Policy Evaluation of Michigan's Statewide Naloxone Standing Order

Key Informant Interviews and Stakeholder Focus Groups

September 2020
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This evaluation was funded by the Michigan Department of Health and Human Services (MDDHS) Michigan Overdose Data to Action (MODA) program (Agreement #s: E20203597-00 and E20212442-00) with funds from the Centers for Disease Control and Prevention (CDC) Overdose Data to Action (OD2A) grant.

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Executive Summary

The number of people who die from opioid overdose each year is staggering. Naloxone is a medication that can reverse opioid overdoses and save lives. To increase naloxone accessibility, Michigan's legislature instituted a statewide naloxone standing order in 2017. The standing order allows individuals to get naloxone at participating pharmacies without an individual prescription.

As part of the Michigan Overdose Data to Action (MODA) program, the Calvin University Center for Social Research (CSR) was tasked to carry out a policy evaluation of Michigan's statewide naloxone standing order. CSR conducted 11 individual interviews with key informants and five online focus groups with stakeholders from a variety of fields.

Outcomes to measure the success of the standing order

Participants identified many outcomes that would indicate that the standing order was a success. Across the interviews and focus groups, eight recurring success outcomes emerged:

1. Increased pharmacy involvement in the standing order
2. Increased awareness
3. Decreased stigma
4. Increased distribution of naloxone through the standing order
5. Increased per capita rate of people who have naloxone on hand
6. Increased proportion of overdoses that are successfully reversed
7. Decreased per capita opioid overdose death rate
8. Comprehensive and standardized data collection and reporting

Barriers to success

Participants highlighted barriers that prevent the standing order from being maximally successful. The top seven barriers to the standing order's success are:

1. Lack of education and awareness
2. Stigma
3. Cost
4. Overdose factors
5. Lack of naloxone in the community
6. Lack of standardized and centralized data collection and reporting
7. Lack of naloxone distribution channels

Standing order flowchart

Focus group participants gave feedback on a flowchart that illustrates how Michigan's statewide naloxone standing order works. The revised version of the flowchart not only incorporates participants' input, but also includes the eight success outcomes (see Figure 6). The flowchart, coupled with ongoing tracking of the success outcomes through existing data and new evaluation tools, will form the basis of ongoing evaluation of Michigan's statewide naloxone standing order.

Background

Opioids include prescription pain medicines such as oxycodone and hydrocodone, synthetic opioids such as fentanyl, and heroin (National Institute on Drug Abuse, *Opioids*). Common side effects of opioids include sedation, dizziness, and nausea. In the case of an overdose, opioids can greatly slow a person's breathing, leading to death. Naloxone, sold using the brand names of Narcan and Evzio, is an opioid antagonist that counteracts the depression of the central nervous and respiratory systems (National Harm Reduction Coalition). Naloxone can reverse an opioid overdose and save lives.

Even though naloxone can prevent death in the case of an opioid overdose, the opioid overdose death rate has increased dramatically. In 2018, an average of 128 people in the United States died from an opioid overdose each day (National Institute on Drug Abuse, *Opioid Overdose Crisis*). The economic cost of opioid misuse in the United States is estimated to be more than $78.5 billion per year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement (Florence et al., 2016).

In response to the opioid crisis, Michigan's legislature passed a change to the public health code, allowing pharmacies to dispense naloxone without an individual prescription. Thus, Michigan's statewide naloxone standing order went into effect on March 28, 2017.

As part of the Michigan Overdose Data to Action (MODA) program, the Calvin University Center for Social Research (CSR) was tasked to carry out a policy evaluation of Michigan's statewide naloxone standing order. In the first year of the evaluation, CSR conducted 11 individual interviews with key informants and five focus groups with stakeholders from a variety of fields who have experience with the standing order, opioid use disorder, recovery, harm reduction, and other related areas.

Key Informant Interviews

Method

Design

The evaluation team conducted 11 individual interviews in late fall 2019. Each interview lasted 20 – 60 minutes. Most of the interviews were conducted in person, although some were conducted over the phone. There were two interviewers present for each interview; one asked the questions, and the other took notes and created an audio recording of the interview.

Audio recordings were transcribed. The evaluation team reviewed interview notes and transcriptions to identify recurring themes and illustrative quotations for each theme. The interview protocol was reviewed and approved by the Calvin University Institutional Review Board (IRB).

Recruitment

Email invitations to participate in the interviews were sent to a list of key informants identified by Jan Fields, a Program Evaluator for the MODA program. Once a participant signed up for an interview, the evaluation team emailed the list of interview questions to allow the participant to prepare if they wished to do so (see Appendix B: Interview Questions). Participants signed a consent form either via email before phone interviews or at the beginning of in-person interviews (see Appendix A: Interview Consent Form).

Results

Barriers to proper implementation of the policy

We asked the key informants about the barriers they perceived as limiting the proper and full implementation of Michigan's statewide naloxone standing order policy. The three largest barriers were (a) inadequate understanding of the standing order among pharmacists, (b) cost and lack of insurance coverage, and (c) stigma.

Inadequate understanding of the standing order among pharmacists

Several participants explained that pharmacists may not have an adequate understanding of the naloxone standing order; therefore, they are not prepared to use the standing order. This results from a lack of training and guidance on using the standing order as well as lack of clarity in the standing order's language and requirements. The following quotes and paraphrases illustrate this barrier:

> *There is no training for pharmacists.*
>
> *Standing order instructions were not written to be read by pharmacists.*
>
> *If you want someone to use the tool, they should be involved in creating it.*
>
> *A substance use pamphlet should be distributed when patients receive naloxone, but pharmacists don't know where to get that pamphlet. There are no contacts for each region. How is a pharmacy supposed to do their job? Take information, digest, and disseminate. What independent pharmacy is going to do that? You have to become an expert… [There's] not enough time to do that.*
>
> *There could be a clarification document to make the policy more user-friendly—a special document for pharmacists.*

We need a clarification from the lawmakers themselves. If it is from someone else, then it's just interpretation.

Cost and lack of insurance coverage

A second barrier to the proper and full implementation of the standing order policy is the out-of-pocket cost to get naloxone through a pharmacy. In some cases, people may use health insurance to reduce the cost of naloxone. However, some insurance companies either do not cover naloxone through the standing order or have a limit on the number of naloxone doses covered. Even for those with insurance, copays tend to be high and serve as a deterrent to accessing naloxone through the standing order.

Insurance is extremely frustrating. Very few insurances are paying for naloxone even though there is a standing order.

The price of naloxone is a barrier. People don't want to pay for it.

To fix [the standing order] we need to legislate insurance coverage of naloxone. Insurance companies won't do it.

There is no financial assistance for people who cannot afford it.

One problem that needs to be addressed aggressively or legislatively is that insurance companies are classifying people who have received naloxone as high risk, and their insurance rates increase. There should be a legislative restriction on whether insurance companies can do that.

Insurance companies don't want to pay for medication on one person's insurance that is going to be used by someone else.

Stigma

Many individuals have the perception that naloxone enables continued risky behavior involving opioid use. Stigma may dissuade community members from seeking naloxone. Stigma may also cause people who have naloxone on hand to be shamed or discriminated against as a "dope-user" or "drug-seeker." This stigma occurs both in the community and in pharmacies among pharmacists and pharmacy technicians.

I think the most important area of stigma to address is in the public.

There's a ton of misconception about the neurobiology of disease and the fact that people should just be able to quit and all the brain damage can be fixed miraculously. I was horrified to see that there are people working in the state and are paid by Medicaid and work with these clients that have these sorts of toxic beliefs.

One of the barriers to accessibility is [people] actually coming to you as the pharmacist and asking for naloxone.

I think the overall stigma has been reduced in the general public. I think people are definitely more willing to walk into a pharmacy and get the naloxone. Again, it depends on whether they are getting it for free or [if] they are paying for it, but you can see stigma in the fact that there were a lot of leftovers when we were giving out naloxone for free. There was also no instructions or education given to the public except for what was written on the box.

A lot of the practitioners need stigma training along with the actual training.

Outcomes to measure the success of the standing order

Next, we asked the key informants to define what the successful implementation of the policy would look like and how it could be measured. Three of the recurring outcomes that would indicate success were (a) an increase in education and awareness, (b) an increase in naloxone access, and (c) a decrease in the number of opioid overdose deaths.

Increase in education and awareness

Some participants defined the success of the policy as an increase in education and knowledge among pharmacists, patients, and the community at large. Pharmacists must have a good understanding of the standing order, when naloxone should be used, and how to administer it. Pharmacists, in turn, can teach their patients. Participants expressed that far too few people in the general public are aware of naloxone, the standing order, and when and how to use naloxone.

Pharmacists need to receive proper and complete training surrounding the standing order, naloxone use, and how to educate patients who receive naloxone.

