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Pilot testing a tool to determine the costs and time associated with community pharmacy-based administration of injectable naltrexone

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ABSTRACT

Background: Medications for opioid use disorder (MOUD), including injectable naltrexone (IN), are part of evidence-based OUD treatments. MOUD access often is limited, especially in rural communities. When authorized to administer non-vaccination injections, pharmacists can increase IN accessibility. However, inadequate reimbursement for pharmacist-administered IN can hinder widespread adoption.

Objectives: To pilot test a process to obtain a preliminary estimate of the total costs and time associated with community-pharmacist administered IN.

Methods: A purposively-selected sample of key informants at community pharmacies administering IN were surveyed about time and cost for *best practice* IN activities. Respondents estimated the time to perform activities and average pharmacist/pharmacy technician hourly salary, which were used to calculate administration costs.

Results: The approach to estimate time and costs was feasible. Administrative costs (mean = \$93, range: \$48-\$164) and time (mean = 123 min., range: 63-220 min.) to administer IN varied widely. Pharmacists'/pharmacy technicians' roles varied by pharmacy.

Conclusions: Pharmacists allocate significant time and resources to administer IN. Insufficient reimbursement may disincentivize pharmacy-involved OUD treatment and ultimately slow needed expansion of MOUD services. Increasing IN services requires engaging pharmacies to expand their practice through educational campaigns, along with a commitment to reimburse the cost of medications and related administration activities.

1. Background

The opioid epidemic, fueled by the overuse of prescription opioids and the use of heroin and illicitly-manufactured fentanyl, has resulted in substantial morbidity and mortality in the U.S. and internationally.¹⁻⁶ In 2019 alone, approximately 2.4 million people were diagnosed with an opioid use disorder (OUD).⁷ Food and Drug Administration-approved medications for OUD (MOUD)⁸ reduce harms and mortality associated with OUD.^{9,10} Such MOUD include extended-release injectable naltrexone (hereafter referred to as injectable naltrexone, IN).^{11,12}

Naltrexone in an FDA-approved opioid antagonist indicated for "prevention and relapse of opioid dependence, following detoxification." Manufacturer guidelines indicate that naltrexone be refrigerated before use.¹³ This instruction necessitates that patient appointment be scheduled to allow for the medication to reach room temperature (approximately 45 min) prior to administration. Manufacturer guidelines also recommend that the patient with an OUD have a negative urine drug screen (UDS) for all opioids immediately prior to the first injection and exhibit no opioid withdrawal symptoms.¹³ IN is not a

controlled substance and does not require a DEA-X waiver,¹⁴ which may enhance practitioner appeal. Although treating OUD with IN is successful,¹⁵⁻²⁰ it remains an underutilized treatment option in the U.S.¹⁷

Pharmacists are well-suited to help fill this MOUD treatment gap, given their:

- (1) Understanding of medication pharmacology,
- (2) Typical review of medication management before prescriptions are dispensed,
- (3) Capacity to provide patient follow-up after dispensing medications,
- (4) Skills and training to provide patient education, and
- (5) Awareness of available community resources, which can facilitate patient contacts for services related to mental health/counseling, harm reduction, recovery support, or employment.²¹

In addition to such qualifications, a state's statutory/regulatory environment can grant pharmacists the legal authority to administer

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non-vaccine medications via injection after fulfilling training and reporting requirements.²¹ Despite the professional authorization, preparation, and willingness to administer IN, the uncovered costs associated with such services can be a significant obstacle to pharmacist involvement.²²

Non-pharmacist providers are reimbursed for their time and resources to provide the injection, in addition to the cost of the drug (depending on how the drug is covered by a patient’s insurance). However, current pharmacy reimbursement models apply only to a pharmacy’s drug cost for IN (approximately \$1300)²³ and the dispensing costs associated with providing a drug product, since insurers do not classify pharmacists as “providers.” Typical reimbursement models do not compensate injection administration time in the pharmacy or the time and cost of related activities and supplies (e.g., conducting UDSs, monitoring for post-injection adverse events, scheduling appointments, and paperwork completion). Cumulatively, the IN administration-related procedures can require substantial resource allocation, depending on the pharmacy infrastructure and staff workload. The resulting unremunerated expense to individual pharmacies can be substantial and may be a barrier to initiating or sustaining an IN-administration service in their community.

