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Challenges facing providers caring for HIV/HCV-coinfected patients

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Abstract

Despite the high prevalence of Hepatitis C virus (HCV) infection among injection drug users also infected with Human immunodeficiency virus (HIV), and the synergistic adverse effect of the two diseases on patients' health and survival, the research on the clinical management of these patients and particularly the low uptake of HCV therapy is limited. We conducted qualitative interviews with 17 HIV providers from two urban public hospitals. We discovered that the limitations of the current state of medical knowledge, the severe side effects of HIV and HCV therapies, and the psychosocial vulnerability of HIV/HCV-coinfected patients combined with their resistance to becoming informed about HCV posed significant challenges for providers. To contend with these challenges, providers incorporated key dimensions of patient-centered medicine in their practice such as considering their patients' psychosocial profiles and the meaning patients assign to being coinfected, and finding ways to engage their patients in a therapeutic alliance.

Keywords

health care; health care professionals; hepatitis C; HIV/AIDS; marginalized populations

In the United States, approximately 33% of persons infected with Human immunodeficiency virus (HIV) are coinfected with Hepatitis C virus (HCV), and among HIV-infected past or current injecting drug users, 50-90% have been found to be HCV coinfected (Centers for Disease Control and Prevention, 2004; Sulkowski, 2008b). Although HIV accelerates the progression of liver disease, one of the primary causes of mortality among HIV/HCV-coinfected patients, only a fraction of these patients are treated for HCV (Clanon, Mueller, & Harank, 2005; Sulkowski, 2008a). Based on conservative estimates, 30% of the HIV/HCV-coinfected patients are medically eligible for HCV treatment, yet across different studies only 3-13% of those eligible receive treatment (Adeyemi et al., 2004; Fleming, Tumilty, Murray, & Nunes, 2005; Fultz et al., 2003).

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To address the extensive under-treatment of HCV among HIV-coinfected patients, the medical community has issued guidelines and recommendations that encourage wider treatment of HCV among HIV-coinfected patients, and state that being an active drug user and/or having a psychiatric diagnosis should not automatically disqualify a patient from HCV therapy (Strader, Wright, Thomas, & Seeff, 2004; Sulkowski, 2008a). However, recognizing the challenges of applying treatment guidelines in practice, the community also recommended that each coinfecting patient must be evaluated for HCV treatment “on a case-by-case basis.” (Sulkowski, 2008a, p. 5)

This realization that coinfecting patients' eligibility and readiness for HCV treatment ought to be individually assessed suggests the need to practice patient-centered medicine that respects the patients' values and preferences and empowers them to share in the control of their therapeutic experience by “incorporating patients' perspectives into medical care.” (Laine & Davidoff, 1996, p. 154) Although a variety of definitions of patient-centered medicine have been offered (Balint, 1969; Keirns & Dorr Gool, 2009; Stewart et al., 2003), five key dimensions characterize practicing this type of medicine. These are to: consider the biopsychosocial features of a patient's life; understand the meaning patients assign to their illness experience; develop an egalitarian patient-provider relationship that allows patients to collaborate in their care; establish a therapeutic alliance with each patient; and recognize that the providers' own values and experiences shape how they practice medicine (Mead & Bower, 2000).

In this article, using data from a sample of HIV providers, we demonstrated that patient-centered medicine was the overarching strategy they adopted to manage the variety of challenges they encountered in treating their HIV/HCV-coinfected patients' HCV. Some of these challenges have been classified in the literature under four interrelated domains: the arduous nature of HCV therapy, the patients' complicated medical and psychosocial profiles, environmental or systemic obstacles (such as, delays in referrals to liver specialists; lack of psychiatric services), and provider-related barriers (such as, lack of HCV knowledge; perceptions of non-adherence) (Dore & Thomas, 2005; Mehta et al., 2005). The intersection of treatment-, patient-, and context-related challenges, we suggested, determined the providers' own readiness for treating HCV in patients with HIV and supported their patient-centered practices. Researchers, as discussed below, have identified many of the challenges providers of coinfecting patients face, but have not examined their impact on their practice or whether they engage in “case-by-case” medicine.

To date, pegylated Interferon in combination with Ribavirin (IRT) is the only approved treatment for HCV. The duration of this therapy is long, ranging from six to twelve months. Also, the Interferon is administered weekly with an injection, which patients with injecting drug use (IDU) history perceive as a possible trigger for drug relapse, and thus, as a deterrent to initiating treatment (Bova, Ogawa, & Sullivan-Bolyai, 2010; Fleming et al., 2005).

The physical and especially neuropsychiatric side effects associated with IRT underlie both providers' reluctance to prescribe and patients' hesitation to undergo the therapy (Fleming et al., 2005; Grebely et al., 2008; Mehta et al., 2008; Thompson et al., 2005). The flu-like

symptoms (such as fever, myalgia, headaches, sweats, and fatigue) commonly experienced by those on IRT undermine the patients' quality of life (Dore & Thomas, 2005; Silberbogen, Ulloa, Janke & Mori, 2009; Wagner & Ryan, 2005). Further, these debilitating physical side effects, particularly fatigue, are akin to the symptoms of depression, and thus might intensify the severity or contribute to the onset of depression (Marcellin et al., 2007; Weiss & Gorman, 2006). Depression, anxiety, and suicidality, Interferon's most common neuropsychiatric side effects, have been identified as major obstacles to placing coinfecting patients on IRT and reasons for provider- and patient-initiated treatment discontinuity (Sulkowski, 2008a; Weiss & Gorman, 2006). Given IRT's severe side effects, some providers view the therapy as "too burdensome to patients," especially given its limited efficacy (Wagner & Ryan, 2005, p. S192), and this perception detracts from their motivation to offer the treatment. A few provider surveys have revealed reasons for classifying patients as ineligible for IRT (Fultz et al., 2003; Thompson, Ragland, Hall, Morgan, & Bangsberg, 2005). However, there is a lack of data on how providers' treatment decisions are shaped by their assessment of IRT's side effects against its effectiveness (see exception, Wagner et al., 2009).