Pharmacists are high on the levels of trust, so they are the perfect spokesperson [to educate their patients].

Success revolves around education.

Not enough people know about the standing order.

We must be educating people about what naloxone is.

Training, education, and understanding. The knowledge that this is a broader issue and that law enforcement and first responders are not the only ones that are tackling this problem.

Increase in naloxone access

Some participants stated it is important to know how much naloxone is distributed by pharmacies through the standing order. Distribution should increase the accessibility of naloxone, and greater access should allow people to administer naloxone when an opioid overdose occurs. Other participants expressed that it is important to have many channels of naloxone distribution

in the community. While some people may feel comfortable requesting naloxone at a pharmacy, others may feel more comfortable getting naloxone at a community organization like the Red Project.

> *The purpose is to increase access. The more people with naloxone, the more reversals, and the more lives saved.*
>
> *Ultimately, saving lives is what this is about, but steps towards it is how many prescriptions are being filled.*
>
> *Does having access to naloxone decrease overdose death rates in the community? That's really the question we want to answer.*
>
> *I would define success as there being multiple touchpoints within a community where naloxone can be accessed on demand. With respect to socioeconomic comfort, the Red Project is great, but an East Grand Rapids wife is not going to find herself at the Red Project. It's important to make sure that we're touching all populations and communities.*

Decrease in opioid overdose deaths

As the previous quotes illustrate, participants tended to mention naloxone distribution and access as an important outcome of success because it can lead to fewer opioid overdose deaths. Many participants noted that the ultimate goal of the standing order is to rescue people from an overdose and decrease the number of deaths from opioids.

> *The purpose should be to rescue people. The overall goal is to decrease the number of deaths from opioids. Keep the eye on the ball.*

Unintended consequences

Finally, we asked key informants to reflect on whether there were any unintended or unanticipated consequences of the naloxone standing order. The four most frequently mentioned unintended consequences were (a) stigmatization, (b) enabling risky behavior, (c) disparities, and (d) untreated chronic pain. The first two unintended consequences are related to the standing order itself, while the last two unintended consequences are about more general responses to the opioid crisis.

Stigmatization

Although the standing order is intended to make naloxone more easily accessible, people who seek naloxone through the standing order are at risk of being stigmatized, especially at pharmacies. Some pharmacists may have or express stigma toward those who want or need naloxone, and fear of stigmatization may prevent people from requesting naloxone through the standing order. Participants expressed that stigma could be addressed through enhanced pharmacist education and training.

If a pharmacist doesn't understand [the standing order] and a community member has the courage to ask for naloxone, they get stigmatized.

Pharmacists do not understand harm reduction. They don't have the information.

Pharmacists' stigma is combative: "I don't want those people in my pharmacy."

Discussions in the pharmacy community revolve around whether it is more of a risk to dispense Narcan or to not dispense Narcan.

There was a physician or a pharmacist that went to go get naloxone for himself so that he could be a Good Samaritan and carry it in his car. His health insurance company called him and enhanced his premium because of it. So, the stigma is embedded [in the system].

Enabling risky behavior

Several participants explained that people believe that the standing order enables continued risky behavior among people who use opioids. Some participants expressed this view themselves, whereas other participants acknowledged this belief among others even though they do not personally believe it. A few participants mentioned that distributing drugs in a way that bypasses primary care providers may increase risk.

One risk is to embolden people to use higher and higher doses [of opioids].

But I would tell you from years of experience I have with people who use opioids, they would not conceive of it [the availability of naloxone] at the time they're getting a fix. They think, "I don't care if I die, because I need this." The fact that there may or may not be an antidote does not affect their decision of whether or not to use. It may affect how they use, but not whether they use.

There's always the issue of enabling behavior, and that's somewhat of an issue.

We are seeing [people having] multiple doses of naloxone, whether it's over a day or a period of days, that I think is having a negative impact. People are banking on the magic cure of naloxone, thinking they don't have to call 911 or go to the emergency room and seek medical treatment after an overdose. I think part of the negative impact is that we might be generating almost a cycle of overdose, naloxone, mild withdrawal, use, then back to overdose, back to naloxone, back to mild withdrawal, and so on. We may not see this impact immediately, but down the road do we see an increase in potential deaths or do we see a potential increase in withdrawal issues because of repeated naloxone use?

When it's a standing order and you don't have to talk to your doctor about it—maybe you don't want your doctor to know about your problem with opioids—it could create a risk. By bypassing doctors, drugs are not going through the right channels. Maybe the doctor should be part of the solution.

The primary care provider is the key—taking away from that may have adverse effects.

Disparities

The third unintended consequence noted by participants is not directly related to the naloxone standing order. Instead, it is about the response to the opioid crisis more generally. Specifically, participants noted disparities between the response to the opioid crisis and the response to other substance use crises in the past.

With the crack cocaine epidemic, people leaned on public safety. Now with the opioid crisis, we lean on public health.

A woman I met once said, "Funny, you call it a public health crisis. When my son dealt crack, he was arrested and is still in jail today. It wasn't called an SUD or an illness. It was a crime."

I talk about the fact that addiction doesn't have boundaries, so it doesn't care what color your skin is or what gender you are. Addiction affects all parts of our community. We've heard time and time again that quote on how nobody cared about addiction until it started hitting White people, meaning that there was some racism in our response. Certainly there was [racism] in our response to cocaine in the 80s, and we know that retrospectively and looking back.

Bruce Alexander famously says the opposite of addiction is connectedness. And I think that that's what the public health policy needs to understand [and address].

Untreated chronic pain

The final unintended consequence is also not directly related to the naloxone standing order. Instead, it focuses on the effects of tighter regulations on prescription opiates for people with chronic pain. In particular, people who cannot manage their pain through prescription opiates may turn to non-prescription opioids or other drugs. Furthermore, untreated chronic pain is a risk factor for suicide.

There is the chronic pain piece. A lot of people to whom physicians will no longer prescribe opiates to are not well treated.

I think as a population, as a culture, we feel like we should never be in pain. Pain is there for a reason. There's a reason we prescribe more opiates than in any other country. And so I think a big part of it is that we don't look at alternative medications.

Chronic pain can be more dangerous than opioid addiction. Pain can be the cause of suicide. How many chronic pain patients take their own lives because they can't handle the pain?

Summary

In sum, individual interviews with 11 key informants highlighted potential outcomes to measure the success of the standing order, barriers to the standing order's full success, and unintended consequences of the standing order. To confirm and expand on the ideas expressed by the interviewees, the evaluation team sought additional feedback from a broader group of stakeholders.

Stakeholder Focus Groups

Method

Design

The evaluation team conducted five online focus groups during July 2020. Each focus group had 4 – 9 registered participants. Focus groups took place virtually via Zoom and Miro and lasted between 1.5 – 1.75 hours. The meetings were recorded, and CSR research assistants took notes and compiled the ideas participants wrote in Miro. The focus group protocol was reviewed and approved by the Calvin University Institutional Review Board (IRB).

Recruitment

Email invitations to participate in the online focus groups were sent to people on the Kent County Opioid Taskforce's mailing list as well as other people with whom the evaluation team had connected during the evaluation. These stakeholders included individuals working in healthcare, law enforcement, recovery programs, non-profits, harm reduction, academia, and community programs. Each participant received a $40 gift card.

Once a participant registered, they received an email with instructions for signing up for an account with Miro (an online whiteboarding system), the focus group agenda, and a link to a background survey. The background survey included a consent form to participate in the focus group (see Appendix C: Focus Group Background Survey).

Participants

A total of 29 participants completed the background survey. Participants reported the primary focus of their organization: prevention, intervention, or recovery. As shown in Table 1, nearly half of participants indicated that their organization focused primarily on prevention. Approximately 30% of participants' organizations focused on intervention, and approximately 20% of participants' organizations focused on recovery.

Table 1: Primary focus of focus group participants' organizations

Primary Area of Organizational Focus	*N*	%
Prevention	13	44.8%
Intervention	9	31.0%
Recovery	6	20.7%
No answer	1	3.4%

Next, participants indicated their experience with the standing order through a check-all-that-apply question. All participants who answered this question reported that they were aware of the naloxone standing order. As shown in Table 2, close to half of participants had read the standing order, while 39% understood how it worked, 27% had been trained on it, and 15% had obtained naloxone through it.

