UNDERSTANDING MEDICAL ERROR

Karachi Bioethics Group

Preface

This handbook is an overview on medical error. It addresses concepts related to the subject and attempts to clear understanding of related terminologies . The text also highlights the importance of reporting , its analysis and how to disclose medical errors . In addition a legal opinion on Pakistani laws pertaining to the subject is also given . The readers will find this book of immense help in not only identifying medical error but also managing it.

The Karachi Bioethics Group (KBG), a voluntary group of healthcare related professionals provides a common platform for discussion on bioethics issues. In December 2013, the group identified the need for a booklet on medical error . It was observed that there is a lack of understanding and dialogue on the subject . This was highlighted by the growing distrust of the society toward the healthcare professionals and ambiguity of media reporting on the events and incidents related to healthcare.

For the purpose, a sub-committee was identified including Dr. Naima Zamir and Dr. Tayyaba Batool, pediatric surgeons at the National Institute of Child Health (NICH), Dr. Yasmin Wajahat, an obstetrician and gynecologist at Sindh Government Qatar Hospital, and two general surgeons Dr. Nida Wahid Bashir and Dr. Bushra Shirazi at Patel Hospital and Ziauddin Medical University respectively. Ms. Sharmeen Khan, an advocate, gave the legal opinion on Pakistani law .

Over the last one year the committee members met approximately 15 times reviewing the literature and jotting down various points on the subject. In this tenure of meetings an initial draft was made and shared with the Karachi Bioethics Group. Followed by several communications with the larger group and incorporating their comments, today in hand we hold the final product in print.

Table of contents

Introduction:

Errors must be accepted as evidence of system flaws, not character flaws.[1]

Medical errors affect clinical practice and can occur with anyone involved in the medical profession. Understanding what constitutes medical error, its timely identification and judicious reporting is the mainstay of safe and ethical medical practice. This handbook is an initiative not only to guide and understand medical errors; its implementation will also help to improve the standard of care.

Every day, Pakistani media are reporting incidents of death or disability of patients without any discrimination between medical error, i.e. an unintentional act of omission or commission in the delivery of care and medical negligence i.e. a failure to meet the standards of care. Concepts regarding the two are unclear not only to the media, but also to doctors, paramedics and all related personnel. In

addition, in Pakistan, there is no definite mechanism or guideline that helps healthcare providers to analyze and deal with these events.

A report from Harvard School of Public Health referenced in the Times of India states that approximately 43 million people are injured from medical errors world over causing 23 million deaths.[2] The same article proceeds to say that two thirds of these cases occur in developing countries.

In the United States, medical error is the third leading cause of death after cancer and heart attack.[3]In addition, we see literature quoting that approximately 2 to 4.5 million people face preventable medical harm.[4] One of the studies suggests that 70 % of adverse events result from medical error and are preventable.[5] In European Union countries, like the United Kingdom, Spain and France the reported incidence of medical error are about 8% to 12% of hospitatization[6] while Canada has 17% incidence of self reporting medical errors.[7]

Not all medical errors result in harm; therefore, many of them go unnoticed. It is of equal importance to identify these near misses to prevent possible adverse events.

A key concern associated with medical error is a financial burden as shown by reports from the United States, illustrating a total annual cost ranging from $985 million in 2008 to over $1 billion in 2009.[8] This is a measurable impact of medical error. There are many immeasurable outcomes like death, disability, pain, and suffering of the patient and family. Furthermore, features like time away from work and home based medical investigation have not been taken into account in the available literature. Another major impact of medical errors is increasing public distrust in the medical system. In addition, healthcare providers also face moral discomfort and distress.

Tt is important to realize that the identification of medical error helps in bringing about policy changes in the system that prevent repetition of

such events in the future. It should be understood that it is impossible to achieve risk free interactions between humans and machines so the aim should be to keep the incidence of error As Low As Reasonably Possible (ALARP).

DEFINITIONS

Before proceeding to error reporting guidelines, it is essential to have a clear concept of important terminologies and the differences between them.

