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Item Type	Article
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Citation	Meyerson, B. E., Agle, J. D., Jayawardene, W., Eldridge, L. A., Arora, P., Smith, C., ... & PharmNet Research Team. (2019). Feasibility and acceptability of a proposed pharmacy-based harm reduction intervention to reduce opioid overdose, HIV and hepatitis C. <i>Research in Social and Administrative Pharmacy</i> . https://doi.org/10.1016/j.sapharm.2019.08.026
DOI	10.1016/j.sapharm.2019.08.026
Publisher	ELSEVIER SCIENCE INC
Journal	RESEARCH IN SOCIAL & ADMINISTRATIVE PHARMACY
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Download date	28/08/2022 04:02:01
Item License	https://creativecommons.org/licenses/by-nc-nd/4.0/
Version	Final published version
Link to Item	http://hdl.handle.net/10150/641340



Feasibility and acceptability of a proposed pharmacy-based harm reduction intervention to reduce opioid overdose, HIV and hepatitis C



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ARTICLE INFO

Keywords:

Pharmacy practice
Harm reduction
Consolidated framework for implementation research
Opioid overdose reduction
Syringe access
Naloxone access
HIV
Hepatitis C

ABSTRACT

Background: Evidence-based harm reduction intervention components which might benefit pharmacy patients have not been integrated and studied.

Objective: To investigate the feasibility and acceptability of a proposed pharmacy-based harm reduction intervention to reduce opioid overdose, HIV and hepatitis C called PharmNet.

Methods: Indiana managing pharmacists were surveyed in 2018 to assess the feasibility and acceptability of an intervention for opioid misuse screening, brief intervention, syringe and naloxone dispensing, and referrals provision. The Consolidated Framework for Implementation Research informed the survey development and analysis.

Results: The sample included 303 (30.8%) pharmacists; 215 (70.9%) provided detailed written comments. Intervention Characteristics: 83.3% believed PharmNet would benefit patients, and that staff could deliver the intervention with adequate training (70.0%). Inner Setting: While 77.2% believed their pharmacy culture supported practice change, 57.5% of chain pharmacists believed their pharmacies would not have time for PharmNet. Outer Setting: 73.3% believed additional addiction and overdose screening is needed in their community, and pharmacies should offer new services to help reduce opioid overdose and addiction among their patients (79.5%). A vast majority (97.7%) were asked by patients in the past 2 years about syringe related issues; 67.7% were asked about syringes for non-prescription injection drug use. Individuals Involved: While 62.4% believed PharmNet was within pharmacy scope of practice and 90.1% were comfortable consulting about syringe use, pharmacists reported that they had limited control over the implementation environment. Process: 38.0% of pharmacists indicated interest in advising the development of PharmNet.

Conclusions: An implementation trial of a modified version of PharmNet is likely feasible; yet will be challenged by structural pressures particularly in chain pharmacies. Successful implementation will involve the development of resources and policy components to manage outer and inner setting characteristics and align the intervention to the implementation environment.

Introduction

Community pharmacists and pharmacies are increasingly recognized as important contributors to community health access.^{1–4} This

is especially apparent with the opioid epidemic in the United States (U.S.), as pharmacy-based research seeks ways of approaching screening and/or risk assessment,^{5–7} opioid consultation,^{8–10} and naloxone and syringe dispensing.^{11,12} The need for opioid and related

Abbreviations: CFIR, Consolidated Framework for Implementation Research; SBIRT, Screening, Brief Intervention, and Referral to Treatment; MI, Motivational Interviewing

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<https://doi.org/10.1016/j.sapharm.2019.08.026>

Received 6 March 2019; Received in revised form 6 August 2019; Accepted 8 August 2019

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harm reduction services in pharmacies is especially acute in the U.S. health system with limited prescribing guardrails and prescriber oversight.^{13,14} Pharmacist education and training programs recognize these needs and issues, as evidenced by innovative training programs.^{15,16} Further, pharmacies are part of the overall public health system, especially in rural communities and in U.S. states such as Indiana, where the public health infrastructure is not well funded¹⁷ and harm reduction services are nascent.¹⁸

Our prior studies of Indiana managing pharmacists identified several harm reduction-related service opportunities such as syringes sales for nonprescription use,¹¹ naloxone stocking and dispensing,¹² and PrEP (Pre-exposure prophylaxis for HIV prevention) consultation.¹⁹ These services are useful in isolation, but require further integration within the pharmacy system, the overall healthcare system, and the community – similar to much of the research on integrated care.^{20,21} At the same time, such work would also benefit from an integration model or framework that has been tested with opioid misuse.

