FDA 101: Medication Errors

A medication error is any preventable event that may cause or lead to inappropriate medication use or harm to a patient. Since 2000, the Food and Drug Administration (FDA) has received more than 95,000 reports of medication errors. FDA reviews reports that come to MedWatch, the agency's adverse event reporting program.

"These reports are voluntary, so the number of actual medication errors is believed to be higher," says Carol Holquist, R.Ph., Director of the Division of Medication Error Prevention and Analysis in FDA's Center for Drug Evaluation and Research.

FDA works with many partners to track medication errors, including the U.S. Pharmacopeia (USP) and the Institute for Safe Medication Practices (ISMP). "Every report received through the USP/ISMP Voluntary Medication Error Reporting Program (MERP) automatically gets sent to FDA's MedWatch program," says Mike Cohen, R.Ph., Sc.D., President of ISMP. "It takes a cooperative approach to monitor errors, evaluate them, and educate the public about strategies to keep errors from happening again."

Medication errors occur for a variety of reasons. For example, miscommunication of drug orders can involve poor handwriting, confusion between drugs with similar names,

FDA Reduces the Risks by:

- ✓ **Reviewing drug names to minimize confusion**
- ✓ **Working with drug companies to improve labeling/packaging**
- ✓ **Requiring bar codes on certain products**
- ✓ **Analyzing reported errors**
- ✓ **Creating guidances for industry**
- ✓ **Educating the public**

poor packaging design, and confusion of metric or other dosing units.

"Medication errors usually occur because of multiple, complex factors," says Holquist. "All parts of the health care system—including health professionals and patients—have a role to play in preventing medication errors."

FDA'S ROLE

✓ **Drug Name Review:**
To minimize drug name confusion, FDA reviews about 400 drug names a year that companies submit as proposed brand names. The agency rejects about one-third of the names that drug companies propose.

✓ **Drug Labels:**
FDA regulations require all over-the-counter (OTC) drug products (more than 100,000) to have a standardized "drug facts label." FDA has also improved prescription drug package inserts for health care professionals.

✓ **Drug Labeling and Packaging:**
FDA works with drug companies to reduce the risk of errors that may result from similar-looking labeling and packaging, or from poor product design.

✓ **Bar Code Label Rule:**
In accordance with an FDA rule that went into effect in 2004, bar codes are required on product labels for certain drugs and biologics such as blood. When used with bar code scanner and computerized patient information systems, bar code technology can help ensure that the right dose of the right drug is given to the right patient at the right time.

✓ **Error Analyses:**
FDA reviews about 1,400 reports of medication errors per month and analyzes them to determine the cause and type of error.

✓ **Guidances for Industry:**
FDA is working on three new guidances—one on complete submission requirements for analyses of trade names, one about the pitfalls of drug labeling, and another on best test practices for naming drugs.

✓ **Public Education:**
FDA spreads the message about medication error prevention through public health advisories, medication guides, and outreach partnerships with other organizations.

EXAMPLES OF MEDICATION ERRORS

Misuse of Tussionex Prescription Cough Medicine:
On March 11, 2008, FDA informed health care professionals about adverse events and deaths in children and adults who have taken Tussionex Pennkinetic Extended-Release Suspension (Tussionex). Tussionex is a long-acting prescription cough medicine.

Hydrocodone, the narcotic ingredient in this medicine that controls cough, can cause life-threatening breathing problems when too much medicine is given at one time or when the medicine is given more frequently than recommended. Tussionex should not be used in children less than 6 years old.

Reports indicate that health care professionals have prescribed Tussionex for patients younger than the approved age group of 6 years old and older, more frequently than the labeled dosing interval of every 12 hours ("extended release"), and that patients have administered the incorrect dose due to misinterpretation of the dosing directions and the use of inappropriate measuring devices. Overdose of Tussionex in older children, adolescents, and adults has also been associated with life-threatening and fatal breathing problems.

For more information, see FDA Issues Alert on Tussionex at *www.fda.gov/bbs/topics/NEWS/2008/NEW01805.html* and the FDA Public Health Advisory at *www.fda.gov/cder/drug/advisory/hydrocodone.htm*

Overdoses of Cough and Cold Products in Children:
Roughly 7,000 children ages 11 and younger are treated in hospital emergency rooms each year because of overdoses of OTC cough and cold medication, according to a recent study by the Centers for Disease Control and Prevention. About two-thirds of those incidents occurred when children took medication without a parent's knowledge. Parents should keep medication out of children's reach and should never describe medication as "candy."

OTC cough and cold products can be harmful if more than the recommended amount is used, if they are given too often, or if more than one product containing the same active ingredient is used. In January 2008, FDA issued a public health advisory recommending that OTC cough and cold products not be used in infants and children under 2.

