

Medical and Legal Aspects of Hepatitis C in Corrections

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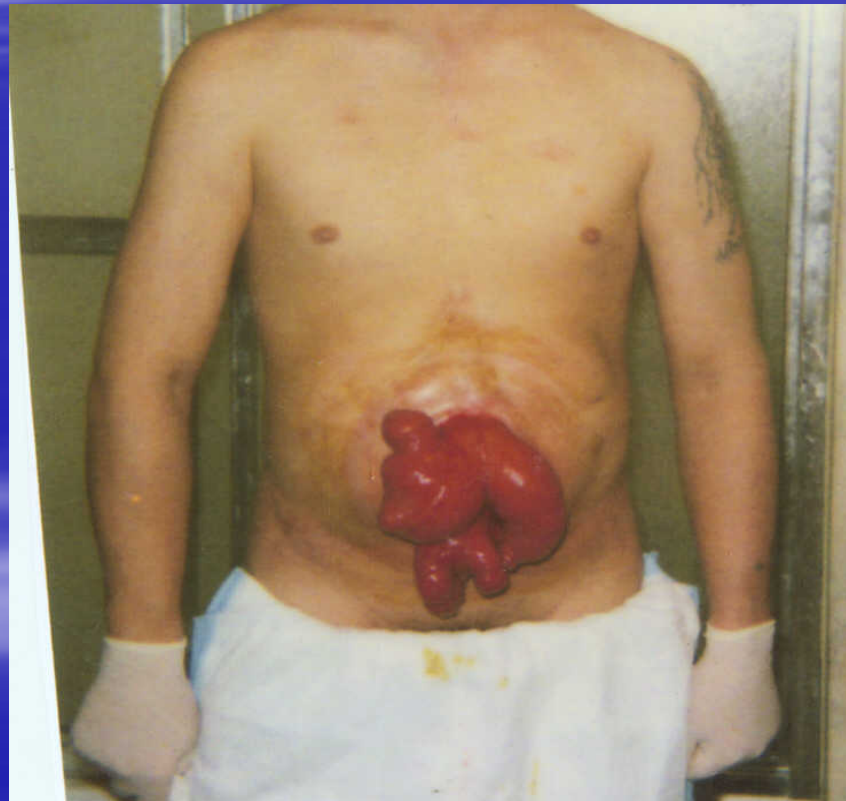
Overview of Ethical and Legal Aspects of Hepatitis C in Corrections

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Constitutional Requirements

- 1. Access to Health Care
 - 2. A Professional Medical Opinion
 - 3. Receive the Care that is ordered
-
- Breaches are Deliberate Indifference
 - Estelle v. Gamble (1973)
 - **NECESSARY HEALTH CARE**

The Need For Treatment- This Patient Clearly Needs Treatment



The Need For Treatment- Does This Patient?



In the Broad Spectrum of Constitutional Care

- Does Hepatitis C need to be treated?
- Does it need to be treated in SOME patients if not all of them?
- Are there ANY patients that NEED treatment? (In the Constitutional sense of LEGAL NECESSARY CARE?)
- What is the Problem with Hepatitis C and why is there discussion?

The Problem

- Between 2.5 and 4.0 million Americans are infected with Hepatitis C
- About 10,000 deaths and 10,000 liver transplants are related to Hepatitis C infections every year
- Difference of perspective between Public Health Officials and Gastroenterologists (and some Infectious Disease physicians)

The Problem- 2

- Treatment for Genotype 2 & 3 gives SVR 75-80% of the time
- Treatment for Genotype 1 approached SVR 45-50% of the time
- Over the past seven to eight years- a reasonable standard of care has been approached:
 - Pegalated Interferon/Ribavirin
 - Improved liver morphology if not SVR

The Problem- 3

- Primary mode of transmission is blood-borne through injection drug use; (sexual transmission is also known to exist)
- **Same risk behaviors that lead to this disease- lead to incarceration**
- Same is true for HIV
- HCV much easier to acquire

The Problem -4 Corrections

- Size of the problem- Texas Study that Lannette Linthicum and Mike Kelley were involved in:
 - 3712 samples over six months (98-99)- about 27% for males 45% for females- interestingly the rate was higher among whites than people of color
 - Baillargeon J, Wu H, Kelley MJ, Grady J, Linthicum L, Dunn K. Hepatitis C seroprevalence among newly incarcerated inmates in the Texas correctional system. Public Health. 2003 Jan;117(1):43-8.

