Sonoma County Indian Health Project
Hepatitis C Program

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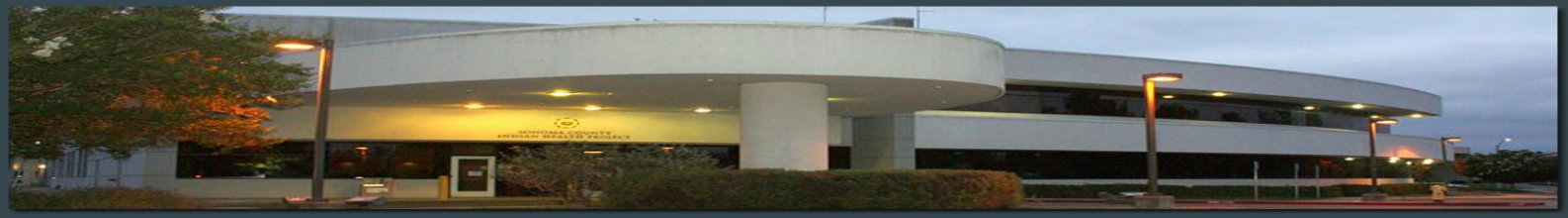
OBJECTIVE

- Our initiative with Hepatitis C screening and treatment
- Resources/Support
- Initiation of Hepatitis C Committee and workflow
- Pharmacy involvement
- Success/Challenges
- Future Plans for SCIHP

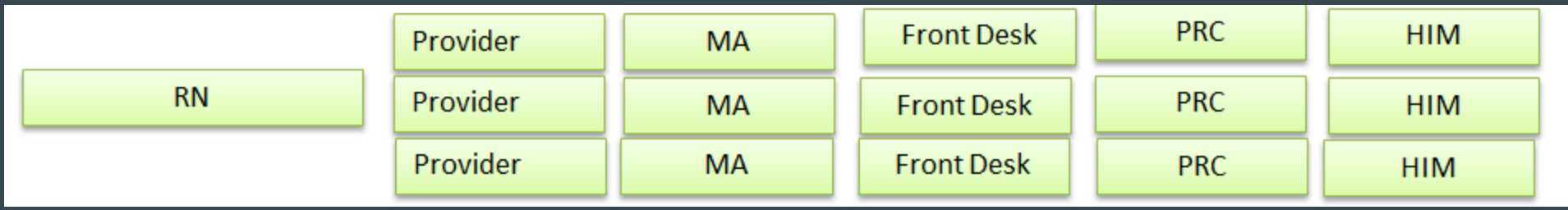
Who we are?

- Sonoma County Indian Health Project, Inc. is located in Santa Rosa, CA
- Family Primary Clinic
- ~5,500 active patients
- 90% of patients are Native American
- In-house Pharmacy, Behavior Health, Nutrition, Healthy Traditions (Diabetes department)
- AAAHC and Patient Centered Medical Home (PCMH) certified



Medical Department Structure

- 8 FTE and 2 PT Primary Care Providers
- Contracted Specialty: Herbal, Rheumotology, Podiatry, GYN and Pediatric
- Public Health Nurse and IMZ Coordinator
- 3 PODS of Primary Care Providers
  - Each pod consist of:

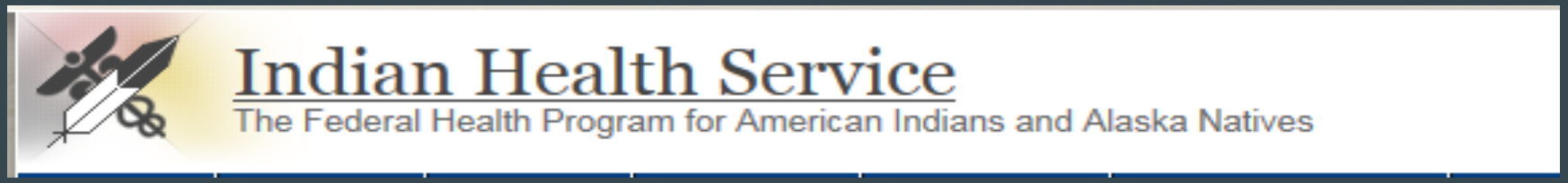


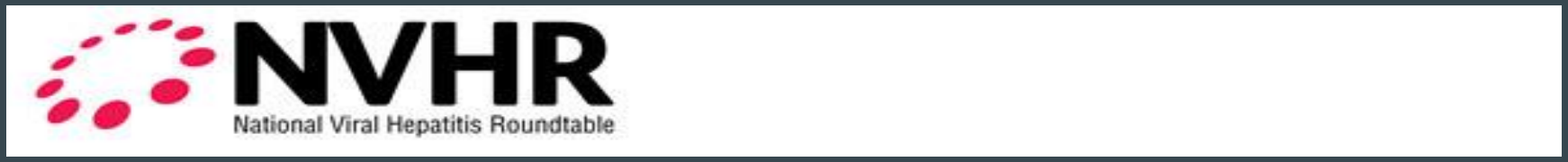
May is Hepatitis Awareness Month

Thanks to…..

