

Community Pharmacy-Provided Injectable Naltrexone

A Year in the Life of a Resource Development Project

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Conflicts of Interest

The author has no conflicts of interest.



- The opioid epidemic is an ongoing public health crisis compounded by the COVID-19 pandemic, which resulted in greater healthcare utilization¹⁻⁴ and a 40% increase in overdose deaths.^{5,6}
- Access to medications for opioid use disorders (MOUD) is a crucial public health strategy in confronting the opioid epidemic.^{9–12}
- Injectable naltrexone is an MOUD that can be prescribed by a licensed provider without a controlled substances registration, which should make naltrexone more accessible than other MOUD (e.g., buprenorphine, methadone).^{13,14}
- Injectable naltrexone treatment is an effective treatment that reduces healthcare utilization (e.g., ED visits)^{3,8} and relapse,^{15,16} and improves medication adherence,^{8,17} treatment continuation,¹⁸ and employment.⁷
- Despite evidence of effectiveness comparable to other MOUD, naltrexone access is limited.



- Community pharmacists in Wisconsin are well-positioned to expand naltrexone access due to their:
 - 1) Legal authority to administer naltrexone since 2016,¹⁹
 - 2) Greater patient accessibility than other practitioners,
 - 3) Training to inform patients about what to expect pharmacologically with naltrexone, and
 - 4) Availability for patient follow-up once naltrexone is administered.^{20–23}
- Passage of <u>Wisconsin Act 98</u> gives the pharmacist "provider status," which allows pharmacists to bill administration fees for administering injections.
- Community pharmacists' acceptability as care providers makes them a viable resource for expanding naltrexone access in locations across Wisconsin.²⁴

Reference Act 98 https://docs.legis.wisconsin.gov/2021/related/acts/98



• Study 1 (2019)

Snowball sampling to identify pharmacists offering community pharmacy-provided injectable naltrexone (CP-naltrexone) and identification of relevant statues and regulations from Lexis Academic.

• Study 2 (2020)

Exploratory sequential mixed-methods design. A descriptive analysis of a pharmacist survey about MOUD. An inductive/iterative content analysis of interviews with pharmacists, prescribers, and community stakeholders.

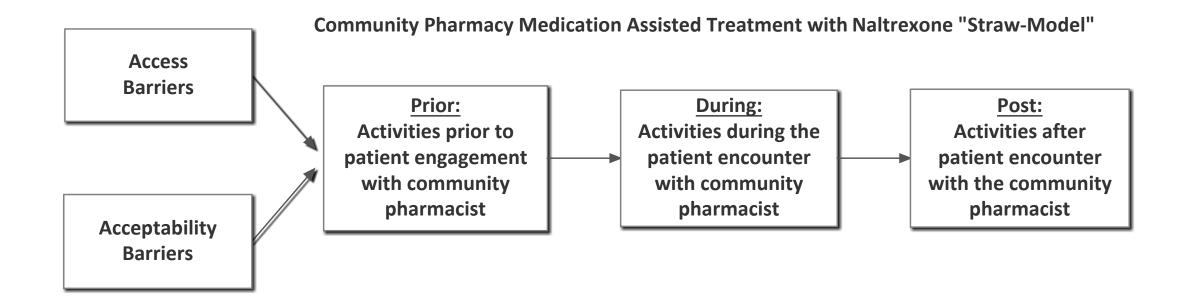
• Study 3 (2021)

Developed a cost-estimator based on literature and semi-structured interviews. Surveyed to ask purposively-select sample of pharmacists to determine the administrative costs of CP-naltrexone.

• Study 4: (2021-2022)

Focus groups with key referral sources (nurse practitioners and treatment court professionals) to identify benefits of CP-naltrexone to patients, prescribers, referral sources and what to expect at the pharmacy.