Table 2: Focus group participants' experience with the statewide naloxone standing order

Awareness and Experience	*N*	%
Aware of naloxone standing order	26	100.0%
Have read the statewide naloxone standing order	12	46.2%
Understand how the statewide naloxone standing order works	10	38.5%
Have been trained on the naloxone standing order	7	26.9%
Have obtained naloxone through the statewide standing order	4	15.4%

Results

Outcomes to measure the success of the standing order

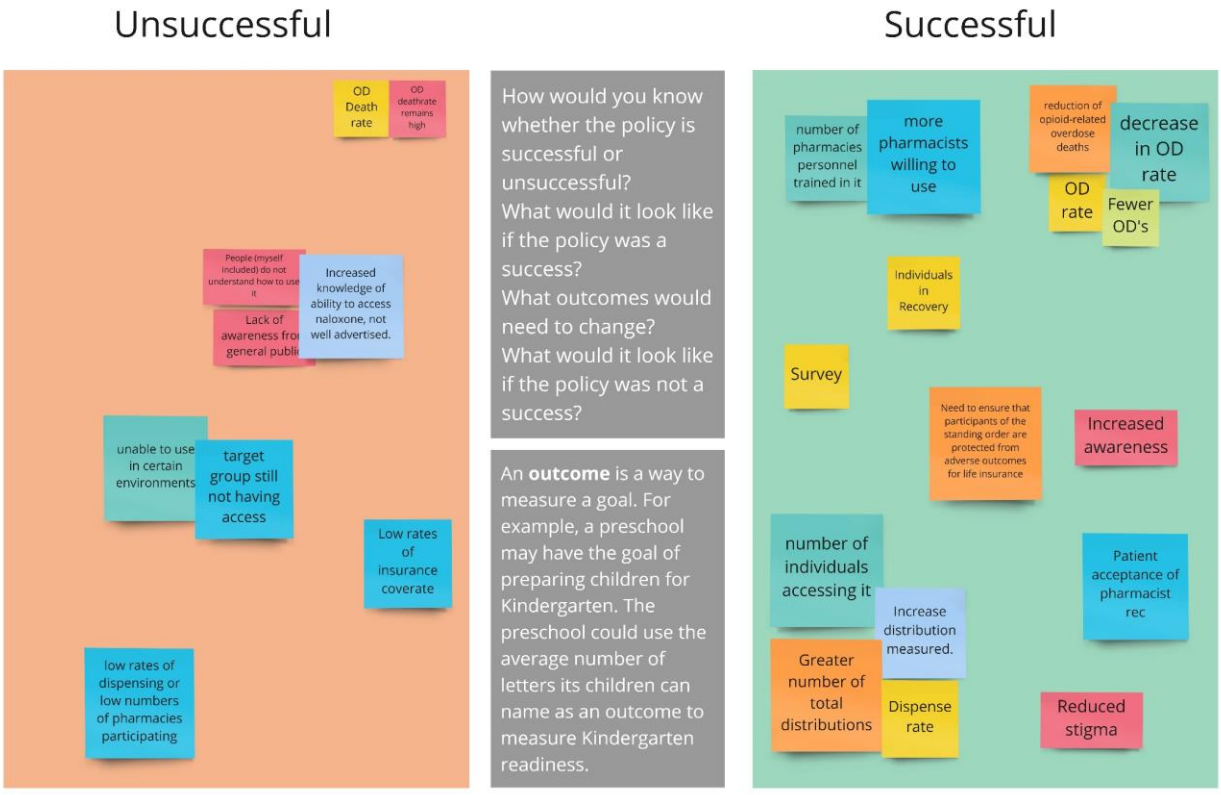
In the first activity of the focus groups, participants were asked:

> *How would you know whether the naloxone standing order policy is successful or unsuccessful? What would it look like if the policy was a success? What statistics, outcomes, or indicators would need to change, and how would they change? What would it look like if the policy was not a success?*

Participants recorded their ideas on an online Miro whiteboard. Each participant used the same color of sticky notes throughout the focus group. They recorded one idea per sticky note, then dragged the sticky note to one or the other side of the Miro board to indicate whether the outcome would indicate that the standing order has been unsuccessful or successful.

After participants brainstormed outcomes individually, the focus group facilitator called on participants to share their ideas. While participants shared their ideas, other participants could add new sticky notes or create affinity groups of similar ideas by dragging sticky notes into groups representing similar ideas. Through this process, participants in each focus group identified seven or eight outcomes that could be used to assess the successfulness of the standing order. An example of a completed whiteboard for this activity is shown in Figure 1.

Figure 1: Example Miro whiteboard for outcomes brainstorm activity



After all focus groups were complete, the evaluation team compiled the sticky notes generated by participants from all five focus groups into one list. In all, participants generated 94 sticky notes listing potential outcomes. Potential outcomes were reviewed and coded into categories, yielding eight outcomes

that were listed by multiple participants across focus groups. These outcomes are listed in Table 3, followed by a more detailed description of each outcome.

Table 3: Outcomes indicating that the standing order is a success

*	*Outcome*	*N*	%
1	Increased pharmacy involvement in the standing order	11	11.7%
2	Increased pharmacist awareness and decreased pharmacist stigma	6	6.4%
3	Increased public awareness and decreased public stigma	10	10.7%
4	Increased distribution of naloxone through the standing order	14	14.9%
5	Increased per capita rate of people who have naloxone on hand	6	6.4%
6	Increased proportion of overdoses that are successfully reversed	4	4.3%
7	Decreased per capita opioid overdose death rate	24	25.5%
8	Comprehensive and standardized data collection and reporting	4	4.3%
	Other ideas	11	11.7%

* Indicates success outcome number on revised flowchart (see Figure 6)

Increased pharmacy involvement in the standing order

Pharmacies and pharmacists play a key role in implementing the naloxone standing order. Therefore, increasing pharmacy involvement is an important outcome. Pharmacy involvement includes enrolling pharmacies to distribute naloxone through the standing order; training pharmacists about the standing order, opioid use disorder and related topics; and, ultimately, having pharmacists recommend that patients receive naloxone through the standing order when appropriate. In these ways, increased pharmacy involvement would lead to greater accessibility of naloxone in the community.

Increased pharmacist awareness and decreased pharmacist stigma

Participants noted that increasing awareness and decreasing stigma among pharmacists is an important indicator of success. Pharmacists need to understand the standing order and when they should recommend naloxone to a patient. Further, they need to understand OD symptoms and how to use naloxone so they can share their knowledge with patients who receive naloxone. Finally, people may avoid asking for naloxone if they think they may be stigmatized by pharmacy staff.

Increased public awareness and decreased public stigma

Similarly, the public needs to know about naloxone, the standing order, and when and how to administer naloxone. Even if people are aware of these things, actual or perceived stigma can remain challenging. When combining people's reluctance to request naloxone, pharmacists' lack of understanding or knowledge about the standing order, and having people shamed for carrying/using naloxone, stigma can seem insurmountable. One participant emphasized the role of stigma and shame among people with opioid use disorder, which can discourage them from seeking help of any kind.

Increased distribution of naloxone through the standing order

Pharmacy involvement paves the way for an increase of naloxone distribution through the standing order. The number of naloxone kits distributed through the standing order is expected to be an important contributor of the availability of naloxone in the community.

Increased per capita rate of people who have naloxone on hand

An index of the availability of naloxone in the community is the percentage of the general public who keep naloxone on hand, whether or not they know people who are at a risk of opioid overdose. Participants emphasized that carrying naloxone is not enough—people must also know when and how to administer it.

Increased proportion of opioid overdoses that are successfully reversed

When discussing overdose deaths, some participants stated that it is important to distinguish between the number of overdose deaths in the population and the number of overdoses successfully reversed by using naloxone. An increase in reversals would indicate that naloxone is not only being distributed, it is also being administered successfully. One participant noted that increased education could lower overdose rates, which would also lower the number of overdose reversals. In other words, improvement in one

area (education) could make it appear like another area (reversals) is getting worse when, in reality, the overall situation would have improved.

Decreased per capita opioid overdose death rate

The most frequently mentioned outcome that would indicate the success of the standing order was a decrease in the number of deaths resulting from opioid overdose. One participant noted that although this may seem like the most important outcome, there are many factors at play between getting a naloxone kit from the standing order and avoiding an overdose leading to death. Another participant commented that someone might be using drugs without knowing what kind of drug they are using, much less that naloxone could save their life. They might not carry naloxone even if it is made available to them.

