HHS Research Portfolio on Pain Treatment and Prescription Opioid and Heroin Use and Overdose

Background

The Research Portfolio encompasses the targeted activities of HHS and is stratified into the three areas of the Secretary's Opioid Initiative:

1. Improving opioid prescribing practices;

2. Expanding access to medication assisted treatment for opioid use disorder; and

3. Increasing use of naloxone.

In addition, a fourth section includes other program, research, and evaluation activities related to pain treatment and opioid abuse and overdose that reflect the range of ongoing projects.

Activities included in the report span the spectrum of basic science research, epidemiology, clinical practice interventions, and policy and program evaluation. The activities were reported by HHS operating and staff divisions and are up to date as of 7/1/2016. View a narrative overview of the current HHS Research Portfolio on Pain Treatment and Prescription Opioid and Heroin Use and Overdose.

Improve Pain Treatment and Opioid Prescribing Practices

(research projects as of 7/1/2016)

Agency	Type of Activity	Description	Extramural	Partners
NIH	Pain Treatment - Basic science research	Cannabinoids have demonstrated efficacy in ameliorating pain in multiple sclerosis. Their potential for combination therapy may reduce risks for opioid addiction (DA009158).	Y	Northeastern

NIH	Pain Treatment - Basic science research	Epigenetic regulation of mu opioid signaling may provide a novel approach to inhibit visceral pain (DK099052)	Y	Univ of Texas
NIH	Pain Treatment - Basic science research	Inflammatory mediators may inhibit the transition to chronicity of pain and are of interest as potential analgesic targets. A novel anti- inflammatory lipid mediator is being developed for chemotherapy induced pain (NS082985).	Y	Duke
NIH	Pain Treatment - Basic science research	Fatty acid binding proteins and G protein-coupled receptor 55 are being tested on pain behaviors in preclinical models (DA35949) (DA35926).	Y	SUNY Stony Brook
NIH	Pain Treatment - Basic science research	Ion channel blockers have potential to inhibit pain signaling. Research is exploring: NaV1.7 sodium channel modulation to treat chronic pain (RX001727-01).	Y	VA CT
NIH	Pain Treatment - Basic science research	Transient receptor potential cation channel A1 (TRPA1), a signal integrator for sensory nerve cells; antagonists may provide peripherally acting analgesia (DA028017AR065330).	Y	Southern Illinois Univ
NIH	Pain Treatment - Basic science research	Calcium channels are involved in key pain signaling steps (NS086343).	Y	AFASCI

NIH	Pain Treatment - Basic science research	NIH Blueprint Neurotherapeutics supports development of promising drugs supporting FDA approval of small molecule inhibitors of fatty acid metabolites as an oral analgesic and a non-addictive Kappa opioid antagonist for migraine (NS094258, NS093030).	Y	Eicosis
NIH	Pain Treatment - Basic science research	Epigenetic regulation following stress may provide treatment options (DK098205).	Y	Univ of Michigan
NIH	Pain Treatment - Basic science research	Pain phenotype of catastrophizing, fear of pain, and depression is being explored (AG044710).	Y	Univ Colorado
NIH	Pain Treatment - Basic science research	Sodium homeostasis in migraine pathophysiology is being studied (NS072497).	Y	Huntington Med Rsch Institute
NIH	Pain Treatment - Basic science research	Identification of biomarkers for pain conditions is challenging and is being approached through imaging studies of pain-altered brain function as well as molecular markers. A matrix metalloproteinase inhibitor will be evaluated as a potential biomarker for pain response and tolerance (GM109469).	Y	Aquilus Pharma
NIH	Pain Treatment - Basic science research	Neural hypersensitivity induced by repeated activation of pain fibers is associated with the transition from acute to maladaptive chronic pain. Epigenetic regulation of such neural plasticity is being studied (NS078050).	Y	UCSF

NIH	Pain Treatment - Basic science research	This study This study will investigate the temporal & cellular expression of AdK (& its enzymatic activity) & A3AR in SC glia & neurons (immunofluorescence & genetic/proteomic analysis). In parallel, purine nucleoside concentrations in SC & CSF (from lumbar puncture) will be measured by targeted metabolic approaches. We will (1) characterize the pharmacological profile of A3AR agonists via dose- response curves & time course studies as well as effect of gender on A3AR effects & (2) examine the contribution of the SC as a site of action. As a corollary, we will explore the clinical generalization of findings by testing oxycodone & A3AR agonists & examine the contribution of the rostral ventromedial medulla (RVM), as an additional site of action. To gather a mechanistic understanding of how A3AR agonism confers protection, we will begin our initial exploration in signaling pathways engaged at the level of the SC dorsal horn.	Y	Saint Louis Univ
NIH	Pain Treatment - Basic science research	This proposal directly addresses two key criteria for the C.E.B.R.A. program: 1) We are testing a completely new hypothesis by testing whether reducing activation of post-injury infiltrating macrophages at the site of a nerve injury will reduce pain-like behavior in animals. 2) We are introducing a completely novel technology to pain research by using imaging-supported targeted nanoparticle drug delivery.	Y	Duquesne Univ

NIH	Pain Treatment - Basic science research	We propose to transplant cells derived from the mouse embryonic medial ganglionic eminence (MGE). We will continue our analysis of the circuits in which the transplants participate and will use electrophysiology to assess the extent to which inhibitory controls derive from the transplants. We will assess the ability of the transplants to alleviate the persistent pain produced by peripheral nerve injury, including those produced by chemotherapeutic agents. Using selective antagonists to counter the effects of the transplants, we will determine whether GABA is indeed the major contributor to recovery. Finally, in Specific We will use a novel chemical-genetic approach to achieve in vivo spatio-temporal control of the activity of the transplants	Y	UCSF
NIH	Pain Treatment - Basic science research	The long-term goals of our proposed studies are to understand the role of the neuropeptide calcitonin gene-related peptide (CGRP) in promoting neuron-glia interactions in the trigeminal system that facilitate development of persistent pain, and test novel therapeutic strategies to treat temporomandibular joint disorders (TMJD) (DE024629).	Y	Missouri State Univ

NIH	Pain Treatment - Basic science research	The goal of the current proposal is to understand how manipulation of the limbic regulation and downstream output of the HPA axis affects both behavior and urogenital sensitivity in mice that were exposed to early life stress. Our central hypothesis is that comorbid urogenital pain syndromes and mood disorders in NMS mice arise from increased output of the HPA axis, due to diminished negative regulatory input from the hippocampus, and can be differentially attenuated by peripherally- and centrally-mediated interventions (DK103872).	Y	Univ of Kansas
FDA	Pain Treatment – Product development	Improving our understanding of pain measurements in clinical trials in chronic low back pain, osteoarthritis, painful diabetic peripheral neuropathy, postherpetic neuralgia, and fibromyalgia. There is wide-spread interest in improving the assessment of pain as a means of improving the assessment of new pain treatments. The group is conducting meta-analyses of placebo group response in osteoarthritis trials and systematic reviews are being conducted to compare assay sensitivity of average pain and worst pain primary outcome measures.	N	None
NIH	Pain Treatment - Product development	Optical stimulation using infrared laser light to inhibit activity in pain neurons (EY018241).	Y	Univ Calif Berkley

NIH	Pain Treatment - Product development	In this proposed project, our goal is to develop novel orally active mu agonist/delta antagonist compounds. The approach builds upon the structure-activity relationships determined for the lead series. The medicinal chemistry lead optimization strategy includes rational drug design utilizing crystal structure information on mu and delta receptors that became recently available as well as multi- parametric lead optimization for the improvement of physicochemical and pharmacokinetic properties. To achieve the goal of identifying lead preclinical candidates we will (1) design and synthesize new compounds based upon activity and in vitro pharmacokinetic properties (2) perform in vitro screening to determine opioid receptor binding and functional activity (3) determine the in vitro and in vivo pharmacokinetic profile (bioavailability, half-life and CNS levels) to select compounds for (4) comprehensive in vivo analgesic efficacy and side effect profiling in rodents (DA038635-01A1).	Y	Southern Research Institute
NIH	Pain Treatment - Product development	The project will primarily focus on two therapeutically beneficial profiles: (a) bifunctional MOR agonists/DOR antagonists known to reduce tolerance and side effects of opioid therapy, and (b) allosteric ligands that modulate DOR activity only in the presence of endogenous opioid (DA038858-01).	Y	Univ of Southern California

NIH	Pain Treatment - Product development	This study will: 1. Test the efficacy of CGRP8-37 microneedle patches in two rat neuropathic pain models: the Spared Nerve Injury model of regional pain and a more localized neuropathic model, the Tibial Neuroma Transposition model. 2. Investigate local dermal toxicity following the transdermal application of microneedles in rats and rabbits, and evaluate toxicity following systemic administration of CGRP8-37 in rats. 3. Examine means of optimizing manufacturing processes of microneedle patches in order to prepare for future IND studies. This Phase II project, if successful, will provide an evidence-based go/no go decision toward IND enabling studies that can lead to first-in-human testing of CGRP8-37 microneedles in volunteers and patients supported by competitive renewal of this Phase II SBIR project (DA026363).	Y	AFASCI
NIH	Pain Treatment - Product development	This project will develop and characterize a ropivacaine- CTx loaded injectable chitosan hydrogel as a local control delivery system and evaluate the in vitro bioactivity of the formulation using cell culture model. We will also evaluate the in vivo biological performance of the ropivacaine and CTx - loaded chitosan hydrogel. If successful the proposed study will have a significant impact in the clinical translation of prolonged local pain relief systems for efficient musculoskeletal pain management.	Y	Univ of CT

NIH	Pain Treatment - Product development	The present proposal aims to develop and employ a new fluorination strategy to rationally improve biophysical properties of peptide-based probes with insufficient drug-like properties, and to allow for these probes to enter the CNS (DA036730-01A1).	Y	Univ of Kansas
NIH	Pain Treatment - Product development	The proposal is divided into two specific aims that support the execution of a Lipella-sponsored Phase IIB randomized clinical trial to evaluate two different doses of LP-08 in IC/BPS patients compared to a placebo dose (DK085733).	Y	Lipella Pharmaceuticals
NIH	Pain Treatment - Product development	This Phase II project further develops Sustained Acoustic Medicine for OsteoArthritis (SAMOA) and moves towards commercialization of the technology for the symptomatic management of OA. First, the SAMOA device will be engineered for improved ergonomic function in the arthritic community, ensuring that all user-interface elements are streamlined for those who may have reduced manual strength or dexterity. Second, the device will be evaluated in a larger clinical trial, providing a statistical demonstration of the treatment's benefit across minority groups which will be essential for regulatory approval and acceptance in the medical community. Third, the SAMOA device will be tested in the field for a real-world evaluation of how physicians prescribe, and patients adopt and interact with the device, providing a critical final test of the system (MD008597).	Y	Zetroz

