) side effects of medication. An important reason why patients do not take their medication. Risk of non-compliance. 2) accumulation, hoarding of medication (e.g. for suicide, substance abuse)	1 of 11	4 of 11	1	7	• Clarify patient's needs • Information about effects and side-effects • Information on exercising and nutrition • Monitor medication intake
A1.3	*Risks associated with mental illnesses*	Statements about individual illnesses (e.g. addiction, schizophrenia, acute psychosis, mania, depression, anxiety attacks, personality disorder. . .), that could increase certain risks	4 of 11	*10 of 11*	6	*21*	• Assessment tools • Evaluate contractual capacity • Intensive support
A1.3.1	*Hospitalization against the will of the patient*	Hospitalization against the will of the patient and/or against the will of next-of-kin. Also lack of insight regarding illness	3 of 11	*8 of 11*	3	12	• Non-voluntary hospitalization, compulsory measures • Admit voluntary patients only • Involuntary commitment
A1.3.2	Substance abuse	Drugs, smuggling of substances	1 of 11	4 of 11	1	4	• Search patients • Sign addiction contract
A1.4	*Absconding*	Patient escapes from psychiatric clinic. This can happen for various reasons, e.g. hears imperative voices, suicidal tendency	3 of 11	*6 of 11*	4	9	• Internal transfer of patient • Closing of ward • Search by police
A2	Common clinical risks	Common clinical risks occurring in mental health care, but that are not specific, e.g. medication errors, infections. There are also grey areas such as with falls					

Table 1 Detailed overview of the main risk themes of clinical risk management in mental health care *(Continued)*

A2.1	*Medication risks*	Common medication risks not specific to mental health care, e.g. confusing medication.	5 of 11	*9 of 11*	7	*33*	
A2.2*	*Infections and hygiene*	Infections, disease transmission.	5 of 11	*7 of 11*	5	*26*	• Hygiene, hygiene standards, everything that protects against infection
A2.3	Falls	Falls and their consequences. Likely to be very important with withdrawal symptoms and in geronto-psychiatry	1 of 11	5 of 11	1	12	
A2.4*	*Staff risks*	Lack of staff, high workload. Staff absenteeism due to illness (maybe especially high in mental health care?) Shift change, etc. → a latent condition that can increase risk of errors	1 of 11	*9 of 11*	2	*28*	• Absence management, reintegration, training • Hire sufficient staff • Attractive training programs
A2.5	Technology and equipment	Technical equipment used in the treatment of patients	2 of 11	3 of 11	2	4	• Control procedures and repair of electronic equipment • Correct application and periodic maintenance
A2.6	High rate of internal patient transfers	Patient transfers that represent risks at the interface (change of primary caregiver, organization of transfer, etc.)	0	2 of 11	0	3	
B*	*Other risks (non-clinical)*	Common, non-clinical risks (e.g. financial, structural risks, risks relating to image, etc.) e.g. fire, data protection, that represent only an indirect clinical risk	6 of 11	*11 of 11*	14	*47*	
C*	*Risks for the staff (Staff safety)*	Explicit risks that mainly concern staff members	1 of 11	*11 of 11*	2	*38*	• Preventive measures (e.g. raising awareness, staff training) • Active measures (e.g. de-escalation techniques, compulsory measures) • Follow-up measures (e.g. debriefing, care teams)

Description of the individual columns in Table 1:
• *Risks*: numbering of risk categories and sub categories (A > A1 > A1.1 etc.).
• *Main category / sub category*: names of the risk categories.
• *Risk description*: explanation of the meaning of the mentioned risk.
• *Number of spontaneously mentioned risks*: shows in how many of the 11 interviews the corresponding risk was spontaneously mentioned at the beginning of the interview.
• *Total number*: shows in how many of the 11 interviews the corresponding risk was mentioned during the interview.
• *Total number of spontaneously mentioned risks*: shows how often the corresponding risk was spontaneously mentioned in total at the beginning of all 11 interviews (multiple mentions in the same interview are included).
• *Overall total of mentioned risks*: shows how often the corresponding risk was mentioned in total during all 11 interviews (multiple mentions in the same interview are included).
• *Mentioned CRM practices (selection):* selection of possible measures on how to deal with the corresponding risk mentioned during the interviews.
The most important risks mentioned in more than half of the interviews or more than 20 times in total are *italicized*.
* Marked with an asterisk are those risks that are important to patient as well as to staff safety.

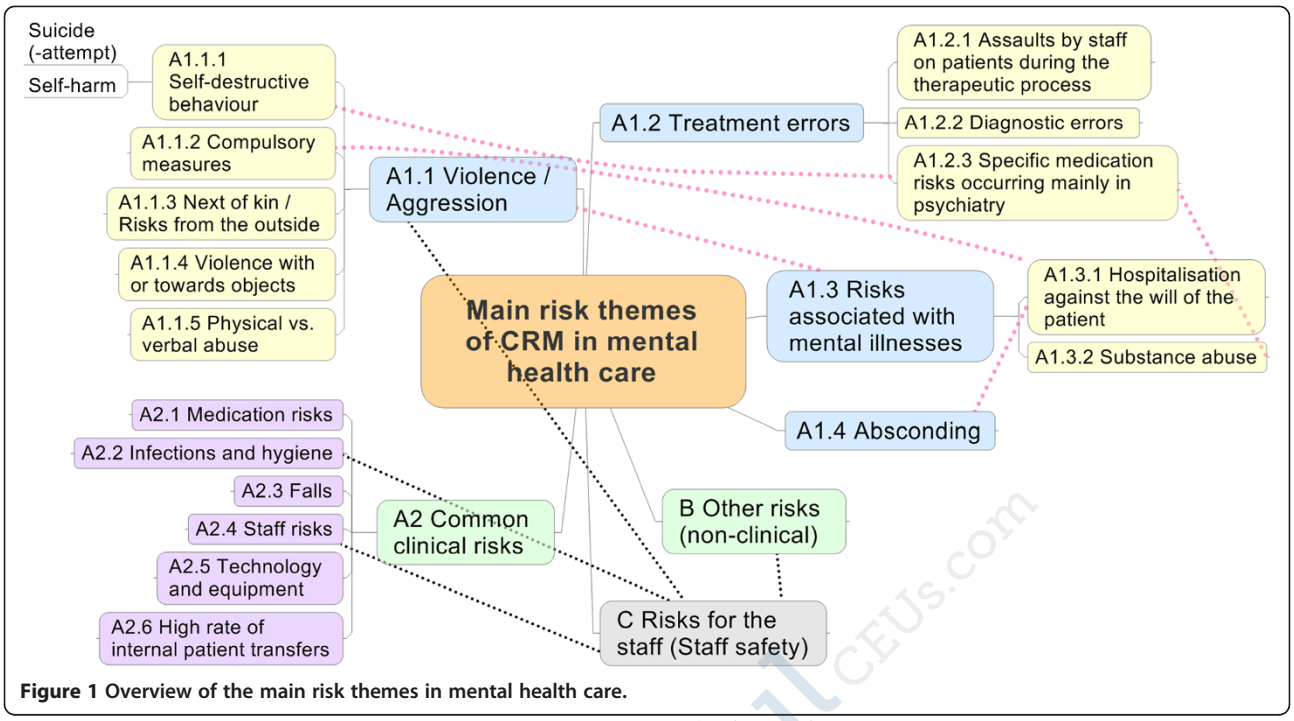

Figure 1 Overview of the main risk themes in mental health care.

treatments such as surgery are not found in psychiatry. Therefore, clinical risks such as iatrogenic infections play a somewhat minor role. Overall, CRM in mental health was judged to be less advanced than in medical health care, but a rising awareness of the topic was noted. CRM was seen to support patient safety, but also to be important for staff and family safety: "Service provider and receiver should not be harmed. [. . .] A patient should always leave the ward healthier than on admission" (I3, P17).

