

The Evolution of US Policy Responses to the Opioid Epidemic

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Introduction

The 'opioid epidemic' in the US is the most recent drug-abuse challenge from the misuse of prescription medicines or the use of illicit drugs. It is a particularly difficult challenge because thousands of patients benefit from the prescription pain killers that originally fuelled the crisis. Ceasing production and use of such medications, then, is not the right answer. But the crisis has recently entered a more lethal phase, one that involves the use of illicit synthetic opioids which are both more addictive and more deadly.

This lecture is divided into three sections. The first describes the characteristics of the opioid abuse problem in the US. A crucial point here is that the data needed as the basis for decision making are incomplete, at best. The second section focuses on policy responses, in particular how treatment has been affected. The final section discusses 'supply-side' interventions, which have largely been discredited by the failed War on Drugs but now may need to be reconsidered.

Defining the US Opioid Problem

Figure 1 shows the trend in mortality for opioid poisoning in the US over the past two decades. The green line is the trend in mortality from poisoning with any opioid. If this line was extended back to 1989, it would be an almost perfect exponential growth curve,

expanding at an average of just over nine percent a year for several decades, then faster in recent years. This graph also shows death by type of opioid. The purple line is prescription opioids, the orange is heroin, and the black line is death from synthetic opioids, fentanyl in particular.

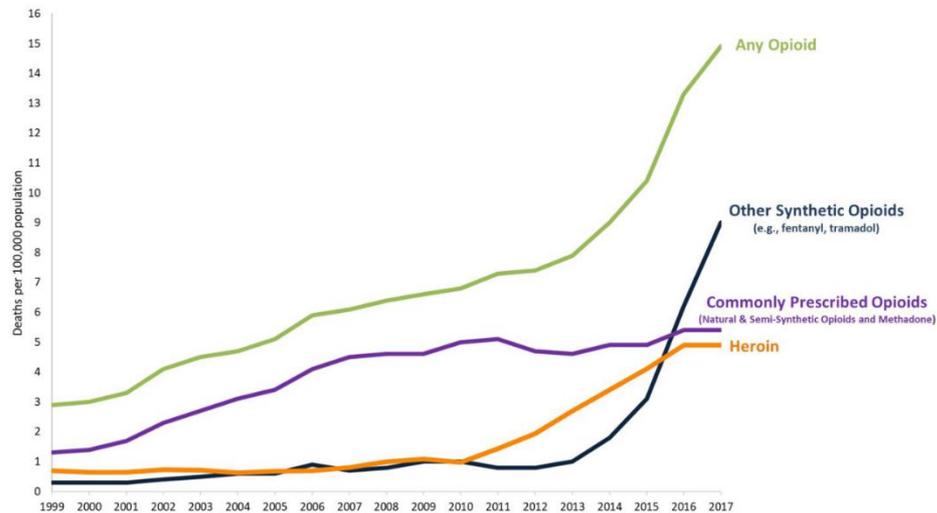


FIGURE 1. OVERDOSE DEATH RATES INVOLVING OPIOIDS, BY TYPE, UNITED STATES, 2000-17

Source: CDC/NCHS (2018)

As Figure 1 shows, prescription opioid overdoses were responsible for most of the growth in mortality at the outset, but fentanyl has been the worst killer more recently. In 2000-01, 100 percent of the increase in mortality was from prescription opioids; today, all of the increase in mortality is from fentanyl. Part of the shift to fentanyl was an unintended consequence of a measure intended to reduce opioid misuse: a so-called abuse-deterrent version of oxycodone. That created a demand for heroin and synthetic drugs, which is when fentanyl use rose sharply.

Reports in the news media suggest that the epidemic has become extraordinarily widespread in the US, no longer confined to a small minority, most of whom live in poverty and are part of an ethnic minority. To some extent this is true. With respect to ethnic composition, Native Americans, African-Americans and low-income white people are more likely to be affected than Latinos or Asians. Over half the people who have opioid use disorder (OUD) have incomes below 250 percent of the US poverty line (now \$12,490 a year per person). The highest risk age group is 18 to 29; those with a high school education or less also are more at risk. Opioid addiction still is largely a disease of lower income, less fortunate people.