This decision is also complicated by patients' psychosocial profiles. Most IDUs and therefore many coinfecting patients are psychologically disadvantaged and socially marginalized. These features increase the risk of Interferon-induced depression and suicidality and further undermine the providers' motivation to prescribe IRT. Providers' perception of their coinfecting patients as psychosocially vulnerable often accounts for classifying them as ineligible for HCV therapy. Many providers consider depression and other mental illnesses (e.g., schizophrenia, bipolar disorder), illicit drug use (typically injection drug use), heavy alcohol consumption, and living instability (e.g., incarceration, homelessness) as contraindications to offering or reasons for deferring HCV treatment (Adeyemi et al., 2004; Fleming et al., 2005; Fultz et al., 2003; Nunes et al., 2006). Patients with these psychosocial vulnerabilities are also more likely to refuse treatment, even when offered (Fleming et al., 2005; Grebely et al., 2008; Mehta et al., 2008).

Although researchers have unequivocally demonstrated that these psychosocial disadvantages are barriers to initiating IRT, the ways they factor into the providers' treatment decision-making and account for the therapy's low uptake have not been adequately explored. Moreover, there is an inconsistency across studies in how these disadvantages are conceptualized and therefore differences in the explanations offered for how they undermine the prescription and use of IRT. For instance, patients' lack of motivation or refusal to initiate IRT in some studies is placed in the same category as drug use and severe mental illness, and is defined as a contraindication to provider offering HCV treatment (Adeyemi et al., 2004; Thompson et al., 2005). In other studies, patient treatment refusal is defined as a barrier providers face after they had deemed a patient eligible and offered treatment (Fultz et al., 2003; Nunes et al., 2006).

Although researchers have recognized the important impact of environmental or clinic resources on treatment uptake, in their analyses they decontextualize treatment contraindications from the particular clinic settings. Delays in referrals and evaluations of coinfecting patients (including the performance of liver biopsies) by gastroenterologists (GE)

have been identified as treatment barriers that detract from both the providers' and the patients' motivation to engage in HCV therapy (Thompson et al., 2005). Reviews of the medical literature have suggested that integrating liver specialists in HIV clinics will increase the uptake of IRT, and have advocated the integration of GE services in HIV clinics (Dore & Thomas, 2005; Wagner & Ryan, 2005). The provision of substance use and psychiatric services also has been recommended as necessary for increasing IRT's uptake (Corcoran, 2003; Fuller, Loftis, Rodriguez, McQuesten, & Hauser, 2009; Weiss & Morgello, 2009).

A multidisciplinary team approach has also been advocated by researchers as a means to overcome provider-related obstacles to HCV treatment. The complexity of treating HCV in the presence of HIV, the potential hepatotoxicity of HIV antiretrovirals, the risk of interactions between IRT and HIV regimens, and the lack of provider knowledge and experience in engaging their coinfecting patients in IRT have been identified as treatment barriers (Mehta et al., 2005; Soriano et al., 2007; Sulkowski, 2008a). A few empirical studies have also indicated that providers from a variety of specialties (including infectious diseases) lack HCV knowledge and the ability to accurately assess their patients' substance use and mental health, and thus, evaluate their readiness to adhere to HCV treatment (Clanon et al., 2005; Fultz et al., 2003).

In this article, based on interviews with HIV primary providers managing coinfecting patients, we examine the reasons underlying the low rates of HCV treatment among these patients and shows that providers practice "case-by-case" or patient-centered medicine.

Methods

Sample Description

This analysis is based on semi-structured qualitative interviews with 17 primary medical care providers, 7 nurse practitioners (NPs) and 10 physicians (MDs), who practiced in the HIV clinics of two urban public hospitals. These clinics served large HIV-infected and HIV/HCV-coinfecting patient populations (1300 and 600 patients, respectively) that were mostly socioeconomically disadvantaged. Most of the coinfecting patients had a history of IDU. From these clinics, the research team also recruited and interviewed 132 coinfecting patients about their two diseases.

To be eligible for inclusion in the provider sample, a NP or MD had to be a primary medical care provider of HIV-infected and HIV/HCV-coinfecting patients and to practice in one of the two HIV clinics collaborating with the study. Five of the physicians were trained in infectious diseases (ID) and one had also trained in hepatology; among the rest of the providers (NPs and MDs combined), four trained in family medicine, three in internal medicine, one in obstetrics/gynecology, and four had a variety of other specialties. Most had extensive experience with HIV-infected patients (Average =10.3 years; range =3-18 years). Each provider on average saw 32.2 HIV-infected and 10.2 HIV/HCV-coinfecting patients per week. The providers were mostly women (11 women and 6 men); five of the women and two of the men were NPs. Twelve providers identified as White non-Hispanic, three as Hispanic, one as Black non-Hispanic and one as Asian. Providers' mean age was 45 years

(range =34-57 years). The 17 individuals we interviewed were all the HIV primary providers of the two clinics, and not a sample.

Data Collection and Qualitative Data Analysis

The research team invited all NPs and MDs who worked with coinfecting patients in the two HIV clinics to participate in the study, and they all accepted. Providers were familiar with the study because the team had presented its research goals at provider staff meetings and, at times, had asked providers to refer coinfecting patients to the study. The provider protocol and consent form were approved by the Institutional Review Boards of both universities affiliated with the authors and the two clinics. Provider interviews were conducted from December 2004 to February 2006.

The first author of this article, an experienced qualitative researcher, interviewed all 17 providers. All but one of the interviews were conducted in the providers' private offices; one provider elected to be interviewed in the interviewer's office. Interviews lasted on average one hour and a half. After signing a consent form, the provider completed a brief interviewer-administered questionnaire eliciting sociodemographic data and information about their medical education, training and experience treating HIV-infected and HIV/HCV-coinfecting patients. This part of the meeting lasted on average 10 minutes. The remaining of the session was devoted to a semi-structured qualitative interview designed to elicit the providers' perceptions of the challenges they face caring for coinfecting patients. The interview guide addressed four overarching topics: (a) the knowledge-related challenges providers encounter in caring for coinfecting patients; (b) the resources they need to care for these patients; (c) the challenges they face in establishing trust and effectively communicating with these patients; and (d) the strategies they use to address these different challenges. Presenting these general topics to providers allowed them to define in their own words and according to their clinical experiences the features of their practice they viewed as challenging and the strategies they used to cope. When necessary, the interviewer probed for clarification and completion of a provider's statement.