Other research has investigated the utility of screening, brief intervention, and referral to treatment (SBIRT) frameworks in mitigating harm from opioid misuse in emergency departments (ED). Rather than proposing a one-size-fits-all ‘SBIRT panacea,’²² these approaches recognize the general importance of risk identification, provision of a service (be it counseling, medication, or advice), and either treatment initiation or engagement with referral. Within this framework, we highlight two recent randomized clinical trials in the ED. The first study found fewer overdose risk behaviors and reduced non-medical opioid use following a 30-min motivational interviewing (MI) session with enhanced usual care in the ED (vs. enhanced usual care alone).²³ The second measured increased engagement in addiction treatment at 30 days and decreased self-reported illicit drug use following a brief negotiated interview, ED-initiated buprenorphine, and referral to primary care for medical management, compared to ‘traditional’ SBIRT or basic referral to opioid addiction treatment.^{24,25}

In reviewing the interface between all of these studies, we concluded that: (a) pharmacy practice is an important but often excluded component of integrated care and harm reduction; (b) there are several evidence-based services likely to benefit pharmacy patients but have not yet been systematized, and (c) there is an extant, effective framework for identifying risk, providing a service or medical device, and facilitating entry into the medical treatment system.²⁶

With this in mind, we designed a system-level pharmacy intervention called PharmNet to reduce, among pharmacy patients, frequencies of opioid overdose and misuse while reducing risk of hepatitis C (HCV) and human immunodeficiency virus (HIV) infection and transmission as an ancillary outcome of opioid injection. As a primary step in intervention development, we conducted a study among all Indiana managing pharmacists at community pharmacies to assess the feasibility, acceptability and likely adoption of this pharmacy-based harm reduction intervention. Findings from this study, shared herein, will inform the evolution of PharmNet as we prepare for a pilot multi-site randomized intervention trial in Indiana.

Methods

Data collection

A hybrid paper invitation and online census of Indiana community managing pharmacists was conducted from July to October 2018. As has been described elsewhere,²⁷ a list of Indiana community pharmacies was obtained from Hayes Directories, Inc (Mission Viejo, CA) for 2018. This list provided the street address of all community pharmacies in Indiana. Hospital, clinic-based, and compounding pharmacies were removed from the list, along with pharmacies that had closed. The result was a list of 1,018 community pharmacies that composed our initial sample. In reviewing the data for this study, an additional 34 pharmacies were excluded, leaving the number of community pharmacies at

984. Pharmacies on the final list were located in 90 of Indiana's 92 counties. These pharmacies were then classified as one of four types of community pharmacies: independent, chain (> 5 locations), food store (pharmacies located in grocery stores), and mass merchandiser (pharmacies located in stores that sell mass merchandise and are not primarily pharmacies).

As the managing pharmacist is a singular role in every pharmacy, we addressed a paper invitation letter to the ‘Managing Pharmacist’ for each pharmacy. Survey invitations contained study information, a \$5.00 cash pre-incentive, a unique identifier, and a web address and QR code that led to an online survey hosted in Qualtrics (Qualtrics International, Inc.). The inclusion of the monetary pre-incentive had precedent in our prior work with Indiana pharmacists.^{10,11}

The initial invitation was followed by a second letter (without pre-incentive) sent to non-respondents within 18 days of the first mailing. Finally, up to two attempts for telephonic follow up were made with those who had not completed the survey within 17 days of the second mailing. The list of telephone numbers was generated by an internet search for non-responding pharmacies. Calls were made by two pharmacy students and one doctoral student. The study was deemed exempt by the Indiana University Institutional Review Board.

Questionnaire

Survey items and their interpretation were selected and developed to closely align with the Consolidated Framework for Implementation Research (CFIR),²⁸ as this survey would measure aspects of intervention feasibility and acceptability. The CFIR is a multilevel implementation framework informing several interventions in the past decade;^{29,30} though less so in the pharmacy practice sphere.^{31–34} To our knowledge, there have been no pharmacy studies which assess intervention feasibility and acceptability using the CFIR framework at the design stage. The CFIR domains of interest and associated survey measures are found in Table 1. As shown, we selected 25 constructs from the 5 CFIR domains based on the ability to measure them at the implementation planning stage; and therefore excluded those constructs measurable only during implementation. Discussion with the research team, which was comprised of implementation researchers, pharmacy research-practitioners, and interventionists, resulted in the selection of the constructs shown in Table 1. This approach is not unlike other studies that attempt to select CFIR constructs for research in particular settings.³⁵

The survey questionnaire included quantitative and qualitative response items. Quantitative response structures included selection lists (e.g., “Please indicate whether your pharmacy has the following characteristics: [select all that apply]”), Likert-type scales (e.g., “1 = Strongly disagree; 5 = Strongly agree”), rank ordering (“Rank the PharmNet components by ease of delivery in your pharmacy by dragging and dropping them in order. [Assume Rank #1 is the Easiest]”), and forced choice (“In your current or past pharmacy work, have you used validated screening tools to identify patient level of substance use, anxiety, or similar health conditions? [Examples of these tools include the Alcohol Use Disorders Identification Test {AUDIT-10} or the Generalized Anxiety Disorder Scale {GAD-7}]”).

