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The State of The Opioid Crisis in North Carolina

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Background to the Opioid Epidemic

Today, the US faces a crisis from both legal and illegal opioids. Remarkably, the US market accounts for almost all of the world's hydrocodone and approximately 80% of the global consumption of oxycodone[1]. Opioids are distinctly an American problem and the White House has declared it a national public health emergency[2].

In the 1990s, the sheer number of Americans suffering from chronic pain led the federal government and the pharmaceutical companies to expand the use of opioids beyond cancer and palliative care, leading to a marked increase in the prescribing of these drugs. In the years between the early 1990s and 2010, the number of prescriptions for opioids tripled to over 200 million per year. To compound matters, over the same period the potency of these drugs increased significantly. As a result, communities across the country have been devastated. To put it in perspective, opioids have recently killed more people annually than guns or car accidents combined[3]. Nearly 2 million Americans are misusing prescription opioids and in 2016, an estimated 64,000 Americans died from drug overdoses, of which two thirds were attributed to opioids[4]. Sales from opioid prescriptions in the U.S. nearly quadrupled from 1999 to 2010. In 2016 alone, 289 million opioid prescriptions were written[5]. If the trend continues, over 600,000 American could die in the next 10 years from an opioid overdose.

The White House estimates the overall cost of the opioid epidemic on the U.S. economy at approximately $500 billion annually[6], but the human costs are much greater, leaving families and communities severely impacted. The highest overdose death rates occur among the 25-44 year old age group. This is particularly devastating given that this age group is in the prime years of their lives, building families and contributing to the community and economy. Addiction does not, therefore, affect the individual alone but the whole family, community, economy and the healthcare system. More ER services are used because of opioid misuse. Pregnant women on opioids give birth to babies with severe withdrawal symptoms and have to be treated in hospital. Children of people with an opioid misuse disorder end up in disproportionately high numbers in foster care because of neglect or death of one or more parent[7]. Not only do people with opioid addiction disorder cost employers on average more than twice as much in medical expenses as non-users, but also cost employers in absenteeism and productivity loss[8].

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OPIOIDS KILL more people annually than **guns** or **car accidents** combined

#1 Wilmington

is the **number one** hotspot in America for opioid abuse, with 3 other NC cities –
Hickory / Jacksonville / Fayetteville
IN THE **TOP 25** IN AMERICA

The cost of the opioid epidemic is estimated at **$500 BILLION**

In North Carolina, there are **97 painkiller prescriptions per 100 people**

At current trends, **600,000 Americans** could die in the **next 10 years** from an opioid overdose

WHO IS AFFECTED?

The opioid epidemic has hit populations from small cities and rural areas the hardest. The US healthcare system is such that not everyone has equal access to quality healthcare services everywhere. In general, it is easier to prescribe a pill than a more expensive and longer-term treatment such as physical therapy to treat, for example, lower back pain. Even if the patient has insurance and the physical therapy is covered, oftentimes patients need to get a prior authorization form adding to more paperwork and hassle.

The epidemic affects men and women differently as well. Men and women misuse prescription drugs for different reasons[9]. In the past, women had been diagnosed more frequently with chronic pain and were prescribed higher doses of opioids for longer durations than men. While substance misuse treatments are widely thought to be underutilized, fewer women receive treatment than men. The overdose death rate for women from 1990 to 2015 has risen 400% while the increase for men has been 237% during the same period[10]. Interestingly, women younger than 45 years of age have lower rates of opioid use disorder than men in the same age group[11]. Gender-sensitive prevention and treatment interventions should therefore be considered.

Adding to the difficulty of controlling or reversing the trend of the opioid epidemic is that prescription drug use has been more acceptable than illicit drug use. The individual's reluctance to treat opioid addiction is also caused by the shame and stigma attached to addiction itself, the lack of health insurance, and poor access to healthcare services and treatment facilities. Specifically, rural areas see a shortage of providers and mental health experts. Compounding the problem is the fact that individuals diagnosed with mental health issues, regardless of the underlying diagnosis, are three times more likely to misuse drugs[8]. Generally, people with mental health problems are often unwilling to seek help due to perceived societal stigma attached to psychotherapy. In rural communities, the problem is exacerbated due to provider shortages. Additionally, lack of health insurance and the cost-prohibitive nature of treatments prevents them from seeking the appropriate help.

Challenges in Controlling Opioid Availability & Distribution

WHAT ARE OPIOIDS?

