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Introduction to the Special Issue on Innovative Interventions and Approaches to Expand Medication Assisted Treatment: Seizing Research Opportunities made available by the Opioid STR Program

Dennis P. Watson, PhD^a, Barbara Andracka-Christou, JD, PhD^b, Thomas Clarke, PhD^c, Julie Wiegandt, MS^d

^aContact Author; Center for Dissemination and Implementation Research, Department of Medicine, University of Illinois College of Medicine at Chicago, 818 S. Wolcott Ave., Chicago, IL 60612

^bDepartment of Health Management and Informatics, University of Central Florida, 4000 Central Florida Boulevard, Orlando, FL 32816

^cThomas Clarke, Substance Abuse and Mental Health Services Administration. 5600 Fishers Lane, Rockville, MD 20866

^dPublic Health Manager, Arnold Ventures

Abstract

The 21st Century Cures Act is the most significant piece of U.S. legislation aimed at tackling the opioid epidemic to date. This special issue comprises papers reflecting medication-assisted treatment (MAT)-related research made possible through the Cures Act-authorized State Targeted Response (STR) grant mechanism. Work related to both STR evaluation and original research conducted within the context of STR activities are included in the issue, with topics including community assessments of MAT-related needs, MAT access and linkage, criminal justice-oriented MAT implementation, and adjunctive MAT supports and treatments. All of the research represented this issue is early-stage, with results reflecting data collected primarily within the first of STR's two year funding cycle. While such formative work does have inherent limitations, the gravity of the opioid epidemic requires rapid assessment and dissemination of results to inform the public health response in a manner that will have a timely and meaningful impact.

With an estimated 47,600 Americans having died of an opioid-related overdose in 2017, the opioid epidemic is truly one of the most pressing public health issues facing the United States today (Scholl, Seth, Kariisa, Wilson, & Baldwin, 2019). The 21st Century Cures Act is the most significant piece of legislation aimed at tackling the epidemic to date, having authorized more than \$1 billion in funding to support prevention and treatment initiatives including implementing and expanding access to clinically appropriate *evidence-based treatments for opioid use disorder* (OUD) (21st Century Cures Act, 2016). When it comes to

OUD, no intervention has more evidence supporting it than medication assisted treatment (MAT). Also known as “medication for addiction treatment” and “medication for opioid use disorder”, MAT refers to the use of one of three U.S. Federal Drug Administration-approved medications: methadone, buprenorphine (known popularly by the brand name Suboxone®), or naltrexone (known popularly by the brand name injectable Vivitrol®). The 16 articles in this special issue represent some of the MAT-related research made possible through the 21st Century Cures Act-authorized State Targeted Response (STR) to the Opioid Crisis grant mechanism administered by the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA; Substance Abuse and Mental Health Services Administration (SAMHSA), 2016). In all, STR distributed \$485 million over two years (2017–2018) through grants made to 57 U.S. states and territories. We (DPW and BAK) proposed this special issue as a means of highlighting the important MAT expansion research made possible through STR activities. We have invited two co-authors (JW and TC) because their perspectives as representatives of organizations (SAMHSA and Arnold Ventures respectively) that have supported STR-related MAT research provide additional and unique insights into the importance of this work we felt should be emphasized in this introduction.

The evidence for MAT in general is strong, demonstrating it leads to longer periods of abstinence, reduced risk of overdose and death, and is highly cost effective (Connery, 2015; Fullerton et al., 2014; Lee & Ripley, 2017; Murphy et al., 2019; Schackman, Leff, Polsky, Moore, & Fiellin, 2012; Thomas et al., 2014). Despite these benefits, MAT is largely inaccessible to many of those living with OUD (Dick et al., 2015; Ludwig & Peters, 2014; Sigmon, 2014). When it is available to patients, they are often faced with system or individual barriers that prevent them from initial or continued treatment engagement (Deering et al., 2011; Knudsen, Abraham, & Oser, 2011; Kourounis et al., 2016). The STR mechanism provided funding that could be used to expand and improve MAT access, and MAT-related initiatives are highlighted in 45 (76%) of the funded STR grant abstracts. This special issue provides a sample of some of the research related to these initiatives. It is important to note that these studies represent early-stage research, with most of the results and findings discussed relating to data collected within the first year of the STR grants. Work related to both STR evaluation and original research conducted within the context of STR activities are included in this issue. While one of the evaluation-focused articles stems from SAMHSA's national, cross-state STR evaluation, the rest are the result of activities supported by states using STR and/or other funds. The original research studies represented in this issue were supported by unique funding mechanisms from the National Institutes of Health or Arnold Ventures that required researchers to work in collaboration with the entity leading STR efforts within a specific state in order to enhance relevance, feasibility, and impact of the resulting work.

The papers in this issue represent a range of activities along the intervention development and testing continuum including initial assessment and planning, program implementation, and early-stage effectiveness research. On the planning end of the spectrum, two studies describe results of *needs assessments* in underserved communities. Moreland et al. (2019) employed a survey to investigate barriers to MAT in state-funded community agencies in South Carolina, a predominantly rural state, while Zeledon et al. (2019) present preliminary

results of a qualitative needs assessment in California among American Indian and Alaskan Native communities that have been disproportionately impacted by the opioid epidemic.

