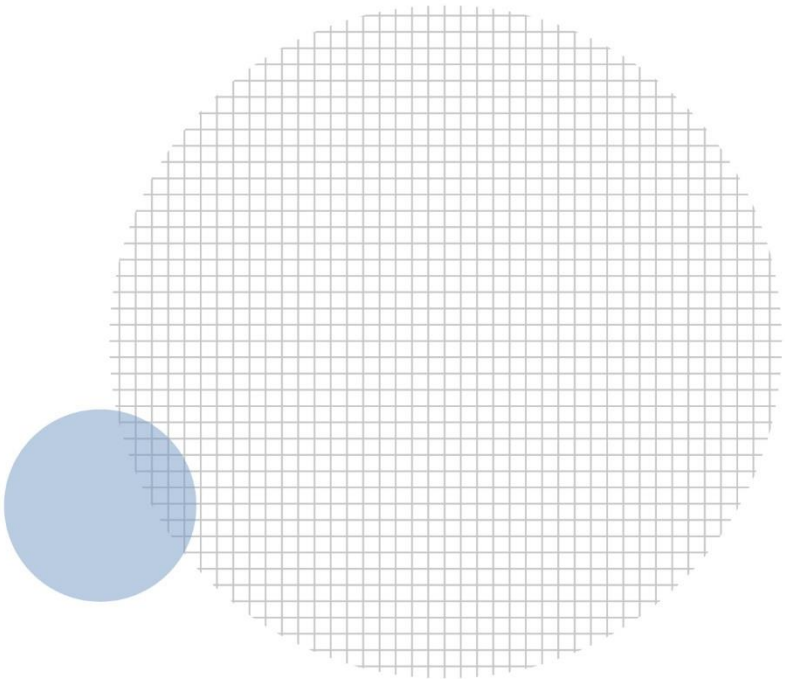
Institute for Healthcare Improvement

INNOVATION REPORT

Addressing the Opioid Crisis in the United States



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This IHI innovation project was conducted from October to December 2015.

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Executive Summary

The morbidity and mortality from opioid misuse, abuse, and overdose continues to rise, creating a crisis for patients, families, and communities throughout the United States. The problem of opioid overuse and misuse in the US is thought to originate primarily in the outpatient care setting. The problem is multifaceted, however, with different challenges in the inpatient setting, in the emergency department, in ambulatory clinical practice, and in the community. Addressing this epidemic requires a multi-pronged, context-sensitive approach that engages different stakeholders and methods for making inroads in a health system, in a community, and in a state or county.

The primary aim of the innovation project described in this report was to address the challenges related to prescription opioids by exploring the roles of health care, communities, and individuals in this crisis, and to identify system design challenges and solutions in each case.

This report discusses key reasons why efforts to reduce opioid use, misuse, and abuse in the US have thus far been largely ineffective in stemming the crisis; highlights gaps in current efforts that underscore the need for a coordinated and collaborative community-wide approach; identifies four primary drivers to reduce opioid use; and proposes a high-level construct for a system approach at the community level to address the US opioid crisis.

Intent and Aim

The intent of this IHI 90-day innovation project (conducted from October to December 2015) was to identify current gaps and lay out an approach to address the challenges related to prescription opioids in the United States. (Note that this report does not discuss the use of opioids for palliative care or cancer-related pain, for which there is a separate set of recommendations for opioid prescribing.) Specifically, the aim was to explore the roles of health care, communities, and individuals in this crisis, and to identify system design challenges and solutions in each case.

The IHI 90-day innovation project on the opioid crisis in the US included these activities:

- Scan existing interventions to identify different points in the pathway of opioid misuse and abuse;
- Conduct expert interviews with stakeholders from different parts of the system, including health care providers, payers, law enforcement, addiction treatment, emergency medical services (EMS), and public health (see Appendix B for list of interviewees);
- Map existing interventions to understand resource allocation and identify gaps;
- Develop a system view of the opioid epidemic, considering initiation of use in both inpatient and outpatient settings;
- Convene a strategy session with the US Surgeon General and other experts (see Appendix B for list of attendees);
- Develop a draft change package (i.e., a collection of specific, evidence-based changes in practice that are expected to result in improvement to the system) for inpatient and outpatient initiation and use of prescription opioid use; and
- Create a community-wide roadmap to help all actors in a community address the opioid crisis in a coordinated manner.

Background

In 2013, 16,235 Americans died from prescription opioid misuse — four times more than in the entire previous decade and greater than the number of deaths that year from heroin, cocaine, and benzodiazepines combined.[1] From 2000 to 2009, the number of opioid prescriptions increased by 68 percent, reaching 202 million prescriptions.[2] Opioids — both prescription painkillers and heroin — are the primary drug associated with drug overdoses; in 2014, opioids were involved in 61 percent of all drug overdose deaths. From 2013 to 2014, there was a 9 percent increase in deaths attributed to overdose of commonly prescribed opioid pain relievers.[3] In 2010, hydrocodone/acetaminophen was the most commonly prescribed drug in the United States, with 131.2 million prescriptions; the US uses 99 percent of the world's supply.[4]

Meanwhile, the US has seen a commensurate increase in heroin use, abuse, and overdose; the abuse of prescription opioids is tightly linked to heroin use. Abuse of prescription opioids increases the risk of heroin use by a factor of 40, and 45 percent of heroin users are also addicted to opioid pain medication.[5] The morbidity and mortality from opioid misuse, abuse, and overdose continues to rise, creating a crisis for patients, families, and communities throughout the country.[6]

The current crisis results from a confluence of several factors. Providers had traditionally been wary of prescribing opioids due to their addictive potential. In the late 1980s and 1990s, guidelines from the US Agency for Health Care Policy and Research,[7] the American Pain Society,[8] and the World Health Organization[9] pointed to this concern as an important underlying cause for undertreatment of pain. From 1991 onward, opioid prescriptions steadily increased.[10] This upward trend in prescriptions accelerated when newer opioids (such as OxyContin) were released in the mid-1990s and pharmaceutical companies marketed them as non-addictive and conducted an intensive marketing campaign to encourage providers to prescribe them. This marketing campaign, aimed largely at primary care, enlisted pain management experts who often touted "evidence" that providers should treat pain aggressively, that a ceiling dose of analgesia for opioids was unnecessary, and that addiction was rare.[11] Such "evidence" has now been refuted even by the educators who originally cited it.[12,13,14,15,16] Furthermore, in 2007, Purdue Pharma (the maker of OxyContin) pleaded guilty to federal charges that they misrepresented the drug's risk of addiction and potential for abuse to regulators, physicians, and patients; they paid $600 million, the largest fine ever paid by a pharmaceutical company.[17]

