 <p>Winnipeg Regional Health Authority Office régional de la santé de Winnipeg Caring for Health À l'écoute de notre santé</p> <p>PRIMARY HEALTH CARE OPERATIONAL GUIDELINES</p>	<p>Operational Guideline: Working Towards Latex Safe Environments</p>	<p>Guideline Number: PCOG #31</p>
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1. INTENT:

- 1.1 To work towards creating latex safe primary care environments for both primary care teams and patients in the prevention and management of latex allergies while supporting staff and treatment for patients. Persons at higher risk include: Children with Spina Bifida and/or who undergo many surgeries, congenital urological or urogenital abnormalities, quadriplegia or paraplegia, atopy (asthma, rhinitis, and eczema), allergies to some fruits (banana, avocado, and kiwi) and nuts (chestnuts) and those repeatedly exposed to latex (HealthCare Workers).¹ Center for Disease Control (February 2011) indicates while there are no overall statistics on the prevalence of latex allergy in the work force, studies do indicate that 8-12% of health care workers regularly exposed are sensitized, compared with 1-6% of the general population.²
- 1.2 To engage internal Service Delivery Organizations, external partners and the overall Healthcare system to respond to the need to work towards creating latex safe facilities where primary care clinics exist.
- 1.3 To create education, awareness and vigilance regarding the use of non-natural rubber latex equivalent purchases (equipment and supplies), operating and practice techniques across Leadership, Clinic teams and Patients.¹ ***Noting identification of Natural Rubber Latex is an evolving area, the allergenic risks of individual medical products are still being identified. The exact latex-avoidance measures necessary to prevent IgE-dependent allergic- sensitization reactions are not clearly established.***

United States Food and Drug Administration (Draft Guidance)

United States Food and Drug Administration (FDA) (2013) states “there are no regulations requiring a manufacturer to state that natural rubber latex was not used as a material in their medical product or medical product container”. If a manufacturer elects to include a statement in medical product labeling indicating that natural rubber latex or synthetic derivatives of natural rubber latex were not used as materials in the manufacture of their medical product and container, FDA recommends the use of the statement **“Not made with natural rubber latex.”** If this statement is made without any qualification, it must apply to the entire product and all of its packaging. For certain medical products, statements regarding “not made with natural rubber latex” may be appropriate only for certain components. In this case a manufacturer may elect to make a statement that the specific component is not made with natural rubber latex. For example, if the particular presentation or part of the presentation (i.e., vial stopper) is not made with natural rubber latex, FDA recommends the statement **“The <vial stopper> is not made with natural rubber latex.”**^{4, 5}

These statements **“Not made with natural rubber latex”** and **“The <vial stopper> is not made with natural rubber latex”** communicate that natural rubber latex was not

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used as a material in the finished product or as a material in the container. At the same time, the statement does not make the unsupportable claim that the medical product is “free” of or “does not contain” natural rubber latex (i.e., materials or contamination), which may promote a false sense of safety to users who are allergic to natural rubber latex. Use of a consistent scientifically supportable labeling statement will reduce confusion among FDA staff, medical product manufacturers, and medical product users.”^{4, 5}

FDA (2013) states “Manufacturers who currently include statements such as “latex-free” or “does not contain latex” in medical product labeling should update their medical product labeling to show the recommended labeling statement **“Not made with natural rubber latex”** or **“The <vial stopper> is not made with natural rubber latex”** as appropriate. Alternatively, manufacturers should consider removing “latex-free” type statements from medical products and medical product packaging. Manufacturers may contact the Center that regulates the medical product for guidance on the appropriate regulatory mechanism to update the labeling.”^{4, 5}

Use of these terms may give users allergic to natural rubber latex a false sense of security when using a medical product. FDA is recommending that a consistent, scientifically accurate statement be used by all manufacturers who wish to convey that natural rubber latex was not used as a material in the manufacture of a medical product or medical product container.”^{4,5} Based on FDA guidance it is currently not possible to be latex free in either our equipment and supplies or our practice environments and we need to recommend staff not overpromise to patients or staff that we are latex free.


