Hepatitis C Database and Program Evaluation Project

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Purpose

- The purpose of this project was
  - to establish a sustainable database for collecting and evaluating Hepatitis C treatment among inmates and
  - to examine several quality indicators related to HCV treatment
    - Demographic characteristics of inmates treated
    - Virologic response
    - Reasons for early treatment discontinuation

Background

- Chronic Hepatitis C infection is a major cause of morbidity among inmates
- Increasing number of inmates are being treated for HCV
- Massachusetts DOC/UMASS Correctional Health has treated more than 510 inmates which represents one of the larger cohorts of treated adults in the U.S.

Issue that led to this project

- Data were collected in multiple locations throughout the system
  - Data at the health service units
  - Treating physicians were keeping their own data
  - Data sheets were being kept centrally
  - A new data base was developed for on-treatment inmates – which had some data (but not all relevant data)
  - There were paper copies, medical record notations, hepatitis C worksheets (multiple) and data files
- The problem: Not one location contained all of the data or at least enough data to fully evaluate the program and/or conduct research

The Project Goals

- Establish the data base
  - Reviewed all data sources
  - Developed a data extraction sheet
    - Extracted data from all available sources and entered into one database
  - Modified the hepatitis C worksheet and extraction sheet based on comments from the team
    - New form approved by the HCV committee
    - Put the new form into place: worked with the ID nurse managers
    - SPSS training to run data
- Describe the population of inmates who have been treated for HCV according to demographics, clinical factors and response rate to treatment

Development of the New Data Collection Worksheet

- After running preliminary data - decided to re-work the data sheet (one page) to capture important data that was frequently missing
  - Hepatitis C medications and dose
  - Length of treatment
  - HIV status
  - Race
  - Alcohol and Drug use history
  - Mental Health Conditions
  - Current Medications
  - History of prior treatment
  - Adherence
  - Labs: Glucose, Cholesterol, triglycerides, TSH

Results

- Data will be presented as follows:
  - A = All inmates treated pre-combination therapy
    - February 1999 – July 2002 (N =240)
  - B = All inmates treated since the start of combination treatment
    - August 2002 - present (N = 270)
  - Total – All inmates ever treated for HCV
    - February 1999 – present (N = 510)

Age at start of treatment

	A (pre comb) N = 140 Mean (range)	B (comb) N = 370 Mean (range)	Total N = 510 Mean (range)
Age	41.4 (26-60)	43.3 (22-71)	42.9 (22-71)

Gender

	A pre comb N (%)	B comb N (%)	Total N (%)
Gender			
Male	114 (81.4)	353 (95.4)	467 (91.6)
Female	3 (2.1)	14 (3.8)	17 (3.3)
Missing	23 (16.4)	3 (0.8)	26 (5.1)

Race

	A pre comb N (%)	B comb N (%)	Total N (%)
Race			
Caucasian	47 (33.6)	177 (47.8)	224 (43.9)
Black/AA	6 (4.3)	57 (15.4)	63 (12.4)
Hispanic	13 (9.3)	53 (14.3)	66 (12.9)
Other	1 (0.7)	2 (0.5)	3 (0.6)
Missing	73 (52.1)	81 (21.9)	154 (30.2)

HIV Co-Infection

	A pre comb N (%)	B comb N (%)	Total N (%)
HIV +			
No	62 (44.3)	200 (54.1)	262 (51.4)
Yes	21 (15.0)	55 (14.9)	76 (14.9)
Unknown	57 (40.7)	115 (31.1)	172 (33.7)

HCV Genotype

	A pre comb N (%)	B comb N (%)	Total N (%)
Genotype 1	57 (40.7)	234 (63.2)	291 (57.1)
Genotype 2	10 (7.1)	41 (11.1)	51 (10.0)
Genotype 3	21 (15.0)	57 (15.4)	78 (15.3)
Genotype 4	4 (2.9)	16 (4.3)	20 (3.9)
Missing	48 (34.3)	22 (5.9)	31 (13.7)