NIH	Pain Treatment - Product development	The following specific aims should result in the development of three prototype drug delivery systems with improved therapeutic characteristics for smoking cessation, opiate withdrawal, and chronic pain treatment. Specific Aim 1: to quantify the nicotine, fentanyl, and clonidine flux rates through the CNT membranes as a function of size, polarity and binding affinity of the molecular gate keeper at the entrance to each CNT pore. Specific Aim 2: to prove the ability to open and close the pore entrance with applied bias to charged long-chained molecules- bonded to CNT tips. Specific Aim 3: to study the transdermal delivery rates in human skin in vitro for constant rates and voltage gated delivery rate changes, including the quantification of the dynamic response time to gated release. Specific Aim 4: to characterize the pharmacokinetics of the drugs in hairless guinea pigs and Yucatan miniature pigs in order to evaluate the in vivo success of constant rate and gated delivery (DA018822).	Y	Univ of Washington
NIH	Pain Treatment - Product development	A few early phase human trials focus on the opportunities gained from knowledge of the microbiome-pain interaction. They include evaluation of dietary fiber based prebiotic analgesia, E-coli based probiotics and nutrition based approaches for relief of chronic abdominal pain (DK102807, DK088525).	Y	Northwestern

NIH	Pain Treatment - Product development	Modifications and innovative approaches for delivery of peripheral nerve stimulation to treat neuropathic pain are being evaluated (HD067094).	Y	SPR Therapeutics
ASPE	Pain Treatment - ADFs	Evaluating the impact of OxyContin reformulation among nonmedical users of prescription opioids using data from the National Survey on Drug Use and Health	N	FDA and AHRQ
FDA	Pain Treatment - ADFs	Research to date has focused on evaluating the abuse deterrent properties of ADF manufactured at FDA using direct compression method and via hot-melt extrusion process. Properties of the products critical to abuse-deterrent products were then assessed: hardness and syringeability, extractability under a wide variety of conditions of heat and solvents, morphology, crystallinity, and dissolution and particle size after manipulation	N	None

FDA	Pain Treatment - ADFs	FDA has approved 5 opioids with abuse-deterrent properties based on clinical studies and in vitro testing conducted before marketing, consistent with our guidance on the development of abuse-deterrent opioids. A critical aspect of enhancing the development and use of abuse-deterrent opioids is to assess the actual performance of these products in the post marketing setting to actually reduce abuse. Each company has a PMR, and the purpose of these PMRs is to require the collection of post-marketing data on actual prescription of these ADF products and assess their impact on abuse.	Y	Industry
NIH	Pain Treatment - ADFs	A partnership with Signature Therapeutics to develop an abuse-deterrent formulation of OxyContin that uses prodrug technology—attaching an extension to the opioid molecule that renders it inactive unless it is taken orally.	Y	Signature Therapeutics
NIH	Pain Treatment - ADFs	The research plan for the current proposal is to compare the effectiveness of nalfurafine as a punisher of oxycodone self- administration to other established drug punishers in monkeys. We will also determine if nalfurafine and other drug punishers modulate the anti-nociceptive effects of oxycodone. Lastly, we will use quantitative observational procedures to compare the side effect profiles of oxycodone-nalfurafine mixtures to the effects of oxycodone mixed with other drug punishers known to produce significant aversive effects (DA039167-01A1).	Y	Univ Miss

OASH	Epidemiology - Legal	Examine state laws and regulations on mandatory opioid training for licensure/re-licensure and then an overview of the core competencies needed for such training	N	ASPE
AHRQ	Epidemiology - Patient behaviors	The project aims to first, clarify risk factors for ADEs from high priority medications through a literature review and translate them into a working set of clinical quality measures that can be implemented in primary care and second, use a community engaged action (CEA) research approach to test the impact of a refined set of preventive strategies for ADEs on practice performance on clinical quality measures in a group-randomized trial. Three significant innovations in the proposed method are: 1) identification of primary care-relevant ADE risk factors for HPM and strategies to prevent them, 2) development of acceptable, reliable and valid ADE CQMs using a modified Delphi method among primary care providers and 3) inclusion of patients in a community engaged action research intervention among "real world" primary care practices (AHRQ-R18 HS23454).	Y	Medical Univ of South Carolina

AHRQ	Epidemiology - Patient behaviors	Characterizing Visits after Index Hospitalizations for Opioid-Related Diagnoses. This study will involve: 1) a descriptive analysis of select patient demographic, admissions, and hospital characteristics for the opioid-related index inpatient stays by four treatment groups (detoxification only, rehabilitation only, both detox and rehab, no treatment); 2) a description of the trajectory of events (e.g., mean number of and time to subsequent hospitalizations, type of subsequent hospitalization) up to two years after the opioid-related index stay by treatment group; and 3) a multivariate analysis to evaluate the relationship between outcome events (i.e., mean number of and time to subsequent hospitalizations) and treatment groups, controlling for other factors.	N	None
ASPE	Epidemiology - Patient behaviors	Assessing the predictive value of various patient metrics on prescription drug abuse and overdose using linked PDMP and other health data.	Y	RAND and Brandeis
CDC	Epidemiology - Patient behaviors	Recent evidence suggests that opioid misuse and disability may be closely linked. In this project CDC will examine the role of opioid misuse as a potential pathway to disability programs. CDC will examine trends in opioid use, possible misuse and addiction among disabled Medicare enrollees by state and age, using Medicare claims data for 2006 through 2013.	Y	TBD

CDC	Epidemiology - Patient behaviors	Dual eligible patients who misuse or overdose on prescription opioids are a largely understudied high risk population. In the project, CDC plans to combine Medicare and Medicaid claims data to identify PDO patients with dual eligible status at state level. CDC will then measure their medical cost paid by Medicare and state Medicaid program.	N	TBD
FDA	Epidemiology - Patient behaviors	A prospective, observational study designed to quantify the serious risks of misuse, abuse, and addiction associated with long-term use of opioid analgesics for management of chronic pain among patients prescribed ER/LA opioid analgesics for at least one year (PMR 3033-1).	Y	Industry
FDA	Epidemiology - Patient behaviors	An observational study designed to measure the incidence and predictors of opioid overdose and death (OOD), as well as opioid abuse/addiction, using patient health records, insurance claims, and death records (PMR 3033-2).	Y	Industry
FDA	Epidemiology - Patient behaviors	A prospective observational study designed to assess the content validity and patient interpretation of the Prescription Opioid Misuse and Abuse Questionnaire (POMAQ). Patient understanding of the concepts of misuse and abuse will also be obtained (PMR 3033-3).	Y	Industry

FDA	Epidemiology - Patient behaviors	An observational study to validate measures of prescription opioid Substance Use Disorder and addiction in patients who have received or are receiving opioid analgesics for chronic pain (PMR 3033-5).	Y	Industry
FDA	Epidemiology - Patient behaviors	An observational study to develop and validate an algorithm using coded medical terminologies to identify patients experiencing prescription opioid abuse or addiction, among patients receiving an ER/LA opioid analgesic (PMR 3033-7).	Y	Industry
FDA	Epidemiology - Patient behaviors	An observational study using coded medical terminologies and other electronic healthcare data to define and validate doctor and/or pharmacy shopping outcomes by examining their association with abuse and/or addiction (PMR 3033-8).	Y	Industry
FDA	Epidemiology - Patient behaviors	An observational study using a validated patient survey to evaluate the association between doctor/pharmacy shopping outcomes and self-reported misuse and abuse. (PMR 3033-9).	Y	Industry
FDA	Epidemiology - Patient behaviors	An observational study using medical record review to evaluate the association between doctor/pharmacy shopping outcomes and patient behaviors suggestive of misuse, abuse and/or addiction (PMR 3033-10).	Y	Industry

NIH	Epidemiology - Patient behaviors	We propose to examine 3 models related to the development of PTSD/chronic pain pairing and development of substance abuse in people initially presenting with acute pain (not caused by a traumatic event) in a 6-month prospective design. First is the Main Effects Model in which the level of PTSD symptoms at baseline will predict the likelihood of a transition from acute to chronic pain and development of substance abuse at 6 months. Second is the Moderation Model in which baseline vulnerability and resilience factors interact with PTSD symptoms to predict the likelihood of developing chronic pain and substance abuse 6 months later. Third is the Mediator Model in which relationships between baseline levels of PTSD symptoms and the development of chronic pain and substance abuse 6 months later are mediated by vulnerability and resilience factors at 3 months (DA039522-01A1)	Y	Rush Univ Med Ctr
NIH	Epidemiology - Patient behaviors	The objective of this proposal is to characterize NMPO use among PLHIV and explore the intersection of NMPO use, chronic pain, and marijuana use in a large HIV clinic in the Southeastern US where the joint epidemics of HIV and PO use are acutely felt (DA039743-01).	Y	Vanderbilt Univ

NIH	Epidemiology - Patient behaviors	This research will clarify individual risks among patients initiating chronic opioid therapy, laying the foundation for early identification of patients at high risk of unfavorable psychological and functional outcomes. Among middle aged and older adults initiating long-term opioid use, this research will: 1) identify predictors of sustained opioid use; 2) evaluate risk factors for psychosocial dysfunction; and, 3) develop practical methods for early identification of patients at increased risk of unfavorable psychosocial outcomes (AG034181).	Y	Group Health
ASPE	Epidemiology - Provider behaviors	Conducting a national hospital- level analysis to assess the relationship between HCAHPS scores and opioid prescribing	N	CMS
ASPE	Epidemiology – Provider behaviors	Funding a study to evaluate the impact of electronic heath record (EHR) opioid prescribing defaults on prescriber behaviors of Schedule II opioids. Two health systems, including one FQHC and one academically affiliated medical center, are participating practice sites. The primary research aim is to determine how changing the defaults for the duration of opioid prescriptions in EHRs affect opioid prescribing behavior.	Y	Mathematica
CDC	Epidemiology - Provider behaviors	Identify clusters of counties with both high-risk opioid prescribing and mortality and other characteristics associated with these prescribing/utilization patterns.	N	IMS, NCHS

