Tufts Health Care Institute Program on Opioid Risk Management
Advancing Safe Opioid Prescribing through
Prescriber Training and Behavior Change

March 10 and 11, 2011

Executive Summary

Prescription opioid misuse and addiction represent significant challenges to the medical profession and to society at large, resulting in considerable costs, both in financial terms and in terms of human suffering. Professional organizations, government agencies, and other stakeholders have spent substantial time and effort developing guidelines and recommendations for best practices in opioid prescribing, pain management, and the diagnosis and treatment of addiction. However, the value of these guidelines is only realized to the extent that they are understood, embraced, and adopted on a large scale by the medical community that oversees the use of these medications. The ultimate purpose of such guidelines is to ensure that individuals with chronic pain receive the medications they need, while minimizing the risks of misuse and addiction.

On March 10 and 11, 2011, the Tufts Health Care Institute (THCI) Program on Opioid Risk Management convened a summit meeting, "Advancing Safe Opioid Prescribing through Prescriber Training and Behavior Change". This meeting brought together physicians, researchers, regulatory officials, and experts in medical innovation to examine how the adoption of opioid prescribing guidelines could be improved by the use of implementation science. Implementation science is the scientific study of methods to promote the systematic uptake of research findings ─ in this context, the process of disseminating, testing, and adopting best practices for safe prescribing of opioids. The meeting had three major themes. First, presenters focused on how implementation science is applied to the dissemination of medical innovations. Second, participants shared findings from a range of existing programs to improve opioid use, and discussed lessons learned and plans for future initiatives. Third, speakers presented

potential uses of computer-based learning and simulation programs to improve education in this area and allow for more widespread utilization of guidelines.

The Role of Implementation Science

Many studies have described the low rates at which even relatively simple guidelines are adopted by physicians, other caregivers, and medical organizations as a whole. Even guidelines as well disseminated and widely accepted at the American Diabetes Association's recommendations for target blood glucose levels among diabetics and the American College of Cardiology's guidelines for blood pressure control among hypertensive individuals are generally adhered to at rates ranging from only one-third to one-half of eligible patients. The purpose of the THCI Program on Opioid Risk Management summit meeting was to examine how the methods of implementation science can be brought to bear on this problem in the realm of opioid prescribing and chronic pain management.

Efforts to disseminate innovations such as new opioid prescribing guidelines are most efficient when they lead to widespread diffusion, which is defined here as the process by which an innovation is spread among members of a social system, such as a health care organization or a physician group. Factors that can affect diffusion include the attributes of the innovation, opinions of potential adopters, parameters of the social network, and the desired timing. Considerable research has shown that providing information alone is seldom enough to change physician or organizational behavior. Successful, widespread adoption of an innovation requires adoption by key individuals, who then influence others in the social system to follow their lead. Implementation science can be used to study such social networks, leading to the identification of influential individuals, and allowing for targeted interventions.

Implementation science has also identified a series of important phases in the process of disseminating an innovation, which include a pre-implementation phase, a redesign and implementation phase, and an evaluation phase.

Pre-implementation. This phase seeks to improve diffusion and acceptance of a desired innovation by developing a more thorough understanding of the targeted system. Researchers study how existing practice patterns vary from best practices, define priorities, and identify barriers to and facilitators of change. This process can also be used to engage stakeholders, facilitate collaboration among groups within the system, and make realistic estimates of time,

cost, and other resources needed for successful implementation. Multiple methods and resources can be used, including field observations, review of patient charts, one-on-one interviews, focus groups, and others. One potential outcome of this process is to form an advisory body, consisting of stakeholders, leaders, experts, and others, who will develop a plan and oversee the implementation process.