Overview of risks in mental health care

Figure 1 provides an overview of the most important risks in mental health. Blue (main categories) and yellow (sub categories) fields show risks that are specific to mental health. Dotted red lines show relations between different categories and dotted black lines show risks that affect staff safety, as well as patient safety. The full overview of the main risk themes of CRM in mental health care mentioned in the interviews and related organizational management practices is given in Table 1.

The focus of this paper is clinical risks specific to mental health care (see A1.1-A1.4 in Figure 1). These were the clinical risks mentioned most frequently in the interviews (n=237), emphasizing their importance. All interviewees also mentioned clinical risks known from medical care that also appear in mental health care (A2, n=106). Additionally, all interviewees mentioned non-clinical risks that are mostly not specific for mental health care (B, n=47). All interviewees also referred explicitly to staff safety (C, n=38), highlighting the importance of this topic in mental health care.

Results from the focus group

The participants of the focus group for reflecting interview results agreed that a comprehensive and systematic overview of clinical risks in mental health care is lacking, and that a categorization of these risks is complex and challenging. Aggression and self-destructive behavior were approved as main themes in patient safety in mental health (A1.1). An alternate categorization of risks originating in the patient (peril to self or to others) and risks originating from treatment was outlined, but it was judged not to simplify the categorization.

A1) Clinical risks specific to mental health care

Violence and aggression (A1.1), treatment errors (especially errors in the process of therapy, A1.2), and risks associated with mental illnesses (A1.3) were the most important clinical risk themes specific to mental health care. An additional theme was leaving hospital against medical advice or absconding from the hospital (A1.4). A thorough admission interview was generally considered as an important measure for managing these risks. Other more specific measures are listed below in conjunction with the corresponding risks.

A1.1) Violence and aggression

The greatest focus was on violence/aggression (A1.1, n=141). This is in line with Flewett [14], who describes

suicide, violence and self-harm as the most common risks. Violence against others was mentioned 42 times. This means physical (e.g. assault, breach) or verbal/psychological (e.g. threat) violence against fellow patients, staff or other persons (e.g. family members, next of kin). Training and education (aggression management training, fixation technics etc.) were recommended as possible measures against general violence as were violence risk assessments [e.g. prediction instruments such as the Brøset-Violence-Checklist, cf. 27].

Self-destructive behavior (A1.1.1) was mentioned most frequently (n=51), and was also the most frequent spontaneously stated risk. This category comprises suicide, attempted suicide and self-harming (e.g. cutting). All interview partners emphasized the importance of self-destructive behavior: one stated, "I have never seen a patient who could completely exclude suicide" (I5, P20). An assessment of suicidal tendency during admission and in subsequent interviews, no-suicide contracts and good anamnesis as well as architectural protection and intensive support and monitoring of endangered patients, were recommended as possible measures against self-destructive behavior. If something did happen, good follow-up care and debriefing for fellow patients, staff and next of kin is important. Therefore, many psychiatric hospitals developed standard procedures (e.g. procedures after (attempted) suicide).

Compulsory measures (A1.1.2) that are intended to be an activity to calm down violent patients were also seen as a risk (n=31). Compulsory measures are risky as they are usually applied against the will of the patient and sometimes require force to be administered. Training and education, and the use of standardized procedures, were recommended as CRM measures.

Other risks mentioned were violence from the outside (A1.1.3>, e.g. family of patients that threaten other patients or staff), violence with objects (A1.1.4, e.g. weapons) or towards objects (e.g. to destroy furniture etc.) and physical or verbal abuse (A1.1.5, e.g. death threat).

In sum, violence/aggression is linked closely to particular mental illnesses that increase the possibility for violent behavior. This topic is discussed more deeply in the section on risks associated with mental illnesses (see below, A1.3).

A1.2) Treatment errors (especially errors in the process of therapy)

The second focus regarding specific clinical risks in mental health care was on treatment errors, especially errors in the process of therapy (A1.2, n=49). Standard procedures for consultations, interdisciplinarity, sufficient staff, and anamnesis with pro-active risk assessment were generally mentioned as CRM measures. Three sub-categories could be identified. The first was assaults by staff on patients during the therapeutic process (A1.2.1, e.g. sexual contacts or abuse of power by the therapist). Suggested as possible measures were, special training, intervision (peer consulting) and supervision for staff, the recommendation to avoid one-to-one consultations, and the implementation of an ombudsman service that a patient can turn to.

The second sub-category was diagnostic errors (A1.2.2). This encompasses the misdiagnosis of a mental illness when it was a physical illness and the misdiagnosis of psychiatric illnesses [cf. 13]. This can result in incorrect treatment (therapy, medication) that can worsen the patient's condition. Differential diagnoses are crucial to prevent diagnostic errors. Thus, many psychiatric hospitals use specific instruments to differentiate between physical and mental diagnoses.

The third sub-category concerns specific medication risks occurring mainly in psychiatry (A1.2.3). Here, side-effects of medication are most important (e.g. weight gain, loss of libido), as they are a primary reason for patients being non-compliant and not taking their medications. Another risk is apparent if patients accumulate medications for substance abuse or with the intention to commit suicide. Therefore, patients should be informed and educated about medications and their possible effects and side-effects, and patients' needs should be clarified and taken into account. The distribution and intake of medication needs to be monitored rigorously.

The interviews showed that this very mental-health specific topic of errors in the process of therapy, especially in psychotherapy, is insufficiently discussed and still rather vague. Treatment errors are seldom recognized or if they are, it is often too late, as therapy deals with the psyche and not with the observable body. In mental health care it can even be that a patient is judged to be "resistant to therapy, something that would never be accepted for a knee injury" (I3, P70). Furthermore, there are often different ideas among the mental health care professionals of what the right therapy might be for which illnesses. In addition, sometimes it is "rather the environment and not the patient that needs treatment" (I6, P53).

A1.3) Risks associated with mental illnesses

The third focus regarding specific clinical risks in mental health care was on risks associated with mental illnesses (A1.3, n=37). This contains mentions of particular illnesses (e.g. addiction, acute psychosis, mania, depression, anxiety disorders, or personality disorders) that might increase the possibility for certain risks (e.g. violent behavior or suicide). Risks associated with schizophrenic/psychotic disorders were mentioned most frequently. Most private psychiatric hospitals in our sample select patients according to their mental illnesses

as they are not obligated to accept all patients (in contrast to public hospitals). For example, patients with psychoses, addiction or major depression may not be accepted by a private hospital; thereby minimizing possible risks for the hospital. Overall, tools to assess the level of depression, suicidal tendencies, violence, etc. are most important to identify risks.

Most interviewees also mentioned that many psychiatric patients ("15-18%", I11, P117) are in hospital against their will (A1.3.1). The patients might have an involuntary commitment or do not believe that they are ill, which can result in violence, compulsory measures (see above) or leaving hospital against medical advice. Another risk is substance abuse and its consequences (A1.3.2) if, for example, drugs and injection devices (e.g. syringes) are smuggled into the hospital. CRM practices mentioned are to require patients to sign a binding addiction contract and to search patients to prevent them from smuggling drugs into the hospital.

A1.4) Leaving hospital against medical advice (Absconding)

Six out of 11 interviewees mentioned leaving hospital against medical advice or absconding from the hospital as another specific risk in mental health care (A1.4, n=9). There are various reasons why a patient might want to escape from a psychiatric hospital. It can be a consequence of the mental illness (e.g. hearing imperative/bidding voices that command a patient to escape) or because a patient is hospitalized against his/her will (see above). An escape from treatment might have severe consequences (e.g. (attempted) suicide, assault). CRM measures mentioned were the internal transfer of endangered patients to a closed ward, a very close observation/support of the patient and, if the patient did escape, a search by police.

A2) Clinical risks in common with medical health care

All interviewees also mentioned clinical risks that are known in medical health care but are also important in mental health care (A2, n=106). They are described briefly as they are well documented in the literature and not the focus of this study. Medication risks were mentioned most frequently (A2.1, n=33): confusion of medication, incorrect dose, incorrect administration, etc. Some interviewees judged medication risks to be just as important as in medical health care, whereas others found them not to be as critical in mental health. Infections and hygiene (A2.2, n=26) were also mentioned, but were not considered as important as in medical health care. One reason for this being that psychiatric hospitals have no surgery. Falls (A2.3, n=12) were also a topic in some interviews, especially regarding geronto-psychiatry or in the context of withdrawal symptoms.