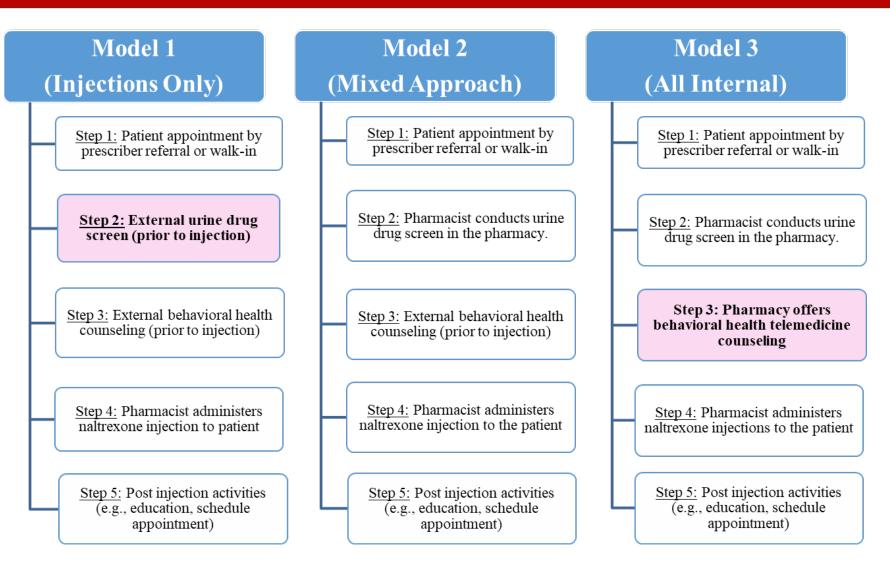
Ford, J. H., 2nd, Gilson, A., & Mott, D. A. (2019). Systematic analysis of the service process and the legislative and regulatory environment for a pharmacist-provided naltrexone injection service in Wisconsin. Pharmacy (Basel, Switzerland), 7(2), 59. https://doi.org/10.3390/pharmacy7020059.



- Pharmacist identified two patient perceived barriers:
 - Access barriers related to infrastructure (e.g., prescriber unaware of medication) and general access (e.g., prescriber access in rural areas), and
 - Acceptability barriers from the prescriber perspective (e.g., negative perceptions of OUD patients) and patient perspective (e.g., stigma associated with medications).
- Pharmacy facilitators including trust, flexible schedules, skills to provide the service.
- Internal pharmacy barriers include costs, lack of reimbursement.
- External barriers such as coordination with prescriber or lack of supportive wrap-around services.



Study 2: CP-Naltrexone Delivery Models





Study 2: CP-Naltrexone Referral Sources^a

Patient Referral Sources (Check all that Apply) ^b	Chain Pharmacy ^c (n=7)	Independent Community Pharmacists (n=10)	Mass Merchandiser ^d (n=2)
Total Number of Different Referral Sources	15	38	2
Average Number of Referral Sources	2.1	3.8	1.0
 Referral Source (Number and %) Behavioral Health Practitioner (e.g., psychiatrist) County Health Department Criminal Justice Emergency Department or ED Physicians Local Substance abuse or mental health provider Nurse Practitioner Physician Walk-in clients Other 	3 (20.0) 1 (6.7) 1 (6.7) 0 (0.0) 1 (6.7) 1 (6.7) 4 (26.7) 2 (13.2) 2 (13.2)	9 (23.7) 5 (13.2) 3 (7.9) 2 (5.3) 7 (18.4) 4 (10.5) 6 (15.8) 2 (5.3) 0 (0.0)	$\begin{array}{c} 0 \ (0.0) \\ 0 \ (0.0) \\ 0 \ (0.0) \\ 0 \ (0.0) \\ 0 \ (0.0) \\ 0 \ (0.0) \\ 0 \ (0.0) \\ 0 \ (0.0) \\ 2 \ (100.0) \\ 0 \ (0.0) \end{array}$

a. Reproduced from Ford et al, 2021 (https://doi.org/10.1016/j.sapharm.2020.10.004). Showing responses from 68 surveys where 20 pharmacies offered naltrexone injection services

b. Pharmacies could check more than one referral source. One pharmacy located in a clinic or affiliated with an HMO offers injections but did not provide information on referral sources

c. Walgreens and CVS are examples of a chain pharmacy

d. Walmart or ShopKo are examples of a pharmacy affiliated with a mass merchandiser