We audio-recorded the qualitative part of the interview and produced verbatim transcriptions for content analysis. We transcribed all audible utterances (e.g., "um", "you know,") including repetitions of words, pauses in speech, laughter, and sounds accompanying speech such as snapping fingers or hitting the desk top for emphasis.

Interview transcripts were entered in ATLAS.ti, a software program for textual analysis (Muhr, 1997). Given the manageable size of the sample, the first two authors read all interview transcripts in their entirety to begin the analysis. Reading and interacting independently with the transcripts, each author identified the emergent analytic themes. Next, the authors met and jointly defined the themes that consisted of: "knowledge-related challenges," "treatment-related challenges," "patient-related challenges," and "strategies for managing patients." These themes and their definitions were entered into ATLAS.ti. The two authors separately defined codes and subcodes that referred to specific dimensions or aspects of each theme. For instance, one of the codes under the theme "treatment-related challenges" was "psychiatric side effects of IRT" and the two related subcodes were: "lack of mental health services" and "lack of patient networks of support." Under the theme

“strategies for managing patients,” one of the codes was, “bringing the patient in the treatment process” and the four related subcodes were: “building trust by discussing with patients limitations and demands of IRT,” “educating patients by comparing HCV to HIV,” “discussing HCV with patients over multiple visits,” and “respecting patients' treatment wishes.” Next, the authors shared their codes and subcodes and produced a joint finalized coding scheme that the first author used to code all 17 transcripts in ATLAS.ti.

The third author, a co-investigator in the study and the clinical director of the two collaborating HIV clinics, was also one of the ID physicians included in the provider sample. Although he was interviewed in the same manner and by the same researcher as his colleagues to provide comparable data, including his interview data in the analysis would raise the possibility of bias (Morse, 2009). To address this issue and protect his colleagues' confidentiality, the other two authors conducted the data analysis. By comparing the themes that emerged from the third author's interview data with those from the remaining providers, the other two authors found that the former's experience and views did not differ in any meaningful way from those of his colleagues. At the completion of the coding scheme, the third author read the identified themes and confirmed that they accurately reflected his personal and his colleagues' experiences.

Findings

Two Approaches to HCV Management in Coinfected Patients

All providers agreed that there were guidelines for treating hepatitis C in HIV/HCV-coinfected patients and indicated familiarity with these guidelines. However, they perceived them as too general thus allowing for a variety of interpretations and practices. Their accounts revealed two primary “schools of thought,” one endorsing a more aggressive therapeutic stance than the other. The significance providers assigned to the coinfected patients' psychosocial fragility and associated ability to withstand the side effects vis-à-vis the effectiveness of HCV treatment largely determined which treatment stance they adopted. Some believed that the low efficacy of the IRT did not justify subjecting psychosocially vulnerable patients to the therapy's severe physical and neuropsychiatric side effects. They preferred to wait for more effective and less toxic therapies, and thus offered IRT to fewer patients. Others were less concerned about the short-term side effects of IRT and indicated that all patients who met the medical criteria for IRT should be offered the therapy, and thus the chance to realize some benefits or even a cure. The two ID physicians quoted below represent the two treatment approaches –the first, the less aggressive and the second, the more aggressive:

Another school of thought that's more, that's acting more, that is treating [HCV] more aggressively... If we do have time, and for the people that have time, we are going to be able to offer treatment therapies that are not as toxic and as challenging... It's like a lack of consensus, since the current therapies are, are so hard to tolerate and offer such a limited response ... It's not an easy therapy... For something that is not very that easy to do, one expects, you would have a bigger response that would justify, you know. So, “We're doing this, but you know what? Everybody gets cured with it.” It's not the case.

There are always people who are more aggressive and less aggressive... . Some would say, “Don't worry about it. You know, we'll repeat your liver biopsy in three years,” and, you know, there are others that say, “Well, look, this is a good chance to get rid of it now, and maybe we should treat you now.” ... There is some consensus to some extent on what to do, but, you know, there are guidelines, and, there is the real world, and for a patient that is very concerned, you may elect to treat, even though the current recommendation might suggest that maybe you should wait... . I'm probably a little bit more aggressive.

The divide between guidelines and “real world” practice and the patient's role in the management of HCV both suggest a patient-center approach, and underlie the providers' accounts of the practice challenges they faced and strategies they adopted.

Knowledge-Related Challenges and Strategies

All providers attributed the lack of consensus about the management of coinfecting patients to the limited scientific data on the risks and benefits of treating HCV in the presence of HIV and in psychosocially fragile patients. The lack of longitudinal data on the efficacy of IRT for coinfecting patients and the potential bias in the samples of most published studies largely accounted for the providers' skepticism towards the literature's treatment recommendations. The existing studies' samples, providers argued, typically consisted of mono-HCV-infected patients, or patients who were younger, physically healthier and psychosocially less disadvantaged than the ones they treated in their HIV clinics. Therefore, providers believed they could not readily generalize these studies' findings to their coinfecting patients. These limitations of the literature and the clinical uncertainty they generated were discussed below by two ID physicians:

The knowledge base, it is not as deep in hepatitis C as it is per se in HIV, and it's certainly less deep in the coinfecting patient than it is in the patient who's only hepatitis C infected and not one who comes dually infected. The first real big studies on coinfection were only done within the last couple of years. So there's not the breadth of data that say, there is in the mono-infected patient that were, that are there for the present, or, for longer periods of time. I still think that we're feeling our way through this process.

[They] say that HIV gets worse in patients with hepatitis C although I think the data is still a little scarce; one study may show that it does and another study shows that it doesn't necessarily and then the study that does show that HIV gets worse may be attributed to the fact, the patient's an active IV drug user ... . There's always you know studies where patients are like the ideal patients [non-drug users] and stuff like that.