Opioids are types of painkillers, some highly addictive, that are prescribed to relieve chronic and acute pain. Structurally, opioids are similar to a group of hormones the brain produces, called endorphins, which are the body's own natural way to fight pain and improve mood. When opioids are ingested, they take the place of natural endorphins by activating their receptors, giving users a feeling of euphoria. It is the nature of addictive substances that their use leads to these pleasurable feelings, which is what makes people use those substances repeatedly. Opioids do not treat the underlying cause of pain, but the symptoms. Moreover, tolerance builds quickly, and patients soon require larger dosages to reach the same effects. In fact, 1 in 5 people who use a 10-day opioid prescription becomes a long-term user. Eventually, as dependence and tolerance build, users will require a larger dose to get the "high" or relief they crave. Taking high doses of opioids risks leading to such high endorphin receptor activation, that it can depress critical areas in the brain that control breathing and heart rate. These vital functions slow down and death comes gradually within 1-3 hours after taking the lethal dose[5].

Opioid painkillers can be divided into three main groups with distinctive markets, potencies, and characteristics. These are natural and semi-synthetic (Oxycodone, Hydrocodone), synthetic (Fentanyl, Carfentanil) and heroin. While the synthetic opioids are the most potent and, therefore, dangerous category, the leading cause of opioid-related deaths is related to oxycodone and hydrocodone because of their widespread use in pain management. In 2010, lawmakers began to make it harder to get opioid prescriptions as a result of better monitoring. Manufacturers of opioid medications reformulated some of the drugs to make them more resistant to abuse and many of the so-called "pill mills" – clinics where drugs were prescribed inappropriately and for profit – were shut down[12]. As a result, dependent users of legal painkillers switched to illegal synthetics and heroin which were more potent, cheaper, and often easier to obtain[13].

I. PHARMA-PROVIDER RELATIONSHIP

In the 1990s, many pharmaceutical companies were either unaware of the addictive properties of their drugs or made false claims. Unlike most other developed countries, in the US, pharmaceutical companies are allowed to advertise their prescription drugs. Not long ago, pharmaceutical companies courted physicians with handouts including travel, research money, speaking fees, and meals to promote their drugs. In particular, Purdue Pharma, the maker of OxyContin, which contains oxycodone, has been blamed for its misleading and aggressive marketing practices to target physicians to prescribe their drug in high numbers[12].

The Physician Payments Sunshine Act which was passed in 2010 to increase transparency around the financial relationships between physicians, teaching hospitals, and manufacturers of drugs, medical devices and biologics, has since restricted pharmaceutical marketing tactics directed at physicians[14].

Additional measures to prevent addiction to opioids have been attempted. For example, many states have now enacted legislation to limit the duration of first-time opioid prescriptions. Although pharmaceutical companies were slow to act, they are making some strides, including making pills that cannot be misused. If the capsule is broken, the powder takes a gel-like form which cannot be snorted or injected[15].

II. PATIENT-DOCTOR RELATIONSHIP

Though physicians have a genuine desire to cure patients of pain, the level of pain is often difficult to assess, doctors rely on patients to self-report their pain intensity, and physicians cite the need for more education and support in this regard. One of the unintended consequences of the widespread implementation of patient satisfaction ratings is the tendency for physicians to overprescribe pain medication to treat what has become formally recognized by the medical community as "the 5th vital sign". Patients often demand opioid painkillers, and doctors who refuse to prescribe opioids to patients are sometimes threatened or harassed. More likely, patients would go "doctor shopping" until they could find another physician who would prescribe pain medication. There was no easy way to track the amount of prescriptions made to an individual patient. Laws to curb opioid availability have been put in place and the Centers for Disease Control has published guidelines on when and how to use opioids to manage pain. In addition,

prescription drug monitoring programs have been set up in most states to allow providers and pharmacists to monitor a patients' prescription history[16]. The use of prescription drug monitoring programs (PDMP) by primary care physicians and pharmacists has proven beneficial for preventing drug abuse, diversion, and deaths in many states that have incorporated it as part of other chronic pain initiatives.

III. ILLICIT DRUG USE

It is very difficult to track individuals who trade prescriptions. Prescriptions and pills can be stolen by family members. Some patients will endure their pain and sell their prescriptions to help support their family and pay for medical expenses. Opioid addiction often leads to a heroin addiction since they are related compounds and act on the same receptors in the brain. Heroin can be cheaper and more readily available than prescription painkillers. Illegal drug trafficking is a difficult and dangerous market to track. It is, therefore, out of scope for this paper's purpose.

> Survey respondents identified population health management, chronic disease management, elder care, and patient empowerment as some of the best untapped opportunities for digital health.

THE STATE OF OPIOID MISUSE IN NORTH CAROLINA

According to a recently published study by Castlight Health, Wilmington was named the number one city in America for the highest opioid misuse rates[8]. Of note, 22 of the top 25 cities for opioid misuse rates are located in Southern States, including four in North Carolina. In addition to Wilmington, Hickory, Jacksonville, and Fayetteville are the other cities in NC highly affected by the epidemic. Importantly, Jacksonville and Fayetteville house the U.S. Marine Corp's Camp Lejeune and Fort Bragg U.S. Army Base, respectively.

