

Milbank in Conversation: The Milbank Quarterly Podcast

Episode 1: What Opioid Prevention Policies Should States Consider?

ALAN COHEN: Hello, and welcome to our debut episode of Milbank in Conversation, a new podcast from the *Milbank Quarterly*. I'm Alan Cohen, editor of the *Quarterly*, and today I am chatting with Amanda Mauri of the University of Michigan and her colleague Rebecca Haffajee of the Rand Corporation.

They are two of the authors of a research Milbank research article that evaluated state opioid misuse prevention policies. As we know, there is an opioid crisis in the United States. Opioids misuse is a major driver of declining life expectancy, and treatment costs are consuming ever-larger portions of both state government budgets and family resources. The need for good policies that prevent opioid misuse has never been greater.

So let me turn to you, Amanda, first. What motivated you and your colleagues to undertake this review of evaluations of state opioid misuse prevention policies?

AMANDA MAURI: Of course. Well, thank you, first of all, for having us. We're really excited to be here today to talk about our paper and opioid misuse policy more generally.

But we were motivated to conduct this review for several reasons. State policymakers are implementing a myriad of interventions to address the severe consequences associated with opioid misuse, and researchers have responded to these state efforts by conducting evaluation to determine their effects, looking at a variety of different types of outcomes.

And other researchers have responded by synthesizing the evidence from these empirical evaluations into review papers that speak to the body of evidence on the effects of state policies.

However, despite the existence of previous reviews, we determined that an updated review would be useful for a couple of reasons. The first is that, as I said, despite the existence of review papers, they emphasized that evidence quality remained quite low, and that more research was needed to establish policy effects.

And then the second reason is that over the past five years, we've seen a dramatic increase in the number of evaluations of state opioid misuse prevention policies. In fact, 41 of the 71 articles included in our review were published between 2016 and 2018.

And so for those two reasons, we determined that an updated review would prove useful to both policymakers and researchers. We hope that policymakers can use our findings to help determine which interventions are associated with some evidence base, and then which policies still remain associated with some uncertainty. And then we hope researchers can use our findings to help direct research resources that aim to study the effects of these policies.

ALAN COHEN: That would certainly be the goal. Thank you. Those are very interesting findings. Rebecca, let me turn to you. Can you expand on the role of state government in prescription drug oversight, and how does that relate to opioid misuse prevention policies?

REBECCA HAFFAJEE: Yeah, sure. So I really view states as the engines and the initiators of a lot of these opioid policies to try to address overprescribing, misuse, all of these kind of root causes—although there are many others—to the opioid crisis and where we are.

States were really the first movers, and so, you know, for example, we had about 1,300 state bills introduced from 2010 to 2016, about 500 of which became laws that were all in this opioid misuse, treatment, et cetera space. We had another about 2,000 bills that have been introduced just in the time since then. So, 2016 to '18.

So you can see, this is an area where states have been extremely active, and they really are well poised for that for a couple of reasons. They have the primary responsibility to protect the public health, well-being and social welfare of their citizens, so that's where they have the public health powers to really step in and regulate here.

They also are responsible for regulating professional practice and medical practice, also, specifically. So to take some examples, in terms of primary prevention of opioid misuse—so that's really preventing the initial exposure to the drug -- we've seen states do a lot of things in terms of limiting the nature of prescribing and even the volume.

And so that, the idea behind that is to think about alternatives to opioids in treating pain, for example, and then limit the excess amounts of opioids that are going into people's medicine cabinets and then can be diverted to other uses.

Then also, states have the authority and have set up systems to monitor controlled substances and shared that information with prescribers and law enforcement—those are called prescription drug monitoring programs—so that we can better see what is going on and know what's going on and prescribe safely.

Finally, they have been very active on the tertiary prevention side. So that's really, I think of that, once a disease is full blown—so, in this case, addiction—how do we manage

the symptoms? How do we prevent really bad harm from happening to those people affected?

So states have been the driving engines behind naloxone access and put enormous amounts of money towards that to reverse overdoses. Also, they have been leaders in treatment access, these medications that treat opioid use disorder, and really making those more widely available, as well. So states have lots of roles here, and they have been exerting those.

ALAN COHEN: Given the lack of high-quality evidence, what conclusions do you feel you can draw about the effects of state policies on prescribing and dispensing opioids?

