Drug Formularies in Correctional Settings

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Drug formularies are a key determinant of access by incarcerated patients to psychotropic medications. The National Commission on Correctional Health Care (NCCHC) defines a formulary as "a written list of prescription and nonprescription medications that are ordinarily available to authorized prescribers, including consultants, working for the facility" (Ref. 1, p 71). Medications that are not listed on a formulary, often referred to as nonformulary medications, may have different degrees of availability. Some nonformulary medications may be approved for use if patients meet specific clinical criteria, whereas other medications may be entirely unavailable or prohibited from use.

For example, the U.S. Federal Bureau of Prisons (BOP) Health Services National Formulary lists more than 20 medications commonly used in psychiatric treatment that are either nonformulary or require approval prior to use.[2] In these facilities, mental health professionals must navigate restrictions when attempting to prescribe numerous classes of medications, including specific antidepressants, antipsychotics, anxiolytics, gabapentinoids, stimulants, and medications for addiction treatment.[2] While this formulary does not specify why medications in many of these classes are restricted, these restrictions limit which patients can receive specific medications, the types of medication formulations that can be offered by prescribers, and the maximum allowable dose and duration of pharmacotherapy. Additional restrictions beyond the BOP formulary may apply when prescribing to incarcerated patients in U.S. federal prisons.[3] As a case in point, the BOP formulary lists methadone as a formulary medication, but it also refers clinicians to a BOP Pharmacy Services policy that inmates with opioid use disorders "will not be maintained on methadone with the exception of pregnant inmates" (Ref. 4, p 37).

Although most health care settings have some limitations regarding patients' access to medications, drug formularies in correctional settings play a significant and underrecognized role in the practice of psychiatry within the United States. These formularies deserve further attention from both mental health professionals and policymakers because they can restrict incarcerated patients' abilities to access psychotropic medications.

Concerns About Correctional Formularies

Formularies can limit inmates' access to medications commonly used in psychiatric care. In 2017, jails and prisons in the United States handled more than 11 million admissions and held approximately 2 million incarcerated individuals at any one time.[5,6] Incarcerated individuals tend to experience higher rates of mental disorders, substance use disorders, and co-occurring medical conditions compared with the general population.[7-10] Studies of incarcerated

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individuals in the United States suggest approximately 10 to 30 percent have a mental disorder, and more than 50 percent have a substance use disorder.[7-9] Given the excess burden of mental health needs among incarcerated populations, health risks related to limiting medication access may be greater in correctional settings.

Incarcerated patients have less autonomy and fewer potential remedies when denied use of specific medications. In community mental health care settings, patients who encounter formulary restrictions or a lack of availability of pharmacotherapies can find alternative ways to access specific medications, such as bringing supplies of approved medications from home to inpatient units, paying out of pocket for medications, or seeking treatment from different clinicians or facilities. Although U.S. courts have established that incarcerated individuals have a right to mental health care, incarcerated patients generally cannot seek mental health care beyond the correctional facility in which they are detained.[11,12] This inability to choose among mental health care providers is especially important given idiosyncratic and site-specific medication policies of different correctional facilities. As an example, the California Correctional Health Care Services 2019 formulary lists at least 14 commonly used psychiatric medications that are either banned or restricted to some degree.[13] Some of these medications, such as bupropion, quetiapine, gabapentin, and hydroxyzine, are also restricted on the national formulary of the BOP. The California Correctional Health Care Services formulary lists additional restrictions for other commonly used medications, including fluoxetine, venlafaxine, nortriptyline, and nicotine patches. Thus, incarcerated patients' medication regimens may depend more on their physical location than on their mental health needs.

Drug formularies in correctional settings can disrupt psychiatric care during a patient's transition from the community into a prison or jail. Patients whose psychiatric symptoms were well controlled with specific psychotropic medications prior to incarceration may be at risk for psychiatric destabilization, discontinuation syndromes, or other adverse effects if any of these medications are abruptly stopped. A 2019 investigation of more than 400 lawsuits regarding jail medical care noted that "about a third of jail inmates who attempted suicide or took their lives did so after staff allegedly failed to provide prescription medicines used to manage mental illness" (Ref. 14, p 2).

