	Number: 40-001-04 SW
Saskatchewan Health Authority	**Title: Isoniazid-Rifapentine for Treatment of Latent TB Infection – Delivery in Community by Directly Observed Therapy (DOT)** **Role performing Activity:** DOT Worker

STANDARD WORK	**Location:** All jurisdictions and agencies responsible for the delivery of DOT	**Department/Unit:** TB Prevention and Control Saskatchewan (TBPC SK)
	Document Owner: Manager, TBPC SK	**Date Prepared:** February 14, 2019
	Last Revision: April 8, 2020	**Date Approved:** April 13, 2020
	Related Policies/Documentation TBPC SK Clinical Policy and Procedure 40-001: Treatment of Tuberculosis (draft) Saskatchewan Health Authority (former Saskatoon Health Region) Nursing Policy and Procedure 1168: Delegation of Task to Formally Educated Unregulated Care Providers	

Work Standard Summary:

Isoniazid and rifapentine is a once-weekly 12-dose treatment regimen for latent TB infection (LTBI). The combination therapy is as effective for preventing active tuberculosis (TB) as other treatment regimens and may be more likely to be completed given the short duration of treatment.

Isoniazid and rifapentine must be delivered by directly observed therapy as altered dosing intervals and missed doses could jeopardize treatment safety or efficacy. A symptom review for adverse effects must be completed before each dose is delivered. If adverse effects are noted, the dose must be withheld and immediately reported to TB Prevention and Control Saskatchewan. At each encounter, clients must be instructed and/or reminded to report any adverse effects. The following standard work outlines the process for DOT.

Definitions

Delegating nurse means the nurse(s) that is knowledgeable of the individual client's care needs based on ongoing nursing assessment and is responsible for the overall care of the client in the community.

DOT Worker means the care provider responsible for delivery of DOT. This may be a nurse, continuing care assistant, TB Program Worker, or other provider.

Enabler means a practical item given to a client to facilitate adherence to treatment, isolation, clinic appointments or other aspects of treatment.

Incentive means a gift given to clients to encourage or acknowledge their adherence to treatment and/or isolation.

Medication discrepancy means an instance when information on the medication record is not congruent with medication packages or what has been ordered or reported. For example, medications listed on the Tuberculosis Order Set are not the same as what is provided in the medication dose packages.

Medication error means "any preventable event that may cause or lead to inappropriate medication use or client harm while the medication is in the control of the health care professional, client, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order

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communication, product labeling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use" (National Coordinating Council for Medication Error Reporting and Prevention, 2015).

Name alert means a process initiated when two or more clients have the same last name or two or more clients have names that look or sound alike. The process includes: (1) placing a check mark in the name alert box on each TBPC SK Medication Record; (2) placing a name alert label on the medication bag; (3) placing a name alert label on each dose package or writing and highlighting 'name alert' on each dose package.

Essential Tasks:

Preparation	
1.	Remove one dose package from the large zip-lock bag (medication bag). Check that the client identifiers (full name, date of birth, and provincial health number), medication, dose, and dosage form (e.g., tablet, suspension) are the same as what is: • Ordered on the Tuberculosis Order Set, and • Listed on the medication label on the dose package, and • On the TBPC SK Medication Record. Do not give the dose and notify the delegating nurse and TBPC SK Nurse Clinician if the identifiers do not match. • Saskatoon office: 306-655-1740 or SK toll free 1-866-780-6482 • Prince Albert office: 306-765-4260 • Regina office: 306-766-4311 *Note: The client's name is the only identifier on the dose package; the date of birth and provincial health number are not listed on the dose packages.* *Note: An Adverse Effects Checklist will be attached to each dose package.*
2.	Write the client's date of birth on the dose package: • For the first dose of each new shipment of medication (i.e., with the first dose of each medication cycle), • When delivering medication to a client for the first time, **and** • When the *name alert* process is in effect.
3.	Check that the client's full name and TB file number is printed on the Adverse Effects Checklist. Print this information if not already documented on the label. Print the date the dose is being given and the dose number on the label. For example, the client will receive 12 doses in total so if this is the third dose then beside "Dose #" write "3."

Medication Delivery	
1.	Confirm the client's identity using a minimum of two identifiers. Cross-reference the identifiers with the dose package as follows: a. Ask the client to spell their first and last name and state their date of birth if: • The dose is the first dose of the medication shipment (medication cycle), or • It is your first time giving DOT to the client.

