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ETHICS FEATURE

Moral Distress with Obstacles to Hepatitis C Treatment: A Council of Academic Family Medicine Educational Research Alliance (CERA) Study of Family Medicine Program Directors

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Background and Objective: **To determine whether family medicine program directors (PDs) experienced moral distress due to obstacles to Hepatitis C virus (HCV) treatment, and to explore whether they found those obstacles to be unethical.**

Design: **An omnibus survey by the Council of Academic Family Medicine's Educational Research Alliance was administered to 452 and completed by 273 US-based PDs. The survey gauged attitudes and opinions regarding ethical dilemmas in patient access to HCV treatment.**

Results: **Most of the respondents were male. Sixty-four percent of respondents believed that treatment should be an option for all patients regardless of cost. Forty-one percent believed that it was unethical to deny treatment based on past or current substance use, and 38% believed treatment should be offered to patients who were substance abusers. Moral distress was reported by 61% (score >3) of participants when they were unable to offer treatment to patients due to the patient's failure to meet eligibility criteria. In addition, PDs reporting moderate-to-high levels of moral distress were also likely to report the following opinions: 1) treatment should be offered regardless of cost, 2) it is unethical to deny treatment based on past behavior, 3) substance abusers should be offered treatment, 4) it is unethical for medicine to be prohibitively expensive, and 5) Medicaid policy that limits treatment will worsen racial and ethnic disparities.**

Conclusions: **Currently, important ethical dilemmas exist in the access and delivery of HCV therapy. Although a diversity of opinions is noted, a significant proportion of PDs are concerned about patients' inability to avail equitable care and experience distress. In some cases, this moral distress is in response to, and in conflict with, current guidelines. (J Am Board Fam Med 2018;31:286–291.)**

Keywords: **Hepatitis C, Hepacivirus, Medical Ethics, Surveys and Questionnaires**

With nearly 4 million infected individuals, Hepatitis C virus (HCV) is the leading cause of end-stage liver disease, hepatocellular carcinoma, and liver transplantation in the United States.[1] We are at the forefront of significant change in the treatment landscape. In the past, interferon-based regimens were associated with serious side

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Conflict of interest: AS, CMW, RP, NRK, and PJV conceived the study. CMW, AS, and RP analyzed the data. CMW, AS, NRK, PJV, and RP drafted and edited the manuscript. All authors reviewed and approved the final manuscript. AS had full access to all the study data and takes responsibility for the integrity and accuracy of the data and data analysis. No competing interests exist for any of the authors.

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effects and few patients were deemed candidates for therapy.[1–4]

Recently approved direct-acting antivirals, such as sofosbuvir, ledipasvir, and daclatasvir have demonstrated high efficacy with minimal toxicity, making it possible to treat nearly all HCV-infected patients.[6–7] Hepatitis C treatment guidelines jointly developed and issued by the American Association for the Study of Liver Disease and the Infectious Disease Society of America note that treating HCV infection results in a dramatic reduction in all-cause mortality and substantially improves quality of life. In addition, the guideline supports antiviral therapy being offered early in the course of the disease to prevent severe liver disease and other complications.[5]

A 12-week course of sofosbuvir and ledipasvir costs nearly $100,000.[7–9] Historically, substance use and psychiatric disorders were primary reasons patients were not initiated on treatment. Current criteria, put forth by several state Medicaid programs, makes the treatment available only to the most advanced cases AND excludes patients with evidence of substance abuse in the past 12 months.[9] As a result, patients risk being denied access to these therapies because of presumptive judgments about their ability to adhere to the prescribed regimens. As a result, the remarkable recent advances in HCV treatment have elicited an equally dramatic ethical corollary: the difficulty of ensuring equitable access. Beyond issues of capacity to deliver care and resource allocation, policies and unresolved ethical dilemmas limit the successful translation of these advances to patients.