Risky organizational and technological conditions that influence patient safety were also mentioned. Staff risks (A2.4) were identified, including staff shortage, too many shift changes, and stress and workload often resulting in prolonged absences from work and high staff turnover. Some interviewees saw this as a problem specific to mental health care as staff absenteeism due to illness was judged as being much more common than in other domains, including medical health care. Regarding technology and equipment (A2.5), correct application and periodic maintenance were seen as being most important. A high rate of internal patient transfers (A2.6) was also seen as potentially risky as primary caregivers change, knowledge about the patient is lost and handovers must be organized.

B) Other risks (non-clinical)

All interviewees also mentioned non-clinical risks that are mostly not specific for mental health care (B, n=47). Economic, construction, infrastructural and fire risks were mentioned. These risks were not classified further because this was not the focus of this study. However, some risks, such as data protection (to protect patients from stigmatization), or risks relating to hospital image (to avoid negative press) were judged to be especially important for psychiatric hospitals.

C) Risks for the staff

Staff safety is an important topic in psychiatric hospitals and all interviewees explicitly referred to it (C, n=38). It is specific to mental health care insofar as staff face risks, such as aggression and violence, far more often than in medical health care. A prospective 1998 study in six psychiatric hospitals captured all obvious aggressive physical contacts over six months: 144 assaults on 170 members of staff were found [28]. "Working for 8 or more hours a day and being constantly conscious of the possibility of violence, I think, is almost unacceptable" (I2, P94). This can lead to work stress, burn-out and prolonged absenteeism from work due to illness (see above). "We have more than 25% drop-outs because of staff illnesses; this is a very high number" (I10, P55). Fellow staff members and patients suffer from such situations. Staff can also become a second victim [29] as (attempted) suicides, diagnostic errors, medication errors or performing compulsory measures can be enormously burdensome. Therefore, staff and patient safety are closely interrelated and affect each other, at least partially.

Discussion

This study offers, for the first time, an overview of the main risk themes of CRM in mental health care and is independent of specific hospitals. The overview augments previous research, as it is systematic, exhaustive,

and does not focus on selected risks. The result of counting the risks indicates which risks are common and important. Whereas medication errors are in the uppermost position of risks to patients in hospitals for physical disorder [cf. 1,8], CRM in mental health is first concerned with violence and self-harm. Self-destructive behavior (mainly suicide and attempted suicide) was mentioned the most, followed by violence/aggression from patients against others. In terms of CRM, this implies that the main goal, above all, is to protect patients and staff from other patients, as well as to protect patients from themselves [cf. 15]. Professional interventions can reduce violence in many cases. Important to achieving this are sensitization, education and training of staff as well as the use of preventive instruments to predict violence. If something is happening, de-escalation (to calm the patient), diversion, and engagement are recommended as proactive interventions [12]. The consideration between the surveillance of the patient and the possibility to allow the patient to move freely remains a particular problem. Permanent surveillance increases safety and prevents suicides, but the patient is literally imprisoned and the necessary staff resources for the hospital to achieve this are enormous [30]. Therefore, striking the right balance between safety and freedom is also one of the delicate challenges in mental health care.

The second main risk theme concerns treatment errors. In particular, errors in the process of therapy, notably in psychotherapy, are insufficiently discussed and still rather vague (see results above, A1.2) so need further investigation. Diagnostic errors were seldom mentioned and seem to be neglected and underestimated similarly as is the case in medical health care. Despite the fact that they account for about 15% of medical errors and are the leading cause of medical malpractice litigation (twice as many cases as medication errors), diagnostic errors receive little attention [cf. 31,32]. This is probably because they are hard to measure, there being little data of incidence available, and because it is sometimes difficult even for experts to agree on the right diagnosis. However, especially in mental health care, where an incorrect diagnosis can result in incorrect therapy and prolonged stays in the hospital (sometimes for years), sensitization of staff and taking diagnostic errors into account in CRM is essential.

The third specific risk theme was risks associated with mental illnesses, such as psychosis or depression. Furthermore, many psychiatric patients lack insight regarding their illness and do not themselves think that they are ill and are hospitalized against their will. Therefore, due to their illnesses, most patients in mental health care differ greatly from patients in medical health care. Staff safety is directly related to the specifics of mental illnesses and is, as shown, a central theme in mental health care. These are additional main reasons why CRM in mental health care needs specialized concepts and strategies that complement the knowledge from CRM in medical health care. Some clinical risks such as medication risks, infections, hygiene, and falls, are common to various specializations in health care, and would benefit from the application of similar CRM practices.

Limitations

A qualitative approach allows for the exploration of a subject where there is limited previous research. Although this approach proved to be valuable, the data were constrained by the number of participants available for interview. Therefore, the results may not be fully generalizable to all types of mental health hospitals (e.g. psychiatric units for geriatric or pediatric patients) and to other types of hospitals. Secondly, it is possible that the interviewees did not verbalize the full extent of their knowledge because of memory limitations and the fact that not all knowledge is conscious. These limitations are common in many qualitative studies [cf. 13]. However, the expert status and the diversity of the chosen interviewees guaranteed a thorough and expansive view of the subject.

Remarkably, interviewees only mentioned risks in in-patient psychiatry restrained to the period between admission and discharge of patients. The handovers from ambulatory to in-patient as well as the after-care were not discussed. For example, how does one ensure that a patient does not relapse promptly upon discharge only to be readmitted to the hospital? This situation mainly occurs if the ambulatory care setting is not clear, if a patient returns to his or her usual environment or if medications are discontinued.

Conclusions

The current study adds to the understanding of patient safety and raises awareness for clinical risks in mental health. It uses expert interviews as an empirically sound way of generating knowledge in an emerging field that suffers from a shortage of research activity and empirical evidence. The overview of the main risk themes of CRM in mental health care and the proposed organizational CRM practices offer a valuable basis for CRM in psychiatry and an addition to CRM in hospitals in general. Psychiatric hospitals can use the overview to review the completeness of their assessment and knowledge of risks. It can also be used to prioritize the risks that need to be addressed. The CRM practices mentioned in the interviews provide guidance on how to deal with these risks. These guidelines may also be supplemented with a further step, for example by using a quantitative survey to gather information on the probability of occurrence and severity of individual risks, and to collect information about the most effective

and most feasible measures. Overall, research and knowledge of patient safety is growing. CRM offers an essential contribution as it aims to reduce harm to patients [8]. Studying CRM in particular settings, such as mental health care, is imperative in order to build safer health systems and to improve safety in general, but also for patients in mental health, whose illnesses render them extremely vulnerable.

Abbreviations

CRM: Clinical risk management;
I1, P3: This index number indicates the interview and the paragraph where a quote was found.

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Medical errors; causes, consequences, emotional response and resulting behavioral change

ABSTRACT

Objective: To determine the causes of medical errors, the emotional and behavioral response of pediatric medicine residents to their medical errors and to determine their behavior change affecting their future training.

Methods: One hundred thirty postgraduate residents were included in the study. Residents were asked to complete questionnaire about their errors and responses to their errors in three domains: emotional response, learning behavior and disclosure of the error. The names of the participants were kept confidential. Data was analyzed using SPSS version 20.

Results: A total of 130 residents were included. Majority 128(98.5%) of these described some form of error. Serious errors that occurred were 24(19%), 63(48%) minor, 24(19%) near misses, 2(2%) never encountered an error and 17(12%) did not mention type of error but mentioned causes and consequences. Only 73(57%) residents disclosed medical errors to their senior physician but disclosure to patient's family was negligible 15(11%). Fatigue due to long duty hours 85(65%), inadequate experience 66(52%), inadequate supervision 58(48%) and complex case 58(45%) were common causes of medical errors. Negative emotions were common and were significantly associated with lack of knowledge (p=0.001), missing warning signs (p=<0.001), not seeking advice (p=0.003) and procedural complications (p=0.001). Medical errors had significant impact on resident's behavior; 119(93%) residents became more careful, increased advice seeking from seniors 109(86%) and 109(86%) started paying more attention to details. Intrinsic causes of errors were significantly associated with increased information seeking behavior and vigilance (p=0.003) and (p=0.01) respectively.