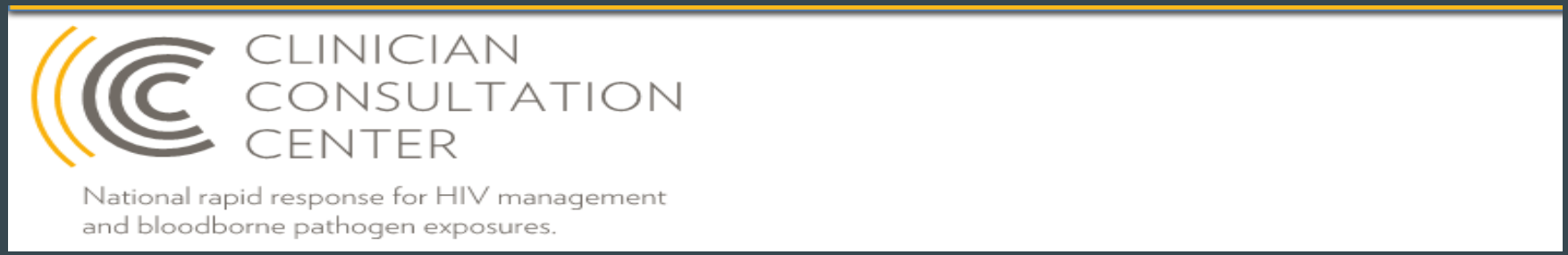
- Dr. Charles Magruder IHS Chief Medical Officer
- Brigg Reilley HIV/AIDS National Program Epidemiologist HIS
- Joshua Opperman, PA

Abundance of Resources





Resources continues…..



Hepatitis C Online

HCV Medications | Course Modules | Tools & Calculators | Resource Library | Master Bibliography

AASLD
AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES

HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C

IDSA
Infectious Diseases Society of America

HEP Drug Interactions

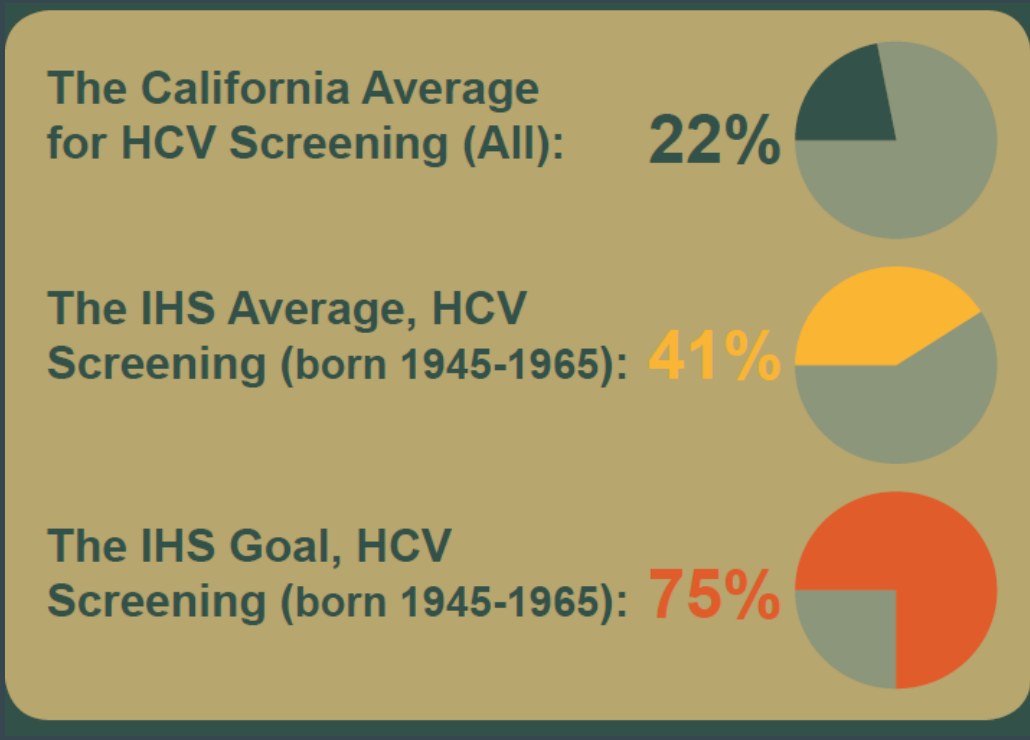
UNIVERSITY OF LIVERPOOL

HepVu

Why is Screening So Important?

