MINISTRY OF NATIONAL GUARD HEALTH AFFAIRS
KINGDOM OF SAUDI ARABIA

Quality & Patient Safety Newsletter

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IN THIS ISSUE

ABOUT THE NEWSLETTER

"By providing important and relevant information to healthcare providers, this Newsletter aims to enhance communication of quality and patient safety information, raise awareness of reported adverse events and maintain ongoing link to all the medical departments of the National Guard Health Affairs (NGHA) facilities. "

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Saudi Medication Safety Center:

Proper Use of Dosage Forms / Devices – Part 3

Dr. Gregory Poff
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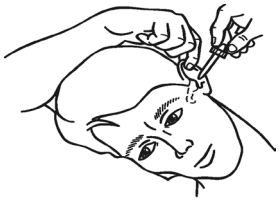
Ministry of National Guard Health Affairs

Guidelines for Administering Eardrops

1. Wash your hands with soap and warm water; then dry them thoroughly.
2. Carefully wash and dry the outside of the ear, taking care not to get water in the ear canal.
3. Warm eardrops to body temperature by holding the container in the palm of your hand for a few minutes. Do not warm the container in hot water. Hot eardrops can cause ear pain, nausea, and dizziness.
4. If the label indicates, shake the container.
5. Tilt your head (or have the patient tilt his or her head) to the side as shown in drawing A. Or lie down with the affected ear up as shown in drawing B. Use gentle restraint, if necessary, for an infant or a young child.



A

B

6. Open the container carefully. Position the dropper tip near, but not inside, the ear canal opening. Do not allow the dropper to touch the ear, because it could become contaminated or injure the ear. Eardrops must be kept clean.
7. Pull your ear (or the patient's ear) backward and upward to open the ear canal as shown in drawing A. If the patient is a child younger than 3 years old, pull the ear backward and downward as shown in drawing B.
8. Place the proper dose or number of drops into the ear canal. Replace the cap on the container.
9. Gently press the small, flat skin flap (tragus) over the ear canal opening to force out air bubbles and push the drops down the ear canal.
10. Stay (or keep the patient) in the same position for the length of time indicated in the product instructions. If the patient is a child who cannot stay still, the doctor may tell you to place a clean piece of cotton gently into the child'sear to prevent the medication from draining out. Use a piece large enough to remove easily, and do not leave itin the ear longer than an hour.
11. Repeat the procedure for the other ear, if needed.
12. Gently wipe excess medication off the outside of the ear, using caution to avoid getting moisture in the ear canal.
13. Wash your hands.

Administration Guidelines for Nasal Drugs

Nasal Spray

- Gently insert the bottle tip into one nostril as shown in drawing A.
- Keep head upright. Sniff deeply while squeezing the bottle. Repeat with other nostril.

A

Pump Nasal Sprays

- Prime the pump before using the first time. Hold the bottle with the nozzle between the first two fingers and thumb on the bottom of the bottle.
- Tilt the head forward.
- Gently insert the nozzle tip into one nostril as shown in **drawing B.** Sniff deeply while depressing the pump once.
- Repeat with other nostril.

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B

Nasal Inhalers

- Warm the inhaler in hand just before use.
- Gently insert the inhaler tip into one nostril as shown in drawing C. Sniff deeply while inhaling.
- Repeat with other nostril.
- Wipe the inhaler after each use. Make sure the cap is tightly in place between uses. Discard after 2-3 months even if the inhaler still smells medicinal.

C

Nasal Drops

- Squeeze the bulb to withdraw medication from the bottle.
- Lie on bed with head tilted back over the side of the bed as shown in drawing D.
- Place the recommended number of drops into one nostril. Gently tilt head from side to side.
- Repeat with other nostril. Lie on bed for a couple of minutes after placing drops in the nose.
- Do not rinse the dropper.

D

Administration of Rectal Suppositories or Enemas

Enemas

1. If someone else is administering the enema, lie on your left side with knees bent or in the knee-to-chest position, facing down. Having the child lie on the left side is preferred for children older than 2 years. If self-administering the enema, lie on your back with your knees bent and buttocks raised. A pillow may be placed under the buttocks.
2. If using a concentrated enema solution, dilute solution according to the product instructions. Prepare 1 pint (500 mL) for adults and 1/2 pint (250 mL) for children.
3. Lubricate the enema tip with petroleum jelly or other nonmedicated ointment/cream. Apply the lubricant to the anal area as well.
4. Gently insert the enema tip 2 (recommended depth for children) to 3 inches (7.6 centimeters) into the rectum.
5. Allow the solution to flow into the rectum slowly. If you experience discomfort, the flow is probably too fast.
6. Retain the enema solution until definite lower abdominal cramping is felt. The parent/caregiver may have to gently hold a child's buttocks closed to prevent the solution from being expelled too soon.