Serious injuries and deaths have resulted from such errors as misunderstanding directions and failing to use the measuring devices that come with the medicine.

For more information, see OTC Cough and Cold Products: Not for Infants and Children Under 2 Years of Age at *www.fda.gov/consumer/updates/coughcold011708.html*

Overdoses of Acetaminophen:
Taking too much of the pain reliever acetaminophen can lead to serious liver damage. The drug is sold under brand names such as Tylenol and Datril, and is also available in many cough and cold products, prescription pain relievers, and sleep aids.

To avoid accidental overdosing, consumers should not take more than the recommended dose on the label. Also, acetaminophen should not be taken for more days than

recommended, and should not be taken with other drug products that also contain acetaminophen without direction from a health care provider.

Parents should be cautious when giving acetaminophen to children. For example, the infant drop formula is three times more concentrated than the children's liquid. So parents need to be sure to give the appropriate dose.

Misuse of Fentanyl Patches:
FDA has issued warnings about the fentanyl transdermal system, an adhesive patch that delivers an opioid called fentanyl through the skin. An opioid is a potent pain medicine. It is also sometimes called a narcotic drug. Other examples of opioids include hydrocodone, morphine, and oxycodone.

The directions on the product label and package insert of the fentanyl transdermal system should be followed exactly in order to avoid overdose. Fentanyl patches should not be used for short-term acute pain, pain that is not constant, or for pain after an operation. The patch is only for moderate-to-severe chronic pain that is expected to last for any number of weeks or longer and that cannot be managed by acetaminophen-opioid combinations, nonsteroidal analgesics, or as-needed dosing with short-acting opioids.

Fentanyl patches are mostly prescribed for patients with cancer. Recent reports to FDA describe deaths and life-threatening side effects after doctors and other health care professionals inappropriately prescribed the patch to relieve pain after surgery, for headaches, or for occasional or mild pain in patients who were not opioid tolerant.

In other cases, patients have used the patch incorrectly. The patients replaced the patch more frequently than directed in the instructions, applied more patches than prescribed, or applied heat to the patch. All of these cases resulted in dangerously high fentanyl levels in the blood.

For more information, see FDA Issues Second Safety Warning on Fentanyl Skin Patch at *www.fda.gov/bbs/topics/NEWS/2007/NEW01762.html*
and the FDA Public Health Advisory at *www.fda.gov/cder/drug/advisory/fentanyl_2007.htm*

Overdoses with Methadone:
FDA has issued a public health advisory cautioning practitioners to avoid overdoses when they are prescribing methadone or managing patients taking the drug.

Since the 1970s, methadone has been primarily used in treating drug abuse, but it is increasingly being used to treat pain. FDA issued the advisory because of reports of life-threatening adverse events and death in patients receiving methadone for pain control.

Like other opioids, methadone causes slowed breathing, affects heart rate, and can also interact with other drugs. An overdose can occur because methadone stays in the body longer than the pain relief lasts.

For more information, see FDA's Public Health Advisory on methadone at *www.fda.gov/cder/drug/advisory/methadone.htm*

Mix-ups Between Edetate Disodium and Edetate Calcium Disodium:
Both edetate disodium and edetate calcium disodium work by binding with heavy metals or minerals in the body, allowing them to be passed out of the body through the urine.

Edetate calcium disodium was approved to treat severe lead poisoning. Edetate disodium was approved as an emergency treatment for certain patients with very high levels of calcium in the blood or certain patients with heart rhythm problems resulting from high amounts of the medication digoxin in the blood.

But a number of uses that are not approved by FDA have emerged. These include the removal of other heavy metals from the blood and the treatment of heart disease, commonly referred to as "chelation therapies."

In January 2008, FDA issued a public health advisory, warning that some children and adults have died when they were mistakenly given edetate disodium instead of edetate calcium disodium (calcium disodium versenate), or when edetate disodium was used for chelation therapies and other uses not approved by FDA.

The drugs are easily mistaken for each other because they have very similar names and are both commonly referred to only as "EDTA." One of FDA's recommendations is that the abbreviation not be used.

For more information, see FDA's Public Health Advisory on Edetate Disodium (marketed as Endrate and generic products) at *www.fda.gov/cder/drug/advisory/edetate_disodium.htm*

This article appears on FDA's Consumer Health Information Web page (*www.fda.gov/consumer*), which features the latest updates on FDA-regulated products. Sign up for free e-mail subscriptions at *www.fda.gov/consumer/consumerenews.html*.