Conclusion: Medical errors committed by residents have inadequate disclosure to senior physicians and result in negative emotions but there was positive change in their behavior, which resulted in improvement in their future training and patient care.

KEY WORDS: Medical errors, Emotional response, Error disclosure.

INTRODUCTION

"To err is human".[1] Medical errors are inevitable and can have a disastrous effect on patient, treating doctor, nurses and the institution as well.[2,3] Building a safe health care system means designing processes of care to ensure that patient are safe from accidental injury. A report on safety in health care by Institute of Medicine publication, To Err is human, focused attention on this problem, particularly its conclusion that every year more Americans die as a result of medical errors than deaths from automobile accidents and indicated that there were up to 98,000 deaths per year because of medical errors.[4]

Virtually all doctors have made mistakes but they often don't tell patients or families about them. In clinical practice human errors are common but they are generally underreported.[5] As a result of

this underreporting very little is known about the causes and consequences of medical errors. Moreover facing to a medical error is never easy and hence it is not disclosed.[6] Often it is difficult to recognize one's mistake, but it is necessary to face the situation and try to learn from it so that future errors can be prevented. Identifying the risk factors for medical errors is crucial first step towards its prevention and is important goal of quality care assurance.[7]

Self-perceived medical errors are common among doctors and are associated with subsequent personal distress. As a consequence of medical error health care providers at all training levels experience feelings of guilt, disappointment, fear and sense of inadequacy of varying degree.[3,8] Impact of medical error on health care provider is a vital area deserving attention. Residents are vulnerable population whose early experience shapes their future behavior. Residency period plays a critical role in defining physicians' future practice and responses to medical error.[9,10] Post-graduate residents and house officers often choose not to disclose their mistakes to the attending physician. Trainees who have accepted responsibility for the mistake and have discussed it were more likely to report constructive changes in practice. Residents were less likely to make constructive changes if they attributed the mistake to job overload.[6]

Residents need special attention because behaviors learnt early in practice are more likely to persist in their later professional carrier.[9] We planned this study to learn how medical errors relate to subsequent changes in practice.

METHODS

This was a prospective hospital based cross sectional study, conducted at Children's Hospital and Institute of Child Health Lahore which is a tertiary care hospital with 650 beds and around 250 postgraduate residents. The study population included pediatric medicine residents. The study proposal received approval from hospital ethical committee. After taking permission from the author Hobgood,[8] her Questionnaire was adopted. We pilot tested the questionnaire on a sample of 25 for reliability that was 0.852 Cronbach's Alpha. Questionnaire was distributed to 150 pediatric medicine postgraduate residents and 130 residents returned the questionnaire proforma with a response rate of 87%. The survey was anonymous as residents were asked to complete the questionnaire without indicating their names. We asked the residents to answer the questionnaire by recalling the most significant error encountered during their residency period using the definitions for key terms. These were medical error, serious error, minor error and near misses. These were defined as follows: Medical error: The failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Serious error: An error that causes permanent injury or transient but life threatening harm. Minor error: An error that causes harm that is neither permanent nor potentially life threatening. Near misses: An error that could have caused harm but did not either by chance or timely intervention,[11] provided at the beginning of the questionnaire. Our study explored the residents' perception of cause of medical error, their responses to these errors, its disclosure and the effect of that error (constructive or defensive) on their behavior. Residents were asked to complete questionnaire about their errors and responses to their errors in three domains: emotional response, learning behavior and disclosure of the error. The three distinctive behavioral changes were information seeking, vigilance and defensive practice. We used 5 point Likert scales (1= Strongly agree, 2= Agree, 3= Neutral, 4= Disagree, 5= Strongly disagree) to assess residents response to errors. Demographic questions included participant's age, sex and year of residency. The names of the participants were kept confidential.

Answers from the questionnaire were entered into Statistical Package for Social Sciences (SPSS) version 20 software for analysis. Descriptive statistics included mean and standard deviations for continuous variables and frequencies and percentages for categorical variables. The chi-square test was used for statistical analysis. A p value of <0.05 was considered statistically significant.

RESULTS

Postgraduate residents reported that errors occur frequently among admitted patients and had both intrinsic and extrinsic attribution of errors. Of the 130 participants providing error data most

Table-I: Types of medical errors.

Medical Errors	*Percentage*
Serious medical error	18%
Minor medical error	48%
Near misses	19%
Never encountered medical error	2%
Not mentioned type of error but mentioned cause and effect	13%

Table-II: Characteristics of residents who participated in the study.

Category	*Total*
	n =130 (100%)
Age	
Mean	28±1.98 Years
25-30 years	118 (90%)
31-35 years	11 (9.2%)
> 35 years	01 (0.8%)
Sex (M:F)	
Male	59 (45%)
Female	71 (55%)
Year of Post Graduate Training	
1st Year	24 (19%)
2nd Year	26 (20%)
3rd Year	46 (35%)
4th Year	34 (26%)

participants 128(98.5%) had encountered a medical error, only 2(1.5%) reported no error involvement and 17(13%) mentioned cause and effect of error but did not specify the type of error. Table-I. The age distribution for the entire participants was 28±1.9 years. Demographic characteristics of the participants are shown in Table-II.

The intrinsic and extrinsic attributions of medical errors are shown in Table-III. The common intrinsic attribution that residents narrated was fatigue due to long duty hours 85(65%), inadequate experience 66(52%), followed by missing of warning signs 51(40%). With respect to extrinsic attribution, 81(63%) reported having other things to take care of, 61(48%) identified that case was complex and 58(45%) narrated inadequate supervision by the senior was the factor. Residents who attribute their error due to fatigue or job overload did not show any constructive change in their behavior. (Table-IV).

Table-III: Causes of medical errors and error disclosure.

Cause of the medical error	*(Who agreed/ strongly agreed) N (%)*
Intrinsic	
I did not have enough experience	66 (52%)
I did not possess enough knowledge	51 (40%)
I missed the warning signs	51 (40%)
There was faulty communication	46 (36%)
I was tired/ fatigued due to long duty hours	85 (66%)
I did not ask for advice from senior	27 (21%)
I hesitated too long	13 (10%)
Extrinsic	
I had many other things to take care of	81 (63%)
The case was very complex	61 (48%)
It was an atypical presentation	57 (45%)
There was inadequate supervision	58 (45%)
There was a procedural complication	37 (29%)
Lab report was wrong so resulted in misjudgment	24 (19%)
Disclosure	
To none due to fear / guilt/ embarrassment	27 (21%)
To my colleague present with me on duty	90 (70%)
To my close friend/ spouse	74 (58%)
To my senior / physician involved in the case	73 (57%)
Discussed with some other senior who is not involved in that case	44 (34%)
To patient family or patient	15 (11%)

All 128(100%) residents who encountered an error reported experiencing some negative emotions as a result of their error. Most 89(70%) experienced sorrows, 88(69%) guilt, 85(66%) emotional distress and 51(40%) inadequacy. (Table-V) Negative emotions were significantly associated with intrinsic causes like lack of knowledge (p=0.001),

Table-IV: Association of causes of medical errors with behavioral response.

