Infectious Diseases and Opioid Use Disorder (OUD)

Policy Issues and Recommendations

Approved: March 2018

Infectious diseases (ID) and HIV clinicians across the country are reporting notable increases in cases of infectious diseases directly linked to injection drug use (IDU), including infective endocarditis (infection of the lining of the heart), hepatitis C (HCV) (including infection in pregnant women and transmission to their newborn infants[i]), HIV, skin and soft tissue infections, and bone and joint infections. Reported increases in HIV cases linked to injection drug use by some jurisdictions and estimates from the Centers for Disease Control and Prevention (CDC) that acute HCV cases related to opioid use increased by 133% from 2004 to 2014[ii] support these anecdotal reports. Infection rates are on the rise despite the availability of tools to prevent, and, in most cases, effectively treat these conditions with early diagnosis, and with access to proper care and integrated services.

Our success at preventing and controlling infections linked to IDU will be limited if our response to this public health crisis fails to recognize addiction as a disease and medical condition that requires a comprehensive and long-term approach to effective prevention, care and treatment.[iii] A heightened national response to the opioid use disorder (OUD) epidemic that offers comprehensive addiction and substance use treatment and includes prevention and treatment of infectious diseases associated with IDU is urgently needed and will require an investment of new public health and research resources. Without additional resources, we risk compromising existing public health efforts, and opening risks for new and reoccurring outbreaks and epidemics including for some areas where we have made progress including immunizations, TB and HIV, and others where we are losing ground, including sexually transmitted infections.

Policy Recommendations

IDSA, HIVMA and PIDS recommend the following policy actions to monitor and track the scope of infectious diseases linked to OUD and reverse these trends.

Expand Evidenced-Based Prevention Strategies

Recommendation – Significantly increase federal funding appropriated to the CDC to fund state and local health departments to monitor and respond to OUD infectious diseases epidemics, including HIV, hepatitis B, hepatitis C, and infective endocarditis as well as other serious, life threatening bacterial infections.

State and local health departments are on the frontlines of the opioid epidemic and need an infusion of funds to conduct surveillance to identify ID threats, expand capacity, train and communicate with health providers, and to implement effective and comprehensive prevention programs that reduce the impacts of opioid use and related ID in communities across the country. Allowing flexibility with the use of funding is essential so that health departments can use available resources to support a range of services based on local needs for preventing or treating infections that are on the rise due to increases in IDU.

Recommendation – Expand access to syringe services programs[iv] and safe injection or consumption sites[v] in the U.S. by increasing available funding.

Syringe services programs are highly effective at preventing transmission of disease as a result of IDU. Safe consumption sites provide supervised and hygienic venues with access to sterile equipment for individuals who inject drug, access to overdose prevention and treatment, health and disease prevention education, and linkage to opioid addiction treatment. By reducing the harms due to injection drug use, safe consumption sites have proven highly effective at reducing deaths due to drug use in Canada and in Europe where they have been employed for nearly three decades.[vi] Jurisdictions that have approved safe injection sites as part of a public health response to their local opioid crisis, including King County Washington, Baltimore, Philadelphia, San Francisco and others, should be supported in implementing and evaluating these programs. Bipartisan congressional action in 2016 allowing the use of federal funds under limited circumstances for syringe services programs was an important step,[vii] but new funding and additional flexibility regarding the use of the funding is needed to support access to these programs throughout the country and is particularly urgent in areas impacted by the opioid epidemic.