Pharmacist and pharmacy characteristics were measured, as well as practice and beliefs related to PharmNet intervention components. Pharmacists were also asked to indicate beliefs about community need for PharmNet services. Survey items measuring pharmacist characteristics, practice experience, continuing education, as well as their interaction with patients and professionals in the past two years were developed as part of our 2016 pharmacy survey, along with pharmacy-level items related to naloxone and syringe access. That instrument was repeatedly assessed for face validity by an interprofessional group of experts, piloted internally and externally, and later administered as a census.^{11,12} Questions were also selected and adapted from the online resource *CFIR Guide* which listed several question options to be used in

Table 1 PharmNet feasibility measures by consolidated framework for implementation research (CFIR) domain, 2018^a.

	Intervention Characteristics	Inner Setting	Outer Setting	Characteristics of Individuals	Process
CFIR Domains and Constructs	<ul style="list-style-type: none"> ● Intervention source ● Evidence strength and quality ● Relative advantage ● Adaptability ● Trialability ● Complexity ● Design quality ● Cost 	<ul style="list-style-type: none"> ● Pharmacy characteristics ● Networks and communications ● Culture ● Implementation climate 	<ul style="list-style-type: none"> ● Patient needs and resources ● Cosmopolitanism ● Peer pressure ● External policies and incentives ● Patient expectations 	<ul style="list-style-type: none"> ● Knowledge and beliefs about the intervention ● Self-efficacy ● Individual stage of change ● Individual identification with organization ● Other personal attributes 	<ul style="list-style-type: none"> ● Planning ● Engaging ● Executing ● Reflecting and evaluating
PharmNet Survey Measures	<ul style="list-style-type: none"> ● Relative advantage of PharmNet ● Perception about PharmNet benefits and costs ● Opinions about PharmNet ● Rankings of PharmNet characteristics ● Perceptions of customer response to PharmNet 	<ul style="list-style-type: none"> ● FTEs ● Pharmacy characteristics ● Leadership perspectives ● Culture for change ● Internal policies and incentives 	<ul style="list-style-type: none"> ● Perception of community need ● Whether asked about related PharmNet-type services ● External policies and incentives 	<ul style="list-style-type: none"> ● Knowledge about PharmNet components ● Experience with PharmNet-like components ● Certifications, CE ● Comfort with aspects of PharmNet 	<ul style="list-style-type: none"> ● Interest in advising PharmNet design and implementation

^a Constructs in bold were selected for PharmNet measurement.

interviews to measure inner setting constructs of culture and implementation climate.³⁶ In addition, questions directly asking about PharmNet components (screening, intervening, and referring) used language drawn from established questions about performance of SBIRT-related behaviors and modified in a face-valid manner.³⁷ Three open-ended survey response items followed a brief intervention description. They included pharmacists' general opinions about the intervention, alterations that needed to be made to improve feasibility, and perspectives about how patients might respond to the intervention. Finally, pharmacists were asked whether they were interested in advising the development of the PharmNet intervention. If so, they were provided a separate means of conveying contact information to the study team.

County-level covariates

Survey data were compared with county-level data related to community need indicators for overdose and harm reduction services. This was done to provide additional clarity about PharmNet feasibility, particularly in areas of high need and low resources. These indicators included: 1) number of organizations confirmed (telephonically by a research team member) as distributing naloxone at no cost to laypersons,³⁸ 2) counties with syringe services programs³⁹ that are confirmed as functioning,⁴⁰ 3) number of locations providing free or sliding scale (cost) HIV testing services to the public as identified by the Indiana state department of health,⁴¹ Planned Parenthood of Indiana and Kentucky,⁴² and a county by county Google search by the research team, 4) 2016 age-adjusted drug poisoning death rate for counties, compared to the U.S. average (19.78 per 100,000 population),⁴³ 5) the number of community pharmacies by county, and 6) Rural and Urban Commuting Area (RUCA) designations⁴⁴ calculated for each address using the geomap tract locator.⁴⁵ Categories were reduced for analysis to: metropolitan, micropolitan, small town and rural designations. For data point number four, the national average was selected over the state average because Indiana had a skewed distribution of age-adjusted drug poisoning death rates (few counties had very high rates). Two additional county-level indicators were derived from the questionnaire itself. These were: 1) number and percent of community pharmacies dispensing syringes for non-prescription injection drug use, and 2) number and percent of community pharmacies stocking naloxone.