Behavioral Response	*Intrinsic Causes of Errors p value*			*Extrinsic causes of Errors p value*		
	Did not possess enough Knowledge	*Missed Warning Signs*	*Fatigued due to long duty*	*Many other things to take care of*	*Atypical Presentation*	*Procedural Complication*
Information Seeking						
Seek more advice from seniors	0.003	0.028	0.141	0.691	0.142	0.017
Ask supervision more often	0.014	0.164	0.807	0.865	0.142	0.103
Read more about cases	0.042	0.143	0.375	0.854	0.245	0.266
Vigilance						
Pay more attention to details	0.016	0.004	0.648	0.966	0.007	<0.001
Use evidence based medicine	0.003	0.753	0.637	0.737	0.395	0.031
Defensive						
Order more test	0.076	0.517	0.963	0.310	0.015	0.341
Keep errors to myself	0.024	0.217	0.507	0.397	0.763	0.041
Avoid similar patients	0.012	0.171	0.182	0.172	<0.001	<0.001
See fewer patients	0.026	0.164	0.213	0.640	0.131	0.010

Table-V: Emotional and behavioral responses to medical errors.

Responses	*(Who agreed/ strongly agreed) n (%)*
Emotional Response	
Negative Emotions	
In reaction to error I felt a lot of:	
Emotional distress	85 (66%)
Sorrow	89 (70%)
Guilt	88 (69%)
Inadequacy	51 (40%)
Frustration	49 (38%)
Fear	38 (30%)
OR	
It was not my fault	20 (16%)
Behavioral Response	
1. Increased Information Seeking	
• Always seek more advice from senior staff	109 (85%)
• Seek more advice from peers	87 (68%)
• Ask supervision more often	96 (76%)
• Ask for more literature reference	86 (67%)
• I read more from the book about the cases	64 (50%)
2. Increased vigilance	
• Pay more attention to details of patient	109 (85%)
• Use more evidence based medicine	99 (77%)
• Personally confirm data	88 (69%)
• Trust others' judgment less	69 (53%)
• Became more careful	119 (93%)
• Always recheck the lab report when in doubt	95 (74%)
3. Increased defensive attitude	
• Order more tests	40 (31%)
• Keep errors to myself more often	29 (23%)
• Avoid similar patients	14 (11%)
• See fewer patients	20 (16%)

missing warning signs (p=<0.001) and not seeking advice (p=0.003). Residents who mentioned extrinsic attribution to the error also reported to have negative emotions that were significantly associated with procedural complication (p=0.001) and atypical presentation (p= 0.018).

Medical errors resulted in significant change in resident's learning behaviors. Eighty five percent sought more advice from seniors, 96(76%) started asking for supervision more often. Increased vigilance was a significant behavior change as 119(93%) became more careful, 109(85%) reported paying more attentions to the details of the case, and 99(77%) using evidence based medicine. Intrinsic causes of errors like lack of knowledge and missing warning signs were significantly associated with increased information seeking behavior and vigilance (p=0.003) and (p=0.01) respectively. (Table-IV) Only few residents reported increased defensive attitude: 14(11%) reported avoiding similar patients, 40(31%) ordering more test and only 20(16%) reported seeing fewer patients. (Table-V)

As far disclosure was concerned most respondents' 103(80%) disclosed the medical error to someone. (Table-III) Those who discussed their error with the senior physician involved in the case were only 73(57%), disclosure to none was 27(21%) and least number of residents 15(11%) disclosed the error to the patient's family. Not disclosing the error to anyone was significantly associated with intrinsic causes like not possessing enough knowledge (p=0.001), not having enough experience (p=0.001), missing warning signs (p=0.01) and extrinsic cause of procedural complication (p= 0.018). Error disclosure to senior was significantly associated with atypical presentation (p=0.037), complex case (p=0.015), not possessing enough knowledge (p=0.024). Those who did not disclose their errors showed more defensive attitude with seeing fewer patient and avoiding similar patients (p=<0.001), ordering more tests (p=0.045) and keeping the errors to themselves (p=0.024).

DISCUSSION

To improve patient safety, it is necessary to know about the causes, frequency and seriousness of medical errors.[12] Residents make medical errors in every clinical context. Residency is a time of learning and resident learns to acquire increasing responsibilities of clinical decision-making and professional development. Future clinical practice is affected by the behavioral response to their errors. Understanding the effect of medical errors on residents' behavior is critical and teaching faculty must understand how resident respond to their errors. Residents can be helped by encouraging them to develop positive error management strategies.

In our study 18% residents reported serious errors and 48% minor errors. Similar findings were noted in different studies, which showed major errors resulting in deaths in 31%, 34% and 39% respectively.[6,13,14]

Among trainees subsequent personal emotional distress is associated with self perceived medical errors.[13] The results of our study showed that

errors that occurred during residency training have substantial negative emotional impact which is consistent with the study done by Hobgood,[8] West[13,14] and result in learning behavior change. The resulting negative emotions due to error were guilt, emotional distress sorrow and inadequacy. These negative emotions were significantly associated with lack of knowledge, missing warning signs, not seeking advice and procedural complication.

Hospitals' functioning is round the clock, post-graduate residents work for long hours. They are often sleep deprived and fatigued. Sleepiness and fatigue affect patient's safety.[14,15] In our study majority 66% of residents reported that fatigue or tiredness due to long duty hours was the cause of their medical error. Lack of experience, inadequate supervision by seniors was also reported by 52% and 45% respectively and are similar to study by Singh and Hobgood.[5,8] All these factors need to be addressed by hospital administration. Poor communication is an important cause of adverse events in health care system, resulting in medical errors that range from delay in treatment to wrong site surgery. In our study 36% of postgraduate trainees reported faulty communication as a cause of error. Routine team checklist briefing has a positive effect on team communication and teamwork.

Unfortunately very few residents have been taught how to disclose the error and majority do not have proper experience of disclosing an error. They generally use the informal way of disclosure such as telling to someone they trust or not fearful of.[16] Same was reported in our study in which 80% residents informally discussed their errors. Trainees often choose not to disclose their medical errors to their senior physicians or supervisors.[3,17] Our recent data suggest that professional modelling of error acknowledgement and discussion of errors needs more attention as only 57% of residents in our study discussed their errors with their senior or supervisors, comparable with the study published in JAMA in which 54% discussed their errors with seniors.[6]

Patients and their families wish to be informed immediately about the medical errors that occur.[18] However, the disclosure to patient is often limited.[19,20] Our results highlighted that disclosing medical error to family members is a challenging task. Consistent with the finding of Wu et al.[6] which showed disclosure to patient in 24%, only 11% of our resident disclosed their error to the family which may be due to their concept that patient's family would not understand or blame them.

Open communication about errors presents huge challenges for residents. Our medical profession should develop disclosure guidelines to help the treating physicians and pediatric residency training should include formal instructions in error disclosure. We don't have well-established hospital incident report system and medical errors in pediatric patients are significantly underreported. Information in incident reports is not a representation of actual medical errors committed in pediatric hospitals.[21] Establishing a proper incident reporting system can lead to more error reporting by doctors.

Very little is known about what and how the residents are taught about medical errors.[22] Although in our health care system there is no proper teaching or lectures about medical errors but mortality and morbidity conference definitely help residents to learn from joint discussions of mistakes.

Senior health care professionals must be supportive and nonjudgmental of their residents' when medical errors take place. Discussing one's own error experience can help to reduce the resident's sense of isolation and guilt.[2]

CONCLUSION

Residents encounter medical errors at all levels of training. Fatigue due to long duty hours, lack of experience, job over load and inadequate supervision by senior were major causes of these errors. Medical errors committed by residents have inadequate disclosure to senior physicians. Errors resulted in negative emotions but there was a positive change in their behavior, which resulted in improvement in their future training and patient care. There is a need for close monitoring of postgraduate training program, adequate round the clock senior supervision, assessment of their professional competence on regular basis, regularization of duty hours to prevent fatigue and also legal protection for doctors and patients.

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Barriers to Medical Error Reporting

Abstract

Background:

This study was conducted to explore the prevalence of medical error underreporting and associated barriers.

Methods:

This cross-sectional study was performed from September to December 2012. Five hospitals, affiliated with Hamadan University of Medical Sciences, in Hamedan, Iran were investigated. A self-administered questionnaire was used for data collection. Participants consisted of physicians, nurses, midwives, residents, interns, and staffs of radiology and laboratory departments.