Recommendation – Fully implement national HIV, hepatitis B, and hepatitis C screening guidelines, including at risk pregnant women, persons in correctional settings and in rural areas affected by the opioid epidemic.[viii]

The U.S. Preventive Services Task Force (USPSTF) recommends that all people aged 15 to 65 be tested for HIV and that certain key populations, including people who inject drugs, be screened more frequently.[ix] The CDC and USPSTF currently recommend that all persons at risk for hepatitis C be screened and adults born between 1945 and 1965 have a one-time screening. Individuals who inject drugs comprise the group at highest risk for contracting hepatitis C.[x] CDC recommends that women of childbearing age receive HCV screening if they are at risk for HCV infection, regardless of pregnancy status.[xi] The USPSTF recommends that individuals at high risk for hepatitis B be screened, including individuals who inject drugs.[xii] CDC reports that only 85% of people living with HIV are aware of their status.[xiii] The U.S. Department of Health and Human Services (HHS) estimates that 54% of people living with HCV are aware of their status and only 33% of people with hepatitis B are aware of their status.[xiv]

<u>Expand Surveillance to Improve Detection and Response to Injection-Related Infections</u>

Recommendation – Enhance funding for public health response to HCV at the state and local level.

Local health departments are often unable to conduct follow up on reports of chronic HCV due to a lack of resources. Pilot programs have demonstrated that with additional funding, local public health departments can significantly improve surveillance to better identify community groups at risk, make sure that those at risk get tested, and assure that those who test positive are connected with treatment resources. Such programs should become the standard rather than the exception at the state and local public health level.

Recommendation – Take steps to evaluate the magnitude of the impact of infective endocarditis and other OUD infections and complications, and generate national and regional data to help inform the development of prevention and treatment programs. Proposals include providing resources to the CDC's Emerging Infections Program to evaluate trends in infective endocarditis and/or to conduct a national study to identify trends in infective endocarditis cases including morbidity and mortality by state. Explore classifying infective endocarditis as a national notifiable disease with resources to support enhanced surveillance.

The rates of infective endocarditis are increasing dramatically among people who inject drugs, but no public health system is in place to monitor this condition. National data to evaluate the scope of the problem is urgently needed to help affected communities identify outbreaks earlier. This is critical because HIV and HCV are

often asymptomatic for years, but infective endocarditis prompts hospital admission due to the severity of the associated symptoms. An evaluation of hospital admission data in North Carolina found a 12-fold increase in drug dependence-associated endocarditis linked to injection drug use from 2010 to 2015 during which total annual hospital costs increased from $1.1 to $22.2 million.[xv] IDSA members report that a single case of infective endocarditis can cost up to $150,000 to treat. They report that the cost of treating infective endocarditis at a single hospital with a significant population of patients who inject drugs can reach $5 million annually.

Recommendation – Support Expanded Surveillance role for the Food and Drug Administration (FDA)

The FDA's Opioid Action Plan seeks to improve the science and policy development behind OUD by enhancing safety labeling, requiring the collection of new data, and improving treatment for addiction and pain.[xvi] FDA should explore opportunities, in collaboration with CDC, to strengthen surveillance of infectious diseases and OUD, including considering opportunities to utilize administrative claims or coding databases for surveillance, as well as developing additional innovative ways to build surveillance into care delivery models.

Build Health Care Workforce Capacity

Recommendation – Leverage telehealth to improve access to expert HIV, hepatitis C and other infectious diseases prevention and treatment and medication for addiction treatment (MAT) through programs, including Project ECHO, e-consults and one-to-one provider-to-patient consultation by: 1) funding grants to support infrastructure through the Substance Abuse and Mental Health Services Administration (SAMHSA) or the Health Resources and Services Administration; and 2) developing innovative reimbursement mechanisms to support telemedicine through the Centers for Medicare and Medicaid Services (CMS). Use authority under the public health emergency declaration to remove barriers to prescribing buprenorphine via telehealth.

Limited access to providers willing and able to prescribe medication for addiction treatment and to infectious disease and HIV experts is hindering our nation's response to the opioid epidemic and leaving rural and underserved urban areas at risk for infectious diseases outbreaks and increased morbidity and mortality due to IDU. Telemedicine or telehealth programs such as Project ECHO have been well documented as increasing provider knowledge and improving patient outcomes.[xvii] [xviii] [xix] [xx] Support for infrastructure development is needed for these programs to be widely expanded and sustainable. In addition, reimbursement for services provided through telehealth, including time devoted to consultation and training, is critical for sustainability.

