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Guidelines for Best Practices for the Natural Rubber Latex Allergic and Metal Allergic Patient

Introduction

The following Guidelines for Best Practices were researched and authored by the AST Education and Professional Standards Committee, and are AST approved.

AST developed the guidelines to support healthcare delivery organization's (HDO) reinforce best practices in the *natural rubber latex* (NRL) allergic patient as related to the role and duties of the Certified Surgical Technologist (CST®), the credential conferred by the National Board of Surgical Technology and Surgical Assisting. The purpose of the guidelines is to provide information operating room (OR) supervisors, risk management, and surgical team members can use in the development and implementation of policies and procedures (P&P) for NRL allergic patients in the surgery department. The guidelines are presented with the understanding that it is the responsibility of the HDO to develop, approve, and establish P&Ps for the surgery department regarding NRL allergic patient practices per HDO protocols.

Rationale

To understand the reasoning behind the guidelines, it is important for the CST to understand the bigger picture of NRL allergy, including the two types of latex and the basics of the manufacturing process that has an effect on the protein content of latex products; definitions of the types of hypersensitivity reactions; and groups at-risk for developing a *latex allergy*.

NRL is obtained from the milky sap of the rubber tree *Hevea brasiliensis* that grows in the rainforests in the Amazon region of South America, including Bolivia, Brazil, Columbia, Ecuador, Peru and Venezuela.[1,2] It is the protein that remains after process the latex that is responsible for Type I hypersensitivity reactions in humans; however, of the 250 proteins that have been identified in NRL, fifteen have been confirmed to be allergenic proteins that can cause an allergic response in the NRL allergic population.[3,4] The protein content of latex made from NRL is affected by the manufacturing process; therefore, latex is used in one of two forms. In the NRL process, the latex is dipped, extruded or coated to create devices such as gloves and balloon-tipped urinary catheters.[2] During the *dry natural rubber* (DNR) process the latex is formed into dried sheets that are used to make items such as intravenous (IV) injection ports and vial stoppers.[2]

Chemical additives, metal compounds, processing temperatures and other substances used during the NRL and DNR processes have an impact on the protein content of the end-product.[5] For example, during the DNR process the NRL is

chlorinated which reduces the protein content.[2] Additionally, the protein content of latex products varies by manufacturer brands and lots.[6] As a point of emphasis, throughout this guideline AST uses the term/abbreviation NRL to denote both NRL and DNR with the exception of Guideline III that discusses DNR vial stoppers.

There are two types of hypersensitivity to NRL:

- Type I: An *IgE*-mediated immediate-type hypersensitivity in reaction to one or more NRL proteins in which histamine is released causing the symptoms. Type I is a systemic reaction that can lead to life-threatening *anaphylaxis*.
- Type IV, also referred to as allergic contact dermatitis: A T cell mediated response that is delayed, usually occurring 48 – 96 hours after exposure. The reaction is to the processing chemicals used during the manufacturing of NRL. The reaction is localized to the area of contact with the NRL.

The incidence of latex allergy is approximately 1% - 2% in the general population.[7] The incidence of immune-mediated anaphylaxis during anesthesia ranges from 1 in 10,000 to 1 in 20,000 patients.[8,9] The wide range of the estimate reflects the challenges in diagnosing if a surgical patient experienced an allergic reaction to be able to come up with a narrower estimated figure. Neuromuscular blocking agents are most frequently involved followed by NRL and antibiotics.[9-11] Perioperative anaphylaxis occurs equally in both sexes of adolescents, but occurs more often in adult females than males.[8]

The populations that are at most risk for developing a latex allergy are the following: [1,4,7,12-19]

- neurogenic bladder patients;
- patients with urogenital malformations such as bladder exstrophy;
- history of *atopy*: a history of atopy increases a person's risk of latex allergy fourfold;
- patients who have had or still undergo repeated urinary catheterization, for example, atonic bladder;
- healthcare personnel (HCP): second highest risk of developing latex allergy, particularly those that work in surgery, hemodialysis centers, and laboratories; data have shown that approximately 10% - 17% of HCP have been diagnosed with latex allergy;
- spina bifida patients including patients with other types of neural tube defects: highest risk for developing latex allergy because of repeated exposure of the mucous membranes to latex during surgeries. The diagnosis of latex allergy in these patients has been estimated upwards to 73%, and their risk for an anaphylaxis episode in the OR is 500 times higher than that of other patients;
- patients who have had surgery early in life and multiple surgeries: pediatric patients without neural tube defects, each subsequent surgery can increase the risk of latex allergy 13-fold; approximately one in 7,700 pediatric surgeries is affected by an anaphylactic episode and of these, 76% are due to latex allergy. Adults who have had more than ten surgeries are at a high risk for developing latex allergy; approximately 12% - 40% of anaphylactic reactions in adult surgical procedures are from latex allergy.

