Exhibit 1

2017 VERMONT SITUATIONAL ANALYSIS

1702: Improving Hepatitis B and C Care Cascades

VERMONT
DEPARTMENT OF HEALTH

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JANUARY 2018

(PS1702) Improving Hepatitis Care Cascade: Situational Analysis

Contents

Introduction

Considering the intravenous drugs use concerns in Vermont and the state's baby boomer population, improving the care cascade of Hepatitis C (HCV) continues to be a priority for Vermont's Department of Health (VDH) under CDC's 1702 FOA: Improving Hepatitis B and C Care Cascades- Focus on Increased Testing and Diagnosis. Of newly reported infections across the state of Vermont, HCV is the second most commonly reported disease among the state's 72 reportable diseases. Furthermore, Vermont has seen an insignificant decrease in newly reported HCV cases, maintaining its status as one of the greatest disease burdens across the state.

The following Situational Analysis aims to provide a comprehensive perspective of the overall burden of HCV across the state of Vermont while further examining the disease prevalence, community resources, and existing policies that guide practices and access to HCV resources.

I. Jurisdiction Burden

According to Vermont's HCV estimates by subpopulations, veterans have potential to experience the greatest disease prevalence ranging from 2,574-5,100 people as seen in Table A, which is not a trend unique to Vermont as it is similar to national findings. Vermont's incarcerated population continues to be significantly impacted by HCV with an estimated 150-189 cases. This estimate does not, however, include Vermont residents that are currently serving time in out-of-state correctional facilities which includes about 200 additional residents[i]. Active military personnel and chronic hemodialysis patients are estimated to have the lowest HCV prevalence among all reviewed subpopulations.

National prevalence ranges were calculated from the 2015 publication, *Toward a More Accurate Estimate of the Prevalence of Hepatitis C in the United States* by Edlin, Eckhardt, Shu, Holmberg, and Swan[ii]. National estimates from Edlin et al's publication were selected over Chak's publication due to illustration of more recent findings[iii]. Subpopulation estimates not included in Edlin et al's article were modeled after Chak's publication, which included healthcare workers, chronic hemodialysis patients, and hemophiliacs with transfusions before 1992. Vermont healthcare worker data is inclusive of dentists, physicians, physician assistants, and nurse practitioners. Additionally, reservations were not included in Table A. due to the lack of formalized reservation recognition by the state of Vermont.

Vermont's HCV data is captured in National Electronics Disease Surveillance System (NEDSS) a data collection system used to connect lab reports with health surveillance activities. All electronic lab reports on HCV are automatically captured into the database. A small proportion of reportable infections come through via fax or mail and are manually entered into NEDSS. Vermont identifies and codes existing HCV case reports differently than new cases so data is de-duplicated in reporting.

Table A: Estimated total prevalence of HCV in Vermont for populations included in NHANES in addition to populations under-represented or excluded from NHANES.

Population	HCV Prevalence in the US (Edlin/Chak)	Point Estimate of Population in VT	Estimated Range of HCV Cases in VT
Homeless	7.5%-52.5%	1,110 [iv, v]	83-583
Incarcerated	7.5%-44.0%	1,997[vi]	150-879
Veterans	5.4%-10.7%	47,664[vii]	2,574-5,100
Active Military Duty	0.48%-0.84%	565[viii]	3-5
Healthcare Workers	0.9%-3.6%	11,460 [ix]	103-413
Nursing Home Residents (certified homes)	2.1%-8.4%	2,690[ix]	56-226
Chronic hemodialysis Patients	2.3%-7.9%	377[x]	9-30
Hemophiliacs with transfusions before 1992	.052%	624,594[xi] .195% of 17,000 (total US estimate of hemophiliacs)	25-33
Hospitalized	4.0%-38.0%	9,655[xii]	386-3,669
SUBTOTAL			**3,389- 10,935**
NHANES	1.3%	593,364[xi] (pop ≤ 5 y/o)	7,714
TOTAL			**11,103- 18,649**

Table B: Chronically infected HCV in Vermont

Criteria	Calculations	Population Estimate
Unaccounted # of HCV Antibody positive in VT	*Subtotal from Table A*	3,389- 10,935
VT population ≤ 5 y/o	*Census Data*	593,364[xi]
Total # of HCV positive in VT Estimated by NHANES	593,364*1.3/100	7,714
Total # of HCV + in VT Estimated by NHANES - veterans underestimated in NHANES	7,714-1,835	5,879
Total # VT HCV cases (HCV Antibody Positive)	5879+3389= 9,268 5879+10935= 16,814	9,268-16,814

Chronically infected in VT: *Assumption-based HCV biology that 26% of persons ever exposed to HCV would spontaneously clear the virus within 6 mos. of infection; 74% will have the infection*	0.74*9268= 6,858 0.74*16814=12,442	6,858- 12,442

Vermont's viral hepatitis surveillance data illustrates higher HCV incidence within Franklin, Windham, and Chittenden counties as seen in Table C. A calculated HCV rate of >2.0 per 1,000 population exists for Franklin and Windham counties, which is significantly higher than the rest of the state. Chittenden county has a lower HCV rate compared to other counties but is home to over 26% of Vermont residents. Based on these factors, Franklin, Windham, and Chittenden counties will continue to be the focus areas of the Situational Analysis.

Table C: Number and Rate of HCV by county, 2016.

County	Total Population	N= 928	Rate per 1,000
Addison	37,035	45	1.23
Bennington	36,317	42	1.17
Caledonia	30,780	46	1.49
Chittenden	161,382	207	**1.28**
Essex	6,163	12	1.95
Franklin	48,799	99	**2.03**
Grand Isle	6,861	2	0.29
Lamoille	25,235	21	0.83
Orange	28,899	33	1.14
Orleans	27,100	36	1.33
Rutland	59,736	104	1.74
Washington	58,612	73	1.25
Windham	43,386	113	**2.60**
Windsor	55,737	90	1.61
Unknown	626,042	5	0.01

Source: Vermont Department of Health, National Electronic Disease Surveillance System

Table D: Demographic characteristics of persons with chronic HCV across VT, in 2016.

Characteristics	No.	%
Sex		
Male	527	56.79
Female	386	41.59
Unknown/Other	15	1.62
Race/Ethnicity		
White	313	33.73
Black	4	0.43
Asian	5	0.54
Hispanic	5	0.54
Native Hawaiian/ Pacific Islander	1	0.11

Native American/ Alaska Native	7	0.75
Unknown/Other	593	63.90
Age Group (Years)		
Under 15	3	0.32
15-24	98	10.56
25-34	289	31.14
35-44	157	16.92
45-54	141	15.19
55-64	170	18.32
65+	70	7.543
Birth Cohort		
Pre 1945	19	2.05
1945-1965	290	31.25
1966-1986	386	41.59

Source: Vermont Department of Health, National Electronic Disease Surveillance System

As captured in Table E, HCV-related deaths illustrate the highest mortality rates in Windham County in four out five years, between 2010-2014. Windham continues to be one of the most resource-poor counties in the state of Vermont paired with higher rates of HCV compared to the rest of the state.

Table E: Vermont Residents HCV-Related Deaths [A], by County [B, C]

	2010		2011		2012		2013		2014		Total: 2010-2014	
County	No.	Rate	No.	Rate	No.	Rate	No.	Rate	No.	Rate	No.	Rate
Addison	3	0.08	8	0.22	4	0.11	4	0.11	6	0.16	25	0.14
Bennington	7	0.19	5	0.14	3	0.08	5	0.14	5	0.14	25	0.14
Caledonia	3	0.10	7	0.22	4	0.13	5	0.16	3	0.10	22	0.14
Chittenden	21	0.13	18	0.11	13	0.08	15	0.09	22	0.14	89	0.11
Essex	1	0.16	1	0.16	0	0.00	1	0.16	1	0.16	4	0.13
Franklin	3	0.06	5	0.10	2	0.04	5	0.10	7	0.14	22	0.09
Grand Isle	0	0.00	1	0.14	1	0.14	1	0.14	0	0.00	3	0.09
Lamoille	5	0.20	5	0.20	2	0.08	0	0.00	3	0.12	15	0.12
Orange	3	0.10	4	0.14	2	0.07	2	0.07	2	0.07	13	0.09
Orleans	5	0.18	7	0.26	5	0.18	6	0.22	3	0.11	26	0.19
Rutland	7	0.11	8	0.13	13	0.21	13	0.21	9	0.15	50	0.16
Washington	14	0.24	3	0.05	13	0.22	5	0.08	6	0.10	41	0.14
Windham	11	**0.25**	10	**0.23**	11	**0.25**	10	**0.23**	6	0.14	48	**0.22**
Windsor	5	0.09	9	0.16	8	0.14	11	0.20	10	**0.18**	43	0.15
All Counties	**88**	**0.14**	**91**	**0.15**	**81**	**0.13**	**83**	**0.13**	**83**	**0.13**	**426**	**0.14**

(A) Deaths with any mention of one or more of these ICD-10 codes : B17.1 - Acute Hepatitis C; B18.2 - Chronic viral hepatitis C; K73-K74.9 - other chronic liver disease and cirrhosis.

(B) Counts from Vermont Department of Health, Vital Statistics System. Population estimates from Vermont Department of Health Center for Public Health Statistics.

(C) Crude rate is per 1,000 population.

Table F: Vermont policies, laws, and regulations related to education, screening and reporting, treatment, and retention in care of Viral Hepatitis.

Focus Area	Existing Policy?
Education	
• Restrictions on HCV-related awareness campaigns, messages, or promotional materials.	No
• Universal training for providers authorized to prescribe opioids.	Yes
• Universal precautions and guidelines on opiate prescriptions for all providers.	Yes
• Universal data system to track opiate prescriptions from all licensed pharmacies.	Yes
Screening and Reporting	
• HCV prenatal screenings for all pregnant mothers.	No
• Available HCV screenings for inmates in public correctional facilities.	Yes
• Laboratory reporting requirements for HCV diagnosis.*	Yes
• Required reflex testing for reactive HCV Ab screening.	No
• Required electronic lab reporting for all providers.	No
Treatment	
• Access to care for HCV+ inmate population.	Yes
• State law authorizing syringe service programs throughout the state.	Yes
• State law exemption on syringes from definition of drug paraphernalia.	Yes
• State decriminalizes syringes for participants of syringe exchange program.	Yes
• State allows for retail sales of syringes in pharmacies without a prescription.	Yes
• Medicaid access to HCV testing and treatment for F0 or higher for Medicaid beneficiaries.	Yes
• Access to treatment regardless of patient sobriety status for Medicaid beneficiaries.	Yes
• Access to treatment for F0 or higher under private insurance.	No
• Access to treatment without being seen by medical specialist.	No
Retention in Care	
• State-level financial assistance for substance abuse treatment.	Yes
• Medicaid access to HCV reimbursement to treatment and care.	Yes
• Mandated linkage to care for released inmates on treatment.	No

** HBV is reportable infection in state of Vermont. HBV screening is also a part of general screening practices for expecting mothers, while HCV continues to vary from provider.*

Policies and Laws Discussion:

A) Laboratory Reporting Practices:

Hepatitis C is a reportable infection in the state of Vermont when there is a positive laboratory result. Reporting takes place for both HCV-Antibody and HCV- RNA results. Similar to many other states, Vermont does not receive negative test results which has demonstrated to be a challenge when attempting to calculate HCV baseline data in order to implement more concrete surveillance activities. While the majority of facilities report HCV cases electronically, there are some facilities that manually report HCV cases to VDH.

B) Medicaid and Other Payer Policies for Testing and Treatment:

Vermont's Medicaid program has made significant strides in expanding access to HCV treatment since 2016 by reducing fibrosis score requirements from an F4 to F2 and removing sobriety restrictions entirely. In January 2018, Medicaid made additional strides forward by considering access to treatment for anyone with an F0 or above, and adding Epclusa®, Mavyret®, and Zepatier® as preferred treatment agents. Consultation with a specialist continues to be a requirement for treatment among Medicaid beneficiaries, which include prescriptions from any of the following: a gastroenterologist, hepatologist, infectious disease specialist or other Hepatitis specialist[xiii]. The consultation must be within a year of receiving treatment. Vermont's oldest and largest private insurer, Blue Cross Blue Shield of Vermont (BCBSVT), has not announced any formal change to their HCV restriction requirements and requires an F2 or higher for beneficiaries to access to treatment. BCBSVT provides coverage to about 250,000 Vermonters[xiv].

C) Screening and Testing Laws in the Correctional Facilities:

Vermont Department of Corrections (DOC) provides HCV screening for inmates on an opt-in basis during their initial well visit. Inmates receive treatment in order of priority regarding severity of condition and a sentence length long enough to complete a course of treatment. Since 2015, Vermont's DOC maintains a contract with Centurion Managed Care[xv], a healthcare contracting company providing service to about 300 correctional facilities across the country, including all of Vermont's seven facilities. There is limited identifiable data on the percent of inmates living with HCV who are treated.

D) Laws Related to Syringe Service Programs (SSPs):

Vermont has maintained Syringe Service Programs since 1998, which are guided by three state statutes- 18 V.S.A. § 4476[xvi], 18 V.S.A. § 4478[xvii], 18 V.S.A. § 4475[xviii]. The statutes collectively govern approval and implementation of SSPs. Drug paraphernalia does not include needles and syringes distributed or possessed as part of an organized SSP, and pharmacies can sell syringes without a prescription but vary from pharmacy to pharmacy across the state. SSPs also provide services beyond clean needles including overdose education and prevention, case management, referrals to health services, HCV and HIV testing, safe disposal of used needles, and Naloxone distribution. Naloxone distribution is available across all state-funded SSPs. Funding and distribution guidelines for Naloxone are lead through a separate division within VDH.

III. Area of Greatest Burden

Vermont HCV surveillance data has shown a significant rise in newly reported cases throughout the past six years, from 541 in 2010 to 928 in 2016[xix]. While Vermont has experienced increases in the overall reporting of HCV, the counties which experience the greatest disease burden have primarily remained unchanged. Among Vermont's 14 counties, three counties are worth noting as having the greatest HCV burden-- Chittenden, Franklin, and Windham counties.

Limitations on race and ethnicity data are worth noting. In Franklin and Windham counties the majority of HCV cases have unknown race identification. Based on the demographic makeup of Vermont, there is reason to speculate most unknown race cases are white identified. Across all high burden counties, the greatest incidence of newly reported HCV are among those who were 25-34 year of age and 55-64 years of age at the time of diagnosis.

Table G: HCV burden in Chittenden County, VT by demographics (2016).

Characteristics	Chittenden County n=172		Franklin County n=85		Windham County n=106	
	No.	% of VT	No.	% of VT	No.	% of VT
Sex						
Male	89	10.9	48	5.9	44	5.4
Female	83	10.1	36	4.4	56	6.8
Unknown/Other	0	0	1	0.1	6	0.7
Race/Ethnicity						
White	123	15.0	31	3.8	19	2.3
Black	3	0.5	0	0	0	0
Asian	4	0.5	0	0	0	0
Hispanic	3	0.4	0	0	1	0.1
Native Hawaiian/ Pacific Islander	1	0.1	0	0	0	0
Native American/ Alaska Native	2	0.2	2	0.2	0	0
Unknown	39	4.8	52	6.3	86	10.5
Age Group (Years)						
Under 15	0	0	0	0	0	0
15-24	16	2.0	12	1.5	21	2.6
25-34	58	**7.1**	21	**2.6**	30	**3.7**
35-44	29	3.5	12	1.5	16	2.0
45-54	24	2.9	17	2.1	16	2.0
55-64	28	**3.4**	20	**2.4**	17	**2.1**
65+	17	2.1	3	0.4	6	0.7
Birth Cohort						
Pre 1945	6	0.7	2	0.2	2	0.2
1945-1965	46	5.6	33	4.0	27	3.3
1966-1986	73	8.9	27	3.3	43	5.3

Source: Vermont Department of Health, National Electronic Disease Surveillance System

Chittenden County is home to over a quarter of Vermont residents, making it the epicenter for health services in terms of scope and reach, captured in Table H. Both Chittenden and Franklin Counties provide services to a substantial population base through their FQHCs and CHCs. Located in the southern most part of the state, Windham County makes up less than 7% of Vermont's population which is reflected in the volume of available health facilities.

Vermont's hub and spoke model is a Medication Assisted Treatment system implemented statewide, with the goal of supporting recovery from opioid use disorder. Hubs are intensive treatment facilities, while spokes include office-based treatment through specialized providers. Both hubs and spokes exist across each high-burden area. It should be noted that Windham County data is combined with a neighboring county, Windsor County, but estimated to make up about 64% (400 people) of the population served in Windham's hubs.[xxvi] The total population among hubs and spokes captured in Table H are only Medicaid patients, which makes up the large majority of those utilizing Vermont's treatment facilities. It is estimated that 32% of patients accessing treatment services are on private insurance, with this in mind a total of about 3,080 people being served in hubs and spokes.[xxvi] The above numbers reflect data from December 2016 (spokes) and January 2017 (hubs) and summarize utilization within a given point and time.

Table H: Various Settings Across High-Burden Areas

High Burden Area	Settings and Reach		
Chittenden County		No.	Total Served
	FQHCs	1	17,889[xx, xxi, xxii]
	CHCs	9	
	Hospitals	1	18,734[xxiii, xxiv]
	Correctional Facilities	1	160[xxv]
	Treatment Facilities (Hub)	1	972[xxvi]
	Specialized Medical Providers (Spoke)	70	596[xxvi]
Franklin County	FQHCs	1	10,126[xx]
	CHCs	8	tbd
	Hospitals	1	2,590[xxiii, xxiv]
	Correctional Facilities	1	238[xxv]
	Treatment Facilities (Hub)	0	0[xxvi]
	Specialized Medical Providers (Spoke)	15	382[xxvi]
Windham County	FQHCs	0	0[xx]
	CHCs	1	tbd
	Hospitals	2	1,674[xxiii, xxiv]
	Correctional Facilities	0	0[xxv]
	Treatment Facilities (Hub)	3	628[xxvi]
	Specialized Medical Providers (Spoke)	10	145[xxvi]

IV. High Burden Priority Sites

Site 1: Community Health Center of Burlington- Riverside Location

The Community Health Center of Burlington (CHCB) is a non-profit, health and human services organization providing services to Vermonters since 1971. CHCB is the only FQHC in the Chittenden County region, serving about 25,000 unique patients annually with about 60% of the patient population on Medicaid.[xxvii] In 2017, CHCB subsidized $514,421 through their sliding-fee scale financial assistance program and provided suboxone treatment to 357 patients.[xxviii] CHCB has seven locations in Chittenden County.

A variety of medical providers, psychiatrists, social workers, counselors, and nurses provide service to patients at the center; however, there are no specialists specific to HCV treatment available on site. HCV screening is available and VDH receives both HCV Ab+ and RNA+ results that are ordered from this site. When a patient requires HCV specialty treatment, a referral will take place to the University of Vermont Medical Center (UVMMC). In addition to maintaining collaborations with UVMMC, CHCB- Riverside continues to have formalized partnerships with twelve organizations in the surrounding area with specialties in school-based health centers, youth health, homeless medical services and outreach, refugee health, and care coordination.[xxix]

In July 2016, CHCB submitted a letter of support solidifying their interest in working with VDH's 1702 Grant- Improving Hepatitis B and C Care Cascades; Focus on Increased Testing and Diagnosis. Since the start of the grant term, VDH has held at least three in-person meetings with the medical director, nurse, and business manager. However, after changes in staffing took place progression in the existing partnership shifted. VDH continues to identify opportunities to maintain a more sustainable partnership with CHCB.

Site 2: Community Health Center of Burlington- Safe Harbor Clinic

Safe Harbor Clinic falls within the larger Community Health Center of Burlington organization. Staffing at this clinic consists of two medical providers, one psychiatrist, and two behavioral health clinicians. The clinic has also been recognized by the National Health Care for the Homeless Council for their Homeless Healthcare Program, serving over 1,200 homeless patients annually.[xxx] The scope of services and HCV treatment referrals are the same as those described for CHCB- Riverside. HCV screening is available and VDH receives both HCV Ab+ and RNA+ results that are ordered from this site.

Site 3: Howard Center- Chittenden Clinic

The Chittenden Clinic is a Medication Assisted Treatment program within the larger organization Howard Center. The Chittenden Clinic provides outpatient services for adolescents and adults working through issues of substance abuse. Specialized staffing provides extensive medical, therapeutic, and case management services to individuals who are opioid dependent. The clinic also provides on-site medical services, supervised dosing, individual and group counseling, psychiatric services, case management, and coordination with other medical and therapeutic providers. HCV screening is provided during intake for patients, and VDH receives Ab+ and RNA+ results ordered from this facility.

There has been great interest from the clinic's lead medical provider to work with VDH on the PS1702 Grant. An initial meeting to discuss partnership plans is forthcoming.

V. Conclusion

Vermont is well positioned to move it's HCV work forward. State policies which permit SSP activities and require laboratory reporting, paired with recent expansion of HCV treatment access to Medicaid beneficiaries create a strong backbone for HCV advancements.

During the initial phase of the grant, Chittenden County will continue to be the priority of partnership development and interventions. Opportunities to build upon existing relationships and strengthen partnership buy-in continue to be priorities across each identified site. The Situational Analysis highlights two main population with the greatest HCV prevalence, baby boomers and those who are ≤30 years of age. Interest in exploring risk factors and sharing information with the younger HCV population who have tested positive at a partner site is an opportunity VDH aims to explore in the coming months. Identifying opportunities to leverage resources within existing systems will continue to be an area of growth throughout the 1702 Grant term.

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Exhibit 2

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October 23, 2018

To the Honorable members of the Joint Legislative Justice Oversight Committee,

Thank you for the opportunity to share an overview and update on the treatment of Vermont inmates who have Hepatitis C (HCV). This is an important topic and the attention from the committee on this issue has been valuable to our work. The Agency of Human Services (AHS), through our Department of Corrections (DOC), has an obligation to ensure that inmates receive health care that is consistent with "prevailing medical standards." 28 V.S.A. § 801. It is through this understanding that we have been working to implement treatment for inmates with HCV that includes direct acting antiviral (DAA) treatment (i.e., "cure" medications).[1]

Changes in Medicaid Standard of Treatment

On December 4, 2017, DVHA sent an update to Medicaid providers that required "cure" medications to be considered regardless of F score.[2] Previously, only patients with a score of F2, F3, or F4 were considered candidates for "cure" treatment medications. While this was a change regarding when to consider use of "cure" medications, it was DOC's existing standard that all patients with chronic HCV be seen in Chronic Disease Clinic for ongoing medical monitoring and the development of a treatment plan.

DOC Processes for Determining HCV Treatment

Screening for HCV begins at intake, with confirmation of new diagnoses within seven days. Patients with HCV are seen by a medical provider within 14 days of admission unless extenuating circumstances exist. 28 V.S.A. § 801. Inmates newly-diagnosed with HCV are monitored for six months to see if they spontaneously "clear" the virus – this is the prevailing medical standard in the community. Patients with a known diagnosis of HCV are enrolled in the Chronic Disease Clinic and are seen every 3-6 months to monitor their condition. Medical providers, in consultation with UVM Medical Center Infectious Disease, review laboratory and other diagnostic information to determine when it is medically necessary to provide a treatment regimen that is in the best interest of the health of the patient. This determination is done regardless of F score, consistent with Vermont Medicaid's guidelines.

Of the total DOC patient population of 1,518 on 10/18/18, 153 or 10.1% came into custody with a known diagnosis of HCV.[3] For those whose status is not known, HCV screening and confirmatory testing is conducted. Since the beginning of 2018, 385 HCV tests have been completed, which have resulted in the diagnosis of 35 new HCV cases. On average, 250

[1] DAAs lead to a cure for HCV when the medications are taken as prescribed as measured by follow-up labs and "sustained viral response."
[2] F Score is a measure of fibrosis in the liver, as measured by a fibrosis ultrasound. F scores are integers and range from 0-4. 0 indicates no fibrosis and 4 indicates the presence of cirrhosis.
[3] There have been some problems with the "current incarceration date" interface between the Offender Management System and the Electronic Health Record which may impact the accuracy of this information. Also, patients that self-report (either accurately or inaccurately) an HCV diagnosis upon intake may not always know when they were diagnosed and might not have records for verification purposes. In these cases, the HCV diagnosis may be entered as the date that the patient came into DOC custody.

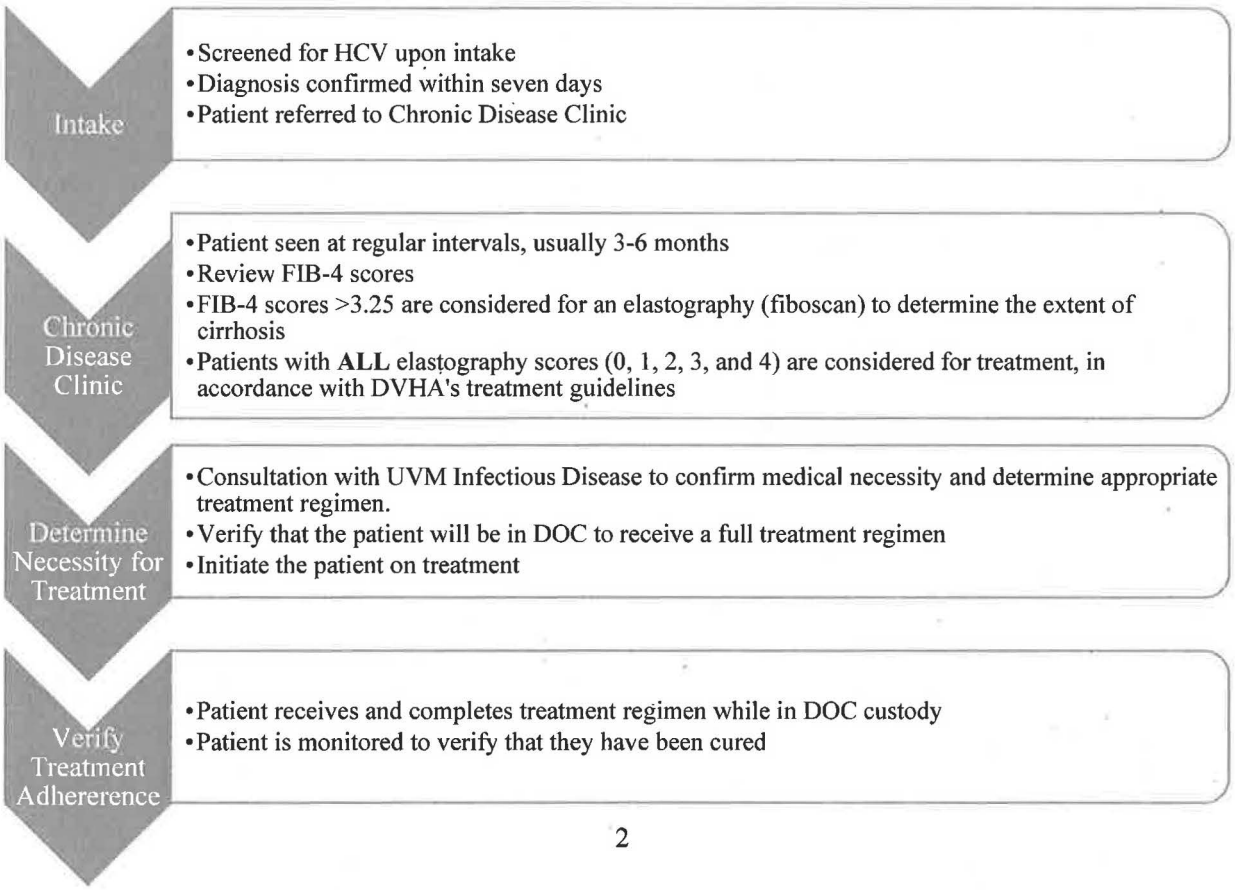
patients (including in-state and out-of-state populations) with HCV are in DOC custody per month. Of those, 24.8% (approx. 62 patients) will be in DOC custody long enough to receive a full HCV treatment regimen. Consistent with best practice, DOC continues patients on their HCV medications if they were on the medications upon intake.

In 2017, prior to the updated Medicaid Standard of Treatment, one patient was diagnosed and treated for HCV with direct acting antivirals which, when taken as prescribed, cure most patients with HCV. Under the updated Standard of Treatment, the number being newly treated increased to 10 in 2018 (one patient refused treatment). The remaining patients on the HCV "watchlist" are being considered for DAA treatment but have not yet received it because their FIB-4 scores are less than 3.25 – values less than 3.25 generally predict that fibrosis is not present. About 12% of patients are refusing diagnostic testing and treatment interventions. We are actively working to maximize the number of patients who receive this treatment, provider they meet all necessary criteria.

Challenges Regarding Length of Stay and Criteria for Successful Completion of Treatment

While we estimate that there are approximately 62 patients that have HCV and will be in DOC custody long enough to receive a course of treatment, they might not be always the same people over time. Further, even if those patients would be in long enough to receive the course of treatment, they may not meet the criteria for DAA treatment according to treatment guidelines. If a patient is expected to be in DOC custody for the length of time that treatment would require, that is not the only factor in determining a course of treatment. Disease progression, labs, imaging studies, other diagnostics, and case-by-case review by medical providers and infectious disease specialists are the cornerstones of "medical necessity" determinations in the DOC and the community.

In DOC, HCV treatment is not provided upon request. Nor is it provided upon request for any person seeking treatment outside of Corrections. The DOC's practice is the same as the community's practice in that patients with HCV are medically monitored to determine when it is appropriate to start the patient on one of the HCV "cure" medications.



It has been argued that DOC should treat patients in custody regardless of anticipated length of stay. To do so would not align with the treatment standard for people who are not in DOC custody. Medical providers strongly emphasize that patients be in a stable place in their lives where they will be able to comply with the full treatment regimen. There are risks to individual patients as well as to public health when treatment is not adhered to. For example, new strains of HCV for which there are no effective DAAs could develop and spread to the population.

Additional $2M Investment

While we are treating patients with "cure" medications once they are determined medically necessary for the course of treatment, the additional $2M requested at the September Joint Fiscal Committee from available funds in the FY2019 budget[4], is meant to address a trend that we are seeing in the number of patients that are being treated at any given time, as well as to allow us to maximize treatment under the relatively new Medicaid Standard of Care. As the number of patients being treated increases, we can expect increased costs. The $2M will help us address the need and goal to provide treatment to more patients over time.

The anticipated number of patients that are in DOC custody long enough to receive a full course of treatment of DAA is about 60 patients. Even with this additional investment in funds, there are still limiting factors since each is at a different stage within the overall treatment process and some may not meet the criteria that would result in treatment. This has nothing to do with funding availability. The standard is the same as in the community – not everyone diagnosed will be treated during a specific period of time because the medical standard takes into account much more than just the diagnosis and ability to complete the treatment regimen.

DOC has done a tremendous job wrapping their arms around this topic and making the connections needed in the medical community to support their implementation. We remain committed to treating inmates with HCV in accordance with standards that align with those in the community.

Sincerely,

Al Gobeille
Secretary, Agency of Human Services

[4] Secs. C.106.2 and C.1000(a)(14) of Act 11 of the Special Session.

Exhibit 3

STATE OF VERMONT AGENCY OF HUMAN SERVICES DEPARTMENT OF CORRECTIONS	Title: HEALTHCARE SERVICES	Page 1 of 3
Chapter: **Programs – Healthcare Services**	**# 351**	**Supersedes:** #351, dated 02/10/1986; #352, dated 10/20/1982; #361.01.07, dated 08/20/1997; #361.01.08, dated 08/20/1997; #363.01, dated 04/09/2004; #408.02, dated 01/05/2004; Interim Memo: *Keep-On-Person Inmate Self-Medication Program*, dated 07/27/2010

Attachments, Forms & Companion Documents:

All attachments, forms, and companion documents will be available on the DOC website.

Local Procedure(s) Required: No

Applicability: All staff (including contractors and volunteers)

Security Level: "B" – Anyone may have access to this document.

Approved:

SIGNED	**11/14/2017**	**11/28/2017**
Lisa Menard, Commissioner	**Date Signed**	**Date Effective**

PURPOSE

The purpose of this administrative directive is to identify the Vermont Department of Corrections' (DOC) philosophy and policies regarding the provision of healthcare services to inmates.

PHILOSOPHY

It is the philosophy of the DOC to provide healthcare services in DOC facilities. These services shall be administered in a humane and professional manner, with respect to inmates' constitutional rights to healthcare and protection from cruel and unusual punishment. Health services staff shall ensure that the basic healthcare rights of inmates are protected, including the rights to:

- Access professional medical, mental health, and dental care in accordance with prevailing medical standards;
- Receive care, treatments, and tests which are ordered by a qualified healthcare professional (QHCP);
- Consent to and refuse treatment;
- Have advanced directives; and
- Preserve the confidentiality of their protected health information.

All healthcare services shall be predicated on sound scientific principles, evidence-based practices, and methods of care optimally tailored for a correctional environment. Services shall be provided by licensed, certified, professionally trained, and appropriately credentialed personnel.

