Risk of harm to patients

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Public Health - VLVZ9X1c
Spring semester 2014

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Introduction:

In our modern society and healthcare systems patients do not have anymore only one clinic, hospital, physician, surgeon, pharmacist or other care providers. They have to move between different healthcare providers and facilities. Along with the important advantages and advanced abilities that a system such as this can offer, the constant dynamics and movements of the patients may become a source of many problems we experience nowadays.

Discrepancy of methodologies for follow-up of patients and their health status, tracking medications and lack of communication are the main causes for adverse events that place the patients at risk for harm. [1]

Adverse events that lead to potential harm can occur in every possible setting starting from first responses, transportation, examination and diagnosis process, treatment, and rehabilitation settings.

Hospitalized patients and outpatients are exposed to many risk factors. In this article we will sample and review some of these problematic aspects, risk factors and possible ramifications.

Organization and management of healthcare systems

As mentioned before, the dispersion of the healthcare services for one patient between multiple health providers and entities constitutes practical issues of absence or lack of necessary information to provide optimal care. [1]

Even within one hospital the system can be disorganized and abrupt. Urgent patient may visit, all in one day, the emergency department, the medical admission unit, diagnostic laboratories, operation theatres, and other specialized wards. Each of these places has a different personal that the patient does not know and vice versa. The staff will not meet that patient again and may not interact personally with others professionals responsible for his care.

The main media for communication is the clinical record and prescriptions charts. Therefore, it is not surprising that errors arise in such a system. [2]

No universally recommended standards exist for proper medications history recording, transfer and discharge documentation or follow-up registration.

Addressing weak points such as uniform follow-up and discharge documentation can be suggested as one of the prevention measures for possible harm.

In the United States of America the National Patient Safety Goals exist, which supposed to provide a national resolution for that matter.

With the aim to improve patient safety, today many healthcare services use computerized prescriptions, documentation, medication review and reconciliation. Nevertheless, learning how to use these systems and implementing them requires learning and transition period, in which increased harm may be realized. It is necessary to create standardization and structure the systems in a way that will ensure proper continuity of care in order to optimize the treatments and eventually improve the survival and life quality of the patients [1].

Factor contributing to medical errors

A proper working and healing **environment** should be clear of distractions, noise or interruptions. There is a key role for a good organization of the working space- ergonomics [3].

Human errors are natural and cannot be eradicated completely. Nevertheless, efforts should be made to avoid the predisposing factors such as fatigue, time- pressure, attending to multiple patients at the same time [3-5]. Another main considerations should be given to communications between the doctor, the patient and the other personal [6-8].

The **patients** have, in most medical care settings, a crucial role in the prevention of medical errors and success of the treatment. For example, patients can decrease the incidences of wrong side, wrong person and wrong operations from being performed [3]. Trying to create trust with the patient, doctors prefer to hide their tendency to make errors and therefore the person how might suffer the harm is unable to take part in the prevention of errors. Compliance, communication and behavior are all key players in the success of the treatment [2].

Medication adverse events

Two wide groups of errors are defined by psychiatrists: Mistakes- errors of knowledge and planning; Slips or Lapses- errors made as a part of the execution of the plans. [2]

Errors of knowledge can be prevented by education. For example, physicians should be educated that Warfarin interacts with many other drugs such as macrolide antibiotics and azole antimycotics.

The World Health Organization personal formulary demonstrated an improvement in prescribing, which reduced the planning errors significantly [9].

In order to address to the slips it is necessary to implement a checking system. It was demonstrated in experimental studies that an independent checking can discover 90% of all prescription errors [10]. For instance, clinical pharmacologists or ward pharmacists are regarded by beginner doctors as a buffer between their pharmacological plan and patient harm.

Insulin is being used increasingly in the United States of America and the United Kingdom. It is the main recommended drug for glycemic control among type 1 and 2 diabetes mellitus patients. Majority of the patients self- administrate the medication or assist a relative for that

purpose. Almost all adverse events occur due to acute secondary care outside the hospital, while a small part arises in primary care settings under direct medical supervision [11, 12].