AMANDA MAURI: Absolutely. So, interestingly there were several policies that appeared to reduce opioid prescribing. So we are able to make some strong conclusions in this area. There were three main policies that stand out. The first are drug supply management policies, and these are policies that limit the quantity and dosage of opioids that can be prescribed, or they impose limitations on the utilization management practices that public and private insurers can apply to different treatments for opioid use disorder.

And evidence in this area suggests that these policies achieve their intended effects of reducing prescribing of the targeted prescription, which in this case were high-risk opioids, while simultaneously increasing access to lower high-risk prescriptions.

The second area, or the second area of interventions that appears to reduce opioid prescribing are robust prescription drug monitoring programs. So PDMPs, as Rebecca said, are electronic databases that track controlled substance prescribing in a state. They can contain a variety of different types of provisions and vary across the country.

But we were particularly interested in—and other researchers have been interested in this, as well—are robust prescription drug monitoring programs. And we define robust PDMPs as PDMPs that contain provisions that are known or hypothesized to increase prescriber use or access of the prescription drug monitoring program. And so an example of such a provision are mandatory access provisions that require prescribers to query the database prior to prescribing an opioid.

And what the literature on these robust PDMPs suggest is that they reduce opioid prescribing both compared to states without PDMPs, and then PDMPs without these robust provisions.

And then the final area of policies that appeared to reduce opioid prescribing are combined interventions.

And there were many articles that fell within this category, but there were several that looked at a series of interventions in Florida in the early 2010s that included law enforcement, pharmaceutical and public health approaches, such as the implementation of a prescription drug monitoring program, as well as a law related to pain management

clinics. And these are policies that impose administrative personnel as well as other requirements on facilities that primarily treat chronic pain.

And what the literature says on the effects of these policies is that they similarly reduce opioid prescribing, but particularly have an effect on high-risk prescribers. So, in sum, our review revealed three intervention groups that reduced opioid prescribing, those being drug supply management policies, robust prescription drug monitoring programs and then combined interventions that include law enforcement, public health and pharmaceutical approaches.

ALAN COHEN: Great. What policies effects did you see when it came to patient behavior and patient health?

AMANDA MAURI: Sure. So, unfortunately, we were unable to synthesize the effects of interventions on patient behavior and patient health-related outcomes for a couple of reasons. And I'll start with patient behavior.

So we were unable to synthesize the evidence in this area largely because very few articles looked at patient behavior-related outcomes. So, just to provide a quick example, one of the interventions included in our review are anti-doctor-shopping laws. And these are policies that prohibit an individual from withholding from a provider that they received a controlled substance from another provider.

And then there was only one study that looked at the patient behavior effects of anti-doctor-shopping laws, and it observed no change in the use of former prescribers.

Moving on patient health-related outcomes, we similarly were unable to synthesize the high-quality evidence in this area, but unlike patient behavior-related outcomes, the reason varied by intervention. So, for example, there were two or fewer studies that evaluated the patient health-related outcomes—of all the interventions that fell within the primary and secondary prevention categories, with the exception of PDMPs.

There were many studies that assessed the patient health effects of PDMPs, but the outcomes varied greatly across the articles. So, for example, some studies looked at fatal and nonfatal overdose. Other studies looked at changes in hospitalization. Other studies looked at drug misuse, drug dependence. Studies varied in terms of the opioids that they were looking at. And so for the reason of diversity in outcomes considered, we were unable to synthesize across all of the different outcomes.

And then finally, tertiary prevention policies, as Rebecca said earlier, is a particular area where we're very interested in understanding the patient health effects of these policies. And while our review revealed growing rigorous evidence assessing the patient health effects of these policies, there remains very few high-quality evaluations. And so this is an area where we do encourage further research, the patient health effects of tertiary prevention policies.

ALAN COHEN: Okay, on that point, where should researchers concentrate their efforts in the future?

AMANDA MAURI: Sure, absolutely. So there are many areas where we encourage researchers to further explore the effects of state opioid misuse prevention policies.

The first area are on the unintended effects of policies that intend to reduce opioid prescribing. And so, as I said earlier, our review revealed three different interventions that reduce opioid prescribing. However, there's also growing evidence suggesting that policies that intend to reduce opioid prescribing may be associated with greater illicit opioid use, as well as greater circumvention opioid use.