AUTHORITY

28 V.S.A. § 102; 28 V.S.A. § 801; 28 V.S.A. § 808; 28 V.S.A. § 808a; 28 V.S.A. § 907

REFERENCE

National Commission on Correctional Healthcare, Standards for Health Services in Jails, 2014; National Commission on Correctional Healthcare, Standards for Health Services in Prisons, 2014;

POLICY

It is the policy of the DOC to provide healthcare services to meet the medical, mental health, and dental needs of all inmates in accordance with the prevailing medical standards. Unreasonable barriers to inmates' access to healthcare services shall be avoided. All clinical decisions and actions pertaining to an inmate's healthcare shall be made by a QHCP, in accordance with prevailing medical standards for correctional environments.

National Commission on Correctional Healthcare (NCCHC) accreditation for the provision of healthcare services in correctional facilities shall be maintained.

Upon admission, the healthcare services program shall identify inmates who require services. In addition, the health services program shall provide emergency and crisis intervention services consistent with the standards of care specified by NCCHC. All inmates requesting healthcare services shall receive medical services provided by a QHCP.

All inmates shall receive an Initial Healthcare Receiving Screening upon admission, including a mental health screening, to ensure that emergent and urgent mental health needs are identified. Inmates who screen positively on the initial screening shall receive an initial mental health assessment performed by a qualified mental health professional (QMHP) and possible further mental health evaluations.

Inmates may submit a healthcare request form to be seen by a member of the health services team. Upon intake, inmates will be provided with information on the process for requesting healthcare services.

Healthcare services provided in correctional facilities are designed to achieve high standards regarding the following factors:

- Continuity of care, with regard to providing ongoing treatment for individuals that are admitted to, and released from, DOC custody;
- Care planning, which aids the ability to coordinate and manage care for individuals as they transition between the community and correctional facilities;
- Data sharing, which facilitates the availability of individuals' health information within and between the community and DOC facilities;
- Standardization of procedures for prior authorization and utilization management;

- Data collection and metrics, which are collected and monitored to achieve transparency, establish accountability, and improve performance;
- Effective governance and oversight of the health services program staff;
- Sound financial management; and
- Continuous Quality Improvement, through regular auditing, reviews of sentinel events, and performance-based indicators.

Exhibit 4

Centurion
A new initiative in correctional healthcare
Of VERMONT

MANAGEMENT OF HEPATITIS C

This guideline describes departmental recommendations for the screening, evaluation, treatment, and monitoring of patients infected with hepatitis C virus (HCV).

A. GENERAL INFORMATION REGARDING HEPATITIS C

1. Hepatitis C is a liver disease caused by the hepatitis C virus (HCV) which is found in the blood of persons who have this disease. HCV is spread by contact with the blood of an infected person.

2. Risk factors for infection may include, but are not limited to, injection drug use, transfusion with HCV-infected blood or blood products, tattooing, vertical transmission from mother to child, and massive exposure to HCV-infected blood during fighting or other trauma.

3. The average incubation period is six to nine weeks, with a range from two weeks to six months. Therefore, acute HCV infection usually is established within 3-6 months of the contact with the infected blood.

4. Those individuals who spontaneously clear hepatitis C usually do so within the first six months of being infected. Many patients have no symptoms of acute hepatitis.

5. Approximately 50-80% of individuals infected with hepatitis C will not spontaneously clear the virus. For them, the infection becomes chronic.

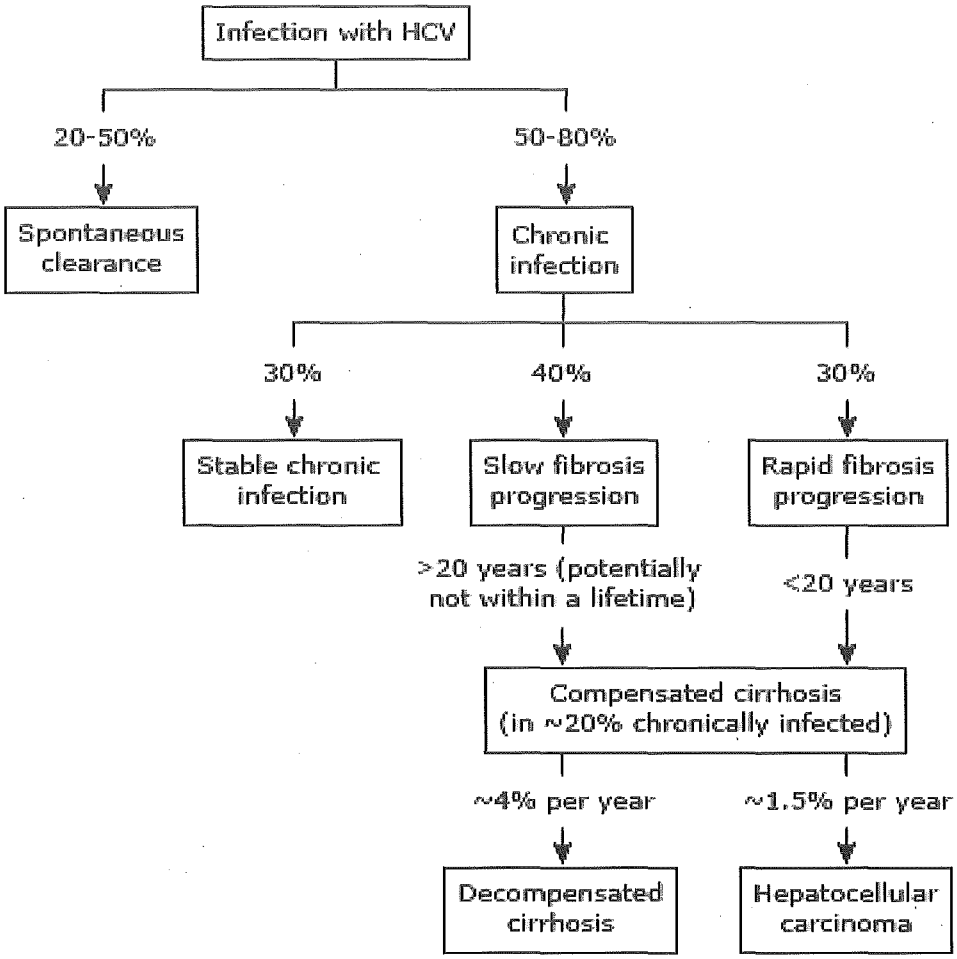
6. Chronic hepatitis C (sometimes abbreviated as "cHCV") is characterized by the persistent presence of HCV-RNA detectable in blood/serum, i.e., the HCV viral load (HCV-VL). Those patients who are HCV-VL+ in the context of the correctional setting usually have chronic HCV disease.

7. The principal consequence of cHCV is infection of the liver, which causes inflammation that may, in turn, result in scarring of the liver, which is known as "fibrosis." The amount of liver scarring a patient has is usually measured on the METAVIR scale.
   On this scale, a person can be classified as:
   F0 (inflammation, but no fibrosis)
   F1 (mild fibrosis)
   F2 (moderate fibrosis)
   F3 (severe fibrosis), or
   F4 (cirrhosis).

8. Liver scarring can significantly impair liver function, and can place a patient at risk for several serious symptoms/complications, as well as liver failure or liver cancer.

9. For a depiction of the natural history of HCV, see Diagram 1.

Natural history of hepatitis C virus



B. THE PROGRESSION OF CHRONIC HEPATITIS

1. Progression of cHCV to fibrosis and cirrhosis may take years in some patients and decades in others, or, in some cases, may not occur at all. The rate at which patients progress along the METAVIR scale, and can progress toward serious symptoms/complications differs among the population, and can be influenced by a variety of factors.

2. Patients with cirrhosis may develop decompensated cirrhosis and/or hepatocellular carcinoma over time. Factors associated with rapid progression or death (less than 20 years from infection to cirrhosis) can include, but are not limited to:
   - ALT elevation (especially if ALT>200, or "ALT flare")
   - Active alcohol and drug abuse
   - Grade 3 inflammation (Batts and Ludwig classification) on liver biopsy
   - Presence of bridging fibrosis (Batts and Ludwig S3+/Metavir F3+) on liver biopsy
   - Genotype 3 infection
   - HIV co-infection
   - HBV co-infection (those with HIV+HBV +HCV co-infection and detectable viremia of both HIV+HBV are at highest risk)

Hepatic steatosis and NASH
Diabetes and insulin resistance
Obesity
Daily use of marijuana
Uncontrolled underlying liver disease.

Also associated with a rapid progression, but less significant in multivariate analysis:
HCV risk behaviors that occur 10 or more years prior to the cHCV diagnosis
Male gender
Whether an individual is age 40 or more at the time of infection

3. The rapid accumulation of data since 2013 regarding hepatic fibrosis and progression to end stage liver disease (decompensated cirrhosis and hepatocellular carcinoma or primary liver cancer) has indicated that the risk for rapid progression within one year begins to be measurable when the patient reaches F2. There is an ~0.5% and ~1.0% one-year risk of progressing to hepatocellular carcinoma and decompensated cirrhosis, respectively, once the patient can be staged as F2 (Whether this is due to underestimation of the actual stage with present staging methods or represents very rapid progression of hepatic fibrosis is unknown). The best data continues to indicate that risks of progression in one year to hepatocellular carcinoma or decompensated cirrhosis in the patient with F3 and F4 fibrosis is 1%, 2% or 1.5-2%, 4%, respectively.

4. On the other hand, the factors associated with non-progression of hepatic fibrosis are not fully understood at this time, and may be less well-studied due to treatment bias.
   Non progression is more likely in patients with the following characteristics:
   Female sex
   Age <40yrs
   BMI<30
   Batts and Ludwig inflammation Grade 0-1
   Batts and Ludwig S0- 1/Metavir F0-1
   IL28B genotype (with C/C and C/T genotypes less likely to be associated with advanced hepatic fibrosis)
   Normal ALT (≥75% do not have advanced hepatic fibrosis)
   African-American race (slower progression/histology less severe in black patients)
   Patients whose HCV risk behaviors have happened in the recent past (usually <5-10yrs)
   Those without an alcohol abuse history

5. The contribution of sobriety/cessation of injection drug use to slowing the progression of hepatic fibrosis is also highly significant in terms of positive lifestyle behaviors associated with improved quality and length of life, especially if the patient achieves a sustained viral response (SVR), which is considered to be a cure. Additionally, statin use has been associated with a lower progression rate, and coffee (caffeinated only) consumption has been demonstrated in both retrospective and prospective trials to be associated with reduced hepatic fibrosis.

6. For a depiction of the progression of cHCV, and priority for treatment, see Diagram 2.

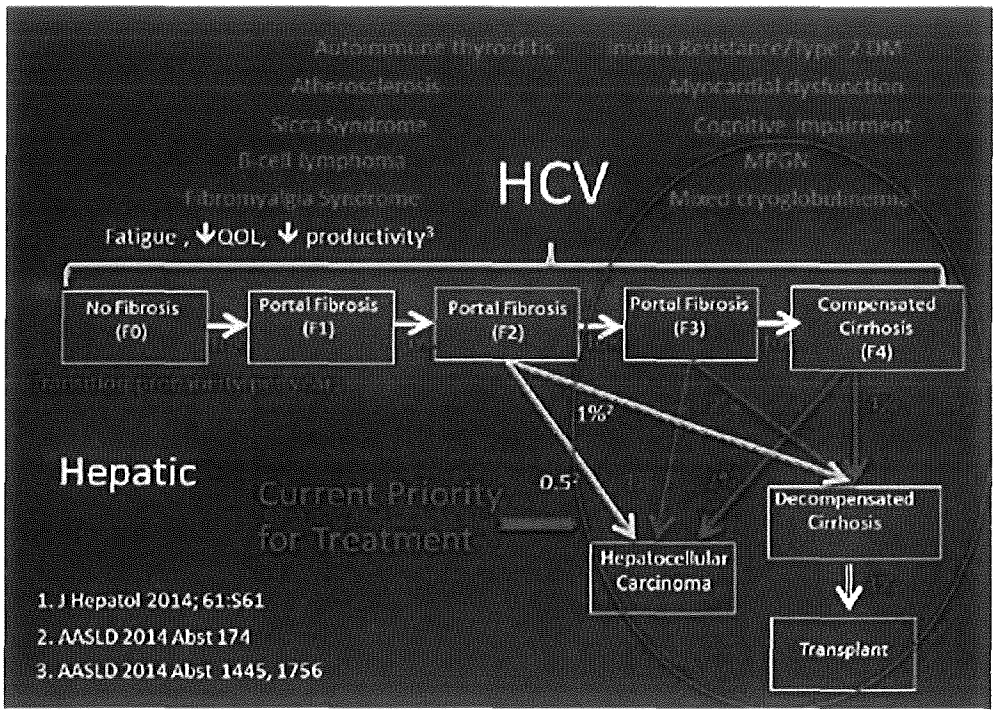


Diagram 2 attribution: Ken Benner, MD/Hepatology, Oregon Clinic, Portland, Oregon.

C. THE NEED FOR COMPREHENSIVE HCV TREATMENT, NOT JUST VIRAL ERADICATION

1. Identifying patients who need treatment sooner than others, and would benefit most, is a complex task requiring evaluation of multiple and diverse factors. The positive outcomes of increased survival and improved quality of life associated with successful viral eradication and a sustained viral response (SVR) are dependent upon sobriety and positive lifestyle change. For example, a long-term Danish study demonstrated an 18.2-fold increased mortality risk among younger patients with chronic HCV that was not due to their liver disease but, instead, was due to unnatural death: i.e., mortality associated with untreated mental illness and substance abuse associated suicide, homicide, and trauma. Liver related mortality only becomes more prevalent as the population ages. Therefore, sobriety is key to an overall harm reduction. (Clin Gastro and Hepatology 2011; 9:71-78).

2. Patients have a responsibility to learn from past behaviors and interact with society positively. Evaluation and treatment of chronic health problems such as chronic HCV and substance abuse play a crucial role in patients establishing trust and developing healthy behaviors, thereby reducing their rates of substance abuse relapse and correctional recidivism.

3. The benefits of evaluation and treatment of cHCV go beyond the immediate goal of viral eradication in the Individual. cHCV treatment is one part of a multi-part strategy to promote healthy lifestyles, which in turn benefits the patient, his/her family, and society.

4. Any patients interested in cHCV evaluation should understand that further laboratory testing, liver biopsy, imaging, or another method for staging hepatic fibrosis may be required prior to and during therapy. The risk and side effects of evaluation, the proposed treatment regimen and the need for monitoring must be fully discussed with the patients.

5. If there is reasonable documented concern about a patient's ability to adhere to and benefit from a

standardized treatment regimen, and these concerns are not able to be resolved through a cooperative treatment plan, treatment should not be initiated. Patients will be re-evaluated for treatment compliance in accordance with their Gastrointestinal Clinic (GC) scheduling.

6. Behavioral risk reduction and substance abuse counseling is an integral part of cHCV treatment. The use of peer educators has been shown to potentially have the greatest impact in this area. Patients should have pro-sobriety attitudes assessed and documented in the medical record. Patients with high propensity for relapse may need more extended time periods of sobriety prior to treatment as deemed appropriate by the clinical care committee or equivalent. Unfortunately, there is no evidence at this time that institutionally-mandated substance abuse programs improve outcomes over incarceration alone. However, patient-driven substance abuse treatment such as Narcotics Anonymous or Alcoholics Anonymous groups with peer educators and sponsors have demonstrated improved outcomes and decreased substance abuse relapse rates post-release. Patients should be encouraged to participate in these programs.

D. EDUCATION FOR NEWLY INCARCERATED INMATES REGARDING HCV

All newly incarcerated patients should be provided with educational information regarding prevention, transmission, risk factors, and screening of HCV. The form for this should include peer-to-peer education.

E. MONITORING OR TREATMENT FOR ACUTE HEPATITIS

1. HCV-VL shall be monitored at 6 months after the date of first diagnosis. If viremia persists after that time, continue to monitor and manage the case as a chronic infection.

2. In some cases when acute HCV infection superimposes on patients with established cirrhosis or advanced fibrosis, there may be a compelling reason to treat the acute infection as a chronic infection in order to prevent severe complications

F. SCREENING OF PATIENTS FOR THE PRESENCE OF cHCV, AND THE AMOUNT OF FIBROSIS

Screening for cHCV will be offered to all patients, regardless of risk factors, at multiple opportunities throughout incarceration. Patients may request screening as well. Screening should include the following components:

1. The preferred screening test for HCV infection is an immunoassay that detects the presence of antibodies to HCV antigens (referred to as HCV-Ab, or Anti-HCV).

2. If there is the presence of HCV-Ab, the specimen should be automatically analyzed for HCV-RNA (the HCV viral load, or HCV-VL) to immediately establish the presence or absence of chronic HCV.

3. In patients with a detectable viral load (HCV-VL), the specimen will also then be analyzed by a proprietary predictive index (e.g. FibroSURE), to initially assess the amount of fibrosis (liver scarring). Note: Proprietary indices that predict hepatic fibrosis stage such as FibroSURE, Fibrometer™ or FibroSPECT™ utilize a combination of age, sex, and a battery of laboratory parameters to predict the fibrosis score (F0-F4). Proprietary indices are widely utilized in the U.S. correctional system and in some communities in combination with ultrasound liver imaging to estimate the stage of hepatic fibrosis, especially in areas which are resource or access challenged, which would make routine elastography or other imaging very difficult.

4. HCV-VL+ patients who have been diagnosed to have F2, F3, or F4 will be reviewed and an abdominal ultrasound ordered to rule out the presence of portal hypertension (indicative of advanced hepatic fibrosis).

G. EDUCATION OF PATIENTS WHO ARE FOUND TO BE INFECTED WITH cHCV

Once patients are found to be infected with chronic HCV, they should be counseled by a clinician during the initial visit regarding the natural history of the infection, measures to assess the progress of cHCV, potential treatment options, and specific measures to prevent transmitting the HCV infection to others.

H. EVALUATION AND MONITORING IN THE GASTROINTESTINAL CLINIC

1. The following patients will be enrolled in the Gastrointestinal Clinic ("GC") for evaluation and monitoring:
   Those with active cHCV who are not being treated with direct-acting antiviral medication
   Those who have had HCV treatment failure
   Those who have had a relapse of HCV infection or reinfection.

2. In the GC clinic, the patient will receive the following:
   Baseline history and physical examination
   Labs and other tests (see below), including a proprietary predictive index, if not previously provided
   Abdominal ultrasound, if not previously provided
   Assessment and discussion with the patient of the results of the proprietary predictive index and abdominal ultrasound
   Evaluation and assessment of the need for preventive health interventions such as vaccines and screenings for other conditions
   Counseling on cHCV infection.

3. Patients who are fibrosis stage 4 (F4), or stage 3 (F3) shall be seen every six (6) months or sooner, if indicated, shall receive laboratory testing every 3-6 months, and shall receive an abdominal ultrasound for hepatocellular carcinoma (HCCa) surveillance every six (6) months.

4. Patients who are fibrosis stage 2 (F2), stage 1 (F1) or stage 0 (F0) shall be seen every six (6) months, and shall receive laboratory testing every six (6) months, and the proprietary predictive indices and/or elastography every twelve (12) months.

5. Each patient's fibrosis stage will be recorded as F0-F4. If available, the patient's Child-Turcotte-Pugh score will be recorded as well.
   In particular, consider the following:
   The history and physical examination:
   Focus on signs and symptoms of liver disease, prior alcohol consumption, and risk behaviors for acquiring HCV infection. Based on this information and the period in which the patient engaged in injection drug use or other risk behaviors, attempt to estimate earliest possible date of infection. Evaluate for other possible causes of liver disease, including alcoholism, non- alcoholic steatohepatitis (NASH), iron overload (hemochromatosis), and auto-immune hepatitis. Inquire about prior treatment for HCV infection, specific medications used, dosages and duration of treatment, and outcomes, if known.
   Laboratory and Other tests:
   Complete blood count (CBC); Prothrombin time (PT) with International Normalization Ratio (INR); and a comprehensive metabolic panel (CMP).

Laboratory testing consistent with cirrhosis may include elevated bilirubin, decreased albumin, and prolonged INR, but these tests are only used to quantify cirrhosis. Use of predictive indices uses laboratory markers to predict the state of hepatic fibrosis.

Elastography methods (using either ultrasound or MRI) may be critical in determining the fibrosis stage. Imaging studies may also identify cirrhosis, and not require further staging. Non-invasive elastography modalities have been shown to be reliable in detecting advanced hepatic fibrosis, are cheaper, easily repeated for serial monitoring, and thus long-term outcomes may be accurately predicted.

A liver biopsy is no longer required unless otherwise clinically indicated.

Abdominal imaging studies such as ultrasound or CT scan may identify findings consistent with or suggestive of cirrhosis, portal hypertension or hepatocellular carcinoma (HCC).

CTP calculators are available at: http://www.hepatitisc.uw.edu/page/clinical-calculators/ctp

Screening for other conditions:

There should be screening for the Hepatitis A antibody (HAV-Ab), and the Hepatitis B surface antigen (HBsAg), unless these were already known from a prior Hepatitis Panel, and also testing for the HIV antibody (HIV- Ab). If risky behavior occurred after previously negative testing, consideration may be given to repeat testing. An anti-nuclear antibody (ANA) and ferritin should be ordered as screening for auto-immune hepatitis and hepatic iron overload.

Counseling:

Patients should be counseled regarding the progression of cHCV, the staging of treatment with direct acting antiviral medication (DAAs), other potential treatment options, the availability of peer-to-peer counseling, and specific measures to prevent transmitting HCV infection to others.

I. PRIORITIZATION FOR TREATMENT WITH DIRECT-ACTING ANTIVIRALS (DAAs)

1. Although many patients with chronic HCV infection may benefit from treatment with direct-acting antiviral medication (DAAs), certain cases are at higher risk for complications or disease progression and require more urgent consideration.

2. Eligibility for DAA treatment should be established via concordance between laboratory, imaging (abdominal ultrasound, and elastography if available), and predictive scoring (proprietary indices). Resource challenged systems may use the combination of proprietary indices and abdominal ultrasound to assess for the presence of F2-F4 hepatic fibrosis.

3. Within the eligible group of patients, the following priority criteria have been established to ensure that those with the greatest need are treated first.

PRIORITY LEVEL 1 - Highest Priority for Evaluation and Treatment

The following individuals should receive DAA treatment within 0-6 months (subject to paragraph K, below):

Fibrosis Stage 4, decompensated cirrhosis, including both symptomatic patients (e.g., with ascites, hepatic encephalopathy, esophageal varices, etc.) and asymptomatic patients with CTP scores greater than or equal to 7.

Fibrosis Stage 4, compensated cirrhosis, with CTP scores greater than 5 and less than 7.

Liver transplant candidates or recipients in consultation with and co-managed by a transplant hepatologist.

Hepatocellular carcinoma in consultation with a hepatologist for correct timing.

Comorbid medical conditions associated with HCV, including cryoglobulinemia with renal disease or vasculitis, certain types of lymphomas, hematologic malignancies or metabolic abnormalities.

Continuity of care for those entering custody already on treatment.

Patients taking immunosuppressant medications for a comorbid medical condition which may cause rapid progression of hepatic fibrosis.

HIV co-infection.
HBV co-infection.

PRIORITY LEVEL 2 - Intermediate Priority for Evaluation and Treatment

The following individuals should receive DAA treatment within 12 months (subject to paragraph J, below):

Fibrosis stage 3 (F3)
Fibrosis stage 2 (F2).
Comorbid liver disease (e.g., autoimmune hepatitis, hemochromatosis, steatohepatitis).
Chronic Kidney Disease with proteinuria.
Diabetes Mellitus.
Patients previously staged as F0, but who advanced in staging to F1 within 1-4 years are considered to have progressive hepatic fibrosis, and should be treated in this priority group.

PRIORITY LEVEL 3 – Active Monitoring for DAA Treatment

The following individuals should be monitored regularly with labs and proprietary predictive indices for re-staging at least annually into a higher priority level:

Fibrosis stage 1 (F1).
Fibrosis stage 0 (F0).

J. OTHER CRITERIA TO BE CONSIDERED BEFORE TREATMENT WITH DIRECT-ACTING ANTIVIRAL MEDICATION

1. In addition to meeting the above criteria for Priority Level 1 and Priority Level 2, patients being considered f or treatment of cHCV infection should:
   - Have no contraindications to, or significant drug interactions with, any component of the treatment Regimen
   - Have sufficient time remaining on their sentence in the Department of Corrections to complete pre-treatment evaluation, a course of treatment, and post treatment SVR assessment at 8-24 weeks, in order for patient education and system efficiencies to be evaluated (generally, this requires approximately 12-18 months)
   - Have a life expectancy sufficient to achieve benefit from HCV viral eradication
   - Demonstrate willingness and an ability to adhere to a rigorous treatment regimen and to abstain from high risk behaviors while incarcerated.

2. A cHCV patient's attitude, functional ability to thrive within the system, and optimal treatment of mental health issues are critical for good outcomes. Patients who have chronic disciplinary issues within the system have very high substance abuse relapse rates upon release, with newer evidence indicating higher re-infection rates. Patients should be counseled and observed on a case-by-case basis, and involvement of mental health professionals is critical. It is also critical to remember that patients who have chronic behavioral management issues, common in jails/prisons, are rarely able to establish and maintain a therapeutic provider-patient relationship which results in completion of treatment and an SVR.

3. Patients who are Priority Level 1 or Priority Level 2, but who:
   - Are unable to demonstrate a willingness and an ability to adhere to a rigorous treatment regimen
   - Do not abstain from high risk behaviors while incarcerated
   - Have chronic disciplinary issues
   - Have chronic behavioral management issues

   May not be eligible for treatment until those issues are considered to be resolved. A patient should be willing to participate in any available counseling or treatment in order to achieve the sobriety/behavior change before treatment with DAAs is initiated.

K. RECOMMENDED TREATMENT REGIMENS

1. Recommendations for HCV treatment regimens continue to evolve, and are changing rapidly as new agents become available and as evidence of the most effective ways to utilize the DAAs accumulates. Usually 8-12 week regimens are preferred due to improved adherence, lower toxicity, and cost-effectiveness.

2. The AASLD/IDSA/IAS3 website, which is found at hcvguidelines.org, presents reliable summaries of drug treatment data and should be used to direct most treatment.

3. Expert consultation is required in patients eligible for liver transplantation.

4. Treatment of chronic HCV during pregnancy is presently not recommended due to the lack of safety data.

L. TREATMENT FAILURE FOLLOWING DAA TREATMENT

1. Treatment failure is defined as a detectable HCV-VL 12 weeks following completion of therapy.

2. If the HCV-VL is <50 copies/ml or in the "non-quantifiable" range then the test should be repeated in 4 weeks as this situation usually represents lab error or very slow clearance of virus; the repeat testing will usually be "not detected."

3. In the case of true failure, the medical record should be reviewed for non-adherence, system failure in drug dispensing (e.g., omissions in directly observed therapy, not providing refills on time, etc.), possible drug-drug interactions, and the patient should be interviewed for illicit drug use and the ingestion of other acid-lowering medications or supplements.

4. If no interfering risk factors are identified, the possibility of viral mutation causing drug resistance (Resistance-Associated Substitutions) should be considered.

5. Further resistance testing and a secondary treatment regimen should be selected according to the principle and treatment recommendations contained in hcvguidelines.org.

M. TREATMENT MONITORING

1. The patient will have an outpatient clinic visit at 2-4 weeks after starting therapy in order to establish adherence to the prescribed regimen, and assess for side effects and the need for treatment modification. DAA regimens usually do not require routine lab monitoring, unless clinical symptoms of increased fatigue or other side effects occur.

2. A CBC and comprehensive metabolic panel (CMP) equivalent may be drawn at 4 weeks to rule out transaminase elevation due to autoimmune hepatitis or HBV reactivation. The CMP may also be used to reassure the patient that there is evidence of efficacy and encourage further adherence and program compliance.

3. Progressive increases in the ALT may require more frequent monitoring or early discontinuation.

4. For regimens containing RIBAVIRIN: a CBC and CMP should also be drawn 2 weeks after starting therapy, then at 4 weeks, then monthly or more frequently as clinically indicated. A Ribavirin dosage adjustment may be required. Mild (1-3x upper limit of normal) elevation of the total bilirubin may be expected as a

consequence of Ribavirin-induced oxidative stress and RBC Lysis. Pregnancy testing is required prior to treatment with ribavirin-containing regimen, and thereafter as risk behavior for pregnancy occurs.

N. POST-TREATMENT MONITORING

1. A post-treatment quantitative HCV-VL assessment will be drawn at 12 weeks after completion of treatment; and if HCV is undetectable, that defines a sustained viral response (SVR).

2. A patient who sustains SVR may be removed from the Gastrointestinal Clinic (GC), so long as the patient has no cirrhosis, complications, or related comorbidities.

O. OTHER HEALTH CARE INTERVENTION RECOMMENDED FOR CIRRHOSIS

1. All patients with cirrhosis shall have additional consultative co-management as follows:
   At first identification of a F4 diagnosis the Platelet/Spleen diameter ratio shall be computed (example: 112,000/131 (mm) = 855). All patients with values <905 shall be referred for EGD for diagnosis of esophageal varices. If varices are present, non-selective beta-blockers to prevent variceal bleeding shall be initiated. Alternatively, some selected patients may require banding of varices; however, beta-blocker prophylaxis is preferred and recommended in accordance with AASLD recommendations.
   Patients with decompensated cirrhosis shall be co-managed by a gastroenterologist or hepatologist. Decisions for co-management including ongoing variceal surveillance, antibiotic prophylaxis if risk factors are present for spontaneous bacterial peritonitis, optimized diuretic therapy for ascites, and optimized therapy for hepatic encephalopathy shall be addressed during the consultation.

2. In general, NSAIDs should be avoided in advanced liver disease/cirrhosis and METFORMIN should be avoided in decompensated cirrhosis. Other resources should be consulted for more specific recommendations related to management of cirrhosis.

P. REFERRAL FOR LIVER TRANSPLANTS FOR PATIENTS WITH DECOMPENSATED CIRRHOSIS

A determination of the UNOS MELD score will be made for all patients with decompensated cirrhosis. If the score meets the listing/eligibility criteria maintained by the consulting liver transplant centers, the patient will be referred to the transplant center. Thereafter, co-management as directed by the transplant center will be instituted if the patient is listed for transplant.

Q. HCV TREATMENT APPROVAL PROCESS

In accordance with HSB 15.03.05 Appendix #8, patients with chronic liver disease should be enrolled in Gastrointestinal Clinic (GC) with baseline information completed prior to start of treatment using DC4-770GG-Gastrointestinal Baseline History and Procedures.

Documentation of evaluation of treatment should be entered on form DC4-701F (*Chronic Illness Clinic*). The encounter should be entered in the OFFENDER-BASED INFORMATION SYSTEM (OBIS) as a GC appointment using the appropriate diagnosis code as shown below.

1. GH08 – Front Page. Add the following codes as determined:
   For Acute hepatitis C - use ICD-10-CM Diagnosis Code **B17.1**
   (Note: Per Section E.1. above, if viremia persists at 6 months after the date of first diagnosis, continue to monitor and manage the case as a chronic infection. This requires a change in OBIS code in accordance with R.1.b. If viremia does not persist at 6 months, remove code B17.1, but continue to monitor for other health issues.)
   For Chronic viral hepatitis C – use ICD-10-CM Diagnosis Code **B18.2**

2. GH08 – back page. Add the following action codes on the GH08 Back page (contact screen):
   DAA = HepC Tx Started
   Enter start date – Required Field
   DAAx = HepC Tx Discontinued
   Enter end date – Required Field **AND**
   Requires remarks (i.e., 12 weeks completed; inmate non-compliant, inmate refused, etc.)
   SVR = Sustained Virologic Response Achieved
   Enter date – Required Field

Exhibit 5

VERMONT LEGAL AID, INC.

OFFICE OF THE HEALTH CARE ADVOCATE

264 NORTH WINOOSKI AVE.
BURLINGTON, VERMONT 05401
(800) 917-7787 (TOLL FREE HOTLINE)
(802) 863-7152 (FAX)

OFFICES:
BURLINGTON
RUTLAND
ST. JOHNSBURY

OFFICES:
MONTPELIER
SPRINGFIELD

March 15, 2018

Lisa Menard, Commissioner
Vermont Department of Corrections
NOB 2 South
280 State Drive
Waterbury, VT 05671-2000

Re: Department of Corrections Hepatitis C Information Request

Dear Commissioner Menard:

The Office of the Health Care Advocate is writing to request information related to the Vermont Department of Corrections (DOC)'s treatment of hepatitis C virus (HCV) for DOC inmates and detainees. It is our understanding that in 2017, DOC opened HCV treatment to all inmates and detainees with fibrosis scores of F2 and greater, consistent with Department of Vermont Health Access (DVHA) policy. We are interested in understanding how this was implemented. Additionally, on January 1, 2018 DVHA implemented updated hepatitis C treatment guidelines, opening treatment to Vermonters regardless of fibrosis score. We would like to know if this change has been implemented at DOC. We are hoping to receive the information requested in this letter by April 5. Please let us know by March 22 if that timeline will work for DOC and if you would like to set up a meeting to discuss this request. We have requested similar information from DVHA.