There is a range of latex sensitivity among patients and HCP. Some patients will experience a serious Type I allergic reaction to a minute level of NRL, such as from the NRL IV injection port; whereas, other patients may only manifest a Type IV reaction even with a larger exposure to NRL proteins.[14,20]

Evidence-based Research and Key Terms

The research of articles, letters, nonrandomized trials, and randomized prospective studies is conducted using the Cochrane Database of Systematic Reviews and MEDLINE®, the U.S. National Library of Medicine® database of indexed citations and abstracts to medical and healthcare journal articles.

The key terms used for the research of the Guidelines include: anaphylaxis; atopy; Dressler's syndrome; dry natural rubber; IgE; latex allergy; latex allergy cart; latex labeling; metal hypersensitivity; natural rubber latex; powdered gloves; rubber vial stoppers; stopper fragmentation. Key terms used in the guidelines are italicized and included in the glossary.

Guideline I

Specific protocols must be followed by the surgical team to prevent the patient from experiencing an allergic reaction to NRL products by following the recommendations of professional organizations such as the American Academy of Allergy, Asthma & Immunology (AAAAI); American College of Allergy, Asthma & Immunology (ACAAI); Anesthesia Patient Safety Foundation; and regulations established by the Occupational Safety and Health Administration (OSHA), National Institute for Occupational Safety and Health (NIOSH), and FDA.

1. Since the latex proteins are an aeroallergen and can be present in the OR air for at least an hour after the use of latex gloves, the NRL allergic patient should be scheduled as the first case of the morning.[1,6,21,22] If additional patients being operated on the same day are NRL allergic they should be scheduled for the same OR.
    A. Scheduling the patient as the first case will contribute to creating an optimal physical environment for patients with a NRL allergy. ORs with high laminar air flow exchange rates have the same latex aeroallergen levels as ones with conventional air exchange rates. ORs that were not used for 48 hours or more contain undetectable amounts of aeroallergens.
    B. If possible, the patient should be transported directly from the patient unit to the OR. Transporting patients directly to the OR minimizes exposure to and/or direct contact with items that contain NRL, and avoidance of NRL airborne particles in the preoperative holding or other areas of the OR.
    C. The patient stretcher or any other type of transport device should have non-NRL mattresses, safety belts, and pillows.
    D. The patient should be wearing a latex-free red allergy alert wristband with "natural rubber latex allergy" clearly written on the band using a black-ink, smudge proof pen, for example, Sharpie® permanent marker.[1,5]
    E. Latex allergic signs should be posted on the patient's ward bed; stretcher; inside and outside of the OR doors to keep traffic to a minimum. The sign

on the stretcher should also indicate it is latex-free, for example, latex-free mattress and pillows.[21]

F. Terminal cleaning of the OR the night before, as well as cleaning in-between procedures in the event that subsequent patients are NRL allergic, should be performed to promote removal of NRL containing dust from all OR surfaces including the floor.[1]
    1) The OR ventilation filters should be changed on-schedule according to manufacturer's instructions-for-use (IFU) and the air-exchange ducts cleaned according to an established schedule per the surgery department P&Ps.
    2) Stretchers and other patient care equipment and devices should be disinfected after each patient.
    3) Latex-free gloves should be worn when cleaning preoperative holding area, OR and post-anesthesia care unit.

