Successful Integration Of Hepatitis C Treatment Into Medical Home;

♥Journey From Capacity Development To Mentorship

Multnomah County Health Department HIV Health Services Center Portland, OR



Learning Objectives

- Identify factors in the Ryan White system that support Hepatitis C treatment
- 2. Learn resources to develop tools for Hepatitis C treatment
- 3. Discuss factors that facilitate or are barriers of adherence to treatment plan

HIV Health Services Center

- Downtown Portland
- 960 active patients
 - Full primary care to PLWH
 - Multi-disciplinary medical and support services
- 83% M, 16% F, 1% T
- 67% W, 12% B, 14% H
- 76%<100% FPL, 28% non-permanently housed</p>
- Insurance mix
 - 61% high risk pool, 9% Medicare, 21% Medicaid, 9% none
 - Part A, C and D funding (TGA 5 counties in metropolitan area)
- \sim 20% Hepatitis C positive = \sim 200 patients
 - Main risk category: IVDU

Unmet Need Identified

1. Majority of Hep C co-infected were not accessing treatment for hepatitis C

2. Providers and staff did not have knowledge or capacity to treat Hepatitis C

Hepatitis Treatment Resources In Community

- Hepatology clinic at university hospital
 - Waiting list
 - Traditional private practice/specialist model
 - Average 1-2 patients per year accessed treatment
- Biopsy options
 - Hepatology clinic
 - Interventional radiology

Hepatitis C Treatment: Capacity Development

- NACHC National Association of Community Health Centers
 - Accepted to participate in HCV Initiative 'Keeping Hepatitis Treatment at Home' (2006-2007)
- Treatment team identified MD, RN and program coordinator
- Provided educational symposium, data collection support and ongoing TA

Getting Started:

- Work with admin and stakeholders to develop support for program
- Develop data collection tools
- Develop and maintain database
- Discuss Logistics
 - Identify specific time/space allotment?
 - Integrate into current workflow?

Staff Education:

- HCV disease education for all staff not just clinicians
- Identify preceptorship opportunities for ongoing consultation and mentorship
- Include ancillary services such as mental health providers, case managers, nutrition

Development Stage:

- Create screening and treatment guidelines
 - New diagnosis support
 - Counseling patients on living with HIV/Hep C
 - Create checklist of expectations regarding treatment plan
- Prepare tools for clinical management, brochures etc
- Patient tracking tools
- Community outreach and awareness of new program

Identify Resources

- Medication resources
 - Insurance PA process
 - Uninsured
- Biopsy resources
 - Insured and uninsured
- Local expert willing to be consultant/ mentor

Tools We Created (paper charts)

- Pre-treatment checklist
 - List of diagnostic tests and screenings
 - Based on treatment guidelines
 - Tests often completed at different times, wanted to be able to view at a glance
 - Can also be used as test order form if desired
- Flowsheet of expected labs and intervals during treatment cycle
- Interim lab flow sheet
 - Use as needed when frequent monitoring is required
 - Example: patient develops anemia

	baseline	Day 1	Wk2	wk 4	wk8	Wk 12	wk 16	wk 20	wk24
TEST									
Date of Test:	I								
WBC									
RBC									
Hgb									
Het									
Platelets									
Neutrophils									
ANC									
CD4									
(AST									
ALT									
T. Bili									
Alk Phos.									
Albumin									
Glucose									
Creatinine									
Calcium 1 otai									
Protein									
INR									
TSH									
Prognancy test									
PHQ-9									
PCR quant									

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Hepatitis C Treatment Flowsheet (draft)

Protocol for Pretreatment

- Checklist for nurse
- Checklist for patient
- Patient consent/treatment acknowledgement form
- Handouts for patient summarizing treatment and side effect management

Patient Readiness

- Patient education class
 - In-house treatment educator vs pharma nurse educator
 - We decided to make class a mandatory step prior to initiation of treatment
- Pre-treatment session with nurse to review self-injection technique and side effect management

Hey – we are good at that already!

