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Implementing Effective Substance Abuse Treatments in General Medical Settings: Mapping the Research Terrain

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Abstract

The National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Institute on Drug Abuse (NIDA), and Veterans Health Administration (VHA) share an interest in promoting high quality, rigorous health services research to improve the availability and utilization of evidence-based treatment for substance use disorders (SUD). Recent and continuing changes in the healthcare policy and funding environments prioritize the integration of evidence-based substance abuse treatments into primary care and general medical settings. This area is a prime candidate for implementation research. Recent and ongoing implementation projects funded by these agencies are reviewed. Research in five areas is highlighted: screening and brief intervention for risky drinking; screening and brief intervention for tobacco use; uptake of FDA-approved addiction pharmacotherapies; safe opioid prescribing; and disease management. Gaps in the portfolios, and priorities for future research, are described.

Keywords

integrated care; implementation science; alcohol; substance use disorders; evidence-based practices; primary care

1.0 Introduction

Decades of investment have yielded effective behavioral, psychosocial, and pharmacological interventions to address substance use disorders (SUD) and sub-diagnostic but hazardous substance use. Despite this strong evidence, relatively few effective treatments and practices have been widely adopted or faithfully implemented within general medical settings. The quality of treatment for people with tobacco, drug, and alcohol use disorders can be

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improved by integrating existing evidence-based approaches into clinical settings in which high-risk populations are engaged in routine medical care.

The integration of SUD treatment into general medical settings is a topical area especially suited to implementation research. Not only is there a need to develop and test novel service delivery models that may achieve these goals, but there is a parallel need for research to develop effective implementation strategies through which evidence-based practices (EBPs) and service delivery models can be spread and sustained. This paper attempts to identify persistent gaps in implementation research in the area of integrated service delivery and suggests priority areas for implementation research needed to better integrate SUD treatment into general medical settings. These observations are offered from the perspective of program directors charged with overseeing portfolios of implementation research within three organizations that have worked to set priorities and stimulate addiction-related implementation research: the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institute on Drug Abuse (NIDA), and the Veterans Health Administration (VHA) Substance Use Disorder Quality Enhancement Research Initiative (SUD QUERI). The purpose of this article is to take stock of where we have been, identify well-trodden ground, and suggest new routes that NIH- and VA-funded research might take to arrive at greater service integration for SUD treatment.

An oft-cited statistic is that it takes 17 years for 14% of clinical discovery to make its way into routine practice (Balas and Boren, 2000). While some treatments prove infeasible for everyday clinical application, there are also numerous practices that stall due to ineffective dissemination or a lack of proven implementation strategies. These “leaks” in the translation pipeline are perhaps nowhere more noticeable than in hospital-based detection and treatment of substance use disorders. In the US, hospitalized patients with alcohol use disorders receive only a fraction of the recommended care for their condition (McGlynn et al., 2003), while SUDs play a prominent role in costly readmissions and overutilization of hospital services among Medicaid patients (AHRQ, 2014; Neighbors et al., 2013). At the same time, many persons with SUDs are unable or unwilling to seek treatment in specialty programs, but routinely encounter other components of the healthcare system (primary care visits, emergency departments, pharmacies). Thus, effectively identifying and addressing SUDs in general medical settings could help engage these patients, lower healthcare expenditures, and make a significant public health impact. This requires that we identify those treatments that might feasibly be delivered outside of specialty addiction treatment programs, and that we develop effective implementation strategies to help bridge this gap in service delivery.

Implementation science explicitly develops and tests interventions (strategies) intended to affect the adoption and sustainment of evidence-based practices and treatments in real world clinical settings. For decades the funding and treatment for SUD has been separated from that for other health conditions, making integration especially challenging (Manderscheid & Kathol, 2014). For the purpose of this article, we define general medical settings to include obstetric, pediatric, and adolescent medicine; primary care practices including family practice and internal medicine; medical services provided through Federally Qualified Health Centers; Veterans Affairs Medical Centers and clinics; as well as settings providing *de facto* primary care for patients who may not otherwise receive it, whether for acute

episodes (e.g., emergency departments, trauma centers, urgent care clinics) or for chronic disease management (e.g., HIV clinics). Importantly, these settings do not include specialty addiction treatment or mental health settings.

In recent years, and largely within the context of the Affordable Care Act, Federal agencies across the US Department of Health and Human Services have increasingly been supporting research to understand the process, cost, and outcomes associated with integrating behavioral health, including SUD treatment, into general medical care. For example, the Agency for Healthcare Research and Quality (AHRQ) funds research assessing the effectiveness of services delivered in integrated care settings, including the impact of behavioral health on primary care and health outcomes. Their Academy for Integrating Behavioral Health and Primary Care (www.integrationacademy.ahrq.gov) serves as a resource for ongoing review and synthesis of the results of research on care integration being conducted across government and the private sector (e.g., AHRQ 2014). The Center for Integrated Health Solutions (www.integration.samhsa.gov), a joint endeavor of the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Health Resources and Services Administration (HRSA), promotes the delivery of integrated primary care and behavioral health services through demonstration projects and a public repository of information on health homes, with a particular focus on safety-net providers. Meanwhile, the Centers for Medicare and Medicaid Services (CMS) has funded two rounds of Healthcare Innovations Awards to develop and test novel payment and service delivery models; these include projects to transform traditional primary care practices into medical homes, and accelerate innovation in service delivery (www.innovation.cms.gov). VHA's Health Services Research and Development (HSR&D) and QUERI programs have for many years funded research to develop and evaluate integrated care models and their implementation (e.g., VHA 2015a). And the National Institutes of Health (NIH) contribute to this endeavor via support of health services research and implementation science. Indeed, there are concerted efforts across government to promote the implementation of integrated service delivery; in this context, NIH and VHA have been at the forefront in supporting hypothesis-driven research in the pursuit of generalizable knowledge about effective and scalable implementation strategies to achieve these ends.