During this period of time, multiple national initiatives were undertaken in the United States to address inadequate pain management. For example, the Consumer Assessment of Healthcare Provider and Systems (CAHPS) patient satisfaction survey was introduced nationally in 1995, with pain control as a key domain. Some clinicians apparently perceived failure to prescribe narcotics for pain as leading to lower patient satisfaction scores, though this connection has now been disproved in certain settings.[18] In 1995 and 1996, the American Pain Society began promoting the idea of assessing pain as a vital sign.[19] In 1999, the Veterans Health Administration (VHA) launched the "Pain as the 5th Vital Sign" initiative to implement pain assessment and management for all of their patients.[20] In 2000, the 106th US Congress passed H.R. 3244 that established the "Decade of Pain Control and Research." The Joint Commission rolled out new Pain Management Standards in 2001 for all patient care organizations that it accredited.[21] And from May 2000 through January 2001, IHI ran a Collaborative with the Veterans Health Administration "to improve delivery or pain management to VHA patients."[22]

While these and other similar initiatives had positive impacts on the problem of undertreating pain, when combined with the accelerating use of opioids, they also, unfortunately, contributed to

the present crisis. There was a loosening of attitudes towards prescribing opioids and an overreliance on opioids to treat chronic pain, despite a lack of evidence that long-term use of opioids is effective for chronic pain.[23] In fact, when opioids are used to treat chronic pain, they can even produce increased sensitivity to pain, leading to more opioid use and the start of a vicious cycle. Alternative pain management options are often limited, due in part to lack of reimbursement from payers. This increased opioid prescribing led directly to some patients becoming addicted and facilitated the illicit use of opioids. The widespread use of sustained-release opioids greatly increased the problems of abuse and addiction because the tablets can be crushed to release a large amount of the drug which can then be ingested or injected.

Coinciding with the rise in opioid prescriptions, there was an influx of a new type of heroin, black tar heroin, into the US. Black tar heroin, predominantly trafficked from a single community in Mexico, was slow to be detected in the US. In contrast with the characteristics of previous drug epidemics, traffickers of black tar heroin sold in small quantities in smaller cities, rotated dealers, and focused on customer service to addicts. In order to deflect law enforcement attention, the traffickers explicitly prohibited violence. In order to maintain addictions, they offered free product when the addict was not able to pay. Black tar heroin did not lend itself to adulteration and was therefore more potent, addictive, and dangerous. Given these differences from the drug crisis of the 1980s, black tar heroin went undetected as a national problem for years.[24]

The problem of prescription opioid misuse and abuse was also slow to be detected, in part because it tends to occur in populations that are not traditionally thought of as drug-seeking. Individuals who abuse and overdose on prescription opioids are more likely to be white, female, and middle-aged.[25] Compounding the problem is the poor availability of and funding for comprehensive substance abuse treatment.

Fortunately, the crisis is now gaining increased local, state, and national attention. This welcome recognition, however, also brings challenges. As initiatives proliferate, they need to be coordinated and aligned. IHI is uniquely positioned to convene disparate groups to channel efforts for maximum impact.

Results of the 90-Day Scan

Many promising efforts were identified, but on the whole the opioid epidemic has not diminished.

The US opioid crisis has received national attention from multiple government agencies, including the White House, Department of Health and Human Services (HHS), the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the Drug Enforcement Administration (DEA), the Centers for Medicare & Medicaid Services (CMS), and the Surgeon General.

As part of our research, we studied 33 ongoing efforts at different levels: governmental (federal, state, local); professional associations; health system and health plan; and academic institutions (see Appendix A). Many of these efforts have shown positive results; for example, legislation passed in Washington State to reform opioid prescribing practices led to a reduction in the mean dose for long-acting opioids, a reduction in the percentage of doses over 120 mg morphine-equivalent dose, and ultimately a 27 percent reduction in the number of overdose deaths between 2008 and 2012.[26] Other efforts include state-based Prescription Drug Monitoring Programs (PDMPs), FDA-required Risk Evaluation and Mitigation Strategies (REMS), and strategies to

address the epidemic released by the DEA, White House, and others. However, after several years, most of these efforts have yet to demonstrate significant or widespread impact.

So, despite many millions of dollars invested, the opioid epidemic continues to worsen. IHI identified several reasons for this:

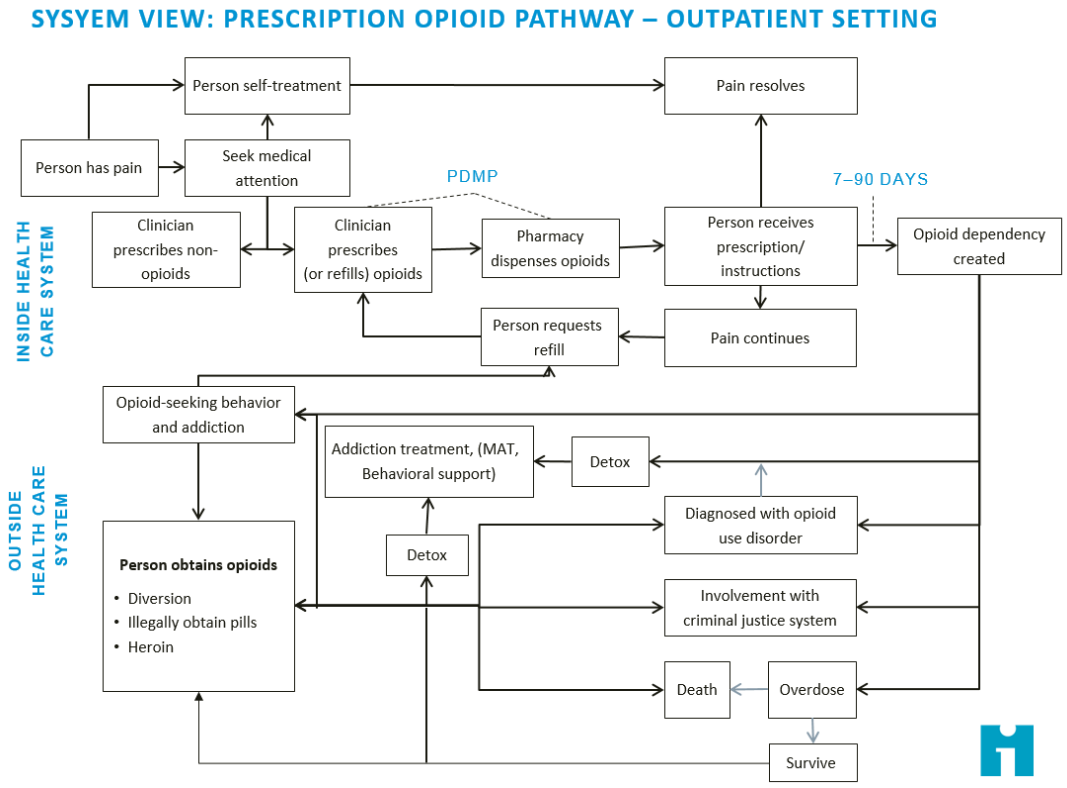
- **Lack of coordination of approaches and resources.** Uptake of many interventions has been variable, and for some, evidence of effectiveness remains limited. Many initiatives remain siloed, addressing only one part of the problem; opioid misuse and abuse is a complex problem, and no single effort will effectively overcome it.
- **Lack of effective implementation of promising practices.** The lack of progress is not, in general, due to a lack of knowledge. Johns Hopkins Bloomberg School of Public Health recently published a comprehensive guide to evidence-based practices and recommendations for actions to address the opioid epidemic at different points in the system.[27] While the guide is useful for understanding potential strategies, it is insufficient to lead to systemic changes. Many efforts have resulted in publication of strategies or guidelines, but without support for execution of those strategies. We need to go a step further and move these guidelines and recommendations into implementation.
- **Failure to engage with local communities and across multiple stakeholders.** To successfully implement interventions, community-wide improvement efforts must engage those members of the community intended to be helped by the interventions. Initiatives must look beyond public health and health care to stakeholders such as law enforcement, community-based organizations that are not primarily focused on health, faith-based organizations, schools, and individuals and families directly affected by opioid abuse. Engagement and understanding of the local context is particularly important, due to the significant geographic variation in the opioid epidemic (see below).
- **Failure to spread promising practices.** There are many encouraging examples in the campaign against the opioid crisis, primarily at the regional, state, local levels. However, these promising practices are often not adopted elsewhere, or even spread from small test sites to the larger geographic area. In other domains, IHI has engaged in a number of large-scale initiatives focused on spread and scale-up of better practices, and we believe our work has application to the opioid crisis.[28,29]
- **Direct and indirect counter-forces by the pharmaceutical industry.** These include developing new opioids and marketing them to patients and providers; lobbying for (and receiving) FDA approval for OxyContin for adolescents; and developing drugs to treat the side effects of opioid use (such as opioid-induced constipation) rather than address opioid dependency.
- **Lack of awareness among patients and consumers of the danger of prescription opioids.** In our research, both expert interviews and informal conversations highlighted the lack of awareness about the danger of opioids. We were surprised to learn how many individuals did not realize that commonly prescribed medications, such as Percocet or OxyContin, are opioids just as heroin is an opioid.

There is a need for a system-level approach across communities.

A new approach is needed to reverse the opioid crisis. IHI's innovation team researched the system design that facilitates opioid misuse, abuse, and dependence. Examining local efforts in

Massachusetts driven by law enforcement and community coalitions (in Cambridge, Gloucester, and Watertown), larger regional efforts driven by health care (in Southern California and Oregon), national endeavors (such as the CDC's guidelines, which were released in March 2016), and individual provider experiences, it became very clear that one of the most significant drivers of the crisis is the lack of a system-level approach across communities. The diagram in Figure 1 illustrates typical patterns and cycles that occur in the outpatient setting. We call this a "system view."

Figure 1. Typical Patterns and Cycles for Opioid Use in Outpatient Settings



A full system view of opioid use, misuse, and abuse reveals the need for coordinated efforts rather than point-in-time interventions. In addition, by mapping the 33 larger-scale endeavors to address the opioid epidemic to this system view, we found that 75 percent of efforts focused on provider prescribing practices, overdose prevention with naloxone, and addiction treatment: 17 focused on prescribing practices (51 percent); 3 focused on Naloxone overdose prevention (9 percent); and 5 focused on addiction treatment (15 percent).

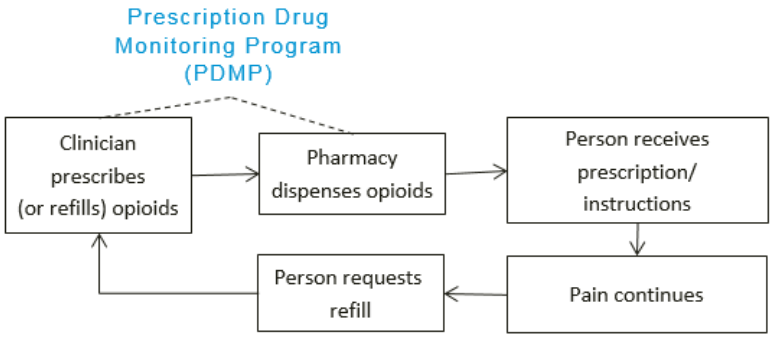
These three practices are highlighted in the system view above. If a community focuses only on those three important, but limited, intervention points, it will miss opportunities for larger scale improvement as well as possible long-term solutions.

IHI's research highlights the following gaps: the absence of health care systems in some community coalitions; the absence of law enforcement, corrections, and social services in others; a shortage of detox beds and addiction treatment facilities; and poor bridging between detox and addiction treatment, which is the most critical time to prevent a fatal overdose. To address these gaps, some communities have capitalized on existing resources in novel ways. For example, in Cambridge, Massachusetts, narcotics detectives and EMTs serve as case managers for individuals addicted to opioids. Drug courts and treatment, often with the support of law enforcement, are

replacing incarceration, and, interestingly, medical examiners are serving as physician educators, relaying information about opioid overdose fatalities back to providers. These creative solutions, predominantly invisible in the resource-rich programs we explored, are achieving successful outcomes (see Appendix A).

In addition to the system view, health care providers prescribing opioids need to be aware of the typical cycle of chronic opioid use, represented in Figure 2.