Recommendation – Increase federal funding available across HHS agencies, including through SAMHSA and Health Resources and Services Administration (HRSA) to support education and training for the diversity of health care providers on the frontlines of the opioid epidemic, including infectious diseases specialists.

Specialty primary care providers that include ID and HIV providers who are at the intersection of infectious diseases and IDU are a critical and logical resource to build capacity and increase access to MAT. Limited physician education and stigma have been identified as barriers to physician prescribing of office-based medication for addiction treatment in addition to limited reimbursement for treatment.[xxi] Health care providers on the frontlines of the opioid epidemic must have greater access to training in addiction medicine and other supportive resources. Guidance also is needed to support the integration of MAT into infectious diseases and HIV clinical practices and to help providers address the potential challenges of co-managing patients with addiction and complex chronic conditions like HIV.

Recommendation – Lift arbitrary limits on the number of patients that physicians and other prescribers can treat with MAT and offer funding to buprenorphine-waived providers to support mental health, psychosocial and support services.

Policymakers should lift patient restrictions on providers with waivers to prescribe buprenorphine to reduce barriers to treatment and address limited provider capacity, especially in underserved rural and urban settings. Greater resources for providers to be able to offer or develop strong linkages to mental health and psychosocial services are needed to increase providers' capacity to support patients with recovery, and to improve care and treatment adherence.[xxii]

Recommendation – Designate substance use disorder (SUD) treatment facilities and HRSA's Ryan White-funded clinics as approved sites for HRSA's National Health Service Corps.

Shortages of addiction and substance use specialists contribute to barriers to substance use treatment that are acute in rural and underserved urban areas.[xxiii] In addition, by 2019 the CDC estimates the HIV medical workforce in the U.S. will experience a significant shortage of expert HIV medical providers relative to demand.[xxiv] A lack of local access to healthcare was an issue in Scott County, Indiana when the HIV outbreak occurred in 2015.[xxv] Offering opportunities for medical providers to receive loan forgiveness in exchange for service at SUD treatment facilities and HRSA's Ryan White-funded clinics will help to attract these specialty providers where they are urgently needed.

<u>Increase Access to Treatment and Improve Delivery Systems</u>

Recommendation – Increase federal funding for SAMHSA to support grants to states and service providers responding to the opioid epidemic, and allow greater flexibility for funding to be used to respond to emerging OUD issues, including infectious diseases.

Access to substance use and behavioral health treatment remains a serious challenge in the U.S. due to provider shortages, poor access to healthcare coverage, stigma and discrimination, and other factors.[xxvi] [xxvii] Recent SAMHSA funding to states allowed federal funds to be used for expanding medication for addiction treatment, offsetting patients' deductibles and co-pays, HIV and HCV screening and referral, syringe services, and other support services.[xxviii] This nearly one billion dollar investment over two years was a meaningful step for states to address their opioid epidemics, but additional funding is needed to both further expand and sustain existing treatment services. Programs to attract providers to rural areas are needed. Treating addiction and reducing injection drug use improves health outcomes for patients with SUDs and reduces the spread of communicable diseases, including HIV, hepatitis B and C, and endocarditis in people who inject drugs, and limits the spread of HIV and hepatitis B and C to the community at large.

Recommendation - Expand access to substance-use and mental health treatment, including MAT, through private insurance coverage, Medicaid and federal grant funding to support treatment for individuals who are uninsured and underinsured. Increase resources to monitor and enforce the Mental Health Parity and Addiction Equity Act. HRSA's Ryan White HIV/AIDS Program also should be fully leveraged to provide access to addiction and substance use treatment to people with HIV affected by the opioid epidemic.