A joint recommendation from both Primary Care Service Area and Community Area Leadership would be to use terminology to patients and staff we are working towards Latex Safe environments. That is, we minimize the risk of a reaction occurring in sensitized or allergic individuals. This is achieved by either removing (when there is an alternate substitute and financially feasible) or reducing inventory of natural rubber latex products that are the most likely to cause a reaction.

Health Canada Guidance on Labeling for Industry

According to Section 21(1)(e) of [Health Canada Guidance on Labeling of Medical Devices](#) if it is not evident whether the product contains natural rubber latex, this must then be identified. There is no specific wording required; there is only the requirement this be identified. The move towards a wording change may be industry driven, but in the end, if the interpretation of the regulations is met there are no issues.

2. DEFINITIONS:

Latex – Nonspecific term that it is used to describe products made using Natural Rubber Latex process or Dry Rubber Latex process. The principal difference between these two substances is the potential for exposure to the proteins found in natural latex rubber.

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Types of Latex - Manufacturers produce two types of products from natural latex sources:

- **Natural Rubber Latex (NRL) Dipped Latex** - Comes from the milky sap of various plants (i.e., the commercial rubber tree *Hevea brasiliensis*) and in its droplet form is coated with proteins. It is this protein substance that can be absorbed through the skin or inhaled if the powder used in the gloves (which absorbs the protein) becomes airborne on removal. Chemicals (rubber accelerators) added to the latex and the starches in the powder are also possible allergens.^{6,7} Dipped latex of this kind is found in some products that are stretchy, such as rubber gloves, balloons and condoms. Most allergic reactions to latex occur with products made of dipped latex because they are often used directly on the skin.
- **Dry Natural Rubber (DNR) Hardened rubber** - This type of latex is found in products such as athletic shoes, tires and rubber balls. Hardened rubber does not cause allergies in most people.⁷
- **Other rubber** - Rarely, some people who are sensitive to latex also may react to other rubber products, including erasers, rubber toy parts, rubber bands, rubber in medical devices and rubber in the elastic in clothing.⁷


Not all latex products are made from natural sources. Products containing man-made (synthetic) latex, such as latex paint, are unlikely to cause a reaction because they don't contain the natural substance. Some waterproof sealants may contain natural rubber latex.

Latex Free – Current term used to describe products (supplies and equipment) not manufactured from Natural Rubber Latex (NRL). This term will not be used within this guideline to describe these products (based on the USA Food and Drug Administration DRAFT Guidance) but instead, the terminology used will be “**Not made with natural rubber latex**”.^{3,6}

Latex Safe Environments - A term used to describe an environment that minimizes the risk of a reaction occurring in sensitized or allergic individuals. This is achieved by either removing (when there is an alternate substitute and financially feasible) or reducing inventory of natural rubber latex products that are the most likely to cause a reaction.^{1,3,6,8}

Types of Allergic Responses

- **Type I** - An immediate hypersensitivity reaction characterized by runny nose, sneezing, itchy eyes, scratchy throat and asthmatic symptoms including coughing, wheezing, shortness of breath, chest tightness and anaphylaxis (swelling of the face, lips and airways). This is a reaction to the latex sap proteins due to IgE antibody.^{6,8}

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- **Type IV** - Delayed Hypersensitivity reactions are more common and usually represent cell-mediated reactions to the chemical additives in rubber rather than the latex proteins. These should be considered as a rubber allergy rather than a latex allergy. The clinical presentation is a vesicular, eczematous, pruritic dermatitis appearing hours to days after contact with the allergen. In latex gloves, the most common type IV allergens are the thiurams, and screening panels for these are found in the most basic patch-test trays. Some cases have also been reported of type IV allergy to latex proteins, without the presence of rubber chemicals (i.e., protein contact dermatitis, with or without concomitant type I allergy), however these are rare.