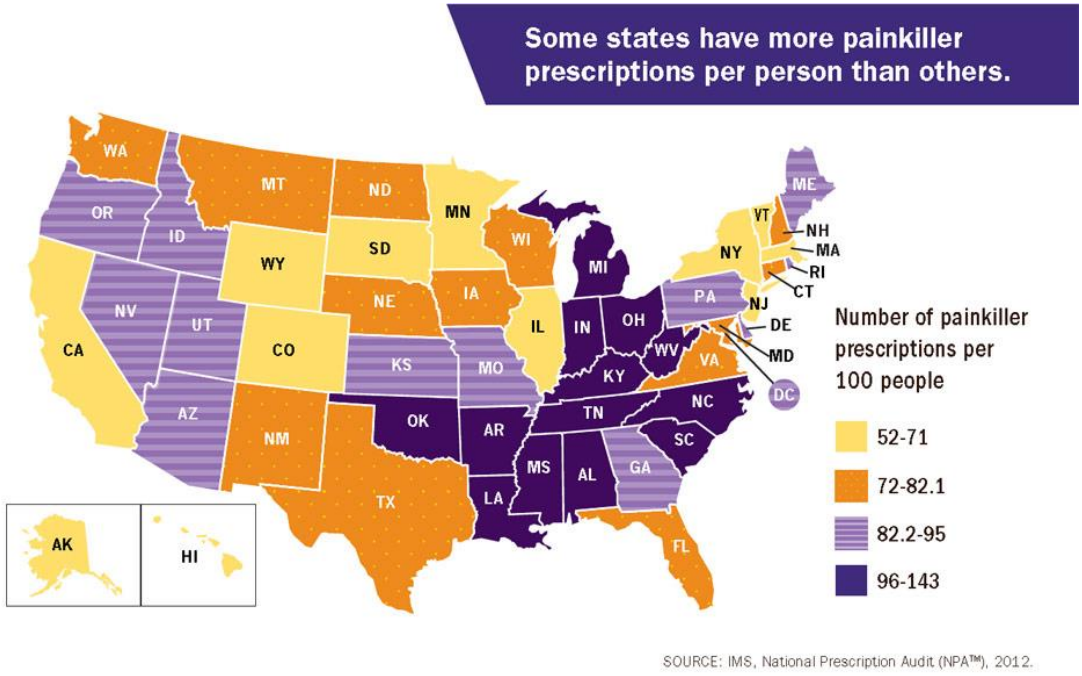
Figure 2. Typical Cycle of Chronic Opioid Use



There is significant geographic variation in opioid use.

There is significant geographic variation in the opioid epidemic, with large regional differences in provider prescribing practices and opioid use, misuse, and abuse. This variation is part of the reason that tailored, local community approaches will be most successful. The map below (see Figure 3) is just one example of this variation; it shows 2012 data on differences in painkiller prescriptions per person.

Figure 3. Geographic Variation of Opioid Use in the US



Even within regions, it is important to consider nuances; for example, in Maine, the type of opioid use differs depending on the time of year. During lobster season, when fishermen have more disposable income, pills are more common, while off-season, heroin is more common because it is cheaper than pills. Understanding specific characteristics of the crisis in different geographic areas will be essential.

There are other regional differences, including:

- Prescription Drug Monitoring Program (PDMP) availability, access, regulatory scope, and use
- Population attitudes about pain and opioid-containing substances
- Law enforcement attitudes towards opioid users and incarceration of opioid users
- Judicial enforcement (presence of drug courts, treatment vs. prison)
- Availability of addiction treatment and referrals to treatment resources
- Reimbursement for addiction treatment
- Insurance reimbursement for screening and risk analysis
- Availability of heroin and other illicitly produced synthetic opioids in the community
- Education for providers and patients
- Oversight of patients and providers who take or prescribe controlled substances
- Community resources and involvement in response to the crisis
- Possible genetic variation or cultural influences affecting certain populations

Four primary populations are affected by opioid use.

Many current approaches do not take into account the different populations that are affected by this crisis. We propose four broad categories of populations, each corresponding to a different mix of applicable strategies. While these categories can be fluid (in particular the third and fourth), interventions need to account for multiple populations at different points in the system.

- Naïve patient: Avoid starting, thus preventing, opportunities for opioid use, misuse, and abuse
- High-dose chronic use: Compassionately taper opioids and move to alternative pain management
- Opioid-dependent, seeking within health care: Address opioid-seeking behavior without moving patients to illegal means of obtaining opioids
- Opioid-dependent, seeking outside of health care: Address addiction behaviors and outcomes

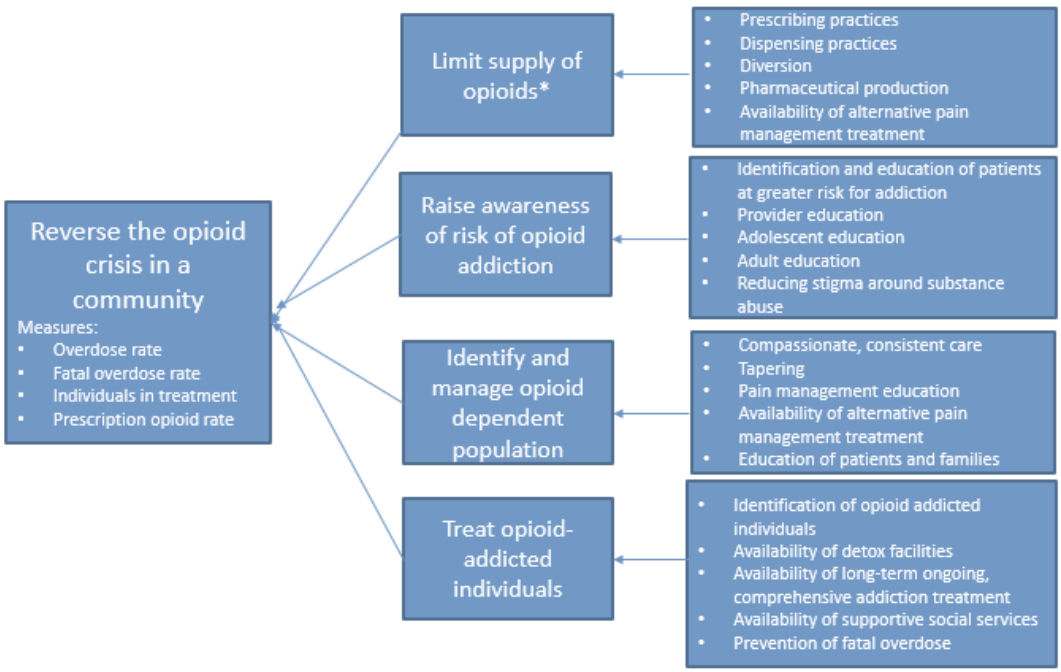
Solution Theory and Operating Principles for Health Care

Based on these gaps and the need for a system approach in communities, IHI's theory of change calls for a coordinated and collaborative community-wide approach. Health care, law enforcement, schools, the judicial system, addiction treatment centers, EMTs, public health officials, and others must find ways to tackle this crisis together. A solution that utilizes a community-wide system view of opioid use, misuse, and abuse, rather than isolated efforts to intervene at different points in time, will have a stronger impact on the trajectory of the opioid crisis.

The driver diagram in Figure 4, which further lays out our theory of change, illustrates four main drivers to reduce opioid use.