For More Information

6 Tips to Avoid Medication Mistakes
www.fda.gov/consumer/updates/medtips062107.html

Medication Errors (FDA)
www.fda.gov/cder/drug/MedErrors/default.htm

Reporting Adverse Experiences to FDA
www.fda.gov/medwatch/how.htm

Institute for Safe Medication Practices
www.ismp.org

National Coordinating Council for Medication Error Reporting and Prevention
www.nccmerp.org

INTRODUCTION: BACKGROUND AND SCOPE OF THE PROBLEM

In 2001, the Florida Legislature passed a law mandating that all licensed health professionals complete and repeat every three years a 2-hour course on the topic of prevention of medical errors. Several years previous to this decision, the Institute of Medicine (IOM) published a document entitled To Err is Human: Building a Safer Health System [1]. The authors reviewed the prevalence of medical errors in the United States which revealed that somewhere between 44,000 and, quite possibly, upwards of 90,000 deaths attributed to medical errors occurred annually in hospitals. A recently published (2004) HealthGrades report stated that annual deaths attributable to medical errors may be as high as 195,000 [2]. This number compared to other causes of death in 2001 (http://www.cdc.gov/nchs/fastats/deaths.htm) is exceeded only by heart disease (700,142) and cancer (553,768). A recent study (2010) from the Department of Health and Human Services found that one in seven Medicare recipients is harmed by hospital acquired infections, poorly administered medication and faulty bedside care during in-hospital medical care (New York Times) in total accountable for an estimated 180,000 patients deaths annually. While the figures of 180,000-195,000 deaths attributable to medical errors when compared to annual hospital admissions in excess of 33 million represents only 0.58%, it sends an important message to healthcare professionals to accept the responsibility to understand the increasingly broad definition of medical errors, their root causes, and to assist in building systems designed to reduce the incidence of medical errors, i.e. adverse events. “Hospitals and doctors and nurses are focused on preventing harm”, says Nancy Foster of the American Hospital Association, “but as the report (HHS) suggests, we do have a ways to go before we are where we want our performance to be” [3].

The course you are taking is designed to satisfy the requirements of the Florida law and to better inform you about the necessity for and wherewithal to effect a

reduction in medical errors and to become knowledgeable regarding existing preventative measures.

WHAT IS CONSIDERED A MEDICAL ERROR?

As defined by the IOM, “the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim”: medical errors which result in harm to the patient are not routinely or automatically considered examples of medical malpractice or negligence. They can occur anywhere in the trajectory of providing medical care, i.e. from diagnosis to treatment, including even when attempting to provide preventative care, i.e. an overlooked allergy when administering a vaccine or the occurrence of C. difficile toxin-mediated diarrhea following the administration of antibiotic prophylaxis. The failure of a planned action falls into two categories: “error of execution” or “error of planning”, the former defined when a correct action plan did not proceed as anticipated; the latter defined when the action intended originally was incorrect [1]. Medical errors, “adverse events” which, in retrospect, are considered preventable are labeled ***sentinel events,*** those which signal a need for immediate investigation [4]. A sentinel event is defined further as “an unexpected occurrence involving death or serious physical (loss of limb or function) or psychological injury, or **the risk thereof**, the latter phrase including the recognition of a variation in process when an unanticipated recurrence carries the risk of a serious adverse outcome (Joint Commission on Accreditation of Healthcare Organizations: ***Root Cause Analysis in Health Care: Tools and Techniques, 2000***). An excellent example (CME Resource, 136:(1) 1-12, 2011 Course # 9133) would be the death of a patient who underwent a successful surgical procedure but died from pneumonia acquired during the postoperative period, an adverse event. Was this event **preventable,** i.e. failure to utilize proper hand-washing techniques?; allowing visitation by relatives with URIs?; or **unpreventable,** i.e. the result of age and comorbidities? The careful examination i.e. **root cause analysis,** of adverse events sets the stage for the discovery of underlying causes of preventable

medical errors. The Joint Commission has established guidelines to facilitate both the recognition and analysis of these events [5]. A thorough and credible **root cause analysis** provides the opportunity to identify the need for improvements in processes or systems; justify requests to hospital administrators to modify hospital staffing patterns and/or to upgrade technical supporting systems; and to develop onsite education for healthcare professionals and ancillary support personnel.