According to the US Pharmacopoeia MEDMARX reporting program 4,764 insulin administration errors occurred during a two-year period. 320 of the incidents resulted in harm to the patient (approximately 6.6%) [11].

The most frequent errors reported were omission errors that lead to hyperglycemia and improper dose or quantity which lead to either hyper- or hypo-glycaemia [12].

In a research recently conducted in the United Kingdom, 16,600 insulin errors were identified. 24% were reported as harmful to the patients. 18 incidents resulted in fatal and sever ramifications, while 1,042 were classified as moderate harm. Errors occurred during all stages from prescription errors (17%), dispensing (10%) and administration (61%). The main error types concluded in that research were wrong dose, omitted or delayed insulin and wrong product of insulin [11].

Usage of out-of-date medications or other medical products may be harmful. The chemical composition and potency of an expired drug may decrease its effectiveness. Storage in inappropriate conditions like in a car exposed to direct sunlight and high temperature or humid bathroom cabin can also alter the properties of the medication, even if it did not reach its expiration date. Some healthcare systems and governments implemented take-back programs for disposal of expired medications [13].

The risks are highly preventable and in order to achieve this it is necessary for both regulators and healthcare providers to work together. Regulators are responsible for similar names,

labels and packaging, while the healthcare providers need to ensure properly safe settings for insulin use.

Post-discharge guidance and patient education regarding proper administration of drugs, routine checkups, regular tests and situations requiring professional medical attention are now acknowledged as important millstones of harm prevention;

In the United Kingdom, the National Health Service (NHS) Institute For Innovation and Improvement launched the 'Think glucose program'- Inpatient care for diabetic people, reduces the length of stay and allows to free more time to treat the increasing numbers of diabetic patients. The program provides a package of products with learning and support materials to improve awareness, better education and ultimately prevent harm (Annex 1) [14, 36].

The independent double check system entails two professionals each checking a component of the work stages. For example, a pharmacist will perform dose calculation, dispense and prepare the drug and eventually compare it to the prescription. Then the nurse will check independently the medication order, calculate the dose and compare the results with the prepared dispassion. The rationale behind this system is that it is less probable for two independent people to do the same mistake [15].

Hospital acquired infections

'Healthcare-associated infections (HAI) are defined as infections not present and without evidence of incubation at the time of admission to a healthcare setting' [16]

'Most infections that become clinically evident after 48 hours of hospitalization are considered hospital-acquired. Infections that occur after the patient is discharged from the

hospital can be considered healthcare-associated if the organisms were acquired during the hospital stay' [16]

Clostridium difficile is a gram-positive spore-forming bacterium that may colonize the intestine if the normal microflora is modified or damaged.

Contact with healthcare workers, other patients and hospital environment can lead to exposure to C. difficile spores. Clostridium difficile infection (CDI) may occur after administration of antibiotic therapy, if the patient is unable to produce a proper antibody immune response to the pathogenic toxin produced by the bacteria. Patients who are able to produce adequate immunological response can revert to an uncolonized status or become carriers without any symptoms with further protection against the pathogen.

Infected patient may manifest with a wide range of clinical pictures starting from asymptomatic infection through diarrhea and some other severe syndromes such as fever, abdominal pain, leukocytosis. A severe form of CDI can be manifested as Pseudomembranous colitis with possible further complications of toxic megacolon, perforation, sepsis and eventually death [17, 18].

Antibiotics are widely used nowadays and often administrated empirically as a substitution for expensive and long lasting laboratory tests. Disrupting the gut microflora, antibiotic drugs play an important role in the development of CDI. Strains of C. difficile that are resistant to the antibiotics thrive in the intestine and lead to the possible manifestations mentioned above [19].

In the past C. difficile strains were resistant to Clindamycin, but susceptible to Fluoroquinolones. Nowadays new strains are resistant to Gatifloxacin and Moxifloxacin (fourth generation of fluoroquinolones) [20, 21].