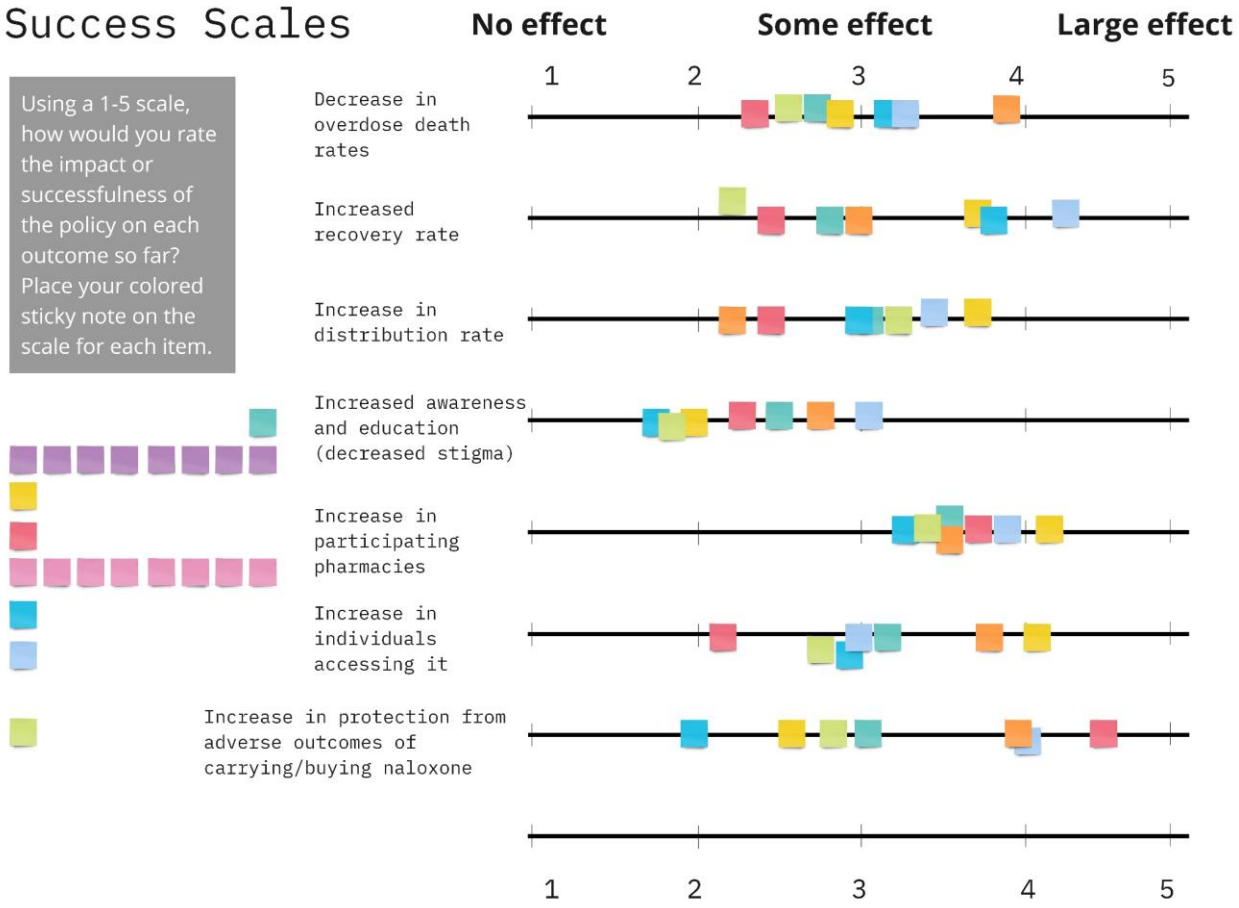
Comprehensive and standardized data collection and reporting

Participants noted that there is inadequate and inconsistent reporting of naloxone distribution, naloxone administration, and overdose reversals. There is no centralized reporting system for law enforcement, first responders, community organizations, and the general public. Moreover, many members of the community are not aware of reporting options that do exist, or they do not provide reports for fear of adverse consequences. Some participants suggested that the health department should serve in the role of collecting confidential data.

Impact ratings of each outcome

In the second focus group activity, participants rated the impact or successfulness of the naloxone standing order on each of the 7 – 8 outcomes their group had identified in the previous activity. The focus group facilitator emphasized that participants were to rate the impact of the policy to date, rather than its potential impact in the future. Participants rated each outcome by placing a small sticky note on a 5-point scale from 1 *(no effect)* to 5 *(large effect).* An example of a completed whiteboard for this activity is shown in Figure 2.

Figure 2: Example Miro whiteboard for outcomes rating activity



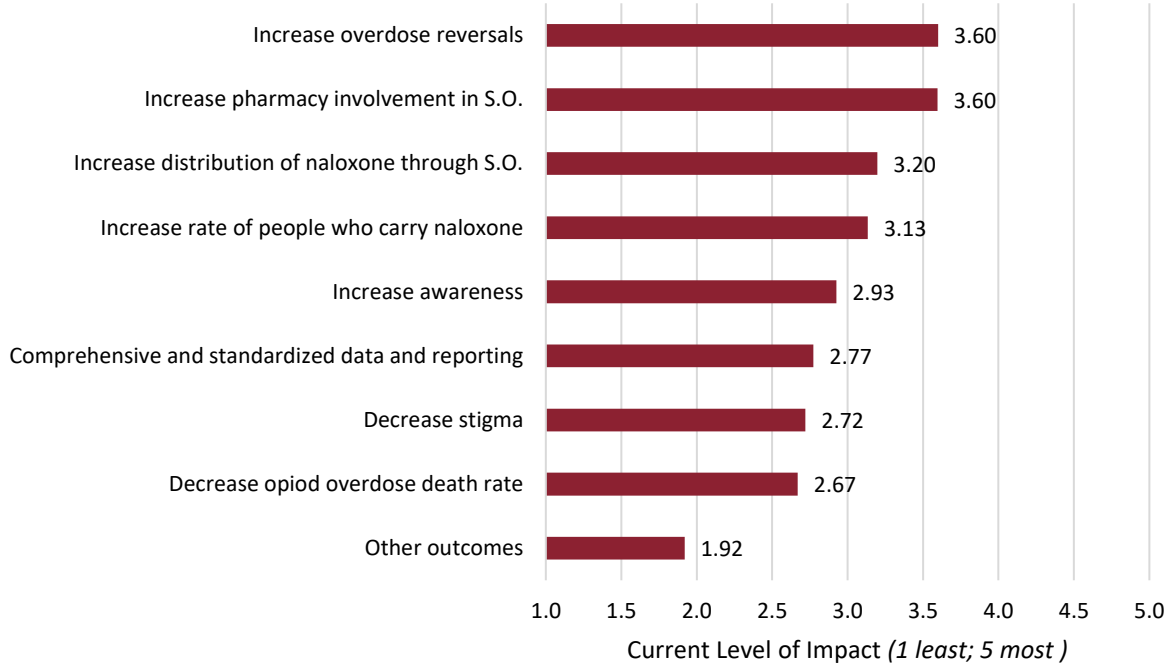
After placing their sticky notes, participants were invited to comment on their own ratings or to ask questions to better understand the ratings of other participants. This discussion highlighted the fact that some participants rated the *potential* impact of the standing order rather than the *actual* impact the standing order has had so far. The evaluation team noted the participants who rated the potential effect and filtered out these participants' ratings from the subsequent analysis.

After the focus groups, the evaluation team assigned each sticky note a score on the 5-point scale. Because participants could place their sticky note anywhere on the scale—not only on whole numbers—a member of the evaluation team measured the distance from the start of the scale to the center of each sticky note. Then, this measurement was converted to the corresponding score on the 5-point scale.

Next, the evaluation team calculated the average impact rating for each of the final eight outcomes identified in the previous activity. These ratings are presented in Figure 3. Outcomes are sorted from strongest to weakest impact

rating. Overdose reversals, pharmacy involvement, and naloxone distribution through the standing order were rated as having been most impacted by the standing order to date. Comprehensive and standardized data collection and reporting, stigma, and overdose death rate were rated as having been least impacted by the standing order to date.