2. Objective

This pilot study developed and evaluated a tool to determine the total costs and time associated with community pharmacy-based IN administration.

3. Methods

3.1. Data collection

A cost estimator survey was developed based on information from a comprehensive literature review and semi-structured interview feedback from community pharmacists who administer IN (n = 9), which identified a list of activities associated with IN services.²⁴ The survey was distributed to a purposively-selected sample (n = 11) of key informant pharmacists administering IN, including 8 interviewed individuals, located at community pharmacies throughout a Midwestern state. The survey elicited time and cost estimates for 12 activities (Table 1) identified as best practices²⁴ to administer IN a community pharmacy. For example, pharmacists who administer IN typically conduct a UDS prior to the injection; however, other best practices (e.g., benefits coordination or telehealth behavioral counseling) characterize frequent expectations when administering IN. The activities are classified into three thematic categories: (1) pre-injection activities, (2) injection activities, and (3) post-injection activities (see Table 1). Informants provided estimates of the average medication cost and reimbursement, and the professional dispensing fee for the delivery of naltrexone.

Key informants reported if each activity was performed for a new or returning patient, who performed the activity (pharmacist and/or pharmacy technician), and the average amount of time dedicated to performing the activity. Two evaluated activities related to administering and interpreting a UDS and making available supplies for an injection, have fixed costs. For these activities, key informants were requested to provide cost estimates.

The feasibility of completing the survey was assessed by examining responses to each question. Questions with missing responses and/or a wide range of responses, suggesting confusion about what the question was asking, were assessed.

3.2. Data analysis

Activity-related costs were calculated based on the time to perform the activity and average pharmacist/technician hourly salaries. Total

Table 1
Administrative Activities associated with a Naltrexone Injection in a Community Pharmacy.

Activity Category	Activity	Activity Description
Pre-Injection Activities	Patient Scheduling Before Appointment	Activities to schedule the injectable naltrexone appointment or calling to remind the patient of the appointment
	Benefits coordination	Activities to determine the client’s insurance and/or co-pays, discussing costs, or helping patient obtain discount cards to cover medication costs
	Extended patient consultation	Activities to help the patient understand the benefits and risks associated with a naltrexone injection, provide information about resources that are available, obtain informed consent, and ensure patients receive educational resources
	Urine drug screen cup/panel	Costs associated with providing UDT (e.g., Acquisition cost for Alere® 14-panel cup and test kit)
	Drug screen interpretation and lab monitoring/management (CMP, Pregnancy)	Activities such as having the patient sign permissions for toxicology screen, providing the patient with the UDT kit and show them restroom, waiting for results, and sending the UDT to the lab.
Injection Delivery Activities	Behavioral Health Consultation	If done in the pharmacy, activities include setting up the behavioral health visit; and confirming with the prescriber about medication dispensing. Note: it does not include time the patient is in the behavioral telehealth visit
	Supplies for injection	Includes supplies associated with providing the injection such as gloves, bandage, alcohol swabs, gauze, sharps disposal, etc.
	Injection professional service	Activities include mixing and drawing the injections including getting the medication out of the refrigerator; and the actual provision of the injection.
Post Injection Activities	Monitoring period	Observing the patient to ensure that they do not have an adverse reaction
	Patient Follow-up Activities (Education and Scheduling)	Activities such as education for the patient to address adverse events (e.g., give resources) and scheduling the next follow-up appointment. If patient needs proof of service (e.g., drug court), would include providing documentation
	Administrative Documentation	Completing all paperwork: documenting the provision of the injection (e.g. when, where, etc.); recording injection provision in the pharmacy system; sending confirmation to the provider; etc.
	Billing	Completion of any activities related to billing for the service including billing for the UDT, injection and/or dispensing fee.

administration costs combined labor and fixed costs were calculated for both new and returning patients.