A comprehensive public health response to the opioid epidemic requires access to behavioral health treatment, including mental health and substance use services. Studies suggest that while health coverage among people with SUD has increased in recent years due to the expansion of Medicaid[xxix], considerable gaps remain with regards to access to effective behavioral health services to treat those with addiction.[xxx] State Medicaid waivers that may require drug screening, work requirements or that may lock individuals out of coverage seriously threaten access to substance treatment and should be reconsidered. MAT is considered the gold standard for effective addiction treatment, with studies demonstrating that it can reduce opioid-related mortality by half.[xxxi] But many barriers exist to its access, including basic access to health care coverage, arbitrary restrictions on the number of patients a provider can prescribe MAT, and a paucity of providers — including people trained to provide drug counseling – in rural areas where the opioid epidemic is currently concentrated. Federal and state

health insurance regulators must maintain the required Essential Health Benefits categories, including the requirement to cover mental health and substance use treatment.

Recommendation – Increase access to curative treatment for hepatitis C, and eliminate coverage restrictions, including those based on the specialty of the prescriber, fibrosis score, and the imposition of sobriety requirements.

Between 2011 and 2014, there was a 250% increase in reported new HCV infections, predominately driven by increases among young white adults in rural areas with a history of injection drug use following use of oral prescription opioids.[xxxii] The total number of HCV-infected people who inject drugs (PWID) is unknown, but estimates suggest a 43% to 95% HCV prevalence among the 6.6 million PWID.[xxxiii] New HCV treatments are highly effective and cure most people with HCV with access to the treatment, including those who continue to use drugs. [30] Third-party payers including state Medicaid programs have placed unprecedented barriers to accessing HCV treatment, including requiring sobriety, limiting coverage according to the prescribers' specialty regardless of the availability of specialists, delaying coverage based on fibrosis score or disease progression, and requiring testing and approval for treating most pediatric age groups.[xxxiv] [xxxv] These restrictions, including those requiring sobriety, are not supported by the latest science or treatment standards and must be lifted to prevent further escalation of hepatitis C cases. By curing HCV, treatment reduces transmission and ultimately will lower the rate of new infections among people who inject drugs. Scaling up access to HCV treatment is essential to preventing large-scale HCV outbreaks.

Recommendation – Fund demonstration projects through SAMSHA and HRSA to evaluate models of care for co-treating patients with addiction and infective endocarditis and other serious concomitant infections.

An increasing number of individuals who inject drugs are being hospitalized for treatment of infective endocarditis complicating treatment delivery, compromising treatment outcomes and increasing treatment costs. Effective treatment of patients with addiction and serious co-occurring infections, including pregnant women and their newborn infants requires a comprehensive, multi-disciplinary approach like the highly successful Ryan White HIV/AIDS Program care model to address addiction and mental disorders as well as the infection.[xxxvi] With successful co-treatment of addiction and infective endocarditis, or other serious bacterial and chronic viral infections, repeat infections can be avoided and risk of morbidity and mortality due to infection or overdose is reduced. Institutions in epicenters of the opioid epidemic are beginning to develop models for co-treatment that warrant evaluation through demonstration projects in other settings, including rural and lower-resourced areas through demonstration projects.[xxxvii]

Recommendation - Allow Medicaid programs flexibility to cover substance use and mental health treatment and other health care services for justice-involved populations to initiate or sustain treatment prior to a conviction or to support a successful transition to the community upon release.

Ensuring care and treatment is not interrupted when justice-involved individuals transition in and out of correctional settings is critical to prevent relapse and drug overdoses and to initiate or sustain access to treatment for individuals with communicable diseases, including HIV and hepatitis B and C. Under current federal Medicaid rules, justice-involved individuals can maintain their Medicaid coverage or initiate Medicaid coverage during incarceration. (Important to note that state laws vary with some terminating eligibility for incarcerated individuals.[xxxviii]) During the incarceration period, federal Medicaid reimbursement is limited to hospitals stays of 24 hours or more.[xxxix] Allowing states to apply for Section 1115 waivers to expand coverage for MAT and other substance use and mental health treatment as well other health care services, including treatment for communicable diseases during these transition periods would support a more successful

transition for the justice-involved individual and prevent the spread of HIV, hepatitis B and C and other communicable diseases within communities.