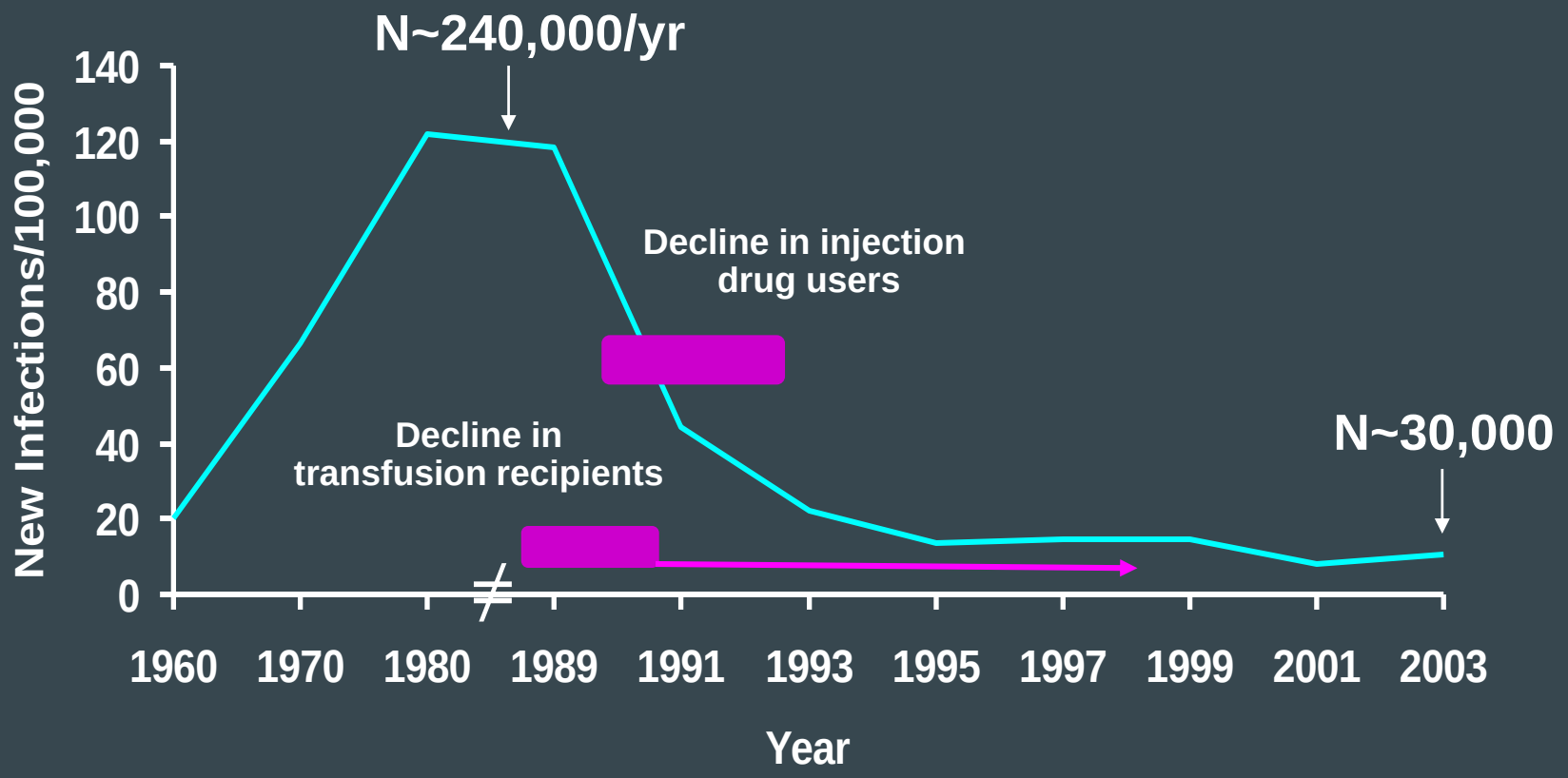
- Can be diagnosed before symptoms develop, up to 75% of people living with HCV do not know they are infected
- The test is reliable inexpensive, and noninvasive
- Huge medical benefits if treatment starts early
- Transmission to others in community can be stopped
- People born from 1945-1965 are
- 5 times more likely to be
- infected with HCV

2016 Data from GPRA IHS



Compiled by CCUIH 4/19/16

Estimated Incidence of Acute HCV, U.S.



Source: Armstrong GL. Hepatology 2000;31:777-82;
Alter MJ. Hepatology 1997;26:62S-65S; CDC, unpublished data

Implemented Standing Orders for MA

Sonoma County Indian Health Project, Inc. Standing Order: Routine Hepatitis C Screening

What: Routine Hepatitis C Screening Any nurse and/or medical assistant employed or contracted by SCIHP may order Hepatitis C test as outlined below:

Why:

Hepatitis C: Screening

Release Date: June 2013

Recommendation Summary

Summary of Recommendations

Population	Recommendation	Grade (What's This?)
Adults at High Risk	The USPSTF recommends screening for hepatitis C virus (HCV) infection in persons at high risk for infection. The USPSTF also recommends offering 1-time screening for HCV infection to adults born between 1945 and 1965.	B

Whom:

- All patients born between 1945-1965
  - without a documented Hepatitis C test lab result in the medical record
- Any patient who requests Hepatitis C testing
- Any of the following Risk Factors:
  - Received a blood transfusion or organ transplant before July 1992
  - Are children born to HCV positive women
  - Current or past intravenous drug use
  - Hemodialysis,
  - High-risk sexual behaviors (particularly unprotected anal intercourse)
  - Incarceration
  - Intranasal illicit drug use
  - Unregulated tattoos
  - recent diagnosis of HIV

How often:

- Once in a lifetime initial Hepatitis C screening for all patients born between 1945-1965
- At least annual screen for patients with ongoing risk factors for Hepatitis C Infection

How:

- Education and Counseling of Hepatitis C and screening test
- Point of Care testing Hepatitis C or Blood for HCV Antibody

Why SCIHP?