Results:

Overall, 50.26% of subjects had committed but not reported medical errors. The main reasons mentioned for underreporting were lack of effective medical error reporting system (60.0%), lack of proper reporting form (51.8%), lack of peer supporting a person who has committed an error (56.0%), and lack of personal attention to the importance of medical errors (62.9%). The rate of committing medical errors was higher in men (71.4%), age of 50–40 years (67.6%), less-experienced personnel (58.7%), educational level of MSc (87.5%), and staff of radiology department (88.9%).

Conclusions:

This study outlined the main barriers to reporting medical errors and associated factors that may be helpful for healthcare organizations in improving medical error reporting as an essential component for patient safety enhancement.

Keywords: Iran, medical error, patient safety, reporting system

INTRODUCTION

Medical error is a serious public health problem that can pose a threat to patient safety. Currently, reducing medical errors has become an international concern.[1] Medical error is defined as "an act of omission or commission in planning or execution that contributes or could contribute to an unintended result."[2] A medical error occurs when a health-care provider chooses an inappropriate method of care or improperly executes an appropriate method of care.[3]

Currently, there is a growing awareness regarding the importance of medical error and its consequences on both the healthcare quality and the patient safety.[4] Therefore, medical error reduction, as the first step of patient safety enhancement, has rapidly become a strategic priority for most healthcare organizations.[5] We can covert threats into opportunities if we learn from our mistakes. Most often, neither healthcare providers nor healthcare organizations advise others when a medical error takes happen. Unfortunately, they do not share what they have learned when an investigation has been conducted either. Consequently, the same mistakes occur many times in different settings and patients continue to be injured by preventable errors.[1]

One solution to this problem is that everybody reports errors in any setting. An efficient reporting system is the cornerstone of patient safety enhancement and a measure of progress toward achieving a safety culture.[1] One of the major problems to error-reduction efforts in healthcare organizations is the lack of data on the incidence rate of medical errors. Despite the high occurrence of medical errors, they are frequently underreported in healthcare organizations.[6,7,8]

Reporting errors is fundamental to error prevention.[1] Therefore, the presence of a well-organized reporting system is essential for effective prevention programs.[9] A majority of investigation in low and middle-income settings have focused on identifying the causes of medical errors rather than the barriers to reporting errors.[10] The incidence and type of barriers may vary across countries and regions because different policies are adopted by the institutes. Until reliable information on the barriers to medical reporting is collected, it is difficult to design effective intervention strategies to progress toward a comprehensive prevention program. Accordingly, this study was designed and conducted to identify the main barriers to medical error reporting in a middle-income country.

METHODS

This cross-sectional study was conducted in teaching hospitals affiliated with Hamadan University of Medical Sciences, in Hamadan city, the West of Iran, from September to December 2012. The hospitals which were recruited in this study included Besat, Ekbatan, Fatemieh, Shahid Beheshti, and Farshchian. The study population consisted of medical specialists, general practitioners, nurses, midwives, physiotherapists, and staffs of laboratory and radiology. Of 2183 study population, 348 participants were enrolled voluntarily in this study. Verbal rather than written informed consent was taken from the participants because no intervention was done in this observational study. Participants were only asked to fill out a self-administered questionnaire. At the beginning of the questionnaire, the participants were told that "If you dislike participating in the study and answering to the questions, you can avoid filling out the questionnaire." The Research Committee of Hamadan University of Medical Sciences approved both the consent procedure and the whole study (No. 920204269).

In order to calculate sample size, assuming probability of medical error (P) equals to 0.5 and considering significance levels of 0.05 and error level of 0.2, we arrived at a sample of 171. Since we run a cluster random sampling, we doubled the sample size to save the statistical power. A stratified cluster random sampling method was carried out considering hospitals as strata and job categories as clusters. Then, the samples were taken proportion to the study population in each hospital.

The questionnaire, which was developed by the authors and used for data collection, composed of two parts. The first part included demographic and individual characteristics of the participants. The second part focused on the reasons for underreporting medical errors. A clear definition of medical error was

provided at the beginning of the second part so that all participants had a unique understanding of the concept of medical error. Then, the participants were asked to announce their agreements to the potential relevant factors that might act as barriers for medical error reporting. The validity of the questionnaire was evaluated by two analysts and interpreters of medical error reporting as well as an epidemiologist. The reliability of the questionnaire was 84.47% using Cronbach's alpha coefficient. The Chi-square test was used for assessing the correlation between dichotomous variables. All statistical analysis was performed at 0.05 significant levels using statistical software Stata version 11.2 (StataCorp, College Station, TX, USA).

RESULTS

The proportion of the participants' positive answers given to the purposed reasons for medical error underreporting is shown in Table 1. The main reasons with which majority of the participants agreed were: Lack of effective medical error reporting system (60.00%), lack of reporting properly (51.84%), lack of supporting a person who has committed an error (55.97%), and lack of personal attention to the importance of medical errors (62.86%).

The proportion of participants who had committed and reported medical errors against those who had committed but had not reported medical error is shown in Table 2. According to these results, 50.26% of subjects had committed but had not reported medical errors.

The relationship between participants' individual characteristics and committing medical error is shown in Table 3. According to these results, the incidence rate of committing medical errors was higher in men (71.4%) than in women (50.4%), in the age group of 50–40 years (67.6%), among subjects with 0–9-year working experience (58.7%), in subjects with the educational level of MSc (87.5%), and among staffs of radiology (88.9%).

The relationship between participants' individual characteristics and reporting medical errors is shown in Table 4. According to these results, the incidence rate of reporting medical errors was higher among women (63.1%), age group of 29–18 years (64.3%), subjects with 29–20-year work experience (61.1%), subjects with the educational level of BSc (65.1%), and nurses (64.4%).

DISCUSSION

We indicated that the incidence rate of committing medical errors was high, but its reporting rate was low. This issue reveals the importance of establishing an effective reporting system for recording, analyzing, and managing medical errors in all organizations providing health care.

According to our results, the fear of legal consequences was 44.4%. This fear may be due to adverse consequences such as a malpractice lawsuit, losing patients' trust, and emotional reactions of the patients and their relatives, or losing occupational position.[11,12]

Based on our findings, other reasons that participants have reported for medical error underreporting were lack of personals' attention to the importance of medical errors and lack of effective medical error reporting system. Nursing administration's focus on the person who committed errors rather than a system in which medical errors can be registered and analyzed.[13] Such system can covert threats into opportunities to learn from the mistakes and prepare a cornerstone to eliminate the preventable causes of medical errors. Evidence has shown that an anonymous, nonpunitive critical incident reporting system can play as a powerful tool for identifying the majority of medical errors and risk factors and may help avoiding preventable adverse events.[14,15,16]

Gluck stated that some errors in health care were inevitable because of both human fallibility and the complexity of the systems. He suggested three strategies for improving patient safety as follows: (a) Prevent errors with estimating functions, reducing complexity, and providing reminders at the point of care; (b) everybody working in health care have to be alert to distinguish and eliminate potential errors

before patients are harmed; (c) defensive barriers must be established to intercept those errors that still occur and prevent them from causing patient injury.[17]

An important limitation of this study was recall bias so that some participants might have committed a medical error, but they could not remember it. This might introduce information bias into the results and might lead to underestimation of the rate of medical error committed by the study population. Furthermore, we enrolled the participants into the study voluntarily and collected data anonymously in order to reduce the non-honest response rate. However, it is possible that some participants have avoided reporting the medical error that has been committed by them. This may again result in underestimation of the true rate of medical error committed by the study population. Despite it limitation, this study indicated the main barriers to medical error reporting in a high-middle income setting. Since factors affecting medical error reporting may vary between different settings, the results of this survey may help avoiding preventable adverse events caused by medical errors in such settings.

CONCLUSIONS

This study indicated the main barriers to reporting medical and associated factors that may act as barriers to error reporting. The factors outlined in this study can assist healthcare providers and healthcare organizations in improving medical error reporting as an essential component for patient safety enhancement.