Descriptive statistics were computed using SPSS v.27 for all time/cost estimates.

4. Results

Responses were received from nine of the 11 key informants contacted November 2020–May 2021, with one of the nine reporting that IN administration was no longer offered due to low patient volume. Administrative cost/time estimates were received from seven key informants. Six pharmacies were in urban counties. Average pharmacist and technician salary was \$57.96 (range: \$50–\$70) and \$18.09 (range: \$15–\$30), respectively.

4.1. Administration costs

Fig. 1 describes the average total administration costs associated with community pharmacist-administered IN, including staff, UDSs, and supply costs (see Table 1 for details). Estimates do not include the cost of the IN or dispensing fee, because those medication dispensing expenses are reimbursable. The sample respondents' average IN administration cost was \$93 (range: \$48–\$164) for a new patient, which was \$27.55 higher than administering IN to returning patients.

4.2. Staff time

Activities involved in preparing for and following up on IN administration are directly associated with the cumulative administration obligation – the greater the number of activities the more that time needs to be allocated and are pharmacy specific (see Table 1). As indicated in Fig. 2, the average total pharmacist and technician time for IN administration was 123 min (range: 63–220 min). On average, the time to complete administration for a returning patient is 40 min less (Fig. 2). Appendix 1 shows activity descriptive statistics for a new patient.

4.3. Activity completion by role

Table 2 outlines the activity-specific tasks performed for new or returning patients and the employee responsible for activity completion. Benefits coordination and extended patient consultation were more common for new rather than returning patients. Patient consultation,

UDS interpretation, the injection, and patient monitoring were performed primarily by the pharmacist for patient groups. Technicians commonly perform the following activities: scheduling, benefits coordination, and billing. Remaining activities were shared by pharmacists and technicians.

5. Discussion

This is the first pilot study to examine costs and time/effort commitments related to administering long-acting IN a pharmacy setting. Results suggest a wide variation in administration costs, time spent on preparation, administration, and patient follow-up, and the roles and responsibilities of pharmacists and technicians. Further research is needed to expand the use of the cost estimate survey tool to additional community pharmacists to validate the approach, confirm preliminary cost and time estimates, and to determine whether the cost/time disparities affected the quality of IN services and patient treatment outcomes.

This cost range (\$48–\$164 per injection for a new patient) likely reflects the difference among pharmacies in the time for administering IN for new or returning patients, rather than being actual cost differences for similar activities. This interpretation is supported by the fact that staff time related to pharmacist-administered IN ranged from 63 to 220 min, depending on the pharmacy and the number/extent of responsibilities surrounding administration. This finding contrasts starkly with estimates of the time needed for vaccine administration. A study of influenza diagnostic testing found that the time to complete a 9-step process – involving allowing patients to arrive without a scheduled appointment, eligibility screening, receiving the vaccination, and monitoring for adverse reactions – was 36 min, with direct pharmacist involvement being about 9 min.²⁵ Thus, administering IN represents a significant commitment on the part of pharmacy staff beyond that required for a vaccination. Future research should examine whether and how IN administration can be streamlined. Specifically, the actual time associated with certain activities (e.g., patient consultation, benefits coordination or injection and monitoring) will vary by patient. To identify potential streamlining opportunities, a pharmacy time and motion study could be conducted over a sample of patients to capture actual times associated with specific activities.