The primary strategy providers used to address the uncertainty of managing coinfecting patients was to consult an ID physician also trained in hepatology [Dr. M] who had been hired to work exclusively in the HIV clinics. All the providers expressed an appreciation for Dr. M's advice, whose expertise enabled her to sort through the general guidelines and “this morass of data” as one physician said. Dr. M developed HCV-evaluation and -treatment steps for coinfecting patients, that is, she “created a protocol” providers used as a blueprint.

Although Dr. M at times advised all providers, it was the standard of care for NPs to refer all their coinfecting patients to Dr. M and jointly manage their HCV. A NP described this collaboration below:

As an NP, I'm working in collaboration with the person that's done this more often than I have. So we work in collab [collaboration], the nurse practitioners work in collaboration with the hepatologist who, the person who's does, who's an expert in, in treating hepatitis C... . She sees them, and then she, we consult her and then she assists us in advising us, what steps to take. We, we then take the patient back, and, we both watch the patient together.

Treatment-Related Challenges and Strategies

Severe physical side effects—Providers identified liver failure, mitochondrial toxicity, and severe anemia as major challenges in the clinical management of their coinfecting patients. Several, including seasoned ID physicians, spoke poignantly about losing coinfecting patients to complications from treating one or both of the diseases, and hinted that these memorable cases made them very cautious in prescribing medications for either HIV or HCV, and influenced their practice. Providers differentiated between HIV-infected and HIV/HCV-coinfecting patients and indicated that managing the latter group was more complicated, fraught with uncertainty and therefore more stressful. Below, a NP described her distress from losing a patient to liver failure:

I did lose a couple of hep [hepatitis] C patients when I changed their medications way back and it's still traumatic to me... . Went into um, advanced [liver] disease like that [snaps fingers], you know, they just overnight almost, one guy only came in and his eyes were yellow and his belly was blown up suddenly. It happened so fast, after change in meds [medications], you know, and I wasn't exactly sure which med. I've gone to a million conferences and begged them to tell me which are the good meds and which are the bad meds and no one really knows.

In their interviews, providers identified different HIV antiretrovirals as being counter-indicated for coinfecting patients, thus confirming that the distinction between the “good” and “bad” medications for these patients was unclear. “Certain protease inhibitors you know might be more [hepatotoxic] than others, but I don't think that's very well established right now,” was how an ID physician expressed this ambiguity about the optimal HIV therapy for coinfecting patients. Similarly, an experienced ID physician shared his concern about hepatotoxicity:

I think there's some data to support certain medicines over others for people with hep C. And there are certain medicines that I would say I'm concerned about using in hep C. And then certain medicines that, if they were to, if we were to even talk about actually um, hep C treatment, then I won't use at all.

To address this lack of clarity regarding which HIV medications were safest for coinfecting patients, providers closely monitored the liver function of all patients, irrespective of their HIV regimen. They also carefully considered each patient's resistance to HIV medications and severity of HCV disease in their treatment decision process. A NP described this complicated process as follows:

One, their resistance profile has to be looked at. Of course you're going to try to put a regimen that doesn't have those toxicities, if you have that available. But if you have a patient who has, who is very sick from HIV you may have to use some of those medications that we do know are going to affect the liver and we're going to have to monitor them on a regular basis... I go under the assumption that all [HIV] meds have some effect on the liver.

Like the internal medicine physician quoted below, providers were also concerned about anemia caused by both azidothymidine (AZT), an antiretroviral used to treat HIV, and Ribavirin, one of the two agents of IRT, the therapy used to treat HCV:

The hepatitis C treatment [pause] it is more toxic because they [patients] were on AZT, to their bone marrow. Um, and I remember the first patient, just pulling my hair out and talking to the liver specialists and um, hematologists about AZT, and “Did they think it could be the AZT when they tolerated the AZT before?” And it was they didn't have a problem with AZT until this. And with that patient, I remember getting told, “No, no, no, no,” until I stopped the AZT, and the guy's bone marrow rebounded, um, just fine.

Severe neuropsychiatric side effects—All providers regarded Interferon's neuropsychiatric side effects, especially depression and suicidality, as significant challenges that made them very cautious about initiating HCV therapy. They identified two factors that amplified the risk of depression: first, the treatment's side effects of fatigue and other flu-like symptoms, and second, the past or current drug use of most coinfecting patients that predisposed them to depression. Providers indicated that the flu-like side effects of IRT (i.e., fatigue, myalgia, fever, and a feeling of malaise) could contribute to feelings of depression and suicidality, and thus increase the risk for these psychiatric conditions. Adding another layer of complexity, fatigue with its potential to intensify depression is also a symptom of HIV and HCV. A NP described below this “vicious circle” created by feeling physically sick from the IRT and/or being coinfecting and becoming depressed. By “flu-like symptoms” she referred to “body aches” and “profound fatigue”:

Well, they're more at risk um, of getting depressed if they're on medication, if they go on treatment. They may be more depressed because they may be sicker... If you're experiencing fatigue all the time from HIV and, and hepatitis C coinfection, I think that might make you more depressed, so [pause] it's a vicious circle... They're very ill all the time. Like flu-like symptoms. They're feeling like they have the flu and lack of energy.

The mental health fragility of most coinfecting patients, related to preexisting psychopathology and past or current substance use, was another challenge for providers. They worried that the prolonged physical side effects and depression caused by IRT could disturb the precarious psychological stability of many of their patients, and result in substance use relapse and discontinuity of their medical care. Below, the ID/hepatologist expressed these concerns:

[Coinfecting patients] have more issues with staying away from drugs, which makes it harder to treat because you have to be absolutely sure how do the people cope

with the depression under treatment. Do they go back to shooting or have you gotten them so far? Jeff [a NP this physician worked with] had two patients who went back [to using drugs].

Assessing the patients' mental status, referring those in need of medication to the psychiatrist, and prescribing antidepressants prior to initiating IRT were among the strategies providers used to protect the mental well-being of the coinfecting patients they treated for HCV. An ID physician discussed how she managed the risk of psychiatric side effects as follows:

The potential of suicidality with the hepatitis C treatment and our lack of mental health [services] is a big issue. So, I, I think I have more anxiety in some ways in treating those patients... . If I start medication [for HCV], I like to see them every week at the beginning. Just to see how it's going. Because really it's all, it's like being a therapist at the beginning... . Because we don't really have that other service [mental health], which maybe I shouldn't be spending more doctor hours doing... . I try to get them an appointment with a psychiatrist with that goal in mind. If it seems like it's going to be too far away, then I will put something in [an antidepressant] that's mild. Yeah proactively.