CDC	Epidemiology - Provider behaviors	Opioid prescribing behavior behavior/trends by gender and age using data from the Prescription Behavioral Surveillance System (PBSS).	Y	Brandeis
CDC	Epidemiology - Provider behaviors	Prescribing trends by drug category to identify increases and decreases, specifically due to rescheduling.	N	IMS
CDC	Epidemiology - Provider behaviors	Collect information about provider knowledge, attitudes and beliefs regarding maternal opioid use, Ob/Gyn screening and referral practices for pregnant and postpartum patients, barriers to screening and treating pregnant and postpartum patients for opioid use, coordination with pediatric staff on NAS and resources that are needed to improve treatment and referral.	Y	ACOG
CDC	Epidemiology - Provider behaviors	Tracking prescribing rates and mortality by demographic characteristics	N	N/A
CDC	Epidemiology – Provider behaviors	Utilizing PBSS data to identify high percentile prescribers and patients getting multiple overlapping prescriptions.	Y	Brandeis
CMS	Epidemiology - Provider behaviors	Analysis of concurrent use of opioid analgesics and buprenorphine addiction therapy in Medicare Part D	N	None
FDA	Epidemiology - Provider behaviors	Prescribing patterns for newly approved opioids	N	ASPE

FDA	Epidemiology - Provider behaviors	Using the FDA contract for outpatient prescription data, FDA is researching trends in opioid use. FDA is monitoring the prescribing of abuse- deterrent opioids as they come onto the market. FDA is evaluating the impact of product approvals of different types on market size and patterns of prescribing.	N	None
HRSA	Epidemiology - Provider behaviors	1-year research project around HHS policy on opioid abuse and/or prescribing patterns.	Y	Univ of Michigan
NIH	Epidemiology - Provider Behaviors	NIH is supporting the first open-access, no-cost, clinically based, retrospective and prospective chronic pain data registry to help identify pain-management interventions that are most effective for specific patient types with chronic pain.	Y	Multiple
SAMHSA	Epidemiology - Provider Behaviors	Using MarketScan commercial and Medicaid claims data to examine trends in opioid prescribing, including days supplied and strength of opioid prescriptions filled.	N	None
CDC	Epidemiology – Provider behaviors and mortality	Identify trends in prescribing and MME at the county-level; discuss how illicit drug use has impacted mortality at the regional level; incorporate messaging from CDC guidelines for high prescribing and high MME geographical areas.	N	IMS, NCHS

AHRQ	Intervention - Clinical Practice	This study funds the team-based best practices approach to safe opioid prescribing for chronic non-cancer pain in rural primary care clinics based on the Group Health Chronic Opioid initiative and findings in our recent work on the national project: Primary Care Teams: Learning from Exemplar Ambulatory Practices (LEAP). Our specific aims are to: 1) implement a team-based best practices approach to safe opioid prescribing in primary care ; 2) examine the effectiveness of the intervention; 3) assess the sustainability of the team-based best practices approach; and, 4) develop and launch a robust dissemination program. The study will be conducted in 14 remote, rural, clinics in Washington and Idaho. Key elements of the intervention are: 1) a COT improvement team in each clinic with at least one clinician champion; 2) revision of current clinic policies using examples from Project LEAP exemplar practices; 3) develop clinic workflow and tasks needed to implement policies; 4) use of a clinic registry for pre-visit planning and visit intake; and 5) use of performance reports to track and make improvements (AHRQ-R18 HS23750).	Y	Group Health

AHRQ	Intervention - Clinical Practice	This project will leverage the strengths of a multidisciplinary research team and combine several health-literacy appropriate educational strategies to create an EHR-based medication complete communication (EMC2) strategy to promote safe use of opioid pain relievers. The EMC2 strategy will impart risk information to patients at multiple points in time and using multiple modalities. We will conduct a three-arm trial at an urban academic emergency department to evaluate the EMC2 and EMC2+SMS text message reminder strategies compared to usual care (N=816 patients; 272 patients per study arm). The primary outcome of interest will be a decrease in medication errors as measured by demonstrated safe medication use. Other safety outcomes will also be examined and patient knowledge will be measured. Additionally, we will assess the fidelity and economic impact of the interventions to identify any necessary modifications to guide future dissemination efforts (AHRQ-R18 HS23459).	Y	Northwestern

AHRQ	Intervention - Clinical Practice	This study will characterize primary care clinicians' information use and decision making patterns during patient visits for musculoskeletal pain to determine how they align with clinical practice guidelines. Data will be collected from medical records, visit audio recordings, and post-visit clinician interviews for up to 125 patient visits. Data will then be qualitatively analyzed to cluster visits into similar sense making narratives and used to identify commonly-occurring missed opportunities in which decision support could have altered the use of clinical information or altered care plan choices to better align with guideline recommendations. Based on the sense making narratives and missed opportunities identified in Aim 1, prototype and preliminarily evaluate new decision support designs to meet clinicians' information needs and guide them toward guideline-based information use and care choices. This aim will involve a three-day design workshop and usability testing with engineers, clinicians, and patients to produce prototypes for novel, guideline-based decision support systems that can be integrated in EHRs. This innovative project will be the first to conduct in-depth analysis of patient visits, clinician interviews, and medical record data to understand primary care clinical decision making for chronic pain (AHRQ-R01 HS23306).	Y	Indiana Univ

AHRQ	Intervention - Clinical Practice	The specific aim is to determine the feasibility and health impact of a registry-facilitated dissemination of a mobile health (mHealth) patient support system that incorporates established evidence-based pain management strategies. The aim will be achieved through the approach of distributing pain self-management strategies via an innovative mHealth tool to those patients with JIA registered in the largest pediatric rheumatology registry in the world (the Childhood Arthritis and Rheumatology Research Alliance - CARRA - registry) and involved in the new pediatric rheumatology Patient- Powered Research Network (AHRQ-R21 HS23980).	Y	Children’s Mercy Hosp

AHRQ	Intervention - Clinical Practice	The fundamental hypothesis of this work is that secondary care, pain specialist practices can serve as rich reservoirs of evidence-generating information. To explore this possibility, Michigan State Univ. (MSU) has partnered with Michigan Pain Consultants (MPC) to create a clinical decision support (CDS) tool based on MPC's rich data repositories. We will utilize their administrative data, their proprietary patient survey data, and their detailed dictations from approximately 80,000 visits per year. The strategy can be summarized as follows: (1) identify, extract, and organize the information content of the MPC data reservoir; (2) create, test, and validate a person-in-pain phenotype model; and, (3) utilize the data, organized according to phenotypes and outcomes, to begin designing a software engine that will provide supplementary diagnostic and treatment support for practicing pain management professionals. This will allow enhanced treatment for the largest and most challenging cause of chronic morbidity in the U.S. (AHRQ-R21 HS22335).	Y	Michigan State Univ

AHRQ	Intervention - Clinical Practice	The proposed study is a randomized trial comparing the effectiveness of usual, guideline-based initial management of newly consulting patients with LBP with sciatica with or without the addition of early physical therapy. Specific aims are to compare the clinical effectiveness, costs (direct and indirect), and cost- effectiveness of the addition of physical therapy. All patients will be managed with advice, education and medication. One group will also receive 6-8 sessions of physical therapy Outcomes will include measures of disability, pain, psychological distress, healthcare, utilization, and costs over 1 year. This study will permit an examination of the effectiveness and costs associated with the use of early physical therapy within primary care for patients with acute LBP and sciatica (AHRQ-R18 HS22641).	Y	Univ of Utah
ASPE	Intervention – Clinical Practice	ASPE, in partnership with other HHS agencies, is currently funding a project to conduct an environmental scan on current coverage policies for non-opioid pain treatments and non-pharmacological pain interventions.	Y	Johns Hopkins Univ., CDC, CMS, NIH

CDC	Intervention - Clinical practice	Prescription Reporting with Immediate Medication Utilization Mapping - The objectives are to (1) assess implementation and changes in prescribing behavior of physicians and healthcare providers when presented immediate feedback on potential misuse or abuse of prescription narcotics through electronic alerts, (2) compare rates of outpatient prescription narcotic complications before and after implementation of an immediate computerized reporting system, and (3) map prescriber and patient behavior in response to implementation of an immediate computerized reporting system for prescription narcotics.	Y	Carolinas Medical Center
CDC	Intervention - Clinical practice	Safe Opioid Prescription Practice - Using a quasi-experimental design we will compare the effect of adopting and implementing a Safe Opioid Prescription Practice (SOPP) protocol within a Level 1 trauma service team compared to a Level 1 trauma service team implementing standard care. Providers at both sites will complete web-based surveys to assess baseline knowledge, attitudes, and barriers related to safe prescription practices. To measure institutional level changes, chart reviews will be conducted. To measure patient level changes, we will assess patient perception of the discharge experience; three month interviews will be conducted to assess opioid usage, pain management strategies, and naloxone use.	Y	Rhode Island Hospital

CDC	Intervention - Clinical practice	Compare and validate five screening tools for detecting substance use among pregnant women (4Ps Plus, SURP-P, CRAFFT, Wayne Indirect Screener, NIDA Quick Screen.)	Y	Yale Univ
CDC	Intervention - Clinical practice	Evaluation of a coordinated care plan on opioid prescribing.	Y	Abt Assoc.
CDC	Intervention - Clinical Practice	The Impact of Pill Mill Laws on Opioid Prescription Dispensing and Utilization - We propose to evaluate the effect of pill mill laws. The investigation capitalizes on a database of 5.2 billion longitudinal prescription claims for more than 50 million Americans and 1.5 million prescribers from 2006-2013. We will characterize the effect of the laws on subsets of patients, prescribers, and pharmacies whose baseline measures suggest unusual patterns of utilization, prescribing, or dispensing. The analyses will be rigorously conducted using advanced epidemiologic and statistical techniques.	Y	Johns Hopkins Univ
CDC	Intervention - Clinical Practice	ICRC; Research Project 3 - Building on previous work, this proposed research seeks to reduce injured patients' risk for opioid misuse by using mobile health (m-health) technology to develop and pilot test an innovative patient education intervention titled Acute Pain Patients' Rx (APPRx). APPRx will include a patient decision aid (PDA) and a smart phone application.	Y	Johns Hopkins Univ