Redesign and implementation. This phase is intended to develop and implement programs that promote best practices based on pre-implementation findings and preliminary planning. Typically this phase progresses from small scale to large, i.e., from pilot projects to small efficacy trials to large effectiveness trials. As they progress, these studies continue to evaluate barriers to change and produce information on program acceptance and impact, in order to help ensure the success of larger and larger investments of time and funding. Another aspect of this phase is the development and testing of evaluation methods that will be used to measure the success of the implementation process and of the proposed innovation. The ultimate goal of this phase is system-wide deployment of best practices on a large scale, in some cases, on a national scale such as the Veteran's Administration medical system.

Evaluation. Implementation science recognizes two types of evaluation: formative evaluation, which is conducted for the purpose of improving programs or interventions while they are being designed and/or implemented, and summative evaluation, which evaluates the efficacy and outcomes of an intervention after it has been completed. Formative evaluations are not designed to test the efficacy of best practices but rather use process measures to determine whether innovations are being carried out consistently and effectively. Such evaluations are also intended to determine whether the new systems and rules that are being put into place lead to practice changes that match the intent of the expert guidelines. They may evaluate the usability, accuracy, and/or feasibility of new guidelines in actual practice. Although not generally randomized or controlled, formative evaluations can also include patient outcome measures that impact patients, such as treatment success and changes in patient retention. Formative evaluation can also promote collaboration and provide constructive feedback by including individuals and groups who are being evaluated in the evaluation process.

Real life Experiences with Systems Changes Intended to Improve Opioid Prescribing

A second major goal of the meeting was to review current evidence on the effectiveness of different approaches to changing clinician behavior, and to define the limitations of traditional approaches to medical education. A series of speakers discussed the successes and challenges of real-life programs intended to improve the safety of opioid prescribing and use by patients.

Operation Unite. Eastern Kentucky faces drug overdose rates that are nearly double the national average. Operation Unite is a multifaceted effort to address this problem, encompassing youth and community education programs, drug and alcohol treatment programs, law enforcement strategies, use of drug courts, and other interventions. Emphasis has been placed on teaching physicians how to prescribe opioids appropriately and to recognize and deal with problems. The program has been associated with declines in teenage drug use in the area that it covers.

Lessons learned: Importance of sharing information among different stakeholders and the high need for prescriber education.

Next steps: Further educational programs for physicians and a symposium at which stakeholders can learn more and share information.

Veterans Administration (VA) pain care agreements. Veterans have high rates of persistent pain complaints and many have significant psychiatric or substance abuse problems, putting them at higher risk for opioid addiction and abuse than many in the general population. The VA has developed a number of interventions including Pain Care Agreements, templates to document pain and assess opioid benefit/risk, methods for dealing with dual diagnoses, and other resources for prescribers. These interventions have increased levels of documentation surrounding opioid use, and promoted the use of pain care agreements and urine drug screening within the system.

Lessons learned: Acceptance of new interventions and behavior changes take time, enforcement can be difficult, and it is important to involve all staff, not just the prescribers, in education and change processes.

Next steps: Developing cross-disciplinary patient-affiliated care teams, implementing pain management programs, and pharmacy restrictions to improve care for patients with chronic pain while reducing the risk of misuse.

New York State tamper resistant prescription pad program. Prescription fraud contributes to the misuse and diversion of controlled substances, including opioids. New York State developed a set of regulations requiring that all prescriptions be dispensed on official forms, that practitioners and facilities be registered, and that all controlled substance prescriptions be reported to state authorities. This program reduced costs, encouraged e-prescribing and use of the state's Prescription Monitoring Program, and reduced stolen, forged, and counterfeit prescriptions while at the same time increasing opioid accessibility for those with legitimate medical needs.
Lessons learned: Be willing to compromise and learn from others, report back to stakeholders and allow them to take ownership, and expect to encounter resistance to change.