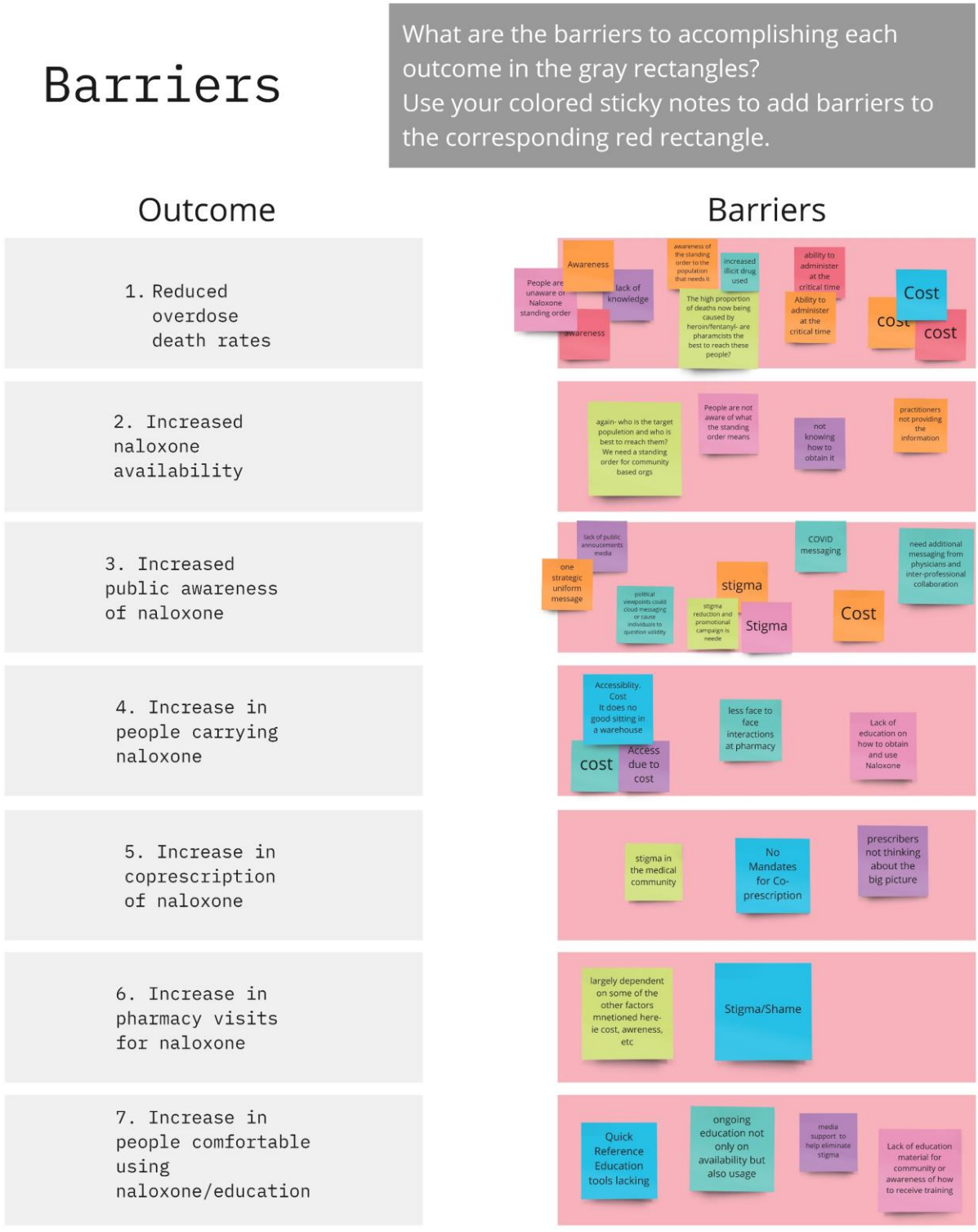
Figure 3: Average impact rating for each outcome



Barriers to success

In the third focus group activity, participants brainstormed barriers for each of the 7 – 8 outcomes their group had identified in the first activity. Participants listed each barrier on a sticky note, then dragged it next to the outcome that the barrier impedes. An example of a completed whiteboard for this activity is shown in Figure 4.

Figure 4: Example Miro whiteboard for barriers activity



After all focus groups were complete, the evaluation team compiled the barriers generated by participants from all five focus groups into one list. In all,

participants generated 155 sticky notes listing barriers that may prevent outcomes from being fully realized. Because many barriers were relevant to multiple outcomes, the barriers were reviewed, coded into categories, and combined to yield a total of seven primary barriers. These barriers to success are listed in Table 4, followed by a more detailed description of each barrier.

Table 4: Barriers to success

Barrier	*N*	%
Lack of education and awareness	60	38.7%
Stigma	29	18.7%
Cost	20	12.9%
Overdose factors	16	10.3%
Lack of naloxone in the community	16	10.3%
Lack of standardized and centralized data collection and reporting	9	5.8%
Lack of naloxone distribution channels	5	3.2%

Lack of education and awareness

Participants noted lack of education and awareness among the general public, pharmacists, and other healthcare providers. Specifically, many community members are not aware of the standing order and do not know when or how to administer naloxone. Participants expressed a need for public service/media announcements or education campaigns. In addition, participants expressed that not all pharmacists received adequate training on the standing order, overdose symptoms, or naloxone administration; therefore, they cannot properly educate people to whom they distribute naloxone. Education and increased awareness could help reduce stigma and shame around opioid and naloxone use.

Stigma

Pharmacists and healthcare providers with stigma toward people who use opioids may be less likely to recommend naloxone to people whose lives may be saved by it. Additionally, people may be hesitant to request naloxone if they sense others' stigma or feel personal shame about their own or other people's use of opioids. People may not feel comfortable carrying naloxone because of what others may think.

Cost

Participants expressed that a major barrier is the out-of-pocket cost of naloxone, both for those with and without medical insurance. Some participants noted a related financial barrier: In some cases, receiving naloxone can increase one's insurance rates or even lead one to being denied life insurance coverage. One participant also mentioned the Health Insurance Portability and Accountability Act (HIPAA) as a barrier, especially to comprehensive data collection and reporting.

Overdose factors

Many contextual factors related to an overdose may prevent optimal outcomes. These factors include the use of more than one drug or different types of opioids leading to an overdose, reluctance to call 911, refusal of EMS transportation and hospitalization, complexities from COVID-19 and quarantine, and a lack of post-reversal care and recovery support.

Lack of naloxone in the community

Although the standing order and other programs are working to increase the presence of naloxone in the community, participants noted that there is not yet enough naloxone—or people trained to administer it—to respond to overdose incidents. In some cases, people may receive one or a few doses of naloxone and use them, leaving none to use in the case of another overdose.

Lack of standardized and centralized data collection and reporting

Participants noted that it is difficult to assess some of the outcomes because there is not a centralized tracking system for naloxone distribution, naloxone administration, successful reversals, etc. Additionally, stigma may keep some people from reporting using systems that do exist. Participants emphasized a need for centralized data collection at the county or state level.

Lack of naloxone distribution channels

Several participants expressed doubt that pharmacies were the best outlet to reach the people who need naloxone the most—people who use or know someone who uses non-prescription opioids. Participants noted that overdose deaths related to prescription opioids use have lessened, while overdose deaths related to non-prescription opioid use remain high. People who use non-prescription opioids may be unlikely to come to a pharmacy for naloxone. Instead, they may feel more comfortable getting naloxone from other places, such as Syringe Services Program (SSPs) like the Red Project. Generally, participants thought that the more channels through which naloxone is distributed, the better. Other naloxone distribution channels participants

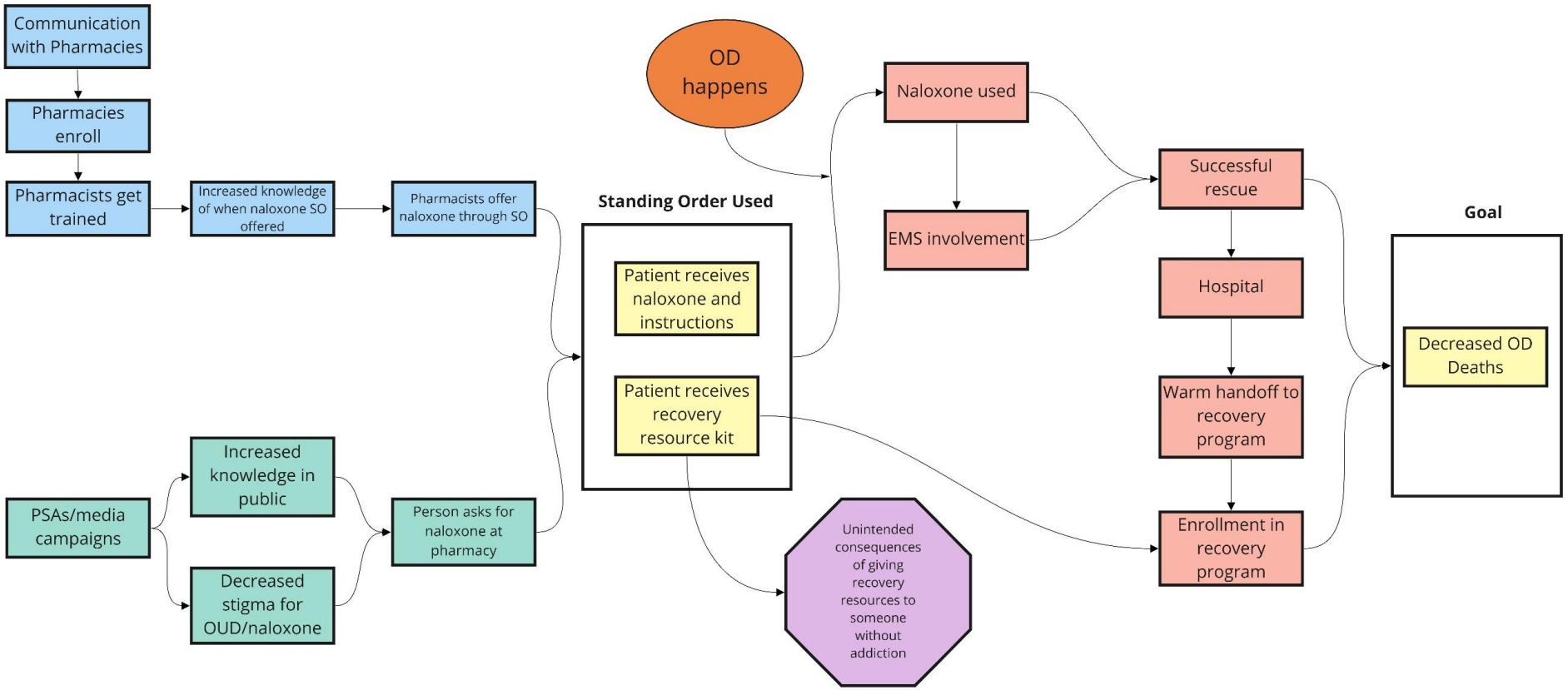
mentioned include distribution by EMS and other first responders, to returning citizens after incarceration, and through other community organizations.