ROOT CAUSE ANALYSIS: Definition and Utilization

Applying the “Golden Rule”, those with the gold make the rules. Accreditation status is accorded healthcare facilities by the Joint Commission which holds accredited facilities responsible for establishing and maintaining a safe environment for patients. To that end, the Joint Commission has identified a subset of sentinel events subject to their review [4]:

1. When the event has resulted in death or permanent loss of function and does not seem related to natural course of the patient’s or underlying condition **or**

2. The event is one of the following:

a. The suicide of the patient being cared for in a staffed around-the clock setting or within 72 h of discharge;
b. Surgery on the wrong patient or wrong body part;
c. The unintended retention of a foreign object in a patient who has undergone surgery or another procedure;
d. A hemolytic transfusion reaction involving the administration of blood or blood products having major group blood incompatibilities;
e. The unanticipated death of a full-term infant;
f. The occurrence of severe neonatal hyperbilirubinemia (bilirubin > 30mg%);
g. The discharge of an infant to the wrong family;
h. Abduction of a patient receiving care, treatment, and services;
i. The rape of a patient;
j. Prolonged fluoroscopy with excessive rads delivered to a single field or the administration of radiotherapy to the wrong body region or > 25% above the planned dose.

The Joint Commission further requires that accredited healthcare organizations have in place processes to recognize these events, conduct thorough and credible root cause analyses which focus on process and systems factors, and are able to provide a risk-reduction strategy and internal corrective plan with built in methods for assessing the effectiveness of these strategies and plans in actually reducing further risks and the incidence of adverse events [4]. Of interest is that the Joint Commission considers a root cause analysis to be acceptable if it focuses on **systems** and **processes**, and **not exclusively on individual performance** and is both **thorough** and **credible** [6]. Furthermore, it should think of sentinel or adverse events as the result of **special causes** in clinical processes as well as **common causes** in organizational processes. The suggested framework for a root cause analysis and action plan initiated in response to a sentinel event is designed to address the following questions: **What happened? Why did it happen? What were the most proximate factors? What systems and processes underlie the proximate factors?** The provision of answers for which correctable actions can be undertaken depend on a **level of analysis** which focuses on the following:

1. The sentinel event
2. The process or activity in which it occurred
3. Human factors
4. Equipment factors
5. Controllable environmental (factors which directly affected outcome)
6. Uncontrollable external factors (outside the control of the organization)
7. Human resource issues (staff qualifications, competence, actual performance, numbers, ideal v actual levels, adequacy of orientation and continuing education procedures)
8. Information management issues (availability, completeness, unambiguousness, accuracy)
9. Environmental management issues (appropriateness for processes being conducted, systems to identify environmental risks, testing and planning of emergency and failure-mode responses)
10. Leadership issues: Corporate culture
11. Encouragement of communication
12. Clear communication of priorities

A credible and thorough analysis of each of the levels of analysis enumerated above gives way to findings, the identification of root causes, an answer to the question “Why?”, and whether action needs to be taken. The actions taken should state clearly the **risk reduction strategy** being employed; and for each, **measures of effectiveness** must be included along with dates of implementation, planned follow up, and the associated measure of effectiveness. To be considered credible, the root cause analysis process must (1) involve the organization’s leadership and include the participation of individuals involved directly or indirectly in the process and/or systems under review; (2) the analysis must be internally consistent, not contradict itself or leave important questions incompletely addressed; (3) findings of “not applicable” or “no problem” must be accompanied by an explanation; and, finally, (4) should include reference to relevant literature. This process is to be completed within 45 days from the date the organization involved becomes aware of the sentinel event [4,6].

DIVISION OF PRACTITIONER DATA BANKS (DPDB)

The National Practitioner Data Bank (NPDB) and the Healthcare Integrity and Protection Data Bank (HIPDB) are components of the Division of Practitioner Data Banks (DPDB), the organization responsible for their implementation. They exist as flagging systems created to facilitate a comprehensive review of the professional credentials of health care practitioners, providers, and suppliers. The National Practitioner Data Bank, established in 1986 through Title IV Public Law 99-660, the Healthcare Quality and Improvement Act, began its operations in 1990. “The intent of the NPDB was to enhance the quality of health care, encourage greater efforts in professional peer review and restrict the ability of incompetent health care practitioners to move from State to State without discovery of previous substandard performance or unprofessional conduct” (U.S. Department of Health and Human Services). The NPDB collects and discloses certain information related to the professional competence and conduct of physicians, dentists, and other health care practitioners and includes information

of the following actions against them: (1) adverse licensure actions; (2) actions related to clinical privileges; (3) actions of professional societies; (4) paid medical malpractice judgments and settlements; (5) exclusions from participation in Medicare/Medicaid programs; and (6) registration actions taken by the U.S. Drug Enforcement Administration (DEA). While the data in the NPDB is available to hospitals, health care entities and professional societies with peer review, State licensing authorities, health care practitioners (self-inquiry), researchers (statistics only), and, in infrequent and limited circumstances, plaintiffs' attorneys, they are prohibited from disclosing specific information to the general public.