Within the current policy and financing context, the US healthcare infrastructure continues to evolve, and examples of innovative and successful service integration models have begun to emerge. There is increasingly a need to subject these candidate models to broader testing, and to develop and deploy systematic implementation strategies to take effective service delivery models to scale and sustain them. Implementation science holds the promise for developing effective scale-up strategies that can leverage facilitators and overcome barriers inherent in the complex contextual environments in which services are delivered. Health services and implementation research funded by the NIH and VHA has begun to provide scaffolding for effective scale-up of integrated care models to address the substance use disorder treatment needs of patients in general medical care settings.

1.1 Research on SUD Service Implementation and Integration at NIH

The National Institutes of Health comprises 27 Institutes and Centers, generally organized by focal disease or condition. Funding for extramural grants is accomplished principally through investigator-initiated applications; these applications are solicited via Funding Opportunity Announcements (FOAs), through which NIH program staff describe needs for research in specific topic areas. In 2005, eight of the 27 Institutes – including NIAAA and NIDA – jointly issued the first multi-institute FOA on Dissemination and Implementation (D&I) Research in Health. As is common when nurturing a new subfield, applications were initially assigned special receipt dates during alternating review cycles, and were assigned to ad hoc peer review committees ("special emphasis panels") that evaluated only D&I applications. Interest in this area has since grown to the point that as of 2014, a total of 14 Institutes and Centers were participating in the FOA, and the flow of applications was sufficient to justify a standing Center for Scientific Review study section, convening every review cycle. Summaries of research supported under this FOA have been previously published (Glasgow et al., 2012; Neta et al., 2015; Tinkle et al., 2013).

A 2012 report by the National Advisory Council on Drug Abuse reviewed the NIDA implementation research portfolio to date and made recommendations for future research and programmatic activities (NIDA, 2012). To promote implementation research on topics related to alcohol and drug treatment services, NIAAA and NIDA have incorporated D&I topics into their respective health services research program announcements. The two institutes also share a joint R34 announcement to fund pilot testing of organizational and systems interventions to support implementation trials.

Implementation research in the area of service integration has been a prominent focus of several recent FOAs. In particular, in 2012, NIDA released a Request for Applications (RFA) on the integration of drug abuse prevention and treatment in primary care settings which yielded 7 funded grants. Other major initiatives to support service integration have included release of the NIDAMed suite of tools to support physicians' identification of problem drug use, along with resources to address safe opioid prescribing for primary care patients with chronic pain (NIDA 2015); NIAAA's release of clinicians' guides to support the screening and identification of patients with problematic alcohol use in primary care (NIAAA 2007, 2010, 2011); and ongoing efforts to promote the implementation of evidence-based screening and brief intervention protocols to address tobacco use and risky drinking in general medical settings.

1.2 Research on SUD Service Implementation and Integration at VHA

VHA's Health Services Research and Development (HSR&D) service funds investigator-initiated research on diverse aspects of service delivery for hazardous substance use and SUD, including but not limited to quality measurement, comparative effectiveness, variation in access and quality, and developing and testing models of behavioral healthcare integration in diverse settings. Although the landscape of implementation research within VHA is undergoing a rapid realignment, from 1998 until 2015, implementation research has largely been supported via the Quality Enhancement Research Initiative (QUERI). Historically, QUERI has been structured around mostly disease-focused Centers, including the Substance

Use Disorder QUERI (SUD QUERI). The QUERI Centers have set national strategic priorities for implementation research in their focus areas, and have served a mentoring and consultative function to investigators developing implementation science proposals to be submitted to a centralized peer-review process. The Centers also directly support small implementation science projects.

The mission of the SUD QUERI is to improve the detection and treatment of Veterans with SUD and hazardous substance use. The main activities are to develop and evaluate strategies to implement evidence-based treatments, as well as strategies to de-implement ineffective practices. The Center strives to 1) produce knowledge and products that are used by operational partners to improve the quality and cost-effectiveness of care for SUD patients; and 2) contribute to the accumulation of knowledge about implementation contexts, strategies, costs, and outcomes.

From 2012 to 2015, SUD QUERI investigators successfully competed for five Service Directed Projects (roughly equivalent to NIH R01s) and over 20 smaller (~$100k) Rapid Response Projects. Many of these projects focused on developing and testing strategies to implement models of integrated care, such as screening and brief interventions for risky drinking in primary care (described below); testing several unique strategies (e.g., academic detailing, patient activation) for increasing pharmacotherapy for alcohol use disorder across diverse clinical settings; integration of HIV and HCV screening and treatment in SUD programs; and developing models of care to address substance use disorder in infectious disease clinics.