We are requesting the following information:

- For calendar year 2017 and for January and February 2018, by month and detention location:
  - The number of:
    - Inmates and detainees tested for HCV
    - Inmates and detainees diagnosed with HCV
    - Inmates and detainees treated for HCV, by fibrosis (F) score and treatment agent
    - Deaths in custody of inmates and detainees known to have HCV
    - Total inmates and detainees
  - The range and average time from HCV diagnosis to treatment
  - The total cost of direct-acting antiviral medication for DOC inmates and detainees

- As of March 1, 2018, by detention location:
  - The number of inmates and detainees known to have HCV who have not been treated
    - For those not yet treated, the reason(s) for lack of treatment
    - The range and average time since HCV diagnosis for those not treated

- Any records regarding DOC's policies or practices regarding testing, diagnosis and treatment for HCV

Thank you. Please feel free to contact me at mfisher@vtlegalaid.org or (802) 989-9806 with any questions.

Sincerely,

s\ Mike Fisher, Chief Health Care Advocate

Exhibit 6

VERMONT

State of Vermont
Department of Corrections
NOB 2 South, 280 State Drive
Waterbury, VT 05671-2000
www.doc.vermont.gov

[phone] 802-241-2442
[phone] 802-241-0000
[fax] 802-241-0020

Agency of Human Services

June 4, 2018

Michael Fisher
Chief Health Care Advocate
Office of the Health Care Advocate
264 North Winooski Ave
Burlington, VT 05401

Re: Record Request #24522

Dear Mr. Fisher:

The Vermont Department of Corrections has found information responsive to your May 21, 2018 request. The Department's responses are included below.

1. The number of people treated in 2017 and the F scores of those treated;
    a. 1; no F-score
2. How many people with F scores below 2 have been treated to date;
    a. Zero
3. The total dollar amount of payments made by the state to Centurion for 1) pharmaceuticals for 2017 and 2) off-site services for 2017;
    a. 1 – $2,719,719, 2 – $2,113,726.78
4. The total amount spent by Centurion on 1) pharmaceuticals for the same time period and spent by Centurion on 2) off-site services for the same time period;
    a. 1 – $1,785,926, 2 - $883,203
5. Copy of attachment J, including appendix 5.23 from contract #28239 between Centurion of Vermont LLC and AHS/Department of Corrections.
    a. Copy of attachment J, is attached.

The Department is also revising one of the answers to questions provided to Julia Shaw on April 12, 2018. The total cost of direct-acting antiviral medication for DOC inmates and detainees – For CY 2017, the total cost was $47,250.

Sincerely,

David Turner
Policy Development and Offender Due Process

Exhibit 7

Clouser, Kristin

From: Gobeille, Al
Sent: Monday, July 09, 2018 8:45 PM
To: Menard, Lisa
Subject: Re: HCV Info Request

Yes

Al Gobeille
Secretary, Agency of Human Services
Al.Gobeille@vermont.gov
(802) 585-4030

From: Menard, Lisa
Sent: Monday, July 9, 2018 8:43:59 PM
To: Gobeille, Al
Subject: Re: HCV Info Request
Yes- include Ben and Matt?

Lisa Menard
Commissioner
Vermont Department of Corrections

From: Gobeille, Al
Sent: Monday, July 9, 2018 8:43:22 PM
To: Menard, Lisa
Subject: Re: HCV Info Request
Can we get a half hour this week to discuss?

Al Gobeille
Secretary, Agency of Human Services
Al.Gobeille@vermont.gov
(802) 585-4030

From: Menard, Lisa
Sent: Friday, July 6, 2018 1:59:00 PM
To: Gobeille, Al
Subject: FW: HCV Info Request
Per our discussion a few weeks ago here are some financial projections
Lisa M. Menard
Commissioner, Vermont Department of Corrections

From: Watts, Benjamin
Sent: Thursday, June 21, 2018 12:10 PM
To: Menard, Lisa ; Touchette, Mike
Cc: Watts, Benjamin
Subject: RE: HCV Info Request
Hello
Here's a brief summary of HCV financial projections and some of the "assumptions" that I've made about the data:
ASSUMPTIONS:

- Patients at each step in treatment will be in custody long enough to receive the entire course of treatment.
- There are many case-specific considerations when determining the appropriate course of treatment, including but not limited to the recency of the patient's diagnosis, patient's FIB-4 score, F score, disease progression, genotype, treatment regimen, and the expected duration of treatment.
- Most therapies will be 12 weeks in duration, keeping in mind that Mavyret and Zepatier may require 16 weeks in some cases.
- Epclusa and Mavyret can be used for all genotypes
- The current costs for a 28-day supply of the four most utilized HCV medications are:
    - Epclusa - $8,288.09
    - Harvoni - $10,784.66
    - Mavyret – 12,847.68
    - Zepatier - $16,913.08
- The average cost of a 28-day supply of the four most utilized HCV medications is $12,208.38.
- The average cost of a 12-16 week course of treatment is $36,625-$48,833

FINANCIAL PROJECTIONS, BASED ON CLINICAL WORKFLOW:

- **Auto-Reflex** – Auto-reflex testing is completed usually within 7 days for patients that screen positive for HCV upon intake. The data indicates that 121-279 inmates with HCV are in custody for 7 days or more. The cost of providing a HCV treatment regimen to all patients at this stage would be $4,431,625 - $13,624,552.
- **Chronic Care Clinic** – Patients with HCV are scheduled to see medical providers in Chronic Care Clinic at regular intervals (usually every 3-6 months) to assess their condition and consider the patient for HCV treatment. The data indicates that 53-123 patients at any given time with HCV could be in custody for 6 months or more. The cost of providing an HCV treatment regimen to all patients at this stage would be $1,941,125 - $6,006,523.
- **Determination that Treatment is Medically Necessary** – Depending on the patient's disease progression, Centurion will present cases to UVMMC for consultation. Patients are clinically worked up to determine their genotype, medications, and length of treatment. Assuming treatment durations range from 12-16 weeks, patients that receive a HCV treatment regimen would need to be in DOC custody for roughly 9-13 months. Approximately 23.3% of patients are in custody for 9-13 months, which works out to roughly 30-70 patients with HCV. The cost of providing treatment to all patients at this stage would be $1,098,750 - $3,418,310.

Needless to say, the data is not perfect and I will continue to work on it. I'm sure you'll have questions and suggestions for tweaking how the numbers are calculated, and I'm happy to sit down at any time to discuss.
Thanks!
Ben

From: Watts, Benjamin
Sent: Wednesday, June 20, 2018 11:48 AM
To: Menard, Lisa <Lisa.Menard@vermont.gov>; Touchette, Mike <Mike.Touchette@vermont.gov>
Cc: Watts, Benjamin <Benjamin.Watts@vermont.gov>
Subject: HCV Info Request

Hello

Here is a summary of my conversation with UVMMC Infectious Disease:

UVMMC provides treatment recommendations for patients that are presented by Centurion's Statewide Medical Director. UVMMC indicated that it's their general practice to wait 6 months for patients with new HCV diagnoses because the virus could spontaneously clear itself. UVMMC does not routinely treat HCV for newly diagnosed patients. Patients that are known to be chronic should be clinically worked up for treatment. UVMMC indicated that it would be a "disservice" for patients to

start them and not verify that they complete their treatment. Patients with a well-established healthcare team could be started on treatment. Patients without sufficient psycho-social support could result in treatment failure which would make it more difficult to treat. There are very few scenarios in which patients with HCV are receiving a partial course. Patients are clinically "worked up" knowing that they will be ready, willing, and able to complete treatment.

FYI, I have reached out to Dr. Strenio to set up a meeting to discuss the provision of HCV treatment in DOC. I'll keep you posted.

When it comes to calculating the cost of providing HCV treatment to more patients, here are some of the issues that we are up against:

- Data integrity, especially as it relates to length of stay
- The many case-specific contingencies that can and do occur
- The complex array of treatment regimens and treatment durations

I'm awaiting a call from the Director of Pharmacy to get some consultation on how to calculate the financials. I'll reply to this email chain when I have more (better) data.

TY!

Ben Watts, MBA
Health Services Administrator
Vermont Department of Corrections
NOB 2 South
280 State Drive
Waterbury, VT 05671 – 2000
802-503-2082 Cell
Benjamin.Watts@vermont.gov

Exhibit 8

Turner, David

From: Watts, Benjamin
Sent: Friday, July 20, 2018 10:13 AM
To: D'Agostino, Matt
Cc: Watts, Benjamin
Subject: RE: HCV workflow

Hi Matt

Your email to Sarah looks perfect. Please CC: me on the correspondence.

Thanks so much

Ben

From: D'Agostino, Matt
Sent: Friday, July 20, 2018 8:43 AM
To: Watts, Benjamin <Benjamin.Watts@vermont.gov>
Subject: RE: HCV workflow

Hi Ben,

I noticed that Sarah Clark wasn't copied and wanted to forward to her. I anticipate she will want to know more details related to when we would see these costs, so I put the following response together. Just wanted to make sure you concur before sending it over to Sarah:

Sarah - FYI in case you haven't already seen this. The introduction is below and the workflow is attached. We are estimating a range of approximately $1.9m-$2.7m above the current budgeted total for HCV treatments, though it is very difficult to predict the timing of these costs. For example, it is not known if they would all occur in year 1 or be spread out over 2 or more years. Also, if every patient that we are currently aware of was to be treated, there is not a reliable way of knowing the amount of ongoing treatment costs, as we could only guess based on percentages of the population how many new cases of HCV we would see in any given year and how many of those offenders would remain incarcerated for a period long enough to go through treatment while in DOC custody.

Thanks!
Matt

From: Menard, Lisa
Sent: Wednesday, July 18, 2018 2:51 PM
To: Gobeille, Al <Al.Gobeille@vermont.gov>
Cc: Fisher, Jaime <Jaime.Fisher@vermont.gov>; D'Agostino, Matt <Matt.DAgostino@vermont.gov>; Watts, Benjamin <Benjamin.Watts@vermont.gov>; Touchette, Mike <Mike.Touchette@vermont.gov>
Subject: HCV workflow

Al-

Following and attached are what we believe you requested at our last meeting. Ben and Matt collaborated on this so are copied in case you need clrifications or additions.

Lisa M. Menard
Commissioner, Vermont Department of Corrections

INTRODUCTION

Screening for hepatitis C begins at **intake**, with confirmation of new diagnoses within 7 days. Patients with HCV are seen by a medical provider within 14 days of admission. Inmates with HCV are enrolled in **chronic care clinic** and are seen every 3-6 months to monitor their condition. Medical providers, in consultation with UVMMC Infectious Disease, review laboratory and other diagnostic information to **determine when it is medically necessary** to provide a treatment regimen.

Due to public health and patient safety concerns, only inmates that are known to be in custody for the entire duration of the treatment regimen will be provided with treatment. On average, 250 patients (including the in-state and out-of-state populations) with hepatitis C are in DOC custody per month. Of those, 24.8% (62 patients) will be in DOC custody long enough to receive a full HCV treatment regimen.

From: Watts, Benjamin
Sent: Wednesday, July 18, 2018 2:05 PM
To: Menard, Lisa <Lisa.Menard@vermont.gov>; D'Agostino, Matt <Matt.DAgostino@vermont.gov>
Cc: Watts, Benjamin <Benjamin.Watts@vermont.gov>; Rose, Jacqueline <Jacqueline.Rose@vermont.gov>
Subject:

Ben Watts, MBA
Health Services Administrator
Vermont Department of Corrections
NOB 2 South
280 State Drive
Waterbury, VT 05671 – 2000
802-503-2082 Cell
Benjamin.Watts@vermont.gov

Exhibit 9

Clouser, Kristin

From: Clark, Sarah
Sent: Wednesday, July 25, 2018 7:38 AM
To: Gobeille, Al
Subject: FW: HCV workflow
Attachments: Length of Stay HCV Rate Calculations 5-24-18.xlsx

From: D'Agostino, Matt
Sent: Tuesday, July 24, 2018 4:47 PM
To: Clark, Sarah <Sarah.Clark@vermont.gov>
Cc: Watts, Benjamin <Benjamin.Watts@vermont.gov>; Morgan, Candace <Candace.Morgan@vermont.gov>
Subject: RE: HCV workflow

Hi Sarah,

Yes, the estimate of 62 inmates is the number of inmates with hep C that would be expected to be in custody long enough to receive an entire course of treatment. The estimate of 62 inmates does not take into account fib-4 scores, F scores, clinical consultation with UVMMC, and other criteria that are generally used by community-based providers when determining the appropriateness of starting a patient on a treatment regimen.

I have attached a spreadsheet which breaks down the numbers in terms of average inmates with positive tests for HCV in DOC custody in each month, as well as the length of stay and what percentage of inmates remain in custody long enough to reasonably go through the full intake*, chronic care clinic, treatment regimen, and post-treatment follow-ups (less than 25% of the total inmates). We have also included the population out of state, as the cost for treatment will ultimately be paid directly or reimbursed by VT DOC.

if we were to treat the estimated 62 inmates who met the criteria determined to be necessary for the treatment regimen to be provided while in custody, there is no way of determining what year 2 or beyond would look like. The challenges are the unknown variables, such as what percentage of total incarcerated population will be diagnosed going forward, if length of stay will remain similar (or increase/decrease), or if, as treatment in the community is increased, the DOC incarcerated population also sees a decline in overall cases of HPV. One would think/hope that as treatment is expanded, future year costs/cases with positive diagnosis should decline, but this is not a certainty.

*we used 46 weeks as the minimum length of stay. This includes 1 week for intake/diagnosis, 26 weeks for the 6-month hold and monitoring, 2 weeks in between to develop treatment regimen and verify that minimum sentence/release date are far enough out to complete treatment, 12 weeks enough time for the treatment regimen, and an additional 5 weeks, which would ensure some additional time in case the 16-week regimen is needed and follow-up after treatment to ensure that the regimen was successful.

Matt

From: Clark, Sarah
Sent: Tuesday, July 24, 2018 12:53 PM
To: D'Agostino, Matt <Matt.DAgostino@vermont.gov>
Cc: Watts, Benjamin <Benjamin.Watts@vermont.gov>; Morgan, Candace <Candace.Morgan@vermont.gov>
Subject: RE: HCV workflow

Matt,
Are all of the inmates included in your estimate long-term, meaning they will be with DOC for a full course of treatment? Can you share your analysis with me?

Thanks,
Sarah

From: D'Agostino, Matt
Sent: Friday, July 20, 2018 10:41 AM
To: Clark, Sarah <Sarah.Clark@vermont.gov>
Cc: Watts, Benjamin <Benjamin.Watts@vermont.gov>
Subject: FW: HCV workflow

Hi Sarah,

FYI in case you haven't already seen this. The introduction is in Lisa's email below and the workflow is attached. We are estimating a range of approximately $1.9m-$2.7m above the current budgeted total for HCV treatments, though it is very difficult to predict the timing of these costs. For example, it is not known if they would all occur in year 1 or be spread out over 2 or more years. Also, if every patient that we are currently aware of was to be treated, there is not a reliable way of knowing the amount of ongoing treatment costs, as we could only guess based on percentages of the population how many new cases of HCV we would see in any given year and how many of those offenders would remain incarcerated for a period long enough to go through treatment while in DOC custody.

Thanks,
Matt

From: Menard, Lisa
Sent: Wednesday, July 18, 2018 2:51 PM
To: Gobeille, Al <Al.Gobeille@vermont.gov>
Cc: Fisher, Jaime <Jaime.Fisher@vermont.gov>; D'Agostino, Matt <Matt.DAgostino@vermont.gov>; Watts, Benjamin <Benjamin.Watts@vermont.gov>; Touchette, Mike <Mike.Touchette@vermont.gov>
Subject: HCV workflow

Al-

Following and attached are what we believe you requested at our last meeting. Ben and Matt collaborated on this so are copied in case you need clrifications or additions.

Lisa M. Menard
Commissioner, Vermont Department of Corrections

INTRODUCTION

Screening for hepatitis C begins at **intake**, with confirmation of new diagnoses within 7 days. Patients with HCV are seen by a medical provider within 14 days of admission. Inmates with HCV are enrolled in **chronic care clinic** and are seen every 3-6 months to monitor their condition. Medical providers, in consultation with UVMMC Infectious Disease, review laboratory and other diagnostic information to **determine when it is medically necessary** to provide a treatment regimen.

Due to public health and patient safety concerns, only inmates that are known to be in custody for the entire duration of the treatment regimen will be provided with treatment. On average, 250 patients (including the in-state and out-of-state populations) with hepatitis C are in DOC custody per month. Of those, 24.8% (62 patients) will be in DOC custody long enough to receive a full HCV treatment regimen.

From: Watts, Benjamin
Sent: Wednesday, July 18, 2018 2:05 PM
To: Menard, Lisa <Lisa.Menard@vermont.gov>; D'Agostino, Matt <Matt.DAgostino@vermont.gov>
Cc: Watts, Benjamin <Benjamin.Watts@vermont.gov>; Rose, Jacqueline <Jacqueline.Rose@vermont.gov>
Subject:

Ben Watts, MBA
Health Services Administrator
Vermont Department of Corrections
NOB 2 South
280 State Drive
Waterbury, VT 05671 – 2000
802-503-2082 Cell
Benjamin.Watts@vermont.gov

Exhibit 10

State of Vermont
Agency of Human Services
Office of the Secretary
280 State Drive
Waterbury, VT 05671
www.humanservices.vermont.gov

[phone] 802-241-0440
[fax] 802-241-0450

Al Gobeille, *Secretary*
Martha Maksym, *Deputy Secretary*

October 23, 2018

To the Honorable members of the Joint Legislative Justice Oversight Committee,

Thank you for the opportunity to share an overview and update on the treatment of Vermont inmates who have Hepatitis C (HCV). This is an important topic and the attention from the committee on this issue has been valuable to our work. The Agency of Human Services (AHS), through our Department of Corrections (DOC), has an obligation to ensure that inmates receive health care that is consistent with "prevailing medical standards." 28 V.S.A. § 801. It is through this understanding that we have been working to implement treatment for inmates with HCV that includes direct acting antiviral (DAA) treatment (i.e., "cure" medications).[1]

Changes in Medicaid Standard of Treatment

On December 4, 2017, DVHA sent an update to Medicaid providers that required "cure" medications to be considered regardless of F score.[2] Previously, only patients with a score of F2, F3, or F4 were considered candidates for "cure" treatment medications. While this was a change regarding when to consider use of "cure" medications, it was DOC's existing standard that all patients with chronic HCV be seen in Chronic Disease Clinic for ongoing medical monitoring and the development of a treatment plan.

DOC Processes for Determining HCV Treatment

Screening for HCV begins at intake, with confirmation of new diagnoses within seven days. Patients with HCV are seen by a medical provider within 14 days of admission unless extenuating circumstances exist. 28 V.S.A. § 801. Inmates newly-diagnosed with HCV are monitored for six months to see if they spontaneously "clear" the virus – this is the prevailing medical standard in the community. Patients with a known diagnosis of HCV are enrolled in the Chronic Disease Clinic and are seen every 3-6 months to monitor their condition. Medical providers, in consultation with UVM Medical Center Infectious Disease, review laboratory and other diagnostic information to determine when it is medically necessary to provide a treatment regimen that is in the best interest of the health of the patient. This determination is done regardless of F score, consistent with Vermont Medicaid's guidelines.

Of the total DOC patient population of 1,518 on 10/18/18, 153 or 10.1% came into custody with a known diagnosis of HCV.[3] For those whose status is not known, HCV screening and confirmatory testing is conducted. Since the beginning of 2018, 385 HCV tests have been completed, which have resulted in the diagnosis of 35 new HCV cases. On average, 250

[1] DAAs lead to a cure for HCV when the medications are taken as prescribed as measured by follow-up labs and "sustained viral response."
[2] F Score is a measure of fibrosis in the liver, as measured by a fibrosis ultrasound. F scores are integers and range from 0-4. 0 indicates no fibrosis and 4 indicates the presence of cirrhosis.
[3] There have been some problems with the "current incarceration date" interface between the Offender Management System and the Electronic Health Record which may impact the accuracy of this information. Also, patients that self-report (either accurately or inaccurately) an HCV diagnosis upon intake may not always know when they were diagnosed and might not have records for verification purposes. In these cases, the HCV diagnosis may be entered as the date that the patient came into DOC custody.

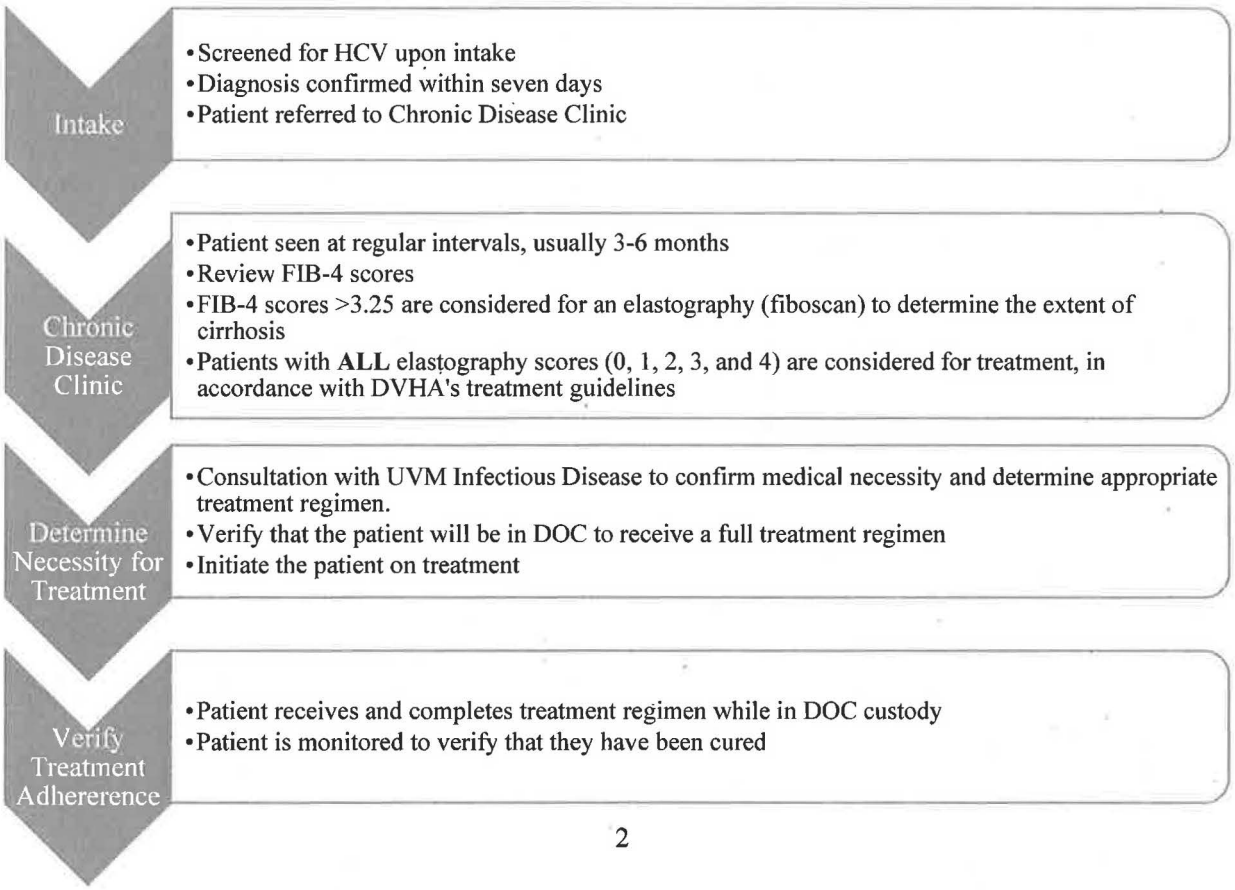
patients (including in-state and out-of-state populations) with HCV are in DOC custody per month. Of those, 24.8% (approx. 62 patients) will be in DOC custody long enough to receive a full HCV treatment regimen. Consistent with best practice, DOC continues patients on their HCV medications if they were on the medications upon intake.

In 2017, prior to the updated Medicaid Standard of Treatment, one patient was diagnosed and treated for HCV with direct acting antivirals which, when taken as prescribed, cure most patients with HCV. Under the updated Standard of Treatment, the number being newly treated increased to 10 in 2018 (one patient refused treatment). The remaining patients on the HCV "watchlist" are being considered for DAA treatment but have not yet received it because their FIB-4 scores are less than 3.25 – values less than 3.25 generally predict that fibrosis is not present. About 12% of patients are refusing diagnostic testing and treatment interventions. We are actively working to maximize the number of patients who receive this treatment, provider they meet all necessary criteria.

Challenges Regarding Length of Stay and Criteria for Successful Completion of Treatment

While we estimate that there are approximately 62 patients that have HCV and will be in DOC custody long enough to receive a course of treatment, they might not be always the same people over time. Further, even if those patients would be in long enough to receive the course of treatment, they may not meet the criteria for DAA treatment according to treatment guidelines. If a patient is expected to be in DOC custody for the length of time that treatment would require, that is not the only factor in determining a course of treatment. Disease progression, labs, imaging studies, other diagnostics, and case-by-case review by medical providers and infectious disease specialists are the cornerstones of "medical necessity" determinations in the DOC and the community.

In DOC, HCV treatment is not provided upon request. Nor is it provided upon request for any person seeking treatment outside of Corrections. The DOC's practice is the same as the community's practice in that patients with HCV are medically monitored to determine when it is appropriate to start the patient on one of the HCV "cure" medications.



It has been argued that DOC should treat patients in custody regardless of anticipated length of stay. To do so would not align with the treatment standard for people who are not in DOC custody. Medical providers strongly emphasize that patients be in a stable place in their lives where they will be able to comply with the full treatment regimen. There are risks to individual patients as well as to public health when treatment is not adhered to. For example, new strains of HCV for which there are no effective DAAs could develop and spread to the population.

Additional $2M Investment

While we are treating patients with "cure" medications once they are determined medically necessary for the course of treatment, the additional $2M requested at the September Joint Fiscal Committee from available funds in the FY2019 budget[4], is meant to address a trend that we are seeing in the number of patients that are being treated at any given time, as well as to allow us to maximize treatment under the relatively new Medicaid Standard of Care. As the number of patients being treated increases, we can expect increased costs. The $2M will help us address the need and goal to provide treatment to more patients over time.

The anticipated number of patients that are in DOC custody long enough to receive a full course of treatment of DAA is about 60 patients. Even with this additional investment in funds, there are still limiting factors since each is at a different stage within the overall treatment process and some may not meet the criteria that would result in treatment. This has nothing to do with funding availability. The standard is the same as in the community – not everyone diagnosed will be treated during a specific period of time because the medical standard takes into account much more than just the diagnosis and ability to complete the treatment regimen.

DOC has done a tremendous job wrapping their arms around this topic and making the connections needed in the medical community to support their implementation. We remain committed to treating inmates with HCV in accordance with standards that align with those in the community.

Sincerely,

Al Gobeille
Secretary, Agency of Human Services

[4] Secs. C.106.2 and C.1000(a)(14) of Act 11 of the Special Session.

Exhibit 11

Clouser, Kristin

From: Gobeille, Al
Sent: Friday, September 28, 2018 5:10 AM
To: Menard, Lisa; Touchette, Mike; Clark, Sarah; Clouser, Kristin; Morgan, Candace; Maksym, Martha; Hurlburt, Laurie
Cc: Watts, Benjamin; D'Agostino, Matt
Subject: Centurion

Lisa/Mike,

Thank you for your efforts to communicate the status of our Healthcare contract. I have some feedback and a few requests.

1. I never received the HepC population data I requested. Please have this to me by Monday morning. If you have questions please have your team reach out.

2. In the letter I wrote to JFC I cited a roughly $455,000 number. Can Matt please provide the spreadsheets that show this math? I want to have this justification in my records.

3. How are we currently paying for HepC treatment? What is the language in the contract that covers the covered services portion of the contract? Has it been amended to reflect the relevant fibrosis score update? Has the PMPM been adjusted to reflect this change?

4. We secured $200,000 in HepC money and have a plan to secure $1.8 million at BAA. I want to personally understand, and I want to personally decide how we spend this money. We must have a plan, be able to articulate exactly how this works and be able to reconcile at the end.

5. I want to meet with this team early next week to review the HepC data, review options for payment, decide our course and communicate this process to the outside world.

I have time today to answer any questions any of you might have.

Al Gobeille
Secretary, Agency of Human Services
Al.Gobeille@vermont.gov
(802) 585-4030

Exhibit 12

VERMONT

State of Vermont
Department of Corrections
NOB 2 South, 280 State Drive
Waterbury, VT 05671-2000
www.doc.vermont.gov

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[phone] 802-241-0000
[fax] 802-241-0020

Agency of Human Services

Mike Fisher, Chief Health Care Advocate
Office of the Health Care Advocate
264 North Winooski Avenue
Burlington, Vermont 05401

April 22, 2019

DELIVERED ELECTRONICALLY

Dear Mr. Fisher:

In response to your March 27, 2019 letter, I am providing you with some additional information concerning the HCV screening and treatment of patients within the Department's custody. I hope this information answers your questions satisfactorily and helps illustrate the DOC's commitment to making curative HCV treatment available to all Vermont inmates for whom it is medically indicated and appropriate. Also, to assist us to achieve that goal, it would be helpful if you could provide us with more information about the people you spoke of in your February 21, 2019 letter that are "in custody of DOC [and] actively trying to get treatment and being denied."

Your first question asks for the time from enrollment in the chronic disease clinic to the initiation of treatment (#1.c) and the time from the determination of a FIB-4 score to the initiation of treatment (#1.d). As we previously stated, a patient testing positive for HCV will begin an individualized treatment plan that depends on various factors, including: (1) the results of the patient's labs and testing, which in turn can necessitate additional labs and testing; (2) the time spent waiting for lab and test results; (3) the availability of appointments with outside clinicians,[1] which may be complicated by security requirements and concerns unique to the incarcerated population, and (4) the individual patient's health status and comorbidities. Moreover, since

[1] Various factors influence how quickly a patient will be seen for a procedure or by a specialist, including the availability of clinicians in any given specialty, a particular provider's work schedule, facility availability and scheduling practices, and the current demand for the required service(s). These delays, and the factors underlying hospital wait times, have been in the media for the last several years. *See, e.g*. D'Ambrosia, D., *Patients struggle with long wait times at UVM Medical Center*, Burlington Free Press (Jan. 13, 2017); WCAX, *Waiting Pains: Why it can take months to see a specialist at UVM* (April 17, 2019).

treatment commences upon a positive HCV screen, the responses to your questions, as posed, would not be indicative (and likely misleading) when determining if the care provided by the DOC is timely or medically appropriate. Review of the details of each patient's course of treatment would be most informative to assess the timeliness and appropriateness of care; however, confidentiality issues—the records contain personal health information—as well as the use of significant staff time prevent disclosure of the detailed information.

You next request a timeline for DAA initiation. As outlined above, there is no one-size-fits-all timeline, and the length of time that elapses prior to the commencement of DAAs will vary. Patients who are expected to be in custody long enough to receive a full course of DAAs and those with F2 scores or greater, regardless of length of stay, are prescribed DAAs as soon as all necessary diagnostics are completed.

In response to your next question, the DOC does not use a "brand name" product for screening; it draws blood at the facility, which it sends to an external lab for processing. If it is determined to be positive for HCV, further testing performed by the DOC typically involves additional blood draws (no brand name) which are sent offsite for processing, or the patient is scheduled for a FibroScan, which I understand is a registered trade name for the non-invasive diagnostic procedure.

As of the date provided, there were 311 patients with HCV in the chronic disease clinic, about whom we provided generalized information. It would take a significant amount of staff time to produce the detailed information you requested; in addition, it would contain potentially identifiable PHI that we are precluded from disclosing. In response to #4.f., however, there is no material distinction between placing an inmate in the chronic disease clinic and in pre-treatment; once diagnosed with HCV, the patient is assigned to the clinic and scheduled for testing and follow-up visits.

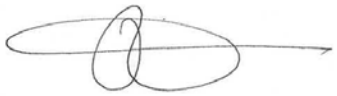
Fourteen patients completed DAA treatment in 2018. Eleven patients that began DAA treatment in 2018 continued treatment into 2019.

Since at least February 2015, opt-out HCV screening has been offered to all inmates upon intake, and all inmates admitted to DOC custody since that time would have been screened with the exception of those that opted-out. Inmates who refuse screening are again offered testing at their annual health assessments, but they may request screening sooner if they so choose or if they have engaged in behavior that puts them at risk of contracting HCV.

Last, we recently met with CoreCivic's Medical Director and the facilities Health Services Administrator to ensure that the out-of-state inmates with HCV will be scheduled for timely and appropriate treatment. At this time, there are 16 inmates (one was transferred back to Vermont) with HCV; all are in chronic disease clinic with the goal of initiating DAAs, and the current timeline anticipates that all will have completed their full course of treatment within twelve to fourteen months. We will continue to monitor these patients, and we expect to see the movement of patients from pre-treatment to DAAs in the facility's weekly medical reports.

Feel free to contact me if you have further questions. We would be happy to set up a phone conference or in-person meeting with you in the near future.