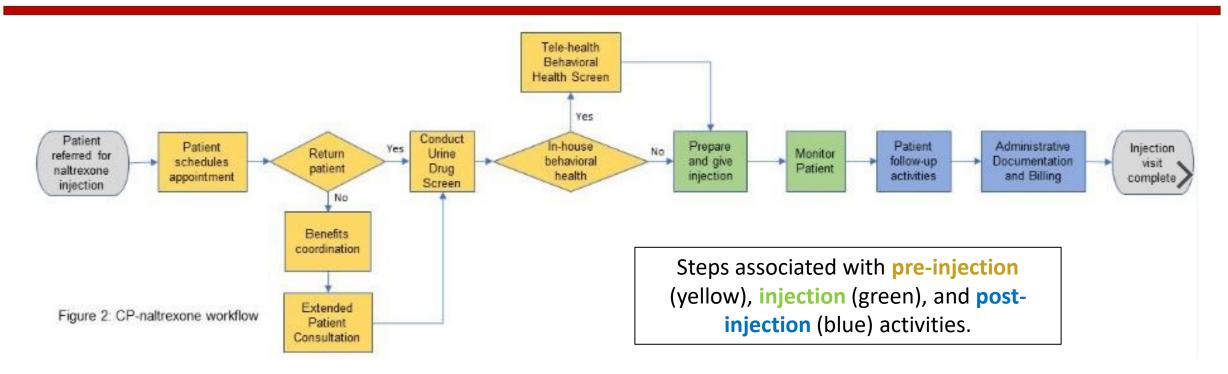


Top 5 CP-Naltrexone Service Barriers			
CP-Naltrexone Barriers	Chain (n=35)	Community (n=21)	
Mission Fit	31.4%	14.3%	
Process Steps	25.7%	33.3%	
Awareness of regulations	20.0%	14.3%	
Insufficient staffing	17.1%	23.8%	
Lack of training	14.3%	28.6%	
Workflow disruptions	14.3%	9.5%	

 In addition, community pharmacies were more likely to cite barriers associated with financing (e.g., reimbursement), infrastructure (e.g., lack of space), or stigma versus chain pharmacies who were concerned about the liability of providing CP-Naltrexone.



Study 3: CP-Naltrexone Service Delivery Process



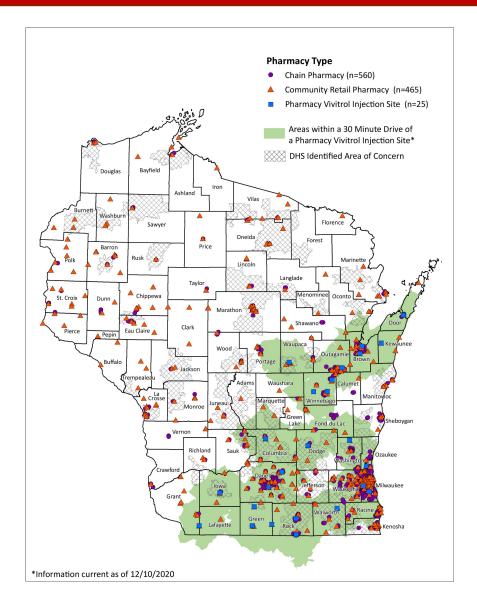
We utilized the service delivery process to determine the average time and administrative costs to complete the process tasks for new and returning patients – 123 minutes/\$93 and 83 minutes/\$66, respectively.