The Problem 5 Corrections

- From Risk Management studies- (therefore not eligible for publication) the Florida Department of Corrections-performed on all entrants to one male and one female reception center for a period of one month (5/02)
- 17 % of all Male entrants- Hepatitis C +
- 33% of Female entrants- Hepatitis C +

The Problem- 6 Corrections

- Estimates- Low 20% to a high of 70% of inmates in correctional systems have HCV
- Higher **rate** among women, but much smaller **numbers** because of the fewer number of females incarcerated
- It is a disease of Corrections- about one third of those with Hepatitis C have been incarcerated

The Correctional Approach to Hepatitis C

- Initially- nothing- don't see it; don't hear it; does it really exist?
- Then some lawsuits (and some interest groups- but unlike HIV these were not populated with high profile actors and media people- therefore the interest groups did not have the impact of the AIDS activists)

The Correctional Approach to Hepatitis C- 2

- About 1999, mostly in fear of litigation- the State of Pennsylvania promulgated health care directives that any patient who wanted to find out HCV status would be tested and those that wanted treatment would be evaluated and if medically appropriate- would be treated
- About 2000 state of New Jersey won lawsuit concerning lack of testing and treatment

The Correctional Approach to Hepatitis C -3

- About 2001 Pennsylvania backed away from its universal testing and treatment model
- Still- courts were not finding for prisoner plaintiffs for testing or treatment
- AND THEN, May 28, 2003 in New York the state supreme court determined that the State could not impose certain restrictions on treatment---

The Law of Hepatitis C

- Early on- all of the lawsuits failed
- There was enough **diversity among the opinion of medical professionals** as to treatment and whether to treat and the treatment results were so dismal (Ron Koretski UCLA)- Courts were hesitant to step in
- Personal service for several states involved in those suits

Diversity of Opinion



WHY- Diversity among the opinion of medical professionals?

- Variable Disease course
 - 20% infected- clear completely- acute infection only
 - 80% develop chronic disease
 - 10-30 year course
 - Comparatively few have severe liver damage
 - True Natural History of Disease not really known
- No clinical test to predict which of the 2.5-4.0 million infected people

WHY- Diversity among the opinion of medical professionals?- 2

- Liver Function Tests – NOT A PREDICTOR
 - may be high, low or in between and do not indicate if disease is progressing
 - Disease can create severe liver damage with normal to slightly high LFT's
 - Very high LFT's may create no significant liver damage

WHY- Diversity among the opinion of medical professionals?- 3

- Viral Loads- NOT A PREDICTOR

- High viral load patients may or may not develop significant liver damage
- Low viral load patients may or may not develop significant liver damage

NO OTHER SURROGATE MARKER WORKS FOR THIS DISEASE AS A PREDICTOR

Serial Liver Biopsies- (Do not even want the first one)

Predictor of Problems



WHY- Diversity among the opinion of medical professionals?- 4

- NO IMMUNITY- Can clear the disease and if exposed to it again (e.g. if continue IVDU or sex) can re-infect
- Most individuals- (more than 80% is suggested by many experts) **do not develop complications from HCV**
- HCV mutates easily, therefore no vaccine on the horizon

Sexual Transmission of Disease- good for health care providers- Always have a job



WHY- Diversity among the opinion of medical professionals?- 5

- Public Health Doctors- 2.5 to 4 million people with a disease and only 20K have a problem-
 - With limited resources- other more problematic diseases need to be addressed
 - Treatment regimens inconvenient & uncomfortable- Injections and oral- therefore many drop out of treatment
 - Direct resources at prevention and lower the incidence of infection (National Hepatitis C Prevention Strategy- A comprehensive Strategy for the Prevention and Control of Hepatitis C Virus Infection and Its Consequences CDC Summer 2001)
 - Health Care Planning Meetings



PLANNING

MUCH WORK REMAINS TO BE DONE BEFORE WE CAN ANNOUNCE
OUR TOTAL FAILURE TO MAKE ANY PROGRESS.