The Healthcare Integrity and Protection Data Bank was established in 1996 as an addition to the Social Security Act and a component of the Health Insurance Portability and Accountability Act; it became fully operational in March of 2000. "The intent of the HIPDB is to combat fraud and abuse in health insurance and health care delivery" (U.S. Department of Health and Human Services). This data bank contains the following information, and, similar to the NPDB, is prohibited from disclosing specific information to the public related to a practitioner, provider, or supplier: (1) civil judgments against health care providers, suppliers, or practitioners related to the delivery of a service or health care item; (2) Federal or State criminal convictions (see (1) above; (3) actions by Federal or State agencies against organizations responsible for licensing and/or certifying health care providers, suppliers or practitioners; (4) exclusion of providers, practitioners, or suppliers of health care from participation in Federal or State health care programs; and (5) any other adjudicated action taken against providers, suppliers, or practitioners of health care.

Through May 23, 2009, the NPDB for Florida listed more than 18,000 medical malpractice reports for physicians (MD and DO) and more than 500 Medicare/Medicaid exclusion reports.

FLORIDA LAW

In addition to what has already been discussed regarding the reporting of adverse incidents (sentinel events) to the Joint Commission, Florida law mandates the reporting to its Agency for Health Care Administration (AHCA) within 15 calendar days from their occurrence a set of serious adverse events associated with and occurring possibly as a result of medical intervention and which have resulted in an adverse outcome. To assure that this occurs, the JCAHO accredited facility must have in place a well developed risk management program which includes an incident reporting system requiring all healthcare providers and employees to report adverse incidents to the risk manager or his or her designee within 3 business days of the incident. Florida law defines an adverse incident as: ***An event over which healthcare personnel could exercise control and which is associated in whole or in part with medical intervention rather than the condition for which such intervention occurred*** [7]. The following injuries resulting from an adverse event must be reported to the Florida AHCA:

1. Death
2. Brain or spinal damage
3. Permanent disfigurement
4. Fracture or dislocation of bones or joints
5. A resulting limitation of neurological, physical, or sensory function which continues following discharge from the facility
6. When informed consent was not obtained for a non-emergent medical intervention which required specialized medical attention or surgical intervention;
7. Any condition requiring transfer of the patient to a facility providing a more acute level of care, the result of the adverse event and not the pre-existing condition;
8. Regarding a surgical procedure, was it:
    a. performed on the wrong patient?
    b. the wrong surgical procedure?
    c. performed on the wrong site?
    d. unrelated to the patient's diagnosis or condition?
    e. a surgical repair of damage resulting from a planned surgical procedure?
    f. performed to remove a foreign object remaining from a prior procedure?

Each reported incident is reviewed by the AHCA which determines the penalty to be imposed on the party held responsible for the adverse event. The organization feels that all healthcare professionals who practice in licensed facilities share the responsibility to ensure that risk management systems are in place to detect and report adverse incidents in an accurate an expedient manner [7].

During 2008, the Florida AHCA received reports of 579 adverse incidents of which 193 deaths were included, 1/3rd of which were considered the result of hospital error. The next most common injuries related to surgical procedures: unrelated to the patient's primary diagnosis or medical needs (24.01%); to remove a foreign object from a previously performed procedure (18.65%); and for surgical repair or damage resulting from a prior surgical procedure (10.02%) [8]. Based on sentinel events reported, the Joint Commission has compiled **Sentinel Event Alerts** which it sends to all accredited organizations. These reports emphasize areas of potential concern so that a facility providing health care can review constantly its internal processes as a means of reducing risks to patients, the number of adverse events, and to have in place preventative measures. The goals of the Joint Commission and Florida's AHCA are in concert to keep healthcare professionals aware constantly of and to be sensitive to circumstances in which adverse events can be anticipated and, thereby, prevented [9].

REDUCING AND PREVENTING ERRORS

An analysis of sentinel events reported to the Joint Commission from 1995 to March 31, 2010 indicated that 6782 events impacting 6920 patients resulted in 4642 deaths [10]. The six most common categories were:

1. Wrong-site surgery (13.4%)
2. Patient suicide (11.9%)
3. Operative and postoperative complications (10.8%)
4. Delay in treatment (8.6%)

5. Medication errors (8.1%)
6. Patient falls (6.4%)

Upwards of 70% of these sentinel events resulted in death or loss of function , and close to 75% occurred in general or psychiatric hospital settings (JCAHO 2009 data). These events are more likely to occur in error-prone situations and in healthcare facilities providing care to special populations,(i.e. the elderly, those with diminished cognitive function, developmental or learning disabilities, psychiatric patients, infants and young children). It has been determined as well that a better informed, educated public is more likely to become more involved in its own health care as relates especially to **medication use** and **events impacting on surgery** (peri-operative, pre-operative, operative, and postoperative). The Joint Commission (www.jointcommission.org) provides public education through their "***Speak Up™***" program.

