LEGAL AND ETHICAL ISSUES IN TB 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
2. Discuss the legal framework regarding TB care in California that supports both of these ethical principles
3. Apply this knowledge to understand the limits and opportunities of these laws in their own jurisdictions to enforce best practices of TB care

INDEX OF MATERIALS

1. Legal and Ethical Issues in Tuberculosis Control – slide outline
   Presented by: Chris Keh, MD
   Pages: 1-20

SUPPLEMENTAL MATERIALS

1. Sample Legal Order
ADDITIONAL REFERENCES

- Moszynski P. Doctors disagree over detention of patients with extensively drug-resistant tuberculosis. BMJ. 2007 Feb3;334(7587):228.


Legal and Ethical Issues in Tuberculosis Control

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Objectives

• Describe the ethical principles of protecting patient rights and public health
• Discuss the legal framework regarding TB care in California that supports both of these ethical principles
• Apply this knowledge to understand the limits and opportunities of these laws in their own jurisdictions to enforce best practices of TB care
Legal enforcement of laws to control TB is a balancing act

Patient rights | Public Health
---|---
HIPAA | State Health and Safety Code, e.g. Title 17

Local Ordinances

The Balance: Patient Rights

Patient rights | Public Health
---|---
Establish trust
Avoid stigma
Preserve patient autonomy

Legal and Ethical
Patient Rights

- Confidentiality/Privacy
- Autonomy
- Access to own medical records and information
- Right to refuse treatment

The Balance: Public Safety

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

Patient rights

- Establish trust
- Avoid stigma
- Preserve patient autonomy

Public Health

- Prevent disease transmission
- Protect the public
- Prevent drug resistance
Public Health Police Power

- Gives TB Control officials authority to take action to protect public health (this authority rests solely with the public health system)

However:

- Public health officials do not have unlimited authority
- Must balance protecting the public health and respecting individual autonomy because the US Constitution places certain restraints on public health officials
- Patients have a constitutional right to procedural due process and equal protection.

Duties of Health Officers
(HSC 120175 and 121365)

- Must take measures to prevent spread of communicable diseases or occurrence of additional cases.
- May issue any orders (TB examination, isolation, completion of appropriate treatment, DOT, detention, 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.
Risks of Public Health Measures to Individual’s Autonomy

- Loss of privacy (through reporting or contact identification)
- Loss of liberty and self-determination (through health orders for DOT, home isolation or involuntary confinement)
- Loss of patient rights
- Justice (unequal imposition of restrictions/interventions)

Minimizing Risk to Individual

- Use least restrictive alternatives first
  - Education
  - Incentives/enablers
  - Engage family, medical providers
- Institutional requirements (school, health care facilities)
- Individualize assessments
- Ensure due process
- Establish policies to protect against discrimination
Legal Framework to Support TB Control Activities in California

Scenario

You request information from a patient’s provider due to suspecting the person to have TB or exposure to TB. They will not release medical information, citing HIPAA.
Scenario

• Response:
  – California Health and Safety Code; HSC 121375
  – Can cite exception to HIPAA when requesting medical records from clinics and institutions for patients with TB disease, suspected to have TB disease, or exposed to TB disease.

ARS: Scenario 1

You receive a report from a laboratory regarding three AFB positive sputa specimens from a 73 yo Asian M with multiple comorbidities.

The PMD has not reported the patient. Dr. C doesn’t want to treat the patient and wants to wait for culture.
## Reporting Requirements: Treating Provider Obligations

- **Case finding**
  - Report known or suspected TB
  - Examine or cause to be examined contacts of infectious TB patients
- **Ensure appropriate therapy and response**
  - Provide clinical/treatment updates every 3 months or as requested by health officer
- **Ensure continuous therapy**
  - Written plan for d/c of TB pts requiring health officer approval
- **Ensure completion of therapy**
  - Report when patient ceases treatment

