LEGAL AND ETHICAL ISSUES IN TB CARE AND CONTROL

LEARNING OBJECTIVES

Upon completion of this session, participants will be able to:

1. Describe the ethical principles of protecting patient rights and public health and apply knowledge gained to ensure best practice use of legal resources and approaches in their work setting

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SUPPLEMENTAL MATERIAL

1. Sample legal order

ADDITIONAL REFERENCES

• Moszynski P. Doctors disagree over detention of patients with extensively drug-resistant tuberculosis. BMJ. 2007 Feb 3;334(7587):228.
CMCI Colorado:
Legal and Ethical Issues in
TB Care and Control

Ann Hause, JD & Pete Dupree, TB Program Manager
CDPHE
Objectives for the Session

• Describe the ethical principles of protecting patient rights and public health
• Discuss the legal framework regarding TB care in Colorado that supports both of these ethical principles
• Apply this knowledge to attendee's own jurisdictions to enforce best practices of TB care and treatment

Legal Enforcement of Laws to Control TB is a Balancing Act

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The Balance: Patient Rights

- Use least restrictive measures
- Establish trust
- Avoid stigma
- Preserve patient autonomy and liberty

Patient Rights

- Confidentiality/Privacy
- Autonomy and liberty
- Access to own medical records and information
- Right to refuse treatment and the limitations to and implications of such a refusal
**The Balance: Public Safety**

*Weigh risk to one individual vs. Benefit to other individuals*

- Establish trust
- Avoid stigma
- Preserve patient autonomy & liberty
- Least restrictive measures
- Prevent disease transmission
- Protect the public
- Prevent drug resistance

**Public Health Police Power**

- Gives public health TB officials authority to take action to protect public health (this authority rests solely within the state and local public health system)

**However:**

- Public health officials do not have unlimited authority
- We must balance protecting public health while also respecting individual autonomy
- Patients have a constitutional and legal right to procedural due process and equal protection.
Duties of Public Health Officers
(C.R.S. 25-4-501 et seq. & 6 CCR 1009-1)

- Must take measures to prevent spread of communicable diseases or occurrence of additional cases.
- May issue any orders:
  - TB examination
  - Isolation -- exclusion from attendance at the workplace if infectious) s/he deems necessary to protect public health or the health of any other person, and may make application to a court for enforcement of the orders
  - Completion of appropriate treatment
  - DOT

Minimizing Risk to Individual

- Use least restrictive alternatives first:
  - Education
  - Incentives/enablers
  - Engage family, medical providers
- Individualize assessments
- Ensure due process when implementing least restrictive measures such as isolation orders
Legal Framework to Support TB Prevention and Case Management Activities in Colorado

TITLE 25. PUBLIC HEALTH AND ENVIRONMENT
DISEASE CONTROL
ARTICLE 4. DISEASE CONTROL
PART 5. TUBERCULOSIS

C.R.S. 25-4-507 (2018)
25-4-507. Isolation order - enforcement - court review

(1) (a) Whenever a health officer determines that isolation of a person in a particular tuberculosis case is necessary for the preservation and protection of the public health, the health officer shall make an isolation order in writing.

(b) When a health officer is determining whether to issue an isolation order for a person, the health officer shall consider, but is not limited to, the following factors:

(I) Whether the person has active tuberculosis;

(II) If the person is violating the rules promulgated by the board of health or the orders issued by the appropriate health officer to comply with rules or orders; and

(III) Whether the person presents a substantial risk of exposing other persons to an imminent danger of infection.
Key Colorado TB-related legal documents

- **Letter requiring treatment for active disease**
- **Warning letter for patient refusing TB treatment**
- **Tuberculosis isolation order**
- **Warning letter for TB contact evaluation**
- **TB patient treatment contract**

Scenario I

Your agency requests information from a patient's provider. The patient is presumptive for TB or exposure to TB. The provider will not release medical information, citing HIPAA.

If an individual has signs and symptoms compatible with tuberculosis in the infectious stages, the chief medical officer may require examination pursuant to Section 25-4-506, C.R.S. The screening may be performed by an institution, organization, or agency acting at the direction of the county, district, or municipal public health agency. The results of the screening shall be given in writing to the person screened...

Do Not Board (DNB) / Public Health Lookout List (PHLO)

- Federal air travel restrictions for persons with communicable diseases who fly on aircraft, and attempt to cross the border
- Administered by the Department of Global Migration and Quarantine (DGMQ)
- NOT the same as “Do Not Fly” list = security risk
- Criteria based on suspicion that person in question will travel while considered infectious
  - Usually means that the person has traveled while smear positive or threatens to travel while infectious
  - May not have produced documentation overseas to clear them for travel back to U.S.
- Also revokes any active visas and can result in exclusion from U.S. for years
Criteria for DNB Addition

1. Infectious, likely infectious, or at risk of becoming infectious with a serious contagious disease that poses a public health threat to the traveling public

AND

2. Nonadherent with public health recommendations, unaware of diagnosis, or unable to be located

3. At risk of traveling on a commercial flight or of traveling internationally

OR

4. Travel restrictions needed to respond to a public health outbreak or to help enforce a public health order


Slide courtesy of Robynne Jungerman, CDC/DGMQ.
Scenario 2

50 yo Somali man working as a chef dx with smear positive TB w/ low level INH resistance. Pt has already been served a legal order for home isolation. He comes to medical appointments and drives to the public health office for DOT. He is refusing home visits.
Scenario 2a

You get a call from the chef’s co-worker at the restaurant reporting that the patient is still coming in to work.