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MENTAL AND BEHAVIORAL HEALTH – SPECIFIC ERRORS

Of the above common medical errors categories, patient suicide, delay in treatment, medication errors (see first document "FDA Medication Errors") and patient falls are the most relevant to mental or behavioral health practice. A failure to report abuse and a failure to identify medical conditions presenting as psychosis, while not included explicitly in the above list, also clearly fall in the purview of social workers, psychologists and mental health professionals and arguably constitute delays in appropriate treatment. With modifiable risk factors, root cause analysis may achieve error reduction for these errors. Through extra diligence by professionals and a willingness to identify personal shortcomings and evolve, the typical mental and behavioral health-specific errors may be greatly lessened.

As identified in Florida Administrative Code Rule 64B19-13.003, the most serious potential errors in psychological or behavioral settings include "inadequate assessment of suicide risk, failure to comply with mandatory abuse reporting laws, and failure to

detect medical conditions presenting as a psychological disorder" [35]. Failure to detect medical conditions presenting as a psychological disorder is akin to delay in treatment. These errors affect pediatric, adolescent, adult, and senior patients across the board.

SUICIDE OF A PATIENT

The event having quite possibly the greatest emotional impact on mental health professionals, not to mention patients' families, is the suicide of a patient. According to a 2010 Joint Commission Sentinel Event Alert, 75% of inpatient suicides occurred in psychiatric hospitals or behavioral health units of general hospitals [36]. After that the numbers are: surgical, intensive care, telemetry, or oncology units (14.25%); emergency departments (8%); and home care, rehabilitation units, and long-term or residential care facilities (2.5%). General hospitals are inherently less safe for suicidal patients than psychiatric hospitals or units, offering the patient more time alone and various potential suicide options (such as jumping, intentional drug overdose, cutting with a sharp object, hanging, strangulation) and means (tubing, bandages, plastic bags) as they are designed outside of psychiatric settings [36].

Patient suicide is perhaps surprisingly highest among those 65 years of age or older. That being said, for patients 17 to 39 years of age admitted to hospitals for one medical condition, suicidal ideation increases from a baseline of 16.3% in the general population to 25% and the rate increases to 35% for those admitted with two or more conditions [37]. The root causes of patient suicide that have been identified are listed below in order of frequency [38]:

1. Inadequate patient assessment
2. Poor communication between staff
3. Human factors
4. Poor leadership
5. Dangerous environment
6. Information-related factors
7. Poor care planning

8. Poor continuum of care
9. Lack of special interventions
10. Lack of patient education

The healthcare facilities which reported have recommended a number of risk reduction strategies which include: updating the staffing model, monitoring consistency of the implementation of observation procedures, revising information transfer procedures, engaging family and friends in the process of contraband detection, and implementing education of family and friends regarding suicide risk factors [36]. Healthcare and mental health providers can avoid painful and impactful inpatient suicides by putting in place some rather routine preventative strategies (e.g. removing harmful items and screening *carefully* in the admission process).

SUICIDE: ASSESSING RISK

Plenty of suicide risk assessment tools are available for health and mental health professionals to use; but very few have been empirically tested, if any [39]. It is not uncommon that these tools are not sufficient in preventing a suicide if and when they are used. While clearly the available assessment tools are best put to use by competent and trained mental health professionals, this is no guarantee for success. Here are some of the reasons given for professional assessments that missed the mark or were inadequate [40]:

1. Suicide risk assessment training was never provided to the mental health professional, physician, or nurse.
2. The risk of suicide is minimized or overlooked by the professional due to personal anxiety related to suicide in general.
3. The professional has a fear of documenting thought processes because those actions could come under scrutiny in a malpractice suit.
4. Risk assessment is performed but not documented.
5. The task of suicide risk assessment is delegated to another professional who is incapable of performing an adequate assessment or who does not complete the task.
6. Suicide risk assessment is simply not indicated.
7. A systematic suicide risk assessment is never performed.

8. The professional is reluctant to assess suicide risk due to excessive false positives.

The recommendation is that every patient be screened using a systematic and tailored suicide risk assessment that is administered by a trained professional and that scrupulous attention is paid to documenting the results of this assessment [40]. It is obligatory for a social worker or counselor to protect a client from self harm when a high-risk client has been identified and the professional must consult a supervisor or colleague. In such a case, confidentiality has not been breached for preventing harm is an ethical obligation and self harm threats should be viewed as seriously as homicidal threats.