G. A section of the PACU should be designated as an isolated area for the recovering NRL allergic patient.
    1) Signs should be posted indicating it is a latex-free isolated area and latex-safe protocols are to be implemented.[14]

2. All NRL containing supplies should be removed from the OR and replaced with non-NRL containing supplies including replacing sterile and non-sterile latex *powdered gloves* with non-latex gloves.
    A. Recent studies have reported that establishing a latex-free environment in HDOs has significantly decreased the occurrence of latex sensitization and allergy in myelomeningocele and spina bifida patients, and patients with a history of multiple surgeries.[23]
        1) It is recommended HDOs complete a financial analysis to develop a plan that meets their needs for converting to a latex-free facility while identifying cost-saving measures. The conversion will most likely sustain some initial capital costs; however, those may very well be offset by avoiding future costs of diagnosing, treating and paying for patient-related latex allergic incidents.[24]
    B. All equipment, packages and supplies should be confirmed as being latex-free prior to opening and/or using on the patient. Packing material of devices should also be confirmed as latex-free including the sealant and contents.
        1) If in doubt that an item is latex-free the surgical team member should review the manufacturer's documentation that should be kept on file in the surgery department. (see Guideline II)
    C. Beginning January 18, 2017, the FDA banned the use of powdered sterile gloves, non-sterile exam gloves and absorbable powder for lubricating sterile gloves.[24-26] The FDA made the determination that "the risk of illness or injury posed by powdered gloves is unreasonable and substantial."[24]
        1) The most common powder that has been used is cornstarch. The danger from the powder has been wound inflammation; post-operative adhesions; granulomas; lung inflammation; and allergic

reactions from patients inhaling aerosolized powder that is carrying the proteins from the NRL glove.[24-26]

2) The ban was absolute, meaning there was no grace period and the FDA recommended that HDOs including medical clinics dispose powdered gloves like any healthcare waste either by burial in a landfill or incineration.[24,25]
3) According to the FDA, non-powdered sterile and non-sterile alternatives are commercially available that provide the same level of dexterity, performance, protection and tactile sense.[24]

D. The surgical team must not wear sterile or non-sterile NRL gloves during a surgical procedure involving a NRL allergic patient. This includes double-gloving by the sterile team in that both gloves should be non-latex gloves.
E. The patient and surgical team should wear hair covers that are latex-free, that is, bouffant hair covers that do not have an NRL elastic band.
F. It is recommended that surgery departments maintain a *latex allergy cart* utilized exclusively for surgical procedures that involve a NRL allergic patient. NRL free supplies should be identified, assembled and stocked in the cart to assist the surgical team in the assurance that items containing NRL will not be used.
    1) The following is a list of NRL-containing supplies that are common to the OR; each should be replaced with an equivalent that is latex-free (the list is not all-inclusive):[27]
        - Ureteral stents;
        - Sterile and non-sterile gloves;
        - Sterile magnetic instrument pad;
        - Asepto and bulb syringes used for irrigation;
        - Latex mattresses – patient stretcher and OR table;
        - Surgical drains, e.g. Penrose, hemovac, Jackson-Pratt;
        - Rubber shods placed on jaws of clamps, for example, Pean, cardiovascular;
        - Self-retaining and non-self-retaining (Red Robinson) urinary catheters;
        - Bean bag patient positioning devices, for example, partial- or full-length, also called vac pac;
        - Routine plastic syringes with latex-tipped plungers substituted with glass syringes;
        - The surgery department may want to consider replacing drugs that come in vials with DNR stoppers with drugs in glass ampules.[28] (see Guideline III)
    2) The following list of NRL-containing supplies are unique to anesthesia and should also be replaced with an equivalent that is latex-free (the list is not all-inclusive). The CST in the assistant circulator role can help the anesthesia care provider with obtaining the necessary latex-free supplies as well as confirming the anesthesia machine is equipped with latex-free components.

- EKG leads;
- Latex IV tubing should be used;
- Plastic face masks must be used;
- Tourniquets and Esmarch bandage;
- Latex-free Ambu bags, pediatric and adult, must be used;
- Nasopharyngeal tubes are made of NRL; an acceptable substitution is the use of uncuffed PVC endotracheal tube;[28]
- Routine plastic syringes with latex-tipped plungers substituted with glass syringes;[28]
- The regular circle circuits are plastic, but the bags are latex that can be replaced with a neoprene bag;[28]
- The anesthesia department may consider replacing drugs that come in vials with DNR stoppers with the drugs in glass ampules;[28] (see Guideline III)
- IV tubing has latex injection ports; tubing without ports is commercially available or alternately, place tape over the ports to prevent their use or use stopcocks for injection;[28]
- Blood pressure cuffs – if a rubber BP cuff is used, Webril™ should be stocked in the latex allergy cart and applied to the patient so it is underneath the cuff;[21]
- Not all ventilator bellows are latex free. Based upon the manufacturer's information, the anesthesia care provider will know which type anesthesia machine has ventilator bellows that are latex-free and which need to be replaced by a neoprene ventilator bellow.[28]