## Contact Investigations

- Health Officer shall use every available means to immediately investigate TB cases and suspects (HSC 121365)
- Health Officer may order examinations for TB infection for purposes of directly preventive measures in the jurisdiction (HSC 121364)
- Health Officer shall notify the corresponding Health Officer* if exposed persons who should be evaluated for TB lives outside the jurisdiction (17 CCR 2501)
- Providers must examine or refer household contacts for examination, and report results when requested by the Health Officer (HSC 121363)

*or the California Department of Public Health

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Reporting Requirements: Laboratories

• To Health Officer* evidence suggestive of TB within 1 working day of report to provider (17 CCR 2505)
  – Acid fast bacillus (AFB) positive smears
  – Positive cultures
  – Positive NAAT
  – Pathology results suggestive of TB

*For jurisdiction where submitting health care provider is located

• From out-of-state labs (17CCR 2504 and 2505)

Reporting Requirements: Laboratories

• To ensure an acceptable standard of care for TB, labs shall:
  – Perform drug susceptibility testing, unless done in past 3 months
  – Culture AFB smear positive specimens unless culture done in last 30 days
  – Submit MDR MTB cultures to the California Department of Public Health Microbial Diseases Laboratory (17 CCR 2505)
Scenario 2

It is July 1 and a new medicine intern calls to inquire into the discharge of an active TB suspect that she started on TB medications.

Reporting Requirements: Health Care Facilities

- Also known as “GOTCH Law”, HSC 121361, 121362
- Shall not release a person with known or suspected TB until:
  - Providing a written treatment plan to the Health Officer of the jurisdiction in which the health facility is located
  - Obtaining Health Officer approval for patient discharge from hospital*
  - Health Officers have 24 hours to review the treatment plan

*Except in case of immediate need for higher level of care or return to a correctional facility

**HS §121361 Discharge, release or transfer of persons with active tuberculosis**

**HS §121362 Reports to local health officers; Documentation; Parolees**
Reporting Requirements: Jails and Prisons

Shall not release a TB suspect or case until providing a written treatment plan* to:

- Local Health Officer
- Chief Medical Officer of the receiving penal institution
- Health Officer of the county receiving the parolee (if paroling from state prison)

*Does not apply to transfers between prisons or within a local detention system.

ARS: Scenario 3

Patient with suspected TB disease with large pleural effusion admitted to a local hospital. Thoracentesis reveals an exudative effusion that is AFB smear negative. Sputa x 3 smear negative. Patient started on TB meds. On HD#7 request for discharge and pt reveals that she may be flying to India the next day.

The hospital requests discharge approval.
Do Not Board / Lookout List

- 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

ARS: Scenario 4

33 yo Vietnamese M real estate agent with smear positive TB, 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.
ARS: Scenario 4b

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

### Stepwise Progression of Legal Health Orders

#### Legal Orders
- Medical examination for TB
- Home isolation while infectious
- Exclusion from attendance at the workplace
- DOT
- Treatment completion (but not involuntary administration)

#### Additional tools
- Sheriff/police (peace officer) escort
- Education
- Random visits by staff
- Monitoring tools (e.g. ankle bracelet)
- APS/CPS, other providers

#### Civil Detention
- Detention in a treatment facility for the purposes of examination, isolation and treatment completion

- 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

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To Protect Individual Rights, Legal Health Orders Must:

- Include the legal authority under which the order is issued
- Include an individualized assessment of the patient and the less restrictive options that were attempted and were unsuccessful, or were considered but rejected and why
- 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
- Engage primary medical provider to bring patient in for med exam
- Health Officer “Order to Appear for Medical Examination”
  - Requires CDI 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
- Adult Protective Services
**Tools for Monitoring Treatment or Compliance**

- Health Officer “Order of Home Isolation”
- Deliver DOT at different times during the day to ensure that patient is at home
- If suspect noncompliance with order, issue work restriction order to employment that pt may not appear at work
- Some PHD 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
  - Second order with sheriff escort (HSC 101029)

**ARS: Scenario 4c**

The patient has been reported at work several instances despite education and legal order for home isolation and exclusion from work. He remains smear positive.
Civil Detention