Population of baby boomers born between 1945-1965

Much improvement since 2015 but still 12% was very low compared California, IHS and National targets

Medical Assistant: Chart prep, standing orders

Compiled by CCUIH 4/19/16

MILESTONE

5/2015

- Met with Brigg Reilley at the GPRA conference
- Information on implementing successful Hep C Program

8//2015

- Resources and support from HIS;
- Consultant visited to Sonoma to assist with flow

10/2015

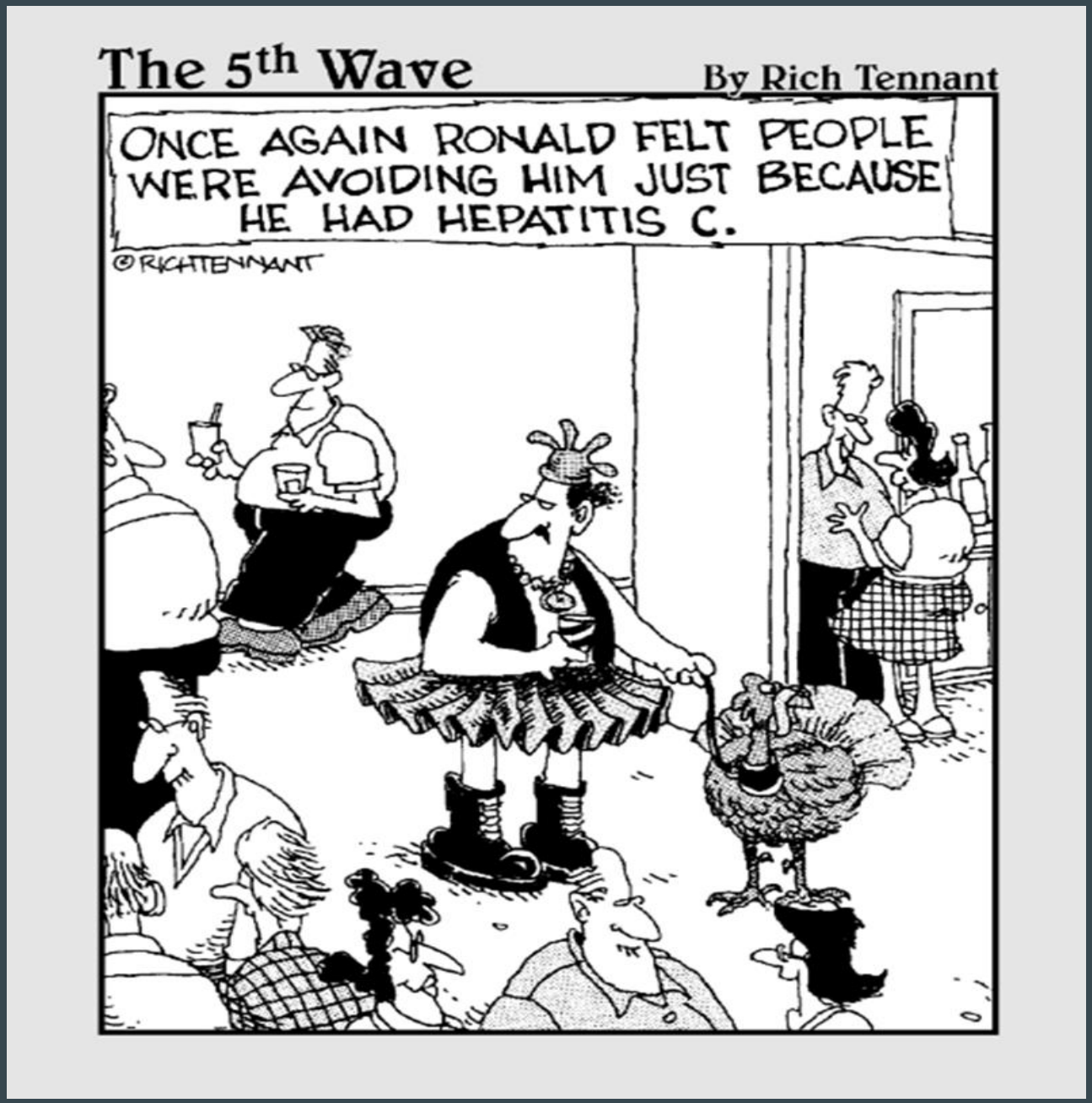
- IHS reached out to SCIHP to assist with training and implementation
- Implemented Standing orders and Chart prep for Hep C Screening