Such basic demographic and socio-economic data offer little guidance for policy decisions. Resource allocation requires understanding where the harm originates. For the opioid epidemic, this means distinguishing between people who have OUD that is likely to be affected by treatment and those who are unfortunate casual users. Treatment can be very effective in stemming harm for those with OUD, but it cannot prevent deaths from casual use. For the latter, investment should focus on prevention and harm reduction such as overdose reversal measures. Unfortunately, our data at this point provide insufficient detail to separate one type of user from another.

The problem of reliable data is illustrated by the set of results in Figure 2, based on the largest national survey used to track the epidemic, the National Household Survey on Drug Use and Health. Data are collected continuously for this survey and include a variety of questions intended to tease out symptoms of mental illness, addiction and other related disorders. The red line in the chart shows an epidemic or a condition where the growth is either flat or slightly downward drifting, but that is implausible given what we know from emergency room records, hospitalisation records, physician visits, arrests and first-responder reports.

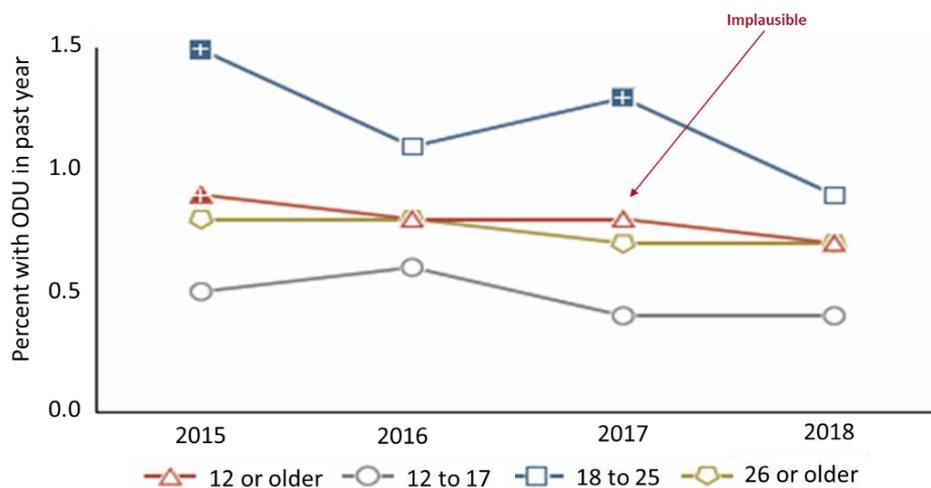


FIGURE 2. OPIOID USE DISORDER IN THE PAST YEAR AMONG PEOPLE AGED 12 OR OLDER: 2015-18

Source: SAMHSA (2019), p. 23

A study done recently in Massachusetts compared the survey results from the National Household Survey to those from a study using a capture/recapture method for estimating the prevalence of the disorder. For 2015, the prevalence rate was estimated at 4.6 percent using a capture/recapture approach—four times the 1.1 percent finding in the National Household Survey (Barocas, et al. 2018). One year and one study is not conclusive, of course, but other research has raised similar questions. For example, in another study, males who had been arrested were given drug tests, both urine and blood. The prevalence rate for heroin use exceeded total population estimates from the National Household Survey by a factor of 3.2 (Kilmer, et al., 2014). To date, every prevalence estimation study has shown numbers that are far larger and trends that are quite different from the National Household Survey. The data deficiencies for policy making are clear just from these few examples.

With respect to treatment for OUD, between 11 and 26 percent of people with OUD obtain some treatment. Of that 11 to 26 percent that are treated, 34 percent receive treatment that is likely to work, i.e. medication-assisted treatment with methadone, buprenorphine or naltrexone in combination with counselling and drug testing. Of that 34 percent, only 40 percent continue treatment long enough to achieve the maximum effect. Calculating that to its conclusion, less than 4 percent of people with OUD are likely to receive treatment that can produce maximum results (Blanco, et al., 2013). This is the treatment challenge we face.