• Gives the Health Officer authority to issue a health order for involuntary civil detention of TB patients in a treatment facility
• Allows for involuntary detention for examination, isolation or treatment of TB but not forcible administration of TB medication
• Jails or prisons cannot be used for civil detention
• No criminal charges are filed, no record
• No forced medications
• Detained until cured

Civil Detention

Less restrictive alternatives must be attempted and documented
– Education/counseling (medically trained interpreters are vital)
– Removing cost as barrier
– Voluntary DOT
– Incentives/enablers
– Housing
– Social services
– Alcohol and drug rehabilitation
– Health officers orders: isolation, DOT, completion of therapy, medical examination

* CDPH-CTCA Guidelines for the Civil Detention of Persistently Non-Adherent Tuberculosis Patients in California
Civil Detention

- Decision to detain should be based on comprehensive / individualized assessment
  - His/her medical condition
  - Course of treatment
  - Risk of transmission if therapy not completed
  - Barriers which prevent him/her from completing therapy
  - Written documentation of the least restrictive measures that have been attempted
  - Behavior or events that have led to health officer orders
  - Substantial likelihood that pt cannot be relied upon to finish TB treatment.

HS §121367 Required contents of orders

Civil Detention

- Client can request release from detention at any time
- Patient can be detained up to 60 days without a court order. Detention beyond this requires a court authorizing the detention.
- If the patient requests release:
  - LHO must apply to the court within 72 hours of the patient’s request AND
  - Courts must authorize continued detention within 5 business days of the patient’s request

HS §121366 Removal or detention for examination without prior court order; request for release; length of detention
Civil Detention Examples

- Pulmonary smear (+) MDR patient who traveled to U.S. for medical care and divided time between Nepal and U.S.

- Popular Asian entertainer (laryngeal TB) who traveled to home country and back without clearance, ICE placed ankle bracelet on him. New HIV diagnosis.

- Young undocumented Latino man with meningoencephalitis and cognitive deficits, limited social support agreed to placement at mental rehabilitation center. Locked facility so agreed to voluntary civil detention.

- Marginally housed, psychotic man with poor insight into disease, cavitary smear positive

- Marginally housed, AIDS with cognitive deficits, smear positive, h/o elopement from two hospitals

Civil Detention Examples

- Marginally housed, HIV/AIDS, smear (+) disseminated TB with narcissistic personality disorder vs. cognitive deficits, flight risk

- Deaf mute, developmentally delayed, HIV/AIDS, substance use, homeless and history of violent behavior, AFB smear (+)

- Homeless, HIV positive, smear (+), visitor from China, meth addiction

- Chronic alcoholic, depression, hx of TBI; multiple attempts at outpatient DOT, case management over 4-5 months failed due to ongoing alcohol use
Regional Civil Detention Example

- Cordilleras Mental Health Rehabilitation Center, Redwood City
- Admissions criteria
  - Clinically non-infectious
  - Axis I diagnosis and require care/rehab in 24-hour setting
  - Age 18-65 yo
  - Cannot be sexual predator, acute psychiatric illness, unmanageable behavior (e.g. violent), outstanding arrest warrant or pending crime conviction
- Health officer / court order for detention in place
- CDPH approval

Criminal Detention

- Detention must be preceded by a warrant and an arrest for violation of the health order (misdemeanor)
- Health Officer notifies the District Attorney who prosecutes
- Place of detention is usually a jail but for no longer than a year
- Person may be confined, placed on probation or released
Questions?

Special THANKS to Jan Young (CDPH, TBCB) and Julie Higashi (LAC)

- Western Region - Curry International Tuberculosis Center Warmline
- Local Health Jurisdiction / State TB Control, Liaison
- Colorado: https://www.colorado.gov/pacific/cdphe/tb-forms-phia
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

ORDER ISSUED TO:

Name: xxxxxxxx
Name of parent/legal guardian: N/A
Address: 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 xxxxxx 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, xxxxx 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.
  • xxxx 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