PharmNet feasibility, acceptability and likely adoption

PharmNet is an adaptation of a Screening, Behavioral Intervention, and Referral to Treatment model designed for delivery in the pharmacy and based on prior formative studies by others^{10,33} and by members of our research team.^{12,19,46,47} Our interdisciplinary research team (pharmacy research and practice, SBIRT implementation, harm reduction interventions, and implementation scientists) designed the PharmNet intervention model in November 2017. In the survey, we described the intervention to participants prior to soliciting their feedback as follows (verbatim):

PharmNet has 3 components:

Screening for opioid misuse and addiction - Patients can independently and privately complete screening questions within 15 min using a handheld device containing questions from PainCas [™(Inflexxion, Inc Newton, MA)], a scientifically validated web-based clinical tool for assessing pain and opioid misuse risk.⁴⁸ This can be privately completed in the pharmacy waiting area in 15 min, during which the pharmacy serves other patients.

Brief Intervention using Motivational Interviewing focused on the outcome of the screening: A conversation lasting no more than 15 min designed to reduce patient ambivalence about - as necessary - accessing addiction treatment, reducing opioid use, use of naloxone for overdose risk reduction, and safe syringe use.

Table 2
Community managing pharmacist and pharmacy characteristics, Indiana 2018 (N = 303).

Community Managing Pharmacist and Pharmacy Characteristics, Indiana 2018 (N=303)	
Pharmacy Characteristics	#(%)
Staffing	
Number of Full Time Pharmacists at this location (non-float)	mean=2.02 (SD:0.96, r:0-6)
Number of Part Time Pharmacists at this location (non-float)	mean=0.64 (SD:1.09, r:0-10)
Number of Floating Pharmacists	mean=0.67 (SD:1.06, r:0-6)
Pharmacy has overlap pharmacy staffing	164 (54.1%)
Structural Characteristics	
Pharmacy has a consultation room	135 (44.6%)
Pharmacy has a medical clinic (such as Rediclinic, Minute Clinic, etc)	29 (9.6%)
Pharmacy has a programmable kiosk at the counter to gather patient information	28 (9.2%)
Pharmacy Practice	
Pharmacy currently stocks naloxone	271 (89.4%)
Pharmacy currently dispenses naloxone	226 (74.6%)
Pharmacy currently sells syringes for non-prescription injection drug use	103 (34.0%)
Pharmacist offers clinical services for a variety of health conditions	97 (32.0%)
Community Setting	
Metropolitan area	214 (70.6%)
Micropolitan area	52(17.2%)
Small town	27 (8.9%)
Rural area	10(3.3%)
Pharmacy is in a county with a syringe access program	47(15.5%)
Number of free/sliding scale HIV testing sites in the county	Mean= 1.9 (r:0-7, SD:2.3)
Managing Pharmacist Characteristics	
Gender	
Male	156 (51.5%)
Female	147 (48.5%)
Race & Ethnicity	
White	286 (94.4%)
Asian/Asian American	11 (3.6%)
African American	5 (1.7%)
Alaskan Native	1 (0.3%)
American Indian	1 (0.3%)
Native Hawaiian/Other Pacific Islander	2 (0.7%)
Hispanic	3 (1.0%)
Age	mean=41.7 (SD:12.02, r:24-78)
Years in pharmacy practice at this location	mean=8.6 (SD:9.4, r:0-48)
Years as a licensed pharmacist	mean=16.5 (SD:12.5, r:0-50)
Continuing Professional Education Received in the Past 2 Years	
Pain Management	73 (24.1%)
Opioid Use Disorder	66 (21.6%)
HIV Management	32 (10.5%)
Motivational Interviewing	27 (8.9%)
Other specialization related to HIV, HCV or Addictions	12 (4.0%)

Referral to Treatment at local or nearby service providers in the community in cases where it is indicated: At a minimum, a written referral to addiction treatment and/or additional health screening such as for HIV or hepatitis C (the PharmNet research team will assist with identifying local agencies for referral). If time permits, utilize a ‘warm handoff’ such as a three-way phone call to introduce the patient to the referred provider.

We will work with pharmacies to **develop a question to identify patients who might benefit from this intervention** in order to ensure patient comfort and reduce environmental bias.

The CFIR domains and constructs allowed the organization of concepts related to PharmNet feasibility, acceptability and likely adoption.

Analyses involved description of quantitative survey items focused on intervention feasibility, acceptability and likely adoption; and their triangulation with analyzed qualitative data in cases where qualitative themes aligned with quantitative subject matter. Qualitative data were approached with open coding following the organization of data into the following *a priori* CFIR constructs: acceptability (attitudes about the intervention and likely patient response to it), feasibility (changes needed to improve feasibility), and cost (likely patient response to PharmNet). Qualitative rigor was achieved through a congruency analysis conducted at the time of data translation (the extent to which qualitative themes reflected quantitative responses by those offering both),⁴⁹ the fact that qualifications and background of the investigators reflected those being studied,⁵⁰ and through the adoption of credible

research procedures.⁵¹ Congruency between qualitative and quantitative survey data was observed (no conflicts), the research procedures used here were used in our prior survey studies among this population,^{11,12} and the research team composition reflected pharmacy-based research and practice, survey research and qualitative analysis.