CDC	Intervention - Clinical Practice	Evaluation of the impact of the CDC Guideline for Prescribing Opioids for Chronic Pain on prescribing behaviors and health outcomes.	N	None
CDC	Intervention - Clinical Practice	Impact of real-time PDMP data reporting and access on opioid prescribing.	N	None
CDC	Intervention - Clinical Practice	Evaluation of state interventions related to PDMPs such as delegates, registration improvements (states funded through CDC's Prevention for States Program)	Y	RTI
CDC	Intervention - Clinical Practice	Evaluation of state pill mill laws with cross-state comparison (states funded through CDC's Prevention for States Program).	Y	RTI
CDC	Intervention - Clinical Practice	Effect of academic detailing on opioid prescribing.	Y	RTI
CDC	Intervention - Clinical Practice	Impact of clinical quality improvement measures in a large health care setting and prescribing.	N	None
CDC	Intervention - Clinical Practice	Impact of proactive PDMP reporting on opioid prescribing.	Y	RTI
CDC	Intervention - Clinical Practice	Impact of PDMP prescriber mandate on opioid prescribing.	Y	Brandeis

CDC	Intervention - Clinical Practice	ICRC; Research Project 4 - The primary goal of this proposed study is to evaluate the addition of a proactive reporting component to North Carolina's prescription drug monitoring program (PDMP) to assess improved provider prescribing behaviors, reduced patient controlled substance (CS) abuse, and increased outpatient treatment for drug abusing patients.	Y	The Univ of North Carolina at Chapel Hill
FDA	Intervention - Clinical Practice	Develop a model Opioid Patient Prescriber Agreement (PPA) to be used by healthcare providers to inform patients about the risks or benefits of opioid treatment for pain.	Y	NYU
FDA	Intervention - Clinical Practice	Reduce long term use of opioids following surgery by identifying patients at the highest risk of becoming long-term, high dose opioid users following orthopedic surgery, adapt an opioid-sparing educational intervention, and estimating the efficacy of the intervention to reduce opioid medication after surgery.	Y	Kaiser Foundation Research Institute
FDA	Intervention - Clinical Practice	Improve the use of pain medications through development of a treatment model utilizing nurse-educators.	Y	NEMA
FDA	Intervention - Clinical Practice	Improve the appropriate prescribing of opioids by identifying high prescribers of opioids and opioid/benzodiazepine combinations using data from the New York State Prescription Drug Monitoring Program (PDMP). Educational materials will be developed and evaluated for their impact on prescribing behaviors.	Y	Brandeis

FDA	Intervention - Clinical Practice	An observational study to evaluate the validity and reproducibility of the Prescription Opioid Misuse and Abuse Questionnaire, which will be used to identify opioid abuse and misuse behaviors among participants who have chronic pain which requires long-term opioid analgesic use (PMR 3033-4).	Y	Industry
NIH	Intervention - Clinical Practice	A trial in Kaiser is comparing integrated pain management with standard care for pain management (NS088731).	Y	Kaiser Foundation Research Institute
NIH	Intervention - Clinical Practice	COPE trial for benefits of combined treatment for pain, disability, and disease pharmacotherapy (CA163803).	Y	Mayo Clinic
NIH	Intervention - Clinical Practice	Research network evaluating efficacy of commonly used drugs for pediatric migraine (NS077108).	Y	Univ of Iowa
NIH	Intervention - Clinical Practice	Complementary and alternative medicine treatments such as acupuncture, spinal manipulation, and massage, as well as mind-body approaches such as mindfulness meditation, stress reduction, and yoga are being assessed to determine mechanisms, long and short term efficacy, utilization, decision points of care, and cost effectiveness (AT005896, AT005956, AG034078).	Y	Kaiser Foundation Research Institute
NIH	Intervention - Clinical Practice	Research includes mechanism-based clinical studies on acupuncture (AT005819).	Y	Mass Gen Hosp

NIH	Intervention - Clinical Practice	Neural stimulation technologies for chronic pain: transcranial magnetic stimulation, transcranial direct current stimulation, electrical deep brain stimulation, and stimulation devices for peripheral nerves/tissues show promise for the treatment of chronic pain (DA038971, NS074357,AR061755).	Y	Medical Univ of SC
NIH	Intervention - Clinical Practice	Cognitive behavioral therapy (CBT) and its delivery through web-based technology, parent training for CBT for pediatric pain, exercise, mindfulness-based stress reduction, and other coping strategies may contribute to the biopsychosocial model of pain care (HD062538, MH097827).	Y	Seattle Children's Hospital and Baylor SOM
NIH	Intervention - Clinical Practice	Behavioral strategies to improve treatment adherence and opioid safety using clinical decision support for providers (AT008319, AG034181).	Y	Northern California Institute
NIH	Intervention - Clinical Practice	The primary question addressed by this 2-phase RCT is to answer: What is the value of combination treatment with high-dose duloxetine (DUL) plus a symptom-specific and age-appropriate intervention called Problem Solving Therapy for Depression and Pain (PST-DP) for older adults living with MDD and CLBP when primary pharmacotherapy with low-dose duloxetine and supportive management (DUL/SM) has led to partial or non-response (AG033575).	Y	Univ of Pittsburgh

NIH	Intervention - Clinical Practice	The NIH Pain Consortium coordinates collaborative pain research initiatives activities at NIH and funds 12 Centers for Excellence for Pain Education (CoEPEs) that act as hubs for the development, evaluation and distribution of pain management curriculum resources for medical, dental, nursing and pharmacy schools.	Y	Multiple
CDC	Intervention - Insurance Strategy	The Impact of Benefit Design and Formulary Practices on Opioid Abuse and Overdose - The proposed study will research whether benefit design and formulary management can be applied to address the public health problems of prescription drug abuse and overdose. We propose to evaluate the impact of changes in these strategies on (1) claims-based measures of opioid utilization that are indicators of misuse, (2) health outcomes associated with opioid misuse and abuse and extrapolated from claims data, and (3) associated health system spending. We propose to conduct our evaluation in two different but related patient populations and healthcare settings, namely worker's compensation and SSDI-eligible disabled Medicare populations in two states, Texas and California. The quasi-experimental differences-in-differences evaluation methodology will contribute to the evidence base linking policy tools to changes in outcomes.	Y	RAND Corporation

CDC	Intervention - Insurance Strategy	Opioid Analgesic Policies and Prescription Drug Abuse in State Medicaid Programs - The objective is to quantify how pharmacy benefit designs in three state Medicaid programs (Oregon, Oklahoma, Colorado) impact opioid analgesic utilization, inappropriate use, abuse, and adverse health outcomes. We will estimate the effects of PA policy for long-acting opioids implemented in Oklahoma. We will evaluate the impact of an opioid high dose limit implemented in Oregon. For both these aims we will employ a quasi- experimental approach to compare utilization and overdose-related outcomes to states without opioid policies. Finally, we will link Oregon Medicaid and PDMP data to assess the frequency and characteristics of patients who circumvent Medicaid policies by paying cash for opioids.	Y	Oregon State University
CDC	Intervention - Insurance Strategy	The Influence of Formulary Management Strategies on Opioid Medication Use - This study will examine the effect of formulary management strategies on patterns of problematic prescription opioid consumption and overdose in the Pennsylvania Medicaid program. The study will identify patient- and provider-level risk factors associated with opioid overdose and trajectories of opioid consumption that precede overdose in Medicaid, and examine effects of formulary/utilization management tools on overdose and problematic use.	Y	Univ of Pittsburgh

CDC	Intervention - Insurance Strategy	Washington State Medicaid managed care plans and care coordination elements.	N	None
CDC	Intervention - Insurance Strategy	Medicaid prior authorization evaluation of MaineCare.	N	MaineCare
CDC	Intervention - Insurance Strategy	This project is to evaluate the policy effectiveness regarding prior authorization in Medicaid that reduces prescribing of opioids. CDC will focus specifically on Oklahoma's Medicaid program. Oklahoma's Medicaid implemented three different prior authorization policies sequentially (2007, 2009, and 2010) to control hydrocodone prescriptions. CDC will evaluate the outcomes of these policies in three categories: utilization, cost and medical outcome.	N	CDC
CMS	Intervention - Insurance Strategy	Analysis and implementation in Medicare Part D of 3 opioid measures developed by the Pharmacy Quality Alliance.	N	None
CMS	Intervention - Insurance Strategy	Number/Percent of Medicare Part D beneficiaries identified in the Part D OMS as potential opioid over utilizers in CY2015.	N	None

Expand access to medication assisted treatment for opioid use disorder

(research projects as of 7/1/2016)

Agency	Type of Activity	Description	Extramural	Partners

NIH	Opioid Use Disorder - Basic science research	This study will examine morphine- induced adaptations in synaptic strength and glutamate-related plasticity within corticostriatal brain circuits by combining whole-cell electrophysiological approaches with viral-mediated expression of light sensitive opsins (optogenetics), and fluorescent reporter mice in operant models of drug-administration (K99DA038706-01).	Y	Univ of Minnesota
NIH	Opioid Use Disorder - Basic science research	This study will identify mechanisms by which LC neurons become dysregulated by chronic morphine at a systems or cellular level such that they are more sensitive to stress. It will define stress- induced molecular and cellular plasticity that alters LC activity and predisposes to substance abuse. It will determine the influence of sex on opiate-induced LC neuronal activity. The proposed work will elucidate how dysregulation of the LC-NE system impacts stress and opiate sensitivity, decisions underlying substance abuse, and sex differences in opiate actions (R01DA009082-17).	Y	Drexel Univ
NIH	Opioid Use Disorder - Basic science research	This study will test whether glial TLR4 activation induces release of cytokine in morphine withdrawal. Test whether activation of cytokine receptor induces mitochondrial ROS in morphine withdrawal in the PAG. Test whether mitochondrial ROS in the PAG is involved in MW through the pCREB (R01DA034749-02).	Y	Univ of Miami

NIH	Opioid Use Disorder - Basic science research	Animal models of compulsive drug seeking and dependence will be developed for oxycodone and compared to drug seeking for heroin and buprenorphine. Using such animal models, individual differences in compulsive drug seeking, withdrawal and re-escalation of compulsive drug seeking will be characterized. In parallel, dysregulation of neural systems known to drive the development of compulsive opioid seeking will be characterized. These include alteration of the brain corticotropin releasing factor (CRF) systems and brain dynorphin kappa systems in brain reward and stress circuits. Finally, microinjection of antagonists of the CRF system and the kappa system in specific brain regions and gene silencing of specific CRF and dynorphin neurocircuits will be employed to reverse neuroadaptive changes and consequent re-escalation of drug seeking in subgroups of rats with high levels of compulsive drug seeking (R01DA035281-02).	Y	Scripps Research Institute