It is possible to have other reactions to latex, which aren't always allergies to the latex itself. They include:

- **Allergic contact dermatitis** - This is a reaction to the chemical additives used during the manufacturing process. Signs and symptoms — usually a skin rash similar to that of poison ivy, including blisters — develop 24-48 hours after contact. This reaction predisposes individuals to developing Type I allergy.^{6,8}
- **Irritant contact dermatitis** - Not an allergy, this form of dermatitis most likely is an irritation caused by wearing rubber gloves or exposure to the powder inside them. Signs and symptoms include dry, itchy, irritated areas, usually on the hands.^{6,8}
- **Atopic** - Individuals with the predisposition for atopy – Natural Rubber latex is more common among patients with other allergic diseases. There is an association between allergy to certain fruits and vegetables and latex allergy (latex-food syndrome), particularly avocado, banana, kiwi, chestnut, tomato, potato; this is a co-phenomenon due to cross-reactivity rather than a true risk factor but patients reporting allergy to these foods need to be enquired about problems with NRL.^{6,8}

Routes of Natural Rubber Latex Exposure include:

- **Cutaneous** – via gloves, tapes, masks, urine drainage bags;
- **Mucous membranes** - via products in dentistry, anesthesia, intubation, rectal, urological and gynecological examinations (including intra-uterine devices), eye and ear droppers;
- **Inhalation** – via aerosolisation of latex glove powder;
- **Internal tissue/organs** - via latex products used in surgery;
- **Intravascular** - via latex products used in intravascular devices (i.e., IV cannula), devices used to deliver IV fluids and injectables (syringes and IV administration sets) or products stored or drawn up through rubber bungs or devices containing latex.

Natural Rubber Latex is both a contact and airborne exposure. For a list of natural rubber latex containing products (non-exhaustive) see *Appendix A - Latex Safe Checklist and Procedures*.

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3. GUIDELINE:

Role of Primary Care Leadership

3.1 Primary Care Service Area Leadership and Community Area Directors to partner with Logistics to advocate for manufacturers to consider FDA recommendations when manufacturing supplies/equipment for sale in Canada whenever possible.

3.2 Community Area Directors, Site Medical Leaders and Team Managers to partner and work towards achieving the following:


3.2.1 Logistics to procure products not made with natural rubber latex (where a substitute is available and financially feasible) within Primary Care clinics. There will be extenuating circumstances where it is not financially feasible (for example rubber latex condoms versus condoms containing no rubber latex). In this example, Team Managers to purchase a small supply to have on hand for patients who may be prone or have a latex allergy and the clinic team to provide evidenced based information on the differences between rubber latex condoms versus condoms containing no rubber latex.

3.2.2 Eliminate the use of powder latex gloves. The Royal College of Physicians (2008) recommends that the use of powder free, low protein non-latex gloves as an alternate to powdered latex gloves significantly reduces the incidence of latex allergy and latex-induced symptoms. Powdered latex gloves should not be used in the workplace.⁸

3.2.3 Purchase products that are labeled according to Health Canada Regulations and advocate for changes to the regulations that align with the FDA draft guidelines. Logistics to work towards procuring from manufactures who label their products with the warning as per FDA draft guidance recommendations that this product “**Not made with natural rubber latex**” or “**The <vial stopper> is not made with natural rubber latex**” as appropriate.

3.2.4 Procure and stock not made with Natural Rubber Latex Products. The material file contained within Material Management Database (SAP) identifies latex free products “not made with natural rubber latex” or “(uses LF)” in the material description. Once ordered and received, the not made with Natural Rubber latex products be stored separately from latex.

3.2.5 Partner with Pharmacies to ensure injectable medications prescribed and medical devices or products recommended do not contain natural rubber latex. So far as reasonably practicable, Pharmacy to endeavor to dispense commonly used emergency equipment and drugs that do not contain natural rubber latex and provide advice on drugs that may potentially contain latex.

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3.3 Community Area Directors (or designate) to partner with Diagnostic Services of Manitoba and Private Lab services who are co-located at Primary Care clinics to work towards supporting the adoption of creating latex safe environments.

3.4 Community Area Directors (or designate) to partner with Cleaning Contracts to work towards providing “not made with natural rubber latex products” to be used in all Primary Care clinics and support both patients and staff. Primary Care Site Leadership is responsible to communicate this requirement to Logistics when contracts are established.