Ford, J. H.*, Gilson, A. M., Bryan, G. M., Gicquelais, R. E., Gassman, M., & Mott, D. A. (2022). Pilot testing a tool to determine the costs and time associated with community pharmacy-based administration of injectable naltrexone. Research in Social and Administrative Pharmacy. 18 (7): 3210-3215. https://doi.org/0.1016/j.sapharm.2021.10.007



Availability of CP-Naltrexone Services

- Our surveys indicated that twenty-eight pharmacies, including 9 chain pharmacies, self reported providing approximately 1,040 naltrexone injections.
- We estimate that at least 40 community pharmacies in Wisconsin offer naltrexone injections.
- How do we increase access from community referral sources?





Study 4:

Pharmacy

Brochure

CP-Naltrexone

BENEFITS TO THE PATIENT

BENEFITS TOTHE PROVIDER

WHY USE THE PHARMACY?

- Increases access to naltrexone injections and related services
- Flexible scheduling (including evenings and weekends)
- Increases convenience to access services outside of clinic visits
- Capitalizes on existing trusted relationship with pharmacist
- Reduces stigma (pharmacy preserves anonymity)
- Minimizes travel
- Makes it easier for patients to stay compliant
- Creates clearer patient expectations
- Creates critical access point for people leaving the criminal justice system
- Assists patients with insurance issues

- Reduces client treatment load, especially for stabilized patients
- Flexible patient scheduling (same day treatment is possible)
- Allows for mutual agreement about the clinical information that the pharmacist shares with the provider, such as:
 - ⇒ Patient keeping the appointment
 - Urine drug screen results (including screening for agreed-upon substances, including alcohol)
 - ⇒ Injection site delivery and adverse reactions
 - \Rightarrow Other information as warranted
- Pharmacist is available to answer specific treatment questions (e.g., about medication side effects, withdrawal, etc.)

- Pharmacists have specialized training on how to provide injections
- Pharmacists have experience providing naltrexone injections
- Private consultation rooms are available to maintain patient anonymity
- Pharmacy has established protocols, including injection delivery and adverse events management
- Pharmacists can offer medication counseling about naltrexone
- Pharmacists can conduct a urine drug screen prior to the injection, as needed
- Public has existing trusted relationship with community pharmacy
- Pharmacy-provided injectable naltrexone decreases cost burden for the healthcare system

So, I have a lot of trust and faith in our pharmacists in the community, here at the clinic, and in our community itself.

~Interviewed Physician

PATIENT EXPECTATIONS

INJECTABLE NALTREXONE



Study 4:

Pharmacy CP-Naltrexone Brochure

WHATTO EXPECT AT THE PHARMACY



- The initial patient appointment will take longer to account for activities such as medication counseling and benefits coordination, as needed
- The patient will be required to wait approximately 15 minutes after receipt of the injection to monitor for adverse events
- A pharmacist will take time to talk with the patient about injectable naltrexone, including how to monitor for adverse reactions
- The patient will be able to schedule a follow-up appointment with the pharmacist
- The patient can receive a reminder call about subsequent appointments from the pharmacy, as desired
- The pharmacist will coordinate communications about receipt of the injection with the provider and/or, if necessary, the drug court

WHAT IS INJECTABLE NALTREXONE?

Injectable naltrexone (or Vivitrol®) is an **FDA approved medication** for the treatment of an opioid use disorder and alcohol use disorder.

The medication delivery schedule involves monthly injections administered by a trained provider or pharmacist.

To learn more about naltrexone from the Substance Abuse and Mental Health Services Administration, click on the QR code below.



This brochure content was compiled as part of a project supported by the University of Wisconsin-Madison Institute for Clinical & Translational Research to the University of Wisconsin-Madison School of Pharmacy (Dr. Jay Ford, Pl). It was created as part of the outreach mission of School of Pharmacy and does not represent an endorsement of any specificcommercialproduct andshould not be readtoimply a relationship with any manufacturer.

