FNIHB- OR Nursing Policy and Procedure

Section:	**Pharmacy**	Policy Number:	**III - 08**
Subject:	**Methotrexate**	Issued: Revised:	**March 31, 2015** **July 2016**
Distribution:	**All Nursing Facilities**		

STANDARD: All FNIHB healthcare personnel and employees of health facilities in contact or working with methotrexate (MTX) shall demonstrate competency in the safe handling and administration (direct involvement) and assistance (indirect involvement) with MTX therapy.

RATIONALE: This policy outlines the FNIHB comprehensive strategy for the management of high alert medications in general. Its purpose is to ensure that processes and procedures are in place to ensure safe administration, handling, transportation, disposal, client monitoring and counselling practices as well as conscientious management of accidental exposure, spills and/or injury and related incident reporting as per the FNIHB MTX Guidance Document 2016: *Handling and Administering of Methotrexate for Non-chemotherapy Indications.*

MTX is classified as a cytotoxic drug that is available in oral and injectable forms. It is used in lower dosing protocols, as an immunosuppressive agent to treat non-chemotherapy indications such as rheumatoid arthritis, psoriasis or Crohn's disease. It also can be used as a chemotherapeutic agent to treat cancerous conditions; however the FNIHB MTX Guidance Document 2016 is for non-chemotherapy indications only.

MTX is identified by the Institute for Safe Medication Practices (ISMP) Canada as a high alert medication because it can result in significant client harm when used in error. Reports of medication incidents through ISMP involving MTX include prescribing, dispensing, and administration errors due to the lack of clients' and healthcare personnel's knowledge about this medication.

The handling and administration of MTX, in both oral and injectable forms, is potentially hazardous to the clients receiving it as well as to the caregivers and healthcare personnel involved either directly (i.e. administration) or indirectly (i.e. assistance with administration). On the one hand, risks to clients are well documented (see the FNIHB MTX Guidance Document 2016) and can be balanced against the clinical benefits. On the other hand, understanding of the potential hazards of MTX exposure to caregivers and healthcare personnel is derived largely from theoretical risk analysis largely related to the mixing, dosage, duration and frequency of exposure to MTX. It is therefore necessary to take every reasonable precaution to protect healthcare personnel and caregivers from unnecessary exposure.

1. **POLICY:** All FNIHB healthcare personnel who are in contact or work with methotrexate (MTX) shall understand and comply with recognized, current safe practices to enhance the benefits of MTX therapy to clients and to minimize the risk of harm for all those involved prior to, during and in the immediate period after MTX handling and/or administration according to the following procedures as detailed in the FNIHB MTX Guidance Document 2016: *Handling and Administering of Methotrexate for Non-chemotherapy Indications*.

2. **PROCEDURES:** Safe MTX handling practices include transportation, administration, client monitoring and counselling as well as the management of spills, accidental exposure and disposal of material waste. Therefore, the following procedures apply:

3.1 Initiation of Treatment: Only physicians may initiate MTX therapy. Physicians must administer the first two (2) doses.

3.2 Drug Supply: Client-specific MTX, either in oral or injectable formats, should only be available in its final dose or form to the clients. Client-specific MTX should be ordered from and prepared by external pharmacy providers and should only be available in its final dose and form to clients and FNIHB healthcare programs. Nurses should use the FNIHB NIHB Procurement and Reimbursement process to obtain pre-filled MTX syringes for clients under the exception process, where applicable (see the FNIHB MTX Guidance Document 2016, Section 6.8).

3.3 Transportation: MTX Packaging and transport systems should ensure that adequate protection and storage instructions are adhered to during delivery.

3.4 Handling Restrictions:

2.4.1 TDG Certification: All FNIHB Healthcare Personnel handling the biohazardous waste associated with administering MTX are to be certified in accordance with the requirements of the *Transportation of Dangerous Goods Act, 1992* and regulations.

2.4.2 Pregnancy: Individuals who are or may be pregnant, or who are contemplating pregnancy, should avoid handling cytotoxic drugs. This also applies to care providers, family etc. FNIHB personnel should be reassigned to alternative duties prior to or during pregnancy (National Institute for Occupational Safety and Health (NIOSH) Guidelines 2014).

2.4.3 Allergies: Individuals with a history of allergies to MTX or other cytotoxic drugs should not handle MTX. Open skin lesions must be covered at all times.

3.5 Pre- Administration Precautions: Note: Nursing personnel administering MTX must; (some items are physician-dependent; however, nursing personnel need to be aware)

3.5.1 Have current general knowledge of the medication being given. They should be aware of the correct administration procedure. They should be aware of the possible immediate, short and long term systemic and local side effects of the medication and take the necessary actions as required. They should also be aware of clients' and families' educational, psychological, supportive care needs and the overall treatment plan.