Suppositories

1. Gently squeeze the suppository to

determine if it is firm enough to insert. Chill a soft suppository by placing it in the refrigerator for a few minutes or by running it under cool running water.

2. Remove the suppository from its wrapping.
3. Dip the suppository for a few seconds in lukewarm water to soften the exterior.
4. Lie on your left side with knees bent or in the knee-to-chest position, facing down. Lying on the left side is best for self-administration of a suppository. Small children can be held in a crawling position.
5. Relax the buttock just before inserting the suppository to ease insertion. Gently insert the tapered end of the suppository high into the rectum. If the suppository slips out, it was not inserted past the anal sphincter (the muscle that keeps the rectum closed).
6. Continue to lie down for a few minutes and hold the buttocks together to allow the suppository to dissolve in the rectum. The parent/caregiver may have to gently hold a child's buttocks closed.
7. Remember that the medication is most effective when the bowel is empty. Try to avoid a bowel movement after insertion of the suppository for up to 1 hour so that the intended action can occur.

Guidelines for Applying Vaginal Antifungal Products

1. 1. Start treatment at night before going to bed. Lying down will reduce leakage of the product from the vagina.
2. Wash the entire vaginal area with mild soap and water, and dry completely before applying the product.
3. Vaginal cream: (If prefilled applicators are being used, skip to step 4.) Unscrew the cap; place the cap upside down on the end of the tube. Push down firmly until the seal is broken. Attach the applicator to the tube by turning theapplicator clockwise. Squeeze the tube from the bottom to force the cream into the applicator. Squeeze until the inside piece of the applicator is pushed out as far as possible and the applicator is completely filled with cream. Remove the applicator from the tube. Vaginal tablets/suppositories: Remove the wrapper and place the product into the end of the applicator barrel.
4. While standing with your feet slightly apart and your knees bent, or while lying on your back with your knees bent, gently insert the applicator into the vagina as far as it will go comfortably.
5. Push the inside piece of the applicator in and place the cream as far back in the vagina as possible. To depositvaginal tablets/suppositories, insert the applicator into the vagina and press the plunger until it stops.
6. Remove the applicator from the vagina.
7. After use, recap the tube (if using cream). Then clean the applicator by pulling the two pieces apart and washing them with soap and warm water.
8. If desired, wear a sanitary pad to absorb leakage of the vaginal antifungal. Do not use a tampon to absorb leakage.
9. Continue using the product for the length of time specified in the product instructions. Use the product every day without skipping any days, even during menstrual flow.

With the ever-expanding number of new medications, a wide variety of novel medication devices have also been introduced. Nearly 40% of all medication error reports submitted to ISMP (Institute for Safe Medication Practices) are related to product or device problems. A number of newly marketed medication devices have been identified as potentially prone to medication error. These include medication delivery "pens."

Medication Device Pens

The use of "pens" as medication delivery systems has grown in recent years. Medication pens are designed to allow easier administration of subcutaneous medications. However, a variety of medication errors have been reported with these devices resulting from device malfunctions or confusion with using the delivery devices themselves.

There have been a number of reports of health care practitioners and patients

using pens like vials and withdrawing doses of medication from the pen device with a syringe and needle. Following withdrawal of medication from a pen, large pockets of air can occur in the cartridges of insulin pen injectors. If the pen injector and cartridge is subsequently used without removal of the air pocket, the patient may receive a lower than desired dose of insulin and a subcutaneous injection of air. Healthcare providers should instruct patients to use the medication with the pen device and not to attempt to withdraw it from the cartridge.

The EpiPen® pen delivery device for EPINEPHRrine has also been reported to be prone to errors. Patients and nurses have injected EPINEPHRrine into their thumbs while removing the black cap. This black cap contains the needle and is not meant to be removed. When the black cap is pressed against the thumb (while erroneously trying to remove it) the injection is activated and injected into the thumb. Healthcare providers should advise patients to leave the black cap on the pen when performing an injection.

Another example of a pen-dosing error is when multiple-dose pens are treated as if they were single-dose devices. Some of the pens are designed to contain enough medication for one month of daily doses. Let patients know when they have multi-dose devices versus single-dose devices.