Comparison of feasibility measures with pharmacy, pharmacist and community characteristics was accomplished through bivariate Pearson goodness of fit, chi-square testing, and analysis of variance. Because these were exploratory analyses only, we did not apply a correction to significance levels for multiple comparisons (e.g., Bonferroni). This is because significance adjustments are designed to control for group-wide type one error,⁵² whereas these tests are not assessing a shared hypothesis but rather indicating areas of potential interest in numerous domains toward which it might be prudent to place attention during implementation. SPSS (v.25) and QSR NVIVO (v.12) were used to organize and analyze data. Qualitative comments are reported with quantitative responses to provide additional clarity.

Results

Complete survey responses were received from 303 Indiana managing pharmacists for a response rate of 30.8%. Of this group, 70.9% (215) responded to at least one open-ended survey item. Those responding with written comments did not vary by pharmacy type, rurality, or county age-adjusted drug poisoning death rate from those that did not provide written comment. All responding pharmacists worked in 74 (82.2%) of Indiana's 90 counties that had community pharmacies. Of the 16 counties with no responding pharmacists, half had no more than 2 pharmacies (5 of which had only 1 pharmacy).

Pharmacy characteristics

The sample included 37.3% chain, 24.8% food store, 22.8% independent, and 15.2% mass merchandiser pharmacies. This partially reflected Indiana's distribution of community pharmacy types. As compared to the sample's distribution of pharmacies by type, Indiana had a lower percentage of independent and food store pharmacies (13.3% and 13.6% respectively) and a higher percentage of chain and mass merchandiser pharmacies (53.2% and 19.9% respectively). The gender and race/ethnicity distribution of responding managing pharmacists reflected Indiana's pharmacist population according to the Indiana 2012 workforce report (latest available).⁵³ Pharmacy, pharmacist, and community characteristics are found in Table 2.

Staffing levels varied by pharmacy type: the mean number of full time, non-floating pharmacists at chain pharmacies and mass merchandisers were 2.3 and 2.2, respectively, whereas for independent and food store they were 1.6 and 1.9, respectively ($F = 9.0$, $df = 3$, $p \leq .05$). Mass merchandisers had a larger mean number of floating pharmacists (1.1) compared with 0.6 each at chain, food store, and independent pharmacies ($F = 3.2$, $df = 3$, $p \leq .05$). Over half (54.1%) of pharmacies had overlap pharmacy staffing. While metropolitan area respondents comprised a majority each pharmacy type, pharmacists from rural areas worked primarily in chain and independent pharmacies ($X^2 = 11.4$ [chain], $X^2 = 31.9$ [independent], $df = 8$, $p \leq .05$).

PharmNet feasibility, acceptability and likely adoption

Indicators of PharmNet feasibility, acceptability and likely adoption are arrayed by CFIR domain and construct in Table 3. This table also classifies responses as implementation facilitators or barriers. Association with county-level variables (pharmacy type, community rurality, or age-adjusted drug poisoning death rate) was tested for each identified barrier and facilitator but is reported only when exceeding baseline statistical significance ($\alpha < 0.05$). Results will be discussed by CFIR domain.

Intervention characteristics

Relative advantage

The CFIR construct of relative advantage is an acceptability indicator referring to perceptions about the benefit or burden to pharmacy patients. There appeared to be a bifocal view of PharmNet's burden and benefit to patients; in that a majority of pharmacists (83.3%) agreed or strongly agreed that their patients would benefit from the PharmNet intervention, though this belief was less common among rural pharmacists (77.8% [small town], 94.2% [micropolitan], 83.2% [metropolitan], vs. 60% [rural], $X^2 = 9.1$, $df = 3$, $p < .05$). In stark contrast was the opposing (and simultaneously held) view that patients might feel burdened by the intervention process (83.3%). Pharmacists providing written explanations indicated that stigma and the conflict with prescribing behavior might influence patient receptivity to PharmNet.

If the patients approached us for the intervention, I assume they would be pleased with the service. However, if we approached them and misidentified them as a candidate for a screening this could result negatively. (Respondent 153)

It would be a tough change because doctors make patients think that pain pills are the only pain management solution in our area. Other options seem to be rarely explored. (Respondent 175)

Pharmacists also indicated that negative customer response to PharmNet might be linked with customer expectations about time spent in the pharmacy.