Standing order flowchart feedback

In the fourth focus group activity, the focus group facilitator presented a draft version of a flowchart illustrating how the standing order works (see Figure 5). The left side of the flowchart focuses on what leads up to the standing order being used. The blue path in the upper left illustrates pharmacy involvement, including enrollment in the standing order, training, and pharmacists recommending naloxone to patients. The green path in the lower left illustrates public awareness leading to individuals requesting naloxone at pharmacies. The rectangle in the center signifies the use of the standing order: a patient receives naloxone, instructions, and a recovery resource kit at a pharmacy.

The right side of the flowchart focuses on what happens after the standing order has been used. The orange oval indicates a potential overdose, which could lead to naloxone administration. In some cases, EMS is called. After a successful rescue, the patient may be transported to the hospital, receive a warm handoff to a recovery program, and enroll in a recovery program. As shown in the rectangle on the right, the end goal is to decrease opioid overdose deaths.

Figure 5: Draft flowchart of Michigan's statewide naloxone standing order



After the facilitator walked participants through the draft flowchart, participants provided verbal feedback if time allowed. In some focus groups, the allotted time had been used and participants were invited to share feedback via email. Participants' feedback included the following suggestions:

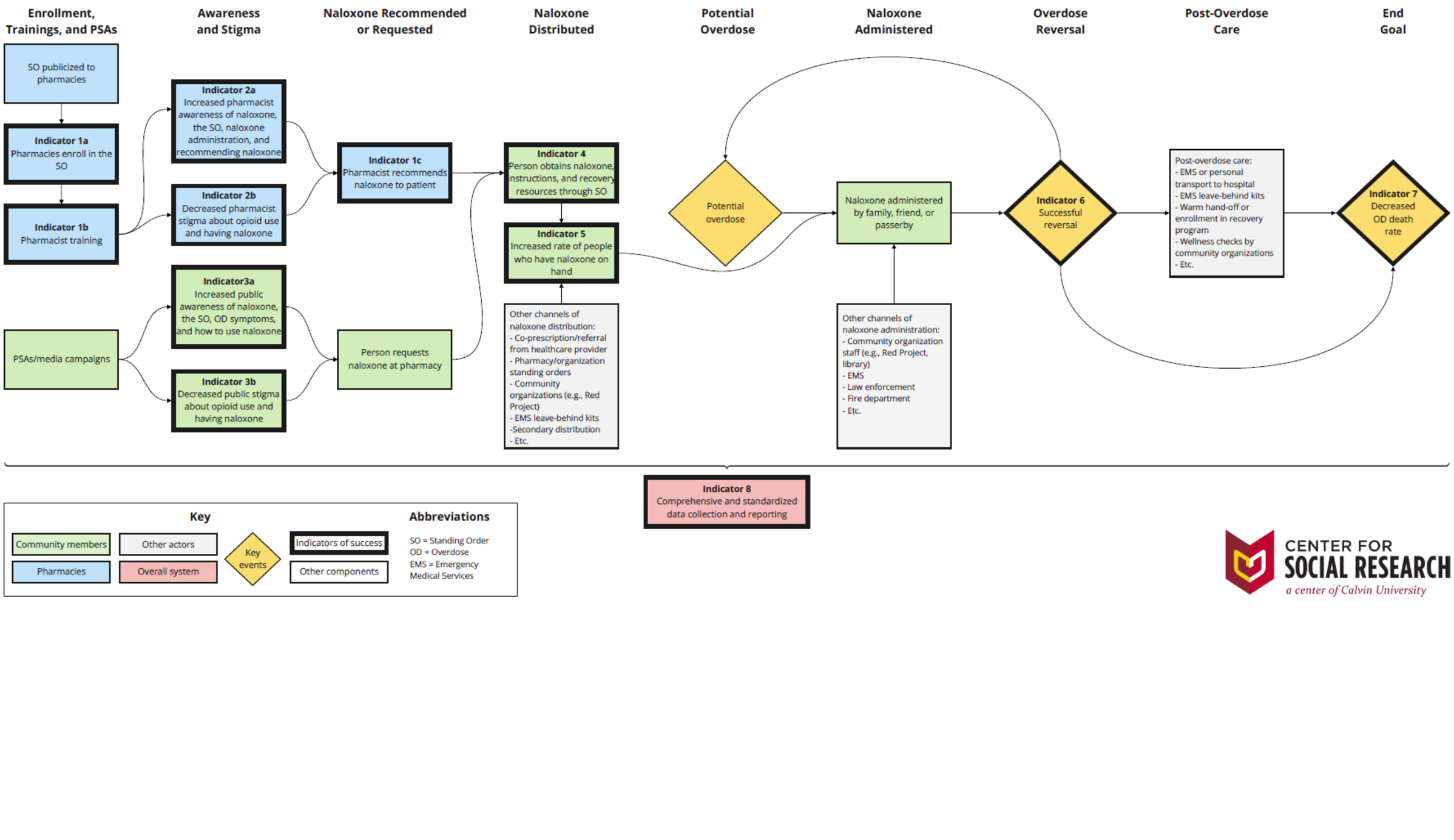
- Many times, successful rescues lead to repeat overdoses. A feedback loop between successful rescues and overdoses should be added.
- Especially on the right side of the flowchart, which represents the aftermath of an overdose, the flowchart presents an ideal scenario that does not often reflect real life. It may be helpful to see the flowchart as a leaky pipe, with people "leaking" between each part of the flowchart. For example, people may refuse EMS transport, may not go to the hospital, and may not enroll in a recovery program. One participant noted that recovery is not a landing pad for most people, as few people who use opioids are connected with recovery services. Moreover, recovery treatment is not always necessary because overdoses are not always a result of addiction.
- There are also "leaks" in the left side of the flowchart, which represents what leads up the standing order being used. For example, pharmacists are unlikely to be trained in adverse childhood experiences (ACEs) that may put people at risk of using opioids, may not recommend naloxone due to stigma about opioid use, and may not provide enough instruction about overdose symptoms and naloxone administration due to lack of time and privacy concerns.
- Although the intention was for the flowchart to focus on naloxone distribution through the statewide standing order, several participants gave feedback suggesting that the flowchart be expanded to show naloxone distribution more generally. In some cases, participants mentioned methods of naloxone distribution that were not shown in the flowchart that may be through the standing order. For example, organizations can request naloxone using this online form, and one participant shared about recent changes that allow EMS to leave behind a naloxone kit after responding to an overdose. An expanded version of the flowchart would also highlight the important roles of the Red Project, other community organizations, healthcare providers, peers, and family members in naloxone distribution and administration.

Based on these and other comments, the evaluation team revised the flowchart (see Figure 6). Colors represent the role of the person or organization involved with each flowchart component (e.g., green=community members; blue=pharmacies/pharmacists). Flowchart components that align

with the eight outcomes identified by focus group participants are highlighted with thick borders.

In one iteration, the flowchart was expanded to illustrate naloxone distribution through multiple channels, including distribution through the Red Project, first responders, and co-prescriptions. However, this expanded version become so complex that it was overwhelming; therefore, it was not a useful tool. In the end, the revised flowchart focused on Michigan's statewide naloxone standing order while acknowledging the roles of other organizations in naloxone distribution, naloxone administration, and post-overdose care in the three gray boxes.

Figure 6: Revised flowchart of Michigan's statewide naloxone standing order



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Questions for future evaluation

Finally, participants could make suggestions about what the evaluation team could focus their work on during the remaining time of their evaluation of the statewide naloxone standing order. Most suggestions were about how best to measure outcomes and barriers, how "leaky" each step in the flowchart is, and how to promote and measure education and awareness.

Summary

In sum, five online focus groups with a broad group of stakeholders provided additional feedback about outcomes to measure the success of the standing order and barriers to achieving these outcomes. In addition, participants gave valuable feedback on a naloxone standing order flowchart and avenues for future evaluation.