- **Limit supply of opioids:** Both prescription and heroin (note that this innovation project did not focus on heroin)
- **Raise awareness of risk of opioid addiction:** Both within the health care system to change prescribing and expectations and outside of health care to prevent adults and youth from recreational use (in addition, stigma reduction has proved necessary to reach the point of treatment)
- **Identify and manage the opioid-dependent population:** Strongly focused on the health care system, as it will need to compassionately treat and wean chronic opioid use
- **Treat opioid-addicted individuals:** Stakeholders throughout the entire community need to be engaged (i.e., a collaborative, community-wide approach)

Figure 4. Driver Diagram: Reverse the Opioid Crisis in a Community



Opioid misuse is a sensitive topic. Providers may resent the implication that they are inappropriately prescribing medications; patients may resent being treated as potential addicts and may fear that their pain will be ignored; and pharmaceutical companies are putting substantial pressure on providers to continue current prescribing practices. Given these realities, it is important to lay out a set of operating principles.

The list below focuses on operating principles for a health care system committed to addressing the opioid crisis:

- Patients with pain need appropriate pain management.
    - Cancer pain and palliative care are excluded from this conversation. These patients should not be counseled to reduce opioid use.
- Scientific and clinical knowledge about how opioids work in the body and brain has evolved, so policies and practices must also evolve.
- The latest evidence about appropriate use and risks of opioids for both acute and chronic pain needs to be disseminated to providers and integrated into routine care.
- Opioid prescribing crosses many different types of providers with varying degrees of training on pain management and opioid use, so provider education must take these differences into account.
- Patients need to be better informed about the effectiveness and risks of opioids.
    - The majority of prescription overdoses and deaths are accidental, and can happen to any patient on chronic, high-dose opioids (usually due to respiratory depression, and the highest risk is in combination with Benzodiazepines, sleep medications, and/or "muscle relaxants").
    - Many patients become opioid-dependent unintentionally.
- Use of prescription opioids is linked to heroin use and needs to be recognized as such.
- Any intervention effort needs to take into account possible unintended consequences for other parts of the system.

Strategy Session with the US Surgeon General

In December 2015, IHI, in collaboration with 100 Million Healthier Lives, convened a small strategy session with the US Surgeon General, Dr. Vivek Murthy. The Surgeon General has named addiction as one of his priority areas for his time in office, and he is planning a multi-pronged campaign to address the epidemic.

IHI invited experts from communities across the country with different perspectives on the opioid crisis (see Appendix B), including health care providers, payers, and representatives from government agencies, public health, and law enforcement. This group had a rich discussion with the Surgeon General and his team to provide feedback on systemic challenges and the Surgeon General's proposed campaign components and public messaging strategies.

Conclusion and Recommendations

IHI is confident that a system approach at the community level has strong potential to effectively address the opioid epidemic. To our knowledge, few efforts have defined or are addressing the full

system view of the opioid epidemic, or are using this view to mobilize mutually reinforcing activities by multiple stakeholders. IHI is seeking opportunities to work with communities to utilize a system design as a blueprint for intervention.

Through the research in this innovation project, we identified several key components for implementing a community-wide strategy to address the opioid crisis.

- **Retrain providers:** Over the past 20 years, well-intentioned providers have been given misinformation pertaining to opioids, with respect to both dose and need. In particular, the use of opioids for chronic pain needs to change. Researching Coumadin and antibiotic stewardship efforts, which successfully changed provider prescribing habits, will help to provide background on the approach to retraining providers for opioid prescribing.
- **Consider all providers:** Unlike many other medications, opioids are prescribed by a wide array of providers. Retraining needs to occur for all of them, including pediatricians, sports physicians, orthopedists, nurse practitioners, physician assistants, and dentists (dentists prescribe approximately 12 percent of immediate-release opioids in the US).[30]
- **Identify alternative treatment options for pain management:** Providers and patients both need medications and methods to treat pain appropriately. Asking providers to change practices without offering a substitute will both limit effectiveness and fail to address the needs of patients.
- **Create a role for pharmacists and retail pharmacy ("corresponding responsibility"):** There is a natural but underdeveloped role for pharmacists, who are often the last line of defense before an opioid prescription reaches a patient. A mechanism to build strong learning and feedback loops between providers, pharmacists, and patients is required.
- **Engage in public messaging:** There is a lack of public awareness of the danger of opioids, and that prescription opioids are similar molecularly to heroin. Further complicating the lack of awareness is the fact that many patients place total trust in their providers, and do not believe their doctor would give them something dangerous. An effective public campaign will be a significant factor in making an impact in communities.
- **"Flood the zone":** Efforts will not be successful if conducted in isolation. We need to deploy multiple methods across a community to achieve optimal outcomes.
- **Recognize that geography is important:** Given how different this crisis looks in different parts of the country, geographically based efforts may make sense. Partnerships can then form to create the appropriate scalable unit (e.g., states, regions, large urban areas).
- **Include law enforcement:** As stated by Joseph Foster, Attorney General of New Hampshire, "We can't arrest our way out of this problem." Law enforcement, drug courts, police officers, and social workers are at the front lines of this epidemic. They are acutely aware of detox and treatment availability (or the lack thereof) and the often vicious cycle that accompanies prescription opioid addiction as it shifts into illegal activity. These individuals need to be included as full partners in addressing the opioid crisis.

By combining the research detailing IHI's knowledge of community-wide change efforts and these specific needs, IHI aims to change the trajectory of the opioid crisis in a community or multiple communities across a state.

Appendix A: Key Stakeholders in Addressing the US Opioid Crisis

Federal

Opioid use, misuse, and abuse has received significant federal attention and funding in the US, but these investments have yielded limited evidence of improvement. Practically every federal agency with a stake in either health or drug use/abuse is engaged in some way. These strategies tend to focus on providers in the outpatient setting. US federal strategies include:

- Clinical guidelines that provide recommendations for safe and appropriate opioid prescribing
- Tighten opioid dispensing rules, reducing both the amount of pills dispensed with each prescription and the incidence of new prescriptions
- Expand access to naloxone and medical addiction treatment
- Provide access to safe drug disposal in the community to prevent diversion
- Educate patients and providers on the dangers of opioids and risks of long-term use and addiction
- To advance recommendations, provide funding to states and community health centers, and to educate providers
- General publicity about the opioid epidemic

Federal Entity	Strategy to Reduce Opioid Overuse	Evidence of Improvement / Results to Date
Drug Enforcement Administration (DEA) / Department of Justice	• Tightened opioid dispensing rules in 2014-2015: Hydrocodone is now classified as Schedule II and requires monthly provider visits to renew opioid prescriptions • Drug take-back effort: Authorized community drop-off sites for unused prescription opioids • Resource site for opioid epidemic	Impact is currently unclear — there has been some public push back on the need for provider visits to renew prescriptions
White House Office of National Drug Control Policy	FY16 federal budget includes $99M increase over FY15 for efforts to reduce opioid-related morbidity and mortality Prescription Drug Abuse Prevention Plan (2011): Education, monitoring, proper medication disposal, enforcement	N/A – too soon to determine