Sincerely,



Benjamin Watts
Health Service Director, Department of Corrections

cc: Michael Touchette, DOC Commissioner
Judy Henkin, DOC Deputy Commissioner
Martha Maksym, AHS Deputy Secretary
Ena Backus, AHS Director of Health Care Reform
Julia Shaw, Health Care Policy Analyst

Exhibit 13

VERMONT

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Department of Corrections
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Agency of Human Services

Mike Fisher, Chief Health Care Advocate
Office of the Health Care Advocate
264 North Winooski Avenue
Burlington, Vermont 05401

March 8, 2019

DELIVERED ELECTRONICALLY

Dear Mr. Fisher:

I appreciate the opportunity to highlight the significant progress made by the Department (DOC) to provide timely, physician-driven HCV treatment to patients according to best practices and prevailing medical standards. The HCA's understanding of the DOC's criteria for providing HCV treatment—as included in your February 21, 2018 letter and reviewed with our medical consultants—appears generally correct. We would add that our practice is informed by consultation received from UVMMC's Infectious Disease Department.

We have gathered the information you requested regarding HCV treatment which has been updated to February 26, 2019 and is contained in the following tables and narrative. Although not all of the questions you asked generated a response for each distinct patient, it is important to recognize that a patient's course of care is individualized and subject to factors that include 1) the inmate's comorbidities and health status; 2) outside providers' (including UVM Medical Center and Dartmouth Hitchcock Medical Center) wait times for scheduling, appointments and test results; 3) time periods pending receipt of lab results; and 4) the need for additional testing or other follow-up, based on previous labs and testing. As a result of these variables, responses to your questions about timing of treatment, as posed, would not be reflective of the timeliness, quality, or appropriateness of care provided by the DOC.

In response to your first question, there were 39 patients on DAAs with FIB-4 scores ranging from .25 to 3.71; 35 of the 39 had FIB-4 scores less than 1.45. Because FibroScans are generally not necessary for patients with FIB-4 scores of less than 1.45, only seven of those patients have F-scores, which range from F0 to F3.

Patient	FIB-4 Score	F Score	Min Release Date
1	.55		1/14/2021
2	.63		8/3/2020
3	3.71	F0-F1	
4	1.20		3/5/2020
5	.99		1/31/2020
6	1.43	F3	11/27/2015
7	1.41		5/2/2020
8	.85		8/10/2019
9	.95		9/9/2023
10	.93		2023
11	.79		7/23/2020
12	1.26		5/16/2021
13	.92		3/9/2021
14	.73		2/20/2021
15	1.51	F2-F3	Detainee
16	.49		2/6/2020
17	.73		2/19/2020
18	.99		4/28/2022
19	.92		8/1/2019
20	.93		5/16/2020
21	1.17		9/1/2019
22	.81		2/27/2020
23	.60		2/12/2020
24	.80		3/23/2022
25	.62		10/4/2027
26	.69		4/14/2020
27	1.75	F0-F1	8/2/2019
28	1.01		1/26/2021
29	.45		9/22/2021
30	.87		12/12/2019
31	1.14		9/16/2020
32	.47		7/1/2027
33	.40	F0-F1	9/21/2020
34	.45		10/26/2019
35	.39		2/14/2020
36	.25	F3	3/1/2020
37	.57		7/5/2021
38	3.33	F2	
39	.66		3/13/2020

Regarding your second question, there were 29 patients in the pre-treatment phase with FIB-4 scores ranging from .30 to 6.84. Again, because only patients with FIB-4 scores less than 1.45 require FibroScans, only two of the 29 have F-scores.

Patient	FIB-4 Score	F Score	Genotype	Min Release Date
1	5.40	F4	1a	6/26/2019
2	2.09		1a	1/1/2023
3	.74			Detainee
4	6.84		3	
5	2.08	F4	3	4/17/2017
6	2.02			Detainee
7	2.71			3/21/2021
8	.49			Detainee
9	1.82		3	
10	1.04		3	11/25/2019
11	1.66			Detainee
12	.30			Detainee
13	.98		1	12/1/2020
14	.64		1a	4/21/2020
15	1.05		1a	3/19/2020
16	1.67		3	3/21/2020
17	.60			Detainee
18	.53		6	1/7/2021
19	.77		1a	4/15/2020
20	.73			7/21/2020
21	.58		1a/2	3/2/2020
22	1.64		1a	Detainee
23	.61		1a	3/12/2020
24	1.07		1a	2/19/2020
25	1.44		1a	Detainee
26	1.11		1	9/13/2020
27	.81		1a	1/9/2022
28	.52		3	4/20/2035
29	1.10		1a	6/23/2019

Next, when medically indicated, FibroScans and ultrasounds are performed at either UVM Medical Center or Dartmouth Hitchcock Medical Center. Routine labs are generally drawn at DOC facilities by qualified healthcare professionals and are primarily sent off-site to BioReference for processing, with the results sent to the medical provider. More complicated labs may be sent to an area hospital for testing.

In response to your fourth question, as of February 26, 2019, there were 311 HCV patients in the chronic disease clinic, including those listed in the two tables above. The inmates not in pre-treatment or receiving DAA therapy are largely detainees who may be released at any time by action of the court, meeting their conditions of release, or by posting bail; and sentenced inmates who 1) have minimum release dates that occur before they would be able to complete a full course of treatment; 2) will serve their maximum sentences prior to completing treatment; or 3)

have exceeded their maximum sentences, but have not been released (i.e. inmates who have not secured approved housing, with sanctions up to 90-days, that require additional case planning efforts or programming, or have had their terms extended for public safety). Please note that we are reviewing this group of inmates on an ongoing basis and updating the list as we receive new information (for example, when an inmate is sentenced) to ensure that all eligible inmates who require and consent to treatment will receive it in a timely manner and in strict adherence to prevailing medical standards. We are also close to completing our HCV policy and will forward your office a copy once it is finalized.

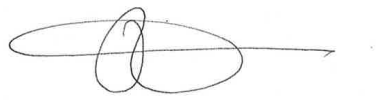
In response to your fifth question, 14 patients completed DAA treatment in 2018, while eleven that began their treatment in 2018 continued treatment into 2019. Thirty-three patients have initiated DAA treatment in 2019.

To address your next question, the DOC began offering HCV tests to all inmates upon intake several years ago and has now tested all sentenced inmates except for those who have chosen to opt-out of testing. In addition, as part of inmates' periodic health assessments, they are offered the opportunity to be tested if they have previously refused.

Finally, you requested information concerning HCV treatment for inmates housed out-of-state. We agree that out-of-state inmates testing positive for HCV should receive the same level of care, consistent with prevailing medical standards and DOC policy, as patients housed in Vermont facilities. DOC staff will be visiting the Mississippi facility next week and will have the opportunity to speak with inmates, tour the facility, and meet with CoreCivic staff. We will be better able to respond to your inquiry once we have gathered additional information and can provide a response in the next two weeks.

I hope the information provided has been helpful. Feel free to contact me if you have further questions.

Sincerely,



Benjamin Watts
Health Service Director, Department of Corrections

cc: Michael Touchette, DOC Commissioner
Judy Henkin, DOC Deputy Commissioner
Martha Maksym, AHS Deputy Secretary
Ena Backus, AHS Director of Health Care Reform

Exhibit 14

From: Hogue, Nancy
Sent: Wednesday, April 18, 2018 2:35 PM
To: Strenio, Scott
Subject: RE: VT Hep C Taskforce

I had to leave the meeting early. Was this discussed and what was the feedback? Not clear from the slides what they actually are treating at this time?

From: Strenio, Scott
Sent: Friday, April 13, 2018 11:22 AM
To: Hogue, Nancy <Nancy.Hogue@vermont.gov>
Subject: FW: VT Hep C Taskforce

What do you think about this?
My hope was that we all were aligned across the State but if DOC isn't going to treat everyone we do we will get stuck

---

From: Nguyen, Song
Sent: Friday, April 13, 2018 10:34 AM
To: mike@pridecentervt.org; lbiczak@ghsinc.com; Butler, Sharon <SButler@CenturionVT.com>; maryc@vtcares.org; dacemp@yahoo.com; prevent@sover.net; tom@vcjr.org; Daltry, Daniel <Daniel.Daltry@vermont.gov>; Finley, Christine <Christine.Finley@vermont.gov>; Fisher, Steven <sfisher@centurionvt.com>; Folland, Anthony <Anthony.Folland@vermont.gov>; kim@ru12.org; Fritch, William <William.Fritch@vermont.gov>; patricia.b.gocklin@hitchcock.org; Dean.Haggerty@Cigna.com; Andrew.Hale@uvmhealth.org; jnheins9@gmail.com; kathy@vtcares.org; ELIZABETH.HOFFMAN@Cigna.com; Hogue, Nancy <Nancy.Hogue@vermont.gov>; peter@vtcares.org; gracek@howardcenter.org; ckletecka@comcast.net; nels@pathwaysvermont.org; Ryan@h2rc.org; steven.lidofsky@uvm.edu; Livingston, Shayla <Shayla.Livingston@vermont.gov>; Moore de Ortiz, Colleen <Colleen.MooredeOrtiz@vermont.gov>; vtpwacadvocate@gmail.com; O'Reilly, Kathleen <Kathleen.OReilly@vermont.gov>; Zpora.Perry@uvmhealth.org; plavinj@bcbsvt.com; RRawson@mednet.ucla.edu; Mary.Ann.Ray@uvmhealth.org; paulwreddeniv@hotmail.com; jshaw@vtlegalaid.org; Strenio, Scott <Scott.Strenio@vermont.gov>; vtpwac@sover.net; THERESA@VTCARES.ORG; Watts, Benjamin <Benjamin.Watts@vermont.gov>; Dudley, Pattie <pdudley@centurionvt.com>; jessica.kirby@mymail.champlain.edu
Cc: Butler, Sharon <sbutler@mhm-services.com>; Biczak, Laureen <LBiczak@changehealthcare.com>
Subject: RE: VT Hep C Taskforce

I'm including a PPT that will be discussed by DOC and Centurion.

Thank you,
Song

-----Original Appointment-----
From: Nguyen, Song
Sent: Thursday, February 22, 2018 10:23 AM
To: Nguyen, Song; mike@pridecentervt.org; lbiczak@ghsinc.com; SButler@CenturionVT.com;

maryc@vtcares.org; dacemp@yahoo.com; prevent@sover.net; tom@vcjr.org; Daltry, Daniel; Finley, Christine; sfisher@centurionvt.com; Folland, Anthony; kim@ru12.org; Fritch, William; patricia.b.gocklin@hitchcock.org; Dean.Haggerty@Cigna.com; Andrew.Hale@uvmhealth.org; jnheins9@gmail.com; kathy@vtcares.org; ELIZABETH.HOFFMAN@Cigna.com; Nancy (Nancy.Hogue@vermont.gov); peter@vtcares.org; gracek@howardcenter.org; ckletecka@comcast.net; nels@pathwaysvermont.org; Ryan@h2rc.org; steven.lidofsky@uvm.edu; Livingston, Shayla; Moore de Ortiz, Colleen; vtpwacadvocate@gmail.com; O'Reilly, Kathleen; Zpora.Perry@uvmhealth.org; plavinj@bcbsvt.com; RRawson@mednet.ucla.edu; Mary.Ann.Ray@uvmhealth.org; paulwreddeniv@hotmail.com; jshaw@vtlegalaid.org; Strenio, Scott; vtpwac@sover.net; THERESA@VTCARES.ORG; Watts, Benjamin; pdudley@centurionvt.com; jessica.kirby@mymail.champlain.edu
Cc: Butler, Sharon; Biczak, Laureen
Subject: VT Hep C Taskforce
When: Friday, April 13, 2018 10:30 AM-11:30 AM (UTC-05:00) Eastern Time (US & Canada).
Where: 1.877.273.4202; 4503704

Hello Hep C Taskforce,

Please find the agenda for Friday's call, attached. We'll also be learning more about HCV in our correctional facilities from Ben Watts (DOC) and Dr. Steven Fisher (Centurion). I look forward to connecting with everyone soon.

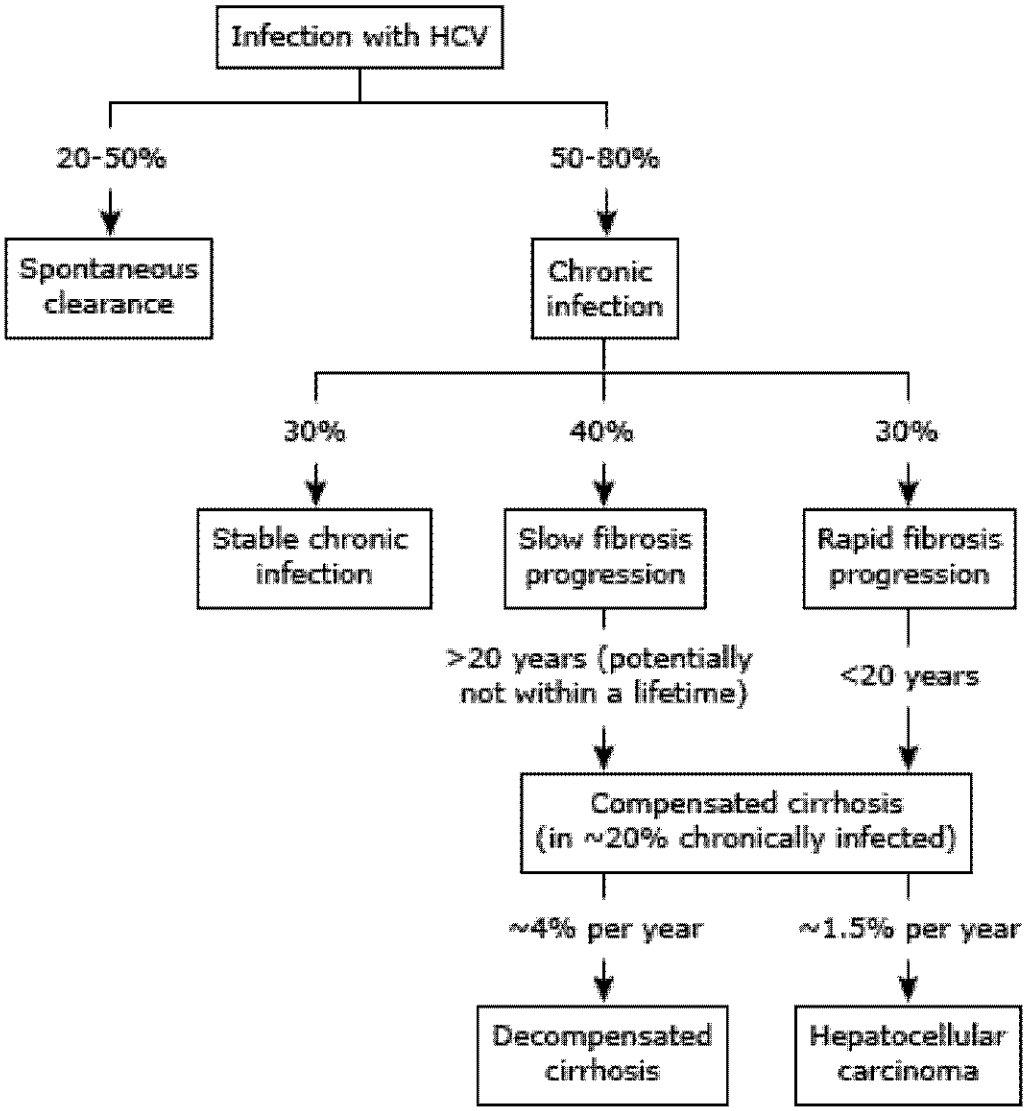
Best,
Song

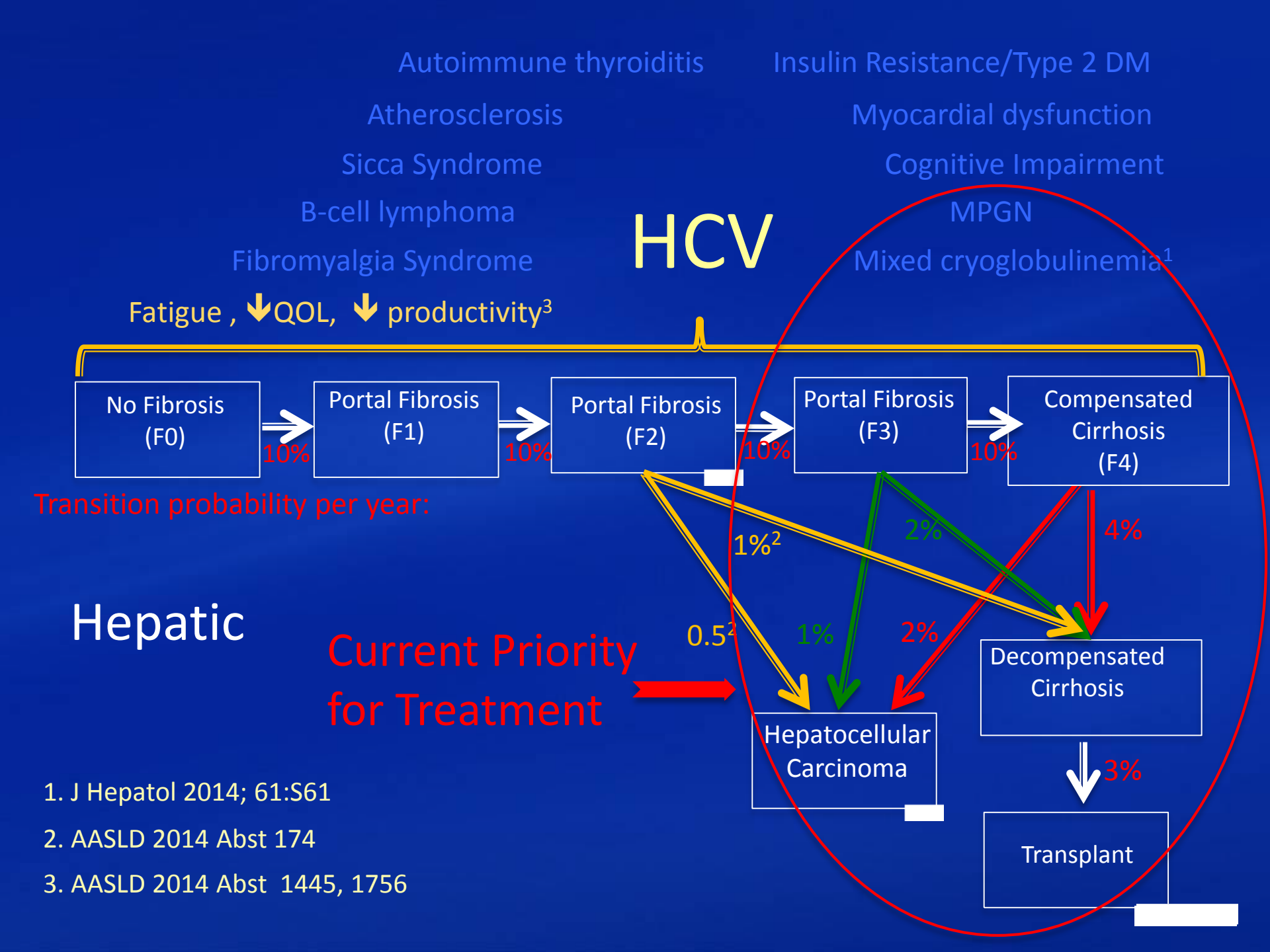
Song Nguyen, MPH

PGPs: She, Her, Hers
Viral Hepatitis Specialist
Division of Health Surveillance
Vermont Department of Health
108 Cherry Street
Burlington, VT. 05402
(P) 802.951.4065 | (F) 802.863.7314
Song.Nguyen@vermont.gov

VERMONT
DEPARTMENT OF HEALTH

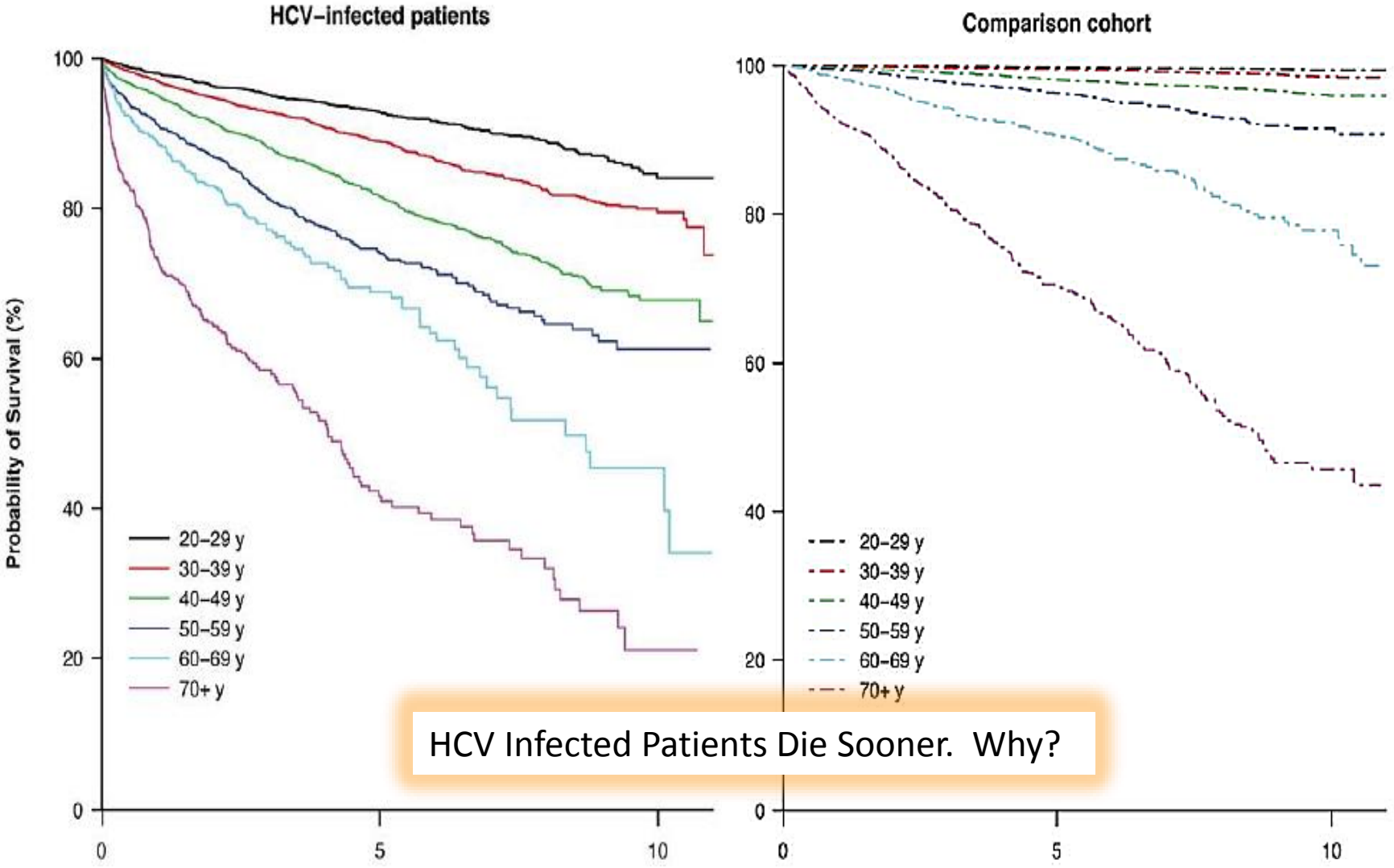
Natural history of hepatitis C virus





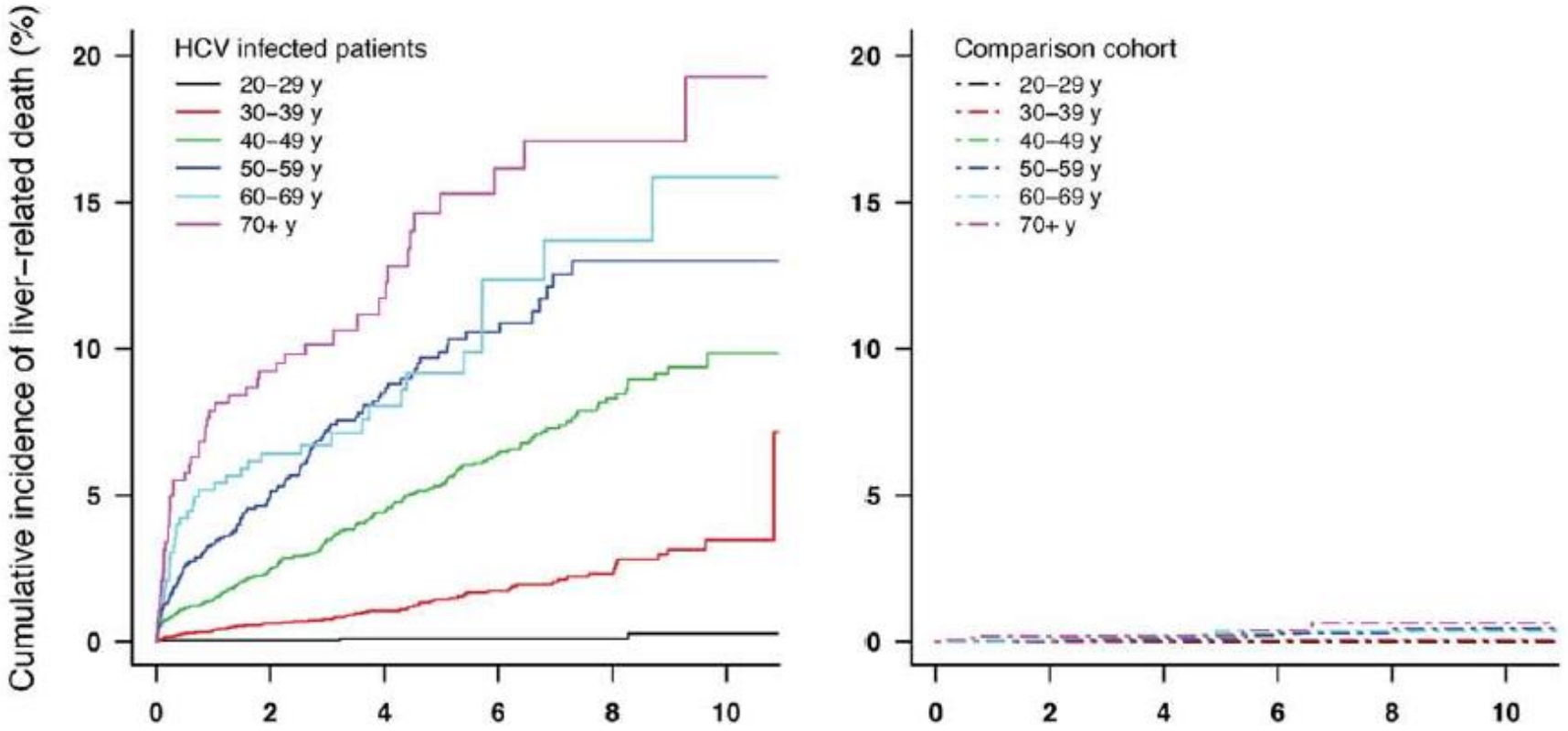
1. J Hepatol 2014; 61:S61
2. AASLD 2014 Abst 174
3. AASLD 2014 Abst 1445, 1756

Survival of HCV-Infected Persons vs. Gen Population; Denmark 1992-2006 (Omland, et al; Clin Gastroenterol Hepatol 2011; 9[1]:71)

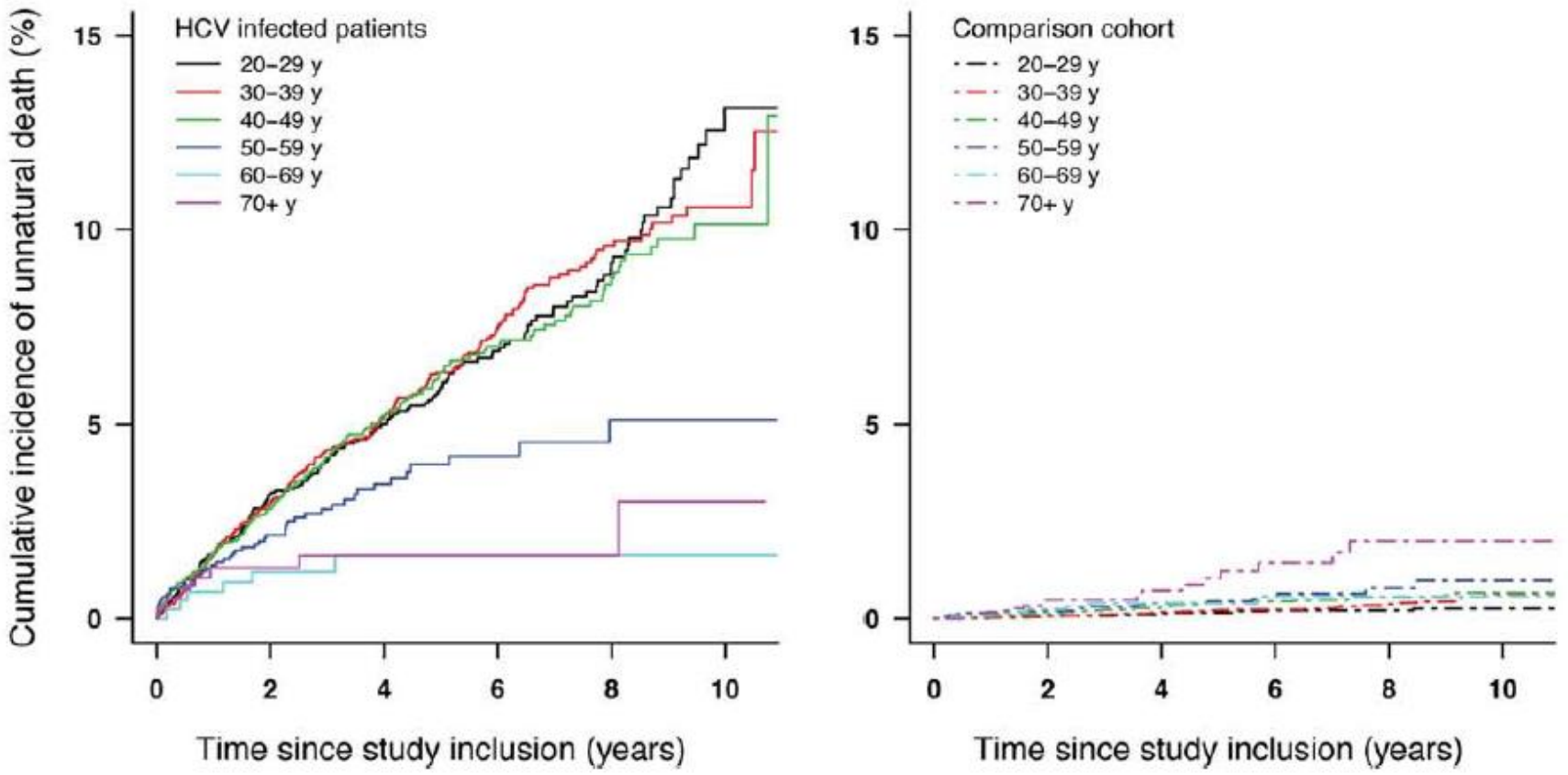


HCV Infected Patients Die Sooner. Why?

Cumulative Incidence of Liver-Related Death by Age
Denmark 1992-2006
(Omland, et al; Clin Gastroenterol Hepatol 2011; 9[1]:71)



Cumulative Incidence of Unnatural Death by Age; Denmark 1992-2006 (Omland, et al; Clin Gastroenterol Hepatol 2011; 9[1]:71)



Survival of HCV-Infected Persons vs. Gen Population Denmark 1992-2006 (Omland, et al; Clin Gastroenterol Hepatol 2011; 9[1]:71)

- Age 20-39: main cause of death was unnatural death ("..death owing to mental and behavioral disorders related to psychoactive substance abuse and death resulting from external causes."), not liver related death.
- Therefore, in younger patients, if they were to be treated to SVR, the associated decreased mortality most likely not attributable to SVR, but to lifestyle changes (mental health Rx, sobriety; leading to decreased suicide, domestic violence or SA-associated accidental death, homicide, etc.)

