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“Seek, test, treat and retain” for hepatitis C in the United States criminal justice system

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Abstract

Purpose—The purpose of this paper is to consider the potential benefits and challenges of applying a strategy of “seek, test, treat and retain” (STTR) to hepatitis C virus (HCV) in the US criminal justice system.

Design/methodology/approach—The authors draw on the published literature to illustrate how each component of STTR could be applied to HCV in the US criminal justice system, and describe challenges to the implementation of this strategy.

Findings—The burden of morbidity and mortality associated with chronic HCV infection in the USA is increasing and without significantly increased treatment uptake, will likely continue to do so for several decades. The authors argue that the US criminal justice system is an ideal focus for HCV case finding and treatment due to a high prevalence of infection and large volume of individuals in contact with this system. STTR would identify large numbers of HCV infections, leading to opportunities for secondary prevention and primary care. Important challenges to the implementation of STTR include treatment costs and training of prison medical providers.

Originality/value—This paper highlights opportunities to address HCV in the US criminal justice system.

Keywords

Criminal justice system; Hepatitis C; Prisoners

An estimated 2.5-3.2 million people in the USA are infected with hepatitis C virus (HCV), making it the most common blood-borne viral infection in the nation (Davis *et al.*, 2010; Razavi *et al.*, 2013). Chronic HCV infection increases the risk of cirrhosis, chronic liver disease and hepatocellular carcinoma (Te and Jensen, 2010; Dore *et al.*, 2002; Freeman *et al.*, 2001), and is the leading indication for liver transplantation (Smith *et al.*, 2012). HCV-related mortality rates have been increasing for the past decade, and in 2007, HCV-related deaths outnumbered those from HIV for the first time (Ly *et al.*, 2012). At current treatment rates, HCV will kill 13 percent of those currently infected – nearly 380,000 people – by 2030, and over one million people by 2060 (Rein *et al.*, 2011).

The burden of HCV infection is disproportionately borne by people in contact with the criminal justice system (Beck and Maruschak, 2004), primarily as a result of higher prevalence of risk behaviors among this population, especially injection drug use (IDU) (Larney *et al.*, 2013). An estimated 29-33 percent of total prevalent HCV cases are in persons detained in a correctional facility annually (Varan *et al.*, 2014), making the criminal justice system an important setting for addressing this epidemic.

Here, we consider opportunities to apply a strategy of “seek, test, treat and retain” (STTR) to HCV infection in criminal justice populations. STTR was developed as a response to the HIV epidemic following evidence that early diagnosis and treatment entry not only produces individual clinical benefits, but is also associated with reduced HIV transmission (Cohen *et al.*, 2011; Montaner *et al.*, 2010). It encompasses identification of at-risk populations, high coverage of testing among those at risk, early initiation of antiretroviral therapy and adherence to and retention in treatment (Hull *et al.*, 2012).

Seek: the potential of criminal justice populations for case finding

The criminal justice population includes persons detained in jails and prisons, and those under community supervision (e.g. probation or parole). Jails are short-term institutions with a rapid turnover of arrestees, pre-trial defendants and individuals with short (< 12 months) sentences. In the 12 months ending in June 2011, there were nearly 12 million admissions to jails in the USA, with the majority of admitted persons spending less than one week in custody (Minton, 2012). In contrast, prisons house those serving sentences of 12 months or longer. At year-end 2010, there were 1.6 million persons in US state and federal prisons; 700,000 individuals entered prison during the year (Guerino *et al.*, 2011). An additional five million adults were under some form of community corrections supervision (Maruschak and Parks, 2012).

HCV prevalence data for this large and dynamic population are largely out-of-date; of US sources collated for a systematic review of HCV antibody prevalence in correctional settings, none reported on data collected during the past decade (Larney *et al.*, 2013). It was recently estimated that nationwide, HCV antibody prevalence among persons entering

prisons is 17.4 percent; in the 12 states that conducted routine HCV screening, prevalence ranged from 9.6 to 41.4 percent (Varan *et al.*, 2014).

With such large numbers of people in contact with jails, prisons and community corrections, and a high prevalence of HCV infection, much of which is undiagnosed, the criminal justice system presents significant “seek” opportunities. To date, this potential has been underutilized; between 2001 and 2012, only 12 state prison systems performed any systematic HCV screening (Varan *et al.*, 2014).

Test: expanding HCV testing through opt-out screening

The Centers for Disease Control and Prevention (CDC) and Federal Bureau of Prisons recommend offering HCV antibody testing to inmates entering correctional institutions who report IDU, other risk factors for infection (e.g. non-sterile tattooing) or certain pre-existing medical conditions (e.g. HIV infection) (Federal Bureau of Prisons, 2012; Weinbaum *et al.*, 2003). This approach requires rapid ascertainment of illegal, stigmatized behaviors that persons entering a correctional facility may be unwilling to disclose. In one large sample of prison entrants, two-thirds of total HCV cases were in persons who denied IDU; that is, risk-based testing would identify only one-third of prevalent infections (Macalino *et al.*, 2005). Screening of the 1945-1965 birth cohort, as recommended by the CDC for the general population, would also likely identify only a minority of cases (Larney *et al.*, in press).