All providers identified the lack of sufficient mental health services and the time- and labor-intensive nature of treating HCV as key aspects of their practice. A part-time psychiatrist, a full-time clinical social worker, and two case managers served both HIV clinics; this small staff could not meet the coinfecting patients' needs. To fill this gap and support these patients, providers scheduled frequent and long appointments with their patients, closely monitored the patients' mental status, and gave patients their beeper, cell, and home phone number to increase their own accessibility. Therefore, providers spent additional time and energy to manage coinfecting patients on IRT. Although they referred patients to off-site mental health and substance abuse programs, they all preferred for such programs to be co-located in the HIV clinics to ensure a quick and coordinated provision of care. A NP discussed these issues below:

They are experiencing a lot of the side effects from the treatment. And sometimes change in mood, uh, change in appetite, this brings them into the morbidity, um, arena. You know, and that, and it takes more time. You don't want, you want to make sure that you're not sending somebody out who's about to jump in front of a car, or somebody who's about to stop their treatment... . Giving them my home number, telling them they can call me. I, tell them that I will call them... . Uh, basically being there for them. And that takes a lot. Part-, particularly when you don't have a supportive system... . [We need] psychologists, psychology, social work... . You cannot refer patients outside, when you're in treatment; everything should be within the facility or within the service.

The lack of professional mental health support was further compounded by most coinfecting patients' lack of informal support. Providers recognized that, because of extensive drug use, many coinfecting patients were alienated from family and friends, and unlikely to have an informal support network. Such a network was seen as an important patient resource, given

the physical and psychological demands of IRT. Therefore, when considering IRT, as the ID physician explained below, providers took into account their patients' social isolation:

Sometimes the [coinfected] patients are more isolated, I find, than uh, other patients. Probably reflected by either their substance abuse histories or the mental health issues that led them to the substance abuse issues ... if they're gonna contemplate treatment for hep C, it's gonna draw heavily on having a support network that's gonna be helpful... I feel a lot of the hep C patients are, have much more limited support than some of the other patients... [I ask coinfecting patients] a lot about their mental health needs... Have they seen a psychiatrist or a psychologist? Do they have a therapist? Do they have somebody they can work with? Do they need somebody they could work with?

The injectable form of Interferon—Most providers did not perceive the fact that Interferon is administered by needle as posing a relapse risk for patients who were former injecting drug users. They indicated that giving their patients needles to inject the Interferon on their own, or having a nurse inject them with the medication was unlikely to provoke flashbacks or drug cravings and thus cause a relapse. One ID physician called the belief that administering Interferon by needle is a relapse trigger, a “mythology.” This mythology, another ID physician said, was created by providers but not substantiated by her experience:

I've heard that before from other providers. I've never had that experience because just for example, I've used the Procrit for many years, with my patients. No problem... Some of them come to the nurses because they are afraid of injecting themselves... I've worked with that patient population, too because uh, I used to be medical director of a women's prison, that's how I got involved into HIV medicine... So they send a lot of heroin [users], and most of my patients are drug users. I don't think that.

As indicated above, some former injecting drug-use patients had an intense aversion for needles, and preferred that a health care provider administer the injectable medications. These patients were accommodated by sending nurses to their homes or by having them come to the clinics for the Interferon. Even the few providers who, like the NP quoted below, expressed concern that the Interferon injection might trigger a drug relapse could not identify specific patients who had such a drug relapse experience:

They got to go, possibly go through 48 weeks of injection... The fear of using the needle is a burden to them, it might, might end up as a trigger to them and so that is a burden of, of coming every week for injection or, or having to, being asked to go home and check them or, or having to ask a family member to inject them because they don't want to use the, the needle because of the trigger.

Patient-Related Challenges and Strategies

Fear and denial of coinfection—Providers knew that most of their patients were poorly informed about hepatitis C and the health ramifications of being HIV/HCV-coinfected. Most indicated that their coinfecting patients did not pose any hepatitis C-related questions or issues during their medical visits. Providers took the initiative to educate them and

eventually ask them to get a liver biopsy to stage the disease. As one ID physician stated, most patient-provider discussions about hepatitis C are “doctor-driven.” In the following excerpt, the ID/hepatologist attributed her patients' passive attitude toward HCV to their profound lack of education:

Patients don't ask, ask very few questions ... it's ascertain passivity... I think part of it is education, lack of education. Um, I think I still overestimate my patients in term of their knowledge. Um, many of my patients don't know where the liver is, where it's located. And I kind of take a step back and ask them first, “Where's your liver? ... Have you ever been offered treatment? Do you know what hepatitis is? Do you know what's going on?”

Another ID physician suggested that the patients not bringing up their HCV was a form of denial and possibly a way of minimizing the health threat and distress this disease raised:

They don't really have a sense of the possible complications of not treating it right now. So if left to their own devices, they don't have much anxiety about it... Once we start talking about it, then they start thinking about, worrying about whether they're going to die of liver disease, whether they're gonna die of liver cancer um, whether they can drink... They don't bring it [pause], they don't want to deal with it. There's a big denial bubble.

Patients' denial of the significance and ramifications of being HCV infected undermined their willingness to become informed about the disease. This perpetuated their poor understanding of what it means to be coinfecting, as a NP explained:

Some don't want to hear about hep C because it's enough dealing with HIV and they say that. Sometimes I give out literature and they don't, they don't want to read it. So, there's been a lot of resistance I found to delivering hep C [info], in addition [to HIV].