The assessment should consider client job contentment (or lack thereof), interpersonal relationship satisfaction as well as a totaling of suicide risk factors, acute and chronic [39]. As severity of personal injury increases (for example, traumatic brain injury with enduring sequelae, loss of limb or loss of motor function, chronic pain, Alzheimer's, cancer and debilitating autoimmune diseases), so does suicide ideation [41]. The following should be considered high risk behaviors and warnings: threats of self harm, actively seeking a means to suicide (e.g. medications, medical instruments or other objects, removal of IV lines or life support apparatus), expressing thoughts about death, dying and suicide.

In one of the few studies that exist on the topic, a refusal or resistance to put into place a systematic suicide risk assessment program has been shown in a study of attending hospital psychiatrists [39]. This illuminates the need for mental health professionals, social workers, counselors, therapists and psychologists to advocate for their clients by ensuring that these risk assessments are not only performed but meticulously documented and that there are follow-ups done regularly.

FAILURE TO REPORT ABUSE

It is mandated in Florida and other states that teachers, nurses, physicians, law enforcement officers, social workers, psychologists and mental health professionals report abuse and in fact workers in these occupations are designated as “professionally mandated reporters of abuse” [42]. Suspected maltreatment, neglect, abandonment and exploitation of children and adults are all considered forms of abuse and must be reported.

In 2009 alone there were roughly 700,000 unique reported cases of child abuse in the US and nearly 1800 deaths resulted [43]. Approximately 81% of the perpetrators were parents and 6% were relatives. Of the reported abuses, more than half came from ‘mandated professionals’ including social service personnel (11.4%) and healthcare personnel (8.2%) – children rarely report abuse themselves [43]. Reports of abuse by professionals have been on the rise since 2005, a disturbing trend deserving attention.

Even when (suspected) child abuse is reported, only about a quarter of these are substantiated or legally deemed maltreatment [43]. But it is not punishable to make a good faith report and reports are confidential (except among protective services personnel) until indicated in judicial proceedings; therefore professionals should not be discourages from intervening [42]. It is an ethical duty to protect clients from harm; additionally failure to comply with mandatory abuse reporting requirements has legal consequences against which professionals may protect themselves by diligent documentation and reporting.

In the realm of adult abuse there are three categories cited by Florida Department of Children and Families: abuse of self, domestic abuse, and abuse/exploitation by a caregiver of a vulnerable individual [42]. In Florida, a vulnerable adult is defined as someone with “mental, emotional, long-term physical or developmental disability/dysfunction, brain damage or infirmities of aging” [42]. Exploitation means taking or selling property, misusing money, inappropriate use of guardianship or power of attorney and failure to use the vulnerable person’s funds for their care. This population has an abuse rate between 4-10 times that of the general population.

They refrain from reporting abuse fearing caretaker abandonment, not being believed and other reprisals [44], but mental health professionals are often the people to whom this abuse is reported.

The Michigan Department of Human Services has published a School Personnel Guide for reporting suspected abuse and neglect and the following list may be helpful in identifying telltale signs:

1. Emotional changes or suspicious injuries
2. Marks and bruises in various stages of healing, especially those resembling objects such as electrical cords or belts and reoccurring regularly
3. Cigar/cigarette burns
4. Burns in the shape of an object (e.g. clothes iron)
5. Missing clumps of hair
6. Marks from being tied down
7. Other injuries with no reasonable explanation [45]

Other conditions to be aware of are recurrent poor hygiene for those in others' care, untreated medical conditions, hoarding of food, sexual behavior or knowledge that is age-inappropriate and unaccounted for injury of genitalia. Harder to detect is abuse that is psychological in nature; but there may be physical manifestations of this abuse as well.

In summary it is crucial for the mental and behavioral health professional to understand that compliance with abuse reporting laws is mandatory, not optional. Additionally, reporting to a supervisor does not satisfy the requirement. Telephone is the method of preferred contact and should be used in emergency situations (anonymity is not guaranteed when a report is filed online). The Florida Department of Children and Families will then make the determination as to whether or not the report meets legal requirements for further action [42].

Florida Abuse Hotline phone number: 1.800.962.2873; TDD 1.800.453.5145; FAX: 1.800.914.0004; online: www.dcf.state.fl.us.

ERRORS IN IDENTIFYING MEDICAL CONDITIONS PRESENTING AS PSYCHOSIS

Many medical conditions cause psychiatric symptoms, or aggravate / create new psychiatric symptoms in people who already have mental illness [46]. Here is a non-comprehensive list of medical conditions that fit this bill:

1. CNS (central nervous system) disorders (e.g., seizure, aneurysm, subdural hematoma, tumor)
2. Infections (e.g., urinary tract infections, pneumonia, sepsis)
3. Cardiopulmonary disorders (e.g., hypoxia, myocardial infarction)
4. Metabolic/endocrine disorders (e.g., thyroid, adrenal, renal, hepatic disorders)
5. Adverse reactions to medications (e.g., corticosteroids, dopamine agnostics)
6. Illicit drug use or withdrawal (e.g., marijuana, amphetamines, heroin)
7. Chemical and plant toxicities (e.g., caffeine, psilocybin, aromatic hydrocarbons) [47]

It has been shown in at least one study that infectious conditions top the list in presenting as psychosis, with pulmonary, thyroid, diabetic, hematopoietic, hepatic and CNS conditions following and listed in order of frequency [48].