Discussion and Future Evaluation Goals

Together, individual interviews with 11 key informants and focus groups with more than two dozen stakeholders yielded invaluable feedback and highlighted the following steps for the next phase of evaluation of Michigan's statewide naloxone standing order.

Clarify the scope of the statewide standing order

Prior to the focus groups, the evaluation team understood Michigan's statewide naloxone standing order to be limited to the distribution of naloxone to individuals at pharmacies; this is what the public health code amended through House Bill 5326 (2016) (Michigan Legislature) and the standing order information packet (MDHHS, *Standing order information packet*) seem to indicate. However, several focus group participants mentioned other channels of naloxone distribution that they believed were under the statewide standing order as well. For example, organizations can request naloxone using an online form (MDHHS, *Naloxone request form*) and one participant explained that, starting in the summer of 2020, EMS could leave naloxone at the site of an overdose through the standing order.

It was important to clarify the scope of the standing order with someone who could provide a definitive answer on what falls within its purview and what does not. In early September 2020, the evaluation team had a conversation with Jared Welehodsky, Senior Analyst of Policy and Strategic Initiatives for MDHHS's Policy and Planning Administration, who was integral to the development of Michigan's statewide naloxone standing order. Mr. Welehodsky confirmed that the statewide naloxone standing order currently is

limited to distribution by pharmacies to individuals. Naloxone distribution by other organizations such as law enforcement and EMS is done so under the organization's own medical director. In many ways, these channels of distribution are akin to other, organization-specific naloxone standing orders. However, there is an effort to expand the statewide naloxone standing order to allow distribution through community organizations.

This clarification will direct the course of the ongoing evaluation of the standing order and will help stakeholders better understand the standing order's role in the large context of naloxone distribution.

Refine the Michigan statewide naloxone standing order flowchart

Following the focus groups, the evaluation team revised the naloxone standing order flowchart (see Figure 6). Although the revised flowchart reflects the feedback of focus group participants, we expect that it will need further refinement. We plan to present the latest version to Kent County stakeholders—both those who were involved in the focus groups and to others—and to key informants who were involved in designing the statewide standing order for additional feedback and vetting. Ultimately, the flowchart will be a useful tool for evaluating the implementation and effectiveness of the standing order and identifying opportunities for improvement.

Identify existing data sources to measure success outcomes

Together, the key informant interviews and stakeholder focus groups led to the identification of eight key outcomes that can be used to gauge the successfulness of the naloxone standing order. These eight outcomes are highlighted in the naloxone standing order flowchart. We plan to identify the optimal data source(s) to track as many of the eight outcomes as possible.

Design and implement policy evaluation tools

For some outcomes, existing data is limited or nonexistent. For example, we are not aware of existing data to assess public awareness and stigma. Further, although one pharmacist survey on naloxone was conducted by Wayne State University's Center for Urban Studies in 2019, additional data will be necessary to assess pharmacists' stigma, knowledge, and recommendations of naloxone over time.

For these outcomes, we plan to design policy evaluation tools that can be used to collect data and track outcomes moving forward. In addition to being

used to measure the successfulness of the naloxone standing order in Kent County, these evaluation tools could be used in other jurisdictions, both within and beyond Michigan.

Synthesize data in a dashboard or scorecard

Together, data collected through these new policy evaluation tools and existing data will be used to create a dashboard or scorecard. This data summary will track the successfulness of Michigan's statewide naloxone standing order according to the eight outcomes identified through the key informant interviews and stakeholder focus groups.

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Appendix A: Interview Consent Form

Interview About the Opioid Crisis and Michigan's Naloxone Standing Order Policy

PARTICIPANT'S STATEMENT OF INFORMED CONSENT

Introduction	Before you participate in this interview, it is important that you read and understand the following:
Procedure and Purpose	**You will participate in an interview.** An interview is a structured conversation to gather information about participant's ideas, experiences, and opinions. The interviewer(s) will ask you questions your organization's work related to the opioid crisis and the naloxone standing order. The interview will last 30-60 minutes. **The interview will be audio recorded** and the recording will be transcribed. The interviewer(s) may take notes during the interview. The evaluators will write a report, including themes that emerge in the interviews and quotations. Results may be shared with stakeholders such as the Kent County Opioid Task Force and the Michigan Department of Health and Human Services.
Risks	**Participating in the interview has minimal risk.** You may experience some emotional distress because you will be asked about your organization's work related to the opioid crisis. You may choose not to answer questions that make you feel uncomfortable.
Benefits	**Your participation may benefit the community** by identifying opportunities for improvement related to the opioid crisis and the naloxone standing order.
Safeguards	**Any information about you will be treated in a confidential manner** and will be used only for this evaluation project. Your name and other identifying information will not be used in reports. The digital files and transcripts will be stored at the Calvin University Center for Social Research. These files will be destroyed three years after the completion of the project.

(The consent form continues on the reverse side)

Withdrawal	**You may refuse to participate in this interview or withdraw at any time without penalty**. If you withdraw from the interview, you may choose whether or not any audio recordings that have already been created may be used for this project.
Contact Information	**If you have questions about this project**, you may contact the project leaders:

Laura Luchies, PhD
Associate Director
Center for Social Research
Calvin University
3201 Burton St SE
Grand Rapids, MI
616.526.7799
laura.luchies@calvin.edu

Keila Pieters
Research Specialist
Center for Social Research
Calvin University
3201 Burton St SE
Grand Rapids, MI
616.526.6241
krp28@calvin.edu

If you have questions about your rights as a participant in this project, you may contact:

IRB Chairperson
Office of the Provost
Calvin University
3201 Burton St SE
Grand Rapids, MI 49546
irb@calvin.edu

Consent

"By signing below, I acknowledge that I have received an explanation of this project and voluntarily consent to participate."

_____
Name (Printed)

_____ ___/___/_____
Signature Date (MM/DD/YYYY)

Appendix B: Interview Questions

Questions in bold type were intended to be asked of all interviewees. Questions in non-bold type were asked if time allowed.

Your organization

1) **Please tell us about your organization, your role, and where your work fits within the overall approach to addressing the opioid crisis? (ST)**
    a) What has your organization done to address the problems of OUD (Opioid Use Disorder) and/or opioid ODs (overdoses)?

The Michigan naloxone standing order policy

2) **What is your experience with the naloxone standing order?**
3) What do you think the purpose of the naloxone standing order *should* be? (CSH-Motivation)
4) **What does successful implementation of this policy look like for you? What would have to happen for you to know that the policy was a success?**
5) How would you rate the impact or successfulness of the policy so far?
6) **In your opinion, what are the three biggest barriers to the proper and full implementation of the standing order policy? Why do these barriers exist? (ST)**
7) Who should benefit from the policy? (CSH-Motivation)
8) How might this policy be perceived as coercive or malignant? (CSH-Legitimacy)
9) **Who might be affected negatively by the policy? Do you see any unintended negative consequences of the policy? (CSH-Legitimacy)**
10) What else needs to be done to address OUD and opioid ODs in Kent County?

Opioid use

11) What are the patterns of opioid use disorder (OUD) and opioid ODs you've seen in Kent County over the past 10 years?
12) What do you believe to be the primary underlying causes of opioid use disorders and/or opioid overdoses?

a) How do you think public health issues, including racism, sexism, and classism, play into the OUDs and ODs, if at all?

13) In your opinion, why does the problem of OUD and opioid ODs persist?

Appendix C: Focus Group Background Survey

Thank you for your willingness to share your experience and stories. Please review the following consent form and indicate your level of consent before proceeding to a brief (5-10 minute) background questionnaire.

Procedure and Purpose

You are being invited to participate in an online focus group. A focus group is a structured conversation to gather information about participants' ideas, experiences, and opinions. The facilitator(s) will ask you questions about the naloxone standing order. The online focus group will last 90-120 minutes and will take place over Zoom. The focus group will be audio and video recorded, and you will be asked to share ideas using Miro, an online whiteboard platform. The recording will be transcribed. The evaluators will write a report, including themes and quotations. Results may be shared with stakeholders such as the Kent County Opioid Task Force and the [State] Department of Health and Human Services. In addition, you are being invited to complete a short background questionnaire about your role and experience with the naloxone standing order.

Risks

Participating in the focus group and background questionnaire has minimal risk. You may experience some emotional distress because you will be asked about the opioid crisis and naloxone standing order. You may choose not to answer questions that make you feel uncomfortable.

Benefits

Your participation may benefit the community by identifying opportunities for improvement related to the opioid crisis and the naloxone standing order.

Payment

You will receive a $40 gift card in appreciation for your participation.

Confidentiality

Any information about you will be treated in a confidential manner. Your name and other identifying information will not be used in reports. By the nature of focus groups, other participants will know who you are and what you

share. Please maintain confidentiality of what other participants share in the focus group.