The previous dilemmas cause moral distress for practitioners. Moral distress is the sense of psychological disequilibrium caused by a situation in which someone believes they know the ethical action to take, but find they are shackled from doing so by institutionalized obstacles.[10–12] Eventually, this disequilibrium results in symptoms of negative stress.[9] In this context, the attitudes and degree of moral distress experienced by family medicine residency program directors (PDs) as a result of the ethical dilemmas surrounding patient access to HCV treatment have not been examined. We report the results of a nationwide survey of family medicine residency PDs to explore ethical dilemmas confronting family medicine thought leaders regarding patient access to HCV treatment, and to measure the degree of moral distress they experience. In addition, we examined whether moral distress strengthens PDs' ethical intentions. We hypothesized that family medicine PDs experience significant moral distress in caring for patients living with chronic HCV who are unable to access treatment and that these PDs would differ in their determination of the point at which benefit outweighs cost under the current guidelines.

Methods

This survey was part of a larger omnibus survey conducted by the Council of Academic Family Medicine Educational Research Alliance (CERA). Each year, 5 to 6 topics are chosen consisting of 10 questions each, in addition to core questions. The CERA Steering Committee evaluates questions for consistency with the overall subproject aim, readability, and existing evidence of reliability and validity. We conducted pilot testing on family medicine educators who were not part of the target population. Questions were modified following pretesting for flow, timing, and readability.

Sample

This study was part of a larger CERA omnibus survey administered between February 2015 and March 2015.[4,13] The study protocol was reviewed and approved by the Institutional Review Board of the American Academy of Family Physicians. Of the 452 PDs who received surveys, 273 responded. Family Medicine PDs were chosen for this survey because they represent key influencers in charge of educational curricula within family medicine. In addition, a recent study by our group documented that most PDs (78%) believe chronic HCV represents a significant problem for primary care. Furthermore, 62% of PDs believe that their program should take steps to build capacity in HCV treatment.[14]

Webb C, Simha A, Kolb N, Prasad R. Do family physicians experience moral distress when confronted with Hepatitis C infected patients? A nation-wide survey of program directors. Presented at the Society of Teachers of Family Medicine Annual Conference, Minneapolis, MN, April 30 to May 4, 2016.

Webb CC, Simha A, Kolb RN, Prasad R. Intent to build Hepatitis C treatment capacity within family medicine residencies: A nation-wide survey of program directors. Fam Med 2016;48:631–634.

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Table 1. Baseline Characteristics of Family Medicine PDs (Responses by US Region*, Collected between February 2015 and March 2015)

Characteristic	Overall (N = 273)	Northeast (N = 52)	Midwest (N = 58)	South (N = 96)	West (N = 67)
Residency Program Context					
Size of community (population)					
<150,000 (n)	**123**	39	25	44	15
150,000–500,000 (n)	**64**	7	17	20	20
>500,000 (n)	**86**	6	16	32	32
Proportion of community-based programs (%)	**78**	84	73	77	82
Average age of program (years)	**32.7**	35.2	33.9	33.8	28.2
Proportion of programs with > 25% graduates from non-US medical school (%)	**48**	63	46	55	28
Residency PD characteristics					
Male (%)	**64**	61	71	64	60
Tenure (years)	**6.3**	7.4	6	6.1	6
PD attitudes toward statements pertaining to HCV treatment-related ethical issues (Agree responses, %)					
"Treatment should be an option for all patients with HCV regardless of cost"	**70**	65	74	69	72
"State Medicaid programs' decision to limit access to HCV treatment will worsen racial and ethnic disparities in health care"	**70**	63	72	74	69
"It is unethical to deny access to treatment based on the patient's past or current behavior"	**47**	44	50	52	39
"It is unethical that a potentially lifesaving medicine is so highly priced"	**69**	52	79	70	69
"Patients with active substance abuse should be offered HCV treatment"	**38**	42	38	42	28
"Benefit outweighs cost only for patients with advanced liver disease"	**35**	38	26	42	30
Moral distress (To what extent do you experience moral distress when you are unable to offer hepatitis C treatment to patients due to them not meeting current eligibility criteria?)					
Moral distress (high level)	**61**	60	60	57	69

*US regions as classified by the Center for Disease Control (CDC), https://www.cdc.gov/std/stats11/census.htm.
PD, program director.
HCV, Hepatitis C virus.