It can be challenging to quickly and successfully differentiate between patients with only medical conditions causing psychiatric symptoms and those with psychosis due to mental illness when these patients present to psychiatric hospitals or emergency departments of general hospitals. Many potential diagnoses must be ruled out during standard medical clearance at a psychiatric hospital or in general emergency departments following a mental status exam. This process of differentiation is made more difficult by co-morbid conditions (e.g. a patient who has pneumonia and is also schizophrenic) and by the gray area between some psychiatric and medical illnesses (for example, seizure disorders) [46]. Other reasons for successful differentiation include: physician and psychiatrist workload, institutional/administrative bureaucracy, the country's population's advancing age, complex and widespread prescription and illicit drug use and psychiatric evaluations administered by less-than-competent people.

Diagnoses are missed; treatments are delayed; psychiatric care may be administered as medical conditions remain undiagnosed, causing morbidity and mortality to increase.

It is estimated that 1 in 10 people admitted as psychiatric patients actually has an underlying medical condition [48], a number which is higher for elderly patients where infections, for example, can easily bring on delirium and the psychological symptoms are targeted rather than the medical condition [49]. The most frequent culprit is urinary tract infections, which can cause a sudden change in cognitive function in older patients, who are often diagnosed with dementia based on age [50].

A resource that should not be overlooked is health history and other information garnered from family, caregivers and acquaintances. Often, social workers and other mental health professionals can 'sit in' for family if they are familiar with the patients and family is not available.

THE ROLE OF PATIENTS AS THEIR OWN SAFETY ADVOCATES

Guidelines have been developed by a number of organizations to encourage patients to share in the responsibility toward insuring their own safety. The Agency for Healthcare Research and Quality has developed a "Patient Fact Sheet" which includes 20 tips for patients to help reduce the incidence of medical errors [34]. These are guidelines only, not intended to shift the responsibility to patients for reducing medical errors. The informed patient who is able to become involved in his or her own care with the assistance of loved ones and friends and who asks the right questions and accepts only those answers which make sense increases the likelihood of a better outcome.

USE OF AN INTERPRETER

From time to time the services of a skilled interpreter may become both necessary and desirable to assure that effective communication is occurring between healthcare professionals providing care and the patient receiving that care. It is essential to be confident that instructions and information conveyed to

the patient are understood. It is important for the physician “in charge” to respect the interpreter as a professional, a member of an interdisciplinary team providing care, who has been trained to negotiate cultural differences and be able to do so ethically, accurately, and with impartiality, able to translate and transmit important information expeditiously when required. The role of the interpreter is critical in circumstances when there is high risk for the occurrence of medical errors (e.g. obtaining informed consent for procedures, making decisions about treatment options, understanding the purpose of recommended therapies, etc).

IN CONCLUSION

Medical errors, adverse events, contribute significantly to morbidity and mortality. They are usually unanticipated and, more often than not, preventable. A careful study of the circumstances surrounding the care of the patient is undertaken when it is felt that the error was preventable, i.e. a sentinel event. A carefully performed root cause analysis is undertaken to identify factors which contributed to the occurrence of the event. The findings generated by the analysis provide information useful to improve systems and processes in the health care facility providing care. The major objectives of the root cause analysis are to identify and correct problem areas and not to assign blame. The Joint Commission has and continues to play an important role in the establishment of reporting guidelines and the publication of sentinel alerts. The Florida legislature has mandated additional reporting requirements for a specific set of medical errors. All healthcare professionals should be increasingly sensitive to the issue of medical errors, alert to circumstances which increase the risk for their occurrence, and work as a team to reduce the risks when identified. We should strive to encourage our patients to assume some responsibility for their own safety as well; education systems are available to make our patients better informed. We must work together so that the public we serve know of our concerns for their safety and trust the system in which healthcare is delivered.

Considering the ethical duty of medical and mental health care professionals to cause no harm, preventable mistakes by these professionals seem particularly troubling. Reluctance to seek help for medical and mental conditions may in part be attributed to widespread public knowledge of the millions of cases of medical errors and ethical offenses that occur every year. Human error will never be eradicated. But, errors can be reduced.

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