Excess Patient Deaths As Compared to National Death Rates In Patients with SVR; Scotland 1996-2011 (J Hep 2017, 66:19-27)

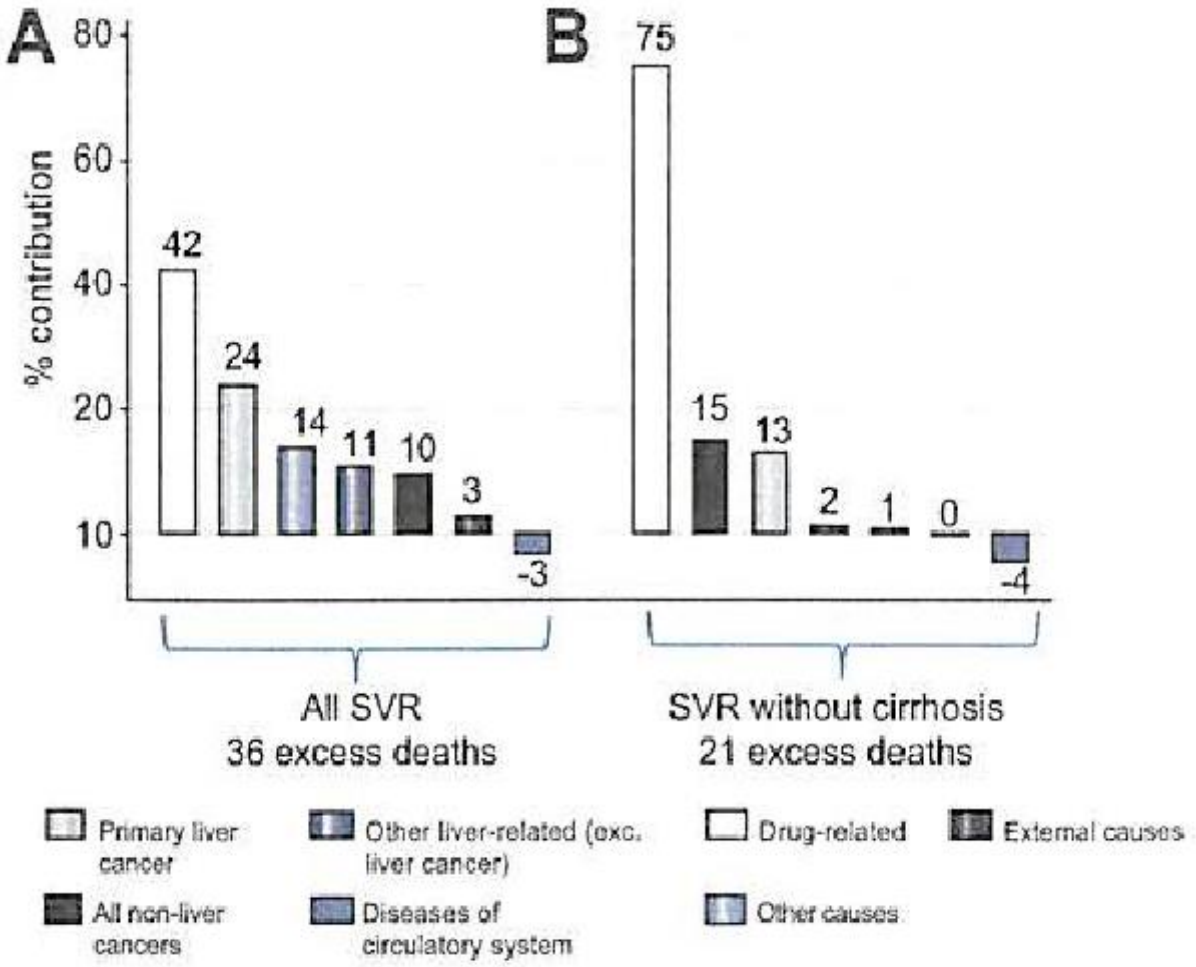


Fig. 2. Absolute contribution (%) to the overall excess for each cause of death. For (A) all SVR patients, and (B) SVR patients without cirrhosis at baseline.

Goals of chronic HCV Treatment:

"…identify and prioritize treatment to the patients who need it soonest and will benefit the most"

- **"While not all patients require immediate treatment, an optimal strategy should treat patients before they progress too far towards end-stage disease; beyond the point when even highly effective treatments can confer only diminished benefit."**

- Editorial "Optimizing HCV treatment – Moving beyond the cost conundrum"
- Journal of Hepatology 2016; 65:222-225
- Authors: DS Fox, JS McCombs (USC, Greater LA VAMC)

HCV Treatment Mis-Information

- Initially perpetuated by “big pharma” underwritten media campaigns
- 3 examples:
  - “*Complete Viral Eradication*”; sorry, just not possible with present agents, development of resistance, long Rx courses, financial toxicity.
  - “*No need for staging*”; unethical d/t high proportion of unrecognized cirrhosis/advanced hepatic fibrosis and need for cirrhosis care. Morphed into “*Treat everybody regardless of staging*”
  - “*Everybody has to be treated*”; still scientifically controversial on an individual basis but a laudable public health goal. Ongoing significant financial toxicities occuring. Still don’t know if treating non-progressors to SVR will reduce their mortality rate.
- Patients will receive unfiltered media and advocacy messages and tend to discredit correctionally “biased” information.

Why Do We Need A Year To Do Staging and Correctly Treat Patients?

- Many times its not really a year (creeping release times: pre-release leave, “good time”, etc.)
- Gives Time for Rx (Usually 12wks; rarely 24 wks)
- Allows Time for SVR assay post Rx (HCV-VL NEG @12wks)
  - Due to high fibrosis burden in Rx’ed patients, SVR info critical to program evaluation
- Allows Time for post RIBAVIRIN Rx Recovery (3-6 months)
- RIBAVIRIN tetratogenicity wash-out: 6m post Rx (alternative: 2 methods BC including one barrier method after release)
- Unable at present to manage a successful community transition on treatment: Too Many Variables.

Exhibit 15

State of Vermont
Department of Vermont Health Access
NOB 1 South, 280 State Drive
Waterbury, VT 05671-1010

Agency of Human Services
[Phone] 802-879-5900
[Fax] 802-241-0268

Important Changes to Coverage for Hepatitis C Agents

December 4, 2017

Dear Medicaid Provider,

Effective 1/1/18, the Department of Vermont Health Access (DVHA), in conjunction with Change Healthcare, is making changes to its clinical criteria for approval of direct acting antiviral agents used in the treatment of Hepatitis C. These agents include but are not limited to: Daklinza® (daclatasvir), Epclusa® (sofosbuvir/velpatasvir), Harvoni® (ledipasvir/sofosbuvir), Mavyret® (glecaprevir/pibrentasvir), Sovaldi® (sofosbuvir), Technivie® (ombitasvir, paritaprevir, ritonavir), Viekira XR® (ombitasvir, paritaprevir, ritonavir, dasabuvir), Vosevi® (sofosbuvir/velpatasvir/voxilaprevir), and Zepatier® (elbasvir/grazoprevir. These changes resulted from review of AASLD and IDSA guidelines, and DVHA's Drug Utilization Review Advisory Board recommendations.

Previously, there was a requirement that the member have a documented Metavir fibrosis score of F2, F3 or F4 to qualify for treatment with these drugs. Approval will now be considered in individuals with **ANY** Metavir fibrosis score, including F0 and F1. Direct Acting Antivirals will continue to require prior authorization to ensure the patient meets clinical criteria and that the most cost effective, clinically appropriate regimen is utilized. Preferred agents are Epclusa®, Mavyret®, and Zepatier®. Clinical documentation supporting the use of a non-preferred agent or regimen must be submitted with the prior authorization.

Due to the complexity and variety of treatment options and potential for drug interactions, the requirement that the prescriber is, or has consulted with, a gastroenterologist, hepatologist, ID specialist or other Hepatitis specialist will remain in place. Consult must be within the past year and include documentation regarding the requested regimen.

The changes described above are incorporated into the Prior Authorization form and DVHA's Preferred Drug List (PDL) available on the DVHA provider website http://dvha.vermont.gov/for-providers/. Please contact the Change Healthcare Provider Helpdesk at 1-844-679-5363 if you have any questions about these changes.

Thank you for your continued support of Vermont's clinical pharmacy programs.

Nancy J. Hogue, BS, Pharm.D.

Director of Pharmacy Services

Exhibit 16

From: Bizzari, MaryBeth
Sent: Thursday, February 20, 2014 9:51 AM
To: Hogue, Nancy
Subject: FW: HCV antiviral meeting
Attachments: HEP C Tx Cost.xlsx

FYI

From: Michael E. Rapaport [mailto:MRapaport@correctcaresolutions.com]
Sent: Thursday, February 20, 2014 9:50 AM
To: Strenio, Scott; Neal, Diane; Bizzari, MaryBeth; Simpatico, Tom
Subject: RE: HCV antiviral meeting

Thanks Scott. I've attached a spreadsheet with the cost of HCV treatment through Maxor, the company that provides corrections with medication.

-Bear in mind that we have about 240 inmates who are HCV positive. All costs come directly out of the State of Vermont tax revenues… treating everyone would bankrupt the state

Michael Rapaport, MD
Regional Medical Director for Vermont

Correct Care Solutions
87 South Main Street
Waterbury, VT 05676
Office: (802) 244-1911
Pager: (802) 749-2289
Cell: (802) 488-4082

From: Strenio, Scott [mailto:Scott.Strenio@state.vt.us]
Sent: Thursday, February 20, 2014 8:38 AM
To: Neal, Diane; Michael E. Rapaport; Bizzari, MaryBeth; Simpatico, Tom
Subject: FW: HCV antiviral meeting

For today's teleconference

J. Scott Strenio, M.D.
Assistant Professor, Department(s) of Family Medicine and Pediatrics
College of Medicine, University of Vermont

Medical Director, Department of Vermont Health Access
312 Hurricane Lane, Suite 201
Williston, Vermont 05495
(802)-871-3194

From: Kristen A. Ray [mailto:Kristen.A.Ray@hitchcock.org]
Sent: Thursday, February 20, 2014 8:25 AM
To: Strenio, Scott
Subject: HCV antiviral meeting

Dr. Strenio,

Dr. Dickson and I look forward to our telephone conference this afternoon with you. I am enclosing some slides for your review.

Thank you,

Kristen
Kristen A. Ray, APRN, MSN
Nurse Practitioner
Department of Gastroenterology and Hepatology
Kristen.A.Ray@hitchcock.org
dartmouth-hitchcock.org
phone: 603-650-5261 | fax: 603-653-9460

Exhibit 17

From: French, Aaron
Sent: Tuesday, March 18, 2014 6:36 PM
To: Hogue, Nancy
CC: Larson, Mark
Subject: Re: Sovaldi

It was my understanding that just in the correctional facilities we were looking at 200+, and Tom shared some numbers that Jennifer ran for him with those with a primary or secondary diagnosis of Hep C. As I explained to Mark that 200+ were just correctional, is this correct?

Respectfully,

Aaron

Douglas Aaron French, MSN, RN, BC
Deputy Commissioner Health Services & Managed Care
Department of Vermont Health Access

Sent from my iPad

On Mar 18, 2014, at 16:55, "Hogue, Nancy" <Nancy.Hogue@state.vt.us> wrote:

> Hi Mark,
> I wanted you to be aware that one of our DURB members, Amanda Kennedy, sent the letter below to our Congressional Delegation and DUR Board yesterday, in case you get any inquiries about it. I worked with Aaron and Scott on this, and she accepted some edits from me accordingly. The final language appears below. Sovaldi is a new very expensive oral therapy for patients with Hepatitis C, and costs $84,000 per one course of treatment per patient, a cost of $1000 per capsule. There are more new oral therapies on the horizon for Hep C and are all expected to be quite expensive. At this time, we do not know what the impact to DVHA's budget will be, as we don't know exactly how many Medicaid beneficiaries have Hep C and are candidates for this treatment. It is believed statewide there are 250 patients with Hep C, some of whom are incarcerated and some of whom are Medicaid eligible. We are doing further research to determine possible budgetary impacts.

Amanda G. Kennedy, PharmD, BCPS
Associate Professor of Medicine: http://ccts.uvm.edu/web/cts_education
Director, Research Coordinator Training Program: vbudget.com
S454, Given Courtyard, 89 Beaumont Avenue, Burlington, VT 05405
Phone: (802) 656-4560
Email: amanda.kennedy@uvm.edu

802-879-5611
Nancy.Hogue@state.vt.us

From: Kennedy, Amanda G [mailto:Amanda.Kennedy@med.uvm.edu]
Sent: Monday, March 17, 2014 11:38 AM
To: Hogue, Nancy
Subject: RE: Sovaldi

Hi Nancy,

Below is the final body of the text that I emailed to Welch, Sanders, and Leahy just now. FYI.

Thanks,
Amanda

I currently serve as a member of the Department of Vermont Health Access' Drug Utilization Review (DUR) Board. The purpose of the DUR Board is to create policy regarding access to medications for patients who are Vermont Medicaid beneficiaries. I have served on this Board since 2011. Federal law stipulates that, other than certain excluded classes of drugs, state Medicaid agencies must cover the drug of any manufacturer that has signed a rebate agreement with the Secretary of the Department of Health and Human Services. The State does not have the authority to refuse to cover a medication, unless it is one of the excluded classes such as weight loss drugs or drugs used for cosmetic purposes. As a result, many drugs require prior authorization utilizing clinical criteria to assure proper use. The strictest prior authorization policy the Board may impose is individual case review by the Medical Director.

The Centers for Disease Control estimates 3.2 million persons in the United States have chronic Hepatitis C virus. A new drug, Sovaldi, from Gilead Sciences was recently approved by the FDA for the treatment of Hepatitis C. This drug offers some important advantages over current treatments, such as shorter treatment duration, possibly fewer side effects, and possibly better rates of patients completing a full course of treatment. However, the pharmaceutical manufacturer has set the average wholesale price at $84,000 per course of treatment, that's $1000 per capsule. One 12-week course of treatment will far exceed the median annual income of Vermonters. In certain cases, some patients require two courses of therapy.

I am gravely concerned that we set a new precedent for unsustainable drug spending for Vermont Medicaid in approving Sovaldi after clinical review by the Medical Director. While the DUR Board has approved expensive treatments in the past, from my perspective none have been to the scale and potential scope of Sovaldi. I fear we are sending a message to all pharmaceutical manufacturers that Vermont will tolerate outrageous pricing.

The solution to the problem of unaffordable drug prices is not within the scope or ability of the DUR Board. I am writing to you to urge you to consider solutions at a state, regional or federal level. The DUR Board creates policies that balance costs with protecting the prescriber-patient relationship. I have no interest in denying drugs like Sovaldi to patients who need it. I also have no interest in slowing the pace of new drug development. However tolerating $84,000 per course drug pricing, especially given the

magnitude of people who are potential candidates for this drug, is unacceptable and unsustainable.

Thank you for your time.

Exhibit 18

From: Rapaport, Michael
Sent: Thursday, March 05, 2015 12:01 PM
To: Strenio, Scott; Simpatico, Tom
Subject: RE: greetings: i wanted to share with you a couple of indicators of HCV goings-on here in MA... VT applicable?

Wow. Sounds like your still a little peeved about the Steelers being sent home early, and Golden Boy Brady, hoisting another SB trophy!

–But I certainly agree with you on the drug rep issue. I think though, that having legislative/executive branch representation could help everyone better understand the economic impact of this disease, and help drive acceptance of more rigorous and unified standards for whom and when to treat. Having BCBSVT and other payers represented would also be reasonable –Not to mention ID/GI providers from UVMC and DHMC. I guess someone from Blue Print for Health should be included as well…

--I misspoke about Harry, I forgot that he was staying on at DPH after no longer being acting secretary of human services.

Might be worth discussing all this over another tasting of libations from Scotland.

Michael Rapaport, MD
Statewide Medical Director for Vermont
Centurion of Vermont, LLC
5430 Waterbury-Stowe Road
Bldg. 1, Ground Floor, Waterbury Center, VT 05677
Direct: (802) 244-1911| Internal: x4002
Pager: (802) 749-2289| Mobile: (802) 488-4082
Email: mrapaport@centurionvt.com | www.centurionmanagedcare.com

---

From: Strenio, Scott [mailto:Scott.Strenio@state.vt.us]
Sent: Thursday, March 05, 2015 9:52 AM
To: Rapaport, Michael; Simpatico, Tom
Subject: RE: greetings: i wanted to share with you a couple of indicators of HCV goings-on here in MA

Left wing propaganda no doubt, LOL

But really sobriety not a requirement?

Rationing medical care never done before? Really?

Highly unethical? To break the bank for this one disease state? Really?

Ramping up moral outrage? Nice touch

Looks to me the drug reps were running the meeting, there were more than just a few
Maybe Mass has lots more money but we clearly do not have the capacity to go down this road

As far as having a coalition – it should be without drug reps, or politicians and unless our specialists here were demanding a change from our current policy- which they do not seem to be-am not sure what the benefit of this would be; outside of what we would do if we had the funding we needed.
But I am open to talk to anyone, anytime, anywhere

Thoughts? (other than sending our members to Mass.)

From: Rapaport, Michael [mailto:mrapaport@CenturionVT.com]
Sent: Thursday, March 05, 2015 9:10 AM
To: Strenio, Scott; Simpatico, Tom
Subject: FW: greetings: i wanted to share with you a couple of indicators of HCV goings-on here in MA

Hi Guys, received this from my counterpart in Mass. Looks like they're being quite proactive with respect to Hep C treatment. –Made me think that we should form a similar more formal coalition here in Vermont. Interested? Is this something the VDH would want to take the lead on? Not sure who's taken over for there for Harry…

The MDPH planning meeting (web link below) looks like it will be very informative –I'm trying to find out if I can sit in.

-Michael

Michael Rapaport, MD
Statewide Medical Director for Vermont
Centurion of Vermont, LLC
5430 Waterbury-Stowe Road, Waterbury Center, VT 05677
Direct: (802) 244-1911| Internal: x4002
Pager: (802) 749-2289| Mobile: (802) 488-4082
Email: mrapaport@centurionvt.com | www.centurionmanagedcare.com

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From: Groblewski, Thomas
Sent: Wednesday, March 04, 2015 10:59 PM
To: Keller, Jeff; Dan Dewsnup (dhdewsnup@icloud.com); Turney, Asher; Fetter, Jeffrey; Rapaport, Michael; Craane, Stephen; Conway, William; Alexander, Jack
Subject: greetings: i wanted to share with you a couple of indicators of HCV goings-on here in MA

http://www.cvent.com/events/mdph-hepatitis-c-state-planning-meeting/agenda-f57a5404a52049c79de584a28b095ee5.aspx?i=c979bd8e-f2f5-48b0-b6e4-19f54117381d

Tom Groblewski, DO
Statewide Medical Director
Massachusetts Partnership for Correctional Healthcare
Tel: 508.285.4018 | Cell: 781.706.1052 | Fax: 800.747.3839
Email: tgroblewski@mpchcare.com

Exhibit 19

From: Hathaway, Carrie
Sent: Thursday, February 02, 2017 7:43 AM
To: Hogue, Nancy; French, Aaron
CC: Corey.gustafson@vermont.gov
Subject: RE: hep C

I am being asked by JFO to provide specifics around the Hep C budget increase. I started to type the response below (which is what we provide to HAC) but decided to compute this out first. We said the amount we would need is $3m annualized, but when I multiply the impact in the statement below, the range is $10.5 - $20m. What am I missing?

Here was our response to House Appropriations on this issue:

What are the details on behind the hepatitis C coverage increase (e.g., number of people to receive the service and cost of service)?: Approximately 70-100 patients will benefit from this change, and the cost per patient can vary between $150,000.00 to $200,000.00. Not all patients will seek treatment or due to other conditions may wait out progression of disease to determine if treatment is necessary.

-----Original Message-----
From: Clark, Sarah
Sent: Wednesday, February 01, 2017 2:38 PM
To: Barrett, Stephanie <sbarrett@leg.state.vt.us>; Gobeille, Al <Al.Gobeille@vermont.gov>; Corey.gustafson@vermont.gov; Menard, Lisa <Lisa.Menard@vermont.gov>
Cc: Hathaway, Carrie <Carrie.Hathaway@vermont.gov>; D'Agostino, Matt <Matt.DAgostino@vermont.gov>; O'Connell, Tracy E <Tracy.OConnell@vermont.gov>
Subject: RE: hep C

Stephanie,
Please see the response below related to the question for DOC. I believe that DVHA is working on their response.

Of the 199 diagnosed with hep C incarcerated at a DOC facility, there are 6 patients who would currently be receiving the treatment under the expanded level of care to include those at liver fibrosis stages between F2-F4.

DOC assumes a cost of $80,000 per 12-week treatment, at $952.38 per person, per day receiving treatment. DOC's health services team and the contractor have determined that at any given time, there would be an average of 6 people receiving the treatment, which would equate to $5,714.29 per day or $2,085,715.85 annually.

The estimate is that 26 people would be treated annually, or about 13% of the total.

Sarah Clark
Chief Financial Officer
Agency of Human Services
802-505-0285
sarah.clark@vermont.gov

PLEASE NOTE: EFFECTIVE 7/27/15 MY NEW EMAIL ADDRESS IS sarah.clark@vermont.gov

-----Original Message-----
From: Stephanie Barrett [mailto:SBARRETT@leg.state.vt.us]

Sent: Wednesday, February 01, 2017 2:15 PM
To: Gobeille, Al <Al.Gobeille@vermont.gov>; Corey.gustafson@vermont.gov; Menard, Lisa <Lisa.Menard@vermont.gov>
Cc: Clark, Sarah <Sarah.Clark@vermont.gov>; Hathaway, Carrie <Carrie.Hathaway@vermont.gov>; D'Agostino, Matt <Matt.DAgostino@vermont.gov>
Subject: hep C

Hi All,
There are still some outstanding questions from SAC on the Hep C change.
1- Can you send the analyst includes the caseload number, up front cost and rebate % estimated that results in the $3m annualized DVHA hep c change impact.
person.

2- what is the current caseload in corrections that maybe impacted by this change

Thank you

Stephanie

Sent from my iPad

Exhibit 20

Clouser, Kristin

From: Clark, Sarah
Sent: Wednesday, February 01, 2017 8:46 AM
To: Watts, Benjamin; D'Agostino, Matt
Cc: O'Connell, Tracy E; Gobeille, Al; Gustafson, Cory; Menard, Lisa; Hathaway, Carrie
Subject: RE: Hep C and DOC

Thanks Ben.

I'm looping Cory, Lisa and Al back in to the discussion as I want to respond to Senator Kitchel with the estimate of roughly $2 million per year in increased costs at DOC today.

Thanks,
Sarah

Sarah Clark
Chief Financial Officer
Agency of Human Services
802-505-0285
sarah.clark@vermont.gov

PLEASE NOTE: EFFECTIVE 7/27/15 MY NEW EMAIL ADDRESS IS sarah.clark@vermont.gov

From: Watts, Benjamin
Sent: Wednesday, February 01, 2017 8:37 AM
To: Clark, Sarah ; D'Agostino, Matt
Cc: O'Connell, Tracy E ; Watts, Benjamin
Subject: RE: Hep C and DOC

Hi Sarah,

I do not have evidence to indicate that the population would decrease over time.

In fact, there may be evidence that the population may actually increase over time. In general, the offender population is aging, and as patients age, more will likely meet criteria for the hep C "cure" drugs.

Thank you,

Ben

From: Clark, Sarah
Sent: Wednesday, February 01, 2017 6:46 AM
To: D'Agostino, Matt <Matt.DAgostino@vermont.gov>
Cc: O'Connell, Tracy E <Tracy.OConnell@vermont.gov>; Watts, Benjamin <Benjamin.Watts@vermont.gov>
Subject: RE: Hep C and DOC

Thanks Matt.

Ben,
From your perspective, is there anything additional to add?

Sarah Clark
Chief Financial Officer
Agency of Human Services
802-505-0285
sarah.clark@vermont.gov

PLEASE NOTE: EFFECTIVE 7/27/15 MY NEW EMAIL ADDRESS IS sarah.clark@vermont.gov

From: D'Agostino, Matt
Sent: Tuesday, January 31, 2017 8:34 PM
To: Clark, Sarah <Sarah.Clark@vermont.gov>
Cc: O'Connell, Tracy E <Tracy.OConnell@vermont.gov>; Watts, Benjamin <Benjamin.Watts@vermont.gov>
Subject: Re: Hep C and DOC

Sarah,

I don't know if there was an actuarial analysis of the anticipated population of those incarcerated over time, but will defer to Ben if he has a better understanding of the calculation with regard to expected cases to be treated.

I agree and suspect that there could be a reduction, particularly as those treated may recidivate. That said, with the heroin epidemic, it is also possible that a greater percentage of our clients will contract help C, so this figure, at least over the next several al years, may still be applicable.

Sorry I missed you earlier. Yes, Lisa and I were meeting with Rep. Hooper this afternoon.

Thanks,
Matt

Matt D'Agostino, Financial Director
Vermont Department of Corrections
802-241-0016

On Jan 31, 2017, at 7:31 PM, Clark, Sarah <Sarah.Clark@vermont.gov> wrote:

> Matt,
> Was there consideration given to the population declining over time? Specifically, do we foresee having 6 people receiving treatment at all times? Will this number decline? I tried to find you today to discuss but I think you may have been meeting with Rep Hooper.
>
> Thanks,
> Sarah
>
> Sarah Clark
> Chief Financial Officer
> Agency of Human Services
> 802-505-0285
> sarah.clark@vermont.gov
>
> ***PLEASE NOTE: EFFECTIVE 7/27/15 MY NEW EMAIL ADDRESS IS sarah.clark@vermont.gov***

From: D'Agostino, Matt
Sent: Monday, January 30, 2017 9:03 PM
To: Clark, Sarah <Sarah.Clark@vermont.gov>; Menard, Lisa <Lisa.Menard@vermont.gov>; Gustafson, Cory <Cory.Gustafson@vermont.gov>
Cc: Gobeille, Al <Al.Gobeille@vermont.gov>; Hathaway, Carrie <Carrie.Hathaway@vermont.gov>; O'Connell, Tracy E <Tracy.OConnell@vermont.gov>; Watts, Benjamin <Benjamin.Watts@vermont.gov>
Subject: RE: Hep C and DOC

Sarah,

Of the 199 diagnosed with hep C, there are 6 patients who would currently be receiving the treatment under the expanded level of care to include those at liver fibrosis stages between F2-F4.

We were previously calculating based on the $94,000 treatment cost for a 14 week course, which amounted to $959.18 per person, per day. If we are now assuming a cost of $80,000 per 12-week treatment, this breaks down to a very similar cost, at $952.38 per person, per day receiving treatment. Our health services team and the contractor have determined that at any given time, there would be an average of 6 people receiving the treatment, which would equate to $5,714.29 per day or $2,085,715.85 annually.

The estimate is that 26 people would be treated annually, or about 13% of the total. I am not aware of the specifics related to the 199 that have been diagnosed within the incarcerated population. My limited understanding is that approximately 15-20% of those with chronic infection will show signs of gradual damage in the liver over time. I am not sure if there were more specific factors used to determine how many would receive the treatment, but trust that this number was derived from a fairly thorough analysis of the current population.

Thanks,
Matt

Matt D'Agostino, Financial Director
Vermont Department of Corrections
802-241-0016

From: Clark, Sarah
Sent: Monday, January 30, 2017 7:02 PM
To: D'Agostino, Matt <Matt.DAgostino@vermont.gov>; Menard, Lisa <Lisa.Menard@vermont.gov>; Gustafson, Cory <Cory.Gustafson@vermont.gov>
Cc: Gobeille, Al <Al.Gobeille@vermont.gov>; Hathaway, Carrie <Carrie.Hathaway@vermont.gov>; O'Connell, Tracy E <Tracy.OConnell@vermont.gov>; Watts, Benjamin <Benjamin.Watts@vermont.gov>
Subject: RE: Hep C and DOC

I spoke with Senator Kitchel on this issue on the phone this afternoon. I told her that we were working to finalize the cost estimate but that I would be in touch tomorrow.

Matt and Ben,
Do you have a spreadsheet that you can share with me to validate these calculations? DVHA has some questions on this analysis. If it's helpful to talk, let's touch base in the morning.

Thanks,
Sarah

Sarah Clark
Chief Financial Officer
Agency of Human Services
802-505-0285
sarah.clark@vermont.gov

PLEASE NOTE: EFFECTIVE 7/27/15 MY NEW EMAIL ADDRESS IS sarah.clark@vermont.gov

From: D'Agostino, Matt
Sent: Monday, January 30, 2017 7:59 AM
To: Menard, Lisa <Lisa.Menard@vermont.gov>; Gustafson, Cory <Cory.Gustafson@vermont.gov>
Cc: Clark, Sarah <Sarah.Clark@vermont.gov>; Gobeille, Al <Al.Gobeille@vermont.gov>; Hathaway, Carrie <Carrie.Hathaway@vermont.gov>; O'Connell, Tracy E <Tracy.OConnell@vermont.gov>
Subject: RE: Hep C and DOC

That is correct. The 199 represents the entire Hep C population. The Health Services team looked at the number who are between F2-F4, and determined that there would be an average of 6 inmates simultaneously receiving the treatment under the expanded level of care.

With regard to the additional $2+ million that this will cost, this is not something that has been budgeted by DOC for FY17 or FY18. The contracted inmate health services provider has been working with UVM in an effort to reduce overall costs for the treatments. That said, this is not budgeted in the health services contract, and will result in increased costs once these treatments are being provided to more patients.

Matt D'Agostino, Financial Director
Vermont Department of Corrections
802-241-0016

From: Menard, Lisa
Sent: Monday, January 30, 2017 7:54 AM
To: Gustafson, Cory <Cory.Gustafson@vermont.gov>
Cc: Clark, Sarah <Sarah.Clark@vermont.gov>; Gobeille, Al <Al.Gobeille@vermont.gov>; D'Agostino, Matt <Matt.DAgostino@vermont.gov>; Hathaway, Carrie <Carrie.Hathaway@vermont.gov>; O'Connell, Tracy E <Tracy.OConnell@vermont.gov>
Subject: Re: Hep C and DOC

I was under the impression 6 of the total fell in this category but am double checking that.

Lisa Menard
Acting Commissioner
VT Department of Corrections

Sent from my iPhone

On Jan 30, 2017, at 7:46 AM, Gustafson, Cory <Cory.Gustafson@vermont.gov> wrote:

Exhibit 21

Turner, David

From: Menard, Lisa
Sent: Tuesday, July 10, 2018 3:08 PM
To: D'Agostino, Matt
Subject: FW: HCV Info Request

Lisa M. Menard
Commissioner, Vermont Department of Corrections

From: Menard, Lisa
Sent: Friday, July 06, 2018 1:59 PM
To: Gobeille, Al <Al.Gobeille@vermont.gov>
Subject: FW: HCV Info Request

Per our discussion a few weeks ago here are some financial projections

Lisa M. Menard
Commissioner, Vermont Department of Corrections

From: Watts, Benjamin
Sent: Thursday, June 21, 2018 12:10 PM
To: Menard, Lisa <Lisa.Menard@vermont.gov>; Touchette, Mike <Mike.Touchette@vermont.gov>
Cc: Watts, Benjamin <Benjamin.Watts@vermont.gov>
Subject: RE: HCV Info Request

Hello

Here's a brief summary of HCV financial projections and some of the "assumptions" that I've made about the data:

ASSUMPTIONS:

- Patients at each step in treatment will be in custody long enough to receive the entire course of treatment.
- There are many case-specific considerations when determining the appropriate course of treatment, including but not limited to the recency of the patient's diagnosis, patient's FIB-4 score, F score, disease progression, genotype, treatment regimen, and the expected duration of treatment.
- Most therapies will be 12 weeks in duration, keeping in mind that Mavyret and Zepatier may require 16 weeks in some cases.
- Epclusa and Mavyret can be used for all genotypes
- The current costs for a 28-day supply of the four most utilized HCV medications are:
    - Epclusa - $8,288.09
    - Harvoni - $10,784.66
    - Mavyret – 12,847.68
    - Zepatier - $16,913.08

- The average cost of a 28-day supply of the four most utilized HCV medications is $12,208.38.
- The average cost of a 12-16 week course of treatment is $36,625-$48,833

FINANCIAL PROJECTIONS, BASED ON CLINICAL WORKFLOW:

- **Auto-Reflex** – Auto-reflex testing is completed usually within 7 days for patients that screen positive for HCV upon intake. The data indicates that 121-279 inmates with HCV are in custody for 7 days or more. The cost of providing a HCV treatment regimen to all patients at this stage would be $4,431,625 - $13,624,552.
- **Chronic Care Clinic** – Patients with HCV are scheduled to see medical providers in Chronic Care Clinic at regular intervals (usually every 3-6 months) to assess their condition and consider the patient for HCV treatment. The data indicates that 53-123 patients at any given time with HCV could be in custody for 6 months or more. The cost of providing an HCV treatment regimen to all patients at this stage would be $1,941,125 - $6,006,523.
- **Determination that Treatment is Medically Necessary** – Depending on the patient's disease progression, Centurion will present cases to UVMMC for consultation. Patients are clinically worked up to determine their genotype, medications, and length of treatment. Assuming treatment durations range from 12-16 weeks, patients that receive a HCV treatment regimen would need to be in DOC custody for roughly 9-13 months. Approximately 23.3% of patients are in custody for 9-13 months, which works out to roughly 30-70 patients with HCV. The cost of providing treatment to all patients at this stage would be $1,098,750 - $3,418,310.

Needless to say, the data is not perfect and I will continue to work on it. I'm sure you'll have questions and suggestions for tweaking how the numbers are calculated, and I'm happy to sit down at any time to discuss.

Thanks!

Ben

From: Watts, Benjamin
Sent: Wednesday, June 20, 2018 11:48 AM
To: Menard, Lisa <Lisa.Menard@vermont.gov>; Touchette, Mike <Mike.Touchette@vermont.gov>
Cc: Watts, Benjamin <Benjamin.Watts@vermont.gov>
Subject: HCV Info Request

Hello

Here is a summary of my conversation with UVMMC Infectious Disease:

> UVMMC provides treatment recommendations for patients that are presented by Centurion's Statewide Medical Director. UVMMC indicated that it's their general practice to wait 6 months for patients with new HCV diagnoses because the virus could spontaneously clear itself. UVMMC does not routinely treat HCV for newly diagnosed patients. Patients that are known to be chronic should be clinically worked up for treatment. UVMMC indicated that it would be a "disservice" for patients to start them and not verify that they complete their treatment. Patients with a well-established healthcare team could be started on treatment. Patients without sufficient psycho-social support could result in treatment failure which would make it more difficult to treat. There are very few scenarios in which patients with HCV are receiving a partial course. Patients are clinically "worked up" knowing that they will be ready, willing, and able to complete treatment.