GETTING TO KNOW YOUR PHARMACY

Pharmacist-Provided Injectable Naltrexone

[space for pharmacy logo]

PHARMACY NAME

Street City, State, Zip

Pharmacist Name pharmacist email pharmacist phone



Study 4:

Treatment Court Flyer

Benefits to Treatment Court Participants

- Increases access to naltrexone injections and related services
- Flexible scheduling (including evenings and weekends)
- Increases convenience to access services outside of clinic visits
- Capitalizes on existing trusted relationship with pharmacist
- Reduces stigma (pharmacy preserves anonymity)
- Minimizes participant travel
- Makes it easier for participants to stay compliant
- Creates clearer participant expectations
- Creates critical access point for people leaving the criminal justice system
- Assists participants with



Community Pharmacy Resources to Mitigate the Effects of Wisconsin's Opioid Crisis

Benefits to Treatment Court Participants

- Increases access to naltrexone injections and related services
- Flexible scheduling (including evenings and weekends)
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 Minimizes participant travel

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- Assists participants with insurance issues

To see the full list of our injectable naltrexone related resources, including a link to the WATCP video, please scan the QR code below.





Exploring the role of community pharmacistprovided injectable naltrexone (Vivitrol[®]) for treatment court participants.

The increased rates of opioid-related deaths and emergency room visits¹ in Wisconsin underscores the fact that the state's opioid crisis continues to be a major public health issue. The preferred evidence-based treatment for persons with an opioid use disorder (OUD) combines the use of FDA-approved medications for OUD (MOUD) with counseling and behavioral therapies. However, access to MOUD has not kept up with increased demand.

As of 8/31/2021, in WI there have been 835 opioid-related deaths in the year.¹

In Wisconsin, pharmacists are able to provide long-acting injectable naltrexone, an approved and effective MOUD treatment. Pharmacists, who are more geographically accessible, have a unique perspective on what to expect pharmacologically with an OUD medication, and they can proactively follow up with participants once a medication is provided.

Since 2018, the Ford Research Group at the University of Wisconsin-Madison School of Pharmacy, lead by Dr. Jay Ford, has been been researching community pharmacist-provided injectable naltrexone services. Part of our goal is to understand how community pharmacists can potentiallly benefit treatment court programs. In 2021, we surveyed and conducted a focus group with treatment court coordinators in Wisconsin. What was evident in our findings was that there was widespread lack of awareness about community pharmacistprovided injectable naltrexone. While many barriers were discussed, coordinators could see the the benefit of this collaboration.

"I think getting pharmacists, especially in rural communities, involved in [MOUD] would be extremely helpful." ~ Treatment Court Coordinator

To further inform treatment court coordinators of this service, we held a joint webinar with the Wisconsin Association of Treatment Court Professionals membership and community pharmacists offering injectable naltrexone. A link to the video of the webinar is available via the QR code to the left.

We hope to further explore this potential collaboration with future research funding.

Questions?

fordresearchgroup@pharmacy.wisc.edu

¹ https://www.dhs.wisconsin.gov/opioids/dashboards.htm

This research was supported by the WI Department of Health Services and the UW Institute for Clinical and Translational Research



Limitations and Next Steps

Limitations

- Models and cost estimators built around information from a small sample of CP-naltrexone service provides.
- Outreach tools have not been formally evaluated.

Next Steps

- Obtain a more comprehensive assessment of CP-naltrexone service locations.
- Assess the impact of implementation strategies to expand CP-naltrexone services.
- Explore the health utilization and economic impact of CP-naltrexone services.



Questions/Contact



Contact Information

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Community Pharmacy and the Opioid Epidemic Research (summary of our research) https://pharmacy.wisc.edu/faculty/ford-research-group/research-project/communitypharmacy-and-the-opioid-epidemic/

Community Pharmacy-Provided Injectable Naltrexone Best Practices Guide (an online guide for community pharmacists)

https://pharmacy.wisc.edu/faculty/ford-research-group/resources/injectablenaltrexone-best-practices/

Injectable Naltrexone Brochure (free download)

https://pharmacy.wisc.edu/faculty/ford-research-group/online-tools/injectablenaltrexone-brochure/



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