NIH	Opioid Use Disorder - Basic science research	First, we will confirm DRN- or 5-HT-specific deletion of the GABAA receptor in these mice using immunohistochemistry, electrophysiology and quantitative autoradiography. Next, we will test these mice in two complementary animal models of relapse in which a swim stress is used to reinstate previously extinguished morphine conditioned place-preference or self-administration. We predict that these mice will be protected from the GABAergic sensitization observed in the 5-HT DRN system following a stress- induced relapse model and will thus be less vulnerable to relapse in these two models (R21DA037523-02).	Y	Temple Univ
NIH	Opioid Use Disorder - Basic science research	Describe the epigenetic and transcriptional mechanisms underlying opioid use disorders (R01DA025674-06).	Y	Tufts Univ

NIH	Opioid Use Disorder - Basic science research	The proposed study will first examine the prevalence of polymorphisms of genes that encode the: s opioid receptor (OPRM1), proinflammatory cytokine (IL-12), and cytochrome P450 hepatic metabolizing enzymes (CYP2D6). In a subset of study participants (150 heroin abusers + 150 prescription opioid abusers + 150 non-drug abusers) we will quantify the effects of ascending doses of oxycodone (0, 10, and 30 mg) in a single laboratory session. Ten individuals of each target genotype (OPRM1:118G, IL-12- 511C (or 31T), CYP2D6 null alleles: *3,*4,*5,*6,*7, or*8) from two of the populations sampled (prescription opioid abusers and non-opioid abusers homozygous for each variant of interest) will complete the laboratory session during which we will quantify the subjective effects of oxycodone (K01DA030446-05).	Y	NY State Psychiatric Institute
NIH	Opioid Use Disorder - Basic science research	This application seeks to identify the genetic basis of opioid reward and aversion. We will use a genetically informative panel of mouse strains and a behavioral model- the place conditioning assay- to screen for differences in the rewarding response to the commonly abused prescription opioid agonist oxycodone (OXY) and the aversive response to the opioid antagonist naloxone (NAL) (R00DA029635-05).	Y	Boston Univ

NIH	Opioid Use Disorder - Basic science research	We are proposing to conduct a laboratory study to evaluate whether the A118G SNP and additional OPRM1 tagging SNPs are associated with a variety of different MOR-mediated functions by evaluating subjective and physiological response to double-blind administration of an opioid medication. We will also evaluate the contribution of OPRM1 on other complex phenotypes related to the MOR activity or opioid dependence (e.g., pain sensitivity, the endogenous opioid-mediated cortisol stress response, and a delay discounting behavioral economic task) (R01DA035246-02).	Y	Johns Hopkins Univ
NIH	Opioid Use Disorder - Basic science research	At present it is not possible to use clinical or biomarker predictors to determine who will most likely benefit from one medication versus the other. Recent research has suggested that a common variation in the delta opioid receptor gene (OPRD1), single nucleotide polymorphism (SNP) rs678849, may predict response (urine drug screen for illicit opioids) among African-Americans (AAs) to these medications. AA opioid addicts with a CC genotype at rs678849 have a greater probability of gaining substantial therapeutic benefit from MET, while those with alternative genotypes (C/T + TT) have a greater probability to responding well to BUP (relative risk = 2.8~ p = 2.2 x 10-5). The current project represents an attempt to confirm the original finding in an independent population. Individuals of AA ethnicity, age at least 18, being treated with methadone (n = 150) or buprenorphine/naloxone (n = 150) for opioid	Y	Univ of Penn

		addiction at treatment centers in New Haven and the Philadelphia Veterans Administration Medical Center, will be invited to participate. Participation involves review of medical records (t determine eligibility and response to treatment), a brief semi-structured interview and a single small (5 ml) venous blood sample. Blood will be used for DNA extraction and the rs678849 SNP will be genotyped. Genotype x treatment interaction analysis is planned, including as co-variates age, gender, age-at-onset of opioid addiction, co-morbid disorders urine drug screen results for opioids during the most recent 20 weeks is the sole endpoint. This phenotype will be analyzed also using generalized estimating equation methods, with the urine drug screen results treated as repeated measures. If the original observation is confirmed, this research may lead to a simple and inexpensive test for optimal agonist treatment of opioid addiction among African-Americans (R21DA036808-02).		
NIH	Opioid Use Disorder - Basic science research	This study will collect an independent confirmatory set of DNA samples from African-Americans being treated with either methadone or buprenorphine for opioid addiction. The entire OPRD1 gene will be sequenced in all samples and variants will be analyzed for associations with treatment outcome. We will also study the effects of the polymorphism of interest on OPRD1 expression in both postmortem brain tissue and neuronal cell lines (K01DA036751-02).	Y	Univ of Penn

NIH	Opioid Use Disorder - Basic science research	There is almost no information comparing the effectiveness of agonist or antagonist maintenance regimens in reducing relapse to drug seeking in either humans or laboratory animals. To address this gap in knowledge, we will study how chronic exposure to maintenance pharmacotherapies modifies the relapse-related priming effects of prescription opioids and drug-paired environmental stimuli in nonhuman primates (R01DA035857-02).	Y	Mclean Hospital
NIH	Opioid Use Disorder - Basic science research	Identify neuroimaging and physiological biomarkers that correlate with long term treatment response. The proposed study will follow a population of recently detoxified male and female patients with prescription opioid dependence through a one month period of inpatient drug rehabilitation treatment, 3 additional months of extended residential care at the Caron Foundation (Wernersville, PA), and 1 and 3 months post-discharge. Recent experience indicates that 5 patients/month would be eligible for enrollment in the study (R01DA035240-03).	Y	Penn State Univ

FDA	Opioid Use Disorder - Product development	There is currently a lack of consensus about the best trial designs to use to develop new products for the treatment of opioid, marijuana, and stimulant use disorders. Improvements in this area could improve the development of drugs in this area. Through the Consortium for Addiction Research on Efficacy and Safety (CARES), the group is working to create consensus on the design and analysis of addiction clinical trials, would be a valuable step towards reducing barriers to drug development. The first meeting on clinical trial endpoints for stimulant addiction trials was held in 2015. Next steps will involve conducting secondary analyses of existing databases to examine potential primary endpoints for cocaine addiction treatment trials, and a meeting to identify unmet needs in the treatment of cannabis addiction.	Y	CARES
FDA/NIH	Opioid Use Disorder - Product development	FDA and NIH cooperation on novel endpoints. There is broad interest in exploring the novel endpoints, in addition to abstinence, that could be used to support approval of new therapies. FDA and NIDA are discussing mechanisms to collect data to support the use of new endpoints for trials of drugs intended to treat opioid substance use disorder.	N	None

NIH	Opioid Use Disorder - Product development	Recent evidence suggests that inactivation of Substance P receptors, either through genetic deletion or pharmacological blockade, significantly attenuates the rewarding effects of opioids in an array of laboratory models and suppresses expression of opioid withdrawal signs. Neurokinin 1 (NK1) receptors for Substance P may offer an attractive novel target for a non-addictive treatment approach. This project proposes two inpatient laboratory studies that will enroll individuals with opioid use disorders. These studies will provide the proof-of-concept evidence of NK1 receptor system involvement in mediating the response to opioids as related to abuse potential, reinforcing efficacy and opioid withdrawal in humans (1R01DA040637-01).	Y	Univ of Kentucky
NIH	Opioid Use Disorder - Product development	This Project will use a novel drug discovery algorithm to rapidly and systematically screen medications that show promise for treating opioid use disorder. The guiding principle is that a medication's effect on drug self- administration is the best laboratory procedure to date in predicting its clinical efficacy. We will test several different medication(s) in Project 3 for their ability to alter opioid-mediated responses including lorcaserin, doxazosin, nabilone in combination with cannabidiol, and zonisamide (U54DA037842-02).	Y	NY State Psychiatric Institute

NIH	Opioid Use Disorder - Product development	L-type calcium channel blocker isradipine as an adjunct to BUP detoxification. L-type CCBs have been shown to alleviate opioid withdrawal in opioid-treated nonhumans, to be safe and effective in alleviating withdrawal symptoms in human detoxification trials, and to have low abuse potential.	Y	Univ of Arkansas
NIH	Opioid Use Disorder - Product development	The aim of this application is to enable the submission of IND applications for Oxy(Gly)4-dKLH, a vaccine directed against oxycodone and related prescription opioids, and M(Gly)4-dKLH, a vaccine directed against heroin and morphine (01DA038876-01A1).	Y	Minneapolis Medical Research FDN

NIH	Opioid Use Disorder - Product development	This study will refine the heroin vaccine formulation to produce optimal efficacy and safety, and adapt heroin vaccine design elements to other opioids. Oxy and hydrocodone share structural features with heroin that beget compatibility with our heroin immunoconjugate scaffold, enabling access to vaccines against these opioids. In addition, non-human primate testing is essential for determining whether the heroin vaccine can be translated to humans. We will evaluate the heroin vaccine in a pilot study in rhesus macaques. Heroin schedule controlled responding (SCR) and heroin pharmacokinetics (PK) will be conducted to accurately gauge the efficacy and compatibility of the heroin vaccine in primates. We will conduct a series of studies that will be broken into three sub-aims including: 4A. Optimize immunoconjugate preparation protocols, and investigate vaccine toxicology and long-term stability. 4B. Examine the vaccine in self-administration models in rhesus macaques; a heroin versus food choice procedure will employed to determine if the heroin vaccine can attenuate drug intake under a variety of conditions that are representative of what human drug addicts experience. 4C. Perform pilot studies investigating oxy and hydrocodone vaccines in monkey SCR and PK studies (UH2DA041146-01).	Y	Scripps Research Institute

NIH	Opioid Use Disorder - Product development	In this STTR Fast Track application, we propose to select a lead heroin vaccine candidate for advancement to clinical evaluation and conduct the IND- enabling activities necessary to initiate clinical studies (R42DA040422-01).	Y	Molecular Express, Inc
NIH	Opioid Use Disorder - Product development	In the proposed experiments, we will characterize the metabolism, pharmacokinetics, target selectivity, safety profile, and effectiveness of JZL184 and structurally related analogues in ameliorating withdrawal symptoms in established rodent and nonhuman primate models of opioid dependence. The following three major hypotheses will be tested: 1) MAGL inhibitors will reduce somatic and affective withdrawal signs in opioid- dependent rodents; 2) MAGL inhibitors will reduce opioid withdrawal symptoms and withdrawal-related increases in heroin self-administration in opioid-dependent rhesus monkeys; and 3) inhibition of MAGL will produce minimal side effects compared to direct opioid and cannabinoid receptor agonists (3R01DA032933-03S2).	Y	Scripps Research Institute
NIH	Comparative effectiveness	Cost-benefit comparisons for opioid use disorder treatment with buprenorphine vs ER naltrexone (R01DA035808-02).	Y	Cornell Univ