Recently, SUD QUERI established updated priorities for addiction-related implementation research in consultation with operational and policy partners and outside implementation and addiction experts through a method that weighed several factors including strength of evidence, expected effect sizes, current quality gaps, organizational barriers and facilitators, and other factors. Five of the six highest priority areas involve coordination with clinical settings outside of addiction programs (e.g., pharmacotherapy for alcohol use disorder) if not explicit integration within them (e.g., screening and brief intervention for risky drinking in primary care).

Conducting and facilitating implementation research within a large integrated health care system comes with opportunities and challenges. On the positive side, the existence of centralized policies and goals make assembling a team of operational partners, clinical managers, and researchers around the development and evaluation of implementation solutions perhaps easier than it might be otherwise. On the challenging side, a model of research that is tightly linked with implementing policy and solving the problems of operational partners depends on the existence of cooperative and research-friendly partners and scientifically sound policy. It is not unusual for implementation scientists to be encouraged to develop and evaluate implementation strategies for practices that have a poor evidence base, just because they have been reified in policy or otherwise are subject to political or organizational enthusiasm. SUD QUERI has worked hard to stay clear of these situations, but it is always a tension. Also, tension can exist between the goal of developing concrete solutions to specific problems versus the production of generalizable

implementation science knowledge. This tension sometimes impacts which targets are chosen as well as design and methodological choices.

As of this writing, VHA is currently undergoing the most extensive reorganization in a generation and the QUERI program is being substantially revised. The existing mostly disease-focused QUERI centers, including SUD QUERI, will stop operations in Sept 2015. The new QUERI will support roughly 12 programs that will each consists of a cross-cutting impact goal, three to five implementation/quality improvement projects, and an implementation science core tasked with coordinating and synthesizing activities between projects and programs to maximize learning. Although the SUD QUERI will not exist, most of the priorities established in its strategic plan have been integrated into several of the new program proposals. Given that QUERI will no longer review investigator-initiated implementation science projects, the HSR&D service will now consider these proposals. A new HSR&D RFA that appears particularly relevant for implementation science proposals is the "Targeted Solicitation for Health Services Research on Provider Behavior - A Learning Health Care System Initiative." (http://www.hsrd.research.va.gov/funding/RFA-list.cfm).

2.0 Implementation of Integrated Care: Domains and Strategies

We reviewed all funded extramural grants (at NIAAA/NIDA) and SUD QUERI projects (at VHA) between 2008–2014. Because NIH tobacco treatment applications may be assigned either to NIDA or to the National Cancer Institute (NCI), and consistent with the aims of the functional integration of addiction research at NIH (see http://addictionresearch.nih.gov), we also reviewed all grants funded by NCI that were specifically related to the implementation of smoking cessation services in general medical care settings. Based on this review, we identified 5 domains in which NIH and VHA have supported or prioritized implementation science to address the integration of drug and alcohol treatment in general medical settings. For each domain, we briefly describe the evidence-based clinical practices or service delivery models that are ready to be implemented; provide examples of some of the implementation strategies being tested; and identify remaining research gaps. Our objective is to provide a broad overview of the current research portfolio in the area of implementation and integration. We provide citations to publicly-accessible documents whenever possible.[1] However, because research studies may not yet have published their findings, formal citations are not always available.

Perhaps the most important components of these projects are the implementation strategies that are being tested. In D&I research, the implementation strategy is the active intervention; it is analogous to the patient-level clinical intervention tested in a treatment development study. Researchers are testing the effectiveness of a particular method (implementation strategy) to change a particular process (service delivery) that should result in a particular implementation outcome (integration of treatment services), which in turn should lead to improvements in service quality and clinical outcomes (Proctor et al., 2009). As with clinical interventions, implementation strategies may involve a single activity or a bundle of

[1]Limited information about every awarded NIH extramural research grant is available in a searchable public-access database at http://report.nih.gov.

activities (Powell et al., 2012). They may engage multiple levels of a medical practice – e.g., organizational structure, technology infrastructure, management/leadership, clinicians, patients – either simultaneously or sequentially.

While there are a limited number of EBPs for SUD that are ready for implementation in general medical settings, there is potentially a much broader array of implementation strategies that can be tested, and research to date has tended to focus only on a limited set. At this point, we can say that "implementation as usual" (whether by passive dissemination, by typical classroom-style training of individual staff, or by policy directive in the absence of other supports) is unlikely to achieve desired results when compared to active, facilitative, and multifaceted strategies. Comparative effectiveness studies that test different implementation strategies or combinations of strategies are needed to move the field forward, particularly when examining service integration. Well-specified and carefully tested implementation strategies tell us *how* integration can be achieved, and allow for replication and scalability (Proctor et al., 2013). Particularly in an era of health reform, SUD treatment service integration may benefit by borrowing effective models of integration from other areas of health care, and comparing different models to determine which strategies most effectively achieve integration, in which settings, at what cost.