11/2015

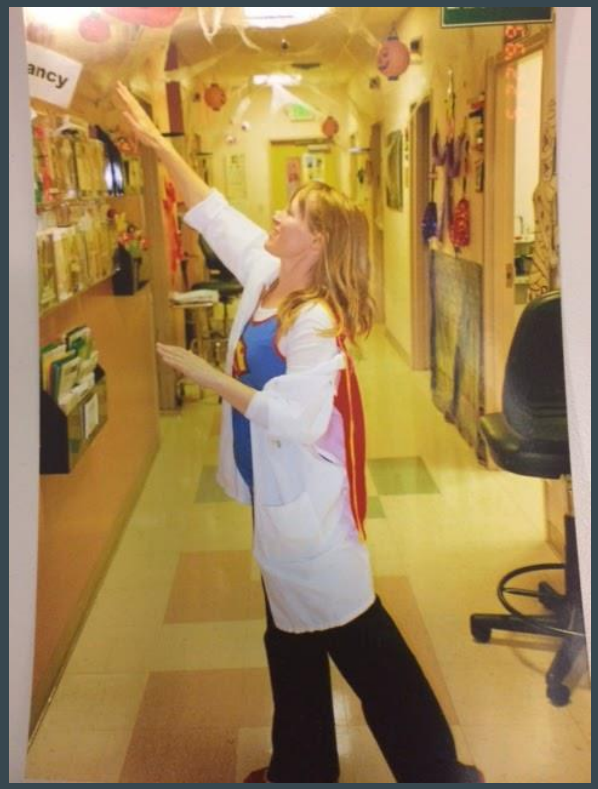
- Successfully treated the 1st Patient

MILESTONE

4/2016	• Selam Attended HCV 101 Training at UCSF via ECHO
11/2016	• Initiated Hepatitis C Committee
2017	• 3 providers are fully trained with ECHO UCSF
5/2017	• Treated ~7 patients; ~4 pending; draft policy and procedure


The 5th Wave
By Rich Tennant
ONCE AGAIN RONALD FELT PEOPLE WERE AVOIDING HIM JUST BECAUSE HE HAD HEPATITIS C.
©RICHTENNANT

Background



- HIV street youth nonprofit in Tanzania
- University of Colorado Medical School 2012
- Santa Rosa FM Residency 2015