On some pen devices the dose that is dialed in is digitally displayed in a small window at the end of the device. While the dose is easy-to-read in the window, if the pen is held upside down with the needle to the right, away from the hand as a left-handed patient may do, the digital display may be misread and the wrong dose may be dialed in. For example, if a patient dials what appears to be 25 units while holing the pen upside down, the actual dose dialed is really 52 units. There are a variety of other doses which can be mistakenly dialed/administered in a similar fashion (i.e., what appears to be a dose of "10" units is actually "1" or 01 unit; a dose of "50" units is actually "5" or 05 units; a dose of "21" units is actually "12" units; a dose of "15" units is actually "51" units; a dose of "62" units is actually "29" units; and so on). These errors can lead to either a significant overdose or underdose.

In addition to these errors, a number of other errors involving pens have been reported. Since these devices appear to be error-prone, be sure to educate patients as to the proper use of these devices.

The above brief overview of proper use of devices should assist the healthcare worker to provide appropriate instructions to patients / caregivers to optimize the medication prescribed (i.e., avoiding underdosing and overdosing due to improper use of the device) and thereby improve patient outcomes.

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What is Risk Assessment in Simple Words?

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Risk assessment is a step in the risk management process. Risk assessment may be the most important step in the risk management process (Figure 1), and may also be the most difficult and prone to error. Once risks have been identified and assessed, the steps to properly deal with them are much more programmatical.

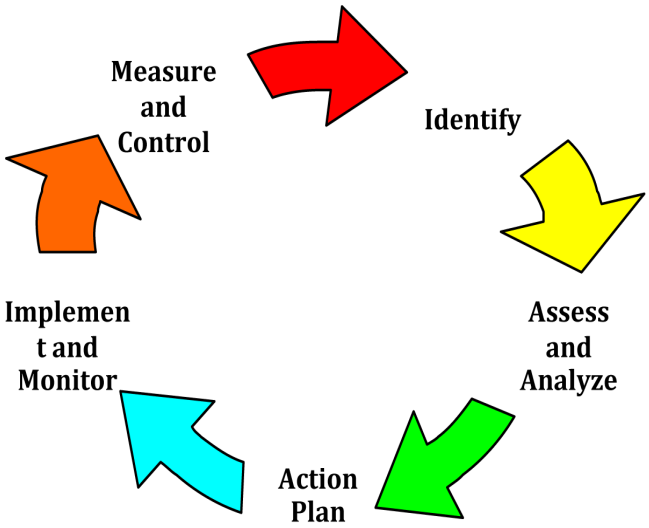


Figure 1: Risk Management Process

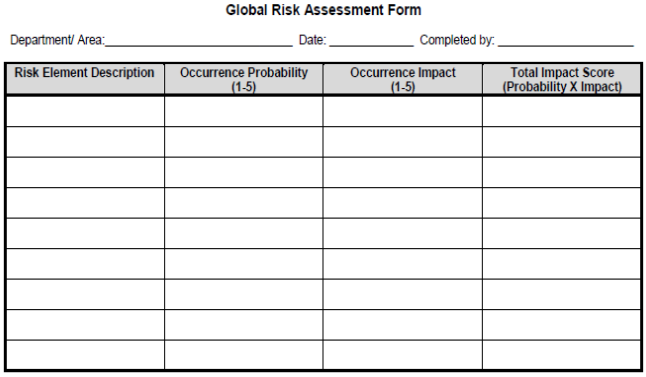
Performing and documenting risk assessments are not only required by the Joint Commission, but are also necessary since nearly all healthcare facilities are limited with regard to the number of staff and capital resources that are available. Therefore, it is necessary to evaluate the probability of risk occurrence and impact for a variety of different situations (risk elements) to determine whether additional action or process changes are necessary. Global Risk assessment is measuring two quantities of the Risk Element RE, the magnitude of the potential loss L, and the probability P that the loss will occur and may impact patient or staff safety or result in damage to buildings or equipment. Hence, the total Risk Impact score is equal to: RI = P x L

It is strongly recommended that a worksheet similar to the "Global Risk Assessment Form" (Figure 2) should be completed for each "Environment-of- Care" area.