2.1 Practices to be Implemented

Consistent across all funded projects in our portfolios is that the practices being implemented must be evidence-based. Scientific review panels as well as program staff pay careful attention to the strength and quality of the evidence base, to avoid premature scale-up of therapies that are unproven. When proposing implementation projects, researchers should review the scientific literature, with an emphasis on the results of well-designed randomized controlled trials in which change in substance use is a primary outcome. FDA approval of medications is usually a signal of readiness for implementation; behavioral (counseling) therapies are less easily declared "ready" for implementation, but high-quality meta-analyses including clinical trials conducted by researchers other than the treatment developer are a key marker. While there are a broad array of practices that are listed on any of a number of "registries" of evidence-based practices, those registries can vary widely in their criteria for inclusion and their process of evaluating research results (Burkhardt et al., 2015; Means et al., 2015); in some cases therapies are listed in the absence of any supportive data from randomized trials. Thus being listed on a registry – or having a set of manuals and training curricula – is not necessarily, in itself, a sufficient indicator of readiness for scale-up. Nor is the popularity of a counseling technique or clinical approach a sufficient substitute for evidence; indeed, a unique challenge is posed for both research and practice when a service delivery model is incentivized or even mandated despite a lack of evidence for its effectiveness (e.g., SBIRT for drug abuse [Roy-Byrne 2014; Saitz 2014]). Because our funded portfolios represent an investment of public dollars, they necessarily reflect a conservative reading of the scientific research base.

In the context of integration into general medical settings, a further consideration is the likely "fit" between the substance abuse treatment practice and the context into which it is earmarked for implementation (Damschroder et al., 2009). For example, prescription

medications are highly compatible (Rogers, 2003) with most primary care practice settings, and are likely to gain traction for implementation relatively quickly once known barriers (e.g., familiarity, cost) are addressed. On the other hand, complex, multifaceted behavioral interventions are difficult to implement with fidelity even in specialty addiction programs; this problem is further magnified on a general hospital unit, where they are incompatible with the skills and workflow of the staff who would bear responsibility for delivery. Accommodations to these constraints are reflected in our research portfolios, which examine a small number of clinical practices that have a clear evidence base to support implementation, and are good candidates for integration into non-specialty settings.

2.1.1 Screening and Brief Intervention for Risky Drinking—Based on accumulated evidence from randomized controlled trials, summarized in a recent systematic review (Jonas et al., 2012), the US Preventive Services Task Force (USPSTF) recommends that clinicians screen adults for alcohol misuse, and that they provide brief behavioral counseling to those who screen positive for risky or hazardous drinking. Because of the USPSTF's assignment of a "B" grade to screening and brief intervention (SBI) – indicating a conclusion of moderate net benefits – the Affordable Care Act requires that its delivery be included as a covered preventive services in health exchange plans. Importantly, the combination of a solid evidence-base and access to insurance reimbursement paves the way for the development and testing of strategies to implement SBI broadly in primary care settings.

A large number of what we might call "pre-implementation" studies have been undertaken in this area, with many researchers focusing on methods or technologies to optimize screening protocols to fit into the routine workflow of busy clinical practice settings. For example, projects have tested the feasibility of embedding screening questions into medical records; using clinical reminders and note templates for the major components of brief intervention; or testing the effectiveness of brief interventions delivered via computer rather than by clinician. By and large, these studies have not been testing implementation strategies to achieve the *integration* of those technologies, but this will be an important next step for research, as we know that even the most effective technologies are not self-spreading.

In our funded grant portfolios to date, projects testing the integration of SBI into general medical settings have focused on two main themes: testing staff-level vs. organizational-level implementation supports, and testing a generalist vs specialist model of SBI delivery. For the most part, these projects are based within primary care settings, although funded research has recently expanded to include hospital inpatient units, trauma centers, and HIV clinics.

The first group of studies tests bundled implementation interventions with *staff and/or organizational-level targets* for change. Typically, staff-level implementation interventions consist of training and coaching to promote effective delivery of brief motivational interventions. These may be coupled or contrasted with organizational-level implementation strategies, such as the development and implementation of quality measures, designed to enhance the local implementation climate, engage leadership in identifying and overcoming existing barriers, and increase the likelihood of long-term sustainment. Where there are local

or national clinical practice mandates that are consistent with implementation, these can be powerful levers for change. For example, one recent study capitalized on a mandate from the American College of Surgeons that Level 1 trauma centers in the U.S. must screen injured patients for alcohol use disorders and intervene appropriately with those who screen positive. This mandate provided a ready-made “mandate only” control condition against which a more facilitative multilevel implementation strategy could be tested (Zatzick et al., 2014).

Studies testing *generalist vs. specialist protocols* attempt to address the concern that physicians have limited time to allocate to any one patient, and that SBI may not fit within the routine workflow of a physician or practice. Likewise, primary care physicians may lack the skill or interest to deliver brief interventions to address risky alcohol use by their patients. Several ongoing studies are testing an alternative service delivery model, namely, the use of behavioral health specialists to deliver brief interventions to patients who screen positive for hazardous drinking. The general design compares a traditional model in which the physician is trained and tasked with incorporating SBI into the patient visit, versus an alternative model in which the patient meets with a designated behavioral health specialist prior to concluding their appointment (see, e.g., Mertens et al., 2013).