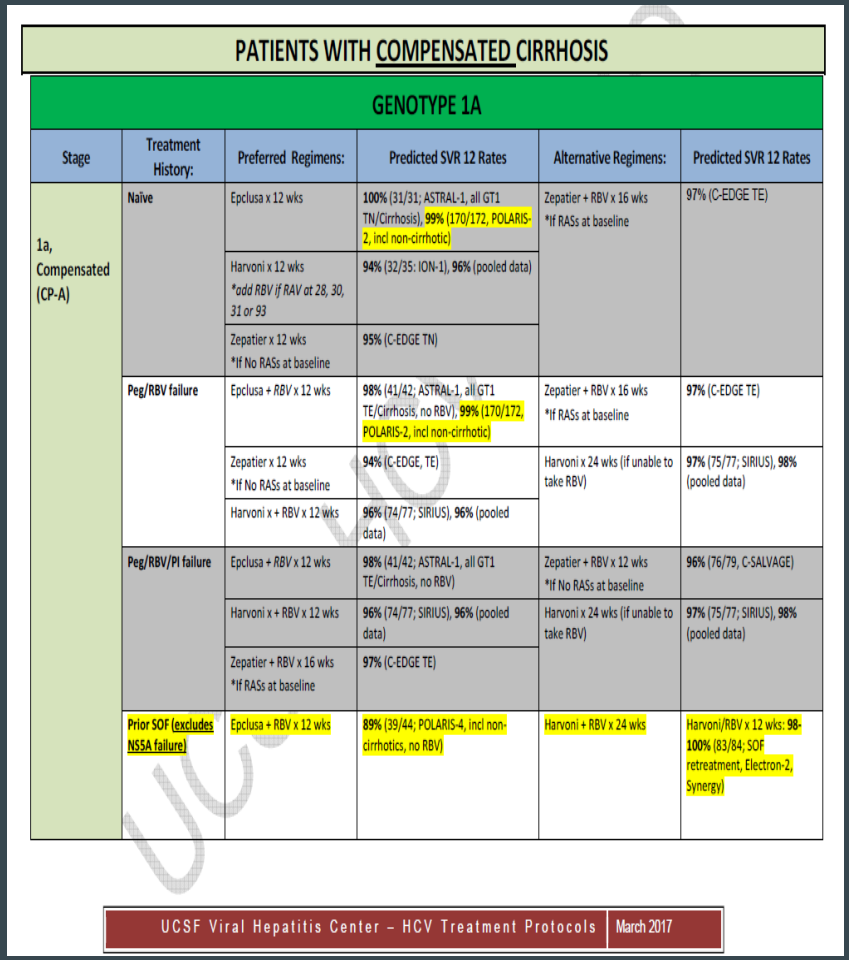
First steps

Decision to create a care team

- build capacity
- provide support

Echo training

- algorithmic tx
- team approach



PATIENTS WITH COMPENSATED CIRRHOSIS

GENOTYPE 1A

Stage	Treatment History:	Preferred Regimens:	Predicted SVR 12 Rates	Alternative Regimens:	Predicted SVR 12 Rates
1a, Compensated (CP-A)	Naïve	Epclusa x 12 wks	**100%** (31/31; ASTRAL-1, all GT1 TN/Cirrhosis), **99%** (170/172, POLARIS-2, incl non-cirrhotic)	Zepatier + RBV x 16 wks *If RASs at baseline	97% (C-EDGE TE)
		Harvoni x 12 wks **add RBV if RAV at 28, 30, 31 or 93*	**94%** (32/35: ION-1), **96%** (pooled data)		
		Zepatier x 12 wks *If No RASs at baseline	**95%** (C-EDGE TN)		
	Peg/RBV failure	Epclusa + *RBV* x 12 wks	**98%** (41/42; ASTRAL-1, all GT1 TE/Cirrhosis, no RBV), **99%** (170/172, POLARIS-2, incl non-cirrhotic)	Zepatier + RBV x 16 wks *If RASs at baseline	**97%** (C-EDGE TE)