Medical error:

> An act of omission or commission in planning or execution that contributes or could contribute to an unintended result.[9]
> The failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.[10]

Examples:

> Reading 15 microgram medication as 15 milligram and giving the wrong dose.
> Marking the wrong side of a reducible inguinal hernia for surgery.

Medical negligence:

Medical negligence is a legal term and is defined here to differentiate it from medical error.

> Failure to meet the standard of care reasonably expected of an average physician qualified to take care of the patient in question.[9]
>
> In law medical negligence is determined as a three-part test establishing that the doctor owed a duty of care, it was breached, and as a direct result of breach the patient suffered a harm.[11]

Examples:

> Leaving a swab in the abdominal cavity during closure.
> Uterine rupture, resulting from an attempt at vaginal delivery in a patient with previous three cesarean sections.

Malpractice:

Refers to an act of negligence by medical professionals which results in further deterioration in the patient's health and may eventually result in his death. At times, it may be related to misdiagnosis of particular diseases. At other times it may be a case of criminal offence done on purpose for financial gains.[12]

Examples:

With a clear history of foreign body aspiration, choking and respiratory distress in a child, physician continues to treat the child with medical therapy instead of taking necessary steps for extraction of foreign body.

Doing multiple root canals on a tooth that needs extraction.

Adverse Event:

An unintended injury to the patient caused by medical management rather than the underlying condition of the patient resulting in a measurable disability, prolonged hospitalization, or both.[9]

Examples:

In a patient with pneumonia when the doctor gives an antibiotic to treat the patient and the patient has an anaphylactic reaction and the outcome is the need of ventilator support.

Rectal perforation caused during a barium enema in a child suspected with Hirschsprung's disease.

Near Miss:

Any event that could have had an adverse consequence for the patient, but did not, and was indistinguishable from a full-fledged adverse event in all but the

outcome.[9] In other words, a variation in health care delivery which did not affect the outcome, but for which a recurrence carries a significant chance of a serious outcome.[13]

Examples:

In a patient with pneumonia when the doctor prescribes a penicillin group antibiotic to treat the patient and the patient while purchasing the medicine from the pharmacy reveals that he is allergic to penicillin.

A doctor writes an illegible prescription that could lead to a harmful overdose, but an alert pharmacist identifies the danger and calls to double check the dose.

Complication:

Complications in medicine are defined as an unanticipated problem that arises following and can be the result of a procedure, treatment, or the illness. A complication is so named because it "complicates the situation".[14]

Examples:

Seroma (fluid collection) formation following mastectomy.

Allergic reaction during blood transfusion.

WHY MEDICINE IS SUSCEPTIBLE TO ERROR

The practice of medicine is inherently interdependent at many levels and it is for this reason that the field of medicine is susceptible to errors. The causes of medical error are varied and include:

System constraints
Staffing problems
Fatigue of health care provider
Lack of knowledge
Inadequate communication and continuity of care
Lack of experience
Complexity and urgency of care
Improper documentation
Illegible handwriting

AREAS SUSCEPTIBLE TO ERROR

It is usually presumed that the medical error is associated with the work done by doctors and nurses in the ward and clinical areas, but it is important to note that every support service associated with healthcare is susceptible to it. It includes the following:

Clinical practice
Nursing
Pharmacy
Hospital administration
Laboratory
Radiology
Infection control
Diet office
Security (e.g. inadequacy of traffic control in clinical areas)

RELUCTANCE TO REPORT

Medical professionals hardly ever report their errors. There are multiple factors responsible for this reluctance including fear of losing one's reputation, losing patient's trust, and being labeled as incompetent. In our culture, blaming the individual rather than the system hinders reporting. It is also seen that there is a lack of understanding of the terminologies 'medical error' and 'negligence'. Finally, a pertinent reason for not reporting is that no mechanisms of reporting exist or it is considered cumbersome and stigmatizing.