In some studies, the specialist is a staff member of a chemical dependency treatment unit operated by or near the primary care practice, and the scope of their intervention includes a referral to treatment, facilitating the patient’s contact with the specialty care program. While this intervention requires a change to the existing workflow of a practice setting, it is likely to minimize the additional workload of any given physician. A variation of this model is a current study testing the use of a clinical liaison service (aNIH Reporter 2015a), through which a physician on a hospital inpatient unit can “order” a brief motivational interview for a patient determined to need one. Because the clinical liaison service is part of the everyday hospital environment and is commonly used by physicians for other types of consults, and because the liaisons assume responsibility for delivering the most complex part of the intervention, a service delivery model that leverages this existing infrastructure should facilitate its uptake and sustainability.

VHA’s experience with implementation of alcohol SBI suggests the potential for sustained impacts on routine clinical practice. In part due to foundational work done by QUERI investigators to develop training materials (http://www.queri.research.va.gov/tools/alcohol-misuse/); research linking alcohol screening scores to medical outcomes; and the development and implementation of quality measures and clinical reminders and note templates, annual screening of VHA patients with the AUDIT-C is near universal (~90%) and rates of documented BI among patients who screen positive are high and increasing (~80%) (Bradley, Williams, et al., 2007; Bradley, DeBenedetti, et al., 2007; Lapham, Achtmeyer et al., 2012; Lapham, Hawkins, et al., 2012; Williams et al., 2010a, 2010b, 2011b, 2014). However, recent work has found that the *quality* of documented SBI is often poor and the association of SBI with outcomes might be weaker in real world practice compared to results reported in efficacy studies (Williams et al., 2014). This “voltage drop” is not uncommon for EBPs being delivered under real-world conditions (Chambers et al., 2013). Other research has found possible unintended consequences of a quality measure for

BI (Bradley et al., 2013). In sum, SUD QUERI's experience suggests that future implementation efforts and research are needed not only to implement these practices, but to attend to the quality of SBI beyond merely motivating its documentation, and to continue to monitor effectiveness and unintended consequences of these services as delivered.

2.1.2. Screening, Brief Intervention, and Treatment for Tobacco Use—The USPSTF recommends that clinicians ask all adults – including pregnant women – about tobacco use and provide tobacco cessation interventions for those who use tobacco products. Their "A" grade for this recommendation not only signals the high impact of this clinical practice, but also includes it among the list of covered preventive practices under the Affordable Care Act. Moreover, a Public Health Service clinical practice guideline on *Treating Tobacco Use and Dependence* (Fiore et al., 2008) provides detailed, easy-to-follow guidance for clinicians on screening and intervening with patients, including information about quitlines, brief counseling, and nicotine replacement therapies. This accumulation of evidence and resources provides the backdrop for a robust portfolio of implementation studies to integrate the guidelines into a variety of medical practice settings.

Given the universal scope of the USPSTF recommendation, and the broad applicability of the PHS guidelines, it is not surprising that funded research in this domain seeks to implement tobacco SBI across a wide variety of health care settings beyond primary care practices, including student health clinics; pharmacies; rural hospitals; emergency departments; county-run free clinics; and dental offices. Across these settings, implementation strategies emphasize three common themes: leveraging technology to support guideline adherence; training; and promoting the use of existing resources to facilitate service integration and sustainability.

Most NIH projects seeking to integrate tobacco treatment into general medical settings have a *technology component* at the heart of their implementation strategy. Recently, the creation and use of patient registries has become a common tool to help clinicians record and track identified tobacco users and monitor the delivery of appropriate services (e.g., via pharmacy records). In other studies, screening questions or clinical alerts are embedded in the patient's medical record, such that physicians can be prompted to complete the "5 A's" (ask, advise, assess, assist, arrange), deliver a brief intervention, prescribe a nicotine replacement therapy, or otherwise address tobacco use during the office visit. Another strategy involves integrating the 5 A's into the patient check-in process, collecting responses directly from patients on a tablet computer used in the clinic waiting area, and transmitting the information to the medical record so that it can be accessed by the physician during the visit. Each of these studies takes advantage of an information technology infrastructure that already exists in primary care settings, minimizing the need for additional resources, and increasing the likelihood of long-term sustainability beyond the research project.

Conventional *training and academic detailing* are common implementation strategies to increase provider attention to tobacco use and appropriate interventions. Given known limitations of training alone as an implementation strategy, studies often embed some form of feedback and/or performance incentive to promote delivery of smoking cessation services. Some studies are testing one or both of these training strategies against a

comparison condition in which only printed materials (posters and brochures) are distributed (e.g., Zillich et al 2012); these allow for comparison of informational campaigns that target physicians directly, versus a more direct-to-consumer dissemination strategy. Outcomes at two levels can thus be considered – clinician delivery of tobacco interventions, and patients' use of pharmacy products and quitline services. Across the portfolio of integration research, this is one of the few domains in which direct-to-patient dissemination of information about available services (medications, quitlines) is a common implementation strategy.

Tobacco is one public health issue for which there are a variety of *free or subsidized resources* available for patients in the community, and implementation studies including these in their protocols both conserve research resources and increase the likelihood of sustainability. For example, patients can be directed to state-run tobacco quitlines, while clinics can often obtain a supply of printed materials to make available in public areas.

As in other areas of substance abuse integration research, researchers are testing implementation strategies with targets at multiple levels – patients, clinicians, and organizations. Multi-level interventions appear to be important for implementation success. Two recent studies demonstrated success in improving organizational-level readiness to change, and improving clinic workflow and data systems to support tobacco interventions; however, these projects were less successful at increasing clinician delivery of motivational interventions (McNamara et al., 2015) or otherwise achieving near-term changes in patient receipt of services (Foley et al., 2012).