Given the low rates of case identification associated with risk – based and birth cohort testing in the correctional context, routine opt-out HCV screening should be part of the standard medical evaluation administered at entry to all correctional facilities. With this approach, the inmate is informed that an HCV test will be performed unless he or she objects and opts out of the test. Care must be taken to ensure true voluntariness of consent, but opt-out screening is already recommended by the CDC for HIV testing in correctional populations, on the basis that it increases diagnoses of HIV infection, streamlines the testing process, reduces the stigma associated with testing and improves access to clinical care (Centers for Disease Control, 2009). Initial studies of opt-out HIV screening in jails report that one-quarter to two-thirds of inmates testing positive were previously undiagnosed (Beckwith *et al.*, 2012). Opt-out screening for HCV has the potential to increase testing uptake, and can be undertaken at the same time as opt-out HIV screening. With a far higher prevalence of HCV compared to HIV in criminal justice populations, opt-out HCV screening will likely identify significant numbers of undiagnosed cases. Furthermore, post-test counselling would provide opportunities to advise HCV-antibody positive individuals to abstain or reduce alcohol consumption, and to offer hepatitis A and B vaccinations.

Treat: implications of emerging HCV therapies for correctional settings

Identification of HCV infection presents significant opportunities for harm reduction and secondary prevention. Diagnosed individuals can receive hepatitis A and B vaccinations and information regarding risk factors for disease progression and transmission. Diagnosis is also, of course, a prerequisite for entry to primary medical care for ongoing clinical management and evaluation for antiviral therapy.

Antiviral therapy for chronic HCV infection has been successfully implemented in correctional facilities, with sustained virological response (SVR; which is tantamount to cure – Pearlman and Traub, 2011) rates comparable to those seen in community settings (Rice *et al.*, 2012). Treatment within the correctional system has remained uncommon, however, largely because of concerns regarding the need to complete the lengthy (up to 48 weeks) treatment regimen prior to release from custody. Most released inmates lack insurance or the means to pay for treatment, making post-release continuity of care unlikely (Spaulding *et al.*, 2013). Access to treatment has thus been restricted to those inmates with longer sentences (e.g. at least 20 months remaining to serve – Martin *et al.*, 2010) so as to allow for treatment completion and follow-up. Psychiatric comorbidity may be listed as a relative or absolute contraindication to HCV therapy in correctional protocols, despite evidence that mentally ill prisoners can be treated safely (Allen *et al.*, 2003). Finally, cost may be a limiting factor in accessing HCV therapy in prison, although lack of resources does not excuse conditions that violate prisoners' constitutional rights, including the right to necessary medical care (American Bar Association, 2011).

Recent advances in HCV therapies have significant implications for treatment provision in correctional settings. All-oral, interferon-free therapies produce SVR rates of 98 percent in those with genotype 1 infection and 93 percent in those infected with genotypes 2 or 3. These regimens can be as short as six to 12 weeks (Sulkowski *et al.*, 2014; Kohli *et al.*, 2014). Thus, although expected length of stay remains a criterion for determining if a patient should begin HCV therapy (Federal Bureau of Prisons, 2012), the reduced duration of treatment regimens will significantly increase the pool of treatment-eligible prisoners.

Retain: ensuring adherence during and after incarceration

The correctional environment offers the opportunity for directly observed therapy as a means to ensure adherence to antiviral therapies (Spaulding *et al.*, 2013). However, a range of factors can negatively impact treatment adherence during incarceration, including staff shortages (Sabbatani *et al.*, 2006), frequent movement of inmates between institutions and unscheduled releases (Chew *et al.*, 2009). There is a need to ensure adequate support systems are in place for prisoners receiving ongoing therapies, both HCV-related and otherwise.

With shorter treatment regimens, it may become increasingly feasible to commence treatment with patients with short (<12 weeks) sentences, with linkage to care in the community following release. Adherence to HCV therapy following release from prison has not been well studied, most likely because of the requirement in many jurisdictions that prisoners be able to complete treatment prior to release. We know from studies of HIV-infected prisoners that linkage to post-release care can be challenging (Baillargeon *et al.*, 2009). Intensive discharge planning, including provision of information regarding treatment providers, a copy of laboratory test results, a supply of medication and assistance with enrolling in relevant community programs, can assist in increasing post-release retention in treatment (Baillargeon *et al.*, 2010). Ongoing case management may not provide any advantages over discharge planning (Wohl *et al.*, 2011).

One of the major barriers to post-release linkage to HCV antiviral therapy, lack of insurance, will be less so under the Affordable Care Act. A large proportion of released prisoners in selected states will be eligible for Medicaid (Cuellar and Cheema, 2012), increasing the feasibility of shared care arrangements where treatment is initiated while incarcerated and completed at a community provider after release. Increased insurance coverage will also assist in increasing access to treatment for substance use disorders, which will help treated individuals avoid reinfection.