I'm not sure what changes could be made [to the intervention]. With the drive-thru mentality, patients are not open to some interventions and the time that it takes to complete them. (Respondent 126)

I suspect that most who use opiates will not like the intervention as there is a whole lot more to the intervention We get yelled at and complained on already holding patients to the 2 day early refill and the insurance 7 day acute opiate rules. (Respondent 254)

Cost

Cost was deemed an indicator of feasibility and likely adoption because it refers to the cost of implementing the intervention to the pharmacy and staff. Findings related to cost were closely linked with inner setting characteristics due to the structure and financing of pharmacy practice (see inner setting below). When pharmacists considered the cost of implementing PharmNet components, 75.7% believed that PharmNet, or key components of it, should be reimbursed. This was particularly the case for the brief intervention focused on screening outcomes (69.8%), which (by design) would require pharmacist time. Cost associated with PharmNet was primarily conceptualized as pharmacy staffing costs.

Adaptability and complexity

The measures related to constructs of adaptability and complexity indicated pharmacist perceptions of PharmNet feasibility, acceptability and likely adoption. In terms of PharmNet's implementation complexity, 70.0% of pharmacists felt that with adequate training, their pharmacy staff could deliver PharmNet services. Thirty-eight percent of pharmacists believed PharmNet had a design similar to other pharmacy interventions focused on screening and behavior modifications, and 65.7% who held this view reported prior experience with these types of interventions. At the same time, 24.0% of pharmacists believed that PharmNet was too complicated for delivery at their pharmacy. This did not vary by perceptions of PharmNet's similarity to other pharmacy interventions or reported experience with screening or brief interventions.

To further understand adaptability, complexity, and likely adoption, we asked pharmacists to rank each of the PharmNet components by ease of delivery in their current pharmacy; and 87.8% of pharmacists responded (N = 266) with rankings (data not shown). Almost 60% of

Table 3
PharmNet acceptability, feasibility and likely adoption by Indiana pharmacists, 2018 (N = 303).

CFIR Domain	Facilitators of PharmNet Implementation	Barriers to PharmNet Implementation	Indicator Type
Intervention Characteristics			
Relative Advantage	83.3% agreed that patients would benefit from PharmNet	83.3% felt that patients might be burdened by the intervention process. 40% of rural pharmacists held this belief.	Acceptability
Cost	75.7% believed PharmNet intervention should be reimbursable; particularly the brief intervention (69.8%).		Feasibility Likely Adoption
Adaptability	65.7% of pharmacists having experience offering brief interventions to patients agreed that PharmNet was similar to other screening and behavioral interventions in pharmacies.		Feasibility Likely Adoption
Complexity	70.0% believed that with adequate training pharmacy staff could deliver PharmNet or similar services. 38% believed PharmNet was similar to other pharmacy interventions. 66% of these pharmacists had experience with intervention aspects.	24.0% believed that PharmNet was too complicated for delivery at the pharmacy.	Acceptability Feasibility Likely Adoption
Inner Setting			
Pharmacy Characteristics	54.1% of pharmacies had overlapping staff.	33% of independent pharmacies had overlapping staff.	Feasibility
Culture	77.2% of pharmacists felt that the pharmacy's culture supported practice change. 79.2% had leadership that supported "new ideas to improve patient health."	20.5% indicated that pharmacy leadership would not support PharmNet's practice change at the pharmacy. 50.0% were from chain pharmacies.	Acceptability Likely Adoption
Implementation Climate	83.8% of pharmacies sometimes implemented new programs to improve patient health. 81.8% of pharmacies used technology such as kiosks, texts/email alerts or automated patient data gathering tools.	48.2% felt that the pharmacy did not have time for PharmNet. Over half (58%) of chain pharmacists held this belief. "Assembly line" culture.	Feasibility Likely Adoption
Outer Setting			
Patient Needs and Resources	73.3% believed there is a need for additional additions and overdose risk screening in the community. 79.5% believed that pharmacies should offer new services to help reduce opioid overdose and addiction among their patients. 28.7% felt that opioid abuse is an emergency in the community. 55.1% felt that it is a major problem, but not an emergency.		Acceptability
Patient Expectations	97.7% of pharmacists had been asked about syringe-related issues. 80.2% of pharmacists had been asked about naloxone access. 67.7% of pharmacists had been asked by patients about syringes for non-prescription injection drug use in the past 2 years.	10.2% of pharmacists were asked by patients in the past 2 years about opioid addictions screening. Over half were chain pharmacists. Patient expectations for quick service and to refill prescription (even if not needed).	Acceptability
External Policies and Incentives		Pressures on pharmacies to fill prescriptions. Lack of reimbursement for pharmacy-based screening and consultation interventions. Lack of prescriber regulation.	Feasibility Likely Adoption
Characteristics of Individuals			
Beliefs about PharmNet	62.4% of pharmacists believed PharmNet is within the scope of pharmacy practice		Acceptability
Self-efficacy	90.1% of pharmacists were comfortable consulting about safe syringe use. 83.5% were comfortable consulting about the need for naloxone. 74.3% of pharmacists were comfortable consulting about opioid misuse reduction. 73.6% of pharmacists consulted with patients in the past 2 years about prescription opioid use reduction.	Limited control by pharmacists over what can happen at the pharmacy level. 35.3% of pharmacists had experience consulting about safe syringe use. 36.3% were comfortable dispensing non-prescription syringes for likely injection drug use. 33.0% of pharmacists consulted with patients about illicit opioid use reduction in the past 2 years.	Feasibility Likely Adoption
Process			
Planning and Engaging	115 pharmacists (38.0%) indicated an interest in advising the development of PharmNet. 85.2% of these pharmacists believed there was a need for additional addiction and overdose risk screening in the community.		Acceptability