It is widely understood that people in rural, low average per-capita income areas are twice as likely to misuse opioids. Eighty percent of North Carolina counties are rural. In North Carolina, there are 97 painkiller prescriptions per 100 people[17]. This is one of the highest rates in the US. Furthermore, around 1 in 3 NC residents are either on Medicare or Medicaid programs and the rate of the uninsured is 1 in 10. In 2015, the average per-capita income for all NC residents was $42,244, whereas the per-capita income for the rural areas was $34,847. Close to 1 in 5 North Carolinians in rural areas lives in poverty[18]. Poorer individuals without health insurance living in rural communities tend not to seek preventative healthcare services and are more likely to suffer from chronic disease states. In terms of overall health, North Carolina ranks 33rd nationally[19]. Moreover, compared to urban centers, rural regions have comparatively fewer providers, particularly much-needed specialists such as surgeons, psychiatrists, dermatologists, and oncologists. In aggregate, this leads to many of the healthcare problems in North Carolina's rural communities.

> In North Carolina, there are **97 painkiller prescriptions per 100 people**. This is one of the highest rates in the U.S.

North Carolina Governor Roy Cooper has outlined strategies to confront the epidemic. The goal is to reduce the oversupply of prescription opioids, to reduce the diversion of prescription drugs, and the flow of illicit drugs. In addition, there are steps to be taken to increase community awareness as well as prevention. All this will go along with an expansion of treatment and recovery systems of care[20].

A separate plan also has been approved by the North Carolina General Assembly, called the *Strengthen Opioid Misuse Prevention* (STOP) *Act* which is based on the Drug Enforcement Agency's (DEA) national recommendations that an electronic prescription database for controlled substances be established to provide physicians and pharmacists with a tool to monitor patients' prescription drug use[21,22]. A newly established reporting system (*NC Controlled Substances Reporting System*) is active, but few physicians actually use it because it is time-consuming to enter and search the system[23].

NC POLICY RESPONSE TO THE OPIOID CRISIS

Anthony Solari, President, Solari Government Solutions

In North Carolina, policymakers on a number of different levels have worked to address the crisis.

Below is a short summary of the most significant public policy responses to the epidemic.

On the Legislative front, the General Assembly passed and Governor Cooper signed the "Strengthen Opioid Misuse Prevention Act of 2017". Known as the "STOP" act, House Bill 243:

- Limits first time prescriptions for most opioids to no more than 5 days for acute pain and 7 days for post-surgical pain;
- Requires medical providers to check North Carolina's Controlled Substance Reporting System to see if the patient is getting medications from other sources;
- Requires electronic prescriptions for opioids by 2020;
- Requires pharmacies to report opioid transactions in a more timely fashion;
- Expands the availability of the opioid antagonist naloxone.

On the executive side, Governor Cooper has shown leadership in directing the Department of Health and Human Services to develop and implement a statewide opioid action plan. This plan will:

- Coordinate the state's infrastructure to tackle the opioid crisis;
- Reduce the oversupply of prescription opioids;
- Reduce the diversion of prescription drugs and the flow of illicit drugs;
- Increase community awareness and prevention;
- Make naloxone widely available;
- Expand treatment and recovery systems of care;
- Measure the effectiveness of these strategies based on results.

Details of this plan can be found at: https://www.ncdhhs.gov/opioids

Governor Cooper is also serving on the President's Commission on Combating Drug Addiction and the Opioid Crisis.

Other significant actions by local policymakers to address the crisis include:

- The Division of Mental Health, Developmental Disabilities and Substance Abuse Services developed an action plan to reduce prescription drug abuse, including the abuse of opioids;
- The North Carolina Industrial Commission has proposed rules that will allow the workers compensation system to help address the opioid crisis. The rules are aimed at curtailing opioid misuse and addiction in workers' compensation claims;
- Attorney General Josh Stein has worked to focus Department of Justice resources to aggressively go after the dealers and traffickers who push heroin and opioids;
- North Carolina will receive about $31 million in federal funding over the next two years to battle ongoing issues surrounding opioid addiction, with 80 percent of the funds going to treatment and the other 20 percent going to addiction prevention efforts. The federal agency, The Substance Abuse and Mental Health Service Administration, awarded the grant.

These are some of the most significant responses on the part of policymakers. We can all hope that these efforts will work to reduce the pain, suffering, and disruption brought on by this crisis.

CASE STUDY: WILMINGTON

While several healthcare officials in Wilmington had questions about the Castlight Health study's methodology and rankings, including concerns over the study's definition of opioid misuse, everyone in Wilmington agrees that there is a drug misuse crisis.

North Carolina's New Hanover County, where Wilmington is located, has the characteristics of an opioid prone area: it has an aging population, located in the rural South, and suffers from a high poverty rate. In Wilmington, 53.8% of all opioid prescriptions are misused while 11.6% of opioid-prescribed individuals are now dependent[8]. These numbers are likely low since they are derived from patients with employer-based health insurance and do not include uninsured/Medicare/Medicaid patients. In 2010, Generation X (born 1966-1985) and the Baby Boomers (born 1946-1965) represented the largest segments of New Hanover County's population[24]. These generations are most prone to opioid dependence because they were prescribed the most opioids in their respective lifetimes.