Challenges to HCV STTR in the criminal justice system

Perhaps the most substantial barrier to the implementation of STTR for HCV in correctional settings is cost. US courts have affirmed that lack of resources is not an acceptable justification for failing to meet prisoners' constitutional or statutory rights, including access to medically necessary care (American Bar Association, 2011). Expanded treatment access has significant budgetary implications, and without concurrent expansion of correctional healthcare budgets, correctional institutions may be reluctant to “seek” and “test”, given the perceived obligation to “treat”.

The substantial costs of determining patient eligibility for treatment and treatment itself, however, must be weighed against the costs of failure to treat, particularly in relation to long-term prisoners. Delayed or denied HCV care may result in decompensated cirrhosis and hepatocellular carcinoma leading to high-intensity healthcare utilization, frequent hospitalizations and potentially, liver transplantation. The healthcare mandate applies equally to medically necessary transplantation, and the enormous costs associated with the transplant procedure and extensive follow-up care may easily exceed those of antiviral therapy at an earlier stage of disease (McKinney *et al.*, 2009; Baillargeon *et al.*, 2007).

The task of expanding HCV testing and treatment may be made more attractive to correctional authorities by incorporating these activities into broader city, county or state programs that are paid for through cost-sharing agreements between correctional institutions and state and federal health agencies. With the availability of all-oral short-course therapies, it may become more practical and feasible for correctional authorities to undertake the less costly “seek and test” activities, with treatment deferred until return to the community, at least in the case of short-term inmates for whom a brief deferral will not interfere with clinical outcomes.

A major barrier to expanded diagnosis and treatment of HCV, in both correctional and community settings, is a lack of appropriately trained treatment providers. Prison health services may lack specialists experienced in hepatitis C treatment; however, primary care physicians with appropriate support can safely provide treatment. Such support can be provided via telemedicine if necessary (Arora *et al.*, 2011). Primary care provider training in HCV treatment and establishment of specialist networks providing clinical support should be priorities for correctional health services.

A final challenge to STTR for HCV is the inclusion of ongoing IDU as an absolute contraindication for treatment in the Federal Bureau of Prisons hepatitis C clinical practice guidelines (Federal Bureau of Prisons, 2012). This is in contrast to other current treatment

guidelines (Ghany *et al.*, 2009, 2012) and research which demonstrates good treatment outcomes among people who are actively injecting drugs (Aspinall *et al.*, 2013). Although it is true that re-infections have been noted among prisoners treated for HCV (Bate *et al.*, 2010; Marco *et al.*, 2013), this is not in itself an argument against treatment for prisoners. Rather, it suggests that treated prisoners require support to reduce HCV risk behaviors in prison and post-release. Federal and jurisdictional guidelines require revision to ensure that they reflect evidence-based practices.

Directions for future research

Given the importance of cost as a barrier to expanding testing and treatment of HCV, there is a pressing need to determine the cost-effectiveness or cost-benefit of not only all-oral combination therapy, but of a comprehensive HCV STTR strategy in US correctional settings. Combination therapy with interferon was shown to be cost-effective in the prison setting (Tan *et al.*, 2008). What is needed now is a full costing of all STTR activities for HCV: opt-out testing, confirmatory testing, determination of treatment eligibility, pharmacy costs and costs associated with treatment monitoring and follow-up.

Hampering the development of cost analyses, and an important knowledge gap in itself, is the lack of recent epidemiological data on HCV infection in US jails and prisons. Varan *et al.* (2014) report on HCV seroprevalence in 12 states with routine testing, with results ranging from 9.6 to 41.1 percent. There is clearly important regional variation in HCV prevalence; there is also evidence of decreasing prevalence in prisons (Varan *et al.*, 2014; Larney *et al.*, 2013). Improved understanding of these and other trends, such as sex differences in HCV epidemiology, will help to inform cost discussions and other policy decisions.

Finally, further research is needed into the provision of opioid substitution therapy (OST) as a means to improve retention in HCV therapy among opioid-dependent prisoners. In a small trial of HIV-positive prisoners receiving combination antiretroviral therapy, retention in OST (in the form of buprenorphine maintenance treatment) following release from prison was associated with viral suppression (Springer *et al.*, 2012). Provision of OST, both in correctional settings and post-release, should also be explored as a means to reduce re-infection risk (Bate *et al.*, 2010; Marco *et al.*, 2013).

Conclusions

The burden of disease resulting from untreated HCV infection is increasing and will continue to do so unless significant efforts are made to diagnose and treat affected individuals. The criminal justice system is an ideal focus for such efforts due to the high volume of HCV-infected persons that are in contact with this system each year. Although there are challenges to applying STTR to HCV in the criminal justice system, the resulting gains to public health would be substantial.

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