FYI, I have reached out to Dr. Strenio to set up a meeting to discuss the provision of HCV treatment in DOC. I'll keep you posted.

When it comes to calculating the cost of providing HCV treatment to more patients, here are some of the issues that we are up against:

- Data integrity, especially as it relates to length of stay
- The many case-specific contingencies that can and do occur
- The complex array of treatment regimens and treatment durations

I'm awaiting a call from the Director of Pharmacy to get some consultation on how to calculate the financials. I'll reply to this email chain when I have more (better) data.

TY!

Ben Watts, MBA
Health Services Administrator
Vermont Department of Corrections
NOB 2 South
280 State Drive
Waterbury, VT 05671 – 2000
802-503-2082 Cell
Benjamin.Watts@vermont.gov

Exhibit 22

Turner, David

From: Menard, Lisa
Sent: Tuesday, November 06, 2018 2:38 PM
To: Turner, David
Subject: FW: Centurion

Lisa M. Menard
Commissioner, Vermont Department of Corrections

From: Watts, Benjamin
Sent: Friday, September 28, 2018 10:32 AM
To: Titus, Max <Max.Titus@vermont.gov>; Touchette, Mike <Mike.Touchette@vermont.gov>; D'Agostino, Matt <Matt.DAgostino@vermont.gov>; Menard, Lisa <Lisa.Menard@vermont.gov>
Cc: Watts, Benjamin <Benjamin.Watts@vermont.gov>
Subject: Re: Centurion

Max, that is understandable. Please proceed.

Mike, something else we could consider is sending out the information in the original analysis tab now. We could also add a statement in our response that we will provide information later which shows the flow of the HCV population. Please advise.

Thank you

Get Outlook for iOS

From: Titus, Max <max.titus@vermont.gov>
Sent: Friday, September 28, 2018 10:10 AM
To: Touchette, Mike; D'Agostino, Matt; Menard, Lisa
Cc: Watts, Benjamin
Subject: RE: Centurion

I'm working on this but it is going to take a little bit because I have to recalculate everything in the analysis tab to do what is being asked.

From: Touchette, Mike
Sent: Friday, September 28, 2018 9:47 AM
To: D'Agostino, Matt <Matt.DAgostino@vermont.gov>; Menard, Lisa <Lisa.Menard@vermont.gov>
Cc: Watts, Benjamin <Benjamin.Watts@vermont.gov>; Titus, Max <Max.Titus@vermont.gov>
Subject: Re: Centurion

One more thing...

The spreadsheets should have the inmate names removed for privacy. I'd like the inmates currently in custody noted on the analysis tab in a separate section, but using the same format. So, just below the 2017 full data analysis. There are not many of them so this should not take long.

Here's the analysis tab info for the 2017 data that should be copied in format and plug in the current custody inmates.

LOS BY CUSTODY STATUS FOR HCV PATIENTS
CALENDAR YEAR 2017 (N=546)
Days in Custody HCV+ Detained (n=185) Sentenced (n=341) Fed (n=20)
0-30 days 60 32% 106 31% 7 35%
31-60 days 12 6% 27 8% 4 20%
61-90 days 9 5% 18 5% 0 0%
91-120 days 14 8% 14 4% 3 15%
121-150 days 9 5% 14 4% 0 0%
151-180 days 9 5% 14 4% 1 5%
181-210 days 5 3% 18 5% 2 10%
211-240 days 1 1% 9 3% 1 5%
241-270 days 6 3% 14 4% 0 0%
271-300 days 4 2% 18 5% 0 0%
301-330 days 5 3% 4 1% 0 0%
331-360 days 8 4% 9 3% 0 0%
>361 days 42 23% 83 25% 2 10%
*Note that the ">361 days" row includes 97 individuals that are still in DOC custody.

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From: D'Agostino, Matt
Sent: Friday, September 28, 2018 9:38:44 AM
To: Menard, Lisa; Touchette, Mike
Cc: Watts, Benjamin; Titus, Max
Subject: FW: Centurion

The draft response to Al is below and all attachments are included. Once you have reviewed, I will send this out to Al and the larger group that was included earlier:

Good morning,

There are a number of attachments and the answers to your questions are all below. Please let us know if there are any questions or more information is needed. We will all make ourselves available next week to meet and review this information with you and the rest of the AHS team.

Thank you,
Matt

Matt D'Agostino, Financial Director
Vermont Department of Corrections
802-241-0016

From: Gobeille, Al
Sent: Friday, September 28, 2018 5:10 AM
To: Menard, Lisa <Lisa.Menard@vermont.gov>; Touchette, Mike <Mike.Touchette@vermont.gov>; Clark, Sarah

<Sarah.Clark@vermont.gov>; Clouser, Kristin <Kristin.Clouser@vermont.gov>; Morgan, Candace <Candace.Morgan@vermont.gov>; Maksym, Martha <Martha.Maksym@vermont.gov>; Hurlburt, Laurie <Laurie.Hurlburt@vermont.gov>
Cc: Watts, Benjamin <Benjamin.Watts@vermont.gov>; D'Agostino, Matt <Matt.DAgostino@vermont.gov>
Subject: Centurion

Lisa/Mike,

Thank you for your efforts to communicate the status of our Healthcare contract. I have some feedback and a few requests.

1. I never received the HepC population data I requested. Please have this to me by Monday morning. If you have questions please have your team reach out.
The information you requested is below and on the "Patients with HCV w LOS Analysis" spreadsheet. My apologies for the delay in getting this information to you all. Please let us know if there are any questions or more information is needed.

> DOC's standard for providing HCV treatment is the same as the community standard. DOC's can verify that patients will be in DOC custody long enough to monitor adherence to treatment. There are processes for screening patients for HCV upon admission. Patients that are newly diagnosed with HCV are monitored for 6 months to see if they spontaneously "clear" the virus. Patients with a known diagnosis of HCV are monitored to determine if HCV treatment is medically necessary. Patients are also considered for treatment regardless of F score which is consistent with Vermont Medicaid's guidelines. Patients are provided with HCV "cure" medications when it's determined (to the extent possible) that the patient is capable of fully complying with the medication regimen (e.g., taking medications as prescribed). All care is provided on a case-by-case basis. Care coordination is provided to patients that cannot complete treatment while in DOC custody. UVM Medical Center provides consultation and guidance on DOC's HCV treatment practices.
>
> The length of stay in DOC custody and the patient's status are just a couple of the many things that are considered when determining whether direct acting anti-virals for HCV are medically necessary. It would be spurious to say that a patient should receive direct acting anti-virals based solely on a review of status and time in custody. Disease progression, labs, imaging studies, other diagnostics, and case-by-case review by medical providers are the cornerstones of "medical necessity" determinations in the DOC and the community.

It would be helpful for the business folks at DOC to determine whether the State reallocated any of the difference between the guaranteed rate and the actual costs that the Contractor had in years 1-3 to any other programs or costs of the Contractor in accordance with provision 8.6.2 in Attachment –
Yes, the language in section 8.6.2 was closely considered. While it was determined that the State had no leverage for requiring Centurion to apply the savings to other areas of the contract, since the amounts for pharmaceuticals and off-site services were less than what was budgeted, Centurion did apply some of the (shadow claims) savings to costs of other services provided like staffing. In addition, in years 1-3, there was no language requiring Centurion to submit savings to the State -- this requirement was added as soon as possible to the Year 4 contract amendment.

2. In the letter I wrote to JFC I cited a roughly $455,000 number. Can Matt please provide the spreadsheets that show this math? I want to have this justification in my records.
The "Summary and detail expense by month 2018Q4" spreadsheet details the actuals claimed for each category (pharmaceutical, offsite, comprehensive and regional) by Centurion for contract year 3.

3. How are we currently paying for HepC treatment? What is the language in the contract that covers the covered services portion of the contract? Has it been amended to reflect the relevant fibrosis score update? Has the PMPM been adjusted to reflect this change?

The contractor had a budget of $353,853 for HepC treatment in contract year 3, but we are still working with them on developing individualized budgets for contract year 4. This is being discussed, along with estimates for MAT and will all be sent to us next week for review and consideration. While there is not language in the contract that specifically addresses the fibrosis score update, there are 2 attachments that reflect the agreement between DOC and Centurion ("VT Hepatitis C Protocol 2018 by Centurion and the "HCV Update" email and the attachments within related to conversations that have occurred between DOC and Centurion.

4. We secured $200,000 in HepC money and have a plan to secure $1.8 million at BAA. I want to personally understand, and I want to personally decide how we spend this money. We must have a plan, be able to articulate exactly how this works and be able to reconcile at the end.
It may be most helpful to discuss this when we all meet early next week. DOC has some thoughts on this but it should be noted that there have been some assumptions made by legislature regarding length of stay (specifically, that length of stay would not be a factor in determining who would be treated). As this is not recognized as a best practice and there are several others components to consider prior to beginning a patient on HepC treatment, it is unlikely that the Legislature's assumptions would be reflected in terms of the actual treatment costs over the next several years.

5. I want to meet with this team early next week to review the HepC data, review options for payment, decide our course and communicate this process to the outside world.
Please just let us know a time that works to meet and we will all prioritize being at this meeting.

I have time today to answer any questions any of you might have.

Al Gobeille
Secretary, Agency of Human Services
Al.Gobeille@vermont.gov
(802) 585-4030

Exhibit 23

GUIDANCE DOCUMENT
HEALTHCARE SERVICES

TABLE OF CONTENTS

GENERAL GUIDANCE

The purpose of this document is to provide guidance concerning healthcare services which may be provided by the Vermont Department of Corrections (DOC) to inmates. The DOC provides comprehensive healthcare services to all inmates, in a humane and professional manner which preserves and fosters human dignity.

TERMS USED IN THIS DOCUMENT

There are many different types of medical staff that are employed by, or contract with, the DOC. As used in this document, the following terms shall mean:

1. DOC Health Services Administrator: The position within the DOC that has ultimate responsibility for the development, implementation, and evaluation of the DOC's health services program.
2. DOC health services program: The comprehensive healthcare services program provided to inmates, through one or more contracted entities, that includes a full range of medical, pharmacy, mental health, substance abuse assessment and treatment, care coordination, dental, off-site and on-site specialty, emergency room, information technology, and corporate, regional, and facility-based administration services.
3. Facility Health Services Administrator: A contractor position within the DOC health services program that oversees the health services program at each facility.
4. Medical staff: Persons employed by the DOC health services program contractor, who provide healthcare services to inmates.
5. Mental Health Professional (MHP): A psychiatrist, psychologist, psychiatric social worker, psychiatric nurse, or others person who by virtue of his or her education, credentials, and experience is permitted by law to evaluate and care for the mental health needs of patients.
6. Provider: A doctor of medicine or osteopathy, podiatrist, dentist, chiropractor, clinical psychologist, optometrist, nurse practitioner, nurse-midwife, or a clinical social worker who is authorized to practice by the State and performing within the scope of their practice.
7. Qualified Healthcare Professional (QHCP): A physician, physician assistant, nurse, nurse practitioner, dentist, mental health professional, or other person who by virtue of his or her education, credentials, and experience is permitted by law to evaluate and care for patients.
8. Qualified Mental Health Professional (QMHP): A person with professional training, experience and demonstrated competence in the treatment of mental illness, who shall be a physician, psychologist, social worker, mental health counselor, nurse or other qualified person designated by the Commissioner of the Department of Mental Health.
9. Specialized provider: A medical provider that has the training and credentials to provide specialized care (e.g. a cardiologist, neurologist, etc.).

CONTINUITY OF CARE

Continuity of care at admission, throughout incarceration, and at release is critical to ensuring that inmates receive appropriate health services and follow-up. Such continuity is in line with

evidence-based practices. It ensures that all health services delivered to the inmate are consistent with his or her providers' recommendations and orders.

When providing continuity of care, medical staff shall operate in accordance with:

- Current National Commission on Correctional Healthcare (NCCHC) Standards for Medical Services in Jails and Standards for Medical Services in Prisons; and
- All applicable Federal and State laws, regulations, policies, and procedures, including privacy regulations.

CONTINUITY OF CARE UPON ADMISSION

1. Continuity of care begins at admission, at which time medical staff shall:
   a. Conduct a receiving screening on all inmates, to ensure all emergent and urgent health needs are met.
      i. This shall generally be done within four hours of admission.
      ii. If an inmate who has been released returns to a correctional facility within 30 days, medical staff may review the information from the inmate's previous healthcare record and conduct a shorter screening for that inmate, known as the "interval receiving screening;"
   b. Verify any medications prescribed to the inmate, to determine whether the inmate will remain on the medications, as described in the Medication Management at Admission section of this document;
   c. Determine whether the inmate will remain on the medications prescribed in the community or determine another course of action as clinically indicated by the treatment plan; and
   d. Request the inmate to sign release of information forms during the receiving screening. These releases, which grant access to treatment information from community-based providers, should be used to collect applicable medical information and records.
2. Medical staff shall adhere to established processes for identifying, tracking, and notifying inmates with chronic or mental illness who require follow-up care during incarceration and upon release to the community or a care or treatment setting.
3. Medical staff shall adhere to established policies and procedures as well, as the current standard of care, to ensure continuity of care in cases when:
   a. The receiving screening indicates an inmate requires follow-up for an acute or chronic problem; and
   b. The inmate is subsequently released prior to being evaluated by a provider.
   c. The inmate may be connected with an appropriate community provider, including a Federally Qualified Health Center (FQHC), Designated Agency (DA), and other specialized provider.

CONTINUITY OF CARE DURING INCARCERATION

Inmates with Verified Community-Based Treatment Plan

For inmates with a verified community-based treatment plan, a QHCP shall:

1. Discuss the inmate with his or her community provider. In cases when the QHCP's efforts to contact the community provider are not successful, he or she shall document all contact attempts;
2. Obtain documentation related to the inmate's assessment and treatment by the community provider in a timely manner appropriate to the inmate's medical condition. This process shall be started during the inmate's receiving screening;
3. Review the community treatment plan, when available, and make clinical determinations as to whether the plan shall be continued, in whole or in part, during the inmate's incarceration. Some reasons for the discontinuation of a community treatment plan may be related to the nature of a correctional setting, including safety and security concerns; and
4. Review and make treatment determinations based upon recommendations from specialty consultations in a accordance with the prevailing medical standards.

Facility Transfers

Mobility Codes ("M Codes")

As part of the receiving screening, inmates are assigned a Mobility Code ("M Code"), which is used to inform security staff about the inmate's suitability for transport. M Codes alert security staff if considerations exist which should be taken into account prior to an inmate's transport, including transfers from one facility to another. The codes are entered into the Medical tab in the Offender Management System (OMS) and the inmate's electronic health record, and are updated as needed to indicate inmates' level of mobility.

1. There are four levels of M Codes, as follows:
   a. M1 – Mobile without restrictions;
   b. M2 – Mobile with special considerations;
   c. M3 – Mobile with special considerations and possible transport issues; and
   d. M4 – Mobile to an infirmary, mental health unit, or hospital only.
2. When considering an inmate for transfer, the Living Unit Supervisor (LUS) or the appropriate Central Office staff member shall check to see what M Code has been assigned to the inmate.
   a. Inmates with an M Code of M1 may be transferred without prior approval from medical staff.
   b. M2 M Codes serve as an alert to the receiving facility that the inmate may require medication or ongoing treatment. Inmates with an M Code of M2 may also be transferred without prior approval from medical staff.
   c. Inmates with an M Code of M3 or M4 shall not be transferred unless the transfer has been approved by a QHCP. Whenever the inmate has an M Code of M3 or M4, the LUS or Central Office staff member shall reach out to medical staff to find out what considerations may affect the transfer, and shall:
      ii. Work with medical staff to make appropriate arrangements for the inmate's transfer; or
      iii. Decide that the inmate cannot be transferred.

Procedures for Transfer

In addition to addressing any special considerations indicated by the inmate's M Code, the following procedures shall be followed when an inmate is transferred from one correctional facility to another:

Sending Facility

A QHCP at the sending facility shall:
1. Complete the Intra-System Transfer Form by entering all pertinent information relative to the inmate;
2. Prepare any medications prescribed to the inmate for transport, by following the procedure outlined in the Medication Management at Inmate Transfer section of this guidance document; and
3. Communicate with the receiving facility about the inmate's specific situation, if the inmate has been designated as having a Serious Functional Impairment (SFI) or as being a Delayed Placement Person (DPP), or if the inmate is in an acute mental health crisis. This communication shall include information concerning:
   a. The inmate's diagnosis and active symptoms; and
   b. Strategies and interventions that have been tried with the inmate, along with how successful each has been.

Receiving Facility

A QHCP at the receiving facility shall:
1. Review the inmate's health record within twelve hours of arrival, to ensure continuity of care; or
2. Perform the inmate's receiving screening within four hours of arrival, if the inmate has not yet had the screening performed.

Transfers to an Out-of-State Correctional Facility

In addition to following the above requirements, medical staff shall follow the medical out-of-state clearance process, as outlined by the administrative directive on out of state selection, transfer, and supplemental facility placement, when an inmate is transferred to an out-of-state correctional facility.

Returns from Emergency Room, Urgent Care, or In-Patient Hospital Stay

When an inmate returns to the facility following an off-site encounter, such as an emergency room, in-patient hospital stay, or specialty provider:
1. Inmates shall be seen by a QHCP to ensure proper implementation of the discharge orders and to arrange appropriate follow-up;

2. Psychiatric, medical, and mental health providers shall be informed of the inmate's release by medical staff, and shall see the inmate as appropriate;
3. Appropriate information regarding the care, custody, and placement needs of the inmate (e.g., self-harm, suicide watch or precautions, etc.) shall be shared between DOC and medical staff upon the inmate's return; and
4. A QHCP shall document the review of the inmate's discharge orders in the inmate's electronic health record, and enter any appropriate notations or pertinent alerts into OMS. These alerts may include new designations, such as SFI or DPP.

Discharges from a Psychiatric Hospital

If the returning inmate was discharged from a psychiatric hospital:
1. The psychiatric provider shall communicate directly with the physician of record at the psychiatric hospital to collect all information relevant to the inmate's discharge to DOC.
2. Follow-up orders shall be transmitted to the psychiatric provider, who shall review, modify, and approve them based on clinical discretion;
3. The psychiatric provider shall communicate directly with medical, mental health, and facility staff at the receiving facility, to ensure the inmate's continuity of care and safety;
4. Medical staff shall schedule the inmate for a follow-up with the psychiatric provider within seventy-two hours of the inmate's return to a correctional facility;
5. A QMHP shall follow-up with the inmate as clinically indicated by the inmate's functional status and designation (i.e., Serious Functional Impaired, Delayed Placement Person, etc.), but no later than forty-eight hours after the inmate's discharge from the psychiatric hospital. This encounter shall be documented in the inmate's electronic health record.

CONTINUITY OF CARE UPON RELEASE

When inmates are released into the community, medical staff shall provide continuity of treatment with respect to treatments and medications. To ensure continuity of the inmate's medical care, medical and mental health staff shall collaborate with DOC Correctional Services Specialists (CSS) "Caseworkers." Caseworkers are responsible for the inmate's release planning, as outlined in the administrative directive on case management. In addition, the inmate's assigned Facility CSS shall coordinate with medical staff and provide the inmate's assigned Field CSS with any other medical information which may be necessary for proper field supervision of the inmate.

Preparation for Release

When medical staff receives advance notice that an inmate will be released from the correctional facility, medical staff shall:

1. Collaborate with the inmate's assigned Facility CSS to provide coordinated transition and reentry services for medical and mental health purposes;

2. Collaborate with providers and others in the community, including FQHCs, DAs, and other specialized providers as necessary, to ensure effective coordination of the inmate's care;
3. Review the inmate's medical records;
4. Establish pathways for communication with community-based providers, make appropriate referrals, and schedule initial appointments, as appropriate. This may include scheduling appointments with:
   a. Specialized providers; and
   b. Primary care providers, in cases when the CSS has not already done so;
5. Discuss the importance of appropriate follow-up and after care with the inmate; and
6. Follow the procedures outlined in the Medication Management at Release section of this guidance document.

Release of Inmates with a Communicable Disease or Other Serious Medical or Mental Health Condition

When medical staff receives advance notice that an inmate with a communicable disease or other serious medical or mental health condition will be released from the correctional facility, medical staff shall do the following, as appropriate:
1. Make a follow-up appointment with a specialized clinic or community health professional; or
2. Document actions taken to arrange for direct admission to a community hospital, respite facility, or nursing home.

Release of Inmates on Medically Assisted Treatment

To assist with care coordination, DOC Casework staff will provide and update inmate release date information for all inmates on MAT to the QHCP.

At Release

At the time of the inmate's release from a correctional facility, medical staff shall provide the inmate with:
1. A discharge summary or other continuity of care document, including the Problem List from the inmate's electronic health record;
2. An initial appointment to a FQHC of the inmate's choice, if applicable;
3. A list of medical resources, including FQHCs; and
4. Information on all follow-up appointments in the community that have been scheduled for the inmate. This information shall include the date, time, and location of the appointment and the provider's name and telephone number.

MULTI-DISCIPLINARY COLLABORATION

Health services staff and facility security staff shall work as a collaborative team to address the healthcare needs of inmates. Health services and security staff have diverse and specialized knowledge, education, and experience when it comes to working in a correctional facility.

A multi-disciplinary team, comprised of health services and security staff, shall meet daily to discuss pertinent cases. The team meetings are consistent with medical standards of care, and are designed to share information particular to specific inmates' care. The team shall determine the interventions necessary to address the unique healthcare needs for each inmate discussed, within the context of the need to maintain a safe and secure facility.

1. These team meetings shall address the needs and treatment plans of specifically identified inmates, including inmates:
   a. Who are designated as SFI and housed in segregation;
   b. Who are housed in the infirmary;
   c. With disabilities who are newly admitted or require newly-identified accommodations;
   d. Who are pose a risk to the safe and secure operation of the facility; and
   e. For whom uses of force are contraindicated. In these cases, appropriate alternatives to force shall be discussed.
2. Minutes shall be taken at each meeting. These shall be maintained by the Facility Health Services Administrator and shared among the members of the team.
3. Health services staff shall update relevant inmate medical files as a result of discussing items from these meetings.

CROSS-TRAINING

Health services staff have a role in the safe and secure operation of correctional facilities in the same way as security staff have a role in maintaining the health and well-being of inmates. There may be identified opportunities for cross-training so that, for the purposes of prevention, all staff can be aware of circumstances that may be indicative of an emerging health or security-related issue.

Upon request, health services staff shall provide trainings on pertinent topics at the correctional academy. Facility health services and security staff may also hold trainings at the facility on topics that are most relevant to the facility. Trainings may include:

1. Signs and symptoms of withdrawal, overdose, and emergent health conditions;
2. Signs and symptoms of mental illness or decompensation;
3. Procedures for emergency response; and
4. Methods of force and corresponding healthcare responses.

ACCESS TO HEALTHCARE SERVICES

Inmates shall have unimpeded access to healthcare services, regardless of housing assignment.

HEALTHCARE REQUEST FORMS ("SICK SLIPS")

Inmates may request access to health care services by completing and submitting a Healthcare Request Form ("sick slip").

Submission of Sick Slips

Sick slips shall be readily available to all inmates. Whenever an inmate wishes to access healthcare services, the inmate shall complete and submit a sick slip.

1. Inmates in general population shall submit sick slips by placing them in a location designated by the facility.
2. Inmates housed in segregation shall submit sick slips by handing them to medical staff during their daily rounds of the segregation unit.
3. Inmates with disabilities that impact participation in the written sick slip process shall be provided reasonable alternative option through which they may access healthcare services.

Response to Sick Slips

Medical staff shall respond to all submitted sick slips as follows:

1. Completed sick slips shall be retrieved from the designated submission locations at least once every twenty-four hours.
2. Each sick slip received shall be time and date stamped upon its receipt.
3. Sick slips shall be triaged within twenty-four hours of receipt.
   a. The triage process shall determine the response to each inmate who submitted a sick slip. Possible responses include:
      i. A face-to-face encounter with an appropriate QHCP;
      ii. A referral to a specialist; or
      iii. A written response to the inmate.
   b. All responses to sick call requests shall be entered in the inmate's electronic health record.

EMERGENT ACCESS TO HEALTHCARE SERVICES

Inmates who experience a medical emergency do not have to submit a sick slip. In emergent situations:

1. The inmate, or any other person, shall inform a facility staff member;
2. The staff member shall notify medical staff; and
3. Medical staff shall respond and provide appropriate medical care.

MEDICATION MANAGEMENT

Correctional facilities in Vermont shall comply with:
1. All applicable state and federal regulations regarding the prescribing, dispensing, administering, procuring, and disposing of pharmaceuticals;
2. NCCHC standards concerning the handling of pharmaceuticals and maintaining accountability for all medications; and
3. DOC health services program policies and procedures for the timely procurement, dispensing, distribution, accounting, and disposal of pharmaceuticals.

All medical staff who administer or deliver prescription medications shall be appropriately trained and licensed. Documentation of their training and testing shall be kept on file within the health services program. In addition, medical staff shall comply with facility security and training requirements.

A medication formulary shall be maintained for clinicians. A formulary is a written list of prescription and nonprescription medications that are authorized for use. The use of any nonformulary medications shall be considered on an individual basis by the Regional Medical Director.

MEDICATION MANAGEMENT AT ADMISSION

Upon admission:
1. Medical staff shall perform a medical intake and verify any prescription medications.
   a. The verification of medications shall be completed through the electronic health record system, other electronic interface, or a telephone call to the inmate's community-based provider or pharmacy.
   b. The first attempt to verify any medications shall occur within:
      i. Four hours of admission, if the pharmacy or community provider can reasonably be contacted and inmate is admitted Monday through Saturday, from 0900 through 2000 hours; or
      ii. Twenty-four hours of admission, if the inmate is admitted outside those hours.
2. Medical staff shall determine whether the inmate will remain on the medications prescribed in the community or determine another course of action as clinically indicated.

MEDICATION ADMINISTRATION

Health staff shall administer medications as ordered by a provider. The routine administration of medication is referred to as medication pass, or "med pass."
1. Medications shall generally be administered at routine times as determined by the facility.
   a. Ideally, med passes should occur at least two times daily, in keeping with the need to operate facilities in a safe and orderly fashion.
   b. With consultation of the Superintendent or designee, health staff shall adjust medication administration times when necessary to meet the needs of inmates who participate in

work details or classes. Such adjustments shall be considered in cases when Keep-on-Person medication is not available or possible, if medically appropriate.

2. Health services staff shall deliver the medications to inmates in their units:
   a. In emergent situations;
   b To inmates housed in close custody or segregation;
   c. To inmates housed in the infirmary; or
   d. When safety security, or population management needs indicate that allowing inmates to travel to the health centers constitutes a safety or security risk or significant interference to facility operations.
3. Medications shall be administered safely and expeditiously by staff appropriately trained in the process and procedure of med passes.
4. All medication administration shall be supervised by security staff.
5. In cases when a health services or other staff member suspects or observes that an inmate is misusing or diverting a medication, the staff member shall
   a. Notify the Correctional Facility Shift Supervisor (CFSS); and
   b. Document the suspicion or observation in the inmate's electronic health record.

Medication Refusal

Medical staff shall document all instances when an inmate refuses a mediation or is not available or able to receive a medication in the inmate's electronic health record.

1. If an inmate refuses or misses med pass for an essential medication, medical staff shall ask the inmate to complete and sign a Refusal of Treatment Form.
   a. If medical staff requests the inmate to sign the Refusal of Treatment Form and the inmate refuses, the QHCP shall document the inmate's refusal on the form and sign the form.
   b. If a Correctional Officer (CO) requests the inmate report to medical staff to sign the Refusal of Treatment Form and the inmate refuses to do so:
      i. The CO shall sign a Refusal to Report to Medical Form, indicating that he or she informed the inmate of his or her responsibility to report to medical to sign a Refusal of Treatment Form, and that the inmate did not comply. This form shall be forwarded to medical staff.
      ii. The QHCP shall then also sign the Refusal to Report to Medical Form, indicating receipt of the refusal notice and that the inmate did not report to receive his or her medications or sign a Refusal of Treatment form.
2. If an inmate refuses or misses med pass for an essential medication, the inmate shall be offered education by the QHCP regarding the risk of refusing the medication.
   a. A list shall be compiled daily, including the names of each inmate who did not take his or her essential medication. For each of these inmates that did not report to medical staff, a QHCP shall go to the inmate's housing unit to provide the inmate with education regarding the risk of refusing the mediation.
   b. Each time a QHCP offers education to an inmate regarding the risk of refusing a medication, the encounter shall be documented in the inmate's electronic health record.
3. If an inmate refuses or misses med pass for a non-essential medication, it shall be documented as a refusal in the MAR section of the inmate's electronic health record.

4. A QHCP shall inform the Superintendent or designee if an inmate refuses or misses a dose of medication that may result in a medical emergency or in a change in mental status that could pose a risk to safety and security. QHCPs and security staff shall monitor inmates who are non-adherent to medications and will communicate when an inmate may be showing signs and symptoms of decompensating health or mental status.
5. An inmate shall not be issued a disciplinary report (DR) for refusing to take a medication, refusing to report to medical staff, or refusing to sign a Refusal of Treatment Form.

EPI-PENS

Epi-pens shall be available for emergency use by trained staff members, including trained work crew leaders.

KEEP-ON-PERSON MEDICATIONS

The Keep-on-Person (KOP) inmate self-medication program is the process by which responsible inmates possess and self-administer identified medications ordered by a provider. Through this program, inmates receive prescribed medications in accordance with the prevailing medical standards, health and training in self-care is promoted to inmates, and medical staff resources are used efficiently.

Approved KOP Medications

The DOC Health Services Administrator or designee shall maintain and distribute a list of medications approved for KOP administration. Medications, both prescriptions and over-the-counter, shall only be added to or removed from the KOP medication list with the approval of the DOC Health Services Administrator or designee, the Director of Facilities, and the Statewide Medical Director.

KOP Local Procedures

The Superintendent of each facility, in consultation with medical staff, shall establish local procedures for the KOP program, including:

1. A list of medications which may be available through the KOP program at that facility. All medications on a facility's list of KOP medications must be included on the list of approved KOP medications maintained by the DOC Health Services Administrator or designee; and
2. Times and days for KOP medication to be reordered or picked up by inmates.

Due to security concerns and building limitations, these local procedures may specify differing rules for individual units within a facility.

KOP Program Enrollment Procedures

An inmate may be enrolled in the KOP program through the following procedures:

1. The provider shall carefully review the medical and mental health record to evaluate the inmate's ability to comprehend and comply with the KOP program rules and regulations. If the provider determines that the inmate is appropriate to participate in the KOP program, the provider shall write the original order for the medication and indicate that it is "Keep-On-Person," or "KOP," on the order.
2. The provider or designee shall instruct the inmate on how to take the medication.
3. Medical staff shall explain the KOP program and the specific medication to the inmate, including the benefits, risks and side effects, and proper dosing (times and amounts) of the medication.
4. The inmate shall be asked to sign the KOP program contract.
   a. If the inmate refuses to sign the contract, he or she shall not be allowed to participate in the KOP program.
   b. The signed contract shall be included as part of the inmate's electronic medical record.
   c. Medical staff shall provide a copy of the signed contract to the inmate.
   d. Medical staff shall provide notification to correctional staff that the inmate is on the KOP program.
5. Medical staff shall indicate the inmate's participation in the KOP program on the "Medical" tab in OMS by:
   a. Clicking on the "Meds" tab;
   b. Entering "KOP – Participation" in the "Medication Name" field; and
   c. Entering the date on which the inmate was enrolled in the KOP program in the "Med. Start Date" field.

Exclusion from KOP Program

1. Inmates may be excluded from the KOP program for the following reasons:
   a. The inmate's previous failure to comply with the rules and regulations of the program;
   b. The inmate's refusal to sign a KOP contract;
   c. The inmate is determined to be at-risk for abuse of the program, or is deemed inappropriate for the program (including a history of diversion), as determined by medical or mental health staff, in consultation with security staff; or
   d. In cases when the correctional facility's local procedures restrict detained inmates from participating in the KOP program.
2. If an inmate is excluded from participating in the KOP program, it shall be documented in all of the following locations:
   a. A progress note in the inmate's electronic health record, specifying the reason the inmate was excluded from the KOP program in the inmate's electronic health record;
   b. The Overview page in the Past Medical History Section in the inmate's electronic health record; and
   c. On the "Medical" tab in OMS by:
      i. Clicking on the "Meds" tab;
      ii. Entering "KOP – Exclusion" in the "Medication Name" field; and
      iii. Entering the date on which the inmate was excluded from the KOP program in the "Med. Start Date" field.