Five papers include activities aimed at *expanding MAT access*. Four of these articles discuss implementation and/or early results related to Hub-and-Spoke models of care. Originally developed and demonstrated to be effective in Vermont (Brooklyn & Sigmon, 2017), the Hub-and-Spoke model is a system-level intervention that entails the use of opioid treatment programs serve as hubs that then transfer clients to spokes in the community, including primary care providers and office-based practitioners. Miele et al. (2019) and Darfler et al. (2019) provide two companion articles focused on the implementation and preliminary evaluation results for California's STR Hub-and-Spoke model, while Reif et al. (2019) and Winstanley et al. (2019) provide descriptive data related to Hub-and-Spoke programs in Washington state and West Virginia respectively. While the Hub-and-Spoke model has an existing evidence-base, these four articles provide important details regarding its adaptation and implementation in new contexts. A different and innovative tactic to expanding MAT is Missouri's Medication-First approach studied by Winograd et al. (2019). Based philosophically in the Housing First approach to low-barrier supportive housing, the Medication First model increases MAT access by eliminating often required but potentially unnecessary additional treatment requirements such as psychotherapy to emphasize engagement and retention. High et al. (2019) also discuss Missouri's Medication First program as a case study in their paper focusing on STR cross-site evaluation activities.

A third group of papers focus on *interventions for linking patients to MAT*. Four of these projects look at emergency medicine-rooted interventions, with the majority focusing on interventions that utilize peer support workers to engage and connect people to MAT. In the context of these articles, "peers" broadly refers to paraprofessionals with lived experience of substance use recovery who provide outreach and recovery supports for people with OUD. There is promising but limited evidence related to the optimal implementation or effectiveness of peers (Reif et al., 2014), and the peer studies in this issue add to the growing literature on the topic. McGuire et al. (2019) qualitatively identify emergent forms and functions of peer specialists working in emergency department settings through a comparative analysis of programs in Indiana, New Jersey, and Nevada. Wagner et al. (2019) examine support for mobile peer recovery units within Nevada's emergency medical services using a mixed-methods approach guided by the Diffusion of Innovation Model (Rogers, 2010). Watson et al. (2019) report the results of an Indiana-based pilot study conducted in preparation for a larger multisite clinical trial that aims to assess the effectiveness of peers for linking patients who present to the emergency department with OUD to MAT. Scott et al. (2019) evaluate the feasibility and preliminary effectiveness of a peer street outreach intervention for connecting members of high-risk communities to MAT in Illinois. In a second Illinois-based study, Scott et al. (2019) present feasibility and preliminary effectiveness of another intervention that utilized but did not hinge on peer support workers to identify, screen, and enroll patients in MAT after an emergency medical services encounter. Finally, a second case study discussed in High et al.'s (2019) cross-site evaluation article discusses a bridge program in Kentucky that initiates buprenorphine within the emergency department before linking patients to long-term MAT. Bridge programs such as this already have a strong evidence-base (Busch et al., 2017; D'Onofrio et al., 2015);

however, barriers to implementation in real-world practice require additional work in this area to help demonstrate their value to relevant stakeholders.

The final three papers in this issue focus on topics that cannot easily be grouped with the others. Hanna et al. (2019) qualitatively evaluate implementation of a corrections and community-based treatment initiative utilizing extended-release naltrexone. Within their work, they successfully employ the Consolidated Framework for Implementation Research to assess implementation of this large, cross-system initiative (Damschroder et al., 2009)—a novel use of the framework, which has mostly been employed to assess implementation of interventions being inserted into relatively discrete clinical settings. Mooney et al. (in press) developed and tested a patient decision aid to facilitate shared decision making at initial MAT clinic visits. While similar tools have been developed previously (SAMHSA, 2016), their utility has not been tested. Finally, Price et al. (2019) evaluate the preliminary effectiveness of a mind-body awareness training designed to be an adjunctive to MAT. Given research on adjunctive MAT treatments has largely focused on psychotherapy and demonstrated limited or mixed results (Dugosh et al., 2016; Sokol, LaVertu, Morrill, Albanese, & Schuman-Olivier, 2018), development and rigorous assessment of novel interventions with potential to improve MAT responsiveness and retention are greatly needed.

Whether evaluation or research, all of these studies faced constraints that likely impacted the design choices researchers made. For instance, all the projects had to work within the context of a highly ambitious two-year implementation timeline for STR activities (Beletsky, 2018). The projects were also being carried out within constantly shifting policy and service system contexts that likely required some level of methodological flexibility. Finally, for those studies attempting to demonstrate effectiveness, the ever increasing saturation of new policies, services, and treatment options targeting OUD present serious potential issues that can confound study results.

In addition to the above limitations, there is an inherent risk conducting the types of early-stage and novel research described in this special issue, as in many cases the interventions and activities described were being planned as they were being implemented. This process is the opposite of the traditional science-to-practice approach favored by researchers in which interventions are first proven efficacious under highly controlled conditions before being put into real-world practice. While a more practice-to-research approach that is reflective of much of the work in this issue raises certain challenges (the most evident being reduced internal validity), it does not mean the resulting research is not rigorous or worthwhile. Indeed, the gravity of the opioid epidemic requires real-time solutions that will not wait for the average 17 years it generally takes an efficacious intervention to move from research to practice (Green, Ottoson, García, & Hiatt, 2009; Volkow & Collins, 2017; Westfall, Mold, & Fagnan, 2007). That said, scientific evidence has already provided a strong evidence base that supports MAT expansion as a key part of the solution to this epidemic, and expanded MAT access is the goal of most of the novel and untested interventions discussed in this issue. Furthermore, these studies take advantage of opportunities that might not have existed outside of the context of the STR grants. As such, they document valuable evidence in terms of both public health accountability and formative information regarding implementation

that would otherwise be lost and can lead to meaningful program and policy improvement and resulting sustainability.

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