To conduct global risk assessment list all of the possible risk elements associated with the department or area that may impact patient or staff safety or result in damage to buildings or equipment using all available data sources, including experience (a guess!) and previous history, insert numerical values for the probability and impact for each element. Calculate the total impact score for each element prioritize in descending numerical order and select a "cut-off" limit. And address accordingly.
The scoring is defined as follows:

Probability	Score Description
1	Very unlikely to ever occur
2	Unlikely to occur in one year
3	May occur in one year
4	Likely to occur in one year
5	Almost certain to occur within one year

Impact Score	Score Description
1	No injury or damage is likely to occur
2	Minor injury or damage is likely to occur
3	Moderate injury or damage is likely to occur
4	Serious injury or damage is likely to occur
5	Death or catastrophic damage is likely to occur



Global Risk Assessment Form

Department/ Area:_____ Date: _____ Completed by: _____

Risk Element Description	Occurrence Probability (1-5)	Occurrence Impact (1-5)	Total Impact Score (Probability X Impact)

Figure 2: Global Risk Assessment Form, courtesy of Healthcare Engineering Consultant

Part of the difficulty of risk management is that measurement of both of the quantities in which risk assessment is concerned can be very difficult itself. Uncertainty in the measurement is often large in both cases. Also, risk management would be simpler if a single metric could embody all of the information in the measurement. In theory both are of nearly equal priority in dealing with first, but in practice it can be very difficult to manage when faced with the scarcity of resources, especially time, in which to conduct the risk management process. However, since two quantities are being measured, this is not possible. A risk with a large potential loss and a low probability of occurring must be treated differently than one with a low potential loss but a high likelihood of occurring.

For all scores above the "cut-off", perform and document the six-step specific risk assessment process that follows for the high priority risk elements as time and other resources and technologies permit. The specific risk assessment steps include:

Step 1: Identify Issues and Select a Team "stakeholders"
Step 2: Analyze Factors
Step 3: Make a Decision
Step 4: Document the Evaluation and Decision
Step 5: Make the Necessary Changes
Step 6: Monitor and Reassess

In the conducting the specific risk assessment, the following quality tools will be instrumental: Plan, Do, Check, Act (PDCA), Root-Cause- Analysis (Fishbone Analysis), and Failure Mode Effect Analysis (FEMA).

In the interest of public health, the risks versus benefits of the possible alternatives must be carefully considered. For example of the specific risk assessment, it might well be that the emissions from hospital incinerators result in a certain number of deaths per year. However, this risk must be balanced against the available alternatives of no incineration (with the potential risk for spread of infectious diseases) or even no hospitals. Unless or until creativity and technological development offer superior methods for hospital waste disposal, the choice based on risk assessment, must be that of the lesser evil. One risk number alone is very rarely sufficient to make an informed decision.

The following websites are good resources for risk management application:

1. The Risk Management at www.scotland.gov.uk
2. OSHA Best Practices for Hospital-based First Receivers at www.osha.gov
3. American Society for Health Care Engineering at www.ashe.org
4. Center for Disease Control at www.cdc.gov
5. National Guard Health Affairs Disaster Plan at http://webapps.ngha.med/applications/disasterPlan/Main.aspx
6. Emergency Preparedness Plan (EPP) Manual at http://webapps.ngha.med/applications/manual/Document.aspx?ID=1365

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A SAFE NURSE always ensures SAFETY FIRST: Patient simulation; an effective teaching strategy to improve patient safety

Manny Mortell CRN - NS: Center of Nursing Education, KAMC-R

Introduction

The goal of a culture of safety is to reduce the risk of harm to patients and health care providers (HCP); however; despite a global transparent culture of safety, there has been nominal awareness focused on incorporating the culture of safety into the education of healthcare professionals and as a consequence numerous threats to patient safety remain (Cronenwett et al., 2007). Nurses need to be well-informed about patient safety and comprehend how knowledge, skills, and attitudes promote the utilization of safety science which leads to higher quality patient care (Finkelman and Kenner, 2009). Primum non nocere 'above all, do no harm' is considered a fundamental of health care practice, however, the Institute of Medicine's (IOM) landmark report of 2000, To Err is Human, revealed that hospitalized patients are not safe. The disturbing escalation in morbidity and mortality among hospitalized patients amplifies concerns about HCP competence (Gaba, 2004). Nurses and other health care professionals are under increased inquiry to deliver

safe and effective care, as are nursing education programs to ensure nurses are competent to provide safe patient care. Current strategies in nursing education utilize both didactic and clinical factors which are instrumental in defining critical thinking and clinical decision making for learners; these methods of health training do not however expose practitioners to errors in clinical judgment or practice. A teaching strategy that promotes critical - thinking, clinical - decision making, use of psychomotor skills; and provides immediate feedback, is patient simulation-based training (Needleman and Buerhaus, 2003).