NIH	Comparative effectiveness	Health Services Research: Extended release naltrexone for opioid-dependent youth. This project will gather comparative effectiveness data for treatment with extended release naltrexone and treatment with buprenorphine and counseling, focusing on the important and vulnerable youth population (ages 15-21).	Y	Friends Research Institute
AHRQ	Epidemiology - MAT Practice	Technical Brief describing literature on MAT in rural PC practices	N	None
ASPE	Epidemiology – MAT Practice	Impact of state regulations on buprenorphine treatment patterns and access to treatment for opioid use disorder.	N	None
ASPE	Epidemiology - MAT Practice	Examining buprenorphine prescribing patterns among DATA 2000 waived providers.	Y	RAND and Brandeis
ASPE	Epidemiology - MAT Practice	This project will identify and highlight the best practices, barriers, and facilitators relevant to using telehealth to identify and manage behavioral health conditions in rural areas. The five main types of telehealth will be included in this study, highlighting the enormous potential of telehealth—not only to increase access to patient encounters with behavioral health specialists, but to enhance asynchronous communication between patients and providers, enhance collaboration and coordination within each patient's care team, engage and educate patients directly using the internet and mobile devices, and enhance access to high-quality provider training and continuing education.	Y	TBD

CDC	Epidemiology - MAT Practice	The overall goal of the MAT evaluation is to improve the evidence-base from which effective policy and practices can be developed to scale up MAT to achieve population level impact	Y	NIDA CTN, ASPE, HRSA, SAMHSA
CMS	Epidemiology - MAT Practice	Characteristics of buprenorphine prescribing and use in Medicaid (pilot)	N	1-4 state Medicaid agencies, ASPE
HRSA	Epidemiology - MAT Practice	Extent to which physicians who practice in rural areas and have a DEA waiver to prescribe buprenorphine are providing this treatment to their patients	Y	WWAMI Rural Health Research Center
HRSA	Epidemiology - MAT Practice	Description on state and local efforts to promote prevention and access to treatment (emphasis on rural)	Y	Maine Rural Health Research Center
SAMHSA	Epidemiology - MAT Practice	Analyses to determine buprenorphine treatment need and capacity at the substate region.	N	None
SAMHSA	Epidemiology - MAT Practice	Using MarketScan data to examine factors associated with receipt of outpatient treatment following an opioid-related hospitalization, determine medications prescribed post-hospitalization, and post-discharge treatment engagement among people with opioid use disorder.	N	None

SAMHSA	Epidemiology - MAT Practice	Currently, the goal of this evaluation project is to assess the state of MAT through a cross site comparison of MAT programs that differ in critical ways. Those differences, i.e., different constellations of services, geographic location, payment structures, etc., will account for differences in client outcomes. This is a collaborative, multi-agency effort.	Y	TBD
SAMHSA	Epidemiology - MAT Practice	This is a small, in-house, pilot evaluation where the data collected by certified Medication Assisted Treatment (including Opioid Treatment) Programs, related to quality assurance/quality control, program performance, treatment, and recovery support is assessed (as supported by CFR 42 part 8, section 8.12).	N	None

SAMHSA	Epidemiology - MAT Practice	This evaluation is being conducted within CSAT's larger training and technical assistance contract for organizations that provide opioid treatment. This includes analyses of use trends, and literature reviews to assess the current science in opioid treatment. This pilot program addresses opioid misuse, whereas the evaluation focuses on describing implementation process and the impacts of each pilot program to address behavior change and changes in clinical practice among healthcare providers. The optional task for the pilot program is designed to support real world development, testing, and evaluation of the workforce development initiatives on the implementation, adoption, quality of, and access to evidenced-based interventions for opioid use disorders. Programs will focus on changing practitioner and organizational behavior.	Y	TBD

SAMHSA	MAT Training/Technical Assistance	This Task Order provides targeted T/TA to states with the goals of enhancing/expanding state treatment service systems to increase capacity and provide accessible, effective, comprehensive, coordinated/integrated, and evidence-based MAT and other “wrap-around”/recovery support services to individuals with opioid use disorders seeking or receiving MAT and to comply with evolving state and federal laws, regulations, treatment standards, standards promulgated for opioid treatment providers (OTPs) by accreditation organizations; and to enhance their clinical knowledge about the appropriate use of buprenorphine/naloxone, methadone, injectable extended release naltrexone. The purpose of the MAT-PDOA evaluation activities is to evaluate the effectiveness of the T/TA in supporting MAT-PDOA grantees as they improve the quality and availability of MAT services for people with substance use disorders.	Y	TBD

NIH	Epidemiology - Patient behaviors	Understanding the factors that accelerate or inhibit transition from oral ingestion of prescription opioids to injection drug use among young people is critical given the risk injection drug use poses for acquiring HIV and/or HCV. Social networks influence pathways into drug injecting and youth are particularly vulnerable to the influence of their social networks. The candidate will use a two-step approach to examine factors that influence the transition from prescription opioid misuse to injection drug use (K01DA036452-02).	Y	Denver Health and Hospital Authority

NIH	Epidemiology - Patient behaviors	The MTF study represents the only nationally representative longitudinal study that has sufficient measures and sample size to test for potential sex, racial, and socioeconomic status differences and to meet the objectives of our study, which aims to: 1) assess the individual patterns and trajectories of medical and nonmedical use of four prescription medication classes (i.e., opioids, sedatives, stimulants, tranquilizers) during the transition from adolescence (age 18) to adulthood (age 35) using cross-sectional and longitudinal panel data; 2) examine the associations between individual patterns and trajectories of medical and nonmedical use of four medication classes from adolescence to adulthood and development of SUDs and other adverse consequences (e.g., health problems, hospitalizations, and legal problems) during adulthood (age 35) using longitudinal panel data; and 3) investigate the risk and protective factors for individual patterns and trajectories of medical and nonmedical use of four prescription medication classes from adolescence to adulthood associated with development of SUDs and other consequences during adulthood (age 35) using a theory-based developmental model and longitudinal panel data (R01DA031160-04).	Y	Univ of Michigan

NIH	Epidemiology - Patient behaviors	The proposed study will examine individual and broader social environmental influences (e.g., relationship, community, and societal) on the association between stress and substance use for Reservists and their partners. Using a multi-wave design, Reservists and their partners (N = 400 couples) will be assessed 3 times over 2 years (i.e., baseline, Year 1, Year 2). Participants will be assessed using state-of-the-science Touch Screen Audio Enabled Computer Assisted Interviews. Using advanced longitudinal analyses (e.g., multilevel and GEE models), this proposal will examine: 1) changes in substance use (alcohol, tobacco, and nonmedical use of prescription drugs) over time in Reserve Soldiers and their partners on the basis of individual (e.g., depressive symptoms), relationship (e.g., partner and peer substance use), community (e.g., workplace/deployments) and societal (e.g., norms) factors; 2) the relation between stress/trauma (e.g., combat exposure/life stress) and substance use; and 3) how the integration of substance use into the relationship impacts marital aggression and dissolution (R01DA034072-03).	Y	SUNY Buffalo

NIH	Epidemiology - Patient behaviors	The proposed study has the following aims: (1) to compare and evaluate the feasibility of two novel sampling methods to recruit young adult NMPO users; and (2), to explore social, macro-social, and drug-related factors associated with HIV risk behavior and transitions to injection drug use among young adult NMPO users (R03DA037770-02).	Y	Brown Univ
NIH	Epidemiology - Patient behaviors	This study will track opioid-using veterans' substance use patterns alongside other physiological, psychological, and social dimensions of their lives, ranging from post-traumatic stress disorder (PTSD) symptoms, depression, and pain severity to social relationships and employment status (R01DA036754).	Y	National Development and Research Institute
NIH	Epidemiology - Provider behaviors	This project investigates the influence of mainstreaming buprenorphine maintenance treatment for opioid dependence into general medicine clinics on the perceived stigma and social networks of patients. Focusing on public clinics that serve low income and ethnic minority patients, but have been slow to adopt buprenorphine treatment, it also examines institutional and professional influences on buprenorphine adoption by providers (K01DA032674-04).	Y	NYU School of Medicine

AHRQ	Intervention - Clinical Practice	The Agency for Healthcare Research and Quality will award a series of 3-year research grants to advance implementation of Medication-Assisted Treatment (MAT) for opioid use disorder in primary care practices in rural areas of the United States. In addition to expanding access to this evidence-based therapy in underserved communities, these research studies will discover and test solutions to overcoming known barriers to implementation of MAT in primary care and create training and implementation resources to support future efforts to expand access to MAT (RFA-HS-16-001).	Y	None
ASPE	Intervention - Clinical Practice	Evaluation of the new buprenorphine rule on physician prescribing limits under DATA 2000.	Y	Urban Institute creating evaluation design

CDC	Intervention - Clinical Practice	Proposal to fund 3-5 state demonstration projects for health department led models for HIV prevention and preparedness in rural jurisdictions with high burden of injection drug use. Project activities to include: Improved surveillance of injection drug use practices; HIV outbreak response planning; Scale-up of HIV and HCV testing in PWID networks; Establishment of PWID-focused HIV prevention, HIV treatment, and substance abuse management services (including but not limited to PrEP, syringe services programs, medication assisted treatment, linkage to HIV care and treatment)	Y	3-5 State health departments
CDC	Intervention – Clinical Practice	The goal of this project is to evaluate the impact of co-locating HCV treatment in a MAT environment.	Y	TBD
HRSA	Intervention - Clinical Practice	HRSA HAB Ryan White medical provider sites will be selected to implement "Integrating Buprenorphine Treatment for Opioid Use Disorder in HIV Primary Care" using an Implementation Science approach to evaluate the implementation process and cost analyses of the interventions while still monitoring patient-level care outcomes. This is part of a larger initiative called "Dissemination of Evidence-Informed Interventions to Improve Health Outcomes along the HIV Care Continuum Initiative".	Y	Boston Univ, AIDS United

NIH	Intervention - Clinical Practice	To date, there are no evidenced-based treatment options which aim to both maximize effective functioning in Veterans with chronic pain while simultaneously addressing problematic opioid use. The overall aim of the present study will be to determine the feasibility of an integrated psychosocial treatment in veterans with chronic pain, who also have evidence of opioid-related misuse. To examine this aim, we will utilize a randomized design to assess the feasibility of integrating two empirically supported interventions: Acceptance and Commitment Therapy for chronic pain and Mindfulness Based Relapse Prevention for substance use and misuse. (R34AT008398-02)	Y	Univ of New Mexico