Fear of the liver biopsy—Providers discussed their patients' dread of undergoing a liver biopsy as another major obstacle to evaluating the extent of their HCV disease and deciding whether to initiate IRT. The invasive nature of the procedure and the possibility of experiencing significant pain undoubtedly deterred patients from having the biopsy. Patients' fear of finding out the severity of their liver disease through the biopsy results was another psychological obstacle to having the procedure. As one NP said, “The liver biopsy scares the hell out of them. I think it's the pain.” Another NP added, “Some of it is just the inconvenience of having another procedure. Yeah. And some of it is just, not wanting to know.” To address these barriers, providers tried to earn each patient's trust, as the ID physician suggested below:

There are lots of psychosocial issues that these patients have to deal with and then on top of that you're like, “Okay, so with hep C, you know what we're going to do next? Is, we're going to do another biopsy,” and then all of a sudden people are like, “Whoa!” ... Given the chronicity of the infection and stuff like that, I think I like to develop a rapport over like a year or more with the patient before I start talking about that.

Another strategy to increase liver biopsies was to integrate GE services in the HIV clinics by hiring Dr. M, the full-time hepatologist and ID specialist who could perform biopsies. This eliminated the need to refer coinfecting patients to the GE clinic and expedited the performance of liver biopsies which resulted in a more accurate staging of patients' HCV disease. Since stage of disease severity is one of the primary factors determining whether to treat HCV, Dr. M's ability to perform biopsies decreased the providers' treatment-related uncertainty and improved their clinical management of coinfecting patients. A NP expressed the view of all providers when she said, "For me, the big difference was the biopsies. You know, I can now tell you whether there's a compelling reason to treat. Makes a big difference." Providers explained that, when in the past they referred their coinfecting patients to the GE clinic for consultation and biopsies, they had to wait three months or longer for an appointment which delayed the evaluation and treatment of their patients' HCV. A few providers also hinted that some GE colleagues had been reluctant to perform liver biopsies on their coinfecting patients, and this complicated the referral process. Below, an ID physician discussed the benefits of integrating a hepatologist in the HIV clinics and not having to depend on referrals to the GE clinic:

Now that we have somebody to do biopsies for us, it [the referral problem] lessens. 'Cause we were stuck with that, getting biopsies, you know, they [GE clinic] didn't want to do them, you know, our patients, and it was, you know, a nightmare... . There are many providers who don't treat HIV patients the same way. They are less prone or eager to do biopsies and invasive procedures in our patients that have these two [diseases].

Familiarity with end-stage liver disease—Coinfecting patients' resistance to becoming informed about HCV, and finding out the extent of their HCV disease through a biopsy coexisted uncomfortably with an intense fear of dying from liver disease. Providers volunteered in their interviews that during their medical visits many patients had revealed that they had witnessed members of their community or family suffer from alcohol-related cirrhosis or advanced hepatitis and were terrified of having the same fate. Providers inferred that as a defense against this intense fear, patients refrained from learning about and addressing their HCV disease. As one ID physician stated, "I think this population has experience with cirrhosis, they, a lot of them have seen, you know, somebody die of cirrhosis; their father or their mother from alcohol. So they know what that is." A NP referred to this tension between patients' lack of understanding of HCV and familiarity with advanced liver disease as an obstacle in addressing the disease:

There isn't that much information out there about the hepatitis C. And, they, the people who they do know with hepatitis C, the people with advanced disease, and they see yellow and bloated bellies and people suffering and swollen bodies and it's pretty terrifying, so that's usually people's association with hep C.

Reputation of the IRT as a difficult regimen—The reputation of IRT as an arduous regimen with difficult-to-tolerate side effects had reached patients, and deterred some from treatment. An internal medicine physician called the HCV therapy's "bad press" a treatment barrier:

A lot of people have preconceived notions about the treatment and how horrible they think the treatment is. The bad press that it's gotten... I guess, you know, people have, I think that preconceived notions about what it's like to be treated... I think that they've heard about issues about depression and suicidality. Um, I don't think those are as much of a concern, as feeling bad on the medication, about the body aches and the chills, and um, feeling like, you're just going to be knocked off your feet and you have to be home.

Providers recognized the significant influence peers' experience with IRT had on patients' motivation to initiate treatment. Given IRT's debilitating side effects, low efficacy and relatively recent advent, only a few patients completed the therapy, and even fewer were successfully treated and could discuss IRT's benefits with fellow patients. The lack of "successful stories," was identified by a family medicine provider as a treatment barrier:

Like in HIV, people are getting better, they are living longer. So, what's the point with hepatitis C? ... I think the biggest barrier that we have is we don't have a lot of, like increased number of patients on-site with a successful story about hepatitis C that we have with HIV... I just can't show numbers about hepatitis C. I cannot show real people that came through [the HCV treatment] fine.

An Overarching Strategy: Including the Patient in the Treatment Decision Process

Given all the aforementioned knowledge-, treatment-, and patient-related barriers to HCV treatment, providers agreed that a necessary condition for initiating IRT was to involve the patient in the treatment decision-making process. Providers indicated that although patient participation in treatment decisions was desirable for HIV, it was imperative for treating HCV. "I require that the patients participate in the decision. More for hep C [than HIV] because it is more cumbersome. So I can't possibly write the prescription if somebody doesn't wanna do it," one ID physician said. Providers candidly discussed with patients the uncertain outcome associated with IRT, and encouraged them to express their concerns and treatment preferences. By inviting patients to contend with the therapy's demands in the presence and with the help of the provider, these discussions aimed to address the patients' fears, increase their trust in the therapeutic relationship, and motivate them to try the therapy. Providers, like the ID physician below, expressed a genuine respect for their patients' treatment wishes even when they disagreed:

I tell a patient that there is uncertainty and the best course of action. I make my recommendations based upon what I perceive to be the pluses and minuses, and I discuss it, uh, with my colleagues. But ultimately, it's, you know, the patient's decision as to what to do, based upon the facts that we provide them... There are people that I have recommended treatment for their hepatitis C who've elected not to be treated. That's their choice... They may say today, "I don't want to be treated with that drug," and so, if there are no what I think are reasonable alternatives, I say fine, and you know, maybe the next time or sometime later on that year I will broach the treatment again.