Interviewing a purposively-selected sample of community pharmacists about cost/time issues for IN administration represents an extension of our prior work characterizing pharmacists' knowledge, beliefs,

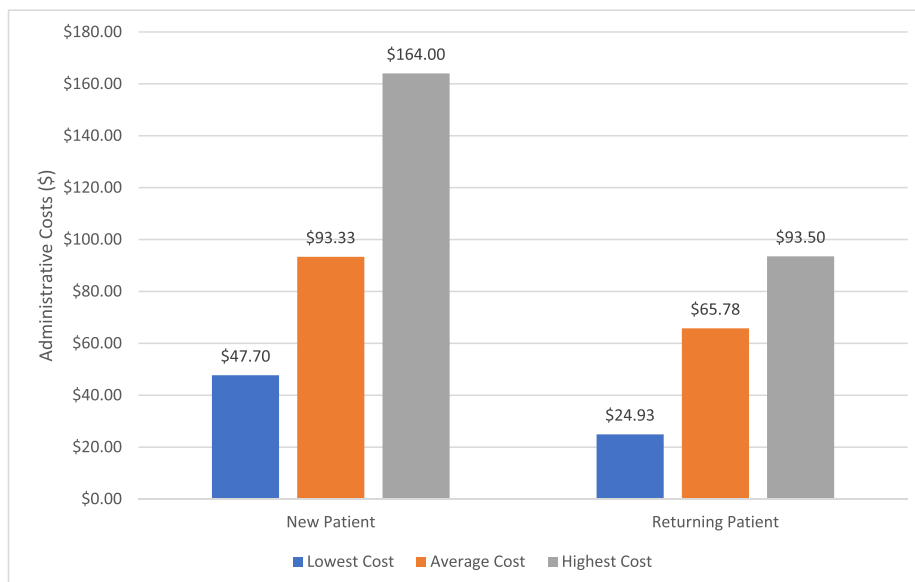


Fig. 1. Average total pharmacy administrative costs associated with injectable naltrexone.

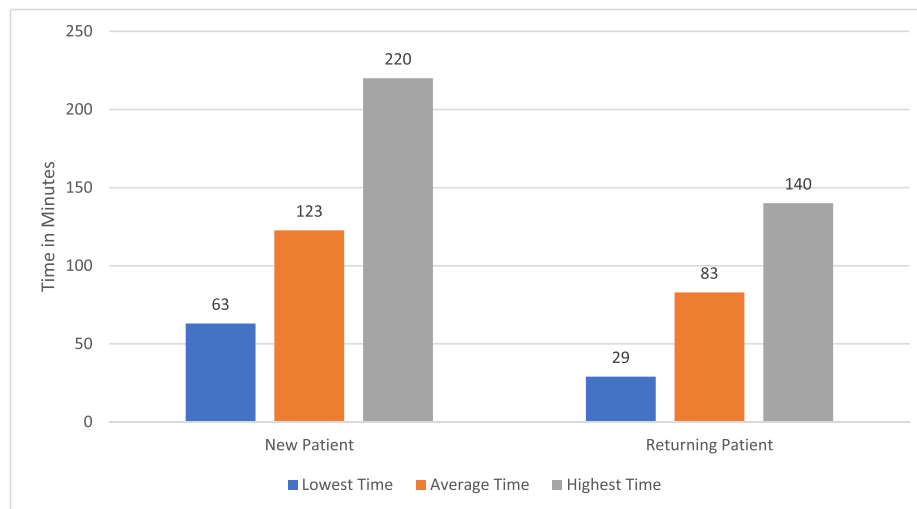


Fig. 2. Total staff time associated with injectable naltrexone.

Table 2

Summary of task completion by role and type of patient.