Recommendation – Amend the Institute of Mental Diseases (IMD) exclusion policy that restricts Medicaid coverage for residential substance use treatment.

Residential substance use treatment is an important component of the care continuum for effectively treating addiction. Despite recognition of the impediment that the IMD exclusion creates for providing comprehensive substance use and addiction treatment for Medicaid beneficiaries,[xl] the policy changes taken to date have not been effective at addressing this issue. Currently states may apply to CMS for Section 1115 waivers to cover residential treatment services but as of March 2018– only five states have been approved.[xli]

Recommendation - Revise Medicare policy to include coverage of methadone in outpatient settings.

CMS currently limits Medicare coverage for methadone for addiction treatment to inpatient care. Methadone may be covered under Medicare Part D for pain only.[xlii] To provide Medicare beneficiaries with access to a full continuum of treatment options, the Medicare coverage policy for methadone should be revised to support coverage of methadone for addiction treatment on an outpatient basis.

Invest in Research to Improve ID and Substance Use Prevention and Treatment Strategies

Recommendation – The National Institutes of Health (NIH) should prioritize and fund additional opioid-related infectious diseases research to determine the scope of prevalent comorbid infections such as infective endocarditis and osteomyelitis.

It is critical for NIH to fund research on other preventable infectious diseases besides HIV and HCV. There is currently a lack of robust data regarding opioid-related osteomyelitis, bacteremia and sepsis, skin and soft tissue infections, and central nervous system infections. For researchers seeking federal grant funding, it is difficult to obtain funding for injection drug use-related applications that do not pertain to HIV. The Office of AIDS Research (OAR) coordinates and approves almost all HIV-related funding for NIH Institutes and Centers, which limits research funding available for other ID and opioids projects. We encourage NIH to work with OAR to increase funding flexibility for grant applications that seek to study ID implications of opioid misuse that may not directly link to HIV/AIDS.

Recommendation – Increase research funding for vulnerable and underrepresented groups, including justice involved individuals and rural populations.

Despite clear health disparities experienced by persons within the criminal justice system and in rural communities, there is a dearth of research on these populations. Funding through the National Institute on Minority Health and Disparities (NIMHD) to date has focused on racial and ethnic minorities, but not on other important underserved populations. Understanding epidemiology and current standards of care for inmates with infections is essential—especially as incarcerated populations can represent a reservoir for continued infectious spread.

Recommendation – Fund implementation studies through NIH, SAMHSA, CDC, HRSA, and the Agency for Healthcare Research and Quality (AHRQ) to improve effective treatment and care of patients with multiple co-morbid conditions.

Additional research funding aimed at understanding how to help patients protect themselves against bacterial, as well as viral injection-related, infections is needed. As federal agencies increase their attention to OUD, there

is a strong corresponding need for implementation research linking providers with patients to implement other evidence-based interventions including pre-exposure prophylaxis for HIV prevention, OUD treatment, and syringe services programs. More information is needed on how to create medical models to expand these treatments, either as co-located or integrated care, particularly in resource-limited areas. As co-infections increase, we need more research on what outcomes can be improved when integrating care, including enhanced provider training for buprenorphine, and introducing methadone into different clinical settings.

Recommendation — Increase support for comparative patient-centered research to help patients and providers make better-informed decisions about their options for preventing, diagnosing, and treating OUD.

Clinical research is needed to address evidence gaps that can reduce the infectious diseases risks associated with opioid misuse. We urge monitoring of infectious-diseases related outcomes to be incorporated into the Patient Centered and Outreach Research Initiative (PCORI) studies that seek to generate information and data to help inform patients and clinicians decision-making that could also help to reduce infection complications.[xliii]

Contacts:

Amanda Jezek, IDSA Senior VP Public Policy & Gov't Relations, ajezek@idsociety.org
Andrea Weddle, HIVMA Executive Director, aweddle@hivma.org

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