2.5.2 Ensure that a chest X-ray has been performed prior to treatment or within the last six (6) months.

2.5.3 Recommend the use of contraceptive methods for both men and women if client is of reproductive age.

2.5.4 Obtain a history of alcohol use by clients.

2.5.5 Check (for) the client's varicella immune status.

2.5.6 Check that the client's Influenza and pneumococcal vaccination status are up to date.

2.5.7 Be familiar with the safe management and reporting of a near miss and/or adverse event, specifically as related to MTX (see the FNIHB MTX Guidance Document 2016, Section 12).

2.5.8 Develop a detailed Management Plan for each client detailing when tests, routine assessments/monitoring and MTX administration should be carried out as well as any special precautions required.

2.5.9 Be trained to safely manage accidental contact, exposure, spills and /or injury related to MTX handing and administration (see the FNIHB MTX Guidance Document 2016, Section 12).

3.6 Administration:

2.6.1 Initial Doses: The two (2) first doses of MTX are administered by a physician.

2.6.2 Administration Techniques: See the FNIHB MTX Guidance Document 2016, Section 8 and 10 - for site selection and administration technique information.

2.6.3 Double-checks: High-alert double-check processes must be performed when administering MTX to avoid error (see the FNIHB MTX Guidance Document 2016, Section 8.3).

2.6.4 Personal Protective Equipment (PPE): Healthcare personnel must wear personal protective equipment (PPE) when handling or administering MTX as outlined in Section 11 of the FNIHB MTX Guidance Document 2016.

2.6.5 Dosages: MTX is never given daily, for seven days a week. There may be a possible exception to this for one week; and only, if specified by the treating physician (ISMP, 2013). MTX doses whether oral or injectable are to be administered as is with no crushing, emptying, tampering etc.

Clients who self-administer must be informed of any change of manufacturer, as this may result in changes to the volume provided in the syringe, storage conditions, expiry date or appearance of the syringes. In addition, clients must also be informed of any potential change in administration technique according to manufacturer's guidelines and be appropriately retrained, if necessary.

2.6.6 Overdose: In cases of inadvertent MTX over dosage, consult the Poison Control Centre for advice on client management.

2.6.7 MTX Administration in the Home: Ensure that clients are willing and prepared to have MTX administered in the home and to manage any incidents that may arise (see FNIHB MTX Guidance Document 2016, Section 8.4).

3.7 Post-Administration: Disposal of Biohazardous Waste**:** Cytotoxic waste shall be separate from general waste and discarded in designated cytotoxic waste containers. Sharp objects contaminated with MTX (e.g., needles, used syringes) shall be placed in designated cytotoxic waste containers and labeled with a cytotoxic hazard symbol (Canadian Standards Association). All staff involved in the disposal of MTX biohazardous waste are to be certified in accordance with the requirements of the *Transportation of Dangerous Goods Act, 1992* and regulations [TDG] (Canadian Standards Association (CSA) 2008; Public Health Agency of Canada (PHAC) 2008) (see the FNIHB MTX Guidance Document 2016, Section 5 and 12.5.4).

3.8 Client Monitoring: Clients receiving MTX therapy should be closely monitored for toxicity and side effects so that these may be detected early and addressed promptly. Nurses must adhere to the correct protocol for baseline monitoring as well as for routine ongoing monitoring during the course of therapy (see the FNIHB MTX Guidance Document 2016, Section 7).

3.9 Managing MTX Contamination Events: Extreme caution should be taken when handling hazardous drugs in order to prevent and /or mitigate accidental contamination of clothing and/or PPE, eye and/or skin contact, needles stick injuries and/or spills. See the FNIHB MTX Guidance Document 2016, Section 12 for all appropriate procedures.

3.10 Client /Family Counseling: In order to obtain optimal benefit from MTX therapy, all clients (and families) receiving MTX should be counseled and provided with verbal and written information for MTX. Clients should also be provided individual written information on their dosage regimen that specifies the client's dose and the day of the week for taking the medication. Clients and families should be advised:

- to take MTX explicitly as ordered in its original form and packaging with attention to their particular dose and the day of the week for taking the MTX; and never to take daily/extra doses for symptom relief (see the FNIHB MTX Guidance Document 2016, Annex D);

- to swallow MTX tablets whole, never to crush, cut or chew tablets and /or use only un-opened, pre-filled syringes when pre-filled syringes are used;

- to not breast feed or become pregnant; all clients (male and female) should be advised to take contraceptive precautions during MTX treatment and for three to six months after stopping the therapy to avoid teratogenesis;

- to drink plenty of liquids and maintain a healthy, balanced diet;