VHA HSR&D and QUERI have funded research examining strategies to implement screening, brief intervention, and treatment for tobacco use disorder in diverse settings (e.g., primary care, medical inpatient units), for patients with specific co-morbidities (e.g., stroke), and employing a diversity of modalities (e.g., face-to-face, web-based, tele-health), and varied interventionists (e.g. nurses, peer specialists) (see descriptions at VHA 2015b). Many of these projects involved effectiveness studies of new treatment care delivery models (e.g., telephone counseling by peers), and pre-implementation studies of barriers and facilitators to implementing promising models more broadly. Less common are studies that evaluate specific implementation and sustainment strategies. Perhaps ironically, the implementation of screening, brief intervention, and treatment for tobacco use disorder in VHA has been more successful in general medical settings compared to addiction treatment programs, where the prevalence of tobacco use disorder is very high. SUD QUERI has historically focused on addressing this gap. For example, a current study is studying a blended facilitation model to implement tobacco use disorder treatment in VA residential SUD programs.

2.1.3. Uptake of FDA-approved Pharmacotherapies—Until recently, much of the NIH implementation research portfolio in the area of pharmacotherapies has consisted of observational studies that characterize clinician attitudes toward medications for alcohol and drug dependence; document the extent of adoption by clinicians and programs; and describe structural barriers to broader use. This segment of the portfolio has overwhelmingly focused on the specialty care system, and while there are few implementation studies in this arena, they too have tended to focus on improving the rates of medication adoption in specialty

treatment settings. In stark contrast to the tobacco treatment implementation portfolio, research on integrating addiction medications into general medical settings is largely uncharted terrain. This is perhaps ironic given that the prescription of medications is the one approach to addiction treatment that is most compatible with primary care practice.

One notable exception is a NIDA study testing the Advancing Recovery implementation model to promote the increased use of buprenorphine within a private health plan (bNIH Reporter, 2015b). Advancing Recovery (Molfenter et al., 2014) is a bundled implementation strategy that builds on the NIATx process improvement approach (Gustafson et al., 2013) to achieve widespread systems change. In addition to the use of site-level change teams, coaching, and learning circles – the core components of NIATx – Advancing Recovery attends to the relevant financing and policy levers by assisting organizations in building the business case for integrating new practices. This type of approach to implementation should maximize sustainability, by building organizational capacity to negotiate with key payers and to integrate new approaches to treatment.

SUD QUERI investigators have three large projects approved to test three different implementation strategies for expanding pharmacotherapy for alcohol use disorder. The first study is testing a multifaceted intervention involving local champion training, ongoing external facilitation, a primary care-based case-finding dashboard, and direct to patient educational materials (VHA 2015c). The second project is evaluating an elaborated academic detailing program that was piloted in diverse clinical settings in 40 VHA facilities, including a real-time panel management dashboard for case-finding and audit and feedback. A third study is planned to evaluate a facilitation based implementation of the primary care-coordinated Alcohol Care Management model (Oslin et al., 2014). Once completed, these projects promise to provide valuable information on the comparative effectiveness, moderators, and costs of these varied implementation strategies. There is also substantial ongoing work to use Social Marketing Theory to identify market segments within groups of primary care clinicians for which targeted implementation strategies and messages might be developed to increase consideration and use of these medications.

2.1.4. Safe Opioid Prescribing—A high priority area related to medications is the need to promote safe prescribing of opiates for chronic non-cancer pain, including avoiding high-dose opioid regimens and co-prescriptions with sedatives. Implementation studies in this area seek to change clinician prescribing behavior in order to curb the epidemic of prescription drug abuse and overdose risk. As such, this may be considered a form of “de-implementation” research – that is, identifying systematic strategies to stop a current practice. In this case, studies use multifaceted implementation strategies that are designed to sensitize physicians to problematic opioid prescribing practices, facilitate information retrieval to monitor high-risk patients, and support good clinical decision making.

Funded NIH studies in this area are similar to other clinical guideline adherence studies, in that they are seeking to align routine practice with consensus guidelines. As with analogous issues in other areas of healthcare (e.g., handwashing [Huis et al., 2012]), implementation to promote guideline adherence hinges on multifaceted strategies that incorporate education, reminders, feedback, and facilitative technology. Current NIDA studies are testing two

different approaches to promote safe prescribing in primary care clinics. One focuses on surrounding prescribing physicians with supports that should facilitate guideline-adherent prescribing, combining education (academic detailing); a nurse-managed patient registry to support monitoring of individual patients and clinic population outcomes; information systems that integrate with the state's prescription drug monitoring program database; and point-of-care reminders. A second study combines physician- and clinic-level implementation strategies, employing physician-targeted education (peer coaching) and information system supports, while engaging clinic leadership in a NIATx-based change team approach to restructure the clinic workflow and procedures – essentially engineering an environment in which guideline adherence is the most likely outcome.

Much of the QUERI-supported work in this area has focused on operationalizing clinical practice guidelines into metrics that have been integrated into system monitoring and quality improvement dashboards (e.g., VHA 2015d). The portfolio also includes pre-implementation work describing gaps in quality before and after the initiation of a major Opioid Safety Initiative and understanding the drivers of variability in quality (VHA 2015e).