Classification of Medical Error (According to Leap 1993)[15]

DIAGNOSTIC	Error delay in diagnosis
	Failure to employ indicated test
	Use of dated tests or therapy
	Failure to act on results of monitoring of testing
TREATMENT	Error in the performance of an operation, procedure or test
	Error in administering the treatment
	Error in the dose or method of using a drug
	Avoidable delay in treatment or in responding to an abnormal test

	Inappropriate care (not indicated)
PREVENTIVE	Failure to provide prophylactic treatment
	Inadequate monitoring or follow-up of treatment
OTHERS	Failure of communication
	Equipment failure
	Other system failure

REPORTING ERRORS

Importance of Reporting:

The reporting of an error is a fundamental step towards error prevention. Reporting those errors that result in patient harm, as well as trivial errors and near misses have the potential to strengthen processes of care and improve the quality of care in future patients. This effectively improves the health care system in the long run.

Ethics of reporting:

Error reporting in medicine encompasses ethical concepts of professionalism, non-malfeasance, patient advocacy and organizational ethics edging towards obligation. Professionalism demands truth telling, auditing and learning from the practice, therefore any time an error is committed or observed, steps should be taken to report, analyze and learn from it.

The Hippocratic Oath binds doctors to do no harm. Patient advocacy is a core concept of

ethical medical practice and demands that a health care worker should report any error observed in clinical practice so that the harm can be prevented or corrected in that particular patient and in future patients.

All this is applicable to and becomes a responsibility of any organization involved in health care delivery. Any ethical organization is required to provide care with compassion. Tt is important to realize that any system of error reporting and analysis will be ineffective without the commitment of policy makers in the organization.

Essentials of error reporting:

Reasons for inadequate error reporting include systems focusing on events that lead to grievous harm and reacting to it, fear of penalization of junior staff and naming and shaming. It is recommended that the following suggestions can help to address these concerns:

- Low threshold
    - Near misses and minor events should all be recorded.
- ♦ Blame-free
    - Reporting error should be taken as a sign of professionalism and responsibility and not as a means to punish others.
- Applied to all levels
    - Not just juniors
- ♦ Systematic analysis for system improvement.[16]

Guidelines for reporting errors:

Error can be reported by a person who has observed it or was involved in it. Reporting policies may differ in different institutions and may be mandatory or voluntary. Before initiating a policy on medical error reporting, it is imperative for institutions to first create awareness about concepts related to the topic amongst all healthcare workers, followed by dissemination of information about the mechanism of reporting.

The first step is to initiate a reporting form. The person who observed the error or by whom the error occurred can fill this form. The form should be available at all times and placed in a neutral venue with drop box facility to submit it. At this point it is important to emphasize that every individual should feel secure in his job or reputation to be willing to fill the form. If this is not the case then reporting mechanisms will fail.

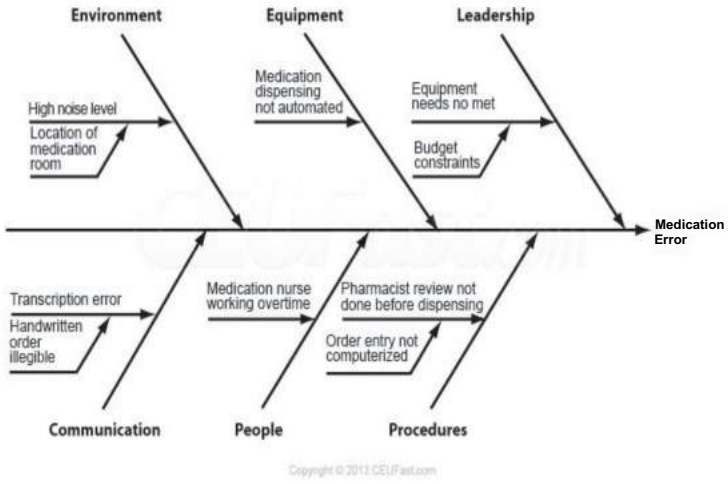
Error Analysis:

Analysis of reported medical errors is crucial to identify deficits in the system and suggest policy changes. This is accomplished by identifying the root cause for the occurrence of the error and suggesting corrective and preventive measures.