Academic detailing to improve opioid prescribing in Utah. Utah has higher than national rates of opioid-related deaths and experienced a sharp increase in such deaths in 2003. In 2007, a Utah House bill allocated funding for provider education on safe prescribing of opioids, which allowed implementation of an academic detailing program that reached over 700 health care providers, including 32 primary care practices and 14 professional groups. These interventions increased prescribers' self-reported rates of compliance with Utah's Six Practices for Safe Opioid Prescribing, and together with other interventions, was associated with a 14% reduction in opioid-related deaths in 2008.
Lessons learned: Facilitate dialogue and collaboration by traveling to practices and involving support staff, provide incentives to get better response rates from surveys, and modify during the implementation process to incorporate new information and improve feasibility.
Next steps: Funding for this intervention has ended but evaluation is ongoing and new programs are being implemented.

New Hampshire Medical Society Opioid Prescribing Improvement Project. The New Hampshire Medical Society is developing a comprehensive set of recommendations on pain and prescription drug misuse via an interdisciplinary, non-academic, open process. They have engaged key organizations and individuals in the state in the process of examining available evidence for best practices, developing guidelines, and identifying resources for prescribers. Their approach combines clinical practice considerations and prescriber education with public policy and education, justice and law, and payor and industry considerations. While clinical outcomes have yet to be measured, they have succeeded in raising awareness of the problem and promoting good will and collaboration among the diverse stakeholders involved.

Lessons learned: Multidisciplinary input into policies and recommendations promotes broader acceptance.
Next steps: Dissemination of recommendations via online posting, development of system for collecting comments and revisions, and measuring levels of change and effects on patient outcomes.

Massachusetts Implementation of Screening, Brief Intervention, Referral to Treatment (SBIRT). Over 25 years of research have supported the effectiveness of brief screening by primary care practitioners in identifying individuals at risk of developing serious substance abuse problems. In Massachusetts, MASBIRT is screening for opioid misuse or risk of misuse, intervening when misuse is suspected, and referring individuals for opioid addiction treatment if necessary. This approach is associated with high rates of identification of at-risk individuals, and reduced rates of substance misuse after 6 months among those screened.
Lessons learned: It can be difficult to distinguish inappropriate drug-seeking from appropriate need for pain relief.
Next steps: Development and dissemination of a single question that can identify prescription drug misuse, further clarification of the issues that need to be addressed surrounding opioid misuse, prescriber education on assessment and handling the results of a positive screen, and identification of the best types of brief interventions. A randomized controlled trial, ASPIRE, is enrolling patients to address these questions.

Close monitoring and treatment for patients at risk for prescription opioid abuse. More data is needed on the most effective interventions to prevent opioid misuse among high risk individuals. The Opioid Compliance Study at Brigham and Women's Hospital in Boston identified high risk individuals and randomized them to receive either conventional or close monitoring, looking at measures of drug misuse including urine screens and addiction behaviors checklists. Subjects were followed for 6 months. High-risk individuals in the experimental group received monthly interventions including urine drug testing, individual motivational counseling, and group educational counseling. High-risk individuals in the control group, who did not receive these interventions, scored significantly higher on a drug misuse index than those in the experimental group, suggesting that such close monitoring may reduce or prevent opioid misuse.

Massachusetts Naloxone Distribution Program Opioid-related fatal overdoses have exceeded deaths from motor vehicle injuries since 2005 in the state of Massachusetts. Naloxone is an opioid antagonist that can be given to overdose victims by bystanders or family members, potentially averting fatalities. The Naloxone Distribution Program in Massachusetts is a pilot program that provides education on overdose prevention and treatment, trains bystanders to administer naloxone, and distributes doses for use in emergencies. The pilot program has demonstrated that bystanders can recognize overdoses and use naloxone successfully, with few adverse events and without the need for a medical provider encounter. *Next steps*: Expand program sites and types of venues, reduce liability for bystanders, analyze overdose rates and their association with the implementation of this program, and adapt the program to specific opioid user populations.