Federal Entity	Strategy to Reduce Opioid Overuse	Evidence of Improvement / Results to Date
Centers for Disease Control and Prevention (CDC)	• State-based grants • New clinical guidelines – released March 2016 • Recommendations in several different publications and highlighting epidemic in *Morbidity and Mortality Weekly Review*	Guidelines released in March 2016 and have been receiving significant press, but it's too early to see results
Veterans Affairs (VA)	• VA National Pain Management Strategy, including Pain Management Toolkit, "Pain as the 5th Vital Sign" campaign and toolkit, and stepped care model of pain management • Opioid Safety Initiative Toolkit	VA has not released any results
Centers for Medicare & Medicaid Services (CMS)	• Guidance to help states implement evidence-based substance use disorder treatment • Partnership for Patients Network (P4P): Opioid Knowledge Self-Assessment and Organization of Safe Opioid Practices • Audit of Managed Medicare Plans for high opioid utilization (>120 mg MED/day + 4 prescribers + 4 pharmacies) and requirement of action plans for each patient [*MED = morphine-equivalent dose]	55% decrease in rate of opioid-based adverse drug events in some systems that participated in Partnership for Patients
Department of Health and Human Services (HHS)	HHS Secretary's initiative to combat opioid abuse has three priority areas: • Opioid prescribing strategies to reduce opioid use disorder and overdose • Expanded use and distribution of naloxone • Expansion of medication-assisted treatment (MAT) September 2015: Convened 50-state meeting on opioid overdose prevention and opioid use disorder	N/A – too soon to determine
Food and Drug Administration (FDA)	Risk Evaluation and Mitigation Strategy (REMS) (2011) for DEA-registered providers for all extended-release/long-	Peppin et al. (2011): Concluded that proposed REMS is unlikely to reduce prescription drug abuse that occurs with non-patients

Federal Entity	Strategy to Reduce Opioid Overuse	Evidence of Improvement / Results to Date
	acting opioid drugs to encourage providers to: • Educate themselves • Counsel patients • Emphasize patient and caregiver understanding of medication guide • Consider other pain management strategies	Slevin and Ashburn (2011): Surveyed primary care physician opinion on REMS, found that 50% of responding physicians would be willing to comply with REMS mandatory education component, including the requirement to provide education to patients • For some REMS components, willingness to continue to prescribe despite the restriction was higher (up to 90%) • However, this leaves a substantial proportion of physicians who would not be willing to prescribe opioids controlled by the new REMS (could have unintended effect of decreasing access to these medications for legitimate medical purposes)
Health Resources and Services Administration (HRSA)	$100M in new funding available in early 2016 to 300 community health centers to expand substance abuse treatment, including Medication-Assisted Treatment (MAT) for opioid use disorder	N/A – too soon to determine
National Institutes of Health (NIH)	National Pain Strategy – six areas: • Determine just how big and how severe chronic pain is as public health issue • Better emphasis on prevention of acute and chronic pain • Improve the quality of pain care AND reduce barriers to underserved populations at risk for pain • Make sure that access to optimal pain management is available to all • Provide more education and training for the people who deliver care • Create a national pain awareness campaign and promote safe medication use by patients	Released March 2016
Substance Abuse and Mental Health Services Administration (SAMHSA)	$11M in funding to 11 states to expand and enhance MAT services in 2015	N/A – too soon to determine

Professional Associations

Practically all relevant professional provider and pharmacist associations have some information available on opioid use on their websites. Since they can issue only recommendations, not regulations, their impact may be limited, but members listen to these associations of their peers and they can be a good platform for disseminating information. Professional association strategies include:

- Release statements in support of regulations and laws and suggestions for members regarding prescribing practices; raising awareness of opioid overuse and overdose
- Pharmacists: Access to naloxone for at-risk patients without a provider's prescription; access to prescription monitoring programs
- Physicians and dentists: Guidelines and policy statements (but unclear what actions have been taken by members as a results of these)
- Generally focused on outpatient settings (except for hospitalists and ED doctors)

Professional Association	Strategy to Reduce Opioid Overuse	Evidence of Improvement / Results to Date
Consumers Union	In 2012, *Consumer Reports* published a report encouraging patients to seek alternate, less risky pain relief options Choosing Wisely issued statements on not prescribing opioids	Has a large readership — may have been helpful for patient education about the risks of opioids
National Association of Boards of Pharmacy (NABP) **American Pharmacists Association (APhA)**	NABP: Policy statement (October 2014) to expand access to naloxone for pharmacists APhA: Policy statement on the role of the pharmacist: • Education for pharmacists and students • Recognition of pharmacists as health care providers in exercising professional judgment in assessment of patients to fulfill responsibilities around substance misuse, abuse, and diversion • Pharmacist access to and use of prescription monitoring programs • Support development of laws that permit pharmacists to have and initiate naloxone, including education about appropriate dosing and initiation	Unclear what members are doing with these suggestions

Professional Association	Strategy to Reduce Opioid Overuse	Evidence of Improvement / Results to Date
Alliance of Community Health Plans	2012 report for community health plans: Ensuring Safe and Appropriate Prescription Drug Use, including plan profiles of seven plans that have done good work on this	Great case studies of plans with good results, including CareOregon and Group Health
American Medical Association (AMA)	Federal and state advocacy to prevent prescription drug abuse and diversion The AMA Task Force to Reduce Opioid Abuse wants physicians across the nation to join together and take action to prevent opioid abuse — five suggestions for physicians: • Register and use your state prescription drug monitoring program to check your patient's prescription history • Educate yourself on managing pain and promoting safe, responsible opioid prescribing • Support overdose prevention measures, such as increased access to naloxone • Reduce the stigma of substance use disorder and enhance access to treatment • Ensure patients in pain aren't stigmatized and can receive comprehensive treatment	Unclear what members are doing with these suggestions, but the AMA has significant clout with physicians
American Academy of Family Physicians (AAFP)	Guidelines for how to monitor opioid use for patients with chronic pain Published report for members on using opioids to manage chronic, nonterminal pain and a position paper on pain management and opioid abuse	Unclear what members are doing with these suggestions
Society of Hospital Medicine	No official statements; they have written some articles for their members on issues in opioid prescription, overdoses, and pain management for hospitalists.	Unclear what members are doing with these suggestions