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Figures and Tables

Table 1

Barriers	A	B	C	D	E	F	Total	*P* value
Lack of information on how to report a medical error	68.6	45.0	11.8	46.4	73.3	25.0	48.5	0.001
Lack of affective medical error reporting system	76.0	54.3	22.2	74.1	86.7	50.0	60.0	0.001
Lack of proper reporting form	66.0	49.4	11.1	59.3	73.3	50.0	51.8	0.002
Lack of enough training regarding patient safety and medical error	55.1	40.4	11.1	66.7	50.0	0.0	43.4	0.001
Lack of trust medical error reporting system	12.8	24.7	22.2	25.9	33.3	0.0	22.6	0.37
Lack of knowledge of the importance of reporting medical errors	43.8	40.4	38.9	28.6	50.0	20.0	39.9	0.65
Lack of adequate information about medical errors and patient safety	44.9	37.1	33.3	37.0	53.3	0.0	38.7	0.40
Lack of enough time for reporting medical errors	34.9	30.8	58.8	44.0	36.4	20.0	35.1	0.23
Inappropriate content of the reporting forms	40.0	38.5	33.3	29.2	45.5	25.0	37.8	0.90
Lack of feedback from the system after reporting medical errors	45.2	43.0	23.5	54.6	54.6	25.0	43.2	0.41
Lack of peer support from a person who has committed an error	73.8	54.5	50.0	44.0	63.6	25.0	56.0	0.10
lack of personals' attention to the importance of medical errors	61.9	62.1	77.8	64.0	66.7	40.0	62.9	0.70
lack of supervisors' attention to the medical errors reported	48.8	29.9	44.4	36.0	54.6	20.0	35.5	0.15
Fear of losing occupational position after reporting medical error	48.1	43.6	33.3	35.7	26.7	50.0	42.3	0.62
Fear of losing job after reporting medical error	24.5	35.8	27.8	32.1	33.3	25.0	32.6	0.77
Fear of legal consequences after reporting medical error	49.0	45.7	38.9	39.3	33.3	25.0	44.4	0.78
Fear of administrative punishment after reporting medical error	38.0	42.0	38.9	46.4	33.3	25.0	40.5	0.92

(A): Specialists, general practitioners, residents, and interns (*n*=69); (B): Nurses and nursing students; (n=202); (C) midwives (*n*=19); (D) laboratory staff (*n*=35); (E) radiology staff (*n*=18); and (F) physiotherapists (*n*=5)

Proportion (%) of the participants' positive answers given to the purposed reasons of medical-error underreporting by job categories using Chi-squared test

Table 2

Committed medical error	Reported medical error				
	Yes		No		Total
	Number	Percent	Number	Percent	
Yes	95	49.74	96	50.26	191
No	94	68.12	44	31.88	138
Total	189	57.45	140	42.55	329

Distribution of reporting medical errors among those who had committed and those who had not committed medical error (Chi-square test: 11.0688; *P*=0.001)

Table 3

Variables	Committed medical error				*P* value
	Yes		No		
	Number	Percent	Number	Percent	
Gender					0.001
Male	75	71.4	30	28.6	
Female	114	50.4	112	49.6	
Age (year)					0.098
18-29	54	51.4	51	48.6	
30-39	81	59.6	55	40.4	
40-52	48	67.6	23	32.4	
Work experience (year)					0.718
0-9	88	58.7	62	41.3	
10-19	70	63.0	41	37.0	
20-29	20	57.1	15	42.9	
Educational level					0.054
Diploma	14	43.7	18	56.3	
Associate degree	45	56.2	24	34.8	
BSc	85	51.8	79	48.2	
MSc	7	87.5	1	12.5	
Medical doctorate	22	66.7	11	33.3	
Specialist	21	63.6	12	36.4	
Job categories					0.004
Nurses	98	49.0	102	51.0	
Midwives	12	66.7	6	33.3	
Laboratory staff	23	69.7	10	30.3	
Radiology staff	16	88.9	2	11.1	
Physicians	43	65.1	23	34.9	
Physiotherapists	3	60.0	2	40.0	

Relationship between participants' individual characteristics and committing medical error using chi-squared test

Table 4

Relationship between participants' individual characteristics and reporting medical errors using Chi-square test

20 Tips to Help Prevent Medical Errors

One in seven Medicare patients in hospitals experience a medical error. But medical errors can occur anywhere in the health care system: In hospitals, clinics, surgery centers, doctors' offices, nursing homes, pharmacies, and patients' homes. Errors can involve medicines, surgery, diagnosis, equipment, or lab reports. They can happen during even the most routine tasks, such as when a hospital patient on a salt-free diet is given a high-salt meal.

Most errors result from problems created by today's complex health care system. But errors also happen when doctors* and patients have problems communicating. These tips tell what you can do to get safer care.

What You Can Do to Stay Safe

The best way you can help to prevent errors is to be an active member of your health care team. That means taking part in every decision about your health care. Research shows that patients who are more involved with their care tend to get better results.

Medicines

1. Make sure that all of your doctors know about every medicine you are taking. This includes prescription and over-the-counter medicines and dietary supplements, such as vitamins and herbs.

2. Bring all of your medicines and supplements to your doctor visits. "Brown bagging" your medicines can help you and your doctor talk about them and find out if there are any problems. It can also help your doctor keep your records up to date and help you get better quality care.
3. Make sure your doctor knows about any allergies and adverse reactions you have had to medicines. This can help you to avoid getting a medicine that could harm you.
4. When your doctor writes a prescription for you, make sure you can read it. If you cannot read your doctor's handwriting, your pharmacist might not be able to either.

5 Ask for information about your medicines in terms you can understand—both when your medicines are prescribed and when you get them:

- What is the medicine for?
- How am I supposed to take it and for how long?
- What side effects are likely? What do I do if they occur?
- Is this medicine safe to take with other medicines or dietary supplements I am taking?
- What food, drink, or activities should I avoid while taking this medicine?

6 When you pick up your medicine from the pharmacy, ask: Is this the medicine that my doctor prescribed?

7 If you have any questions about the directions on your medicine labels, ask. Medicine labels can be hard to understand. For example, ask if "four times daily" means taking a dose every 6 hours around the clock or just during regular waking hours.

8 Ask your pharmacist for the best device to measure your liquid medicine. For example, many people use household teaspoons, which often do not hold a true teaspoon of liquid. Special devices, like marked syringes, help people measure the right dose.

9 Ask for written information about the side effects your medicine could cause. If you know what might happen, you will be better prepared if it does or if something unexpected happens.

Hospital Stays

10 If you are in a hospital, consider asking all health care workers who will touch you whether they have washed their hands. Handwashing can prevent the spread of infections in hospitals.

11 When you are being discharged from the hospital, ask your doctor to explain the treatment plan you will follow at home. This includes learning about your new medicines, making sure you know when to schedule follow-up appointments, and finding out when you can get back to your regular activities.

It is important to know whether or not you should keep taking the medicines you were taking before your hospital stay. Getting clear instructions may help prevent an unexpected return trip to the hospital.

Surgery

12 If you are having surgery, make sure that you, your doctor, and your surgeon all agree on exactly what will be done.

Having surgery at the wrong site (for example, operating on the left knee instead of the right) is rare. But even once is too often. The good news is that wrong-site surgery is 100 percent preventable. Surgeons are expected to sign their initials directly on the site to be operated on before the surgery.

13 If you have a choice, choose a hospital where many patients have had the procedure or surgery you need. Research shows that patients tend to have better results when they are treated in hospitals that have a great deal of experience with their condition.

Other Steps

14 Speak up if you have questions or concerns. You have a right to question anyone who is involved with your care.

15 Make sure that someone, such as your primary care doctor, coordinates your care. This is especially important if you have many health problems or are in the hospital.

16 Make sure that all your doctors have your important health information. Do not assume that everyone has all the information they need.

17 Ask a family member or friend to go to appointments with you. Even if you do not need help now, you might need it later.

18 Know that "more" is not always better. It is a good idea to find out why a test or treatment is needed and how it can help you. You could be better off without it.