Support adherence

- Ongoing case management
- Aggressive side effect management
- Frequent interaction with patient
- Quick access to mental health provider
 - Psychiatric side effects very common
 - Begin to worsen in early months of treatment, can have sudden onset and be very extreme
- Support groups

Get started!

- Patient 1
 - Modify tools and process as you proceed
- Spread capacity
 - Other teams in clinic
 - We have spread capacity to all of our medical teams in the clinic
 - Other clinics in system
 - Discussions with other high prevalence clinics in system



Hepatitis C Treatment Outcomes

- Most data is with HCV mono-infected, not HIV/HCV co-infected
- Length of treatment considerations
 - Genotype 1, 2, 3
 - Standard 24 vs 48 weeks
 - Experimental modifications
- Current standard of care: Pegylated interferon weekly injection (SQ) plus ribavirin capsules (twice daily)
 - Ribavirin dose varies in published studies

Published Outcomes For Co-infected

- Apricot study
 - -40% SVR pegInf + 800mg RBV daily
 - 18% geno 1 and VL>800,000 (=majority)
- ACTG 5071
 - 14% SVR in genotype 1

Based on these results; should co-infected be offered treatment?

Outcomes Before Integration in Medical Home

- 7 patients (5 geno1, 2 geno2)
 - treated with standard of care: peg-Inf/ribavirin
 - 3 early DC due to side effects (weeks 24-28)
 - 1 viral relapse (g2)
 - -3 SVR (6 mo post treatment)-- \rightarrow 43%
 - (2 g1 , 1 g2)

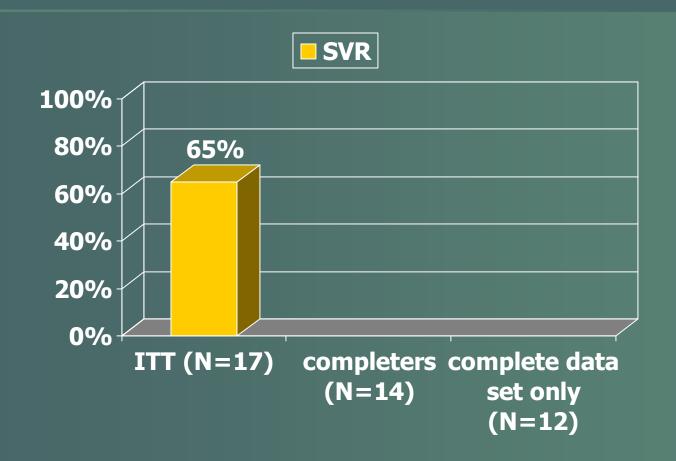
Our Outcomes To Date

- 17 patients treated to date
 - All on ARV, well controlled virus.
 CD4 range 181-952
 - 13 genotype 1, 1 geno 2, 3 geno 3
 - Only 1 patient stopped early due to side effect: week 6 due to worsening depression
 - 2 patients stopped at 12 weeks due to inadequate response (g1)

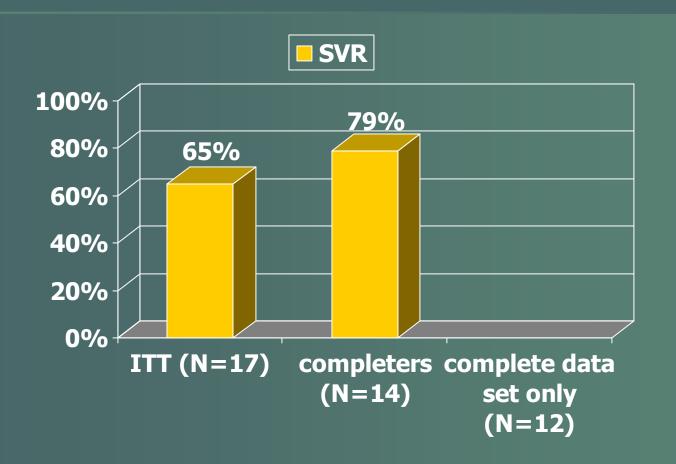
Outcomes cont.

