

Nursing Protocol for Preventing Psychiatric Adverse Events Associated with Cycloserine



December 2010



UTAH DEPARTMENT OF
HEALTH

Tuberculosis Control

Physical Address: 288 North 1460 West Salt Lake City, Utah 84116

Mailing Address: Box 142104 Salt Lake City, UT 84114-2104

Phone: (801) 538-6191

Fax: (801) 538-9913

Website: http://health.utah.gov/cdc/tb_home.htm

Utah is a low prevalence state for tuberculosis (TB), with a rate of 1.1 cases/100,000 as of 2009, and we see 1 – 2 cases of MultiDrug Resistant TB (MDR-TB) per year. In April of 2010, an MDR case that we had been treating for over a year committed suicide. There were multiple stressors involved. The patient's regimen included cycloserine and ethionamide. While the likely cause of his actions was not due to his medications (cycloserine level was acceptable), we felt that we needed to institute preventive measures for the future. Thus this procedural guide was written.

This guide is meant to serve as a screening tool to be used by outreach workers and nurses. It is in no way intended to make a psychiatric diagnosis, but rather to ensure proper monitoring is maintained, and appropriate preventative action(s) are implemented as necessary.

Larry Niler, RN, Utah Department of Health

Thanks to the following for their help in making this information available and usable:

Lisa Chen, MD, Francis J. Curry National Tuberculosis Center

Cristie Chesler, BA, Utah Department of Health

Madison Clawson, RN, Salt Lake Valley Health Department

Charles Daley, MD, National Jewish Medical and Research Center

Debbie Dean, RN, FNP, Salt Lake Valley Health Department

Gwen Huitt, MD, MS, National Jewish Medical and Research Center

Richard Kanner, MD, University of Utah Health Sciences Center

Marcee Mortensen, BS, Utah Department of Health

Rex Olsen, JD, Utah Department of Health

Ann Raftery, RN, PHN, Francis J. Curry National Tuberculosis Center

Fred Reimherr, MD, University of Utah Health Sciences Center

Debbie Sorensen, RN, Salt Lake Valley Health Department

Adriana Vasquez, MD, University of Texas Health Sciences Center

Cycloserine Nursing Protocol

Before starting cycloserine, current depression and increased suicide risk should be assessed. The nurse should take a thorough social history regarding living situation, stressors, family history of mental illness/suicide. **Zung's Self-Rating Depression Scale**, and the **Medication Side Effects / Mental Health Screening** tool should be administered and scored at baseline. Based on depression screening results and clinical judgment, the nurse will decide whether to start cycloserine or refer for a psychiatric out-patient evaluation. An initial evaluation may also be ordered by the MD, without other criteria. Referral for a psychiatrist/psychologist visit requires preapproval from UDOH.

If the patient is deemed acceptable for cycloserine therapy, the following will be instituted during treatment:

- Re-administer **Zung's** (weekly, bimonthly, or monthly, per provider), and the **Medication Side Effects / Mental Health Screening** tool weekly (more often if necessary). It will be beneficial to ask a family member (or someone else who spends a lot of time with the patient) to also respond to these tools with their perspective.
- Cycloserine peak blood level within 1-2 weeks of starting this drug. Level should be drawn 2 hours after morning dose.
 - Note:** Few laboratories are familiar with performing cycloserine drug level testing and errors have occurred with laboratories performing cyclosporine level vs. cycloserine level resulting in substantial delays in obtaining important drug level information necessary to inform need for dose adjustment. To avoid this, it is recommended to identify a laboratory that has experience performing cycloserine drug level testing (e.g., National Jewish Medical Research Center Laboratory in Denver, CO).
 - Note:** The therapeutic drug level is between 20-35mcg/ml. CNS toxicity is associated with levels > 35mcg/ml, but may occur at even lower concentrations.¹ Use caution if level > 30.
- Cycloserine level should be monitored as needed (per MD instruction) until therapeutic level is achieved. If dose adjustment is necessary, check peak level 3-4 days after adjustment. Generally, once therapeutic level is achieved, further drug level monitoring is not required unless the patient becomes symptomatic.
- Provide B6 adjuvant therapy, 50mg for every 250mg cycloserine.² If patient is also taking ethionamide, consider increasing B6.³
- If any new concerns for depression/suicide risk, refer patient for outpatient psychiatric evaluation as needed (and with UDOH preapproval), and discuss with MD need to stop drug. If suicide risk is evident, refer to **Mental Health Side Effects Screening Procedures** for guidance on how to proceed.

^{1, 2} Francis J. Curry National Tuberculosis Center and California Department of Public Health, 2008: *Drug-Resistant Tuberculosis: A Survival Guide for Clinicians*, Second Edition, pg. 66.

³ Francis J. Curry National Tuberculosis Center and California Department of Public Health, 2008: *Drug-Resistant Tuberculosis: A Survival Guide for Clinicians*, Second Edition, pg. 70

**Procedures for the Use of the Medication Side Effects / Mental Health Screening tool and
Response to Results**

Complete the **patient form**, and the **family/friend form** (if applicable) on a weekly basis.