NIH	Intervention - Clinical Practice	Given the known medical, psychiatric and substance use comorbidities associated with patients with POM, a health care system approach is required to address the complexity associated with this problem. Therefore specific research aims of this proposal are to: 1) Inform content for a collaborative care model (RxCC) to decrease POM and related comorbidity by conducting semi- structured interviews with the target patient population and their care providers; 2: Refine RxCC by enrolling participants and conducting semi-structured interviews at one month to explore barriers and facilitators of healthcare utilization within the framework of collaborative care; and 3) Pilot a randomized control trial of RxCC delivered over six months compared to usual care using adaptive randomization procedures for patients in the ED with POM for feasibility and acceptability (K23DA039974-01).	Y	Univ of Washington

NIH	Intervention - Clinical Practice	We suggest that initiation of buprenorphine during inpatient detoxification, and linkage after detoxification discharge to maintenance buprenorphine in primary care practices where drug use, medical, and psychiatric disorders can be treated will reduce drug use and expensive health service use (hospitalization, ED visits) that results from medical complications of illicit drug use among opioid dependent persons. PRIMARY AIMS 1) To determine if buprenorphine, initiated during inpatient detoxification and continued after discharge (LINKAGE), will reduce illicit opioid use compared to a buprenorphine detoxification (DETOX) condition among opioid dependent drug users. 2) To determine if buprenorphine, initiated during inpatient detoxification and continued after discharge (LINKAGE) will reduce emergency department and hospital utilization compared to a buprenorphine detoxification (DETOX) condition among opioid dependent drug users (R01DA034261-04).	Y	Butler Hospital
NIH	Intervention - Clinical Practice	This R01 proposal seeks to pair medication-assisted treatment (MAT) with an evidence-based, smartphone- delivered relapse prevention system (A- CHESS) to improve long-term recovery from opioid use disorders (R01DA040449-01).	Y	Univ of Wisconsin-Madison

NIH	Intervention - Clinical Practice	In this project, we seek to add a novel supporting framework for patients in treatment for opioid prescription drug addiction called The BupPractice.com: Patient Support Center. Components include: 1. Patient and provider matched data collection and communication functionality to facilitate open and accurate communication and allow the patient and provider to work in tandem to treat opioid addiction. Via the functionality they can collect and communicate patient data, request information, and communicate plans. We will investigate integrating our service into an EMR; 2. A patient support extension that provides patients with the knowledge, skills, encouragement, and awareness to fully participate in office-based buprenorphine treatment; 3. Additional provider training to assist providers in implementing a more patient-centered approach (R44DA034404-02).	Y	Clinical Tools, Inc
NIH	Intervention - Clinical Practice	A team of researchers from the University of Wisconsin-Madison College of Engineering and Oregon Health & Science University will test whether clinician training and the use of organizational change strategies are sufficient for disseminating an evidence-based practice (EBP) for buprenorphine for OUD, or if changes to both organizational systems and payer policy result in greater EBP use (R01DA030431-04).	Y	Univ of Wisconsin-Madison

NIH	Intervention - Clinical Practice	Protocols for tapering off buprenorphine using naltrexone and induction on naltrexone using low dose buprenorphine. The proposed investigation will seek to 1) improve long-term outcomes for the buprenorphine taper method of detoxification by adding naltrexone and 2) develop a procedure using buprenorphine and low-dose naltrexone treatment initiation to permit outpatient induction onto long-acting naltrexone (R01DA030484-05).	Y	NY State Psychiatric Institute
NIH	Intervention - Clinical Practice	This study addresses gaps in knowledge about the behavioral services needed to optimize BUP/NX adherence and substance use (SU) outcomes in the treatment of prescription opioid dependence. We propose a randomized trial of two group-based models of care for BUP/NX patients in SU specialty treatment: Standard Medical Management (SMM) and Intensive Outpatient Treatment (IOT). There is little evidence on what level of behavioral services can support BUP/NX adherence and improve outcomes, particularly for complex patients with medical and psychiatric comorbidities who present to specialty treatment (R01DA036603-02).	Y	Kaiser Foundation Research Institute

NIH	Intervention - Clinical Practice	This SBIR Phase I application proposes development of MedicaSafe's Implicit Prescription Abuse Cognitive Toolkit (IMPACT), a technology-enabled suite of cognitive assessment tools to significantly add to physicians' ability to detect signs of opioid misuse and abuse in patients on opioid therapies. MedicaSafe's IMPACT will comprise prescription opioid-specific versions of two of the most validated implicit measures -- the Implicit Association Test (IAT) and Drug Stroop Task. IMPACT assessments will be brief, computerized measures that will inform physicians of the specific, unconscious opioid-related cognitions of their patients that affect substance use behaviors, significantly improving upon the measures currently available to providers and improving clinical care overall for patients on opioid therapy (R43DA037630-01A1).	Y	Medicasafe, Inc
NIH	Intervention - Clinical Practice	Development and testing of new treatments for OUDs including Buprenorphine implants (Probuphine), a novel formulation developed with NIDA support that provides stable round the clock dosing for six months. Current studies are comparing Probuphine vs depot naltrexone vs psychosocial treatment only upon community re-entry among offenders.	Y	Braeburn

NIH	Intervention - Clinical Practice	This application takes a novel, broad approach to address the problem of PO dependence by determining the 1) utility of adjunct gabapentin (GBP) during outpatient BUP detoxification to improve initial outcomes and 2) feasibility of transitioning PO-dependent patients to depot NTX following detoxification, which may improve longer-term outcomes. GBP, an N-type calcium channel blocker with low abuse potential, potentiates opioid analgesia, decreases both postoperative morphine consumption and movement- related pain, and reverses tolerance to the antinociceptive effects of morphine (R01DA039088-01).	Y	Univ of Arkansas
NIH	Intervention - Clinical Practice	The primary objective of the proposed Stage II study is to evaluate the effects of CBT in combination with tDCS in (1) improving pain and functionality, (2) reducing severity of opioid use disorders, and (3) reducing impairment in associated mental health areas (e.g., other substance and prescription drug use, depression, anxiety, PTSD, sleep) (5R01DA038971-02).	Y	Medical Univ of South Carolina
NIH	Intervention - Clinical Practice	Comparing Treatments for HIV-Positive Opioid Users in an Integrated Care Effectiveness Study (CHOICES). This study will provide comparative effectiveness data for extended release naltrexone and opioid agonist therapy for treatment of HIV positive opioid users, with the additional goal of linkage to HIV care (NCT01908062).	Y	Oregon Health & Science Univ

NIH	Intervention - Clinical Practice	Evidence-based clinical decision support for OUD management in general healthcare settings	Y/N	NIDA CTN, extramural PIs, SAMHSA, ONC
NIH	Intervention - Clinical Practice	Interim buprenorphine treatment to bridge waitlist delays - utilizes technology to deliver and monitor patients waiting to enter formal Tx (Med-O-Wheel to deliver Bupr, Interactive Voice Response for daily and random monitoring) (R34DA037385).	Y	Univ Vermont
NIH	Intervention - Clinical Practice	NIDAMED Initiative developing CME/CE course on adolescent substance use for general healthcare providers, specifically focusing on Rx drugs	N	Coalition of Health Care Orgs
NIH	Intervention - Clinical Practice	Target areas for learning in each training domain are directly linked to the specific aims of this research study, which include (1) the development of an integrated cognitive behavioral treatment manual for opioid dependence and anxiety disorders (I-CBT), (2) pilot testing the efficacy of I-CBT for reducing opioid use and anxiety symptoms compared to standard CBT for opioid dependence, (3a) the examination of the association between pre-treatment reactivity to stress and opioid use outcomes following treatment, and (3b) the examination of changes in stress reactivity following treatment (K23DA035297-02).	Y	Mclean Hospital

Increase use of naloxone

(research projects as of 7/1/2016)

Agency	Type of Activity	Description	Extramural	Partners
FDA	Naloxone - Product development	OTC naloxone. FDA is actively discussing the development of these products with interested manufacturers. FDA has laid out the regulatory requirements for non-prescription naloxone products, including the potential for over-the-counter naloxone. FDA is working to create parts of the labeling and conditions of use that could be used to support non-prescription naloxone and is planning on testing those products before making them public.	Y	Industry
CDC	Epidemiology – Naloxone practice	The primary objective of this evaluation is for CDC to conduct an evaluation of the 11 states funded through SAMHSA's naloxone education and distribution program (http://www.samhsa.gov/grants/grant-announcements/sp-16-005) to describe and understand the scope and impact of the program on overdose fatalities. Secondary objectives are, to the extent possible, increase understanding of how program effectiveness may vary among different sub-populations and settings, and to increase understanding of the barriers and facilitators to program implementation in these populations and settings.	Y	SAMHSA, ASPE
FDA	Epidemiology - Naloxone practice	Naloxone use on ambulances using NEMSIS data	N	NHTSA

SAMHSA	Epidemiology - Naloxone practice	Using National Survey on Drug Use and Health (NSDUH) data and other data to assess the impact of passage of state-level naloxone access laws and country-level naloxone programs on overdose deaths and non-medical use of prescription drugs is examined.	N	None
CDC	Intervention - Patient behavior	ICRC; Research Project #1: Brief Prescription Opioid Overdose Intervention in an Urban Emergency Department - Three specific aims are clearly outlined, which are to develop a tailored emergency department based prescription overdose prevention intervention; examine the intervention's effects on precursors of overdose risk behavioral change; and examine the intervention's effects on their overdose risk behaviors after six months of the intervention. The role of gender and other motivations for opioid use, and the role that peers in the social network may have in mediating the influence of opioid use will also be assessed.	Y	Univ of Michigan
FDA	Intervention - Patient behavior	FDA is exploring the use of phone 'apps' that could help locate individuals with naloxone nearby, to facilitate making naloxone available quickly at the location of the overdose.	N	None