- Undetectable viral load at 4 wks
 - 10/16 (1 unknown)
- Undetectable viral load at 12 weeks
 - 14/16 (both non-responders geno 1)
- Responders for those who completed treatment
 - -14/14
- SVR (6 months post-treatment sustained response) 1 moved unknown, 1 due for labs in Sept
 - -11/12
 - 1 relapse (g1, adherence challenges during treatment, non-suppression wk 4, full at wk 12)

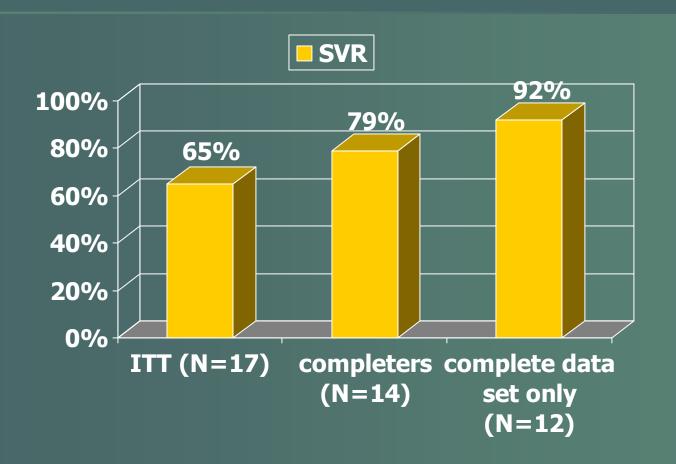
Breaking down the numbers:



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Side effects

- Dose reduction of ribavirin was not required for anemia
- All significant side effects were psychiatric.
 - early: presents after wk 4
 - Need frequent visits with aggressive rx
 - Late: 2 patients stopped at >wk 40-44 due to significant psychosis.
 - Despite early discontinuation, both obtained SVR and included as completers in data

Wow! How did we do that?

- Services at Ryan White Clinics are ideally suited to treat Hep C
 - Comprehensive care
 - Multi-disciplinary staff
 - Culturally competent
 - Highly skilled and knowledgeable
 - Routine adherence support and side effect management

Additional Learnings

- Little published data available for the post treatment period
 - need ongoing support side effects can last months after end of treatment
 - Mental health
 - -A/D
 - Cardiovascular risk factors
- Challenges when converting to EMR
 - Patient management tools did not transfer well

Only ~10% of our co-infected have been treated so far

- Many of our Hep C patients are not ready yet for to treatment
- Barriers include:
 - Unstable co-morbid conditions such as diabetes
 - Mental Health issues
 - Alcohol or Drug use
- Ryan White care system designed to address such barriers

Moving forward Mentoring: role of AETC

- Developed preceptorship/TA to support other HIV clinics adding Hep C treatment to their program
 - Set up 3 day program
- One preceptorship completed to date

Useful websites

Patient handouts and fact sheets: HCVadvocate.org

Top news articles regarding HIV, Hepatitis and co-infection: HIVandHepatitis.com

Care and Prevention for Hepatitis C and HIV Co-infection: Expanding Access through the Ryan White Care Act http://hab.hrsa.gov/tools/coinfection/index.html

Clinical modules for providers: http://www.hcvu.org/index.php

Side Effects Management Handbook http://www.projectsinknowledge.com/Init/G/1628/index.html#order

Hepatitis CME modules from NWAETC: HCV webstudy http://depts.washington.edu/hepstudy/

Management of Chronic Hepatitis C Virus Infection in HIV-Infected Patients; Clinical Infectious Diseases 2008; 47:94-101

Questions??

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