Another ID physician in her discussions with patients juxtaposed the time-limited HCV therapy to the lifelong HIV therapy to encourage them to contemplate initiating IRT:

I try to explain to them that I can't tell them what the right thing to do is. I can't, that there's a lot of uncertainty in what we're doing... But if they [patients] feel like they wanted to commence [IRT], it's more what they want to do. If they want to try the treatment, then I give it a try. And I present it as a trial... It's a limited treatment. It's not like HIV. We're going to give it a certain amount of time... And we either cure it, or we don't. And that's the way to get through it. That there's an end to it. It's not like you're stuck on these antiretrovirals for the rest of your life which is an awful thing to hear.

Contrasting the life-long HIV therapies to the time-limited HCV therapy that could potentially “cure” hepatitis C and engaging in long-term discussions with patients about their HCV were the strategies almost all providers used to encourage their patients to initiate IRT. Discussing the differences and similarities between HIV and HCV and their therapies was an effective educational approach given patients' familiarity with HIV.

This process of educating patients, motivating them to comprehensively evaluate their liver disease and possibly initiate IRT was a delicate and time-consuming endeavor. Providers were concerned that making hepatitis C abruptly salient to their coinfecting patients could raise their anxiety, undermine their psychological balance, and threaten the continuity of their medical care. As a NP explained, “I have to be careful because if I scare someone too much, you know, then they're traumatized. And if I don't scare people enough then they don't take it seriously... So it's hard to get the right balance.” These discussions took months or even years, as providers gently and slowly brought up the topics of HCV, liver biopsy and IRT while assessing the patients' fears and receptiveness to even listen to this information. An ID physician used the “dance” metaphor to describe this communication process with one of his patients:

One patient that I was thinking, we, we've been doing this dance for probably 10 years of, he comes in, he tells me, “Gee, you know, how's my liver doing?” And I'll tell him, “Well I really don't know because we haven't done the biopsy.” And with him it's, we're probably not doing the biopsy because it would have to be done under general just because he doesn't tolerate local anesthetics... So, he, he doesn't wanna do it under general. But then he'll tell me that he's drinking. Sometimes he's, he's sniffing some cocaine. But then we'll get back to talking about his liver.

Discussion

This analysis reveals that the clinical management of HIV/HCV-coinfecting patients and especially the treatment of HCV with Interferon/Ribavirin were fraught with challenges related to three domains: the state of medical knowledge, the treatment options for HIV and HCV, and the psychosocial vulnerabilities of this patient population. Providers addressed these challenges primarily by practicing patient-centered medicine.

As providers indicated, the lack of longitudinal data on how best to treat HCV and HIV when both conditions are present and the higher-functioning patients typically included in clinical trials on HCV treatment limited the usefulness of the extant scientific literature. In

contrast to the patients in clinical trials, providers realized that their own patients were physically and psychologically more compromised because of their extensive drug use and social marginalization. Trials on HCV treatment systematically have excluded active drug users, patients with psychiatric diagnoses (Weiss & Gorman, 2006), and patients deemed biomedically “hard-to-treat” because of advanced disease or the virus' genotype (Wagner & Ryan, 2005). Therefore, the providers' skepticism about the efficacy and safety of IRT and reluctance to directly apply the literature's clinical recommendations to their coinfecting patients were justified.

To address these gaps in the literature and limitations in their own clinical knowledge, providers evaluated their coinfecting patients on a case-by-case basis and developed individualized clinical plans. This strategy was facilitated by integrating in the HIV clinics an ID physician who was also a hepatologist, who shared her expertise in managing HCV in the presence of HIV and created an HCV-treatment protocol. These resources enhanced providers' understanding of how the two diseases interface and their treatment confidence. This ID/hepatologist also performed liver biopsies that increased the accuracy of disease severity assessment, thus further decreasing the providers' treatment uncertainty. Also, having an in-clinic provider that performed liver biopsies better integrated patient care, and addressed the concern that coinfecting patients might face delays and discrimination when referred to gastroenterologists outside the HIV clinics. This finding that the integration of specialty services in HIV clinics increased providers' confidence and motivation to treat thus enhancing patients' clinical management highlights the significant impact of clinic environment on therapy uptake.

Individually evaluating and tailoring the clinical management of each coinfecting patient to his or her unique medical and psychiatric profile was also a strategy providers used to address these patients' HIV and HCV. The side effects of both diseases' regimens, the risk of drug interactions when treating both diseases simultaneously, and especially the potential hepatotoxicity of many HIV antiretrovirals and the neuropsychiatric side effects of Interferon increased the burden of treatment for patients and complicated their clinical management. These findings are corroborated by a growing literature on coinfecting patients that identifies the neuropsychiatric and physical side effects of IRT as both patient- and provider-related deterrents to initiating and reasons for discontinuing HCV treatment (Fleming et al., 2005; Grebely et al., 2008; Mehta et al., 2008). The risk of Interferon-induced depression and suicidality has received particular attention by researchers that study the low uptake of HCV therapy among coinfecting patients (Corcoran, 2003; Weiss & Morgello, 2009). We contribute to this literature by revealing how providers factor these side effects in their treatment decision-making process and practice.

Providers were aware of their coinfecting patients' psychosocial fragility associated with their history of drug use and long-term social marginalization. These vulnerabilities raised the possibility of preexisting psychopathology and worsened the risk for depression, suicidality and drug relapse, thus amplifying the potential costs of IRT. Based on their experience with drug-using and non-drug-using patients, providers also knew that their drug-using lifestyle had deprived most coinfecting patients of informal support networks. This realization informed their decision to prescribe IRT, given its severe side effects and demands for

informal support. Recognizing the severity of the psychosocial and biomedical challenges facing their coinfecting patients, and including them in their treatment decisions, constitutes a primary feature of these providers' practice and a key dimension of "patient-centered medicine" (Mead & Bower, 2000).

To practice "patient-centered medicine" with their patients, providers had to invest substantial time and energy to gather the appropriate information for placing patients in their social context, evaluate and monitor their mental health, and if needed, prescribe antidepressants and/or refer them to psychiatric or substance use services. Although they made referrals to mental health and substance treatment facilities, providers expressed a preference for integrating these services into their HIV clinics to ensure seamless and coordinated care for patients. The lack of sufficient mental health services in the HIV clinics amplified the providers' tendency to prescribe antidepressants and act as "therapists," as one stated. Preventively prescribing antidepressants to patients on IRT because of insufficient psychiatric support (Weiss & Morgello, 2009), adopting a multidisciplinary approach that includes mental health and substance use services, and spending additional time with the patient (Fuller et al., 2009) recently were identified in the literature as essential for increasing IRT's uptake.