By finding trends and crafting solutions in the local area, Wilmington has the potential to serve as a model of improvement for the US in the battle to stop rising opioid deaths. Despite, or maybe because of the extent of the opioid epidemic, Wilmington has one of the strongest recovery communities in the state. Following are some of the efforts currently undertaken in Wilmington to address the epidemic. Nearly every one of these programs is community driven:

PROJECT LAZARUS

Project Lazarus is a non-profit organization that takes a multipronged approach to combat the opioid epidemic on a local level. It provides training and technical assistance to communities including clinicians on prescription medication misuse by raising public awareness using data and evaluating outcomes. Furthermore, they provide education on how to recognize drug misuse and also support screening and proper treatment for mental illness, addiction, and pain by leveraging local resources. They work to reduce the amount of unused controlled substances with Project Pill Drop and provide naloxone (opioid antagonist) rescue kits to reduce overdose deaths[25]. Project Pill Drop is an initiative to increase the availability of permanent medication drop-boxes to properly dispose of unused or leftover medications to prevent them from being misused or diverted.

MEDICATION TAKE BACK EVENTS

Twice a year in fall and spring, the New Hanover Regional Medical Center partners with the local health department, law enforcement, and a variety of community partners to hold a Medication Take Back Event at the medical mall. This event typically receives more than 700 pounds of medications twice a year. Also, the county has invested to develop permanent drop-off locations for expired and unused prescriptions all over town. This initiative has been adopted in other counties as well[26]. This is in accordance with initiatives taken across the country. Since 2010, the DEA has collected 4,508 tons of expired, unused or unwanted prescription drugs at their 5,300 collection sites[27]. Remarkably, just in 2011 alone, Americans have been prescribed 4.2 billion prescriptions suggesting a high number of unused drugs in the medicine cabinet[28].

CAPE FEAR COALITION FOR A DRUG FREE TOMORROW

The coalition, encompassing community-based organizations, businesses, schools, youth, and families is aiming to support the community to raise awareness and encourage action on youth underage drinking, impaired driving, and substance misuse. The group plans to achieve this goal through education, advocacy, and policy change[29].

By finding trends and crafting solutions in the local area, Wilmington has the potential to serve as a model of improvement for the US in the battle to stop rising opioid deaths.

Current Treatment Strategies

I. MEDICATION-BASED TREATMENT COMBINED WITH MENTAL HEALTH/ BEHAVIORAL THERAPY

Opioid addiction is a particularly challenging condition to treat for physical, mental, and social reasons. Recovery often requires several attempts in a rehabilitation facility. Patients who are in recovery and then go back to using the drugs, are more likely to overdose due to lower tolerance. As an emergency rescue to reverse an opioid overdose, naloxone is used.

Currently, the first line of treatment for opioid addiction includes medications such as buprenorphine, methadone, and extended release naltrexone. Contrary to common perception, these drugs do not substitute one addiction for another (30). Rather, the drugs reduce opioid cravings and withdrawal symptoms allowing the brain to regain its healthy chemical balance (31). However, medication alone may likely not suffice to achieve a sustainable recovery but should be combined with behavioral counseling. Medication Assisted Treatment (MAT) is considered the gold standard and will not only increase the patient's social functioning but help him/her stay in treatment[32, 30]. MAT is the use of medications, in combination with counseling and behavioral therapies, to provide a "whole-patient" approach to the treatment of substance use disorders. Research shows that a combination of medication and therapy can successfully treat these disorders, and for some people struggling with addiction, MAT can help sustain recovery. As previously mentioned, people who have been diagnosed with a mental health problem have a significantly higher rate of opioid misuse. Without treating the underlying mental health problem, a sustained recovery will be hard to achieve.

As has been advocated generally for the management of other chronic disease conditions such as diabetes, a reasonable solution to address pain and related prescription drug addictions which are considered a chronic brain disease, would be best achieved through a team approach, where primary-care doctors, pain specialists, mental health providers, addiction specialists, and family members work together to find the best solution for a patient[5, 33].

II. ALTERNATIVE THERAPIES TO ASSIST IN PAIN MANAGEMENT

Interestingly, states with medical marijuana laws have a lower opioid misuse rate than those that do not. In fact, there is a 48% lower misuse rate of prescriptions[8]. Marijuana has been shown to be highly effective in relieving pain which is the primary reason for actions to allow use of marijuana grown for medical purposes. Marijuana is safer than opioids in that it is less addictive and does not lead to overdose deaths[34].

Other alternatives include physical and chiropractic therapy, massages, Chinese and herbal medicine. Indeed, there is an increasing body of clinical evidence which suggests that modalities such as botanicals, nutritionals, acupuncture and massage/bodywork can be effective alternative treatments. For example, research studies have shown that acupuncture has clinical efficacy on chronic pain and disability but with minimal side effects.