Although not all cases of CDI are associated with antibiotic therapy, it still constitutes as the main risk for this infection [22]. All types of antibiotics are related to development of CDI, nevertheless some has higher risk to do so. For example, Clindamycin, Cephalosporin and now also Fluoroquinolones [19, 21, 23-25].

Many healthcare centers, such as Virginia Manson Hospital in Seattlle, already begun to apply specific projects to reduce antibiotics errors and risk of CDI and MRSA (Methicillin-Resistant Staphylococcus Aureus) [26].

A very careful and attentive treatment, considering the ramifications of antibiotic therapy may help with the prevention of this kind of infections. A complete and thorough investigation, including microbiological cultures, of the possible primary complaint may serve as a door-keeper for such healthcare-associated infections.

The Food Control Authority of Geneva and researchers from the University Hospital of Geneva, Switzerland, tested chicken meat delivered to the central kitchen of the hospital which prepares more than 8,000 meals a day. They discovered that about 86% of the sampled meat was positive for Extended-Spectrum Beta-Lactamase producing E. coli bacteria.

Although E. coli is a physiological component of the human intestinal microflora, it can cause urinary tract infections and even more severe invasive infections in susceptible patients [27].

In light of these disturbing findings, a serious attention should be given to food hygiene in health care facilities.

Patient falls

The second most common adverse event after medication errors is hospital falls. Due to its high incidence rate it is defined by the Medicare & Medicaid Services and as a known hospital-acquired condition (2012) and falling incidents reductions was defined by the Joint

Commission (2011) as a national priority goal. Falling incidents may occur and inflict injury in any age. Nevertheless, old adults have higher chance to get injured these incidents [28]. Sometimes a previous falling incident might cause fear of falling and altered mobility, which is increasing the probability to further falling [29].

An integrative study published on 2012 identified evidence- based possibilities to prevent falling incidents; environment and equipment interventions and maintenance, armbands and signs in the room and on doors, education and communication, safety rounds, patient aids, multidisciplinary consultation and collaboration [30, 31].

Surgery of wrong site

'Wrong site of surgery is a broad term that encompasses surgery performed on the wrong body part, wrong side of the body, wrong patient or at the wrong level of the correctly identified anatomical side' [3].

A survey conducted among Ophthalmologists in Scotland concluded that preventive recommendations to avoid such mistakes are not being implemented in practice. It was identified that lack of communication and verbal verification of the correct side in the operating theatre was the main reason for such an error [32, 33].

Prevention of wrong side surgery could be achieved by developing mandatory protocols and guidelines that will include all personal involved: surgical, anesthesia, nursing, theatre staff and the patient.

The WHO launched in 2008 the "Safe Surgery Saves Lives". It is a very effective checklist (annex 2) [35] composed of three parts according to the preoperative stages: Sing-in- is before induction of anesthesia, Time-out- after induction and before the surgical incision, Sign-out- during or after the wound closure but before the patient is transported out of the theatre [3].

Discussion:

The constant movements of the patients between health care entities may become a source of many problems we evident today. Mismatch resulted from different methods for follow-up of health state, tracking medications and lack of communication are the main causes for adverse events, placing the patients at risk for harm [1].

Potential harm can present itself in every possible setting starting from first responses, transportation, examination and diagnosis process, treatment, and rehabilitation settings.

From the aspect of the organization and management of healthcare systems, the most significant weak point is the dispersion of the healthcare services for one patient between multiple health providers and entities [1]. Unfortunately, there are no unified and universal standards for proper medications history recording, transfer and discharge documentation or follow-up registration.

Many healthcare services use computerized prescriptions, documentation, medication review and reconciliation. It is our belief that it is necessary to create standardization and structure the systems in a way that will ensure proper continuity of care.

Medication adverse events can be divided into Mistakes- errors of knowledge and planning; or Slips or Lapses- errors made as a part of the execution of the plans. [2]

Errors of knowledge can be prevented by education. Such an example is the WHO personal formulary, which reduced the planning errors significantly [9].

Slips may be prevented by a checking system. A serious consideration should be given to fact that some studies that demonstrated a strong preventability only by implementing an independent checking of prescriptions [10].