- to avoid aspirin or products containing aspirin, unless authorized by a physician;

- to avoid taking NSAIDS (i.e. Ibuprophen, Naprosyn), unless authorized by a physician;

- if the client is on a folic acid supplement, he/she must be aware of the similar appearance of oral MTX tablets and folic acid tablets and the difference in the dosage of the two medications;

- to avoid excessive use of alcohol while on MTX , as this can increase the risk of hepatotoxicity and gastrointestinal adverse effects;

- to check with their physician/nurse before receiving any type of vaccination or immunization;

- to tell their physician/nurse if they are taking blood thinners as doses may need to be adjusted;

- to avoid direct sunlight since MTX can cause an abnormal skin reaction; clients should use sunscreen as well as wear eye protection and a hat;

- to adhere to the monitoring schedule for ongoing blood tests;

- to report side effects, particularly: rash, excessive fatigue, mental confusion, fever, chills, mouth sores, shortness of breath, dry cough, rapid heartbeat or palpitations, unusual bleeding or bruising, black stools, persistent stomach disturbances, changes in urinary frequency or any other disturbances (see the FNIHB MTX Guidance Document 2016, Section 6.5);

- to store syringes and/or tablets of MTX as per pharmacy instructions (i.e., at room temperature away from excessive heat, cold and direct light);

- to store the medication, injection supplies and sharps containers out of the reach of children, vulnerable adults and household pets;

- to keep emergency phone numbers (i.e., treating physician, Poison Control Center etc.) handy (i.e., on refrigerator).

4. INDICATORS:

4.1 Regional/Community Level Indicators:

4.1.1 Orientation of Pertinent FNIHB Personnel: All FNIHB healthcare personnel involved directly or indirectly with MTX handling, administration or assistance receive a comprehensive orientation in a timely manner that includes an overview of the *FNIHB Handling and Administering of Methotrexate for Non-chemotherapy Indications* as per the FNIHB MTX Guidance Document 2016 and the related policy ;

4.1.2: Training in TDG for All Pertinent FNIHB Personnel: All Healthcare personnel handling the biohazardous waste associated with administering MTX are certified in accordance with the requirements of the *Transportation of Dangerous Goods Act, 1992* and regulations.

4.1.3: Reporting Adverse Medication Events: All MTX-related Adverse Medication Events are formally reported (in writing), analysed and improvements made in a timely manner, as necessary. Results are shared with Management and designated FNIHB personnel for the context of ongoing safety improvement.

5. APPENDICIES: Please refer to the FNIHB MTX Guidance Document 2016: *"Handling and Administering of Methotrexate" for Non-chemotherapy Indications*.

Annex A: Flowchart for the Administration of Methotrexate;

Annex B: Advice for Clients, Families and Caregivers on the Disposal of Cytotoxic Waste in the Home;

Annex C: How to give a Methotrexate Subcutaneous Injection;

Annex D: Client Education and Information;

Annex E: Sequence for Donning and Removal of PPE;

Annex F and G: Methotrexate Medication Charts – Tablets and Injectable;

Annex H: Top 10: Methotrexate Checklist for FNIHB Nurses;

Annex I: Methotrexate Blood Work Monitoring Record.

6. GLOSSARY: Please refer to the FNIHB MTX Guidance Document 2016: "*Handling and Administering of Methotrexate" for Non-chemotherapy Indications*.

7. REFERENCES: Please refer to the FNIHB MTX Guidance Document 2016: "*Handling and Administering of Methotrexate" for Non-chemotherapy Indications*.

8. RESPONSIBILITIES FOR APPLICATION: Regional nursing[1] is responsible to ensure that all FNIHB staff involved directly or indirectly with MTX handling are aware of the policy and that the policy is applied and complied with in the community-based setting.

9. REVISION: The Office of Primary Health Care, Inter-professional Practice Support – Pharmacy will review the FNIHB Methotrexate Guidance Document and accompanying policies every five (5) years or as needed when new guidelines and evidence becomes available or a change in practice or regulations.

10. **RELATED POLICIES:**

FNIHB (2008) *Protocol for the Administration and Handling of Methotrexate by Community Health & Home Care Nurses*.
FNIHB-OR Policy: *Dispensing Medications*
FNIHB-OR Policy: *Medication Administration Standards*

<table>
<tr><td colspan="2">Approved by:</td><td rowspan="2">Effective Date:

July, 2016</td></tr>
<tr><td colspan="2"></td></tr>
<tr><td>Director of Nursing Ontario Region</td><td>Date:</td><td rowspan="3"></td></tr>
<tr><td colspan="2"></td></tr>
<tr><td>Regional Executive Ontario Region</td><td>Date:</td></tr>
</table>