III. HOW WELL ARE THEY WORKING?

A major problem for treating opioid addiction is lack of treatment facilities or access to them. Equally of concern is that MAT is offered in less than half of privately-funded substance use disorder treatment programs and merely one third of patients with opioid addiction at these treatment programs gets it[30]. Most states do not have sufficient treatment capacity to provide MAT to all patients with an opioid use disorder. Provider availability and willingness to prescribe, limited insurance coverage, and cost are commonly cited barriers. Studies looking at the capacity of opioid treatments have demonstrated significant access barriers to methadone, long waiting lists to enter treatment, limited geographic coverage, limited insurance coverage, and the requirement that many patients receive methadone at the federally regulated opioid treatment programs daily[32]. Buprenorphine isn't as restricted as methadone, but represents the same access challenges based on the lack of physicians who can prescribe the medication. As of 2015, only 2.2% of physicians in NC have a Buprenorphine waiver, and 82% of rural counties do not have a waivered physician[35]. As a result, on average only 1 in 5 opioid addicted people actually receive a treatment and 40% of them do not even seek treatment[5].

EMERGING OPERATING STRATEGIES

There are other local and statewide organizations that are working to control and reverse the opioid epidemic. There are initiatives for clean syringe exchange programs to prevent communicable diseases, such as HIV, Hepatitis B and C, supported by the Olive Branch ministries[36]. Some programs such as LEAD (Law Enforcement Assisted Diversion), recently passed by the New Hanover Law Enforcement, aims to move prescription drug misuse from being considered a criminal justice issue to being a health issue. Under the program, people with drug problems who turn themselves in and report their addiction problems can get amnesty and be enrolled in programs where they are treated for their addiction[37]. Other programs are geared towards directly preventing lethal overdoses by making naloxone, widely available to patients, their family members and the law enforcement agents by dispensing standing orders to provide naloxone. These programs have been supported and advocated for by the NC Harm Reduction Coalition and Recovery Communities of North Carolina, which are valuable resources for communities dealing with drug misuse[38, 39].

Additionally, efforts are underway to improve our care delivery system to facilitate care coordination. With their expertise in medication management, accessibility in the community, and established relationships with primary care physicians, pharmacists can play a crucial role in opioid management for acute and chronic pain to reduce misuse. This is being enabled by the Community Pharmacy Enhanced Services Network (CPESN)[40]. 250 plus pharmacies in North Carolina (Figure 1) are providing medication management services for patients with chronic conditions. Through CPESN USA, the network is growing where more than 30 networks have been created across the U.S. Expanding enhanced services around chronic pain management and opioid medication assistance treatment programs could facilitate appropriate opioid prescribing, dispensing, educating and monitoring through team-based care activities with primary care physicians.

Jon Easter, Director, UNC Center for Medication Optimization through Practice & Policy

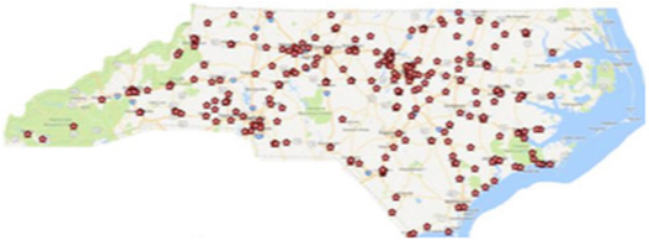


Figure 1: Community Pharmacy Enhanced Services Network in North Carolina

There are important initiatives at the health system level as well. The North Carolina Healthcare Association (NCHA), is working to build a framework for hospitals across the state to align their work. In collaboration with the NC Department of Health and Human Services, NCHA has formed the Coalition for Model Opioids Practices in Health Systems which includes representatives from all 130 hospitals in NC. They are working to develop and spread best practices and tools to address the opioid crisis[41].

As North Carolina communities continue to face the growing challenges presented by the opioid epidemic, health systems are striving to adopt an ecosystem approach to reduce opioid misuse, abuse, and overdose deaths. As such, the Coalition for Model Opioids Practices in Health Systems represents a partnership between the North Carolina Healthcare Association and the North Carolina Department of Health and Human Services[41]. The coalition has 3 working groups, including Prevention and Safe Pain Management, Health System Response, and Healthcare Worker Diversion Efforts, that help to frame the areas of focus that North Carolina health systems must prioritize as they develop best practices and tools to combat the ongoing crisis. Coalition members include representatives from 130 hospitals in North Carolina, professional societies, and government agencies that are working to address the epidemic at a system level. Many provide organizational leadership around their opioid efforts with a focus on communication across sectors to maximize resources and avoid duplication of efforts.