Advancing safety awareness

Safety is defined as freedom from psychological and physical injury; and all health care organizations comprise of many physical and psychological factors that influence or affect the life of a patient. (Joint Commission International, 2011; Agency for Health-care Research and Quality, 2011; Institute for Health care Improvement, 2011). A safe environment reduces the risk for illness and injury, improves or maintains the patients' functional status, and increases the patients' sense of well-being. The Joint Commission International (JCI) is a United States-based organization that accredits health care organizations and programs. The JCI declared mission is to continuously improve health care for the public, in collaboration with other stakeholders, by evaluating health care organizations and inspiring them to excel in providing safe and effective care of the highest quality (JCI website, 2013). A JCI strategy to improve patient safety and provide effective care was the implementation of the international patient safety goals (Table 1).

JCI PATIENT SAFETY GOALS - MODIFIED
Identify patients **correctly**
Improve staff communication
Reducing **harm** to patients who take high alert medications
Reduce the **risk** of health care associated infections
Preventing multi-drug-resistant organism infections
Identify patient safety risks

TABLE - 1. Modified from: The Joint Commission: Hospital National Patient Safety Goals - 2013

Susceptible patient groups who often require assistance in achieving a safe environment include infants, children, older adults, the unwell, the physically and mentally challenged, and the illiterate. When a patient is cared for within a health care facility, risk assessment is mandatory to determine if any potential hazards exist in the care environment. The care environment in which nurses provide treatment to patients can determine the quality and safety of patient care (Gaba, 2004). As principal health care providers, nurses apply their knowledge, skills, and experience to care for the various and changing needs of the patient. To do so, nurses need to possess certified competencies that reflect the nature of nursing in improving patient outcomes, including evidence-based practice for safety and quality improvement (Lake, 2002), prior to commencement in clinical practice (Gaba, 2004). In the IOM report, To Err is Human: Building a Safer Health Care System, simulation training was recommended as an educational strategy for patient safety (Gaba, 2004). The report states that; health care and teaching organizations should participate in the development and use of simulation for practitioner training (IOM, 2000).

Nurses' role - patient environment

In a veritable culture of safety, all HCP in the National Guard Health Affairs (NGHA) organization are committed to patient safety, but, as patient care becomes increasingly specialised and technical, nursing responsibilities have escalated. Whether the patient is a pediatric or geriatric; cared for in day clinic or in

an intensive care unit; ensuring that the patient receives safe, evidence based care is an ongoing challenge. Nonetheless, clinical initiatives such as NGHA safety requirements and checks (Table 2 and 3) reduce the risk of harm to patients and are an integral part of the organizational commitment to patient safety.

NGHA - STANDARD SAFETY REQUIREMENTS
• Orientate patient to environment
• Provide falls brochure
• Ensure furniture & equipment appropriate for the room
• Maintain hall ways clear of obstacles
• Provide adequate lighting
• Ensure water and food is within easy reach
• Ensure bed brakes on
• Maintain patient's bed is in lowest position
• Provide patient clothing does not drag on floor
• Provide non-skid foot wear for ambulation
• Ensure side rails and cot rails are up
• Provide a call bell that is within easy reach
• Ensure floors are not wet and signage is in use

TABLE - 2 Modified from: DPP - 6020 – 020: Fall prevention and management Nursing Services – 2013

NGHA - EMERGENCY EQUIPMENT SAFETY CHECKS
• Check **oxygen equipment** available and functional
• Check **resuscitation equipment** is available and functional
• Check **suction equipment** available and functional
• Check **emergency bell** - alarm is available and functional
• Check nurses are **BLS accredited**

TABLE - 3 Modified from: DPP - NS - 095 Crash cart readiness for use verification - 2013
APP - 1430 - 4 CPR and activation Code Blue - 2013

Emphasizing the important aspects of safety within the patient care environment can be simulated in a clinical skills laboratory using Bloom's revised taxonomy, cognitive (knowledge), psychomotor (skills) and affective (attitude). This assists nurses to achieve higher levels of competence. For example, during the orientation of a new staff member and following learner instruction about patient safety, the learner should have acquired new knowledge, skills and attitudes about patient risks in a hospital environment. The simulation laboratory can be arranged to provide a high risk patient environment, which the learner must appraise, identify patient safety risks and make recommendations to reduce or eliminate those risks. The major advantage of simulation as an educational strategy in nursing education is that it provides learners with an opportunity to make clinical care judgments without apprehension of harming a real patient.

Nurses' role - crash cart readiness

Patient safety continues to be one of the NGHA Nursing Services Executives most challenging healthcare issues with the premise to prevent or improve failure to rescue patient outcomes. "Failure to rescue" refers to a failure to prevent a clinically apparent deterioration resulting from a principal disease for example a patient with escalating respiratory distress may require immediate advanced airway management, however, if essential life-saving equipment is not available or functioning, then a "failure to rescue" outcome could transpire.