2.1.5. Disease Management—It is well established that substance use is a key driver of health care costs, and that patients with substance use disorders consume a disproportionate share of emergency and urgent care services (Cherpitel & Ye, 2008; Neighbors et al., 2013; Walley et al., 2012). In the context of health reform, identifying these patients and minimizing hospital readmissions is a high priority goal (Billings et al., 2007; Pecoraro et al., 2012). Under the Affordable Care Act, healthcare providers positioning themselves as accountable care organizations or patient-centered medical homes have strong incentives to identify ways to increase patient engagement, improve monitoring, and follow up with them more often. This policy change has renewed interest in the application of the chronic care model (Wagner et al., 1996) to SUD treatment in primary care settings.

Chronic care management (CCM) is an approach to service delivery that addresses coordination of patient care by a multidisciplinary team, aided by clinical information systems; shared decision making; restructuring of workflow and practice design to facilitate coordinated treatment; and decision support and clinical practice guidelines that reinforce the use of evidence-based practices. Together, these features are intended to allow primary care physicians to identify, treat, and manage the care of patients with chronic conditions.

While there is a strong evidence base for CCM generally (e.g., Tsai et al., 2005), and for its use in the care of diabetes (Stellefson et al., 2013), mental health (Woltmann et al., 2012) and other chronic diseases in primary care settings, the evidence for its impact on SUD outcomes, or on the increased delivery of SUD treatments, has so far been mixed (Oslin et al., 2014; Park, Cheng, et al., 2015; Park, Samet, et al., 2015). As a chronic condition, it is reasonable to expect that SUD would realize similar benefits from CCM (Watkins et al., 2003). However, with few exceptions (e.g., NIH Reporter, 2015c) our funded research to date has not explicitly tested *implementation strategies* to install a chronic care model for SUD. Rather, research on this topic is largely in the pre-implementation stage – that is to say, research is still testing the *effectiveness* of key components of CCM for their impact on SUD service delivery and outcomes. Ongoing research also includes important observational

studies examining the impact of health reform on state-level care coordination initiatives (e.g., NIH Reporter, 2015d, 2015e).

To be sure, CCM is an area in which the lines between effectiveness and implementation research become blurred. As described above, several studies are utilizing components of CCM as part of their implementation strategies to promote the uptake of other EBPs. For example, a number of funded integration studies use patient registries to monitor the service utilization and health status of patients receiving care from the physicians, clinics, or hospitals in the implementation trials. These registries often are designed to generate clinical alerts or reminders for members of the care team; aggregate data can both provide a snapshot of service utilization and outcomes in the patient population, and serve as performance feedback for clinicians.

In order for integration research to realize its potential, it is critical that researchers accurately distinguish between health services effectiveness studies – i.e., those that test the impact of a service delivery model on patient outcomes – and implementation studies – i.e., those that test the impact of a particular strategy or bundle of strategies on the delivery of evidence-based practices. Both are essential to achieving integrated care for patients with SUD in primary care settings. Specific to the chronic care model, it is important to not only identify which elements are effective implementation strategies for EBPs, but also to better specify the format, content, and contexts of organizational and technical supports that might best facilitate coordinated SUD care. A more mechanistic approach may be needed to determine which elements of CCM, in what combinations and contexts, are essential to support integrated SUD care. This can then provide the basis for strategic implementation of more comprehensive models.

At the same time, CCM is also an area that may especially lend itself to hybrid effectiveness-implementation study designs (Curran et al., 2012). Hybrid designs are becoming more common in implementation science, and have the potential to streamline the research-to-practice pipeline by incorporating both effectiveness and implementation aims in the same study, whether in equivalent or relative emphasis. For example, a study focused primarily on testing the effectiveness of one or more CCM components could simultaneously collect data on feasibility, acceptability, or other elements that inform its implementation (“hybrid type 1”). A study that tests an implementation strategy to integrate CCM in a general medical setting might also include secondary patient-level outcomes to check that the processes are achieving their intended effects (“hybrid type 3”). Rather than pursue a typical (and time-consuming) linear research process that moves to implementation only after effectiveness data have reached a critical mass, the goals of service integration and implementation science can be accelerated by attending to *both* goals in the context of the same study. While CCM might be the best current example of a topic that is ripe for hybrid designs, much of the research in the area of SUD service integration lends itself to this type of approach.

3.0 Discussion

Fitting within the theme of this special issue, we have focused our analysis on ongoing efforts at NIH and the VHA to support implementation research targeting the integration of approaches to address SUD and risky substance use in primary care and other general medical settings. While these efforts are important, intriguing, and far from finished, they are one part of a much larger effort that is needed to promote the identification and treatment of substance use disorder and hazardous substance use across the full spectrum of medical settings– including mental health settings and HIV and other infectious disease clinics that serve people at greatest risk for problematic substance use. In addition, there remains a pressing need for implementation of evidence-based practices in specialty SUD programs, including pharmacotherapies and smoking cessation interventions. Successful implementation research projects in general medical care may provide candidate strategies that could be tested in these other settings.