Hospital acquired infections are 'Infections not present and without evidence of incubation at the time of admission to a healthcare setting' [16]. Antibiotic drugs play an important role in

the development of CDI and MRSA Infections. Therefore their use should be limited and used empirically only in their relevant indications. Otherwise, responsible consideration of the ramifications of antibiotic therapy should be made. A complete and thorough investigation, including microbiological cultures, of the possible primary complaint may serve as a door-keeper for such healthcare-associated infections.

The second most common adverse event after medication errors is hospital falls. Falling incidents reductions was as a national priority goal in the USA.

Some preventive measure can be taken in order to achieve this goal; environment and equipment interventions and maintenance, armbands and signs in the room and on doors, education and communication, safety rounds, patient aids, multidisciplinary consultation and collaboration [30, 31].

Lack of communication and verbal verification of the correct side in the operating theatre was the main reason for Surgery of wrong site [32, 33].

Prevention of wrong side surgery could be achieved by implementing mandatory protocols and guidelines that will include all personal involved in the operation and the patient himself.

A further interface of essential communication is the medical rounds. An adequate interaction among the staff and with the patient is critical for obtaining important real-time information about the status of the patient and his complaints. A proper quality of communication during the rounds allows also the multidisciplinary team to develop a coordinated plan of treatment and is more likely to achieve involvement from the side of patient [34].

We can manage errors with potential harm to patient in three main points of time:

Avoid errors: Stopping the errors before they occur. Tight adherence to guidelines and safety protocols, with no exceptions or room for interpretations.

Trap errors: Early detection of errors when they occur is the most important process of prevention of same future mistakes or slips. Learning from our errors and implementing the preventive measures in the guidelines is a necessary trait.

Manage errors: Reduction of the effect of the errors that occurred and were not caught. Creating incident reports and analysis of soft spots in the system is a key component of better prevention [2].

Conclusion:

A proper working and healing environment has a key role in the prevention of adverse events. Human errors are natural and cannot be eradicated completely. Nevertheless, efforts should be made to avoid the predisposing factors. Communications between the doctor, the patient and the other personal is essential for reducing risk of harm.

The patients have, in most medical care settings, a large part in the prevention of medical errors, complications and success of the treatment.