Guideline II

All NRL containing sterile and non-sterile equipment, medical devices and supplies should be labeled as such.[29]

1. In September 1997, the FDA issued the rule "Latex Labeling Required for Medical Devices" stating all medical devices containing latex to be labeled with the following statement, "Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions"; therefore, similarly, devices with DNR carry the warning "Caution: This Product Contains Dry Natural Rubber".[29] The FDA continued in the regulation stating, "FDA is also requiring that all "hypoallergenic" claims on medical devices be removed because they incorrectly imply that the devices may be safely used by people sensitive to latex."[29] The regulation went into effect a year later on September 30, 1998 meaning that it did not apply to devices sold prior to that date or preexisting devices being used by an HDO.[2]
2. For devices purchased by the surgery department prior to September 30, 1998 or preexisting devices being used, it is recommended that the surgery department should self-label the devices "LATEX" or purchase latex-free replacement devices that meet the FDA ruling. This should include labeling sterile back table packs and syringes.

3. To facilitate *latex labeling*, documentation should be obtained from manufacturers, stating the NRL status of the product, packaging and sealant, and the documentation kept on file for reference by surgery department staff.[29] It is recommended to maintain the documentation with the file of safety data sheets (SDS) to keep the information about the products in the surgery department in one location.

Guideline III

Due to the <u>possibility</u> of allergic reactions from the DNR stopper used for closure of pharmaceutical vials, it is recommended surgical team members utilize strategies that minimize the risk of DNR exposure to at-risk patients.

1. The issue of DNR vial stoppers is controversial with professional healthcare organizations and medical professionals publishing recommendations, but regulatory bodies currently have not accepted the recommendations.
    A. The American Society of Anesthesiologists (ASA) and the American Association of Nurse Anesthetists (AANA) have both published recommendations that DNR stoppers in pharmaceutical vials be removed prior to drawing up the medication for at-risk patients.[30]
    B. An issue within the controversy of DNR stoppers is that they are not required to be labeled according to FDA regulations. Pharmaceutical vial stoppers are under the jurisdiction of the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER), both of which do not currently require DNR in rubber stoppers to be labeled.[2] Concurrently, in 1996, the U.S. Pharmacopeia also rejected a proposal to ban the use of DNR in pharmaceutical vials and bottles.[31]
        1) In October 2015, a group of anesthesiologists from the Beaumont Health System, Department of Anesthesiology in Royal Oak, Michigan submitted a letter to the editor of the Anesthesia Patient Safety Foundation's *APSF Newsletter* expressing the concern that labeling *rubber vial stoppers* was not included in the 1997 FDA regulations (see Guideline II) and therefore, there is no easy method for identifying if the vial stoppers are plastic or rubber. Miaozong et al. refers to this as a "hiding hazard" to those with latex sensivity.[4] The anesthesiologists made three recommendations: appropriate uniform labeling of medication vial stoppers; identification of rubber vial stoppers; or making plastic stoppers mandatory.[32]
        2) The American Society of Hospital Pharmacists (ASHP) has recommended mandatory labeling of DNR vial stoppers.[33]
2. Two mechanisms responsible for contaminating liquid medication with latex protein have been suggested.
    A. The first is contamination when the needle is pushed through the rubber stopper. Most of the DNR protein content is within the interior of the rubber, not the surfaces, and pushing the needle through the rubber might release the proteins into the liquid medication.[34]

B. The second suggestion is the medication is contaminated with proteins when it contacts the undersurface of the stopper.[35] This can occur when the liquid in the vial is shaken during transport or to mix the drug, or horizontally stored.[2]

3. Since the decision of the CDER and CBER, the results of several studies have been published in which the evidence indicates that allergic reaction caused by DNR vial stoppers can occur but is infrequent, involves very low levels of latex proteins and in some cases the results of research are inconclusive.