It is often the nurse's role to check the resuscitation trolley and cardiopulmonary resuscitation equipment (Resuscitation council (UK), 2000) Resuscitation

equipment must be checked on a daily basis, this includes external equipment such as the defibrillator, oxygen devices and suction apparatus, in addition to internal contents, which is performed on a weekly basis. Checking equipment availability, functional viability and expiry dates is mandatory (NGHA DPP - NS - 095, 2013) and in so doing, ensures that patient safety and rescue outcomes improve. Comprehension of crash cart readiness and its importance to patient safety can also be simulated in a clinical skills laboratory using Bloom's taxonomy. For example, during the orientation of the staff member and following instruction about code blue, resuscitation equipment and crash cart location. The simulation laboratory could be arranged to provide a code blue simulation where resuscitation equipment was missing, not functional or medications had expired. Following which the learner must appraise and make recommendations.

Nurses' role - patient advocacy and rights

Nurses, identify that part of our professional role is to act as a patient advocate; "and as the only health care professionals who have contact with the patient 24 hours a day, 7 days a week; nurses are generally passionate about the patients' well-being. As a patient advocate, nurses have an individual responsibility, which requires more than just passion. A patient advocate is an active supporter for a patient's rights. The nurse in this role is required to protect the patient's human and legal rights and provide assistance in asserting those rights if required to do so. During hospital confinement, safe care is an expected patient right which is endorsed by the JCI 2013 and the NGHA Mission, Vision and Core values 2013.

Nursing Education's role in advocating patient safety?

Nursing is a knowledge-based profession and a nurse's ability to be a critical thinker and to use this knowledge in the delivery of nursing care is essential to patient safety (Ballard, 2002). In preparing future nurses who are competent to provide safe care, nursing education has an important role in providing knowledge, developing skills and attitudes of nurses. In addition, fundamental to patient safety is the dynamic interaction between clinical praxis and nursing education, which if conjoined, closes the theory - practice gap. The gap between what nurses do and do not know about patient safety needs to be closed.

Orientation programs for new graduates and continuing education for nurses are essential tools that ensure practitioners maintain and improve their knowledge, skills, and expertise so that safe, quality patient care is provided. However, a preventative approach to patient safety should be the preferred process instead of anticipating that a patient safety event will transpire or performing root cause analysis after a patient's safety was compromised. Patient safety is an issue that should be continuously emphasised in all nursing programs and clinical practice (Needleman, et al, 2002; Sherwood, 2007; 2011).

Traditional nursing education relies on linguistic intelligence and rote memorization; however, in contrast, a well-designed patient simulation program emphasizes multiple intelligences and is learner-centred. In the IOM report, To Err is Human: Building a Safer Health Care System, simulation training was suggested as a tactic to improve patient safety (Gaba, 2004). The report stated that; health care organizations should use simulation for staff training (IOM, 2000). Patient simulation is a technique that provides controlled guided experiences, whilst replicating actual aspects of the real world in a fully interactive manner (Peteani; 2004), thereby allowing the learner to "put it all together" prior to a real patient

experience. Building adaptation and innovation of skills within the learner in the complex health care environment supports learning utilising Bloom's taxonomy, which assists nurses to achieve higher levels of competence. The major advantage of using the patient simulation as an educational stratagem in nursing is that it provides an opportunity for active and interactive learning without risk to a patient. Learners are permitted to make errors without fear of harming a real patient (Beaubien and Baker, 2004).

CONCLUSION

The NGHA mission is to provide safe, evidence-based quality care to patients because all patients regardless of religion, culture, age and gender are entitled to safe, quality care. Nurses as HCP must be patient advocates and as such promote and provide safe patient care. Health care patient dynamics are complex and involve care processes, sophisticated technologies and therapeutic interventions. There are ongoing challenges for NGHA nursing services to advance the quality and safety of patient care within health care organizations. These challenges include, providing a patient safety education program; the development and implementation of patient safety competencies, and therefore ensure clinical practitioner competence. The vision of the NGHA nursing services, centre of nursing education; is to reduce the Theory–Practice Gap and improve patient safety outcomes. Patient simulation is a multidimensional concept, which utilizes exciting technology in nursing education; a teaching strategy that promotes critical-thinking, clinical-decision making, use of psychomotor skills; which also provides immediate feedback, and the integration of behavior, knowledge and clinical practicum. Learners are exposed to patient care scenarios regardless of the nursing specialty without fear of harming a real patient.