HCV RNA Response

	A pre comb N (%)	B comb N (%)	Total N (%)
EVR			
Yes	56 (40.0)	178 (48.1)	235 (46.1)
No	21 (15.0)	54 (14.6)	79 (15.5)
Missing	63 (45.0)	136 (37.3)	196 (38.4)
SVR			
Yes	9 (6.4)	2 (0.5)	11 (2.2)
No	27 (19.3)	30 (8.1)	57 (11.2)
Missing	104 (74.3)	338 (91.4)	442 (86.7)

Changes in ALT

	A pre comb Median	B comb Median	Total Median
Baseline ALT	78.0	68.0	69.5
Week 12 ALT	37.0	55.5	50.0
Week 24 ALT	30.0	76.0	44.0

Treatment Interruptions

	A pre comb N (%)	B comb N (%)	Total N (%)
No	104 (74.3)	183 (49.5)	287 (56.3)
Yes	5 (3.6)	40 (10.8)	45 (8.8)
Unknown	31 (22.2)	147 (39.8)	178 (34.9)

Dose Reductions

	A pre comb N (%)	B comb N (%)	Total N (%)
No	99 (70.7)	199 (53.8)	298 (58.4)
Yes	11 (7.9)	13 (3.5)	24 (4.7)
Unknown	30 (21.5)	158 (42.7)	188 (36.9)

Early TX Discontinuation

	A pre comb N (%)	B comb N (%)	Total N *%)
No	78 (55.7)	106 (28.6)	184 (36.1)
Yes	32 (22.9)	137 (37.0)	169 (33.1)
Unknown	30 (21.4)	127 (34.4)	157 (30.7)

Reasons for Early D/C

	A pre comb N (%)	B comb N (%)	Total N (%)
Poor VL Response	7 (5.0)	24 (6.5)	31 (6.1)
Severe Side Effects	12 (8.6)	67 (18.1)	**79 (15.5)**
Poor compliance	4 (2.9)	19 (5.1)	23 (4.5)
Other	6 (4.3)	19 (5.1)	**25 (4.9)**
Unknown/not specified	111 (79.1)	241 (65.1)	352 (69.0)

Most Common Side Effects cited as reasons for treatment D/C (N = 79)

	N	% of all side effects reported
Multiple Symptoms and poor tolerance= inmate refusal	16	20.3%
Cotton Wool Spots	11	13.9%
Mental Health Issues	9	11.4%
Neutropenia	8	10.1%
Anemia	5	6.3%
Unknown reasons	5	6.3%
Rash	4	5.1%
GI Intolerance/wt loss	4	5.1%
Thyroid Disease	4	5.1%
Vision Problems	3	3.8%
Seizures	2	2.5%
Renal Failure	2	2.5%
Other	6	7.6%

Most Common "Other" Reasons for Treatment D/C (N = 25)

	N	% of all "other" reasons reported
Released/Paroled	17	68%
Poor Adherence	2	8.0%
Death	2	8.0%
Dirty Urine	1	4.0%
Other	3	12.0%

Conclusions

- Developed a usable data worksheet that facilitates communication between the
  - DOC ID Case Managers at the HSUs
  - UMass Correctional Health HCV Program Manager and Medical Director
- Established a database that organizes all of the HCV program data
  - Need to improve reporting, collection and entry of viral load, mental health, substance abuse and co-morbidity data
- Resulted in “just in time” changes in the treatment protocol

Conclusions

- Little change in the age, gender, or number of HIV co-infected inmates being treated
  - Age – average early 40's – is this still too late?
  - Still only 3% of female inmates being treated
  - HIV co-infected stable at 15%
- Greater numbers of African American and Hispanic inmates as well as those with Genotype 1 treated since starting combination therapy
- Treatment interruptions experienced by 11%
- Dose reductions experienced by 3.5%
- Early treatment discontinuation experienced by 37%
- Release from prison is still an important reasons for early treatment discontinuation and unknown SVR data