Professional Association	Strategy to Reduce Opioid Overuse	Evidence of Improvement / Results to Date
American Academy of Pain Medicine	Clinical guidelines: • Use of Opioids for the Treatment of Chronic Pain • Medical Treatment Utilization Schedule Proposed Regulations	Unclear what members are doing with these suggestions
American Society of Addiction Medicine	National Practice Guidelines for the use of medications in the treatment of addiction involving opioid use – to assist providers prescribing to patients with addiction related to opioid use	Unclear what members are doing with these suggestions
Emergency Medicine Physicians: **American Academy of Emergency Medicine (AAEM)** **American College of Emergency Physicians (ACEP)**	Forthcoming guidelines from AAEM ACEP resources for emergency department staff — links to existing resources from CDC, National Institute on Drug Abuse (NIDA), Substance Abuse and Mental Health Services Administration (SAMHSA)	Unclear what members are doing with these suggestions
American Dental Association (ADA) **National Dentist Association**	ADA joined AMA task force and released statement on the use of opioids in the treatment of dental pain: • Continuing education about appropriate use of opioids • Mindfulness of potential for abuse when prescribing • Review compliance with DEA recommendations and regulations • Recognize responsibility for ensuring availability of pain medications to patients who need them and to prevent them from becoming a source of harm or abuse • Dentists practicing in good faith should not be held responsible for drug-seeking behavior of patients • Dental schools should teach about addiction and pain management	Unclear what members are doing with these suggestions

Professional Association	Strategy to Reduce Opioid Overuse	Evidence of Improvement / Results to Date
Pharmacy Quality Alliance (PQA)	PQA develops medication-use measures for the following: • Use of opioids at high dosage in persons without cancer • Use of opioids from multiple providers in persons without cancer • Use of opioids at high dosage and from multiple providers without cancer Under discussion in 2015: Triple Threat: Concomitant Use of Opioids, Benzodiazepines, and Muscle Relaxants	Measures are being used by some Medicaid plans, but it is unclear how the results are being used PQA would like CMS to adopt the measures for Medicare Advantage plans as well in the future
The Joint Commission	Published a Joint Commission Resource, "Pain Management: A Systems Approach to Improving Quality and Safety" Sentinel Event Alerts: • Safe use of opioids in hospitals • Patient controlled analgesia by proxy Checklist for five steps to have been completed when initiating patient-controlled analgesia (PCA) pumps in post-operative patients to reduce risk of opioid-induced respiratory depression.	Increased awareness and development of checklists
State Hospital Associations and Medical Societies	Many have included information on opioids — particularly around patient and provider education and appropriate prescribing — in member newsletters	Unclear what members are doing with these suggestions

States

Some of the best results in slowing the opioid epidemic have come from states, through a combination of legislation, regulation, and active engagement in supporting the implementation of changes recommended by guidelines. These include:

- Prescription Drug Monitoring Programs (PDMP) to monitor prescription patterns

- Access to opioid prescribing education programs (e.g., COPE) for providers
- Regulations on the number of pills available through one prescription and limits on refills
- Reimbursement for non-pharmacologic treatment services for chronic pain

State	Strategy to Reduce Opioid Overuse	Evidence of Improvement / Results to Date
Washington	Collaborative Opioid Prescribing Education (COPE) Washington State Opioid Dosing Guideline and use of opioids for chronic pain (state legislation)	Overdose death rate in WA decreased 27% between 2008 and 2012 and average opioid death rates have declined Franklin et al. (2011): The introduction in WA of an opioid dosing guideline appears to be associated temporally with a decline in the mean dose for long-acting opioids, percent of claimants receiving opioid doses 120 mg MED per day, and number of opioid-related deaths among injured workers
Massachusetts	New law passed in the state House that is currently being reconciled with a bill passed in the state Senate	Implementation forthcoming Statewide collaboration efforts being set-up, in addition to local community efforts
National Association of State Controlled Substance Authorities	State Prescription Drug Monitoring Programs (PDMP) — supported in part by federal funding National Alliance for Model State Drug Laws	Several peer-reviewed articles support PDMPs as an effective way to identify and intervene with individuals misusing opioids

Health Systems and Health Plans

There has also been a lot of good work within individual health systems and health plans. They can focus on identifying, monitoring, and intervening with individual patients and working more deeply with physicians to change prescribing practices and pain management strategies. Some exemplars are highlighted below.

Health System	Strategy to Reduce Opioid Overuse	Evidence of Improvement / Results to Date
Kaiser Permanente	Large-scale, systematic strategy in an integrated health care delivery system (4 million members) included education and	85% reduction in OxyContin prescriptions

Health System	Strategy to Reduce Opioid Overuse	Evidence of Improvement / Results to Date
(Southern California)	academic detailing; automated decision support; leveraging EMR; medication policies and procedures (formulary management) with limits on dosing, quantity, duration, and prescribing specialty; empowering and collaboration with pharmacy ("corresponding responsibility"); pharmacy policies and procedures; ongoing monitoring and surveillance, with lists and feedback reports to prescribers/chiefs; inter-departmental specialty agreements for primary care with pain management, addiction medicine, physical medicine, etc. Supported by multidisciplinary Steering Committee and 13 medical center review teams.	90% reduction in opioid/apap combination prescriptions over 200 tablets 26% reduction in >120 MED/day patients 84% decrease in opioid + benzodiazepines + carisoprodil (Triad) prescribing
Group Health Cooperative Puget Sound (Washington)	Chronic Opioid Therapy guidelines for treatment of non-cancer patients. Initiatives include: • Collaborative care plan • Patient monitoring • Referrals • Patient-centered prescribing guidelines • Clinician training	Between 2007 and 2011, cut by half the percentage of non-cancer patients on high opioid doses of greater than 120mg morphine-equivalent dose (MED) per day and reduced the average daily dose by one-third Between August 2010 and December 2011, the percentage of non-cancer chronic opioid (COT) patients with care plans increased from 3% to 96% (Group Health also increased the percentage of high-dose COT patients receiving urine drug screenings from 15% in 2008-2009 to 65% during the guideline implementation year) Between December 2007 and June 2011, the share of high-dose COT patients dropped from 17.8% to 9.4% of total members on COT (Group Health has also seen a decrease in patient complaints and fewer patients on high doses of opioids) About three-quarters of active PCPs in the group practice completed a 90-minute online training course, which increased confidence of providers in their ability to evaluate and treat