The Potential of Computer-Based Education and Simulation Training

A third major goal of the meeting was to explore innovative approaches to prescriber training on best practices for opioid use, focusing primarily on the use of computer-based simulation technology. Computer simulation allows modeling of real or hypothetical situations, including simulations of people in social or clinical situations, objects such as instruments or parts of the human body, or immersive environments that include multiple types of sensory input. The most widely used examples of simulation training are the flight simulators used in commercial and military aviation. These devices provide safe, consistent training that replicates important features of the cockpit and the mechanics of flying. In the military, simulation based training has also been used to train computer technicians, and to provide operational language and cultural literacy training for individuals who come in contact with host country nationals.

Simulations of people. Computer-based learning in medicine currently relies mainly on case studies, which can be passive reading exercises, or can involve a branched series of choices that teach how clinical situations evolve and promote effective therapeutic decision making. Non-computer modes of patient simulation are already in use in medical training, predominantly in the form of patient actors (also known as standardized patients), or mannequins such as CPR practice dummies. In recent years, medical schools have considerably expanded the use of physical simulators that present diagnostic, medical, or surgical procedures semi-realistically, and have increased their use of standardized patients. However, such methods are expensive and there is little evidence to guide how best to employ them or to show how effective they are.

For the future, virtual patients are under development, which can be designed and deployed more rapidly. Study will be needed to determine how best to integrate these simulated patients into clinical training, but important applications may include the teaching of patient communication and diagnostic skills. Computer-based methods can simulate people in a number of different ways, for example as avatars or with the use of puppetry. Computer-simulated social situations may be especially helpful in teaching physicians how to deal with complex psychological or behavioral conditions, from stuttering to post-traumatic stress disorder. Situations involving groups of individuals may be simulated with the aid of virtual internet environments which may be particularly useful in scenarios calling for teamwork, empathy, and social skills such as bedside manner.

Simulations of objects and environments. Computers can also function as clinical task trainers, where they may be particularly useful for simulating complex and potentially risky tasks like surgical procedures. Simulated, immersive environments can provide safe settings for physicians to attempt such tasks, and may also be useful for patients, for example, individuals with brain injuries who need to relearn kitchen skills. Computerized training programs may also make use of game engines to simulate situations where rapid decision making is necessary. Patients may also benefit from game-based interventions, for example, a diabetes self-care game for children and adolescents that improves self-care behaviors and communication with parents. Simulations can also be used as tools for the visualization and manipulation of complex data, such as computer modeling of physiological processes, or visualization of structures that are otherwise difficult to see like the interior of the human brain or complex molecular structures.

Advantages of computer-based simulation training. Overall, simulation training is used to impart knowledge or skills important for a task in practice or mastery environment where mistakes can be made and are actually encouraged, e.g. pilots who can practice maneuvers or physicians who can respectively respond in reaction to seldom encountered situations or diagnoses, as opposed to real life situations. Simulation training can be used to impart knowledge, improve skills, including communication skills, and to explore attitudes and prejudices. In medicine, such training reduces risks to patients, allows training to be more widely available and more consistent, and reduces expenses. In addition, assessment is more consistent and can evaluate the acquisition of specific skills. Simulation training with the use of computers can solve problems such as lack of access to live training programs, and exposure to infrequent but important scenarios. Computerized simulation training can be standardized but at

the same time allow depiction of patient variability and customization to the learner's knowledge and skill levels. These programs can provide frequent feedback that assists the learner with self-assessment as the training program continues.

A few computer-based learning programs have already been implemented in medical training, but there is as yet no longitudinal data to support the effectiveness of these approaches. Parameters such as retention of learners, level of knowledge acquired, and degree of implementation of changes have not yet been measured. It will be important to identify the most effective modality for each type of training, to determine whether learning should take place as a group or individually, and to analyze what type of infrastructure will best support computer-based simulation training. Application of these methods, together with the principles of implementation science, has the potential to greatly improve opioid prescribing and reduce the toll of opioid misuse and addiction on patients, their families, and society at large.