Stepwise Progression of Public Health Orders

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**Additional tools**

- Sheriff/police (peace officer) escort
- Education
- Random visits by staff
- Monitoring tools (e.g. ankle bracelet - being used in some states)

- Typically want to attempt multiple opportunities to prove / document non-adherence. However, some situations may require immediate civil detention.
- Can allow sharing of limited protected health information to protect the public health on a need to know basis.
To Protect Individual Rights, Public Health Orders Must:

- Include the legal authority under which the order is issued.
- Include an individualized assessment of the patient.
- Be in writing and include the person’s name, the time period the order will be in effect, the location, terms and conditions necessary to protect the public health. A copy of the order must be served to the person.
- Be accompanied by language, visual or hearing interpreters, when necessary, to ensure the person understands the health order.
- Advisable to have a statement of procedures for patient to object, acknowledgement of receipt, choice of action with patient’s signature.

Tools for Examination (patient or contacts)

- Educate patient or family in appropriate language (if necessary)
- Engage primary medical provider to bring patient in for med exam
- Public Health Officer “Order to Appear for Medical Examination”
  - Requires public health authority to serve order in person and offers another opportunity to educate
  - If necessary, we will serve a second order in person with sheriff escort
- If applicable, will notify employment (e.g. HCW, school) that person may not return until med exam is completed.
- Child Protective Services if parents/guardians are uncooperative
- Adult Protective Services if patient is deem incapacitated and unable to make decisions for his/herself
Tools for Monitoring Treatment or Compliance

• Public Health Officer “Order of Home Isolation”
• Deliver DOT at different times during the day to ensure that patient is at home
• If suspect noncompliant with order, issue work restriction order to employer that pt may not appear at work (w/ no mention of reason for confidentiality reasons)
• Some LPHAs in other states are experimenting with other methods: ankle bracelet monitoring, etc.
• Health Officer “Order to Appear for Directly Observed Therapy”
  • Can order to appear
  • Cannot force medications

C.R.S. 25-4-507 (2018) The isolation order shall advise the person being detained that he or she has the right to request release from detention by contacting a person designated in the order and that the detention shall not continue for more than five business days after the request for release, unless the detention is authorized by court order.

Scenario 3

• You receive a report from a laboratory regarding three AFB positive specimens for a 77 yo U.S.-born male with multiple comorbidities including uncontrolled DMII and ESRD. The Chest CT reports, “multiple areas of tree-in-bud and nodular infiltrates, some of which are cavitary.”
• The pt’s doctor has not reported the patient. The doctor doesn’t want to treat the patient and prefers to wait for culture.
A Brief Overview of Lab Reporting (6 CCR 1009-1)

- All confirmed or suspected cases of active tuberculosis disease, regardless of whether confirmed by laboratory tests, shall be reported to the Department or county, district, or municipal public health agency within 1 working day.
- Laboratories shall report within 1 working day any result diagnostic of or highly correlated with active tuberculosis disease, including cultures positive for *Mycobacterium tuberculosis* and sputum smears positive for acid fast bacilli, and shall report the results of tests for antimicrobial susceptibility performed on positive cultures for tuberculosis.
- When a laboratory performs a culture that is positive for *Mycobacterium tuberculosis*, the laboratory shall submit a sample of the isolate to the Department, Laboratory Services Division no later than one working day after the observation of positive findings.

Scenario 4

- 48 yo U.S. born male with history of IV drug-use dx’d w/ smear positive TB and low-level INH resistance. Pt has already been instructed to remain in home isolation; he initially agreed. He has taken 5 doses but is now refusing home visits. No one is answering the door when the PHN comes for DOT. The home is known as a "drug house" and the LHD is receiving reports of random people coming and going from the home all day long.
Scenario 4a

• In the first week while in this home, you are starting your contact investigation. You note an elderly man in a back room who is reported to be the homeowner and step-father of the index case. He is coughing. He states he really doesn’t want to go to the hospital for testing but you also note he is not thriving and lethargic.

Scenario 4b

• The PHN continues to report new people (up to 5-10 new people every day) in the home despite the instruction for home isolation. Despite her best efforts to maintain home isolation and protect the public, no one seems to be complying.
Thanks for your time!

Questions?
ORDER (S) OF THE TB CONTROLLER

Please read all information on this form carefully. Failure to comply with this Order constitutes a misdemeanor punishable by up to six (6) months in jail.