Root cause analysis:

It involves looking at what happened, why it happened, what has been learned and what changed.[17] It includes gathering information, looking at different aspects of the problem, listing sequence of events, looking at contributing factors, identifying root cause and developing corrective action plans and follow-up plans.[18]

Various formats exist to conduct analysis of errors including the framework provided by Joint Commission for International Accreditation (JCIA) and the fish bone framework given by WHO as shown below.[19]



Error analysis team:

Formulation: The team can vary from institution to institution in its composition. It may comprise of a clinician, a pharmacist, a nurse, a member of quality assurance, a member

of an ethics committee and a person from the administration.

Responsibilities: The responsibilities of the team include a detailed root cause analysis of the event through interviewing individuals involved, examination of the site and review of records, followed by suggested corrective and preventive measures. In addition to the above, the team should do a regular audit to look at the frequency and type of medical errors and re-evaluate the status of implementation of suggested policy changes.

Reporting relationship: The team reports to the clinical head of the institute to ensure changes in policy.

Tools to Minimize Error:

- Check lists
- Digitalization of data and procedures
- Departmental audits
- Morbidity and mortality conferences - since early 19OO[20,21,22]
- Performance standards
    - National and international licensing, certification and institutional accreditation
    — Quality assurance programs
    - Patient safety practices and programs
- Disclosure policy

Disclosure:

Disclosure is a process of sharing information about medical error with the patient and/or patient's family. The underlying ethical principles include the right of the patient to know about facts related to his /her medical care and the duty of the care provider to give honest, full and timely information.[23] Disclosure involves acknowledgement of the error, providing its full details to the patient, possible outcome, remedy, ways to manage the complications (if they occur). Communication entails truth telling and opcmicss and should be blame free. The central element of the error disclosure is the relationship of trust between physician and the patients.[24]

Both the physician and the patient benefit from the disclosure of error. It decreases the distress and confusion in the physician and the patient[25] and also decreases the possibility of litigations.[26] In addition, it increases the chances of learning from errors (also the way it was managed), and

the transmission of this information to others in order to prevent such errors in future.

The two main barriers to disclosure are, lack of communication skills in health care providers and the fear of loss of reputation.[27] Therefore, there should be a specific system of disclosure that can provide benefits to all the parties involved in a particular event. The systemic approach results in better understanding by the patients and improvement in the system of health care.[28] In an institute, the system should be taken as accountable and not the individuals.

Disclosure may be done by the primary physician, the person committing the error or by the institutional spokesperson. The disclosure should be in the patients' language in clear and simple words for them to understand and contribute to further management.

Disclosure is a continuing process and not a onetime discussion. The patient should be informed at every step of progress. An example

of the disclosure process and the checklist is included in the booklet. Each individual or institution can modify these according to their circumstances and needs.

CHECKLIST FOR DISCLOSURE PROCESS

- The immediate patient care needs to be met.
- Ensure patient and staff's protection from harm.
- Gather complete information and identify a focal person in the team who will be the representative communicator.
- After compilation of information arrange meeting with the affectee or the family. (Caution: Be aware of emotional needs and support systems should be available)
- Explain in simple language the sequence of events and avoid any blame.

- Apologize using the word “1 am sorry” and invite family to ask any number of questions. Keep in mind the cultural needs.

- Inform the family on the corrective measures taken.[29]

COMPENSATION IN MEDICAL ERRORS

Compensation can be a demand of the affected or the family but also a positive gesture on the part of the individual healthcare worker or organization. Disclosure and apology, waiving of fee by individuals and institutional mechanisms to deal with these cases are various ways of offering compensation.

An expectation or plea of the family is often that such an event never happens again. This can be achieved through reporting and analyses mechanisms.

An interesting and encouraging compensation system is the “no fault” system practiced in

Denmark, Sweden, New Zealand and Finland where clinicians help the patient in compensation claim as a duty of care.

LEGAL IMPLICATIONS TN PAKISTAN

In Pakistan, the legislation on medical negligence is not fully developed and in fact the frenzy created due to heightened awareness of medical negligence did not conclude in a separate standalone law on this area. So medical error, negligence and malpractice, though distinct terms in law are all redressed either within the criminal law space (Pakistan Penal Code which prescribes specific penalties based on the harm caused due to negligence as well as provides for *Diycit* for injury or death) or under the civil process where patients and families impacted by a medical error of a doctor may seek damages under the general laws of Torts by satisfying certain principles established under the common law (such as a duty existed for care that was breached and that caused the damage for which relief is sought. The laws dealing with

this area are Specific Relief Act and the precedents established in Pakistan on civil redress.)