Health System	Strategy to Reduce Opioid Overuse	Evidence of Improvement / Results to Date
		chronic pain and prescribe opioids for chronic pain (52% of providers were confident after the course, compared to 24% before); and providers were also significantly more confident in addressing psychosocial issues with COT patients and counseling patients about long-term opioid use
CareOregon	• Prescription Drug Monitoring Program — electronic database that collects data on certain controlled substances dispensed in the state • Pharmacy and provider lock-in — identify PCPs of members who were overutilizing opioids and connect patients without PCPs to a physician — to reduce receiving prescriptions from ERs and urgent care • Restrict members using five or more pharmacies or providers for opioids to a single pharmacy and/or physician and notify the last prescribing physician that the member has been restricted • Education for health care providers and staff • Prescribing quantity limits to restrict diversion of unused pills for non-medical use — limit to 90 pills every 30 days and require prior authorization to review whether it is medically appropriate to exceed plan prescribing limits • Medical home partnerships — standardized approach to chronic pain in all of plan's patient-centered medical homes • Opened chronic pain clinic (fully funded by CareOregon since not paid for by Medicaid) • Recommend use of non-pharmacological pain treatments	Significant reductions in the number of patients on long-term, chronic opioid therapy by more than 50% between 2011 and 2012 Members placed in restriction (with high utilization rates) — number of filled prescriptions decreased by 69%, pharmacies used by 81%, prescribers by 79%, and ER visits by 56%

Academic Institutions

Institution	Strategy to Reduce Opioid Overuse	Evidence of Improvement / Results to Date
Boston University	Safe and Competent Opioid Prescribing Education (SCOPE) online education program — series of continuing medical and nursing education activities to help providers safely and effectively manage patients with chronic pain, when appropriate, with opioids (includes in-person conferences and three online, case-based modules) OpioidPrescribing.org has guidelines and online education for providers on a variety of topics	2015 article in *Pain Medicine* found that 10,556 participants completed SCOPE of Pain through June 2014 • Immediately post-program, 87% were planning to make at least one change to align their practice with guidance-based care, including: 1) improving opioid prescribing documentation; 2) implement or improve opioid prescribing patient education or communication; and 3) institute or improve Patient Prescriber Agreements • Two months after the training, ~67% reported increased confidence in guideline-based prescribing practices and 86% reported that they improved how they prescribe opioids and monitor patients for benefits and harm • No results on whether SCOPE impacted mitigating opioid misuse risk and harm
Dr. Gary Franklin, University of Washington	Authored position statement from the American Academy of Neurology for opioids for non-cancer pain Has been very active in Washington State's efforts to reduce opioid overuse and abuse (see Washington state's work above)	

Other

Entity	Strategy to Reduce Opioid Overuse	Evidence of Improvement / Results to Date
California HealthCare Foundation (CHCF)	In fall 2015 CHCF launched the Opioid Safety Regional Coalitions grants project, in which 15 counties in California are forming local	Too early for results

	coalitions to address the opioid crisis in their counties	
Pharmacy Benefit Managers (PBMs)	Recommendation for PBMs to provide "flags" or warnings to alert dispensing pharmacist to possible opioid overuse and abuse; can serve as an early warning system for potential issues Checklist to evaluate PBMs' ability to manage opioid prescriptions and identify potential abuse	Unclear what PBMs are doing in this space
Alternative treatment modalities (e.g., cognitive behavioral therapy, physical therapy, acupuncture, yoga)	Provide potentially effective alternatives to opioids to manage chronic pain	Some supporting research to suggest that patients can manage pain using alternative treatment modalities

Appendix B: A Systems Approach to the Opioid Crisis: Attendees of a Strategy Session with the US Surgeon General (December 2015)

Attendee	Title	Organization
Vivek H. Murthy, MD, MBA	Surgeon General	HHS, Office of the Surgeon General
Shavon Arline-Bradley, MPH	OSG Director External Engagement	HHS, Office of the Surgeon General
Nazleen Bharmal, MD, PhD, MPP	OSG Director of Science and Policy	HHS, Office of the Surgeon General
Karen Boudreau, MD	Chief Medical Officer	Boston Medical Center HealthNet Plan
Joseph A. Foster, JD	Attorney General	State of New Hampshire
Joel Hyatt, MD	Community Health Improvement	Kaiser Permanente

Attendee	Title	Organization
	Emeritus Assistant Medical Director	
Safina Koreishi, MD, MPH	Medical Director	Columbia Pacific CCO
John Krueger, MD, MPH	Acting Chief of Staff / Associate Chief of Staff, Primary Care	Veterans Health Administration (VA), Claremore, Oklahoma
Julie Morita, MD	Commissioner	Chicago Department of Public Health
Rita K. Noonan, PhD	Chief, Health Systems and Trauma Systems Branch	CDC/NCIPC, Division of Unintentional Injury
Rab Razzak, MD	Director, Outpatient Palliative Medicine	Johns Hopkins Medicine
David Roll, MD	Primary Care Physician	Cambridge Health Alliance; 100 Million Healthier Lives
Cassidy Tsay, MD, MBA	Regional Medical Director	Blue Shield California
Donald Berwick, MD, MPP	President Emeritus and Senior Fellow	IHI
Derek Feeley, DBA	Executive Vice President	IHI
Mara Laderman, MSPH	Senior Research Associate	IHI
Lindsay Martin, MSPH	Executive Director, Innovation	IHI
Kedar Mate, MD	Senior Vice President	IHI
Marianne McPherson, PhD	Director, 100 Million Healthier Lives Implementation	IHI, 100 Million Healthier Lives
Somava Saha Stout, MD, MS	Executive External Lead, Health Improvement	IHI, 100 Million Healthier Lives

Appendix C: Expert Interviews

Name	Title and Organization
Joe Avellone, MD	Former COO, Blue Cross Blue Shield of Massachusetts, and 2014 gubernatorial candidate, Massachusetts
Holly Boisen, RN	Quality Improvement Specialist, Gundersen Health System
Joseph Foster, JD	Attorney General, New Hampshire
Gary Franklin, MD, MPH	Professor, University of Washington
Robert Haas	Commissioner, Cambridge Police Department
George Kolodner, MD	Addiction Psychiatrist, Kolmac Clinic
Safina Koreishi, MD, MPH	Medical Director, Columbia Pacific Coordinated Care Organization, Oregon
John Krueger, MD, MPH	Acting Chief of Staff / Associate Chief of Staff, Primary Care Veterans Health Administration (VA), Claremore, Oklahoma
Bill Mergendahl, JD, EMT-P	President and CEO, Pro EMS
Julie Morita, MD	Commissioner, Chicago Health Commission
Rita Noonan, PhD, Debbie Dowell, MD, MPH, and Joann Yoon Kang, JD	Division of Unintentional Injury Prevention, CDC
Kelly Pfeifer, MD	California HealthCare Foundation
David Rosenbloom, PhD	Professor, Boston University and Advisor, Gloucester Police Department
Joel Strom, DDS, MS	Strom and Associates General Dentistry
Cassidy Tsay, MD, MBA	Regional Medical Director, Blue Shield of California
Dan Unsworth	Lieutenant, Watertown Police Department

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