pharmacists rated 'Patient Identification', 'Dispensing Naloxone', and 'Dispensing Syringes' as relatively easy by giving them a rank of 3 or lower in the 7-point semantic differential scale (1 = easiest, 7 = hardest). Further, 71% of pharmacists rated 'Delivering Brief Intervention' as relatively difficult by giving it a rank of 5 or higher.

Reasons for this are unknown; however, as previously noted, it was this component of the intervention that was perceived as most costly in terms of pharmacist time. Pharmacists also rated 'Providing the Referrals' (55%) and 'Reviewing the screening score and identifying brief intervention focus' (53%) as relatively difficult.

Table 4
Indiana pharmacist experience and comfort with PharmNet-Like intervention components, Indiana (N = 303).

	Pharmacist Has Done so Personally	Other Pharmacists at this Pharmacy have done this	Technicians at this Pharmacy have done this
	#(%)	#(%)	#(%)
Screening in Current or Past Practice			
Used validated screening tools to identify patient level of substance use, anxiety, or similar health conditions.	34 (11.2%)		
Behavioral and Test Consultations In Past Two Years			
Had experience with briefly intervening with patients to reduce possible harm from substance use, anxiety, or similar health conditions.	164 (53.8%)		
Provided behavior modification consultation about condom use	46 (15.2%)	21 (6.9%)	4 (1.3%)
Provided behavior modification consultation about safe syringe use	107 (35.3%)	40 (13.2%)	7 (2.3%)
Provided behavior modification consultation about prescribed opioid use reduction	223 (73.6%)	116 (38.3%)	8 (2.6%)
Provided behavior modification consultation focused on Illicit opioid use reduction	100 (33.0%)	42 (13.9%)	1 (0.3%)
Consulted about HIV test results	9 (3.0%)	7 (2.3%)	2 (0.7%)
Pharmacy Practice at Current Pharmacy			
Dispensed naloxone	215 (71.0%)	121 (39.9%)	10 (3.3%)
Dispensed naloxone that was free or subsidized	54 (17.8%)	40 (13.2%)	4 (1.3%)
Dispensed syringes to patients for likely injection drug use	89 (29.4%)	64 (21.1%)	32 (10.6%)
Provided education about naloxone	230 (75.9%)	125 (41.3%)	13 (4.3%)
Provided education about naloxone administration	203 (67.0%)	122 (40.3%)	4 (1.3%)
Educated about safe syringe disposal	218 (71.9%)	121 (39.9%)	30 (9.9%)
Referrals to Services			
Provided referrals for addictions treatment	44 (14.5%)	14 (4.6%)	3 (1.0%)
Provided referrals for HIV testing	20 (6.6%)	12 (4.0%)	3 (1.0%)
Provided referrals for Hepatitis C testing	14 (4.6%)	8 (2.6%)	2 (0.7%)
Provided referrals for HIV treatment	8 (2.6%)	11 (3.6%)	1 (0.3%)
Provided referrals for Hepatitis C treatment	8 (2.6%)	8 (2.6%)	1 (0.3%)
Comfort Consulting about			
Safe syringe use	273 (90.1%)		
Safe syringe disposal	285 (94.1%)		
The need for naloxone	253 (83.5%)		
Reducing opioid misuse	225 (74.3%)		
Safer sex practices	196 (64.7%)		
Comfort Dispensing			
Naloxone for overdose reversal	255 (84.2%)		
Referrals for community services	225 (74.3%)		
Syringes to patients for likely injection drug use	110 (36.3%)		

Inner setting: pharmacy culture, structure, and implementation climate

Inner setting characteristics refer to measures of implementation feasibility, acceptability, and likely adoption. When asked general questions about the pharmacy environment, most pharmacists (77.2%) believed their pharmacy's culture supported practice change, and that pharmacy leadership supported new ideas to improve patient health (79.2%). When asked specifically about PharmNet, 20.5% of pharmacists indicated that pharmacy leadership would not support the practice change suggested by PharmNet, and 50.0% of those pharmacists were working in chain pharmacies ($X^2 = 12.2$, $df = 4$, $p \leq .05$).