And so, for this reason, we highly recommend researchers concentrate their efforts in studying some of these unintended effects on patient behavior and patient health.

The second area where we hope researchers concentrate their efforts, as I just said are on the patient health effects of tertiary prevention policies. And I'll quickly walk through where the evidence currently lies to compel why it's such an important area of future research.

So our review revealed three different interventions that fell within the tertiary prevention category, those being naloxone access laws, Good Samaritan laws and policies affecting opioid addiction treatment.

So, starting with naloxone access laws, naloxone is an opioid antagonist that rapidly reverses opioid overdose, and naloxone access laws increase access to naloxone among individuals who may be in a position to administer naloxone in the event of an overdose.

And interestingly, despite that this type of policy directly targets a patient health outcome, there was only one rigorous evaluation of a naloxone access law included in our review. And so we highly recommend researchers further explore or further expand upon this evidence.

The second intervention included in our review that falls within this tertiary category are Good Samaritan laws. And these are policies that provide legal protections for individuals who contact emergency personnel in the event of an overdose.

And there was one more rigorous evaluation of Good Samaritan laws as compared to naloxone access laws. One looked at hospitalization, and one looked at overdose. And so, for that reason, we couldn't really synthesize the effects of GSL across the different outcomes. And so, similarly to naloxone access laws, this is an area where we really need more research on the patient health effects of these policies.

And then the final intervention type that fell within this category of tertiary prevention policies are policies affecting opioid addiction treatment. And this is a very wide care category, all thematically related, because the policy in some way affected treatment for opioid use disorder. So, for example, the policies mandating insurers cover certain treatments for opioid use disorder, changes to public funding for treatments, et cetera.

And interestingly, despite the many different types of state policies that could fall within this category, as well as the relatively high number of articles that assessed policies affecting opioid addiction treatment, there was also only one rigorous study of these type of policies. So, again, another area where we need some more research on the patient health effects.

ALAN COHEN: Well, that certainly is a lot of food for thought for researchers.

ALAN COHEN: Based on your review, which policies should state policymakers pursue first?

AMANDA MAURI: Sure. So, I'll start by saying there is no one-size-fits-all solution to address the opioid crisis across the country. State policymakers really need to look at the epidemic in their state and figure out what policy solutions are most appropriate for their particular population and their jurisdiction.

And then secondly, state policy makers will likely have to implement several interventions to address the myriad of outcomes that they may want to improve upon that relate to opioid misuse.

That being said, as I said earlier, there are several policies that appear to reduce opioid prescribing, those being drug supply management policies, robust prescription drug monitoring programs and policies—and these combined interventions that include law enforcement, pharmaceutical and public health approaches.

However, as we said in discussing where we need future research, if state policymakers implement these policies, we highly recommend they monitor some of the potential unintended effects.

In regards to patient health and patient behavior-related outcomes, our review provides a little less clarity on which interventions are going to improve upon these outcomes. And so, as I said earlier, this is an area where we really hope researchers concentrate their efforts to provide some more insights to policymakers.

And Rebecca, I'm not sure if you have an additional insights here.

REBECCA HAFFAJEE: It's not a one-size-fits-all approach. And so a policy that works in one jurisdiction may not be as apposite or appropriate for another jurisdiction.

So, to take a concrete example, you know, our review showed that many of these policies, particularly robust prescription drug buying programs, drug supply management techniques, do reduce prescribing and dispensing of opioids, including that which is high risk. But some places don't need to do that anymore, and they've made significant progress there. New England states come to mind.

There are other areas where they have not budged the needle quite as much or, you know, or their cresting of prescribing happened a bit later, and they have not

implemented quite as many policies. Some of the Midwest and Southwest states come to mind there.

So that's where we say it sort of depends on the state, and it depends on their goal and what they need to do to mitigate the harms of their opioid crisis at this stage.

We need to be thinking about not just the opioid crisis, but how it fits into the larger drug policy landscape and the drug ecosystem, because we are seeing harmful effects of a number of other drugs right now, including benzodiazepines, methamphetamines and cocaine. The rates of overdoses with these drugs are increasing rapidly.

We also know that when they're co-used with opioids, that's a particular harm. And we don't really yet know what the relationship between those drugs are and what policies might help address that. So I think we need more research there, and policymakers need to have that on their radar, as well.