Treatment, of course, rarely begins when OUD first appears. In the US, between four and seven years elapse before treatment is initiated. Part of the reason is supply: in 2016, only 41 percent of the specialty treatment facilities offered medication-assisted treatment,

which is the gold standard, and just under three percent of those offer all three forms of medication (Jones, et al., 2015). That is important because the nature of the addiction means that medication that works for one person may not work as well for another.

Twenty-three percent of the publicly funded facilities in the country, those that serve people who are low income, offer medication-assisted treatment (Knudsen, Abraham and Roman, 2011). It is important that when clinics do offer medication-assisted treatment, 70 percent of patients receive effective treatment. Currently, 14 states in the US lack a treatment facility that offers medication-assisted treatment under the Medicaid programme, which is the health insurance programme that serves the poor (Jones, et al., 2015).

To summarise: less than four percent of people receive appropriate treatment for long enough to achieve maximum results. Treatment typically begins only after years and its success depends in part on whether the treatment facility offers the most effective treatment. Chances are less than 50/50 of receiving the most effective treatment.

Policy Tools and Responses: Focus on Treatment

Three types of policy tools are available, focusing on access to treatment, ensuring the supply and quality of treatment, and workforce regulation to promote medication-assisted treatment.

Medicaid expansion and the so-called behavioural health parity requirement of the Affordable Care Act have both been essential to increasing the treatment purchasing power of the population most likely to suffer from OUD. Medicaid is a federal-state partnership with shared authority and financing that provides health insurance for low-income individuals, children, their parents, the elderly and people with disabilities. It is managed by the states, which have some discretion over coverage and benefit decisions. The Affordable Care Act 'expanded' the definition of eligibility to allow coverage of everyone with incomes no more than 138 percent above the poverty line (currently \$12,490 per person). For various reasons, not every state has opted to expand coverage; 14 have not (although some might in the future). Nevertheless, Medicaid expansion has been extremely important in addressing the opioid epidemic by enhancing access to naloxone, the overdose-reversal drug, and promoting evidence-based medication-assisted treatment. In addition, Medicaid expansion provided funding for the hospitals and the clinics that were bearing most of the cost of OUD treatment, allowing those programmes to continue.

Until recently, under both private insurance and public programmes, substance abuse treatment has been funded largely by grants. These have supported numerous small programmes, often not professionally run, that have not necessarily been grounded in the modern science of addiction. Coverage for addiction treatment recently has become more common for two reasons: first, Medicaid expansion requires addiction treatments be covered and, second, legislation establishing essential benefits and behavioural health parity requires that both private and public insurance cover addiction treatment on the same grounds as general medical care.

What is striking is that almost all the growth in treatment for OUD has come from either general medical clinics or primary care practices, not speciality clinics. Reimbursement for medication-assisted treatment, integrated into primary care practices, is much more likely to produce programmes that offer effective treatment (Maclean and Saloner, 2017).

With respect specifically to aspects of treatment, naloxone is important as an opioid reversal drug. Between 2009 and 2013, prior to Medicaid expansion, the number of

Medicaid-covered naloxone prescriptions was similar in states that later opted to expand Medicaid—4,025 prescriptions, and those that did not—3,800. After expansion, in 2016, expansion states dispensed 38,000 naloxone prescriptions and non-expansion states just 7,000 (Frank and Fry, 2019).

States have done a variety of other things to facilitate the use of naloxone, such as expanding prescribing authority, enacting Good Samaritan laws¹, and facilitating public access to naloxone kits. But what is important now is how the epidemic has changed because of the increased use of fentanyl. People who overdose with fentanyl die more quickly than those who overdose with heroin, and much larger doses of naloxone are needed to reverse fentanyl overdoses. Because immediate treatment for a fentanyl overdose is crucial, it is not enough to equip only emergency responders with naloxone; people otherwise close to a person at risk need access to naloxone as well. Fentanyl complicates matters even further because the standard naloxone kit, which usually contains enough drug to treat between two and five heroin overdoses, can treat only one fentanyl overdose, if it is enough at all.