		Zepatier x 12 wks *If No RASs at baseline	**94%** (C-EDGE, TE)	Harvoni x 24 wks (if unable to take RBV)	**97%** (75/77; SIRIUS), **98%** (pooled data)
		Harvoni x + RBV x 12 wks	**96%** (74/77; SIRIUS), **96%** (pooled data)		
	Peg/RBV/PI failure	Epclusa + *RBV* x 12 wks	**98%** (41/42; ASTRAL-1, all GT1 TE/Cirrhosis, no RBV)	Zepatier + RBV x 12 wks *If No RASs at baseline	**96%** (76/79, C-SALVAGE)
		Harvoni x + RBV x 12 wks	**96%** (74/77; SIRIUS), **96%** (pooled data)	Harvoni x 24 wks (if unable to take RBV)	**97%** (75/77; SIRIUS), **98%** (pooled data)
		Zepatier + RBV x 16 wks *If RASs at baseline	**97%** (C-EDGE TE)		
	Prior SOF (excludes NS5A failure)	Epclusa + RBV x 12 wks	**89%** (39/44; POLARIS-4, incl non-cirrhotics, no RBV)	Harvoni + RBV x 24 wks	Harvoni/RBV x 12 wks: **98-100%** (83/84; SOF retreatment, Electron-2, Synergy)

UCSF Viral Hepatitis Center – HCV Treatment Protocols | March 2017

Hepatitis C Committee

Multidisciplinary team

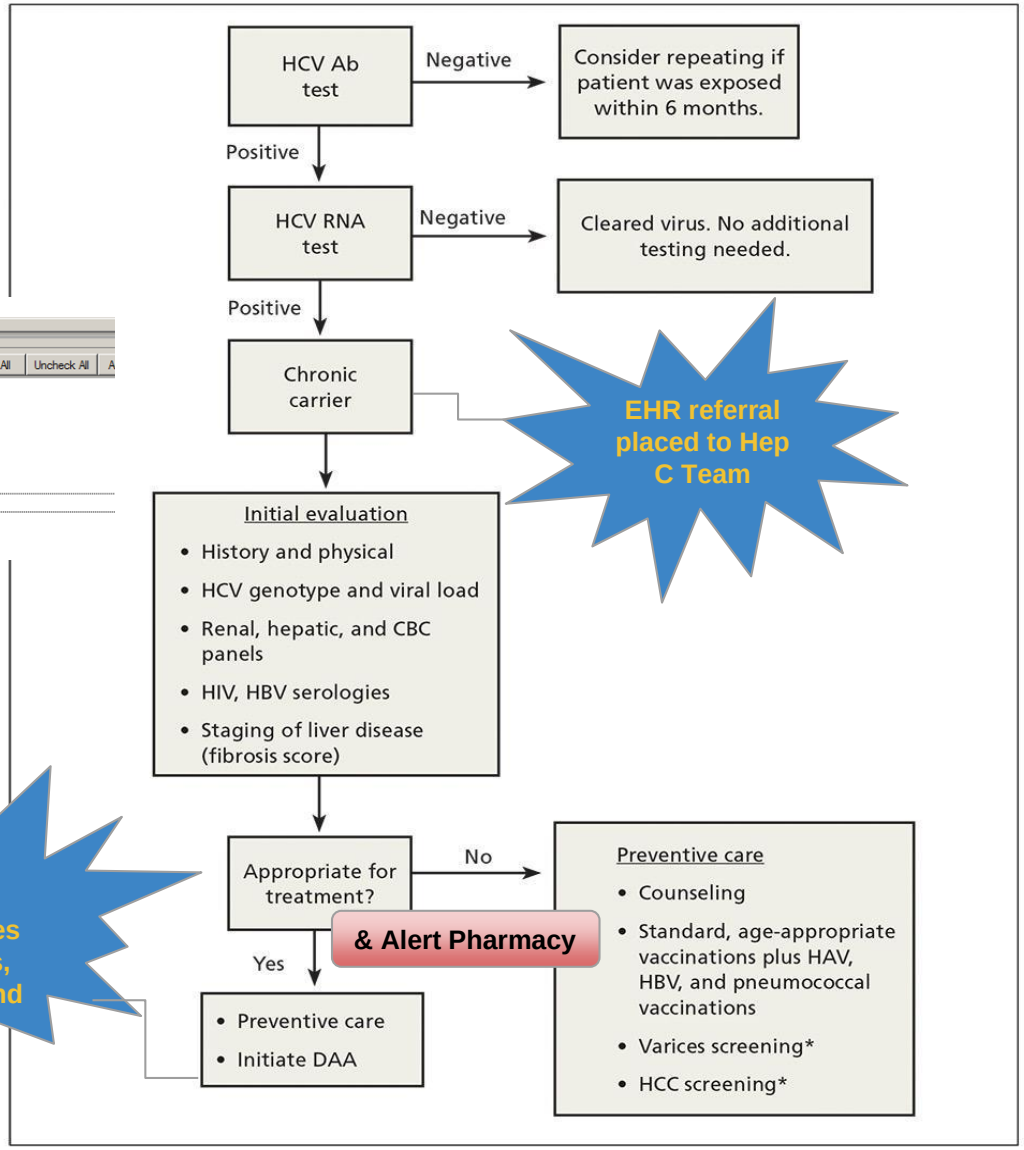
- Three providers
- Pharmacy
- Nurse Case Management