Questionnaire

We assessed attitudes and opinions of PDs regarding the ethical dilemmas inherent to patient access to HCV treatment. A Likert scale ranging from 1 = strongly disagree to 6 = strongly agree was used to assess PD attitudes. In addition, the degree of moral distress experienced by PDs was also measured. Moral Distress was measured by the question, "Moral distress occurs when you know the ethically correct action to take but feel powerless to take that action. To what extent do you experience moral distress when you are unable to offer hepatitis C treatment to patients due to them not meeting current eligibility criteria?" That scale was from 0 to 7, validated on prior moral distress studies.[19]

Data Analysis

Before embarking on the analysis, intercorrelations between the variables were assessed. The recommended procedure was followed for regression analysis.[16] All analyses were performed using SPSS version 24 (Armonk, NY: IBM Corp).

Results

Out of 452 PDs who received the survey, 273 responded, for a response rate of 61%. Most re-

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Table 2. Matrix Highlighting Correlations between PD Characteristics' and Their Attitudes

	Variable	Mean	SD	1	2	3	4	5	6	7	8
1	Program Director Tenure	6.05	5.73	1							
2	Age of Program	32.31	14.31	0.095	1						
3	Gender	1.63	0.49	−0.002	0.044	1					
4	Moral Distress	4.59	1.93	−0.052	0.101	−0.155*	1				
5	Belief in Worsening Disparity	4.21	1.43	0.016	0.022	−0.264†	0.402†	1			
6	Intent to offer treatment to active substance users	3.08	1.48	0.068	0.148*	−0.094	0.177†	0.309†	1		
7	Intent to offer treatment regardless of past or current behaviors	3.34	1.53	0.018	0.08	−0.254†	0.337†	0.427†	0.531†	1	
8	Belief that it is unethical for life saving medicine to be so expensive	4.11	1.56	0.073	−0.026	−0.276†	0.419†	0.477†	0.212†	0.374†	1
9	Belief in Treatment regardless of cost	4.07	1.4	−0.042	0.134*	−0.174†	0.362†	0.413†	0.445†	0.556†	0.280†

N = 272.
*$P \leq .05$.
†$P \leq .01$.
PD, program director; SD, standard deviation.

spondents were male, from community-based programs, and had spent less than 5 years in their position (Table 1). Sixty-four percent believed that treatment should be an option for all patients regardless of cost. A smaller percentage (41%) believed it was unethical to deny treatment based on past or current behavior such as substance use, and 38% believed treatment should be offered to patients with substance abuse. A majority (61%) expressed moral distress (score >3) when unable to offer treatment to patients due to them not meeting eligibility criteria.

The effect of Regional HCV prevalence, residency program context, and PD characteristics on PD attitudes was not statistically significant. Those who believed treatment should be an option for all patients with HCV regardless of cost also believed it is unethical for potentially lifesaving medicine to be so highly priced, and equally were more likely to believe that patients with active substance abuse should be offered HCV treatment.

Table 2 presents the intercorrelations between our variables. All the PD attitude variables correlated significantly with moral distress. The PD attitude variables also correlated significantly with one another. We regressed all the various PD attitudes and beliefs on moral distress, these are shown in Table 3. We found that moral distress had a significant effect on almost all the attitudes we assessed. Essentially, our results indicate that PDs experiencing moderate-to-high levels of moral distress believed that 1) treatment should be offered regardless of cost, 2) it is unethical to deny treatment based on past behavior, 3) substance abusers

Table 3. Association of Moral Distress (Independent Variable) with Program Director Beliefs

	Belief Statement	Beta Weight
1	Belief in offering treatment regardless of Cost	0.36*
2	Belief that Benefit Outweighs Cost Only for Advanced Liver Disease	−0.017
3	Belief that it is unethical to deny treatment Based on Past Behavior	0.333*
4	Belief that substance abusers should be offered HCV Treatment	0.177*
5	Belief that it is unethical for HCV Medicine to be so prohibitively expensive	0.415*
6	Medicaid policy limiting treatment will worsen racial and ethnic disparity	0.397*

*$P < .001$.
HCV, Hepatitis C virus.