A. Russell et al. analyzed the data in the Vaccine Adverse Event Reporting System (VAERS) that provides evidence of the infrequency of latex adverse events.[36] Between 1991 and 2003, 160,000 adverse events related to the administration of vaccines were recorded in the VAERS database and 28 were due to latex.[36] It was not possible for the researchers to determine if any of the 28 persons that experienced a Type I reaction received a vaccine from a vial with a rubber stopper. However, with approximately 200 million doses of vaccine administered annually in the U.S. and the number of vaccines from vials containing DNR stoppers is unknown, 28 adverse events is a very low number of allergy incidents related to vial stoppers.[36]

B. In 2000, Thomsen and Burke researched removing the DNR stoppers from vials when withdrawing medication. They reported the results of examining the level of latex protein in 40 vials that contained sterile saline and closed with DNR stoppers. The saline was withdrawn from 20 vials via a single-stick (puncturing the vial stopper once with a needle/syringe) and the stopper was removed on the other 20 vials to withdraw the medication. Additionally, five vials had saline withdrawn from a needleless system (negative controls) and one vial was intentionally contaminated with latex by placing it inside a latex surgical glove overnight (positive control). Seventeen of the 45 vials that included the five negative control vials, tested positive for a very low level of IgE-specific allergen. Vials that had the stopper removed to withdraw the saline had an equivalent level of latex protein contamination as compared to the vials with a single-stick. However, additional testing reported that the 17 low-level positives could have been false-positives.

C. Lear and English reported an anaphylactic reaction in a patient that was injected with the Hepatitis B vaccine who was later diagnosed as being latex-allergic, but not allergic to the vaccine.[37] The suspected cause of the incident was DNR in either the rubber stopper or the syringe plunger.

D. Wynn et al. reported a rash in a neonate who was receiving total parenteral nutrition (TPN) and latex allergy was suspected since the TPN was administered from a vial with a DNR stopper.[38] Testing was negative for latex antibodies, but the neonate had a family history of latex allergy and the rash disappeared when TPN was administered from a vial with the stopper removed.[38]

E. Another possible source of latex exposure is *stopper fragmentation*, referred to as "coring".[2] Coring occurs from the repeated needle sticks

through the DNR stopper of multi-dose vials and microscopic fragments of DNR lodge within the lumen of the needle. One group of patients particularly exposed to coring is insulin patients who may puncture a multi-dose vial as many as 200 times or more.[2] Asakura et al. studied the occurrence of coring with the use of pen-type insulin injectors with a DNR stopper within the cartridge for self-injecting patients.[34] The researchers collected insulin cartridges from thirty hospitalized patients and studied the primary injection, secondary injection and cartridge remaining preparation.[34] They found that coring occurred at a very high ratio of 97% in the cartridges used by patients.[34] The researchers stated, "coring is considered to occur because needles are repeatedly inserted and rotated at the same spot…coring is a very serious problem from the medical and pharmaceutical points of view."[34]

Even though it has been suggested that the injection of DNR from vial stoppers could be a risk for sensitization of patients to latex, the risks from the exposure have not been confirmed.[39,40] As shown by the results of the study by Asakura, the only factor that has been confirmed is that coring occurs.

4. Two practices that have been most frequently used to prevent DNR vial stopper exposure to patients are removing the stopper prior to the withdrawal of the medication, informally referred to as "pop-the-top", and single-stick.
    A. As previously stated, the ASA and AANA advocate removing the stopper prior to medication withdrawal, but the evidence does not support that this decreases the level of latex exposure to the at-risk patient and there are issues of sterile technique.
        1) The liquid contents of the vial have already been in contact with the stopper during shipping and when horizontally stored; studies have shown contamination with very low levels of latex protein due to these instances. Therefore, removal of the stopper prior to medication withdrawal is a moot point from a clinical stand point.
        2) The risk of microbial contamination of liquid medication when "popping-the-top" has not been determined through evidence-based research; however, there is also no definitive research that clearly supports patient safety in removing the stopper without contamination. Therefore, currently it is recommended that vial stoppers should not be removed for the purposes of withdrawing medication until evidence-based research indicates otherwise.
5. It is recommended that surgical departments perform self-labeling of pharmaceutical vials that contain a DNR stopper.
6. To avoid the issues of coring and contamination, it is recommended that that the single-stick method be used by surgical team members. The majority of HDO pharmacies are not removing the vial stoppers when preparing medications for latex-allergic patients and the single-stick method has been highly recommended for HDO pharmacies, supporting the safety of the practice.[41,42]

Guideline IV

The surgical team should follow the surgery department P&Ps for providing a safe environment for patients who are suspected of or positive for metal allergies.