www.despair.com

WHY- Diversity among the opinion of medical professionals?- 6

- Gastroenterologists & Liver Specialists- **Largest single cause of liver transplant** in the country-
 - 10,000 liver deaths yearly
 - 10,000 liver transplants yearly
 - Therefore **MUST DO SOMETHING ABOUT THIS DEADLY SCOURGE** Right Away
- ID Specialists- In Between- an infectious disease process is their bailiwick, but some feel treat- many feel don't treat- many want someone else to make the decision

Disagreement among medical professionals-tending to lessen

- Genotype Two & Three- good results – SVR (Sustained Viral Response) approaches 80%
- Genotype One- most common in US especially among incarcerated- Poorest SVR- may approach 45-50% with pegalated interferon
- Even without SVR- get morphologic improvements in liver structure (BUT poor controls- this may be the natural history of the disease)

EMERGING CHANGE IN COURT OPINION

- Courts latched onto the following logical sequence

Disagreement tending to lessen- Why?

- Dually diagnosed patients- HIV & HCV-
- Initially- Treat and Control HIV- once that is under control address HCV
- Now- If Liver Damage threatening- Treat HCV NOW and may delay addressing HIV therapy until (if) liver stability achieved
- HIV makes HCV WORSE
- HCV does not seem to impact on HIV

Disagreements lessening- 2

- Virtually all agree dually diagnosed patients need to be treated for BOTH diseases if appropriate
- **If HCV needs to be treated in at least some conditions- then cannot ignore it as a disease entity**
- (e.g. there is an Approved (FDA) Treatment for Dually Diagnosed- Roche's 20 kD pegalated interferon- Pegasys)

Disagreements Lessening- 3

- If most all practitioners agree that HCV needs to be treated in dually diagnosed patients (HCV & HIV)
- And there is an FDA Approved treatment regimen for them (Pegasys)
- ERGO- you cannot any longer ignore the disease
- Courts latching onto this concept

NOW-This Can Impact YOU!



The Law of Hepatitis C- 2

- Early on- In continuing case of Madrid v. Gomez (1995 et. seq) – the Pelican Bay Case in California- Cannot ignore inmates requests for HCV status- if they asked for testing- you had to offer it to them- may or may not have to do anything else
- Applied to only one institution in only one State (Pelican Bay, California)

Inmate Lawsuits



STRIFE

AS LONG AS WE HAVE EACH OTHER, WE'LL NEVER RUN OUT OF PROBLEMS.

The Law of Hepatitis- C- 3

- THEN 2003- “...Furthermore, while the treatment of hepatitis C is still in its infancy-- there being no known cure or even a set protocol for treatment --this court finds **no treatment at all to be repugnant to our standards of decency**”; In the Matter of Angel Domenech, Petitioner, v. Glenn S. Goord, as Commissioner of New York State Department of Correctional Services, et al., Respondents. Supreme Court, Westchester County, May 28, 2003
- State Court case- q.v.

The Law of Hepatitis- C- 4

- When I used to give this talk- I could say with confidence that NO court (other than the very limited holding in Madrid v Gomez) had ever found any correctional system had to do anything about Hepatitis C including testing, treating, harm reduction, or even education
- NO LONGER TRUE

The Law of Hepatitis C- 5

- State Court- (Domenech in New York)- but state courts have very limited applicability outside of their own state- BUT
- One of the cases this court used as a precedent was a little know **Federal** case which now has risen to and been decided on at the Appellate level

The Law of Hepatitis C- 6

- "it was improper for a prison official to refuse to provide an available treatment--with no medical justification underlying the decision--where that treatment had been recommended unanimously by prison and outside treating doctors and was deemed necessary by them for the prisoner to combat a serious illness such as Hepatitis C."

(Johnson, 234 F Supp 2d at 362.)

- Note- this is a Federal Appellate case

The Law of Hepatitis- C- 7

- Federal Appellate cases are applicable to the entire region of the country where the case is decided- (and if no contrary decided case exists other appellate courts in other regions (Federal Circuit Courts) will generally not go out of their way to disagree with the precedent of the a fellow circuit court panel (although it does happen regularly, but generally on controversial issues))

The Law of Hepatitis- C- 8

- It is safe to assume that we will see courts becoming more activist in the area of corrections and Hepatitis C
- How will they Exert their Activism?
- Decision in **Individual** cases in favor of the plaintiff (Inmate) and then eventually selecting or allowing a **Class Action** suit if corrections is not pro-active in this area

The Law of Hepatitis- C- 9

- **Class Action-** Applies to ALL PERSONS SIMILARLY SITUATED in the District or Circuit- Broad applicability
- What does “NO LONGER IGNORE IT” mean?
- Probably- at a minimum
 - Protocols for testing- at least upon individual inmate request

The Law of Hepatitis- C- 10

- Probably:
 - Testing- at least upon request
 - Insuring treatment of recommended by medical staff
 - Insuring continuity of care beyond incarceration if needed
 - Make sure artificial barriers are not created to block access to treatment
- Possibly: – education and harm reduction strategies

What About Transplants?