From what we have seen, we have great confidence in our health systems' efforts to tackle unsafe prescribing and reduce prescription drug abuse. When conducting a review of current health system practices, key themes emerged. First, all are developing documentation tools and implementing changes to ensure compliance with legislation such as the STOP Act. Second, formalized education and opioid safety committees within health systems to centralize the processes of care have begun. As we continue to work on this issue, it is critical that state and local governments, hospitals and health systems, insurers, and individual providers must continue to collaborate to align and improve strategies to further reduce unsafe or unnecessary prescribing, make OUD (Opioid Use Disorder) treatment readily available and affordable, and change community attitudes towards prescription and illicit opioids.

Jai Kumar, MPH, Director of Planning and Development, North Carolina Healthcare Association

On the national level, an effort by the American Medical Association is underway, pursuing policy changes, among others, related to improving coverage and reimbursement for medications used to treat opioid addiction. In addition, there is a concerted campaign to educate clinicians on the appropriate utilization of opioids as well as currently underutilized treatments for opioid addiction[42].

Digital Health Strategies

As discussed earlier, there are many factors impeding the reversal of the epidemic of opioid addiction, particularly in the hard-hit rural regions. Besides societal factors, there are major issues with adequate healthcare delivery and access. At DHIT, we believe that there are tremendous opportunities for digital health technologies on multiple levels to assist and complement community-driven efforts in order to alleviate the crisis. In fact, the federal government addressed the lack of treatment services in rural areas and outlined changes to CMS reimbursement policies. The President's Commission on Combating Drug Addiction and the Opioid Crisis recommends allowing treatment via telemedicine[3].

As rural areas are most affected by the opioid crisis, telemedicine would be a logical answer. Unfortunately, 23.4 million Americans live in rural areas and lack broadband coverage[43]. Furthermore, the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 ("Ryan Haight Act") requires that a practitioner conduct at least one in-person medical evaluation of the patient before remote prescribing any controlled substances (44). While the Ryan Haight Act was aimed at the Internet "pill mills," the unintended consequence is that patients cannot seek care from legitimate telemedicine providers who engage in remote prescribing.

There is good news on the horizon though. Microsoft is taking the lead in reducing the broadband gap with a goal of eliminating it entirely by 2022. Meanwhile, as implementation continues, Health IT Now ("HITN") has formed. HITN is a broad-based coalition of different constituents focusing on improving patient outcomes through technology. The members of HITN carry enough weight in the healthcare delivery system to get Congress to take notice. Some members are McKesson, National Council for Prescription Drug Programs, Centerstone, IBM, Oracle, and Walgreens. In January 2018, HITN announced the launch of its Opioid Safety Alliance.

In testifying in front of Congress on January 30, the Opioid Safety Alliance focused on several reforms, including:

DATA SHARING

- One of the problems with combating opioid abuse is the lack of substance abuse information providers can access. Incredibly, record sharing requirements under federal law restrict access to substance abuse patient records. While still maintaining HIPAA, the Alliance requests that Congress act to ensure providers have a complete medical history;
- Information should flow to providers and pharmacists that is easily accessible, secure, and real-time so much so that a patient could be prevented from filling a prescription across state lines;

VIRTUAL CARE

- As noted in this paper, there are several digital health solutions available. Congress should provide reimbursement for those technologies.

Additionally, the Telemental Health Special Interest Group ("SIG") for the American Telemedicine Association has sent the Drug Enforcement Agency ("DEA") suggestions for improving the Ryan Haight Act to allow providers to prescribe controlled substances via telemedicine while still maintaining the spirit of the Act. Discussions between the DEA and the SIG continue, with the opioid crisis spurring additional urgency to make comprehensive changes.

Telemedicine and health IT is the logical answer to this crisis and there are many efforts abound to ensure that it can be used safely and effectively.

Tania S. Malik, J.D., Chair-elect of the Telemental Health Special Interest Group for the American Telemedicine Association

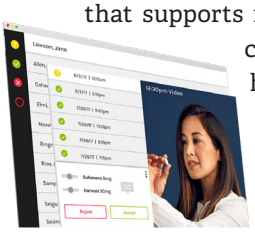
To specifically address veterans' healthcare needs, the senate passed the Veterans in E-Health and Telemedicine Support Act of 2017 (VETS Act) with the goal of expanding the VA's telehealth program. The VETS Act would allow VA providers cross state lines to practice medicine[45]. Considering that two of the four hardest hit cities in North Carolina have a large military presence, there is a sense of urgency to adopt new technologies to confront the health needs of veterans. Veterans live in smaller cities and rural areas close to military bases and this Act, which still has to be signed into law, has been designed with those veterans in mind. Compared to the civilian population, they suffer at higher rates from physical injuries and from mental health disorders such as post-traumatic stress, traumatic brain injury and substance addiction, which, if left untreated, can lead to suicide.