Drug formularies in correctional settings have been the focus of considerable litigation. In recent years, plaintiffs in California,[15] Florida,[16] Maine,[17,18] Texas,[19] and elsewhere have filed suits related to medication access in correctional settings. In 2013, a prison inmate filed a motion requesting that the U.S. District Court for the Northern District of Florida order clinicians to "place him back on Thorazine or Seroquel" for schizophrenia and anxiety (Ref. 16, p 1). The Florida Department of Corrections (DOC) submitted an affidavit from a staff psychiatrist who explained that the DOC maintains a formulary with a standard protocol for antipsychotic use, that the formulary includes six other antipsychotics, and that the inmate was receiving reasonable alternatives to the requested psychotropics. The court denied the inmate's motion, with a magistrate judge writing, "This is not a case where a prisoner—clearly in need of psychiatric treatment—is being deprived of any medication or is being deprived of psychiatric treatment. Rather, Plaintiff's claim is that he is not receiving the brands of medications he wants" (Ref. 16, p 1). This reasoning underscores the constricted role that inmates may play in the informed consent process, considering that their choices for medications are often limited.

Still, not all courts have sided with correctional facilities in these types of proceedings. For example, in 2018, Brenda Smith sued Aroostook County in Maine, alleging that the county jail refused to allow her to take buprenorphine for opioid use disorder during an impending incarceration. An addiction psychiatrist opined as an expert for Ms. Smith about the risks of opioid overdose and the effectiveness of medications for addiction treatment.[17] In 2019, the U.S. District Court of Maine ordered the jail to provide her with this medication, and this preliminary injunction was later affirmed by the U.S. Court of Appeals for the First Circuit.[17,18]

Rationale for Correctional Formularies

Logistical factors, including availability of staffing, medical equipment, and lab monitoring, may affect correctional facilities' abilities to offer specific pharmacotherapies. For instance, a correctional facility cannot provide buprenorphine to inmates with opioid use disorders if none of the staff clinicians have the required Drug Enforcement Administration

waiver.[20] Clozapine initiation to treat schizophrenia might be challenging if the correctional facility lacks resources to coordinate weekly phlebotomy for neutrophil count monitoring.[21,22]

Correctional health systems are under intense scrutiny for expenditures because their budgets are drawn from public funds, and psychotropic prescribing can incur significant costs for correctional systems. For example, California spent $144.5 million on prison pharmaceuticals in 2012, and 19 percent of this spending was for antipsychotic medications.[23] The cost of certain medications is often used as a rationale for making certain medications nonformulary or, in some cases, simply unavailable.[24]

Concerns regarding misuse of medications, including psychiatric medications, often shape drug formularies in correctional settings. Individuals may misuse medications, even noncontrolled medications, for sedating, hypnotic, stimulating, or toxic effects, among other reasons. Incarcerated individuals may be at higher risk than others for these behaviors because of the high rates of substance use disorders in correctional settings.[9,25] Available literature on this clandestine activity suggests inmates may misuse gabapentinoids, anticholinergics, tricyclic antidepressants, quetiapine, bupropion, venlafaxine, and other medications.[25-31]

By incorporating clinical and systems-based evidence into lists of preferred medications, drug formularies can enhance the quality of mental health care and prevent iatrogenic harm in correctional settings. For example, due to concerns regarding diversion and financial costs related to quetiapine use, the New Jersey Department of Corrections Pharmacy and Therapeutics Committee voted to require a nonformulary approval process for quetiapine in 2009. Psychiatrists in that system were given 60 days to either discontinue quetiapine orders or to submit a nonformulary request to justify continuation. Among 254 incarcerated individuals who were prescribed quetiapine, psychiatrists attempted to stop it in 63 percent of cases and were successful doing so 96 percent of the time. There were no significant changes in the number of patients requiring a higher level of care, suicidal behavior, or disciplinary charges.[31] During the study period, no further antipsychotics were needed for 45 percent of cases where an attempt to stop quetiapine was made.[31] These findings suggest that, because of a formulary restriction, a substantial group of inmates were no longer being exposed to unnecessary risks from an antipsychotic medication.

Improving Correctional Formularies

Drug formularies in correctional settings can bring potential benefits, but also significant risks, to incarcerated patients. Strategies are needed to optimize the health, operational, and financial effects of these formularies, and mental health professionals should be at the forefront of these efforts.

The accessibility of psychotropic medications on drug formularies affects many stakeholders throughout any correctional setting. Facility Pharmacy and Therapeutics Committees should rely on multiple perspectives to formally weigh the risks and benefits of formulary decisions and to update formulary policies on an ongoing basis.[1,26,32] With expertise in the management of mental disorders and substance use disorders, as well as the use of psychotropic medications, prescribing mental health professionals should participate on these committees and use their clinical perspectives to better shape the development of correctional formularies.