The other aspect of the response to OUD is medication-assisted treatment. Medicaid expansion has clearly coincided with an increase in buprenorphine maintenance-treatment prescriptions. In 2011, the rate was 36 prescriptions per 1,000 Medicaid enrollees age 12 and older; in 2018 that increased to 124. Per-enrollee prescriptions were far lower in non-expansion states. In states that expanded Medicare in 2014, rates increased from 40 to 138 prescriptions per 1,000 Medicaid enrollees between 2011 and 2018; the increase in non-expansion states was from 16 to 41 (Clemans-Cope, et al., 2019). The differences in the populations of the two set of states may explain some of this; expansion states included those with the largest Medicaid populations and the largest cities.

Improvements as the result of the additional funding available in Medicaid expansion states may have had other positive effects. For example, states that expanded Medicaid and covered methadone as part of the benefit package had lower arrest rates compared to those that did not include methadone in their treatment (MACPAC, 2019). Medicaid states with co-ordinated care arrangements saw higher drug use abstinence rates (Morgenstein, et al., 2009). Medicaid-enrolled OUD patients, when treated with medication-assisted treatment, had a 50 percent lower relapse rate and slightly lower spending levels (Clark, et al., 2011). Note that those spending numbers are very small; the cost is approximately \$8,500 dollars a year to treat someone for OUD.

The third positive effect of additional funding under Medicaid expansion occurred in hospitals. In 2012, two of the states hit hardest by the opioid epidemic, Ohio and West Virginia, had uncompensated care rates for people with OUD in their hospitals of 19 and 22 percent, respectively. By 2016, those rates had fallen in these two Medicaid expansion states to 3.5 percent for Ohio and 2.7 percent for West Virginia. That meant roughly 48 million dollars a year to the bottom line of the hospitals in Ohio, which might otherwise have been pushed to the brink of extinction.

Between 2016 and 2019, the federal government allotted about \$5 billion in grants to states to address the opioid epidemic. But this pales in comparison to the \$5 billion per year that Medicaid expansion by itself added for addiction treatment. Perhaps more importantly, the way states spent the money differed dramatically. States that expanded Medicaid invested in capacity because they had a source of payment for treatment. The

¹ A good Samaritan is someone who renders aid to an ill or injured person in emergency on a voluntary basis. Good Samaritan laws grant immunity to the Good Samaritans, if an error occurs while they render emergency medical care so that they cannot be held legally liable in court.

states that did not expand Medicaid bought services from existing providers, which did little to expand capacity.

The other part of the insurance story is the private side, which covers roughly two-thirds of the US population. The Affordable Care Act's provisions on mental health parity require equal coverage for behavioural health and general medical care. The result has been a dramatic increase in mental health coverage for about 173 million Americans. Utilisation of addiction services among privately insured people has increased and, more importantly, those patients most costly to treat are protected by insurance.

In 2016, Congress enacted the Comprehensive Addiction and Recovery Act. This contained a variety of provisions intended to encourage more physicians to treat opioid disorders. Perhaps more importantly, the law allows nurse practitioners and physician assistants who complete additional training to treat OUD patients as independent providers, a maximum of 30 patients the first year after training, then a maximum of 100 a year. The reason this change is important is that the opioid epidemic has hit rural areas particularly hard, areas where physicians are in short supply. Again, states retain authority for such things as licensing health care professionals; just over half have decided to allow non-physicians a greater role.

The change in the law has meant a near doubling across the board, whether in rural or urban areas, in the capacity to treat people with buprenorphine. Roughly between 30 percent and 40 percent of that increase was due simply to the new role of nurse practitioners and physician assistants, and 40 percent was in the rural areas that needed it most. This includes 286 counties that had previously had no practitioners at all to treat OUD but now have nurse practitioners and physician assistants (Barnett, Lee and Frank, 2019).