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Drug Allergy

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Adverse drug reactions (ADRs) are a significant cause of morbidity and even mortality. The majority of ADRs (Type A) are common, may occur in any individual, dose-related and predictable from the pharmacologic effects of the drug. Examples of Type A reactions include: Toxicity (hepatic failure with high dose Acetaminophen); Side-effect (sedation with antihistamines); Secondary effect (development of diarrhea with antibiotic treatment); and Drug interaction (Theophylline toxicity in the presence of Erythromycin treatment). Whereas Type B reactions have a much less obvious dose relationship, not related to the pharmacologic actions of the drug, are due to individual susceptibility, unpredictable, uncommon and some may involve immune responses against the drug. An example of a Type B reaction includes: Hypersensitivity (anaphylaxis with Amoxicillin administration). Type B reactions involving an immune response are termed 'drug allergy' and / or 'hypersensitivity' and account for 5 to 10% of all ADRs.

The range of "allergic" reactions that patients experience can vary widely. Around one in

10 reported side effects are actually drug allergies. Some patients will report side effects, like nausea or upset stomach, as allergies. But these reactions aren't allergies at all. Other drug reactions, such as hives, rash, difficulty breathing, speaking, or swallowing, wheezing, and severe low blood pressure, ARE allergies. A severe allergic reaction that includes these symptoms is sometimes referred to as anaphylaxis or an anaphylactic reaction. Anaphylaxis can be deadly. A true drug allergy happens as a result of activity of the immune system. Allergic reactions can occur as soon as a drug is taken, or days after. The different types of antibodies that are involved determine how long the reaction takes.

Compared to drugs taken orally, drugs that are either injected or applied to the skin are more likely to cause allergic reactions.

Allergies to Aspirin, Opioids (e.g., Codeine, HYDROmorphone, Morphine, etc.), Penicillins (e.g., Amoxicillin, AUGMENTIN, TAZOCIN, etc.), and Sulfa drugs (Sulfamethoxazole in Co-trimoxazole) are among the most commonly reported. Penicillin allergy is the most commonly reported drug allergy and is reported by about one in 10 patients. About one in 10 adults with asthma may have an allergy to aspirin.

The estimated incidence or prevalence of anaphylaxis in Western countries is in the range of 10 to 50 per 100,000 persons / year, with the mortality rate teaching up to 80% in certain conditions.

Allergic drug reactions may be classified, at least, theoretically, according to one of four implicated immunologic mechanisms, according to the scheme of Gell and Coombs Classification: immediate hypersensitivity; cytotoxic antibodies, immune complexes and cell-mediated hypersensitivity. Others have proposed classifying allergic reactions according to their time of onset:

Reaction Type	Onset (hours)	Clinical Reactions
Immediate	0 – 1	Anaphylaxis,Hypotension, Laryngeal edema Urticaria / angioedema, Wheezing
Accelerated	1 - 72	Urticaria / angioedema Laryngeal edema, Wheezing
Late	Greater than 72	Morbilliform rash, Interstitial nephritis Hemolytic anemia, Neutropenia Thrombocytopenia, Serum sickness Drug fever, Stevens-Johnson syndrome Exfoliative dermatitis

Type I Reactions are the result of an IgE antibody response, which includes immediate-type hypersensitivity reactions. With subsequent drug exposure following sensitization, leading to the release of preformed mediators (e.g., histamine) and the production of newly generated mediators (e.g., leukotriene). The absence of a known prior exposure does not exclude an IgE-mediated reaction because sensitization may have occurred from exposure to a cross-reactive compound. Systemic anaphylaxis, angioedema, bronchospasm or urticaria due to penicillin allergy

is the best understood responses in this category.

The time to onset is influenced by the route of administration: IV (seconds to minutes); Orally on an empty stomach (3 – 30 minutes and Orally with food (10 – 60 minutes). IgE-mediated anaphylactic reactions should NOT begin several days into a course of therapy.

Drug-induced Non-Immune Mediated Anaphylactic (anaphylactoid) Reactions: Scientists are trying to avoid the term 'anaphylactoid reaction' since some healthcare providers consider that category as a benign condition and does not require serious attention; thus they are replacing the term with Non-Immune Mediated Anaphylaxis. The best examples are Aspirin sensitivity and radio contrast media reactions. It is estimated that 20 – 30% of adults with asthma, nasal polyps or chronic urticaria develop worsening rhinitis, bronchospasm or urticaria following Aspirin ingestion. Another example: Angiotensin converting enzyme (ACE) inhibitors are known to cause cough and angioedema. As many as 25% of patients on ACE inhibitors experience cough, while angioedema is much less common, occurring at a rate of 0.2%.