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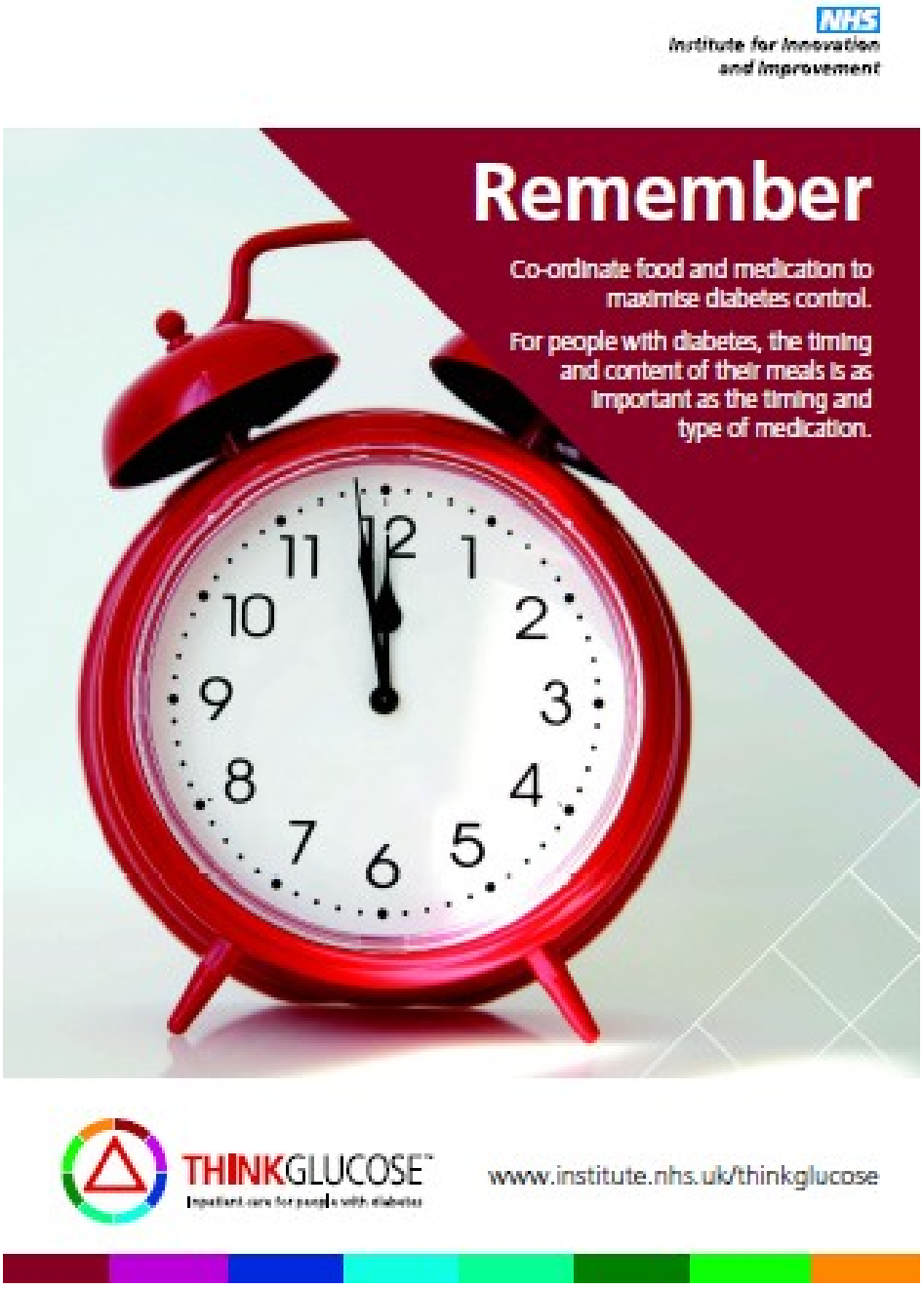
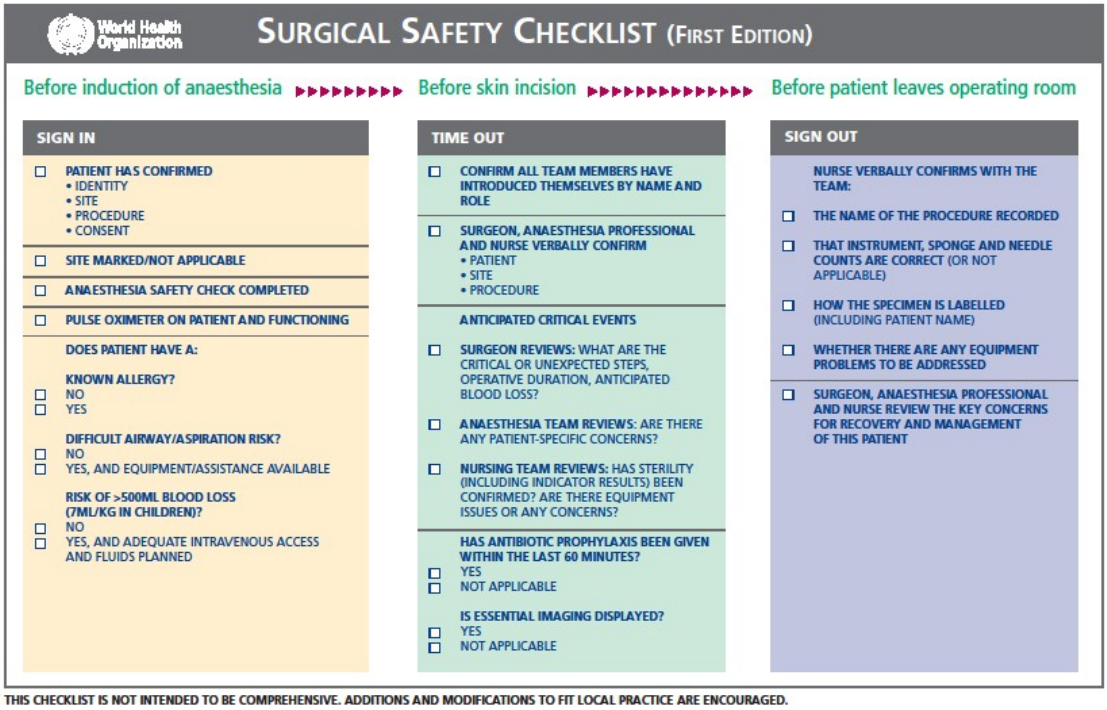
Annex 1: NHS Think glucose program.