Withdrawal

You may choose not to participate in this focus group or withdraw at any time without penalty. If you withdraw from the focus group after it started, what you have already shared will be recorded. However, you may ask the evaluators not to use information or ideas that they can identify as coming from you in the report.

Contact Information

If you have questions about this project, you may contact the project leader: Laura Luchies, PhD, at laura.luchies@calvin.edu

If you have questions about your rights as a participant in this project, you may contact: irb@calvin.edu

Background Information

1. What is the name and contact information of your organization?

   Organization name:

   _____

   Address:

   _____

   ZIP Code:

   _____

   Phone number:

   _____

2. How would you describe your primary role in the organization?

   _____

3. In which area(s) does your organization focus its work?
   Check all that apply.

   ☐ Prevention
   ☐ Intervention
   ☐ Recovery

4. If you had to pick, which ONE area is the primary focus of your organization's work?

☐ Prevention
☐ Intervention
☐ Recovery

5. How would you categorize your organization?
   ☐ Detox/recovery center
   ☐ Peer recovery (e.g., Twelve-step program, SMART recovery)
   ☐ Medication Assisted Treatment facility
   ☐ Law enforcement
   ☐ Emergency medical services
   ☐ Pharmacy
   ☐ Healthcare
   ☐ Harm reduction
   ☐ Funding
   ☐ Government
   ☐ DHHS
   ☐ Other 1: _____
   ☐ Other 2:_____

6. If you had to pick, which ONE category best describes your organization?
   ☐ Detox/recovery center
   ☐ Peer recovery (e.g., Twelve-step program, SMART recovery)
   ☐ Medication Assisted Treatment facility
   ☐ Law enforcement
   ☐ Emergency medical services
   ☐ Pharmacy
   ☐ Healthcare
   ☐ Harm reduction
   ☐ Funding
   ☐ Government
   ☐ DHHS
   ☐ Other:_____
   ☐ Other:_____

About the Naloxone Standing Order Policy

7. Please select all of the following which are true for you
   There is no right answer and your response will not be tied to your name or

organization. We are just looking for an overall pulse on awareness of and experience with the policy.

- ☐ I am aware of the naloxone standing order.
- ☐ I have read the naloxone standing order.
- ☐ I understand how the naloxone standing order works.
- ☐ I received training on the naloxone standing order.
- ☐ I have obtained naloxone through the standing order.
- ☐ I have distributed naloxone through the standing order.
- ☐ None of the above

8. To the best of your knowledge, in a few sentences describe what it looks like when the naloxone standing order is used. If you would like, you may answer the "Five Ws" in your response: Who is involved? What happens? Where does it take place? When is it used? Why is it used?

9. What are your thoughts about the wording, content, and structure of the standing order? Is there anything you would change?

10. What kind of training and resources for carrying out the standing order have you received, if any?

11. OPTIONAL: Is there anything else you would like to share about the naloxone standing order policy or its implementation before the focus group?

Thank you for your willingness to participate in a focus group facilitated by the Calvin University Center for Social Research as part of a broader naloxone standing order policy evaluation.

To thank you for your time, we would like to send you a $40 gift card following your participation in the focus group. Please ensure your contact information is correct so we can send you the gift card via email.

- ☐ I would like to decline the gift card
- ☐ I would like to accept the gift card

Please ensure your contact information is correct so we can send you the gift card via email.

Organization name:

_____

Address:

_____

ZIP Code:

_____

Phone number:

_____

Thank you for your responses!

Appendix D: Focus Group Miro Whiteboard Templates

Introductions and Icebreaker

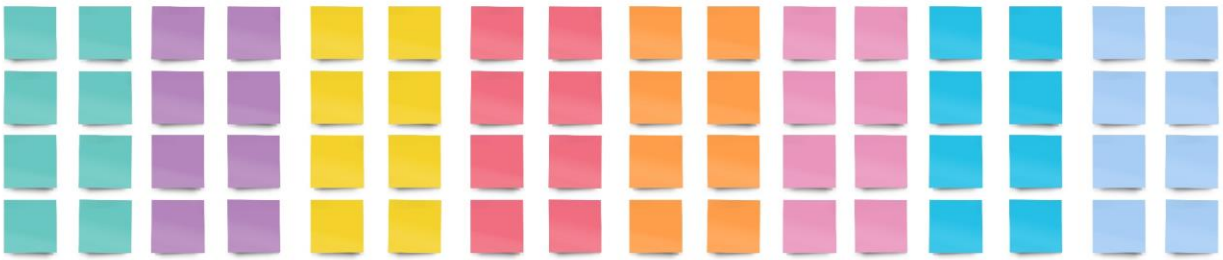
Outcomes Brainstorm Activity

Unsuccessful

Successful

How would you know whether the policy is successful or unsuccessful?
What would it look like if the policy was a success?
What outcomes would need to change?
What would it look like if the policy was not a success?

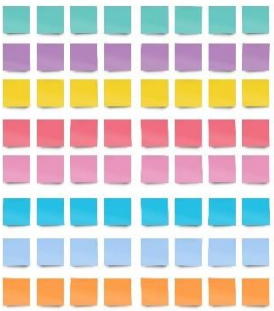
An **outcome** is a way to measure a goal. For example, a preschool may have the goal of preparing children for Kindergarten. The preschool could use the average number of letters its children can name as an outcome to measure Kindergarten readiness.

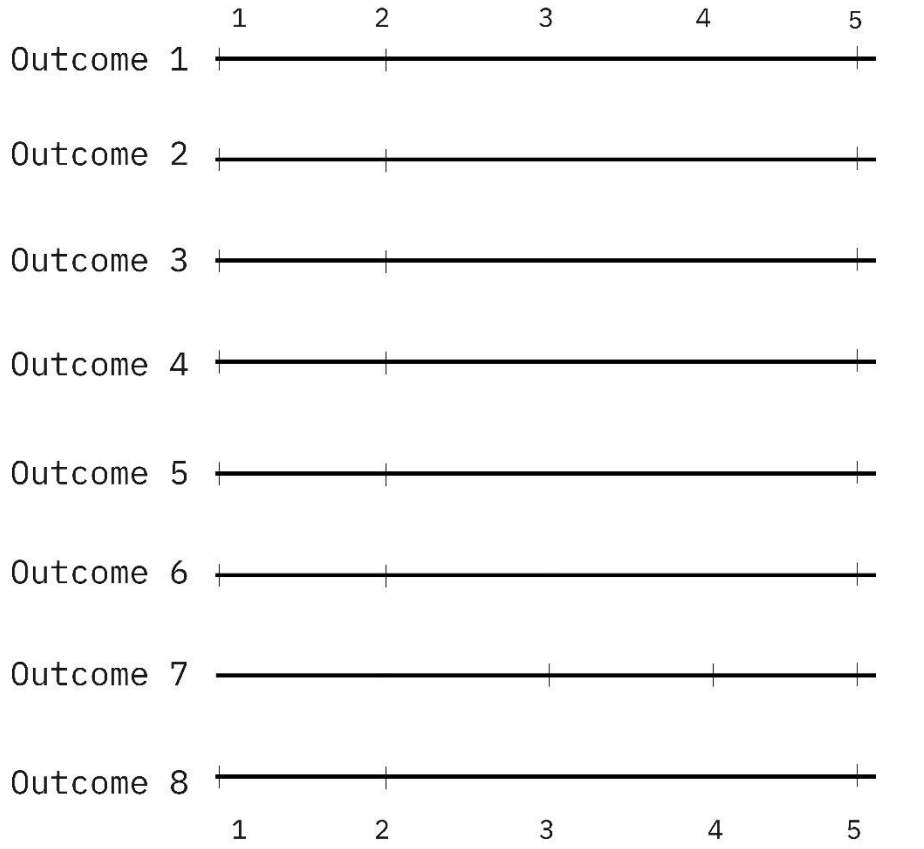


Outcome Rating Activity

Success Scales

Using a 1-5 scale, how would you rate the impact or successfulness of the policy on each outcome so far? Place your colored sticky note on the scale for each item.



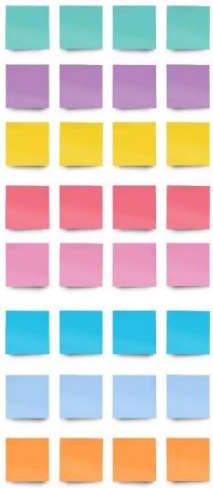


Barriers Activity

Barriers

What are the barriers to accomplishing each outcome in the gray rectangles?
Use your colored sticky notes to add barriers to the corresponding red rectangle.

Outcome	Barriers



Questions for Future Evaluation Activity

From You:

We want to center our evaluation on what people like you would most like to know about the standing order. If you were in charge of our project, what would you focus on? What questions would you want to answer?

Questions & Focuses to Add