Research funding agencies, providers, payers, patients, and advocacy groups often prioritize patient-level outcomes demonstrating the effectiveness of an intervention more than implementation outcomes. The sometimes conflicting priorities of healthcare administrators to achieve measurable quality improvements, and of researchers to contribute to implementation science, is a parallel challenge. Developing (and powering) studies to simultaneously measure patient-level outcomes while also determining implementation intervention effectiveness can be expensive and may be impractical. Addressing this challenge calls for exploration of alternative ways to capture patient-level outcomes along with indicators of successful implementation. Hybrid designs (described above) provide one approach to balancing these twin goals. At the same time, technology that captures patient health status indicators in the form of patient registries, electronic health records, claims data, and other administrative data may help streamline the research process such that patient-level outcomes can be more efficiently measured. Of course, prioritizing the integration of clinical interventions with a clear evidence base strengthens assumptions that improvements in patient outcomes will result from the receipt of integrated services.

Attending to clinical outcomes in the context of implementation research is important not only to assess effectiveness and fidelity during a given study, but also to understand whether and how interventions are sustained and adapted over time to fit the demands and constraints of local service delivery settings. With only a few exceptions, our funded projects largely fail to explicitly test hypotheses about the sustainability of practices that have been implemented, or they view sustainment as a discrete phase that happens only after an implementation phase or research project. Rather, there is a need to understand how the intervention development and implementation processes set the stage for sustainment. Moreover, there is a need to understand the factors that predict and foster sustainment of an adopted practice, particularly in service delivery environments that themselves are constantly evolving to meet changing internal and external demands. While the tendency has been to view local adaptation as a failure to maintain fidelity, it may instead be the case that local adaptation is necessary to ensure the continued fit of the practice to its delivery context (Chambers et al., 2013). Where practical, collecting patient-level outcome data is important

for understanding whether local adaptation degrades the quality of care, or is in fact a beneficial *optimization* of the intervention.

In addition to strategically incorporating patient clinical outcomes in implementation research, it is also important to recognize that patient voice is often absent from substance use care, the research literature, and the development of novel interventions. Yet patient preference is a critical component of intervention uptake and sustainability. With few exceptions (e.g., NIH Reporter, 2015f), our portfolios have included few projects with an explicit focus on shared decision-making between patients, their families, and their healthcare providers. More such research is needed to inform treatment developers about the features that would make SUD care attractive, accessible, and meaningful within the context of patients' lives. The field could also benefit from developing and testing more direct-to-consumer dissemination activities, and "demand-side" implementation intended to build consumer calls for evidence-based interventions. This information could be collected as part of a larger implementation research study examining issues related to taking to scale patient-centered care for substance use.

Despite the fact that the onset and peak of substance use occurs in adolescence, most of the research on developing medications, psychosocial interventions, and models of care has focused on adult populations. Likewise, much of the NIH-funded SUD implementation research to date focuses on integrating evidence-based interventions within settings serving adults. There seems to be an assumption that this accumulating knowledge base will directly apply and translate to adolescent treatment settings. However, we know little about the unique challenges faced by healthcare providers, organizations, and systems seeking to address substance use among their adolescent and young adult patients. It is plausible that these general medical settings will need to surmount additional and unique implementation challenges, including the involvement of patients' families. Research gaps in this area are extensive and could be addressed with pre-implementation studies to determine organizational and systems level barriers to engaging adolescents and their families in treatment, and implementing evidence-based interventions. Implementation research studies could translate this knowledge into unique strategies for fostering uptake of evidence-based prevention and treatment services for substance use, including technology-driven interventions that may be appealing to adolescents.

Finally, outside of the relatively small circle of health services researchers, implementation research is often poorly understood and therefore undervalued. Improving this situation requires the consistent application of rigorous scientific standards including the development and application of conceptual frameworks; identification of intervention targets; clearly specified implementation strategies; addressing the competing pressures for adaptation and fidelity in delivering interventions; and well defined outcomes with appropriate measures. Use of common measures, conceptual models, and definitions will allow for the integration and comparison of data across studies, and must be a near-term goal for implementation science. By the same token, we recognize that implementation research may also benefit from greater coordination and cross-fertilization of SUD implementation research between NIH and VHA. For example, research should seek to test whether implementation strategies determined to be effective in integrating care in the VHA are equally effective in other

sectors, and vice versa. As VHA becomes more of a payer as well as a provider of health care under the Veterans Choice Act, there will be more opportunities and motivations for studying cross-system coordination and comparisons of implementation contexts.

Unprecedented change in healthcare policy, funding, and technology provide the potential to expand the identification, treatment, and ongoing care management of substance using patients wherever they seek medical care. Within this larger context, implementation science provides an opportunity to develop a knowledge base to promote the systematic adoption of evidence-based approaches to substance use treatment in a variety of healthcare and general medical settings. NIAAA, NIDA, and VHA have built portfolios that are leading the addiction health services research field in this area. This research could be pivotal in reducing the public health burden of substance use across the United States.

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Highlights

- Ongoing and recent implementation research on integrated care at NIAAA, NIDA, and VHA is reviewed.
- Research on screening and brief intervention for risky drinking and tobacco use; use of FDA-approved pharmacotherapies; safe opioid prescribing; and disease management is reviewed.
- Gaps in the existing portfolio, and directions for future research are described.