Management of KOP Medications

The following shall apply to all medications issued to inmates under the KOP program:

1. All medications shall be clearly labeled, including:
   a. The inmate's name;
   b. The method by which the medication shall be administered;
   c. The start date;
   d. The stop date if applicable; and
   e. The expiration date of the medication.
2. All documentation of KOP medication administration and distribution shall be maintained in the Medication Administration Record (MAR) section of the inmate's electronic health record.
3. All medication shall be maintained by the inmate in the container as dispensed, and stored according to the facility's local procedures.

Removal from the General Population

In cases when an inmate in the KOP program is removed from the general population to a restricted housing unit:

1. Correctional staff shall return all KOP medication to medical staff;
2. The nurse shall note the suspension of the KOP program:
   a. In the MAR section of the inmate's electronic health record; and
   b. On the "Medical" tab in OMS by:
      i. Clicking on the "Meds" tab;
      ii. Entering "KOP – Removal from General Population" in the "Medication Name" field;
      iii. Entering the date on which the inmate was removed from general population in the "Med. Start Date" field; and
      iv. Entering the date on which the inmate will be returned to general population, if known, in the "Med. End Date" field. In cases when this field is completed, an alert will be sent to the Facility Health Services Administrator on the date entered, as a notice to update the inmate's KOP status;
3. The nurse shall begin administration of that medication through med pass; and
4. The inmate may return to the KOP program when returned to the general population, if deemed appropriate by the medical provider.

Non-Compliance and Termination from KOP Program

Non-Compliance

1. Inmates who are found to be non-compliant with the KOP program rules and regulations may receive counseling and/or have their KOP program privileges suspended or revoked. Such actions may occur whenever an inmate:

a. Is found with more or less of any ordered medication in his possession than anticipated, based on prescribing instructions;
b. Is found with prescription medication in his or her possession which is not labeled according to the standard, including not indicating the name of the inmate on the prescription label;
c. Is found with prescription or over-the-counter medication for which there is no valid physician order; or
d. Fails to store their KOP medication as required according to the facility's local procedures.

2. If an inmate is found to be non-compliant with the KOP program rules and regulations, the QHCP, in consultation with the facility correctional staff, if appropriate, shall determine an outcome on an individualized case basis.
3. In cases when and inmate's KOP program privileges are revoked, his or her medications shall be confiscated.

Loss of Privileges

Any time an inmate loses the privilege of participating in the KOP program for any reason, including termination, the following shall apply:

1. In cases when KOP program privileges are suspended, the duration of the suspension shall be determined by the provider.
2. Medical staff shall document the loss of KOP program privileges, and the duration of any KOP program suspension, as follows:
   a. On the "Medical" tab in OMS by:
      i. Clicking on the "Meds" tab;
      ii. Entering "KOP – Loss of Privileges" in the "Medication Name" field;
      iii. Entering the date on which the inmate lost KOP privileges in the "Med. Start Date" field; and
      iv. In cases when KOP program privileges are suspended, entering the end date of the inmate's suspension in the "Med. End Date" field. In cases when this field is completed, an alert will be sent to the Facility Health Services Administrator on the date entered, as a notice to update the inmate's KOP status; and
   b. In all of the following places within the inmate's electronic medical record:
      i. The Problem List;
      ii. The Progress Notes
      iii. The MAR.

Termination

Any correctional staff member may raise a health or medication-related concern regarding an inmate. When it is believed that an inmate is creating a security concern through his or her enrollment in the KOP program, the staff member shall report his or her concern through the chain of command.

An inmate may be terminated from the KOP program by:

1. The Regional Medical Director or designee, for non-compliance with the KOP program rules and regulations or other healthcare-related issues; or
2. A CFSS or other facility staff member higher in the chain of command, in cases of medication-related security concerns.
   a. In such cases, the CFSS shall notify the Facility Health Services Administrator.
   b. In cases when it is not possible to notify the Facility Health Services Administrator, the CFSS or facility staff member shall notify a medical staff member on duty.

Inmates who have lost their KOP privileges or been terminated from the program shall be directed to return unused medication immediately. If the inmate refuses to return unused doses of medication, medical staff shall immediately inform the on-duty CFSS.

KOP Medication Audits

KOP medications shall be audited on at least a monthly basis.

1. Medical staff shall make at least a monthly check of dosing compliance of at least ten percent of the inmate population on KOP medications.
   a. Medical staff shall randomly select the required number of inmates, visit the housing units escorted by a correctional officer, and check for compliance.
   b. Medical staff shall complete a report for each inmate checked, including the following information:
      i. Name of the nurse completing the compliance check;
      ii. Name of the inmate checked;
      iii. A designation of "Compliant" or "Non-compliant," based on the results of the compliance check. Names of medications should not be included;
      iv. If any inmates were found to be non-compliant, the specific details of that non-compliance;
      v. Date and time of the compliance check; and
      vi. Action taken in response to non-compliance, if applicable.
   c. The medical staff shall forward the report to the Facility Health Service Administrator and the Superintendent or designee.
2. The Facility Health Service Administrator or designee shall provide an updated list of all the inmates participating in the KOP program to the Superintendent or designee monthly.
   a. This list shall include the number of medications each inmate receives through the KOP program.
   b. This list shall not include the names of medications.

Transfers of Inmates in the KOP Program

When an inmate is transferred from one correctional facility to another, instate or out-of-state:

1. The inmate shall be required to relinquish his or her KOP medication to medical staff.
2. Medical staff at the sending and receiving facility shall prepare and verify the medications as described in the Medication Handling at Inmate Transfer section below.

3. In cases when the inmate is transferred to another DOC facility, a QHCP at the receiving facility shall:
   a. Follow the steps described in the Medication Handling at Inmate Transfer section below; and
   b. Determine if the medications the inmate was receiving as KOP in the sending facility will be available to the inmate as KOP in the receiving facility. If the medications are allowable as KOP under the local procedures promulgated in accordance with the Local Procedures section above, the QHCP shall review the KOP program contract with the inmate, and the inmate shall be allowed to continue receiving those medications as KOP.

MEDICATION MANAGEMENT AT INMATE TRANSFER

The following procedures regarding medication management shall be followed when an inmate is transferred from one correctional facility to another:

Sending Facility

A QHCP at the sending facility shall:
1. Review the necessary medications and include prescription information on the transfer form; and
2. Place all inmate-specific, prescribed medications and the transfer form inside a sealed envelope for transfer.

The envelope with the prescribed medication and transfer form shall be delivered to the CO in charge of booking ("Booking Officer"), who shall provide it to the transport officers.

Receiving Facility

A QHCP at the receiving facility shall:
1. Review all medications received;
2. Stock an adequate amount of all prescribed medications;
3. Complete the inmate's medical intake and verify his or her medications, if these procedures had not been completed prior to the inmate's transfer; and
4. Determine if any of the medications the inmate has been receiving may be available as KOP under the local procedures promulgated in accordance with the Local Procedures section above. If the inmate was receiving a medication at med pass in the sending facility that could be made available to the inmate as KOP in the receiving facility, the QHCP shall refer the case to a medical provider for a determination if the inmate may receive the medication as KOP in the receiving facility.

MEDICATION MANAGEMENT AT RELEASE

The following procedures shall be followed when medical staff receives advance notice that an inmate will be released from the correctional facility:

1. A QHCP shall review the inmate's medication orders and include them as part of the discharge planning.
2. A QHCP shall prepare medications to be given to the inmate upon release.
   a. All inmates shall be provided an adequate supply of medications upon release. The prescriber shall have the discretion of determining the amount and category of medication provided at release based on the:
      i. Inmate's known history or risk profile for abuse, diversion, or overdose;
      ii. Dosage and potency of the medication; and
      iii. Inmate's known insurance status.
   b. Inmates who are prescribed HIV medications, shall be provided a thirty-day supply of medications.
3. A QHCP shall request the inmate sign a Medication Handling Upon Release Acknowledgement Form, documenting that medical staff explained that the medications provided at the time of release will be in non-childproof containers. If the inmate refuses to sign, it shall be noted on the form, and two staff members shall sign the form as witnesses.

MEDICAL AND DENTAL DIETS

The DOC provides inmates who have a medical or dental need for a special diet with the means to fulfill those specific dietary needs. These special diets are approved and provided in accordance with the administrative directive on food service operations.

MEDICATION ASSISTED TREATMENT (MAT)

It is the intent of the Department of Corrections that MAT offered at or facilitated by a correctional facility is a medically necessary component of treatment for inmates diagnosed with an opioid use disorder (OUD).

MAT is the use of U.S. Federal Drug Administration-approved medications, in combination with counseling and behavioral therapies, to provide a whole patient approach to the treatment of substance use disorders.

Upon entry to a correctional facility, each inmate shall be screened for substance use disorders as part of the initial and ongoing substance use screening and assessment process. This process includes screening and assessment for OUDs. Based on the results, and a QHCP determination, inmates may be continued, tapered, or inducted onto MAT as medically necessary.

It is the responsibility of DOC staff to support the administration of MAT in a facility.

DOC facility staff are responsible for:

1. Escorting inmates to the dosing location;

2. Remaining at the dosing location for the duration of the treatment;
3. Returning inmates to their housing unit, or other location;
4. Conducting 15-minute checks on inmates after dosing when it is deemed necessary by a QHCP or DOC facility staff;
5. Assisting in continued follow-up by bringing an inmate to medical for re-assessment every 8 hours, when deemed necessary by a QHCP.

END-OF-LIFE PLANNING

ADVANCE DIRECTIVES

An advance directive is a written document that specifies the wishes of an individual related to end-of-life decisions and care. These documents may include the:

- Appointment of an agent;
- Identification of a primary care clinician;
- Instructions on healthcare desires or treatment goals;
- Instructions on anatomical gifts; or
- Instructions on the disposition of remains and funeral goods and services.

Advance directives include documents such as living wills, healthcare proxies, and Do Not Resuscitate (DNR) orders.

Honoring Advance Directives

It is the policy of the DOC to honor inmates' advance directives, as determined appropriate by a medical provider. If an inmate who is terminally ill has a properly executed advance directive, directions for end-of-life care and disposition of the remains shall be followed.

Creating and Modifying Advance Directives

All inmates shall be given the opportunity to create or modify an existing advance directive, regardless of their current health status.

1. At the time of the receiving screening the QHCP performing the screening shall ask the inmate they have any exiting advance directive documents.
   a. If the inmate indicates that he or she does have an existing advance directive, the QHCP shall:
      i. Work with the inmate to obtain a copy; and
      ii. Advise the inmate that medical staff are available to help inmates modify their advance directives, should they choose to do so.
   b. If the inmate indicates that he or she does not have an existing advance directive, the QHCP shall offer the inmate the opportunity to create one.
2. The steps described above shall be repeated at the initial health assessment, if the inmate has not already provided a copy of his or her advance directive by that time.

3. If an inmate is admitted into the infirmary or is terminally ill, and does not have an advance directive, a QHCP shall offer the inmate the opportunity to create an advance directive.
4. If an inmate wishes to create an advance directive at any other time, he or she shall submit healthcare request form ("sick slip"), and shall be assisted in the creation of the document.
5. The appropriate forms and instructions from the Vermont Department of Health's website shall be used when helping inmates create advance directive documents.
6. DOC staff shall neither advocate for nor discourage any end-of-life decision the inmate may make.
7. DOC staff shall not require an inmate to have executed an advance directive as a condition of receiving treatment.
7. DOC and medical staff shall take care to ensure that all end-of-care or advance directive decisions are made by the inmate and are voluntary, uncoerced.

Informed Decision-Making

1. Medical staff shall take care to ensure that all end-of-life care or advance directive decisions are based on medical information that is complete and comprehensible to the inmate.
   a. QHCPs shall provide medical information to inmates involved in end-of-life planning or who request assistance in preparing an advance directive. This information shall include the:
      i. Inmate's diagnosis, prognosis, and care options, both in the facility and in other institutions;
      ii. Consequences of choosing an advance directive; and
      iii. Availability of palliative care and hospice services.
   b. All conversations with an inmate regarding end-of-life planning shall be documented as an encounter in the inmate's electronic health record.
2. The Superintendent shall make the following people available to the inmate, if possible, to help the inmate determine his or her wishes regarding healthcare and the disposal of his or her remains, should the inmate die while in a correctional facility:
   a. Legal counsel of the inmate's choosing; and
   b. A representative of the inmate's faith.
3. Inmates may sometimes be deemed to lack the capacity to make certain end-of-life decisions by a medical provider.
   a. In such situations, medical staff shall consult any valid advance directive when determining appropriate care.
   b. In cases when the inmate does not have a valid advance directive, medical staff shall:
      i. Coordinate with the inmate's guardian or next of kin as appropriate; or
      ii. In cases when the medical condition is considered life threatening, transfer the inmate to a hospital for a medical evaluation and an ethics consultation, if appropriate.
   c. If the inmate is determined by a medical provider to have regained the capacity to make the necessary medical decisions at any time, he or shall immediately resume authority over personal medical decisions, and medical staff shall no longer consult the above sources, unless the inmate is subsequently deemed to lack the necessary capacity again.

Validity of Advance Directives

In circumstances when a QHCP has questions about the validity of an advance directive document, he or she shall bring it to the attention of the DOC Health Services Administrator or designee. The DOC Health Services Administrator shall consult with legal counsel to determine if the document complies with DOC policies and meets witnessing and other legal requirements, to determine its validity. If the document is determined to be invalid, the inmate shall be offered the opportunity to create a new advance directive.

Documentation of Advance Directives

Advance directives that are properly executed by the inmate shall be uploaded to the inmate's file in OMS and the inmate's electronic medical file. The name of the person or people to be notified in case of serious illness shall be documented in the "Contacts" tab under the "Extra Information" tab of the inmate's file in OMS.

Acting on Advance Directives

There shall be an independent review of the inmate's course of care and prognosis before a healthcare proxy, living will, or DNR order is used as the basis for withholding or withdrawing care. This review shall be conducted by a physician not directly involved in the inmate's treatment.

CARE OF INMATES WHO ARE TERMINALLY ILL OR RECEIVING END-OF-LIFE CARE

The DOC provides inmates who are terminally ill with care to address pain and palliative issues when appropriate. Inmates have the right to make healthcare decisions to receive life-sustaining, medically-appropriate treatments, if desired, or to receive care to achieve comfort during the dying process.

Early Release

In circumstances when the Statewide Medical Director determines that care in a community setting may be medically preferable, he or she shall make a recommendation to the DOC Health Services Administrator regarding the inmate's transfer or early release. Upon such a recommendation, the DOC Health Services Administrator shall ensure that all requests for long-term medical furlough are processed in accordance with the DOC administrative directive concerning medical, treatment, and short term inpatient furloughs.

Quality of End-of-Life Care

QHCPs shall provide care of terminally ill inmates that resembles care provided in the community as closely as possible.

Education and Training for QHCPs on End-of-Life Care

QHCPs shall be:
1. Knowledgeable regarding the appropriate Vermont rules and statutes related to end-of-life care, including 18 V.S.A. chapter 231; and
2. Trained in basic end-of-life care theory and techniques.

End-of-Life Care

The DOC shall:
1. Provide end-of-life care to inmates; and
2. When possible, provide hospice services, which are guided by a manual used to assist with the provision of care and are delivered by trained inmate hospice support persons.

Notification Procedures

1. Medical staff shall communicate with the DOC Health Services Division, the Director of Classification and Inmate Placement, the Director of Facilities or designee, and the Deputy Commissioner:
   a. Promptly about inmates who require emergent care or are destabilized; and
   b. Regularly about inmates with more chronic conditions.
2. The medical staff shall ensure that the DOC Health Services Administrator and the Superintendent of the facility are notified whenever an inmate is terminally ill or receiving end-of-life care.
3. Meetings between healthcare staff and DOC staff members to discuss inmates who are terminally ill or receiving end-of-life care shall occur as often as needed, but at least weekly.

Documentation

Medical staff shall document the provision of the following services for inmates who are terminally ill or receiving end-of-life care:
1. The development and maintenance of individualized treatment plans; and
2. All conversations with an inmate regarding end-of-life planning. These conversations shall be documented as an encounter in the inmate's electronic health record.

Death with Dignity

The DOC shall not provide medical aid to hasten the death of inmates. No provider employed by, or under contract with, the DOC may write a prescription for a dose of medication intended to be lethal for an inmate.

Right to Information

Inmates have the right to be informed about all available treatment options relating to their care. Therefore, a provider shall inform any inmate who is receiving end of life care, or who requests information from medical staff about medical aid to hasten his or her death, about the availability of such medication under Act 39 of 2013, and explain that the DOC does not provide medical aid in hastening death for inmates.

Death Procedures

The administrative directive on facility security outlines how security staff shall react to the death of an inmate in a correctional facility. The following procedures outline healthcare-related responsibilities in the event of the death of an inmate:

1. In some cases, when an inmate's death is expected and he or she does not have a valid DRN or Clinician Orders for Life Sustaining Treatment order, a registered nurse (RN) or licensed practical nurse (LPN) may pronounce the death of an inmate, in accordance with guidelines issued by the Vermont State Board of Nursing.
2. In cases when a RN or LPN may not pronounce the death of an inmate, a qualified emergency services worker, physician, or medical examiner or designee shall be the only persons to pronounce the death of an inmate.
3. The DOC shall ensure that:
   a. An administrative review, or assessment of correctional and emergency response actions surrounding the inmate's death, is conducted within thirty days of the inmate's death. The review shall ascertain the sequence of events up to and including the inmate's death and identify areas where facility operations, policies, and procedures can be improved;
   b. A clinical morality review, or an assessment of the clinical care provided and the circumstances leading up to the death, is conducted within thirty days. The purpose of the clinical mortality review shall be to:
      i. Identify areas of patient care or system policies and procedures that can be improved;
      ii. Determine whether the care provided to the inmate contributed significantly to the outcome; and
      iii. Determine whether that care, regardless of its contribution to the outcome, met medical standards;
   c. A psychological autopsy, is conducted within thirty days, if the death is by suicide. A psychological autopsy is sometimes referred to as a psychological reconstruction or postmortem, and is a written reconstruction of an inmate's life with an emphasis on factors that led up to, and may have contributed to, the inmate's death. The psychological autopsy shall be conducted by a psychologist or other mental health professional (MHP);
   d. A root cause analysis is conducted by an independent party, in accordance with protocols established by the appropriate authority (currently the Vermont Department of Health), to identify and analyze underlying process issues that lead to the event, or could result in a serious, reportable event if they are not addressed. The most important component to an

effective root cause analysis is its focus on the underlying process issues, rather than mistakes made by individuals;

e. The medical staff who treated the inmate are informed of the clinical mortality review and administrative review findings;
f. Any findings of clinical misconduct are reported to the appropriate authorities, such as the Office of Professional Regulation or Medical Practice Board; and
g. In coordination with the correctional facility, that appropriate notification is made to respective family member(s) or other person designated by the inmate.

In the event of an inmate death in a hospital or out-of-state facility, or while the inmate was being transported, DOC staff will follow all appropriate procedures, make proper notification, and begin arrangements for the disposition of the body, in accordance with the administrative directive on facility security.

HANDLING OF ETHICAL DILEMMAS

Ethical dilemmas may occur during end-of-life care. Such ethical dilemmas may include:

1. Questioning the validity of an advance directive document;
2. The inmate choosing to forego treatment;
3. Decision making processes;
4. Conflicts among various parties; and
5. Determinations of medical non-benefit, when medical providers determine that further interventions to prolong the life of an inmate will not provide a medical benefit, and the intent of care should be shifted toward comfort and closure.

In the case where an ethical dilemma arises, DOC Health Services staff shall notify the DOC Health Services Administrator or designee of the situation. The DOC Health Services Administrator or designee shall review the situation and consult with legal or ethical counsel or medical providers, as appropriate, for assistance in resolving the dilemma.

Exhibit 24

Health Services	POLICY: Hepatitis C Inmate Testing and Treatment	
	NO. B-01g	Date of Origin: 10/23/2018

REFERENCES: NCCHC Standard (Prison & Jail) B-01 (2014)
https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm;
https://www.cdc.gov/hepatitis/pdfs/Testing-Followup-Exposed-HC-Personnel.pdf

PURPOSE:

To provide opt-out screening, diagnosis, medical monitor, pharmacological interventions using direct acting anti-virals (DAAs), and referrals to appropriate medical care for patients with hepatitis C virus (HCV). To provide care in accordance with prevailing medical standards. To reduce all-cause mortality and liver-related health adverse consequences, including end-stage liver disease and hepatocellular carcinoma, by the achievement of virologic cure as evidenced by a sustained virologic response.

POLICY:

As part of the Initial Healthcare Receiving Screening, all inmates with unknown HCV status shall be offered opt-out screening and diagnosis for HCV. Inmates with confirmed HCV shall be seen by the provider within 14 days of intake (unless extenuating circumstances exist) to develop a treatment plan. Inmates with HCV shall be seen in chronic disease clinic (CIC) at clinically-indicated intervals (usually every 3-6 months) to monitor the status and control of the patient's HCV and to determine what medical interventions, such as DAAs, may be medically necessary. Costs of DAAs shall not be considered in determinations of medical necessity.

The Regional Manager and the Statewide Medical Director are responsible for implementation of this plan.

PROCEDURE:

Upon intake, patients with an active verified prescription for DAAs for HCV treatment shall be continued on those medications upon admission to DOC, in accordance with Policy E-02b, **Medication Verification, E-02c, Timely Initiation of Medication Upon Arrival to a Facility and D-02a Medication Services: Medication Prescribing and Ordering.** These policies assure that medical providers verify existing medical prescriptions and continue them if determined to be clinically appropriate. It also specifies that whenever possible, ongoing treatment regimens that include "no miss medications" should be continued without a single missed dosage, whether the listed medication or a therapeutic substitution is provided.

Patients with an unknown HCV status upon intake are provided with an opt-out screening for HCV. All inmates with a history of IV drug use are given educational information on HCV, including instructions on how to receive HCV screening if they have previously opted out. Positive HCV screening results will prompt the provider to order an auto-reflex test via a blood draw to be completed within seven (7) days of receipt of the patient's positive screening result. When an individual receives a positive auto-reflex result, a 6-month wait will commence to see if the patient spontaneously clears the virus. A positive result after this time period indicates that the patient has active HCV RNA that has not spontaneously cleared, and the patient shall be referred to be seen at the CIC at clinically-indicated intervals for monitoring of FIB-4 score through labs. For negative auto-reflex or for those cases that spontaneously clear, no additional action is necessary.

Patients with confirmed HCV will be given educational information on next steps, how not to spread the disease and how to live with HCV. Patients with a current diagnosis of HCV shall be seen by the provider within 14 days of intake unless extenuating circumstances exist for an initial health assessment and referral to CIC. Patients with HCV shall then be seen regularly as clinically indicated (usually every 3-6 months) to assess the stability and control of their condition. Their treatment plans will be updated regularly to indicate the current diagnostic indicators and next step plan to occur prior to next CIC. The status of patients with HCV will be monitored by lab tests (e.g., FIB-4), other diagnostics, and monitoring of symptomatology for compromised liver function.

Patients with a current HCV diagnosis upon intake are seen by a medical provider at clinically-indicated intervals (usually every 3-6 months) based on the stability and control of the condition. The status of patients with HCV will be monitored by lab tests (e.g., FIB-4), other diagnostics, and monitoring of symptomatology for compromised liver function.

FIB-4 scores will be referenced to clinically determine the need to order fibroscan ultrasounds and/or other diagnostics and to determine the level of cirrhosis and the patient's F score:

FIB-4 of < 1.45 indicates a negative predictive value for advanced fibrosis, and the plan is generally to recheck the FIB-4 in 4-6 months.
FIB-4 of > 1.45is a positive predictive value for fibrosis, and generally an elastography (fibroscan) will be ordered for such individuals to determine the extent of fibrosis (known as "F" score") unless medically not indicated.

F scores from elastographies will be reported in integers: 0, 1, 2, 3, or 4, where 0 means no fibrosis and 4 shows the presence of cirrhosis.

DOC Health Services will adhere to Department of Vermont Health Access's (DVHA's) treatment guidelines, which state that:

Patients will be referred for consultation with an infectious disease specialist regardless of F score.
DAAs will continue to require approval through the non-formulary process and through oversight from an infectious disease specialist to ensure the patient meets clinical criteria and that the most clinically-appropriate regimen is utilized.

The medical provider will confirm the patient's custody length when assessing whether or not to refer a patient to an infectious disease specialist in order to determine and determine

appropriateness for DAA treatment initiation. In general, only patients who are expected to be in custody for the duration of treatment will be started on a pharmacological treatment regimen. In such cases, treatment adherence and side effects can be monitored and sustained virologic response can be confirmed by QHCPs. Providing DAA treatment to patients without considering length of stay could lead to non-adherence within the community and the emergence of treatment resistant strains of HCV, posing a risk to the health and safety of the patient as well as public health.

Patients with FIB-4 scores greater than 1.45 or patients with complicated health profiles (such as those with serious co-infections like HIV or auto-immune diseases) are presented to an infectious disease specialist to determine the medical necessity for initiating the patient on a pharmaceutical treatment regimen. It may take 2-3 months to stage patients because of the number of outside tests required.

An Infectious Disease Specialist will determine the medical need for DAA treatment, and the provider will document the clinical determination outlining the prescribed treatment regimen in the patient's electronic health record . When a clinical determination does not dictate DAA regimen, clinical details and determination will also be documented.

Patient consent will be required to commence treatment. The risks and side effects of evaluation, the proposed treatment regimen, and the need for monitoring will be fully discussed with all patients with HCV. Patients will be informed of the importance of completing the full HCV treatment course, that failure to do so could lead to treatment resistance, which could make treatment more difficult, and could exacerbate negative HCV-related health outcomes. A signed consent form outlining these concepts will be kept in the patient's electronic health record (EHR).

Patients will be re-evaluated for treatment compliance in accordance with their Gastrointestinal Clinic (GC) scheduling. Verification that the patient was adherent to treatment will be documented in regard to the patient achieving a sustained virologic response (SVR). When treatment cannot be completed or initiated during incarceration, patients will be referred to appropriate medical community providers for coordinated care and follow up.

SPECIAL CONSIDERATIONS:

Treatment for those with a short life expectancy who cannot be remediated by HCV therapy, liver transplantation, or another directed therapy shall be managed in consultation with an infectious disease specialist.

The administration of pharmacological interventions for HCV shali be directly observed, as is the norm in prison settings, and the risk of drug diversion is low.

Behavioral risk reduction and substance abuse counseling is an integral part of chronic HCV treatment. Patients will be encouraged to participate in the use of peer educator programs, such as those in Narcotics Anonymous or Alcoholics Anonymous, whenever possible.

Exhibit 25

Turner, David

From: Titus, Max
Sent: Wednesday, November 07, 2018 3:23 PM
To: Watts, Benjamin; Touchette, Mike
Cc: Carr, Emily; Titus, Max
Subject: RE: MAT and HCV
Attachments: Centurion of Vermont - DOC Contract Amendment for 2019 - 11-6-18.docx; HCV Flowchart 10.25.18.pptx

Hi there,

See attached the flowcharts as created last week and the draft of the Contract Amendment.

Let me know if you need anything else.

~Max
(they/them)

From: Watts, Benjamin
Sent: Wednesday, November 07, 2018 11:31 AM
To: Touchette, Mike ; Titus, Max
Cc: Carr, Emily ; Watts, Benjamin
Subject: RE: MAT and HCV
Importance: High

Hello

Please see attached.

Max, please:

- Send the version of the "HCV Flow Chart" which we had planned on discussing at legislative testimony a week or so ago.
- Forward the proposed contract amendment language to Emily for review.

TY

Ben

From: Touchette, Mike <Mike.Touchette@vermont.gov>
Sent: Wednesday, November 07, 2018 10:42 AM
To: Watts, Benjamin <Benjamin.Watts@vermont.gov>
Cc: Carr, Emily <Emily.Carr@vermont.gov>
Subject: MAT and HCV

Good morning,

Lisa just filled me in on the meeting you had this morning.

To follow up, here is what is needed and the time lines:

1. MAT dosing capacity: current, waivers in process, anticipated need and what Centurion's goal is. This is needed by the end of the day.
2. MAT dosing specs – Clarity on who they are dosing – post-min, release eligible, continued from the community, inducted for detox, etc. Several pre-min inmates have been inducted...why? Need this by Friday.
3. HCV – Final process and agreements between DOC, Centurion and UVMMC – who, what, where, why, when. By Friday please.

Number 1 is the priority for today. Thanks!