Last December, the DHHS sponsored a code-a-thon seeking the help of health innovators to address the opioid crisis on three levels, namely prevention, tracking, and usage[46]. In the prevention category, the Visionist Inc. team came on top with a program called "Take Back America", designed to look at the need for opioid pill-drop programs at pharmacies. Meanwhile, the Origami Innovations team's solution is a real-time tracking model for overdoses. This would help healthcare providers in the community to apportion resources where they are urgently needed. Another team called Opioid Prescriber Awareness Tool (OPAT) worked on a device that would help clinicians be aware of their opioid prescription patterns compared to their peers with the help of a visual presentation.

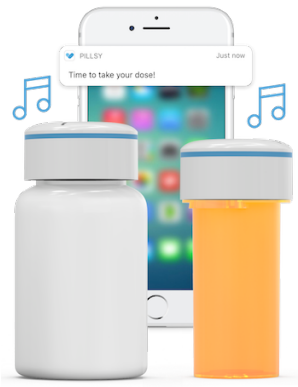
Though most are still in their early stages, there are already multiple digital health solutions available that could be used to intervene in the opioid crisis. For our purpose, we focused on the following areas below and present a few of the technologies. The list is not meant to be exhaustive.

I. Doctor-Patient level intervention to track adherence to medication and to prevent misuse or overdosing:

- **OpiSafe** is a web and app-based tool for providers to prescribe and monitor opioids. It performs risk stratification on individual patients on the basis of dosing ranges, pain and function scores, opioid misuse risk scores, and automated *Prescription Drug Monitoring Program* (PDMP) checks. It also works as a patient engagement tool that prompts patients to report on how they are feeling and if and how much medication they have taken in the last 24 hours[47].



- **emocha Mobile Health** has a HIPAA-compliant mobile application that supports medication adherence with two-way communication between patient and provider. With the help of the *Directly Observed Therapy* tool, the patient takes a video of herself when taking the medication. The patient can report any adverse effects and the provider is alerted if medication is missed, i.e. methadone. The app has shown in clinical studies an adherence rate of over 90%[48].

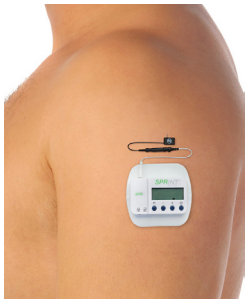


- Smart pill bottles such as **Pillsy**, using a smartphone or tablet app, automatically track when and how many pills have been taken out of the bottle. It also has notification features that can send reminders or alerts to family or care team members if the incorrect number of tablets have been taken out[49]. **Adhere Tech's** Smart Wireless Pill Bottles, iRx-Reminder's iLidRx and **Shark Dreams'** LIVIT device work in similar fashions to monitor use and increase adherence to medication[50-52].

- Recently, the FDA has approved **Abilify MyCite**, a pill that has an inserted sensor. Once the pill is ingested, the sensor sends signals to a wearable patch which transfers the information to a mobile app. Not only can the patient track his/her medication usage, but also their physician and caregiver(s). The technology is made by Proteus Digital Health. Abilify MyCite, produced by Otsuka Pharmaceutical Company, is approved for psychiatric diseases. It is conceivable that in the near future this kind of technology would be approved for other conditions as well[53].

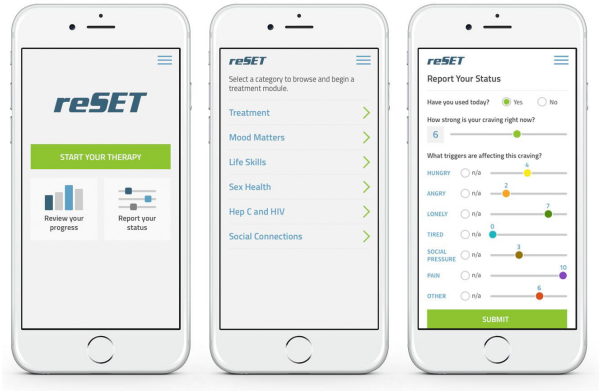
II. Patient-level intervention to manage pain and withdrawal symptoms. Many wearables and device manufacturers in the digital health space are focusing on pain management. There are variations of solutions based on the principle that stimulating nerve endings will reduce pain. Some use implants and others stimulate the nerves using a wraparound as described below. Other wearables can monitor vitals and activity level of the individual to track the pain.

- **Quell** is an FDA-approved drug-free wearable pain-relief technology. The wearable, a cuff, is worn on the calf, regardless of where the actual pain is located, and sends high-frequency currents to stimulate the nerves with enough intensity as to trigger the body's response to produce pain blockers. The relief is felt all over the body. There is also an optional accompanying mobile app for controlling and tracking therapy and sleep (54).
- **SPR Therapeutics** has made a pain management device with the FDA approved *Sprint Peripheral Nerve Stimulation* (PNS) System. The tiny wire that stimulates nerve endings is placed through the skin in an outpatient procedure. The PNS is kept for two weeks. In a small clinical study using PNS, patients who experienced moderate-to-severe post-amputation pain, have reported upward of 70% of pain relief four weeks after the two-week treatment (55). Another company working on disrupting chronic pain is **Neuros Medical Inc.** with their Altius system. It has an implantable generator along with rechargeable batteries that prevent nerve pain signals from reaching the brain (56).