For establishing the wrong under either civil or criminal procedures, the chain of causation has to be established, showing that the harm that was caused was a direct result of the negligence. However, in both arenas of law it is the healthcare specialists (through expertise sought by the court in the shape of expert witnesses etc.) who provide information for the 'standard of care' that is deemed to be required. In any case through the Pakistan Medical and Dental Counsel (and the rules that it crafted) there is a level of self-regulation too that is practiced and this means that the PMDC has a right to debar a doctor under its rules for negligence (but it has not defined the terms either.)

As a note of clarity, the Penal code has not criminalized medical negligence specifically but it has categorized all harms in specific areas of injury and death, grievous bodily harm,

manslaughter etc. In recent history, doctors in the case of Tmanae Malik were charged with murder, manslaughter and aiding and abetting criminal acts - so this is a way of prosecution. However, there is no specific law on medical negligence. This area needs more development in Pakistan because if you ask who benefits more by lack of legislation in this area, the answer would be that neither the healthcare community nor the patients are beneficiaries where such wide discretionary powers are provided to the judiciary or members of the PMDC. In fact, Pakistan needs well-drafted legislation in the area of medical laws.

CONCLUSION

This booklet offers readers introductory knowledge regarding medical error and a realization of the enormity of the issue. We hope it will help people to initiate protocols on reporting medical errors, and form committees to manage events appropriately. Disclosure, employee security, good clinical practice and an appropriate standard in health care will also help in rebuilding doctor-patient trust.

In the end, we recommend that:

The process of minimizing errors must be taken as a responsibility of every individual involved in the health care system.

Medical error reporting systems must be incorporated in hospital policy. All healthcare providers should be trained in the process of quality care, safety and understand the value of a good outcome.

It may lead to safe practice, a practice which abides by the standards of care because of better understanding, rather than by fear of legislation.

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Appendages

Appendage 1:

Medical Error Reporting Form

1. Identification details
    a. Name of the unit where error occurred :
    b. Date of error :
    c. Time of error :am/pm
2. Patient related details (if involved or affected by the error)
    a. Name of the patient:

    b. M.R. # of the patient:

3. Services involved (more than one boxes can be tick marked)
    a. Clinical *I* Medical
    b. Nursing
    c. Diagnostic
        i. Laboratory

ii. Radiology

d. Bloodbank

e. Support services

i. Infection control

ii. Pharmacy

iii. Food services department

iv. House keeping

v. Physiotherapy

vi. Stores

vii. Finance

viii. Human resource

f. Others (Describe):

_____

4. Description of event (if needed) :

_____

_____

_____

_____

Signature and contact number of reporting person
(optional):

_____

Appendage 2:

Error analysis form

(For the use of error reporting and analysis team)

1. Date of analysis:
2. Error analysis details
    a. Root cause (look at the attached form)
    b. Type of error
        i. Medication error
            1. Prescription
            2. Dispensing *I* preparation
            3. Dose
            4. Route of administration
            5. Timing of administration
            6. Error in communication
        ii. Nursing care error (other than medication)
        iii. Error in medical / clinical care
            1. Error in diagnosis
            2. Delay in diagnosis

3. Error in management
4. Error in j udgment
5. Delay in management
6. Error in technique
7. Error in communication

iv. Error in diagnostic services

1. Delay in provision
2. Error in testing
3. Error in technique

v. Blood bank related errors

1. Lack of provision
2. Delay in provision
3. Error in provision
4. Error in technique

vi. Support service related errors

1. Lack of provision
2. Delay in provision
3. Error in provision
4. Error in technique

c. Suggested corrective measures:

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d. Suggested preventive measures:

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e. Lessons learnt:

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f. Name and designation of authorities to whom these suggested measures were forwarded:

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_____

g. Follow up

i. Status of suggested measures at six months from the date of analysis:

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ii. Status at one year:

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iii. Further measures taken

Appendage 3:

WHO guideline for surgical procedure safety

SURGICAL SAFETY CHECKLIST [1]

BEFORE INDUCTION OF ANAESTHESIA

BEFORE SKIN INCISION

BEFORE PATIENT LEAVES OPERATING ROOM

SIGN UN	TIME OUT	SIGN OUT
PATIENT HAS CONFIRMED c IDENTITY c SITE PROCEDURE c CONSENT	CONFIRM ALE TEAM MEMBERS HAVE INTRODUCED THEMSELVES BY NAME AND ROLE	Nurse Verbally Confirms with the Team: o The name of the procedure recorded o That instrument, sponge and needle counts are correct (OR not applicable), o How the specimen is labeled (including patient name) o Whether there arc any equipment problems to be addressed.
Site marked/Not applicable	Surgeon, anesthesia professional and nurse verbally confirm o Patient o Site o Procedure	

Anesthesia Safety Check Completed	ANTICIPATED CRITICACAL EVENT o Surgeon reviews: What are the critical OR unexpected steps, operative duration, anticipated blood loss? o Anesthesia team reviews: Arc there any patient specific concerns? c Nursing team reviews: Has sterility (including indicator results) been confirmed? Are there equipment issues Or any concerns‘?	Surgeon, anesthesia professional and nurse review the key concerns for recovery and management of this patient.
Pulse Oximeter on Patient and Functioning		
Does Patient Have A: Known allcrgy? No Yes Difficult Airway/Aspiration risk? k No 2. Yes, and equipment /assistance available? Risk of >500ml Blood loss (7ml/kg in children)? No Yes, and adequate intravenous access and fluids planned	Has Antibiotic Prophylaxis been given within the last 60 minutes? Yes Not applicable Is essential imaging displayed? Yes Not applicable	

Appendage 4:[2]

Medications errors prevention guidelines

The following suggestions can help to minimize errors in communication of drug orders:

Storage of medications

- Use both generic names and brand names of drugs and store them in accordance to the disease, not in alphabetic order.

Writing of Prescriptions

A prescription should include:

- Date, drug name in block letter, strength in metric system (example: milligrams or grams)
- Frequency of full words, (for example four times a day, twice a day), route of administration
- Leading zero if a number is less than one (0.1), avoiding a trailing zero after a decimal (5-0)
- Signature and professional designation of authorized prescriber

- PRN/ SOS orders should indicate a specific time interval.
- All known patient allergies in admission and transfer order. The designation "no known allergies" should be used as appropriate.
- An existing order may not be corrected, altered, added to, or modified in any way.
- If change is necessary, the order must be discontinued and a new order written by the authorized prescriber.
- When discontinuing a medication, the prescriber should write the name of the drug being discontinued.
- Verbal medication orders should be discouraged unless there is no other alternative available.

Medication Administration/Documentation

- Check the time, dose, and route of packaged medication against that transcribed on the institution/facility document and check the patient allergy.
- Check the patient name band to verify patient identity.
- Document medication administered on the appropriate documentation tool and any adverse reaction noted.
- All corrections and late entries should be clearly marked as such.
- Do not erase, obliterate, or attempt to edit notes previously written.
- Indicate errors by drawing a single line through the error, writing the word "error" above the error, and initialing the error.
- Late entries, entries made out of time sequence, or addenda should be clearly marked as such in the record, and properly dated, timed and signed.
- Explanation of any omitted doses

Appendage 4[3]

For diagnosis error

- Obtain your own complete medical history.
- Perform a focused and purposeful physical examination.
- Generate initial hypotheses and differentiate those with additional history, physical exam, and diagnostic tests.
- Pause to reflect—take a diagnostic "time out."
- Was I comprehensive?
- Did 1 consider the inherent flaws of heuristic thinking?
- Was my judgment affected by any other bias?
- Do T need to make the diagnosis now, or can 1 wait?
- What is the worst-case scenario?
- Embark on a plan, but acknowledge uncertainty and ensure a pathway for follow-up.

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