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should be offered treatment, 4) it is unethical for the medicine to be so prohibitively expensive, and 5) Medicaid policy limiting treatment will worsen racial and ethnic disparities. The only attitude that was not predicted by moral distress was the one pertaining to the belief that benefit outweighs costs only for patients with advanced liver disease. These findings essentially indicate that PDs believe that HCV treatment should be offered to all patients regardless of the cost of treatment, patient history, or patient substance usage status. In addition, the Medicaid policies and the expensive nature of these drugs are viewed as unethical and problematic by the surveyed PDs.

Discussion

This is the first study to report on the attitudes and moral distress experienced by family medicine residency PDs due to the ethical dilemmas surrounding patient access to HCV treatment. The opinions of Family Medicine PDs are particularly valuable because they represent key influencers in charge of educational curricula within family medicine. Our results reveal that while a diversity of opinion exists, the majority of PDs experience ethical dilemmas pertaining to the inability of their patients to access HCV therapy.

Currently, a course of HCV therapy can be up to $100,000 for a 12-week course of antivirals. Most PDs believed that treatment should be available regardless of cost to patients in need of therapy. This is in line with available evidence that suggests that early treatment of hepatitis C infection is cost effective.[17]

Currently, patients with a history of prior substance use are sometimes at risk of being denied access to HCV therapy because of presumptive judgments about their ability to adhere to medical regimens. Significantly, most PDs (53%) agreed that it was unethical to deny access because of substance abuse. Furthermore, a smaller percentage expressed the believed that even patients with active substance abuse should be offered treatment. These attitudes are consistent with the available evidence as studies reveal that that even among persons who inject drugs, adherence to treatment programs can be high and rate of reinfection is low.[18]

With safe and effective therapy available, the decision to defer treatment is equally as deliberate as the decision to start treatment. The decision to defer treatment exposes patients to several dilemmas: 1) limitations in accurately staging liver disease with commonly available tools in primary care; 2) limitations in the ability to predict the progression of fibrosis; 3) an uncertain timeline for the availability of newer agents at more affordable prices; 4) even existing patient insurance status may change over time; 5) in addition to the development of liver cirrhosis, liver failure, and liver cancer, other health comorbidities may arise from chronic hepatitis C infection; and 6) transmission of hepatitis C to other patients. Current policies do potentially pose a situation where patients may be told to wait until they have more advanced disease.[8–9,15] In light of these risks, physicians have a moral obligation to ensure that patients understand the risks and benefits of deferral, just as they would if treatment was given. Applying the principles of shared decision making is particularly important in the context of life-threatening illnesses.[20]

Limitations

The response rate of our study was 60%. We did not have data for nonrespondents. While data reflected the opinions of thought leaders within family medicine, it may not reflect the opinion of all family medicine physicians. Since this article examines the 2 main reasons patients are denied HCV care: money and substance use, the possibility of confounding exists. A future study conducted on a larger sample of family medicine physicians may be necessary to establish the generalizability of our findings. In addition, future research should examine the social justice implications of varying levels of restriction by state Medicaid programs.

Conclusion

Currently, important ethical dilemmas exist in the access and delivery of HCV therapy. While a diversity of opinions is noted, a significant proportion of PDs are concerned about patients' inability to avail equitable care and experience distress. In some cases, this moral distress is in response to, and in conflict with, current guidelines. A concerted effort should be made involving all stakeholders to address these issues at policy and practice levels.

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