TASK DESCRIPTION	TASK PERFORMED FOR PATIENT ACROSS ALL PHARMACIES (n = 8)		WHO COMPLETES TASK ACROSS ALL PHARMACIES (New Patient)		WHO COMPLETES TASK ACROSS ALL PHARMACIES (Return Patient)	
	New	Return	Pharmacist	Technician	Pharmacist	Technician
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Patient scheduling before appointment	7 (87.5%)	7 (87.5%)	4	7	2	6
Benefits coordination	7 (87.5%)	5 (62.5%)	3	8		5
Extended patient consultation	7 (87.5%)	4 (50.0%)	8	1	4	
Urine drug screen cup/panel	6 (75.0%)	6 (75.0%)	3	1	3	1
Drug screen interpretation and lab monitoring/management (CMP, Pregnancy)	6 (75.0%)	6 (75.0%)	7	4	7	3
Behavioral health consultation	5 (62.5%)	5 (62.5%)	4	4	3	3
Supplies for injection	6 (75.0%)	6 (75.0%)	5	2	5	2
Injection professional service	7 (87.5%)	7 (87.5%)	8	2	8	1
Monitoring period	7 (87.5%)	6 (75.0%)	7	2	6	2
Patient follow-up and activities (education/scheduling)	6 (75.0%)	6 (75.0%)	7	5	5	5
Administrative documentation	7 (87.5%)	7 (87.5%)	7	7	7	7
Billing	6 (75.0%)	6 (75.0%)	2	8	2	8

and experiences about various types of MOUD treatments.^{21,24} This study piloted an approach to determine the administration costs of providing IN, which is currently the least commonly-used MOUD.²⁶ Despite its low-prevalence use, IN deserves consideration as a viable treatment because it has substantial benefit in reducing time in inpatient OUD and mental health treatment,¹⁸ decreasing opioid use,¹⁹ and improving employment, mental health and psychosocial functioning and mitigating opioid craving.²⁰ IN's therapeutic value is further enhanced by its cost-effectiveness.²⁷

Given that, in 2019, approximately 2.4 million people nationally were diagnosed with an OUD, it can be argued that IN administration costs are minor when measured against treatment benefits. For example, in the state where this study was conducted, approximately 700 naltrexone injections were provided in a community pharmacy.²⁴ Combined with these administration cost estimates, pharmacy reimbursement for IN administration would range, approximately, \$46,000-\$65,000 USD depending on whether patients were new or returning. Complete reimbursement to pharmacies of these costs would outweigh any reductions in short-term costs associated with alternate and less effective treatment models^{20,28,29} and could help avoid common and costly punitive responses to OUD such as incarceration. Given the evidence-based health and cost benefits of IN, comprehensive reimbursement of a pharmacy's administration costs/time should be considered a necessary step to expanding IN access by incentivizing this practice. Future studies are needed to examine how to expand pharmacy

IN practice and the effects of increased pharmacist-administered IN treatment on patient access, care quality, and treatment outcomes.

5.1. Strengths and limitations

Although based on a small but representative sample size from a single state, the findings offer the first evidence about aggregate IN administration costs, whether an initial dose or for follow-up services. The data collection tool was designed specifically for assessing pharmacist-administered IN. However, the tool provides a framework to facilitate future studies of cost and time and could be adapted for administering other long-acting injectables (e.g., buprenorphine, antipsychotics) in a community pharmacy setting.

Despite this unique research and objective, a few limitations must be considered. First, results are based on a small purposefully-selected sample of key informants from community pharmacies that administer IN. Second, it is possible that the accumulated time data, based on pharmacists' reports, may not accurately represent the time to complete each activity associated with IN administration; future efforts should validate the reported time estimates through direct observation. Finally, results obtained from community pharmacies in a single state may not generalize to independent pharmacies in other states or to pharmacists/technicians from chain pharmacies (e.g., Walgreens or CVS).

6. Conclusions

Pharmacists administering IN to treat OUD allocate significant time/resources to meet patients' treatment needs and reduce relapse. Although community pharmacists remain a vital, but untapped, MOUD access point in the state and throughout the country, lack of reimbursement for administration costs can disincentivize pharmacists from beginning or expanding their services related to OUD treatment. At a time when more patients need access to MOUD, combined with the costs of poor MOUD access, regulatory agencies could regard failure to reimburse pharmacists for IN administration as a missed opportunity. Efforts to increase pharmacist-administered IN should extend beyond promoting pharmacy awareness and interest, to include a commitment to ensure insurance coverage not only of medications but also of related treatment activities. The state pharmacy association introduced a bill, using information from this study, to reimburse pharmacists for services provided under the scope of their license. If signed into law, discussions about actual Medicaid reimbursement would occur, which could inform commercial insurers reimbursement for IN administrative cost.