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		b. Ask the client to state their first and last name for all remaining doses of the medication shipment (medication cycle). Direct facial recognition is considered the second identifier when the DOT Worker already knows the client AND the dose is not the first dose of the medication shipment or the first time delivering DOT to the client. c. Ask the client to spell their first and last name and state their date of birth for every dose if the *name alert* process is in effect. Do not give the dose and notify the delegating nurse and TBPC SK Nurse Clinician if what is on the dose package does not match what the client states.
2.		Ask the client if they are having any of the symptoms listed on the Adverse Effects Checklist. If the client answers YES to any of the symptoms: • Do not give the dose, **and** • Notify the delegating nurse and TBPC SK Nurse Clinician immediately. If the client answers NO to all of the symptoms, sign the label and proceed with medication delivery.
3.		Give the medication to the client and directly observe them swallow it. Do not give medication to the client to take later. Provide a small snack for the client to take with the medication. *Note: All TB medication must be taken at the same time so if one pill falls on the ground or the client refuses to take one of the medications then the other medication(s) must be withheld. Notify the TBPC SK Nurse Clinician immediately if this occurs.* *Note: Medications may be crushed and mixed with food and then taken immediately. Tablets may be cut in half and placed in gel capsules supplied by the TB Pharmacy. Gel capsules may be useful for clients that have difficulty swallowing tablets or for those that do not like the taste of the tablets.* *Note: Deliver medication once weekly, on Monday. If the dose is missed on Monday it may be given on Tuesday, Wednesday, or Thursday. To ensure there is at least 72 hours between doses, a missed dose should not be given on Friday as the dose on the following Monday will need to be given at the same time it was given on the Friday or later. TB physician review must occur if two consecutive doses are missed. The day of the week for once weekly DOT may be changed on an ongoing basis if necessary due to workload or client preference provided it is approved by the TBPC SK Nurse Clinician.*
4.		Place all used/unused medication packaging in the dose package. Date and initial the dose package. Do not throw any packaging out. *Note: Medication audits are completed for clients receiving TB medications. Used and unused packaging is counted during the audit process. Adjustments to treatment and/or the length of treatment will be made based on audit results.*
5.		Instruct the client to immediately report any adverse effects they experience.
6.		Provide incentives and/or enablers in accordance with the client's plan of care.
7.		Immediately notify the TBPC SK Nurse Clinician and, if applicable, the delegating nurse if: • The client reports adverse effects or misses a dose Notify the TBPC SK Nurse Clinician and delegating nurse, if applicable, within one working day if: • There is a medication error or discrepancy,

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	- The client plans to be away from the community or has been admitted to a facility such as a hospital or treatment centre, - Adherence concerns or issues arise, or - Any other concerns arise.
Documentation	
1.	Document the medication delivery on the TBPC SK Medication Record as per Appendix B.
2.	Place the signed Adverse Effects Checklist label on the reverse side of the TBPC SK Medication Record.

Supplies

- Medication bag with dose packages and Adverse Effects Checklists attached
- TB Prevention and Control Saskatchewan Medication Record
- TB Prevention and Control Saskatchewan Tuberculosis Order Set
- Incentives and enablers, if required
- Pill crusher or cutter, as necessary
- Gel capsules, as necessary
- Food to be given with the dose

References

Saskatchewan Health Authority. (2019). TB Prevention and Control Saskatchewan policy position: *Isoniazid and Rifapentine for Treatment of Latent TB infection – Guidelines for Use.*

Saskatchewan Health Authority. (2018). TB Prevention and Control Saskatchewan policy and procedure: *Treatment of Tuberculosis* (DRAFT).

Saskatchewan Health Authority. (2015). TB Prevention and Control Saskatchewan policy and procedure: *TB Medication Administration, Delivery and Management in Saskatchewan First Nations Communities.*

Saskatchewan Health Authority – former Saskatoon Health Region. (2013). Policy and procedure 7311-60-017: *Verification of Identification.*

Saskatchewan Health Authority – former Saskatoon Health Region. (2017). Nursing policy and procedure # 1168: *Delegation of Task to Formally Educated Unregulated Care Providers.*

National Coordinating Council for Medication Error Reporting and Prevention, 2015.