3.5 Community Area Directors (or designate) to engage co-located external partners to create an awareness to support the adoption of creating latex safe environments.

3.6 Community Area Directors (or designate) to ensure natural rubber latex allergy to patients and staff risks are mitigated and managed by adhering to this guideline and all associated protocols and procedures.


3.7 Community Area Directors, Site Medical Leaders and Team Managers to ensure specific Latex Safe risk assessments are completed at a minimum annually for patients and staff who are identified as being allergic to natural rubber latex. See *Appendix A - Latex Safe Checklist and Procedures* to ensure what is considered natural rubber latex supply and equipment inventory is in use so planning for non-natural rubber latex equivalent supplies and equipment or reductions in the amount of latex can occur.

Role of Primary Care Clinic Team

3.8 Team Managers and Senior Primary Care Assistants to order supplies or equipment on contract (where practical and fiscally reasonable) that are not made with natural rubber latex or a rubber latex equivalent. Note: DSM or private laboratory services are unable to completely eliminate latex supplies entirely (lab collection tubes and vaccine vials). Some types of lab collection tubes have natural rubber latex tube stoppers with or without equivalent non-natural rubber latex equivalent. See *Appendix A - Latex Safe Checklist and Procedures*.

3.9 In cases where latex equipment is being used the latex equivalent should occur through either mechanical failure or repair; a cost comparison should be conducted of the latex equipment to determine cost feasibility.

3.10 Primary Care Clinic providers should communicate with the pharmacy about a patient's latex allergy and ensure that all prescriptions clearly identify the patient has a latex allergy. Patients should be encouraged to consistently use one pharmacy so that pharmacy becomes familiar with the necessary latex precaution (i.e., using latex-free gloves in preparing bubble packs). Where necessary, pharmacies should also be contacted for advice on medications that may potentially contain latex. Where patients are suspected of having a latex allergy, insulin vials should not be used. The presence of dry natural latex (DNR) is currently used in some manufacturing processes which reduces the risk of a reaction. Unopened vials

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containing DNR may be used once using a “single stick” method (Heitz, Bader, 2009). This method has been used widely in the U.S. and studies have shown it to be as effective as removing the bung (which may cause microbial contamination). Insulin vials may be punctured as many as 200 times during the shelf life so a non-natural rubber latex alternative should be used if available.¹¹


3.11 Based on the FDA (2013) recommendations “*There’s No Guarantee of Latex Free*” and not being able to control our external environment, it is prudent to advise patients and families that both Primary Care Leadership and the clinic team are continually working towards a latex safe environment to avoid giving a false sense of security to patients and families who are allergic to natural rubber latex.^{1,3,4,5}

3.12 If a patient demonstrates a Type I or Type IV latex reaction, a discussion should occur with the patient, Clinical Leadership and Primary Care Provider post event to review the reaction and look for possible causes and remove them or reduce exposure. It is everyone’s responsibility to work towards a latex safe environment. An occurrence should be reported through regular occurrence reporting mechanisms (RL6) to support clinic and system improvements.

3.13 The clinic team should engage and educate patients and visitors (where practical) of the importance to not use or bring in latex products. Posting of clinic signage within high traffic areas is recommended - see *Appendix B - Signage Latex Safe Zone*.

4. SOURCE/REFERENCES:

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5. **APPENDICES:**

- **Appendix A** - Latex Safe Checklist and Procedures
- **Appendix B** - Signage Latex Safe Zone (English and French)
- **Appendix C** - Your Latex Allergy Checklist (Patients)
- **Appendix D** - Response from BD Diagnostics – re: Laboratory Supplies

SCOPE: Applicable to all Primary Care Direct Operations Clinics (including Walk-In Connected Care Clinics), Midwifery Services, Antenatal Home Care Program, My Health Teams and Interprofessional Team Demonstration Initiative (ITDI) Staff.

NOTE: While the Funded Community Health Agencies are out of scope of Primary Care Operating Guidelines, it is recommended the content and/or processes be adapted/adopted where applicable.

****Questions regarding this or any other Primary Care Operating guideline should be directed to Primary Care Service Area Leadership***