19 If you have a test, do not assume that no news is good news. Ask how and when you will get the results.

20 Learn about your condition and treatments by asking your doctor and nurse and by using other reliable sources. For example, treatment options based on the latest scientific evidence are available from the Effective Health Care Web site (effectivehealthcare.ahrq.gov/options). Ask your doctor if your treatment is based on the latest evidence.

Appendix A: Sample Risk Management Policy, Health Resources and Services Administration

Medication Dispensing Errors

POLICY

Dispensing error is defined as:

1. Failure to dispense a medication on receipt of a valid physician order or omission of a medication from the medication order.

2. Dispensing an incorrect quantity or sending an incorrect quantity of medication for use by the provider.

3. Dispensing an incorrect medication, strength, or dosage form.

4. Incorrectly compounding medication.

5. Omission of supplementary labels.

6. Incorrect, incomplete or inaccurate labeling of medications.

7. Dispensing a medication to which the patient has an allergy as listed on the pharmacy medication profile.

PROCEDURE

1. Presumed pharmacy errors detected by nursing services are to be reported on the Medication Error Data Collection Form**.**

2. Medication Variances are reviewed by the Pharmacy & Therapeutics Committee for use in trending and as performance improvement issues.

DOCUMENTATION

Dispensing errors are documented on the Medication Error Data Collection Form.

Medication Errors Data Collection Form

Date: _____ Provider: _____

Medication Error	Directions: Please indicate implicated medication and *briefly* describe error. Access to the patient's medical record (MR) may be necessary. PLEASE remember to note the total number of medications the patient is receiving.					
Medication Name(s)	MR#					
Total number of medications	Severity Level:		Severity Level:		Severity Level:	
	Prescribe	Dispense	Prescribe	Dispense	Prescribe	Dispense
Prescribing errors / Dispensing errors						
Incorrect indication/contraindication for the med.						
Incorrect dose based on weight, renal/hepatic function prescribed or dispensed						
Incorrect number of doses dispensed (DISPENSING ERROR ONLY)						
Expired medication dispensed (DISPENSING ERROR ONLY)						
Medications prescribed/dispensed with incorrect or missing Route of administration Frequency Strength Duration Dosage form Miscellaneous (_____)						
Inappropriate abbreviation or poorly written order (PRESCRIBING ERROR ONLY)						
Therapeutic duplication for prescribed or dispensed drug						
No rational indication for prescribed or dispensed drug						
Drug allergy to prescribed drug not noted in medical record/ Drug allergy to dispensed drug OR no allergy noted in medical record						
Significant drug interaction to prescribed/dispensed drug not noted in medical record When necessary, prescribed/dispensed medications are not appropriately monitored or are NOT monitored						
Miscellaneous Drugs to avoid during pregnancy , i.e. Accupril						

Exceptions to the above: _____
_____

Follow-up:

_____
_____
_____

Performance Improvement:

_____
_____
_____
_____

Person Completing Form: _____ Date: _____

Date: _____

Medication Error Definition

Severity Levels

Level O:

Circumstances or events occurred that have the capacity to cause errors, but checks and balances in the system identified it before reaching the patient.

Level 1:

An error occurred, but it resulted in no harm to the patient.

Level 2:

An error occurred that resulted in the need for increased patient monitoring, but caused no harm to the patient.

Level 3:

An error occur that resulted in the need for increased patient monitoring and a change in vital signs, but caused no harm to the patient, or an error occurred that required blood draws for additional laboratory monitoring.

Level 4:

An error occurred that resulted in temporary harm and required intervention treatment with another drug, increased length of stay, or affected the patient's ability to participate in an investigational protocol.

Level 5:

An error occurred that resulted in permanent harm, or a near death event (e.g., anaphylaxis, cardiac arrest) to the patient.

Level 6:

An error occurred that contributed to the death of the patient.

ADVERSE DRUG REACTION (ADR)

POLICY

Definition: An adverse Drug Reaction is any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function. This excludes therapeutic failures and those reactions, which may normally be anticipated side effects.

Reporting: Adverse drug reactions are to be reported immediately according to procedure.

Documentation: Adverse Drug Reactions are to be documented in the Medical Record, and Adverse Drug Reaction (ADR) Assessment Form.

Review: The Pharmacy and Therapeutics Committee is to review adverse drug reactions. Significant reactions are those reactions that are unexpected and will be reported to the FDA as determined by the Pharmacy and Therapeutics Committee.

PERSONNEL QUALIFIED TO PERFORM PROCEDURE

Registered Nurse, Licensed Practical Nurse, Pharmacist, Physicians and other personnel authorized to administer medications.

EQUIPMENT NEEDED

Medical Record, Adverse Drug Reaction Assessment Form

PROCEDURE

1. The assigned Nurse is to notify the attending physician of known or suspected Adverse Drug Reaction.

2. Prescribed treatment is to be carried out promptly.

3. All known or suspected Adverse Drug Reactions are to be reported to the pharmacy by phoning any pharmacy extension. Report name and suspected drug reaction.

4. Document reactions in the patient medical record.

5. Initiate Adverse Drug Reaction (ADR) Assessment Report.

6. Completed reports are to be forwarded to the Unit Director, the Pharmacy and Risk Management/CQI.

7. The Pharmacy is to evaluate and trend Adverse Drug Reactions identified through spontaneous reporting and retrospective review. The pharmacy is to review all reported adverse reactions.

8. Adverse Drug Reactions and summary reports are represented to the Pharmacy and Therapeutics Committee for review.

9. Adverse Drug Reactions are to be reported to the FDA as determined by the Pharmacy and Therapeutics Committee.

DOCUMENTATION

1. The Assigned Nurse is to document Adverse Drug Reactions in the patient's medical record to include the suspected medication and the reaction observed.

2. An Adverse Drug Reaction (ADR) Assessment Report is to be prepared by the assigned nurse and routed to the above, as listed in #6.

ADVERSE DRUG REACTION RECOGNITION

Recognition of adverse reactions is essential to appropriate intervention to improve patient outcome. Adverse Drug Reactions include anticipated side effects as well as allergic reactions, extension of the therapeutic effect, and toxicities. Examples of indicators of adverse reactions include the following:

1. Physical systems, such as a rash.

2. Changes in mental status, such as lethargy in patients on sleeping aids.

3. Hypokalemia in patients on diuretic therapy.

4. Changes in serum creatinine in patients on aminoglycosides.

5. Toxic serum drug concentration levels, such as serum digoxin levels above 2.0.

Adverse Drug Reaction (ADR) Assessment Form

DEFINTION

An Adverse Drug Reaction (ADR) is any unintended, undesirable, or unexpected response to a drug. It includes any reaction that results in the discontinuation of a drug, necessitates additional drug therapy, or causes a hospital admission, prolongation of hospital stay, permanent injury, or death.

Patient: _____ **Age**: ____ **Sex**: __

Diagnosis: _____

Date of Reaction__/_____/____

Known Drug Allergies: _____

Current Medications: _____

Medication Suspected (generic and trade name, route, dose, frequency, lot #):

_____

Reaction Description: _____

Relevant Lab Data (drug serum concentration, electrolytes, etc.)_____
_____

Physician Notified _____ **Yes**_____ **No** **Dat**e: ___/___/___**Time:**_____

Name of Physician: _____

Name of Person Reporting Reaction: _____ **Date**:_____/_____/_____

Treatment: _____

Additional Comments: _____

Patient Outcome
_____ Slight morbidity-may/may not require change in drug therapy
_____ Moderate morbidity-drug therapy must be discontinued
_____ Severe morbidity-potential for life threatening or irreversible reaction
_____ Death

Classification

_____ Definite-reaction appears after rechallenge
_____ Probable-reaction disappears after drug DC'd, but without rechallenge
_____ Possible-reaction fits known response pattern, but may also be caused by other elements of the patient's disease.
_____Unrelated-reaction is unrelated to drug therapy (does not meet ADR definition)
_____Unclear

Follow-Up_____

_____
_____
_____
_____

Person Completing Follow-up_____ **Date**_____