1. Surgical instruments, orthopedic implants, and stainless steel sternal wires, as examples, are composed of a variety of metals, including cobalt, molybdenum, nickel, and titanium, that can cause a reaction in the metal allergic patient.[46,47] Nickel allergy is the most common *metal hypersensitivity* with approximately 15% of the population testing positive, while hypersensitivity to titanium has been rarely reported.[46,47,51]

   The issue is the lack of evidence-based clinical guidance for the management and care of patients with a suspicion of metal hypersensitivity.[49,50] There is a scarcity of clinical information on the appropriate approach to evaluating, diagnosing, and managing patients with a suspected metal hypersensitivity and studies have provided results that further complicate the issue.[50] For example, several authors have reported that patients with a diagnosis of metal allergy who underwent a total knee replacement with metal alloy prostheses implanted presented no postoperative clinical evidence of metal hypersensitivity reactions.[49] Further research is needed to confirm the physiology of metal ions in sensitization and metal hypersensitivity to be able to scientifically approach the issue leading to definitive patient care protocols .[48,49,50]

   A. During the preoperative assessment, the patient should be asked if he/she has experienced cutaneous contact sensitivity with metals, for example, wearing jewelry or specific to their employment, such as a construction worker, or if there is a family history of nickel allergy.[48,49,50] If the patient indicates a history of cutaneous metal sensitivity or a family history, the surgeon will make the determination if the patient should undergo preoperative testing. The most commonly used preoperative test is the skin patch, and in the opinion of dermatologists, is considered the gold standard for detecting systemic type IV hypersensitivity reactions.[46,49,50,52,53]

      Scientific literature supports routine preoperative testing is not needed unless the patient has a clinical history of metal reactions.[54,58,59] In 2016, the American Contact Dermatitis Society (ACDS) published a consensus opinion that routine preoperative testing is not recommended; however, in those patients self-reporting cutaneous metal reactions, evaluation is recommended, but not mandatory.[55] In a survey conducted at the European Society of Contact Dermatitis (ESCD) and subsequently, the ACDS meetings, 54% of respondents considered preoperative patch testing is indicated for patients who report moderate to severe rashes after cutaneous metal contact.[52]

   B. Metal sensitivity should be communicated to the surgical team well in advance of the surgical procedure to provide the team time to implement the necessary precautions.

      1) When performing open heart procedures on a metal sensitive patient, the CST should confirm with the surgeon if he/she wants to use an alternative sternal closure material as opposed to using

stainless steel sternal wires. Sternal wires have a very high nickel content and this has been associated with *Dressler's syndrome* with nickel allergic patients.[48]

2) The surgical technologist should confirm if nonstainless steel surgical instruments are recommended to be used during a procedure performed on a metal sensitive patient, and if the instruments are available. Titanium instruments are an option since hypersensitivity to the metal has rarely been reported.[46,47,50,51]
3) The orthopedic surgeon may take under consideration the patient's history of possible metal allergy when making the implant choice prior to surgery and may request the use of "hypersensitivity friendly" implants, particularly for total joint procedures.[49,50] The two types of implants available on the market are coated and non-allergenic implants.[56,57]

C. The surgery department may want to consider labeling medical devices containing nickel using a similar statement that is used for products containing latex, "Caution: This Product Contains Nickel Which May Cause Allergic Reactions." It is emphasized this is not a requirement of the U.S. FDA or any other state or federal agency.

Guideline V

HDOs should have a multidisciplinary Latex Allergy Practices Committee that is responsible for establishing and reviewing the P&Ps that are specific to the care of NRL allergic patients.

1. HDOs should have a multidisciplinary Latex Allergy Practices Committee that is comprised of representatives from all patient-care focused departments including (this list is not all-inclusive since HDOs vary in size and organizational structure): admissions; anesthesia; cysto lab; diagnostic imaging; dietary; environmental services; GI lab; home-health care; laboratory; pharmacy; physical therapy; respiratory therapy; surgery department; volunteers.[5]
    A. The committee should be responsible for developing P&Ps that address the care of the NRL allergic patient as well as provide input on the purchasing decisions of latex-free products.[1] The committee should also be responsible for the periodic review and revision of the P&Ps.[5]
2. The surgery department should review the P&Ps that are specific to surgery regarding NRL allergic patient practices on an annual basis.
    A. The surgery department should include members of the surgical team and administration when reviewing the P&Ps, including CSTs, surgeons, RNs, risk management, and infection control officer.
    B. The surgery department should document when the P&Ps were reviewed, who participated in the review process and make recommended revisions to the Latex Allergy Practices Committee.
3. CSTs should be familiar with the P&Ps for NRL allergic patient practices. The orientation of new employees should include reviewing the P&Ps.