Diagnosis:

A carefully elicited history is often sufficient to identify hypersensitivity

reactions. Patients with a history of prior allergic drug reactions appear to have an increased risk of subsequent reactions, even to structurally unrelated medications. All medications taken must be thoroughly reviewed, whether or not they were previously well tolerated. The routes and frequency of administration along with a history of prior exposures may be useful. The longer the time from the original administration of an allergen to the next administration, the less chance an IgE-mediated, or Type I, reaction will occur. This includes reactions such as hives and anaphylaxis. About 70% of people with penicillin allergy lose their allergy after five to 10 years. The rapid onset of symptoms such as urticaria, angioedema, bronchospasm or hypotension is characteristic of Type I Reactions. Taking the spectrum of potential manifestations into account, the physical examination of the patient with suspected drug allergy should include the evaluation of the patient vital signs, along with the skin and joints, mucous membranes, respiratory tract, cardiovascular and lymphoid systems.

Documenting allergies, but not including the specific reaction the patient experienced to the medication, does not provide all the information necessary to making therapeutic decisions. The most important information that can be obtained from the patient is the actual reaction that occurred from the medication that prompted the documented allergy.

A variety of immunologic tests for the diagnosis of drug allergy are available, but only intradermal skin testing for IgE antibody has been demonstrated to have a strong predictive value. Prick skin testing if performed under the recommended standards can yield a very negative predictive value to certain medication such as penicillin.

The proper assessment and management of drug hypersensitivity is important, not only because of the potential morbidity and mortality, but also because of the subsequent restriction in therapeutic options for the patient (e.g., a patient

with a Codeine allergy and no specific reaction noted might receive an inferior pain reliever when the reaction is simply an upset stomach – which is not an allergy but a known side effect; or a patient being incorrectly diagnosed as allergic to Vancomycin when in reality the red-neck syndrome observed was subsequent to too rapid administration of the medication).

In an acute drug reaction, the offending drug should be discontinued. Symptoms will resolve within two weeks if the diagnosis of drug hypersensitivity is correct. Symptomatic therapy may instituted, depending upon the nature of the reaction (e.g., antihistamine therapy may be helpful to relieve pruritus and the rash of Type I Reactions; corticosteroids may be necessary for the relief of severe urticaria and other extensive exanthems. In the event of anaphylaxis treatment includes EPINEPHrine 1 mg IM, DiphenhydrAMINE, and Corticosteroids (to prevent or minimize late-phase allergic reactions). Systemic anaphylaxis may also require aggressive cardiovascular support with intravenous fluids and vasopressor agents.

Drugs of similar structure may often be cross-reactive immunologically and clinically. Immunologic Cross-reactivity between penicillins and cephalosporins is as high as 15 – 25% for First Generation cephalosporins (e.g., CeFAZolin, Cephalexin) but appears to be much lower for Third Generation agents (about 1 – 2%). The decision about where it is okay to use drugs from a different class with a similar chemical structure can depend on how severe a patient's reaction to a particular drug is, how long ago the reaction occurred and how badly they need to take the drug to which they may react (e.g., a physician might recommend against using Cefuroxime in a patient who had a life-threatening allergic reaction with penicillin two years ago; however, Cefuroxime would be considered safer in a patient who only had a rash with penicillin). The Saudi Medication Safety Center (SMSC) Board has approved a "Penicillin Allergy Card" and several one page algorithms to assist staff in helping navigate the confusion often associated with cross-reactivity of penicillins, opioids and sulfa drugs, as well as aspirin sensitivity. The following Algorithms have been uploaded on the One Stop Resource ('NGHA Specific Information' and also under the section of 'Medication Safety information / alert / warnings') as of Monday, 19 May 2014:

Penicillin (Beta-lactam) Allergy Cross- Reactivity
Sulfa Drugs Allergy Cross-Reactivity Opioid Intolerance Decision
Aspirin Sensitivity

The Algorithms will also be included as Appendices to APP 1433-16 Allergy & Hypersensitivity Recording & Documentation; and printed as A4 size posters for Medication Room, Satellite Pharmacies, and PHC.

Infrequently, certain medical conditions cannot be successfully titrated with alternative therapy; in these circumstances, drug desensitization is necessary. Standard protocols have been developed for many drugs which based upon the principle of administrating gradually increasing doses of drug beginning with a very small dose and aiming toward a full therapeutic dose.

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