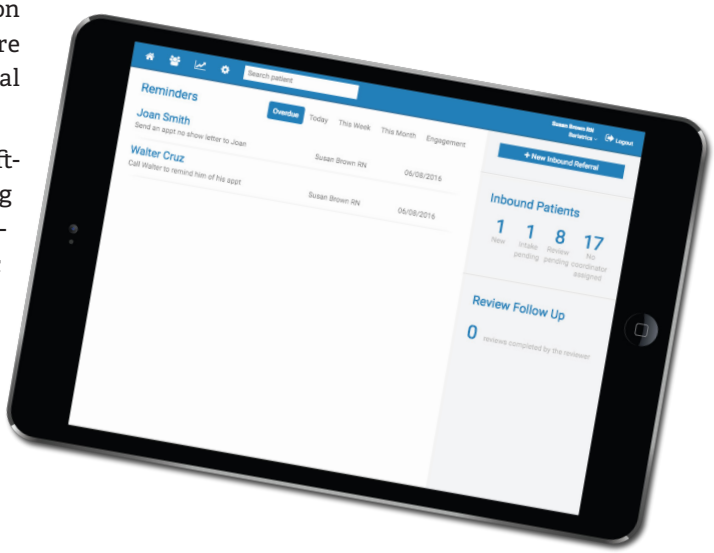


https://www.quellrelief.com/wp-content/uploads/2016/06/Quell_Woman_Walking.jpg
https://www.sprtherapeutics.com/physicians/

III. Rehab/post-rehab interventions to adhere to treatment and prevent relapse. It would be essential to have immediate access to available resources in the community at the time of cravings/relapse, access to a provider-on-call via video conferencing, or to a support group similar to Alcoholics Anonymous. Recently, there has been a surge of digital health technologies addressing problems of chronic care coordination which we think would be useful here as well. Using apps containing modules with relaxation techniques either through meditation or mindfulness-based stress-reduction techniques would be valuable add-ons.



- **Pear Therapeutics' reSET®**, is a digital prescription-based therapy that is to be used along with standard outpatient treatment for mental disorders. It has a patient-facing mobile application and a clinician-facing web interface. In clinical trials, use of reSET along with minimal face-to-face counseling has resulted in higher treatment retention than the standard intensive face-to-face counseling. There are distinct reSET modules available for different mental disorders, including one specifically for opioid abuse[57].
- **Cordata Healthcare Innovations** is a provider of a software application for effective patient management using patient-focused, nurse navigation models. They offer solutions for multiple conditions including one for chronic pain. It contains a patient's comprehensive care history and care plan involving the entire care team members. App features include patient engagement, coordination reminders, and custom intake to identify patients with mental health issues that need to be considered[58].



https://peartherapeutics.com/reset/
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Conclusion

Combating an issue as complex as opioid addiction will require an ecosystem approach including strong local community involvement, a transformation of traditional healthcare systems, and effective commercialization of novel and real-world validated technological innovations in the digital space. Currently, many communities in NC are actively working to help individuals in their neighborhoods. Communities have a very important role to play in disease prevention, educating the public on their health needs and providing moral as well as care support. There is also a need for new potent and non-addictive drugs to manage acute and chronic pain. Finally, we must close the gap in healthcare delivery and access, particularly in rural areas.

Although many of the current initiatives represent long-term solutions due to the lengthy process of drug development, building sufficient medical facilities, and training medical staff, there are several options that can produce accelerated outcomes. Specifically, we can place additional and significant emphasis on the intersection and interaction between care provider and patient/consumer, which is where Digital Health solutions have the potential to produce maximum positive impact. Properly validated digital health technologies such as telemedicine, integrated care management, behavioral management, and precision health will be invaluable tools to fill in the gaps of the current healthcare delivery system on multiple levels as shown in this paper.

Such approaches and solutions offer a means of engaging and empowering the individual to take charge of his or her own health in a very direct and personal way. Moreover, use of digital technologies will provide real-world health and behavioral data that can in turn be used to further develop targeted therapies and interventions. Last, but not least, considering the billions of dollars the U.S. spends on healthcare, we believe innovative digital health technologies have the potential to significantly bend this cost curve, save lives, and effectively combat this burgeoning crisis.

> "Let's get real and put some meaningful context on this crisis, everyone: **More than 100 people die per day** from the Opioid epidemic in the U.S. alone, and some prediction models forecast that daily death toll to reach 250. **That is like a commercial airplane crashing every day.** If a plane crashed today, again tomorrow, and then again the next day, the U.S. government would halt all commercial flights and direct all resources to identify and resolve this issue before a single flight resumes."
>
> **Don Turner, Chairman, DHIT Global**

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