NIH	Intervention - Patient behavior	This prospective, randomized ED trial will study the effectiveness of an intervention that combines overdose prevention and intervention programs with naloxone (OOPIN) with brief behavior change counseling (BBCC) for both heroin users (n=500) and pharmaceutical opioid users at elevated risk for overdose (n=500). The primary outcome is subsequent opioid overdoses, ascertained by follow up interviews conducted at 3, 6 and 12 months as well as via administrative records for up to 24 months (i.e. medical records, ambulance responses, and death certificates).	Y	Univ of Washington
NIH	Intervention - Patient behavior	Specifically our investigation will recruit ongoing and recently detoxified opioid abusers from several sites throughout the NYC area. All participants will receive standard opioid overdose education training and naloxone to carry should they witness another person experiencing an overdose, or overdose themselves. One- third of the participants will be randomized to receive additional in-depth psychosocial education focusing on recognition and prevention of opioid overdose, and appropriate use of naloxone. Another one-third of the participants will receive the extensive training and be required to engage a spouse, partner, relative, or friend in this supplementary intervention.	Y	NY State Psychiatric Institute

NIH	Intervention - Prescriber and Patient behavior	This study will develop a feasible, information-technology supported overdose prevention intervention for use in large health care systems. We will obtain key preliminary data to support a future large scale, multi-site randomized controlled trial of this intervention from patients and providers in three distinct health systems: an academic medical center, a managed care organization, and a safety net hospital system. The intervention will be targeted to medical clinicians who care for high-risk chronic prescription opioid users in primary care, including general medical and HIV clinics.	Y	Univ of Colorado-Denver
NIH	Intervention - Prescriber and Patient behavior	We propose an exploratory study to measure the feasibility of naloxone prescription from multi-provider primary care clinics in a safety net health care system, the acceptability to patients and providers of naloxone prescription, and the validity of electronic medical records (EMR) as a means to evaluate such programs. To maximize naloxone uptake and standardize quality of naloxone delivery during roll-out, trained research staff will provide technical assistance and capacity building to staff in clinics and associated pharmacies leading up to, and during, the execution of the clinic-based naloxone program.	Y	Public Health Foundation Enterprises
AHRQ	Intervention - Clinical practice	Advancing Patient Safety Implementation through Pharmacy-Based Naloxone (AHRQ-R18 HS24021).	Y	Boston Med Center

Other Program, Research, and Evaluation Activities

(research projects as of 7/1/2016)

Agency	Type of Activity	Description	Extramural	Partners

FDA	Communication	Research to Improve Communications to Prescribers and Patients About Safe Use of Opioids. The goal is to gather data that will provide a robust understanding of current knowledge, practice, beliefs, and perceptions about opioid use, misuse, and abuse from a variety of stakeholders and consumers to enhance our future communication efforts.	Y	RTI
FDA	Disposal	FDA is engaged in research to update the evidence used to create the disposal recommendations, using both distribution data and adverse event data.	N	None
CDC	Intervention - Clinical Practice	Reduce viral hepatitis infections by treatment and integrated prevention services (TIPS) among young PWID.	Y	Univ of Cincinnati and Univ of NM
CDC	Intervention – HIV and viral hepatitis and injection drug use	The goal of this project is to develop a model plan for cities and counties to address the syndemics of hepatitis B virus (HBV), HCV, HIV, and opioid abuse, particularly to improve viral hepatitis testing and treatment.	Y	NACCHO
CDC	Surveillance – viral hepatitis and injection drug use	This funding opportunity is to enhance viral hepatitis surveillance among PWID.	Y	TBD
CDC	Surveillance – viral hepatitis and injection drug use	This call for proposals would support the development of technology(ies) to improve SEP surveillance.	Y	TBD

CDC	Surveillance - prescription opioid overdose	Proposed SBIR, Extramural Research Program Office (ERPO): Development of new platforms or algorithms to allow for data linkage of injury-related data. In the area of prescription drug overdose, there is a need for linkage of data from prescription drug monitoring programs, electronic health records, and claims data.	Y	TBD
CDC	HIV and injection drug use	National HIV Behavioral Surveillance among persons who report injection drug use (IDU).	Y	22 state and local health departments
CDC	HIV and injection drug use	Medical Monitoring Project - one question on prevalence of injecting painkillers in past 12 months among HIV-positive persons.	Y	23 state or city health departments
CDC	HIV/HCV and injection drug use	Investigation of HIV-1 / Hepatitis C Virus Outbreak Linked to Injection Drug Use of oxymorphone – Indiana, 2015.	Y	Indiana DOH/ Indiana Univ - Purdue Univ
CDC	HIV/HCV and injection drug use	County-level Vulnerability Assessment for Rapid Dissemination of HIV or HCV Infections Among Persons who Inject Drugs, United States.	N	HHS, DEA
ASPE	Evaluation - Legal	Impact of hydrocodone rescheduling on opioid prescribing and opioid abuse and overdose using multiple data sources.	N	CDC, FDA
CDC	Neonatal abstinence syndrome	Understand long term neurodevelopmental outcomes associated with neonatal abstinence syndrome (NAS).	Y	March of Dimes and TN DOH

CDC	Neonatal abstinence syndrome	Support activities to better ascertain infants born with NAS.	Y	March of Dimes and select states
CDC	Neonatal abstinence syndrome	Prevalence and reasons for re-hospitalization among NAS infants in Oregon	Y	Oregon State Univ
CDC	Neonatal abstinence syndrome	Prevalence estimates of NAS by state and trends between 1999-2013	N	None
ASPE	Opioid abuse/overdose epidemiology	Estimation of the treatment gap for opioid use disorders and how many patients received treatment with MAT between 2010-2015.	N	None
ASPE	Opioid abuse/overdose epidemiology	Trends in NP/PA prescribing of naltrexone using IMS Health data.	N	None
ASPE	Opioid abuse/overdose epidemiology	Examining opioid morbidity and mortality trends in the American Indian and Alaska Native population.	N	HIS
ASPE	Opioid abuse/overdose epidemiology	Longitudinal analysis of concomitant opioid and benzodiazepine use.	N	Johns Hopkins Univ, CDC
ASPE	Opioid abuse/overdose epidemiology	Trends in non-oral/non-injection and injection opioid abuse among treatment admissions.	N	CDC
ASPE	Opioid abuse/overdose epidemiology	Relationship between heroin and prescription opioid nonmedical use with NSDUH data	N	AHRQ
ASPE	Opioid abuse/overdose epidemiology	Examine the relationship between increases in substance use (and opioid use) and foster care	N	ACF, SAMHSA

CDC	Opioid abuse/overdose epidemiology	ICRC; Research Project 3 - seeks to use poison control data to examine opioid poisoning in adolescents and young adults. The applicant makes the case for the use of real-time data to assess this problem, noting that current approaches to data collection have a 2-3 year lag.	Y	Children's Research Institute
CDC	Opioid abuse/overdose epidemiology	ICRC; Research Project #4: Concurrent Drug, Alcohol, and Decedent Characteristics in Deaths Due to Opioids - The aims of the proposed project are to identify potential relationships and interactions between specific prescription opioids and other drugs and alcohol in the context of co-morbidities; and to track these relationships over time for each state over the last five years. The results of the study will have the potential to help guide practice decisions and provide direction to minimize harm when opioids are prescribed.	Y	West Virginia University
CDC	Opioid abuse/overdose epidemiology	New Funding Opportunity Announcement; Research on Prescription Opioid Use, Prescribing, and Heroin Overdose.	Y	TBD
CDC	Opioid abuse/overdose epidemiology	Utilize and identify trends in mortality data	N	NCHS
CDC	Opioid abuse/overdose epidemiology	Examine health care utilization for persons before and after overdose to help better inform interventions.	N	N/A
CDC	Opioid abuse/overdose epidemiology	Examine drug seizure data to identify areas at potential risk for increased fentanyl and heroin-related deaths.	N	DEA

CDC	Opioid abuse/overdose epidemiology	Examining drug seizure data with prescription and mortality data to further highlight the issues with fentanyl.	N	DEA, IMS, NCHS
CDC	Opioid abuse/overdose epidemiology	Validation of hospital discharge data for passive surveillance of NAS.	N	None
CDC	Opioid abuse/overdose epidemiology	Trends in non-medical use of prescription drugs/pain relievers among pregnant and non-pregnant women of reproductive age.	N	None
FDA	Opioid abuse/overdose epidemiology	Work with CDC to expand the NEISS surveillance network to include adverse events from abuse/misuse and self-harm of pharmaceutical products including opioids.	N	CDC
FDA	Opioid abuse/overdose epidemiology	Work with CDC/NCHS to support a National Survey of emergency department (ED) data to replace the defunct DAWN database.	N	CDC
FDA	Opioid abuse/overdose epidemiology	Work with CDC/NCHS to develop programs for identifying specific opioids contributing to overdose deaths, when available on death certificates.	Y	CDC
HRSA	Opioid abuse/overdose epidemiology	Examining rural/urban and regional differences in opioid overdose mortality rates.	N	SAMHSA/CDC
SAMHSA	Opioid abuse/overdose epidemiology	Using NSDUH data to examine the impact of Prescription Drug Misuse and Abuse laws on non-medical use of prescription drugs and heroin.	N	None

CDC	Opioid abuse and overdose epidemiology	This study measures the medical costs and comorbidities of opioid overdose, abuse, and dependence in the national Medicare population. The approach is to measure Medical costs by claim type incurred 12 months around index date, as well as to compare the prevalence of selected comorbidities between PDO patients and non-PDO patients.	N	CDC
CDC	Opioid abuse/overdose epidemiology & surveillance	Proposed SBIR, Extramural Research Program Office (ERPO): Development of new platforms or algorithms to allow for data linkage of injury-related data. In the area of prescription drug overdose, there is a need for linkage of data from prescription drug monitoring programs, electronic health records, and claims data.	Y	TBD
CDC	Evaluation of state-level interventions	Evaluate CDC-funded Prevention for States interventions. Goal is to identify programs that can be scaled up to other states based on efficacy, feasibility, and program costs.	N	RTI
NIH	Overdose prevention	The HOPE intervention is an evidenced-based peer-led social media intervention provided over Facebook that has been successfully used to change health behaviors. This project will explore (qualitatively) how HOPE can be adapted for opioid abuse/overdose prevention among patients on chronic opioid therapy and assess the feasibility, acceptability, and preliminary effectiveness of applying the HOPE model to reduce opioid abuse/overdose risk among high-risk chronic non- cancer pain patients.	Y	UCLA

FDA	Product Packaging	Research on Preventing Opioid Abuse Through Use of Improved Packaging. The Packaging: Abuse-Deterrent Strategies (PADS) Task Force's mission is to define the FDA's data needs and the guiding principles for industry to follow to have their packaging, storage and disposal solutions approved or labeled as having abuse deterrent features.	Y	Industry

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