Drug formulary policies should be transparent to both correctional health staff and incarcerated patients. Prescribers should openly discuss with patients why specific medications may be preferred options while others are unavailable or require nonformulary approval. Pharmacy and Therapeutics Committees should identify ways to enhance staff awareness of these policies, such as providing orientation to newly hired prescribers, integrating formulary information into electronic medical record systems, and publishing changes to formulary policies in an accessible manner. For example, the California Correctional Health Care Services formulary is published online and is regularly updated with its list of formulary medications, use criteria for nonformulary medications, and announcement dates when specific restrictions were introduced.[13] As practicing clinicians who see the effects of formulary decisions on patients and staff, psychiatrists and other prescribers working in correctional settings are well-positioned to identify what information may be useful in these reports.

When operational reasons limit facilities' capacities to prescribe needed medications, Pharmacy and Therapeutics Committees and mental health administrators should identify and address these problems. For example, requiring a buprenorphine waiver as

part of the credentialing process might eliminate this barrier to treatment for opioid use disorders. Improving laboratory services, either on-site or via outside vendors, may circumvent concerns about prescribing medications that require frequent laboratory monitoring.

Psychiatrists and other prescribers play a key role in coordinating care across correctional and community health systems. Newly incarcerated individuals should be screened for prior psychotropic use.[1,26,32] When indicated, mental health professionals should reach out to community clinicians to gather collateral information about the effectiveness of prior treatments.[26] Similarly, forwarding medical records to community clinicians can facilitate transitions in care when patients leave correctional facilities and return to the community. Prescribing mental health professionals can ensure that incarcerated individuals receive adequate supplies of medications upon reentry to the community.[1,26,32] Formulary policies should allow flexibility for emergencies and other disruptions to continuity of care. The BOP national formulary, for example, includes a "Continuity of Care Provision" to address urgent situations when incarcerated individuals are processed outside regular working hours and the facility does not have appropriate formulary substitutes for specific medications. If withholding the medication from the patient would "pose a significant risk to the patient" (Ref. 2, p 5), this provision allows prescribers to administer the nonformulary medication for up to four days while awaiting nonformulary approval.

Moving Toward Model Formularies

By conducting research into these formularies, mental health professionals can improve understanding of these systems of care and identify potential reforms that both protect incarcerated patients from the potential risks of formularies and maximize the therapeutic value of these frameworks. Medical organizations, such as the American Academy of Psychiatry and the Law (AAPL),[26] the American Society of Addiction Medicine,[33] and the American Psychiatric Association (APA),[34] have developed educational resources relevant to prescribing in correctional settings. The NCCHC publishes a set of standards for medication services in jails and prisons.[1,32] Still, many questions remain that mental health professionals can study further. Why are some medications unavailable or designated as nonformulary in certain correctional systems but not others? To what degree do drug formularies vary among different correctional institutions? What are the relationships between formulary decisions for specific medications and psychiatric outcomes?

Considering the diversity of correctional formularies, it may be of value for organizations such as the APA, AAPL, and the NCCHC to collaboratively develop a model correctional formulary. Because the needs of different correctional facilities may vary, a series of model psychiatric formularies, such as ones for small jails, large jails, prison systems, and juvenile facilities, may be more useful. The needs of different incarcerated subgroups, such as elderly or pregnant inmates, should be considered in these endeavors.[35-37] Model correctional formularies should include evidence and rationales for inclusion or exclusion of specific psychotropics.[38] Such model formularies, while nonbinding, may improve consistency of care, limit unnecessary disruptions of treatment, and increase the number of formulary decisions that are grounded in evidence-based practices.

Conclusions

Access to clinically indicated medications is essential to meet the psychiatric needs of incarcerated individuals. By determining whether and how incarcerated individuals access psychiatric medications, drug formularies have considerable influence on the delivery of mental health services in the United States and warrant additional attention within the field of psychiatry. Mental health professionals should recognize that drug formularies in correctional settings are necessary and can be health-promoting, but, unless carefully constructed and monitored, these formularies can also pose health risks to incarcerated individuals with mental health needs.

Correctional systems must weigh interrelated health, operational, and financial factors when developing drug formularies for incarcerated patients. Balancing these competing concerns requires coordinated efforts to maximize the therapeutic value of drug formularies and to mitigate the health risks associated with these frameworks. Mental health professionals can foster the development and the improvement of correctional formularies by providing input to formulary decisions, promoting transparency of formulary policies, supporting continuity of care for incarcerated patients, and conducting research on formularies. Finally, by developing model

psychiatric medication formularies for correctional settings, organizations that support psychiatry and correctional health care can help mitigate variations in medication access across correctional settings and standardize the delivery of evidence-based psychiatric care.

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