Annex 2: Safe Surgery Save life- WHO checklist.



World Health Organization

SURGICAL SAFETY CHECKLIST (FIRST EDITION)

Before induction of anaesthesia ▸▸▸▸▸▸▸▸▸▸ Before skin incision ▸▸▸▸▸▸▸▸▸▸▸▸▸▸ Before patient leaves operating room

SIGN IN

- ☐ **PATIENT HAS CONFIRMED**
  - IDENTITY
  - SITE
  - PROCEDURE
  - CONSENT
- ☐ **SITE MARKED/NOT APPLICABLE**
- ☐ **ANAESTHESIA SAFETY CHECK COMPLETED**
- ☐ **PULSE OXIMETER ON PATIENT AND FUNCTIONING**

DOES PATIENT HAVE A:

KNOWN ALLERGY?
- ☐ NO
- ☐ YES

DIFFICULT AIRWAY/ASPIRATION RISK?
- ☐ NO
- ☐ YES, AND EQUIPMENT/ASSISTANCE AVAILABLE

RISK OF >500ML BLOOD LOSS (7ML/KG IN CHILDREN)?
- ☐ NO
- ☐ YES, AND ADEQUATE INTRAVENOUS ACCESS AND FLUIDS PLANNED

TIME OUT

- ☐ **CONFIRM ALL TEAM MEMBERS HAVE INTRODUCED THEMSELVES BY NAME AND ROLE**
- ☐ **SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE VERBALLY CONFIRM**
  - PATIENT
  - SITE
  - PROCEDURE

ANTICIPATED CRITICAL EVENTS

- ☐ **SURGEON REVIEWS:** WHAT ARE THE CRITICAL OR UNEXPECTED STEPS, OPERATIVE DURATION, ANTICIPATED BLOOD LOSS?
- ☐ **ANAESTHESIA TEAM REVIEWS:** ARE THERE ANY PATIENT-SPECIFIC CONCERNS?
- ☐ **NURSING TEAM REVIEWS:** HAS STERILITY (INCLUDING INDICATOR RESULTS) BEEN CONFIRMED? ARE THERE EQUIPMENT ISSUES OR ANY CONCERNS?

HAS ANTIBIOTIC PROPHYLAXIS BEEN GIVEN WITHIN THE LAST 60 MINUTES?
- ☐ YES
- ☐ NOT APPLICABLE

IS ESSENTIAL IMAGING DISPLAYED?
- ☐ YES
- ☐ NOT APPLICABLE

SIGN OUT

NURSE VERBALLY CONFIRMS WITH THE TEAM:

- ☐ **THE NAME OF THE PROCEDURE RECORDED**
- ☐ **THAT INSTRUMENT, SPONGE AND NEEDLE COUNTS ARE CORRECT** (OR NOT APPLICABLE)
- ☐ **HOW THE SPECIMEN IS LABELLED** (INCLUDING PATIENT NAME)
- ☐ **WHETHER THERE ARE ANY EQUIPMENT PROBLEMS TO BE ADDRESSED**
- ☐ **SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE REVIEW THE KEY CONCERNS FOR RECOVERY AND MANAGEMENT OF THIS PATIENT**

THIS CHECKLIST IS NOT INTENDED TO BE COMPREHENSIVE. ADDITIONS AND MODIFICATIONS TO FIT LOCAL PRACTICE ARE ENCOURAGED.