Discussions of engaging their coinfecting patients in HCV therapy revealed that providers integrated in their practice another key dimension of patient-centered medicine: understanding the meaning the illness has for the patient (Mead & Bower, 2000). Providers recognized that the meaning their patients assigned to being coinfecting was shaped by four interrelated factors that contributed to and reproduced patients' resistance to become informed about their HCV and IRT. These factors were: denial that they have HCV, fear of a liver biopsy, familiarity with the ravages of end-stage liver disease, and exposure to selective information about IRT's debilitating side effects from fellow patients. Denying, to some extent, their having HCV was one way coinfecting patients coped with the threat of having another life-threatening illness alongside HIV. This denial was maintained by deflecting information about the disease offered by providers and remaining purposefully ignorant about hepatitis C. This reluctance to address their HCV disease coupled with the invasive nature of a liver biopsy also explained many patients' refusal to undergo this procedure to assess disease severity.

Providers also realized that many patients had witnessed relatives or other members of their communities becoming sick and dying from alcoholism-related cirrhosis or end-stage liver disease. Although witnessing the physical deterioration and suffering caused by end-stage liver disease had the potential to challenge the patients' denial of HCV and motivate them to treat the disease, it had the opposite effect. The fear these personal experiences provoked seemed to intensify patients' avoidant tendency which was further supported by peer-generated rumors about the debilitating side effects of IRT. Therefore, by understanding how their coinfecting patients' experiences in their communities and in the clinics with peers shaped the meaning and significance they assigned to having HCV and HIV, the providers incorporated another key dimension of patient-centeredness into their practice (Mead & Bower, 2000).

Coinfected patients' lack of understanding of HCV and misinformation about the effectiveness of IRT have been identified as significant obstacles to motivating them to undergo a liver biopsy to assess disease severity and the need for treatment (Bova, Ogawa, & Sullivan-Bolyai, 2010; Grebely et al., 2008; Mehta et al., 2008). The recommendation made is to utilize peers to educate patients about both the disease and its treatment (Dore & Thomas, 2005; Wagner & Ryan, 2005). Our findings offer two insights regarding this recommendation. First, they reveal that trying to educate patients about HCV without addressing the meaning they assign to this disease and the underlying psychological factors that motivate them to remain uninformed will probably fail to increase their readiness for treatment. Second, given the low uptake and demanding nature of IRT, only a few patients initiate and complete the therapy to experience the benefits of IRT, although most suffer its debilitating side effects. Therefore, there are relatively few peers with good treatment outcomes available to educate others about HCV and IRT. Ironically, this situation partly stems from the providers' reluctance to place many patients on IRT because of its intrusive side-effects and the patients' own vulnerabilities. In the future, as more effective therapies become available and more coinfecting patients are treated with and benefit from IRT, using peer educators will become a more viable option.

Finally, providers described how they established a “therapeutic alliance” with their coinfecting patients regardless of whether they chose to undergo IRT thus, integrating another key dimension of patient-centered medicine into their practice. Recognizing that many patients feel overwhelmed by having a second serious disease in addition to HIV, providers slowly educated them about HCV and IRT and encouraged them to undergo a liver biopsy only after carefully assessing their patients' readiness to accept their having HCV. In these discussions, that often unfolded over months or even years, providers used their patients' familiarity with the HIV disease and its treatment to educate them about HCV. By comparing HCV to HIV and defining the former as potentially “curable” and IRT as a time-limited treatment, providers hoped to encourage their coinfecting patients to take in the information about HCV and the liver biopsy and eventually explore the possibility of initiating IRT. Providers also expressed to patients' their own uncertainty about the efficacy of IRT, and proactively brought up its serious side effects. Discussing the limitations and demands of IRT, providers claimed, elicited their patients' trust and motivated them to reveal their treatment wishes. By respecting these wishes even when they differed from their medical advice, providers forged a therapeutic alliance with their patients.

These findings about the ways in which providers establish a therapeutic alliance with their coinfecting patients are novel. Although researchers have recognized the significance of the patient-provider relationship (Adeyemi et al., 2004; Grebely et al., 2008; Mehta et al., 2008) and hinted that the coinfecting patients' long-term and trusting relationship with their HIV provider can contribute to IRT uptake, they have not explained how this partnership increases treatment initiation. Therefore, our analysis that reveals how a trusting relationship between patient and provider can translate into treatment uptake and clinical outcomes can contribute to programs that train HIV and other medical providers of psychosocially vulnerable patients on ways to increase the patients' trust and ensure they become partners in their therapeutic experience.

Given the multifaceted challenges that frame the clinical management of coinfecting patients, not surprisingly, providers varied in how aggressively they evaluated and treated these patients' HCV disease. Providers identified two schools of thought regarding HCV treatment, one more aggressive than the other and indicated that colleagues who regarded the efficacy of IRT as limited and focused on its potential to disrupt the lives of their fragile patients were less likely to offer IRT. This finding of two treatment approaches was recently corroborated by another qualitative study by Wagner and colleagues (2009). Our analysis further substantiated that the patient's readiness for treatment was the most important factor in determining the provider's treatment stance. We offered the additional insight that by practicing patient-centered medicine, providers were able to quite accurately assess their patients' willingness to engage in treatment, and by respecting patients' wishes, concerns and experiences they maintained a trusting patient-provider relationship. The question this analysis raised is whether engaging their patients in the treatment decision process also helped providers cope with their uncertainty about the efficacy of IRT and concern about its disruptive impact on their fragile patients' lives. In conclusion, it is important that HIV providers managed to practice patient-centered medicine with their medically- and psychosocially-compromised coinfecting patients. The overarching question future research must answer is whether these providers integrated the principles of patient-centeredness into their practice despite or because of the knowledge-, treatment-, and patient-related challenges they confronted.

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