- There is currently no case directly on point
- It is reasonably clear that if correctional and non-correctional physicians agree that a transplant is indicated- the court would find it unacceptable (Unconstitutional) if it were not done
- If there is disagreement among the physician providers, until there is a case that all of the physicians are totally in agreement, the court would probably indicate that the plaintiff (inmate) simply disagrees with the evaluation of some of his doctors- they have typically done this in the past

What About Transplants? 2

- Other state's experience (until a court settles a case directly on point)
- Florida- Inmate requiring almost any type of transplant never seemed to make it to the top of the transplant list (except one for bone marrow)
- In other states inmates have received transplants of other organs

What About Transplants? 3

- Depending on the ethics of the correctional providers and their bioethics committees (if they exist and they do in Hawaii and did in Florida, although the one in Florida is now dormant) communication with the transplant providers may be in order.

ETHICS not just of transplants, but of Treatment of Hepatitis C

- Average State- Prisons incarcerate less than three years
 - (South- about 7-8 years)
- Should a prison system have to incur the entire cost of treatment for a disease that has a twenty to thirty year life span??
- Is a Prison system an extension of Public Health??

ETHICS

- If prisons are part of public health-
- Do they have the same responsibilities as a public health system
 - Public health systems can treat patients until they run out of money- then they have NO MANATE to treat
 - Prisons have a federal mandate to provide care
- Funding sources of Public Health and Corrections is same- PUBLIC DOLLARS

ETHICS

- Public Dollars- but different parts of the Public Trough- generally from different parts of appropriations (Health Care vs. Corrections)
- With Limited Resources- what should we do???
- More importantly- to stay out of trouble- What do we Have To Do???

What do YOU Do in Your System?

- DO NOT IGNORE THE DISEASE
- ADDRESS IT AS YOU WOULD ANY OTHER DISEASE
- TEST FOR THE DISEASE (at least upon inmate request or if there is any medical indication)
- IF POSITIVE ON TESTING- FOLLOW THE INMATE

What do YOU Do in Your System?-

2

- REFER THE PATIENT TO APPROPRIATE SPECIALIST (recall difference of opinion between GI and ID)
- IF TREATMENT IS RECOMMENDED-TREAT
- If transplant is recommended- no clear cut court answer yet unless (almost) ALL providers agree

What Other Systems Have in Place- FL

- 2-2-2 ALT two times normal on two different tests 2 months apart- Will we miss some- Possibly
- Refer to NFRC-H for liver bx.
- Evaluation for Treatment
- All Treatment begun at NFRCH hospital
- Once on TX- I/M may go back to his/her institution and continue to receive tx there

Other Systems- Florida Early Results

- As Before- 2/2/2 after a liver bx and appropriate- all begun at our Hospital by same providers
- Over 100 people FINISHED treatment-
- Significant number of refusals
- More than half start- do not finish
- 100% after finish “I did not realize how bad that stuff was making me feel.”

Treatment of Hepatitis C- II

- Results-

- 90+% Genotype 1
- can relax mental health precautions- WITH CARE (Dr. Watson's Study)
- Pegalated Interferon/Ribaviron- most treatment
- So Far- 12 patients success at 12 & 18 months
- Does not seem - at this point- like success rate will significantly improve

Other Systems- Federal Bureau of Prisons Protocol

- WAS Very similar to Florida's 2-2-2
- It has undergone revision – Released October 2005
- Broader indications for assessing patients with possible HCV
- Relaxed requirements for specific LFT elevations
- Points out that treatment may be indicated in patients with normal LFT's and relaxes indications for liver biopsy

New Protocols

- Do NOT Ignore this disease
- Create Rational Policies and Permit People Access to testing and treatment when indicated
- OTHERWISE YOU WILL CREATE LAWSUIT AND OTHER INMATE OPPORTUNITIES



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