PURSUANT TO THE AUTHORITY IN CALIFORNIA HEALTH AND SAFETY CODE § 120100, ET SEQ., THE TB CONTROLLER OF THE COUNTY OF SANTA CLARA HEREBY ISSUES THE FOLLOWING ORDER (S):

DATE ORDER ISSUED: April 21, 2009

ORDER SHALL REMAIN IN EFFECT UNTIL RESCINDED BY THE TB CONTROLLER

DATE ORDER RESCINDED: ___________________ BY: ________________________________

ORDER ISSUED TO:

Name: xxxxxxxx

Name of parent/legal guardian: N/A

Address: xxx

xxx

Date of Birth: xxxx

YOU ARE HEREBY ORDERED TO COMPLY WITH THE FOLLOWING ORDER (S):

- Isolation to place of residence or other location. H&S Code § 121365 (g)
  You are hereby ordered isolated at the above address following the terms and conditions stated in the Isolation Instructions Document until you are considered non infectious and the Order for Isolation has been rescinded.

- Exclusion from workplace or other location ___________. H & S Code § 121365 (f)
  You are hereby ordered to be excluded from attendance at your work place and/or other listed location(s) until you are considered non infectious and the Order for Isolation has been rescinded.
☑  Required medication.
H & S Code § 121365 (b)
You are hereby ordered to complete the appropriate course of medication as prescribed to you by your MD or the TB Controller/Health Officer.

☑  Directly Observed Therapy.
H&S Code § 121365 (c)
You are hereby ordered to appear for daily Directly Observed Therapy (DOT) Monday through Friday at the TB Clinic or by a member of the Santa Clara County Public Health Department staff as arranged by Ms. Karen Anderson, Public Health Nurse, DOT Coordinator, at 976 Lenzen Avenue, San Jose, CA 95126.

☑  To appear for Medical Examination.
H & S Code § 121365 (a)
You are hereby ordered to appear for examination and treatment as prescribed by your physician, Dr. Bhatia on Tuesday April 21, 2009 at 2:30pm at 976 Lenzen Avenue, San Jose, CA 95126 (408) 792-5586 and for any additional appointments.

☐  Other orders: __________________________
__________________________
__________________________

ADDITIONAL INFORMATION:

Date (most recent)
- According to our records, you have been diagnosed with active, infectious pulmonary tuberculosis (TB).
- Sputa smears collected on xxxxx are positive for acid fast bacilli.

Date
- Your workplace was notified that you are under and order of home isolation and should not return to work until they receive notification that you have been released from home isolation.

Date
- You were served a second Order for Home Isolation, and Orders for Required Medication, Exclusion from Workplace, To Appear for Medical Examination, and Directly Observed Therapy (DOT) on xxx

Date
- Sputa smears done on xxxxxxx were positive for acid-fast bacilli, a finding consistent with infectious tuberculosis disease meaning that you may spread this disease to others.
- A chest x-ray on xxxx shows infiltrates which are consistent with pulmonary TB.
- You were served an order for Home Isolation on xxxx.

The individualized assessment of the circumstances or behavior constituting the basis for the TB Controller/Health Officer to issue this order is as follows:
- I have been informed that you were seen at your workplace at xxxxx on xxxxx at 5pm, xxx, xxx xxx, xxx at 10:50am and at 6:50pm with your client.
- I have been informed that you failed to comply with your Home Isolation Order on xxx, 2009 and were seen arriving at home by public health staff.
- You have repeatedly refused to accept visits at home from your public health nurse (PHN) case manager for monthly follow up and general assessment. Attempts to set up home visits were made xxx, xx, xxx, xxx.
• You have also refused to allow public health staff home visits to assess your compliance with the home isolation order.
  • xxxxx at 4pm you did not answer the door. Your car was not parked in front of the house.
  • xxxx you refused to open the door to public health staff.

The following less restrictive treatment alternatives were attempted in your case and were unsuccessful:

• You were provided an education and explanation, in your native language, by your Regional Case Manager (RCM) as to your responsibilities in order to comply with these orders at the time that were served.
• You were educated about the need to comply with home isolation to limit transmission of TB to others.
• You were educated that to ensure that compliance with DOT is essential to cure your TB.

Less restrictive treatment alternatives were considered and rejected in your case for the following reasons: N/A

You are further ordered to follow all instructions and to appear at all appointments given by the Santa Clara County Public Health Department pending final medical clearance.

Violation or failure to comply with this order is a misdemeanor and may result in further legal action including criminal prosecution.

If you believe that this Order was issued in error or otherwise object to its issuance, you may contact the Office of the TB Controller/Health Officer to arrange a time to present any information or evidence for the TB Controller’s/Health Officer’s consideration. The TB Controller may be reached at (408) 885-4214. Be further advised that you may seek judicial relief from this Order pursuant to California Penal Code §1473.

______________________________
TB Controller

cc: xxx, Deputy County Counsel
    treating physician, MD
    case manager, PHN
    , CDI