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APPENDIX A: Medication Packaging Examples

Medication bag containing daily dose packages

Dose package
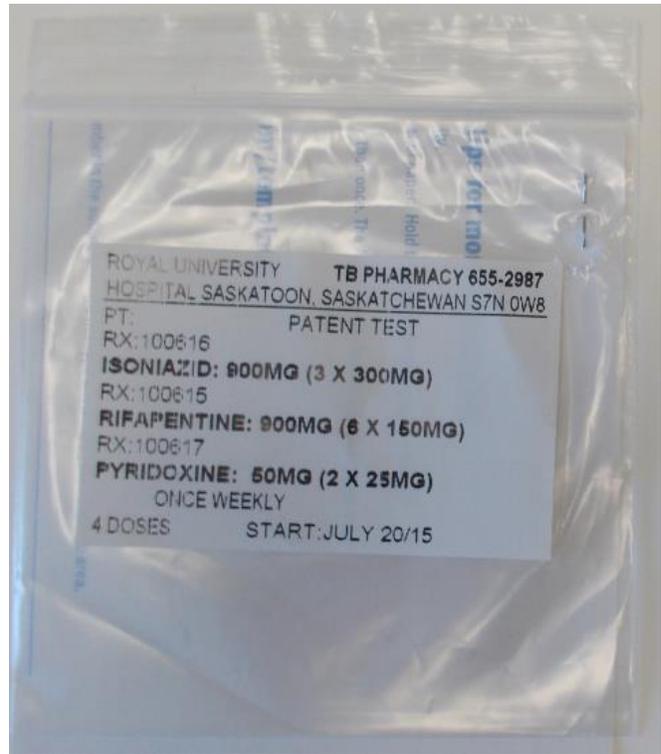
Adverse Effects Checklist

ADVERSE EFFECTS CHECKLIST

Name: _____

TB File #: _____ Date: _____ Dose #: _____

Signature & position: _____

DO NOT GIVE DOSE and CALL TBPC RN if YES to any symptom

Symptom	Yes	No	Symptom	Yes	No
Hives			Weakness or fatigue		
Dizziness			Vomiting		
Wheezing			Abdominal pain		
Swelling eyes, lips, tongue, throat, skin			Aches		
Itchy eyes			Yellow eyes		
Shortness of breath			Itching		
Flushing, chills, sweats			Bruising, easy bleeding		
Fever			Rash		
Peel and stick to reverse side of TB Medication Record					

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APPENDIX B: Missed Doses and Alternate DOT Delivery SCHEDULE for Isoniazid-Rifapentine

Frequency of medication	Days medication to be delivered	Day dose missed	Alternate day(s) to administer
Once a week	Monday	Monday	Tuesday, Wednesday or Thursday
	Tuesday	Tuesday	Wednesday, Thursday, or Friday
	Wednesday	Wednesday	Thursday or Friday
	Thursday	Thursday	Friday
	Friday	Friday	Monday

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APPENDIX C: TB Medication Record Documentation

1. Ensure client identifiers are documented and check that they are the same as those on the TB Order Set (doctor's orders).

2. Place a check in the box if name alert procedures are required.

3. Transcribe the medication orders from the TB Order Set. Example: Isoniazid 900 mg 3 times a week. If already transcribed, ensure they are correct by checking the TB Order Set.

4. Place a check mark in the box when DOT is ordered.

5. Check the TB Order Set with the new shipment of medications to ensure the correct medications, dose and number of doses arrived. Document the number of doses that arrived and the date. Initial once steps 3 and 5 are complete. A new medication record should be used with each new medication shipment.

6. Document height/weight as ordered including the date they were taken.

7. Document the date medication delivery is attempted.

8. Place a number **1** in the column if the client took all of the medication in the dose package. Leave blank if the dose was not given.

9. Place a number **1** in the column if the client did not take the dose or if they only took part of the dose. Leave blank if the dose was given.

10. Document the date the next dose should be given. Example: if the client Is receiving medication three times a week (M-W-F) and the dose was given on Monday, November 2nd, the next dose will be due on Wednesday, November 4th.

11. Count the number of dose packages that remain on hand.

12. Include information such as side effects; missed doses and reason for missed dose; if dose wasted or withheld; and medication errors.

13. Document where the medication was delivered.

14. Sign your name once documentation is complete.

15. At the end of the medication cycle, document the number of full and number of empty dose packages before returning all used and unused medication and dose packages to TB Prevention and Control Saskatchewan. Date and initial once this is completed.

16. Place a check in the corresponding tick boxes to indicate the final location of the Medication Record.

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