Guideline VI

CSTs should complete continuing education to remain current in their knowledge of NRL allergic patient practices.[43]

1. The continuing education should be based upon the concepts of adult learning, referred to as andragogy. Adults learn best when the information is relevant to their work experience; the information is practical, rather than academic; and the learner is actively involved in the learning process.[44]
2. It is recommended surgery departments use various methods of instruction to facilitate the learning process of CSTs.
    A. If the education is primarily lecture, methods to engage learners include presentation of case studies for discussion, and audience discussion providing suggestions for reinforcing NRL allergic patient practices.
    B. Other proven educational methods include interactive training videos, and computerized training modules and teleconferences.
    C. The continuing education should be delivered over short periods of time such as in modules, and not in a one-time lengthy educational session.
3. The surgery department staff including preoperative holding and PACU personnel should be educated in the implementation of latex-safe protocols including utilization of the latex free cart, and devices and supplies that are latex-free.
4. Continuing education programs should be periodically evaluated for effectiveness including receiving feedback from surgery department personnel.
5. The surgery department should maintain education records for a minimum of three years that include dates of education; names and job titles of employees that completed the continuing education; synopsis of each continuing education session provided; names, credentials, and experience of instructors.

Competency Statements

Competency Statements	Measurable Criteria
1. CSTs are knowledgeable of the principles and practices for preventing allergic reactions in NRL allergic patients.	1. Educational standards as established by the *Core Curriculum for Surgical Technology*.[45]
2. CSTs in the assistant circulator and first scrub roles have the knowledge and skills to assist the surgical team in treating a patient who is experiencing an allergic reaction.	2. The didactic subjects of NRL allergy, treatment of allergic reactions in patients including anaphylaxis and products containing NRL that can be substituted with latex-free products are included in a CAAHEP accredited surgical technology program.
3. CSTs in the assistant circulator and first scrub roles confirm the use of latex-free supplies according to surgery department P&Ps including use of the latex allergy cart.	3. Students demonstrate knowledge of the use of latex-free products in the lab/mock OR and during clinical rotation.
4. CSTs are qualified to participate on the HDO Latex Allergy Practices Committee.	4. CSTs complete continuing education to remain current in their knowledge of the

	use of latex-free products and the treatment of allergic reactions in patients.[43]

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Glossary

Anaphylaxis: a severe, potentially life-threatening systemic reaction to an antigen to which the body has become sensitized.

Atopy: genetic (hereditary) tendency to develop allergic diseases that is associated with increased immune responses, particularly to inhaled allergens.

Dressler's syndrome: type of pericarditis believed to be an immune response after damage to the heart tissue or pericardium.

Dry natural rubber: process in which natural rubber latex is milled into sheets to make solid products such as vial stoppers and usually has a lower protein content as compared to natural rubber latex.

IgE: Immunoglobulin E are antibodies produced by the immune system in reaction to an allergen; IgE travels to mast cells causing the release of histamine.

Latex allergy: describes a range of allergic reactions to the proteins that are present in natural rubber latex; the individual usually develops the allergy after repeated exposure to products that contain natural rubber latex.

Latex allergy cart: a cart maintained by HDOs that contains latex-free supplies that the surgery team will place in the OR when operating on a latex-allergic surgical patient.

Latex labeling: Manufactures must label all latex containing products, except for vial stoppers, according to FDA regulations.

Metal hypersensitivity: Immune reaction in response to certain metals that requires a first-step sensitization process and secondary exposure.

Natural rubber latex: latex obtained from the *Hevea brasiliensis* tree that is used to manufacture many products used in society and medicine including blood pressure cuffs, surgical drains, gloves, IV tubing, and tourniquet cuffs.

Powdered gloves: Sterile surgical gloves and non-sterile exam gloves that contain cornstarch that originally used as a lubricant to assist with donning gloves, but the power could become airborne carrying aerosolized latex proteins. The use of powdered gloves has been banned by the U.S. FDA.

Rubber vial stoppers: Closures used for pharmaceutical vials that contain dry natural rubber.

Stopper fragmentation: Also called coring; it occurs when a rubber vial stopper has been punctured multiple times and microscopic pieces of dry natural rubber break off to enter the liquid medication.

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