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CRedit authorship contribution statement

James H. Ford II: Conceptualization, Methodology, Validation, Formal analysis, Investigation, Resources, Data curation, Writing-Original Draft, Supervision, Project administration, Funding acquisition. **Aaron M. Gilson:** Conceptualization, Methodology, Validation, Formal analysis, Investigation, Data curation, Writing – original draft, Visualization. **Gina M. Bryan:** Conceptualization, Writing – review & editing. **Rachel E. Gicquelais:** Conceptualization, Writing – review & editing. **Michele Gassman:** Writing – review & editing. **David A. Mott:** Conceptualization, Methodology, Writing – review & editing.

Declaration of competing interest

All authors declare that they have no conflict of interest.

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Appendix

Appendix 1

Cost and Time for Injectable Naltrexone Activities for a New Patient¹

	Time to Provide Injectable Naltrexone							Costs to Provide Injectable Naltrexone						
	Mean	StDev	Median	Min	Max	25th	75th	Mean	StDev	Median	Min	Max	25th	75th
Patient Scheduling Before Appointment	10.00	6.07	9	3	20	5	15	\$5.99	\$6.05	\$3.10	\$0.83	\$15.00	\$1.25	\$10.05
Benefits coordination	22.13	20.92	15	2	70	13.75	22.5	\$13.09	\$19.74	\$4.00	\$0.53	\$60.00	\$3.52	\$13.91
Extended patient consultation	13.88	7.99	12	5	30	9.25	16.25	\$13.10	\$6.86	\$11.93	\$4.17	\$25.00	\$9.50	\$16.25
Urine drug screen cup/panel	6.25	8.76	3	0	25	0	10	\$12.66	\$6.56	\$13.00	\$4.15	\$24.78	\$8.75	\$14.58
Drug screen interpretation and lab monitoring/management (CMP, Pregnancy)	10.88	6.79	10	0	20	8.75	14	\$9.05	\$2.21	\$10.00	\$5.08	\$11.33	\$8.07	\$10.42
Behavioral Health Consultation	8.13	7.99	5	0	20	3.75	12.5	\$5.54	\$5.47	\$4.17	\$0.00	\$15.00	\$2.04	\$7.75
Supplies for injection	2.38	3.50	1	0	10	0	2.75	\$2.73	\$3.62	\$1.00	\$0.00	\$10.00	\$0.38	\$3.83
Injection professional service	11.25	8.83	9	3	30	5	15	\$11.14	\$10.51	\$6.96	\$3.00	\$35.00	\$4.93	\$13.13
Monitoring period	12.75	4.68	15	2	15	13.75	15	\$10.28	\$5.05	\$12.50	\$2.00	\$15.25	\$6.69	\$13.69
Patient Follow-up Activities (Education and Scheduling)	6.38	4.07	7	0	10	3.75	10	\$3.91	\$2.57	\$4.46	\$0.00	\$7.50	\$2.22	\$5.57
Administrative Documentation	8.25	4.30	10	2	15	5.25	10	\$4.66	\$2.66	\$4.63	\$1.60	\$10.00	\$2.71	\$5.57
Billing	10.38	9.53	8	2	30	3	15	\$4.62	\$5.77	\$2.13	\$0.60	\$16.63	\$0.75	\$5.50

1. Information in this table is provided for reference of the time and costs associated with a new patient. Interpretation of the information in this table should be done with caution as the descriptive statistics are at the activity not the pharmacy level. Therefore, data in the Appendix **will not align with data presented in the manuscript**. Data for a returning patient is not provided because it may allow readers to breach confidentiality and potentially identify participating pharmacies.

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