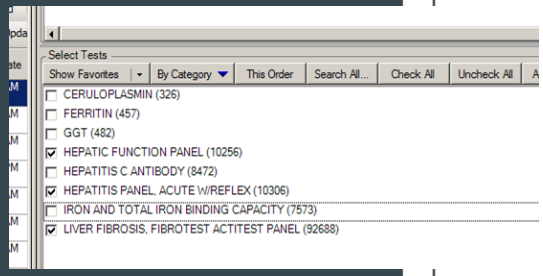
Regular meetings

- Workflow
- Roles and responsibilities
- Cases

FIGURE 1

Initial evaluation of the patient presenting for HCV testing[16]





Case Manager coordinates addlt labs, imaging and appts

Ab, antibody; CBC, complete blood count; DAA, direct-acting antiviral therapy; HAV, hepatitis A vaccine; HCC, hepatocellular carcinoma; HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; RNA, ribonucleic acid.

*Screen if liver is cirrhotic.

Adapted from: Centers for Disease Control and Prevention. Testing for HCV infection: an update of guidance for clinicians and laboratorians. *MMWR Morb Mortal Wkly Rep*. 2013;62:362-365.

Visits

Appt #1: Hep C initial consult

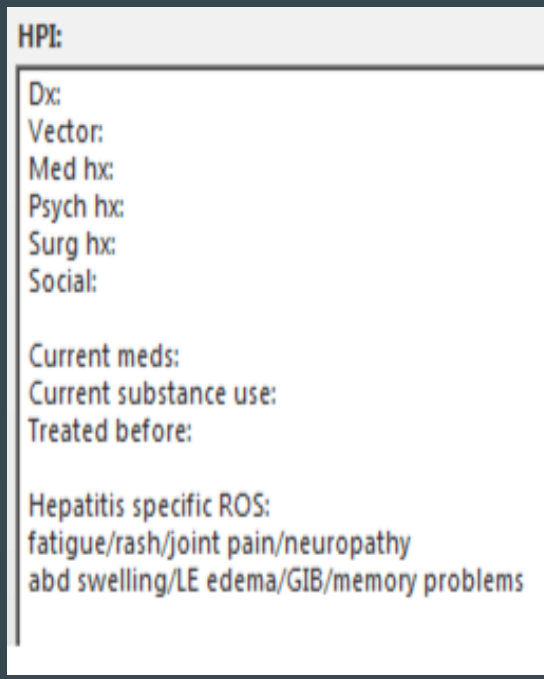
- PMH, liver status, Hep B IZ

Appt #2: Practitioner & Pharmacist

- review DDI, SE, imaging & labs

Appt #3: Mid tx monitoring

Appt #4: End of tx



Tracking

	Age	VL	GT	hct	plts	AST/ALT	Cr	APRI	FIB-4	CT P	Fibrotest	Imaging	Tx naïve	comorbidities	Needs	Ins	SCIHP?	Notes
865 SJ	58 F	843,851 10/5/2016	1a 9/28/2016	47.1 10/5/2016	223 10/5/2016	38/39 10/5/2016	0.68 10/5/2016	0.426	1.58*	A	F2	none	yes	aloholic in recovery since 2008, hx of cervical ca tx	Hep B IZ	BS of CA	N (Harvoni x 12wks)	Initiating tx 11/2--> UD-VL 2wks
34 SJ	51 F	4 million 9/14/2015	2b 9/14/2015	39 9/14/2015	173 9/14/2015	42/37 9/14/2015	0.81 9/14/2015	0.607	2.04*			none	yes	chronic pain (methadone, oxycodone, xanax), RA,		Medicaid/ Medicare	Y (epclusa x12 wks or	No show to HCV consult, hx
764 SJ	58 M	4 million 4/6/17	1b 4/6/17	38.3 3/24/17	96 3/24/17	61/64 4/6/17	0.8 3/24/17	1.589	4.69*	A		none	yes	DM2, HTN, HLD, pain (norco, valium)	Hep B IZ	Medicaid		cirrhosis?- msg to Trent 5/3
749 SJ	63 F	536,000 3/20/2017	3a 3/20/2017	44.9 3/20/2017	144 3/20/2017	131/107 3/20/2017	0.76 3/20/2017	2.274	5.54*	A	F3 4/8/2016	EGD	yes		?hep B?	Medicaid	N - Walgreens (epclusa)	[ ] clarify tx options w Trent
96 SJ	55M	4million 1/19/2017	1a/2b 1/19/2017	29.5 1/19/2017	266 1/19/2017	52/43 3/31/2017	1.12 1/19/2017	0.488	1.64	A	F0-F1	none	yes	chronic pain d/t femur fx - oxy 30mg daily. Cuurent etoh.	Hep B IZ	Medi-cal	N - epclusa x 12w	Erx'd to Tim 4/25.
44 SJ	35F	483,740	3a	39.5 4/14/2017	185 4/14/2017	25/52 17-Mar	0.6 17-Mar	0.337	0.66	A	F0	none	yes	breastfeeding?, sober x 8yrs		Medi-caid	epclusa x 12w	4/12 - approval unlikely given F0
185 SJ	59F	143,217	1a	32.9	240	20/21	4.23	0.208	1.07	A	F0		yes	hepatorenal syndrome? DM2, CKD	HIV	Medicare		msg to Trent 5/1
50 LD	66 F	6.76 millic 12/20/2016	1a	38,1 8/29/2016	197 12/20/2016	21/15 12/20/2016	0.96 8/29/2016	266 12/20/2016	1.8 8/29/2016		F1-2 12/20/2016	none		DM, Chronic pain (Norco)	INR HepB	Medicaid/ Medicare		completed therapy, no detectable virus
47 LD	52 M	3.19 millic 3/31/2017	1a	48.7 5/17/2016	257 5/17/2016	48/33 5/17/2016	0.8 5/17/2016	0.467	1.69 5/17/2016	A		none		Chronic pain (hydrocodone, oxycodone, benzo) MJ	Hep B IZ	Aetna		
63 LD	45 F	351,644 11/21/2016	3a 10/13/2016	42.5 10/13/2016	245 10/13/2016	74/210 10/13/2016	0.75 6/28/2016	0.755	0.94 10/13/2016		F0 10/13/2016	CT: two sub cm low 7/5/2016	DM		INR, load	Solano Partnership	N	finished treatment, no detectable virus
12	46 M	835,663	1a	28.9	131	196/186	0.78	3.74				cirrhosis on CT				Medicaid		

My First Patient

GT 1a VL 843,000 F2

pt uncertainty re: SE

Harvoni x 12w

improved fatigue

Where the Magic Happens

Navigating the insurance quagmire

- Eligibility for Insurance coverage of antivirals is ever evolving

- Current criteria required by BOTH private insurers and Medi-cal Partnership:
  - APRI Score of > 0.7
  - Fibrosure/Fibrotest > 0.48
  - FibroScan > 7.5 kilopascals
  - Prefer treatment naïve

Medi-cal Partnership's special rules

Coverage not considered for Metavir F0-F1 UNLESS

- •T2 DM
- •Active injection drug user
- •Women of childbearing age who wish to get pregnant
- •Cryoglobulinemia with end-organ manifestations (vasculitis) or kidney disease
- •HIV-1 or HBV co-infection
- Debilitating fatigue impacting the quality of life (due to extrahepatic manifestations and/ or liver disease)
- •Other co-existing liver disease (e.g. non-alcoholic steatohepatitis)
- •Porphyria cutanea tarda
- •Long-term hemodialysis
- •HCV-infected healthcare worker who performs exposure-prone procedures
- Men who have sex with men
- HCC with a life expectancy of > 12 months

340B Program

U.S. federal government program that requires drug manufacturers provide outpatient drugs to eligible health care organizations at significantly reduced prices

Insurance reimbursement allows our pharmacy to provide non reimbursable services to our unfunded patients at no cost to them. This includes services such as our herbal clinic, wellness clinic, MTMs, provider consultations, and diabetic education

Challenges

- Clinic Resources
- Ordering appropriate test
- Patient panelling

Future endeavors

- standing orders for labs following a (+) Ab
- improve patient panelling
- expand case management role
- utilize our lobby for learning
- cross-train PCP practitioners

References

Hepatitis C Project at Echo: echo.ucsfhealth.org

Oluwasen, Falade et al. Oral Direct-Acting Agent Therapy for Hepatitis C Virus Infection. Annals of Internal Medicine. REview, 2017.

Shaffer, Mark MD & Divya Ahuja, MD. Hepatitis C: Screening changes, treatment advances. The Journal of Family Practice. 66:3. March 2017.