If the patient **or other family member/friend** responds “YES” to any of the questions other than “Suicidal Ideation”, please contact the case manager (PHN) for instructions. If the patient is in no immediate danger, the case manager will contact the Nursing Supervisor or Bureau Manager within 24 hrs. The attending physician will be contacted within 24 hrs for disposition. If there is concern for the patient’s safety, or the patient replies “YES” to Suicidal Ideations, give the patient the Suicide Prevention Hotline # _____. Contact the Nursing Supervisor, Bureau Manager or _____. If unable to contact a supervisor, call Dr. _____ or Dr. _____. Call 911 if necessary and meet the patient at the receiving hospital.

- If you are not with the patient ask if anyone else is at home with the patient and insist that this person stay with the patient (unless they feel unsafe) until someone arrives or other instructions are given.
- If you feel unsafe or the situation is escalating, do not engage the patient. Create a safe distance between you and the patient (even if that means leaving the immediate area) and wait for the police.
- **DO NOT** go to a patient’s home alone if they are suicidal or agitated. Call the Nursing Supervisor or Bureau Manager immediately before attempting to go to the patient’s home.
- If inpatient hospitalization is necessary, the patient should be admitted to _____.

Never attempt to restrain or put hands on the patient. If there is any doubt about the safety of yourself; get clear of the patient and call 911.

Medication Side Effects / Mental Health Screening – PATIENT INTERVIEW

Patient Name: _____

DOB: _____

Outreach Worker or RN: _____

Date and Time: _____

Reason for Assessment: _____

Current Medications: _____

Questions: Ask the patient if they are having any of the following symptoms or feelings. *For any yes answers, please give brief explanation and contact the case manager.*

- Confusion - Yes / No: _____
- Dizziness - Yes / No: _____
- Disorientation - Yes / No: _____
- Hallucinations - Yes / No: _____
- Nightmares - Yes / No: _____
- Anxiety / Nervous - Yes / No: _____
- Aggression - Yes / No: _____
- Agitation - Yes / No: _____
- Depression - Yes / No: _____
- Suicidal Ideation – Yes /No: _____

- Physical Changes – Yes / No: _____

- Other abnormal or changed behavior – Yes/No: _____

NOTES / DISPOSITION: _____

Medication Side Effects / Mental Health Screening – FAMILY/CLOSE FRIEND INTERVIEW

Patient Name: _____ DOB: _____

Name of Person Interviewed and Relation to Patient: _____

Outreach Worker or RN: _____ Date and Time: _____

Reason for Assessment: _____

Current Medications: _____

Questions: Ask the family member/friend if they have observed the patient (or the patient has reported) having any of the following symptoms or feelings. *For any yes answers, please give brief explanation and contact the case manager.*

- Confusion - Yes / No: _____
- Dizziness - Yes / No: _____
- Disorientation - Yes / No: _____
- Hallucinations - Yes / No: _____
- Nightmares - Yes / No: _____
- Anxiety / Nervous - Yes / No: _____
- Aggression - Yes / No: _____
- Agitation - Yes / No: _____
- Depression - Yes / No: _____
- Suicidal Ideation – Yes /No: _____
- _____
- Physical Changes – Yes / No: _____
- _____
- Other abnormal or changed behavior – Yes/No: _____
- _____
- _____

NOTES / DISPOSITION: _____

Zung Self-Rating Depression Scale (SDS)

Patient Name: _____ Date: _____

For each item below, please place a check mark (✓) in the column which best describes how often you felt or behaved this way during the past several days

Place check mark (✓) in correct column.	None or a little of the time	Some of the time	A good part of the time	Most of the time
1. I feel down-hearted and blue.				
2. Morning is when I feel the best. *				
3. I have crying spells or feel like it.				
4. I have trouble sleeping at night.				
5. I eat as much as I used to. *				
6. I still enjoy sex. *				
7. I notice that I am losing weight.				
8. I have trouble with constipation.				
9. My heart beats faster than usual.				
10. I get tired for no reason.				
11. My mind is as clear as it used to be. *				
12. I find it easy to do the things I used to. *				
13. I am restless and can't keep still.				
14. I feel hopeful about the future. *				
15. I am more irritable than usual.				
16. I find it easy to make decisions. *				
17. I feel that I am useful and needed. *				
18. My life is pretty full. *				
19. I feel that others would be better off if I were dead.				
20. I still enjoy the things I used to do. *				

Adapted from Zung, A self-rating depression scale, Arch General Psychiatry, 1965; 12:63-70.

Scoring

Items are structured in terms of positive and negative statements. Responses are scored 1,2,3 or 4 according to the severity of the symptom. Items marked with an (*) are reverse scored (i.e., 4,3,2,1). The items are totaled to give an overall score.

Scores range from 25-100

- 25-49 – Normal Range
- 50-59 – Mildly Depressed
- 60-69 – Moderately Depressed
- 70 and above – Severely Depressed

Please Note: For any response on question #19 other than *None or a little of the time*, refer to ‘Procedures for Use of the *Medication Side Effects/Mental Health Screening tool*’.