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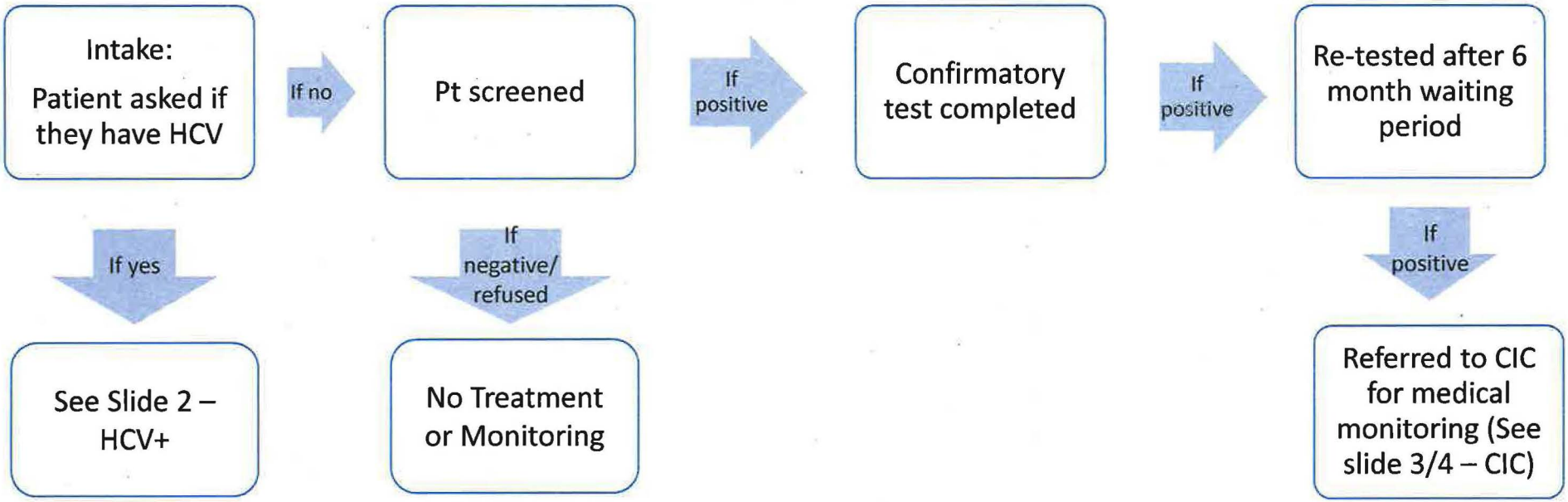
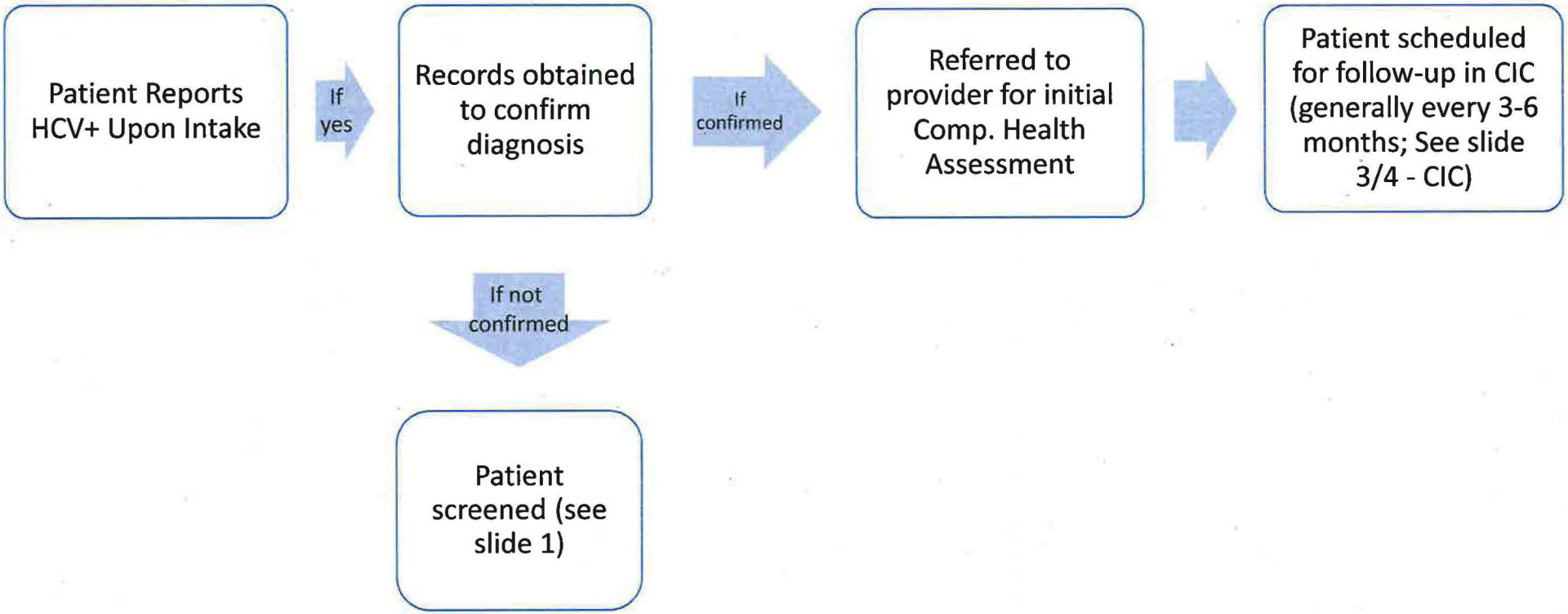
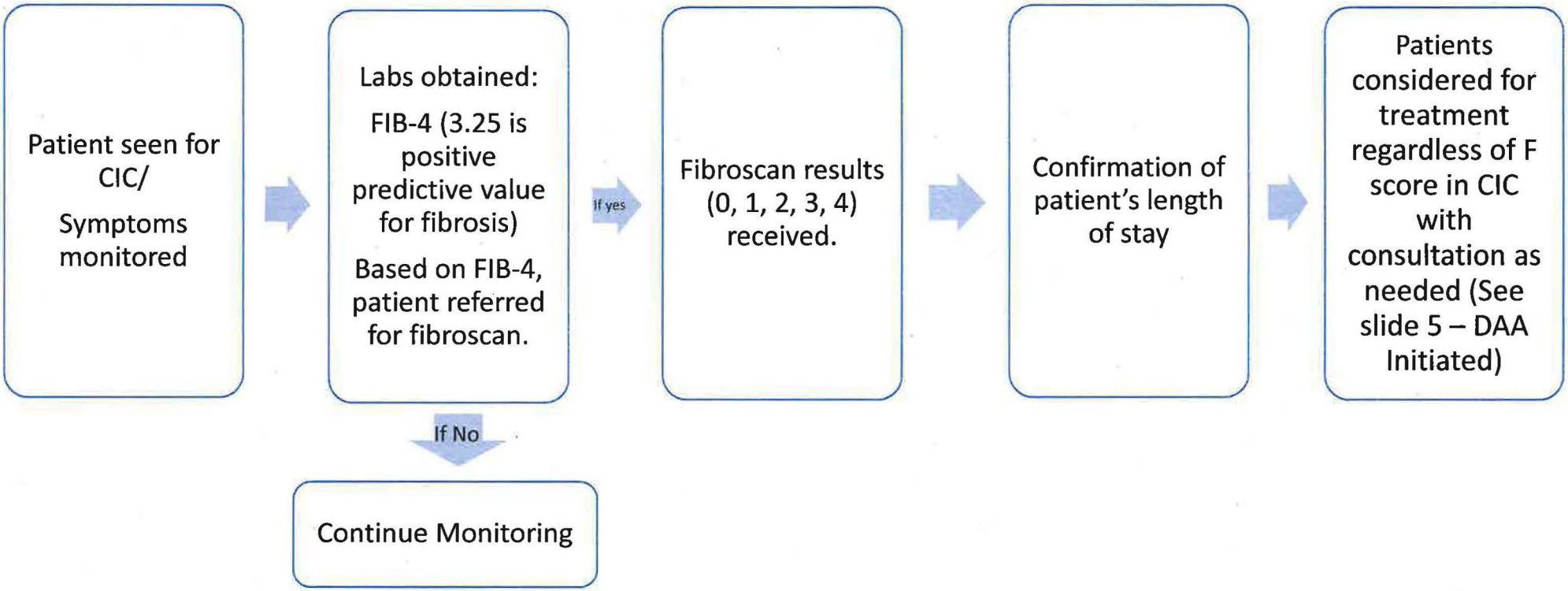
Intake/Screening



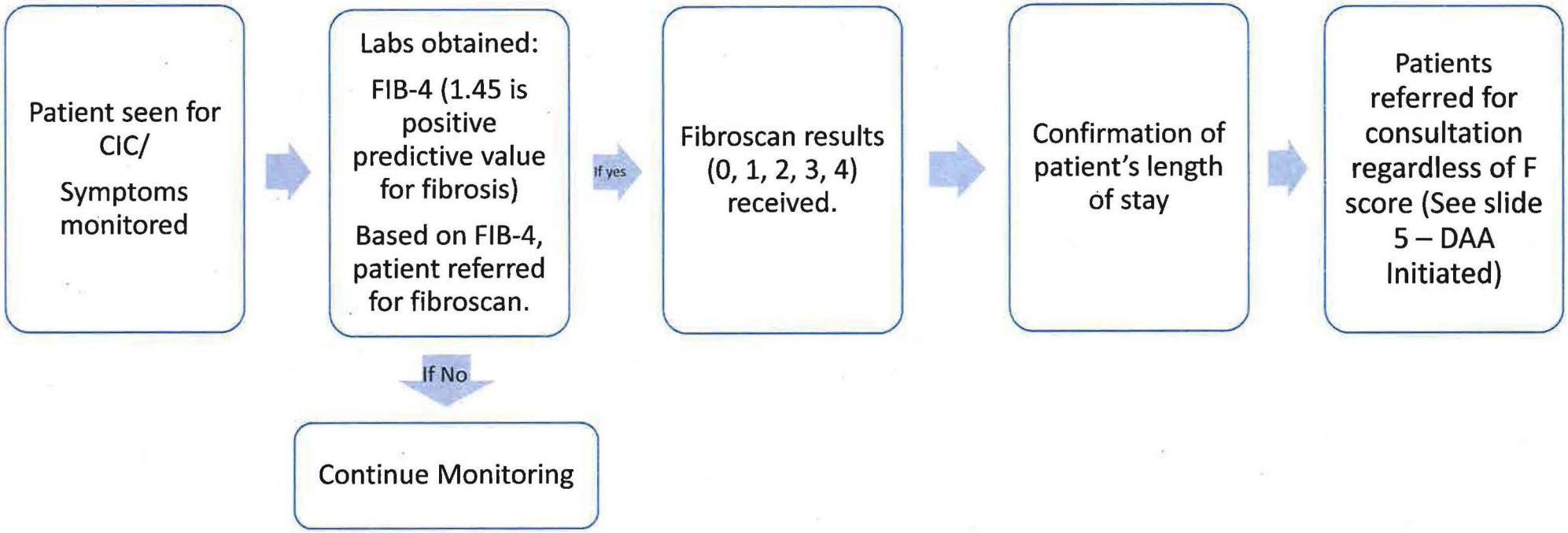
HCV+ at Intake



Chronic Disease Clinic (CIC) - Past



Chronic Disease Clinic (CIC) – Per AHS Secretary's letter dated 10/22/18



Direct Acting Anti-viral (DAA) Initiated

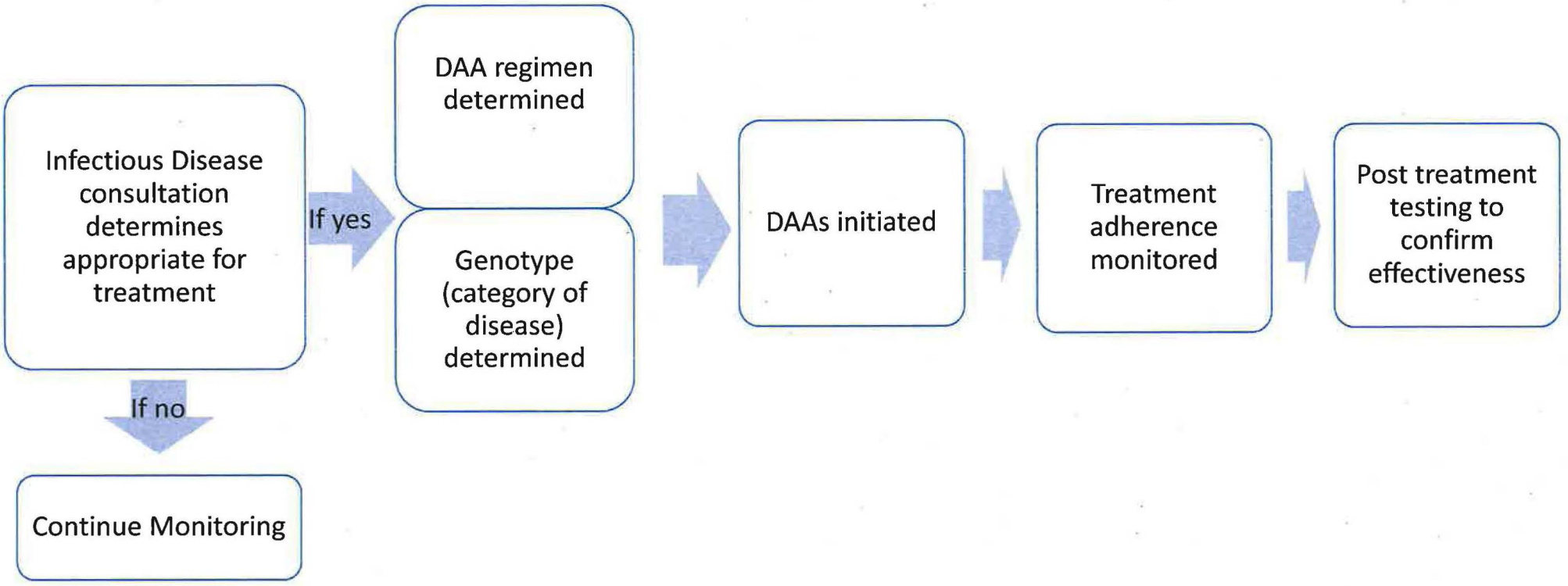


Exhibit 26

Centurion™

Centurion Disease Management Guidelines

CHRONIC HEPATITIS C VIRUS DISEASE (cHCV)

Treatment guidelines do not apply to all patients. Use your clinical judgment.
When these guidelines do not apply, document the clinical rationale for your treatment decision.
Centurion Disease Management Guidelines can be used by clients to develop contract-specific guidelines.

Introduction:
This guideline provides information regarding screening, education, routine laboratory monitoring, and clinical decision-making regarding inmate-patients who have chronic Hepatitis C Virus disease (cHCV). The goal of this guideline is for staff to understand primary care for the cHCV patient, and to identify and prioritize treatment for those patients who need it the soonest and will most benefit.

Rationale for Evaluation and Treatment of HCV-Infected Patients:
In the correctional environment, patients with a reactive HCV-Ab test were previously exposed to HCV by risk behaviors which resulted in exposure to blood, commonly through intravenous drug use or tattooing. Although many persons exposed to HCV are not viremic and resolve their infection, the large majority develop persistent HCV viremia. Patients with HCV-Ab and HCV-RNA detectable in serum have cHCV.

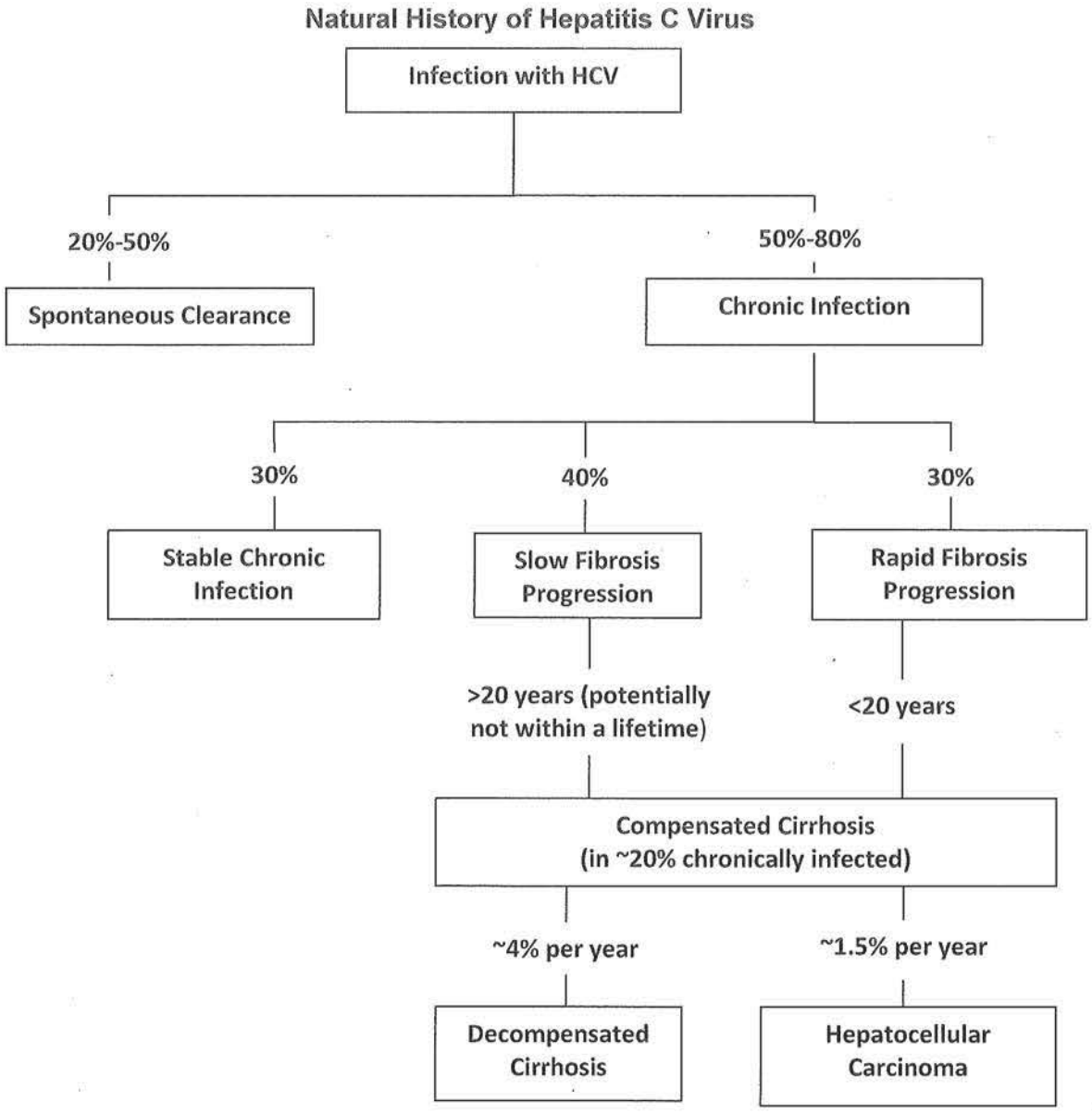
The figure below, based on the most current natural history data, indicates that a large proportion (up to 70%) of the 50% to 80% of patients infected with HCV who develop cHCV are clinically stable. They either do not demonstrate progressive hepatic fibrosis **OR,** if progression is noted, it is very slow, and natural history studies have not been able to document significant progression to end-stage hepatic fibrosis as yet. Published data reflect ~20 years of prospective follow-up, consistent with the identification of HCV in 1989 and the availability of widespread testing for HCV-Ab in 1992.

Factors associated with Rapid Progression (<20 years to cirrhosis) or death are many, including but not limited to:

- ALT elevation (especially if ALT>200, or "ALT flare")
- Non-sobriety/active drug abuse
- Grade 3 inflammation (Batts and Ludwig classification) on liver biopsy
- Presence of bridging fibrosis (Batts and Ludwig S3+/Metavir F3+) on liver biopsy
- Genotype 3 infection
- HIV co-infection
- HBV co-infection (with HIV+HBV +HCV co-infection and detectable viremia of both HIV+HBV at highest risk)
- NASH
- Diabetes and insulin resistance
- Obesity
- Daily use of marijuana
- Uncontrolled underlying liver disease

HCV risk behaviors >10 years prior to diagnosis, male, age >40 years are also associated, but are less significant in multivariate analysis. Generally, it is wise to assume that patients with more risk factors for progression also have higher risk for more rapid progression.

However, even patients with early stages of hepatic fibrosis have low rates of HCV-associated complications such as DM2, cryoglobulinemia-associated kidney disease, B-cell lymphoma, porphyria cutanea tarda, lichen planus, and other diseases which may necessitate earlier evaluation and/or treatment of cHCV. These extrahepatic manifestations of cHCV may also, along with the significant contribution of the adverse lifestyle complications associated with alcohol and drug use, affect mortality rates in patients with Batts and Ludwig S0-2, or Metavir F0-2 hepatic fibrosis.



The likelihood of chronic infection following acquisition of HCV and the rate of fibrosis progression depend on various host and viral factors. As examples, young women and children are more likely to spontaneously clear HCV infection, and if chronically infected, have relatively slow fibrosis progression rates. Refer to the UpToDate topic on the natural history of HCV infection for further details.

Factors associated with Non-Progression of Hepatic Fibrosis are not fully understood at this time and may be less well studied due to treatment bias. Non-progression is more likely in patients with the following characteristics:

- Female, age <40 years, BMI<30
- Batts and Ludwig inflammation Grade 0-1
- Batts and Ludwig S0-1/Metavir F0-1
- IL28B genotype (with C/C and C/T genotypes less likely to be associated with advanced hepatic fibrosis)
- Normal ALT (up to 75% do not have advanced hepatic fibrosis)
- Race/ethnicity (slower progression/histology less severe in black patients)
- Patients whose HCV risk behaviors have happened in the recent past (usually <5 to10 years)
- Patients without an alcohol abuse history

The contribution of sobriety/cessation of intravenous drug use (IDU) to progression of hepatic fibrosis is poorly quantitated but highly significant in terms of positive lifestyle behaviors with associated improved quality and length of life. Additionally, statin use has been associated with a lower progression rate, and caffeinated coffee consumption has been demonstrated in both retrospective and prospective trials to be associated with reduced hepatic fibrosis

Use of predictive scoring is helpful to identify patients who are more likely to have progressive hepatic fibrosis and may help inform the patient's decision as to whether to proceed:

- APRI score >0.5 or FIB-4 score of >1.45 identify ≥ 75% of patients with advanced hepatic fibrosis (Lin, *et al*
- Patients with APRI <0.5 or FIB-4<1.45 have corresponding lower risk

Proprietary indices that predict hepatic fibrosis stage such as FibroSure™ or Hepascore™ are also available with the caveat that these indices may over-predict hepatic fibrosis in the presence of increased hepatic inflammation. Conversely, the indices may do a better job of predicting which patients do not have significant fibrosis (Metavir F0-1, Batts and Ludwig S0-1) than the APRI or FIB-4.

Although an imprecise science, patients usually benefit from a thorough discussion of risk for progressive hepatic fibrosis, resulting in an improved therapeutic relationship as they have their choices informed.

Who Should be Evaluated for cHCV:

Serum antibody screening for HCV-Ab should be offered to all inmates within one year of incarceration. This may be accomplished via "opt-out," "opt-in," or mandatory screening programs.

- "Opt-out" means all inmates have HCV-Ab ordered at some point in their incarceration, and can "opt-out" with a written declination form
- "Opt-in" programs offer screening to all inmates, which can be scheduled at an appropriate date and does not require an official declination if the inmate does not wish to have the testing done at that time. Usually Opt-in programs give the option for inmates to schedule testing at a later date if desired
- Mandatory programs schedule and test inmates regardless of consent to testing.

Patients who test positive for HCV-Ab should have a reflex serum HCV-RNA quantification ("viral load") test done. Patients with HCV-Ab and detectable HCV-RNA in serum have cHCV. These patients should be scheduled with a provider for future discussion of evaluation and staging.

Evaluation of Patients With cHCV - Initial Evaluation/General Guidelines:

- Only patients with HCV-Ab and detectable HCV-RNA are eligible for further evaluation and staging of cHCV. A provider visit should be scheduled as soon as these results are known. The patient may decline further evaluation, and the declination must be documented in the patient's medical record.
- Initial laboratory evaluation of patients with cHCV should include CBC, CMP (or equivalent which must include AST, ALT, TBili, Albumin), and INR. This should be available to the provider at the time of the initial cHCV discussion with the patient.
- If the patient requests further evaluation of cHCV, lab testing including HCV genotyping, ANA, ferritin, and TSH should be ordered.
    - At the time of the initial evaluation, an APRI - AST Platelet Ratio Index (calculated as follows: [AST/ULN AST/PLT]x100=APRI score) or FIB-4 (http://www.hepatitisc.uw.edu/page/clinical-calculators/fib-4) should be computed and discussed with the patient. This screening should occur regardless of genotype.
- Patients with APRI>0.5 or FIB-4>1.45 should be offered further staging for treatment
- If APRI<0.5 or FIB-4<1.45, further staging may be offered if patient has multiple risk factors for hepatic fibrosis progression (see www.hcvguidelines.org), which may include the following:
    - Male
    - Estimated time of infection >20years
    - Age >40 years old
    - History of alcohol abuse
    - Non-alcoholic fatty liver disease
    - Obesity
    - Insulin resistance
    - Genotype 3 infection
    - Co-infection with HIV or HBV
    - Concurrent liver disease (such as hemochromatosis) which has been poorly treated in past.

Evaluation of Patients With cHCV - Patient Eligibility for Further Staging/Treatment:

- All chronic medical conditions which could impact cHCV treatment should be under acceptable control
- Generally, patients who have not been clean/sober for at least 12 months prior to treatment initiation and/or with new tattoos are not eligible for treatment. This restriction corresponds to eligibility criteria for all agents presently approved by the FDA
- Behavioral risk reduction and substance abuse counseling is an integral part of cHCV treatment. The use of peer educators has been shown to have the greatest impact in this area. Patients should have pro-sobriety attitudes assessed and documented in the medical record. Patients with high propensity for relapse may need more extended time periods of sobriety prior to treatment as deemed appropriate by the clinical care committee or equivalent. Unfortunately, there is no evidence at this time that institutionally-mandated substance abuse programs improve outcomes over incarceration alone. Patient-driven substance abuse treatment such as NA or AA groups with peer educators and sponsors have demonstrated improved outcomes and decreased substance abuse relapse rates post-release. Patients should be encouraged to participate in these programs.
- Eligibility based on length of stay post-treatment should:
    - Allow sufficient time for patients to recover from aIFN-inclusive treatment regimens in order for the patient to be optimally functional upon release
    - Ensure patients know that whether or not they have responded to therapy, patients with established sustained viral responses (SVRs) prior to discharge are known to

have decreased rates of substance abuse relapse and re-infection
- Sufficient time for an SVR12 (weeks for Direct-Acting Antivirals) or SVR24 (weeks for aIFN-based treatment) is strongly advised
- Time until release at the initiation of therapy incorporates sufficient time for routine or unexpected system issues, such as inter-institutional transfers, to not compromise treatment.

Since these factors may vary significantly between correctional systems, individual systems may vary in length of stay post-treatment eligibility. In general, one year of remaining incarceration at the time of treatment initiation is a reasonable guideline for eligibility.

- Behavioral Criteria: cHCV patients' attitudes, functional ability to thrive within the system, and optimal treatment of mental health issues are critical for good outcomes.
  - Patients who have chronic disciplinary issues within the system have very high substance abuse relapse rates upon release, with newer evidence indicating higher re-infection rates. Patients should be counseled and observed on a case-by-case basis, and involvement of mental health professionals is critical.
  - Critical to remember that patients who have chronic behavioral management issues, common in jails/prisons, rarely are able to establish and maintain a therapeutic provider-patient relationship which results in completion of treatment and an SVR. Patients who are unable to follow the rules and establish and maintain such a relationship with healthcare staff may be ineligible for treatment.

Staging of Hepatic Fibrosis:
- Patients who have APRI>2.0, FIB4>3.25, evidence of portal hypertension on abdominal U/S (including use of the PLT/spleen diameter ratio), or other clinical/lab evidence of cirrhosis do not usually need further confirmation by elastography or liver biopsy
- Discordance between lab indices should be resolved by elastography or liver biopsy regardless of genotype
- If necessary, APRI and/or FIB4 should be used to prioritize further screening such as mobile ultrasound elastography, MRE, or liver biopsy. Higher numbers receive higher priority

Prioritization for Treatment:
- Patients with S3 (Batts and Ludwig) or F3 (Metavir) or higher hepatic fibrosis will be highest priority for treatment.
- Patients with life threatening extrahepatic manifestations of cHCV will be prioritized for immediate treatment
- Evidence of liver biopsy of G3 (Batts and Ludwig) or higher inflammation in a patient with S2 fibrosis should also be considered for placement in the priority treatment category. In paired liver biopsy studies, this group of patients all progressed to cirrhosis within 9 years and 50% progressed to cirrhosis within 4 years.
- When making less clear prioritization decisions, patients with multiple risk factors for accelerated fibrosis progression should be prioritized. Examples: patients with genotype 3 progress faster, as do patients having co-infection with detectable viremia of HIV/HBV or other co-existent liver disease (hemochromatosis)

Use of concordance in diagnostic modalities to establish eligibility for treatment: In an increasing number of cases, the liver biopsy may not be or is not chosen by local experts to be the definitive answer for eligibility. Some experts presently believe that there is no "gold standard" of hepatic fibrosis staging and prefer to establish presence of advance hepatic fibrosis through concordance between laboratory, imaging, and predictive scoring (APRI, FIB-4, or proprietary indices). In these instances, concordance must exist between at least two of the

listed four modalities (laboratory AND imaging evidence of cirrhosis or imaging AND predictive scoring consistent with cirrhosis). Use of proprietary indices alone to establish eligibility is discouraged because the proprietary indices may over-predict hepatic fibrosis in the presence of increased hepatic inflammation.

Special considerations of patients undergoing liver biopsy: Usually, liver biopsies should be performed only on patients who will be potential candidates for treatment. Liver biopsies remain the best medical evaluation to determine the stage of hepatic fibrosis, which yields information vital to deciding whether to treat and the urgency of treatment. However, liver biopsies may underestimate and never overestimate the level of hepatic fibrosis. This sampling error may result in 1 stage differences between the right lobe (usually sampled due to safety concerns) and the left lobe in ~1/3 of biopsies. In ~1/6 of patients, this is the difference between fibrosis stage 3 and cirrhosis. Other disadvantages include invasiveness with potential for peri-operative events (usually bleeding or vasovagal reactions), and variability of pathologist's interpretation.

If the liver biopsy indicates severely advanced fibrosis, patients should be referred for EGD to assess for the presence of esophageal varices, and regular abdominal imaging with U/S every 6 to 12 months for hepatocellular carcinoma (HCCa) screening should be initiated. EGD referral may also be indicated if the platelet/spleen diameter ratio is < 900 (Gianni EG, Zaman A, Kreil A, et al).

Repeat biopsies in 4 to 5 years may be necessary to establish progressive fibrosis and/or document the presence of S3+/F3+ hepatic fibrosis.

Treatment Recommendations - General Guidelines (December 2014 – Updated January 2016):

- Treatment recommendations are a changing target at the present time and will be amended as new agents become available and as more cost-effective choices can be made within the present standard of care. These changes will be incorporated as new recommendations are added to www.hcvguidelines.org and then evaluated for correctional suitability and relevance.
- All treatment decisions will be made by the appropriate providers, using the clinical practice guidelines and appropriate administrative prioritization based on available resources. When using the present choices for therapy, cost-effectiveness is a valid selection criterion in choosing one agent over another, especially as more medications become available.
- At this time, treatment of patients with fibrosis ≤ stage 2 (Batts and Ludwig) fibrosis of lower priority. (Exceptions could be patients with HIV infection or other diseases for which evidence indicates that progression of hepatic fibrosis is inevitable, and controlling hepatic fibrosis will assist in controlling other underlying diseases. These issues will be discussed at the clinical care committee or equivalent on a case-by-case basis).
- Patients should be involved in decision-making, and prioritization of care should be explained and documented transparently in the medical record. The medical record needs to reflect individualized assessment and assignment to the appropriate treatment priority group and the plan for long-term management of those in the deferred treatment group and whether treatment was deferred medically or administratively.
- Medical record notes referring to discussion of available resources are necessary, very common, and should remain objective. As an example, a clinical oncologist may write:
  "Case reviewed at tumor board, patient is a candidate for [appropriate treatment regimen]. Treatment should be started within [appropriate time period]. Discussed with patient, he agrees to proceed. Treatment deferred pending insurance approval. Will discuss with [appropriate insurance reviewer], review case with patient in [appropriate time period]."

A rheumatologist will write a similar note when advocating for biological therapies. The same elements that we need to put in our notes are there. Example of our note would be:

> *"Case reviewed at [review board name at your institution], and fulfills criteria for [appropriate treatment choice]. Treatment should be started within [appropriate time period] to avoid progression of hepatic fibrosis and further HCV-related complications. Discussed with patient, he agrees to proceed. Referred to [appropriate entity] for administrative review and resource prioritization. Will follow up within [appropriate time period]."*

Our medical record notes should be clear, transparent in regards to evaluation and prioritization, and reflect our ethical principles, while remaining respectful to all people involved.

- Although all medications used in the recommendations are FDA-approved, off-label use of these medications may be recommended as literature evidence interpreted by expert consensus develops.
- Directly observed therapy is strongly advised, with routine adherence checks documented by both nursing and provider staff.

Specific Guidelines Regarding Individual Agent Use: Although treatment regimens are changing rapidly as new agents become available, consensus has developed around several available treatment regimens. Usually 8 to 12 week regimens are preferred due to improved adherence, lower toxicity, and maximal cost-effectiveness:

cHCV-1a:

- HARVONI® 1tab PO QD 8 wks (56 doses) if no previous treatment and VL<6million copies when staging indicates </=S3/F3 and no evidence of cirrhosis on abdominal U/S.
- HARVONI® 1tab PO QD 12 wks (84 doses) if no previous treatment experience and VL ≥ 6 million copies.
- HARVONI® + RBV (weight based dosing) 12 wks in patients with Class A cirrhosis and/or previous treatment experience.

cHCV-1b: As above except patients with Class A cirrhosis or previous treatment experience do not generally need RBV

cHCV-2 (all subtypes):

- SOFOSBUVIR (SOF) + RBV (weight based), 12 weeks if not cirrhotic
- SOF + RBV (weight based) 16 weeks if Class A cirrhosis is present.
- Alternatively, in patients who do NOT have underlying medical conditions such as respiratory disease which would preclude the use of aIFN + RBV (PR), the patient may enter a 4 week PR lead-in, then if a Rapid Viral Response (RVR: VL not detected at end of 4 weeks PR) is present patient completes 24 weeks total PR. In patients who do NOT experience RVR, default to guideline recommended SOF+RBV 12 weeks.

cHCV-3 (all subtypes):

- PR + SOF 12 weeks remains the only presently available regimen with demonstrated SVR>90% in patients with or without cirrhosis. Platelet count <100k a relative contraindication and <75k is an absolute contraindication for aIFN due to acute hepatic failure during treatment with increased mortality.

cHCV-4,5,6 or Unusual cases:

Per www.hcvguidelines.org as applied by the institutional, regional, or system clinical care committee or equivalent on a case-by-case basis

Expert guidance should be sought and incorporated in each case

Guidelines will be revised as new drugs become available and can be used efficiently within the correctional environment (arrival of VELPATASVIR in 2016 may change recommendations for cHCV-3 treatment for patients who are ineligible for aIFN)

Special Treatment Considerations with use of specific antiviral drugs:
For patients who will be taking a regimen containing **RIBAVIRIN**:

- Patient is not pregnant
- Women of childbearing potential and within 6 months of treatment conclusion agree to use of two forms of effective birth control post-release with male partners. This should usually be accomplished by treatment initiation within 12 months prior to release

For patients who will be taking a regimen containing **ALPHA-INTERFERON (Pegasys®),** patients must NOT have the following:

- Platelet count <100k a relative contraindication, and <75k is an absolute contraindication for aIFN due to acute hepatic failure during treatment with increased mortality. Risk for acute hepatic failure during IFN treatment is usually ~2% but with these levels has been observed to be ~4%.
- Major uncontrolled depressive illness
- Solid organ transplant (renal, heart or lung)
- Autoimmune hepatitis or other autoimmune condition known to be exacerbated by aIFN-based therapies (inflammatory bowel disease, rheumatoid arthritis, ITP, SLE, severe psoriasis)
- CHF, LVEF<40%
- COPD, FEV1<1.0

For patients who will be taking a regimen containing **VIEKIRA PAK®** with concurrent cirrhosis, the cirrhosis class must be Class A only. Class B/C cirrhosis patients are excluded due to the potential of drug related hepatotoxicity

Laboratory Monitoring:

- aIFN and/or RIBAVIRIN based regimens: Monthly CBC and CMP every 3 months during treatment
- Patients taking aIFN containing regimens should also have TSH prior to and at 3 months of treatment. At least one post-treatment assessment should be performed to document resolution of aIFN induced hematologic toxicity.
- SVR12 weeks for all regimens.

References:

- American Association for the Study of Liver Diseases (AASLD) and Infectious Diseases Society of America (IDSA) jointly published *Recommendations for Testing, Managing and Treating Hepatitis C.* (www.hcvguidelines.org)
- Lin, *et al*; *Hepatology*, March 2011
- Gianni EG, Zaman A, Kreil A, et al); Am J Gastroenterol 2006 Nov; 101:2511-9; (http://www.ncbi.nlm.nih.gov/pubmed/17029607)
- Uptodate. Clinical manifestations and natural history of chronic hepatitis C virus infection, August 6, 2015