And then both, I think, need to think more about a lot of these evaluations can look at, you know, policies discretely, more maybe even does a state have a policy, or what are its features? But what they rarely do is think about the contextual factors that might affect success.

So, by that, I mean, you know, for a prescription drug monitoring program, for example, is there adequate funding for the program? What is the staffing for that program? How much outreach and education was done to prescribers? How much buy-in do they have in the programs?

Those things all seem to, in some states, have a big effect on how much the program is used, what its effects are. But we don't have a good way of measuring that and really thinking about some of those factors. So it's very time-intensive and laborious. So, you know, thinking about how do we better get a handle on that?

And maybe qualitative methods are the way to go, which we didn't really cover too much in our study. But thinking about, what are some of those contextual factors that might affect whether a policy is successful or not in achieving its intended outcomes? And then also, thinking about what are going to be the scaleup costs, as well, implementing these policies. Like those are things that are real-world issues that often are not tackled in an academic study, but need to be considered.

ALAN COHEN: You both have made compelling arguments for more research in this area, especially evaluations of state-level policies. But let me ask this question. Is there a role for the federal government here?

REBECCA HAFFAJEE: Absolutely. The federal government -- it can complement well what the states are doing. In terms of the opioid area, I've thought of the federal government as a little later to the table in terms of actually aggressively implementing policies. But then in recent years, they've been doing more and more. But I think there is still room for growth.

So, you know, a couple of concrete examples. You know, the Controlled Substances Act is the main piece of legislation that regulates our controlled substances flow and monitoring and all of that in our country.

I think, you know, the opioid litigation is highlighting a number of ways in which the Drug Enforcement Agency perhaps was not enforcing that law as aggressively as it could have, and some actors who may not have been in compliance with that law. So I think, you know, further enforcement of that can help particularly for prescription opioids, you know, where the flow is, where there might be oversupply, those sorts of issues.

The federal government also has played a leading role and needs to continue to do so in funding. They have put more aggregate money in the states—they're funneling money to the states, for example, through the state opioid targeted response grants, and then the states have flexibility with what to do with that money. But a lot of the dollars are coming from the federal government, and so that needs to continue.

But, just for a frame of reference, you know, the federal government has now put, you know, just starting to be tens of billions of dollars into this crisis. But, you know, estimates suggest that it's costing our country about \$100 billion a year, or about a trillion since 2001. So the amount of investments is not on the same plane as the costs of the crisis, and I've always advocated for much more funding for the federal government here.

They also are a leader in payment and incentives for the workforce, particularly on addiction treatment, and continue to play a role there. You know, an example might be further incentivizing buprenorphine waivers, reducing restrictions on opioid treatment programs, those sorts of things. That is all regulated at the federal level, and so they have a role there.

And finally, I think, you know, the Food and Drug Administration has played a large role here and has gotten a lot of criticism over the years in terms of too easily approving opioid analgesics, for example. And then also not doing enough to incentivize innovation on the treatment side and keep costs down by having generics on the market, for example. This is for the treatments for opioid use disorder.

So they have made some progress here, for sure. They have now adopted a different framework for reviewing opioid analgesics that is going to use public health endpoints in addition to like the sort of individual patient endpoints in determining approvals.

They're also going to require that opioids are superior to other treatments if they're going to get approved for the analgesics. They've also said they're going to increase their risk evaluation and mitigation system program for certain drugs, some fentanyl-related prescription opioids.

But I think they still could do more and be a little bit more aggressive there, and particularly in encouraging innovation in this area, both in terms of other pain therapies, but also in terms of addiction treatment, to make sure we just have more options on the

market for people. And that could address some of these unintended consequences, as well.

And I guess lastly, I would say I think a place that the federal government really can play a huge role, where the states are a little less situated, is in terms of the illicit market and entry. And they can partner with states, but they really have more levers at their disposal in terms of controlling the flow, the inflow of illicit into our country and really cracking down on manufacturing within our country, as well.

ALAN COHEN: In closing, I'd like to thank you both for sharing your insights with us today, and for your research contribution to the *Milbank Quarterly*. Thank you.

AMANDA MAURI: Thank you.

REBECCA HAFFAJEE: Thank you for having us.