With respect to facilities, only about 23 percent of publicly funded treatment facilities offer medication-assisted treatment and less than half of private sector programmes report prescribing such treatment. Eight states lack any public or private facilities that offer at least one form of medication-assisted treatment (Grogan, et al., 2016). The federal government now encourages states to ensure that all facilities, to the extent possible, offer either medication-assisted treatment or offer a referral to some place that does. This effort is in its infancy; the approach relies on three approaches: the accreditation process, the licensing process and health insurance contracts.

Is There a Role for Supply-side Interventions?

A different face of the supply side issue is the War on Drugs, initiated in the early 1970s and intended to reduce the illegal drug trade in the US. It has been largely viewed as a failure. One author appropriately termed it an exercise in the politics of denial. Over the last 20 years, the US has been rebalancing its policy to emphasize demand side policy—treatment, prevention, harm reduction, and so on. Much less effort has been expended to cut off the supply of drugs coming into the country. But the current epidemic, and particularly the role of fentanyl, offers a reason to reconsider that. To put the danger of this drug in perspective, imagine that three grams (less than a teaspoon) of ordinary table salt is pure fentanyl—that is enough to be fatal.

Table 1 shows the economics of fentanyl in its simplest form. The profit incentive is all too clear. Note that virtually none of the fentanyl that is being misused and killing people is diverted legal prescriptions. This is all illicit product.

TABLE 1 ECONOMICS OF FENTANYL

Source: US Drug Enforcement Administration

Drug	Cost per 1 kg to DTO*	Approx kgs produced from original drug procurement	Wholesale price/kg in Massachusetts	Revenue to DTO* from 1 kg
Heroin	\$5,000–\$7,000 (purchased from Colombia)	1 kg	\$80,000	\$80,000
Pure fentanyl (99%)	\$3,300–\$5,000 (purchased from China)	16-24 kg	\$80,000	\$1,280,000–\$1,920,000

*Drug Trafficking Organisation

Fentanyl in the US mostly comes from China along three routes: through Canada and Mexico using the usual supply chain for illegal drugs but, because it is so difficult to detect, also directly to the US using the US postal service or courier services such as Federal Express, UPS or DHL. Fentanyl and its precursors are produced in China mostly by legitimate corporations. China is essentially the biggest producer of active pharmaceutical ingredients in the world: it is home to 5,000 firms that produce active ingredients in China and another 400,000 legitimate chemical companies. All can produce fentanyl and its precursors. Although fentanyl is easy to make, it is difficult to produce in a stable form and just as difficult to dose properly. This means that legitimate producers are best equipped to manufacture it, which in turn provides some hope that regulation can discourage its production.

Anyone wishing to import ready-made fentanyl, or its precursors for use in a lab in, say, New Mexico or in Canada, can do so through legal entities in China. Fentanyl is also easily purchased on the Dark Web, where various suppliers are even rated as to the quality of their product. The Chinese have been aware of this and the topic has been part of trade negotiations. But it would be very difficult for China to keep up with this industry, which is growing at nine percent a year and relies on subtle tweaking of chemicals to stay ahead of any regulation.

This combination of forces suggests that rethinking the supply issue may be a critical component going forward. Theoretically, since the producers of the precursors are businesses, some control could be exerted through regulation and narcotics policies. This would require the cooperation of China in a much more systematic and enthusiastic way than has happened to date.

In Conclusion

We remain totally mired in this epidemic, but the favourable unforeseen consequences - luck rather than planning - of the Affordable Care Act have been important. Medicaid expansion and the mental health parity aspect of that legislation paved the way for as good a response as we can muster at this time. The situations that need the strongest focus at this point are, first, supply policy involving China and, second, accreditation measures for health care facilities that require evidence-based data collection for any patient with OUD. Finally, the most vexing problem, and the one on which we have made

the least progress, is figuring out how to engage people with OUD and get them into effective treatment much sooner.

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From 2009 to 2011, he served as the deputy assistant secretary for planning and evaluation at DHHS directing the office of Disability, Aging and Long-Term Care Policy. From 2013 to 2014, he served as a Special Advisor to the Office of the Secretary at the Department of Health and Human Services, and from 2014 to 2016 he served as Assistant Secretary for Planning and Evaluation in the Department of Health and Human Services.

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