Pharmacy practice culture and the structure of work were noted by pharmacists as they responded to questions about the intervention and its 'fit' in the pharmacy environment. Despite the predominance of conceptual support for PharmNet, 48.2% of pharmacists felt that their pharmacy did not have time for a type of intervention like PharmNet. This belief was held at 57.5% of chain pharmacies ($X^2 = 6.2$, $df = 1$, $p \leq .01$), but fewer than half (33.3%) of independent pharmacies ($X^2 = 7.9$, $df = 1$, $p \leq .01$). Time was also noted in the written comments, where pharmacists described the current pharmacy practice environment as extremely busy and pressured with budget and staffing cuts, 19.5%, (42) indicated that owner/corporate control limited what could be implemented in pharmacies.

Increased prescription numbers with drastic pharmacist hour cuts and corporate pressures on clinical interventions required to garner DIR [Direct and Indirect Remuneration] fees greatly reduce time for any

additional services. (Respondent 107)

With high script volumes, reduced labor hours, and more and more responsibilities being placed at community pharmacies, it is very difficult to find time to do these interventions ... (We need to be) burdened with less work so that interventions can take place. We need to be less of an assembly line and be treated like medical professionals. (Respondent 15)

Outer Setting

Patient needs and resources, patient expectations, external policies and incentives

Pharmacists reported whether, in the past 2 years, they had been asked about aspects related to harm reduction services in the pharmacy by patients, other pharmacists, or medical providers. These measures served as indicators of patient needs and expectations, as did reported pharmacist perception of opioid misuse in the community. Nearly all (97.7%) pharmacists had been asked by patients about one or more syringe-related issue (sharps disposal, sale of syringes, and return of unused syringes), and 80.2% had been asked about naloxone access through insurance, at cost, at reduced cost or for free. Pharmacists working for chains were more likely than other pharmacists to report that patients asked about naloxone at reduced cost or for free ($X^2 = 8.6$, $df = 1$, $p \leq .01$). Chain (74.8%, $X^2 = 7.0$, $df = 1$, $p \leq .01$) and food store pharmacists (50.7%, $X^2 = 7.7$, $df = 1$, $p = .01$) were more likely to report that patients asked about return or donation of unused syringes.

Less than 15.0% of pharmacists reported that patients asked about screening for addiction, HIV and/or hepatitis C, or treatment for addiction, HIV, or hepatitis C; however, 86.0% and 90.3% of pharmacists asked by patients about HIV testing or addiction screening (respectively) were also asked about the sale of syringes for non-prescription injection drug use ($X^2 = 7.7$, $df = 1$, $p \leq .01$ and $X^2 = 8.1$, $df = 1$, $p \leq .01$ respectively). In counties with higher drug poisoning death rates, 78.4% of pharmacists reported that they had been asked by patients about sale of syringes for non-prescription injection drug use, compared to 63.3% of pharmacists in other counties ($X^2 = 6.55$, $df = 1$, $p = 0.01$).

Most pharmacists (79.5%) believed that pharmacies should offer new services to help reduce opioid addiction and overdose among their patients. This belief was more likely held by those who believed that opioid abuse was either a “community emergency” or a “major problem” in the community ($X^2 = 26.3$, $df = 4$, $p \leq .001$), and that there was a need for additional addiction and overdose risk screening in the community ($X^2 = 74.3$, $df = 6$, $p \leq .001$).

Characteristics of individuals

The CFIR domain of ‘Characteristics of Individuals’ refers to perceptions held by individuals regarding self-efficacy for implementing intervention aspects, and perceptions about the implementing organization. This domain was measured through perceived control over the implementation environment, experience with PharmNet-like elements, and comfort delivering them. Table 4 reports pharmacy staff experience and comfort with several PharmNet-like components.

While only 35.3% of pharmacists reported providing behavioral consultation about safe syringe use in the past 2 years, most pharmacists (90.1%) reported being comfortable with this pharmacy practice. However, less than half of pharmacists (36.3%) were comfortable dispensing non-prescription syringes for likely illicit drug injection, and only 29.4% had actually dispensed in this circumstance. Independent pharmacists were less likely than other pharmacists to report that they had dispensed non-prescription syringes for likely injection drug use (15.9%, $X^2 = 12.8$, $df = 1$, $p \leq .001$).

Large majorities of pharmacists were comfortable consulting about the need for naloxone (83.5%) and dispensing naloxone for overdose reversal (84.2%). The latter group included more independent pharmacists (71.0%, $X^2 = 10.1$, $df = 2$, $p \leq .01$) and mass merchandiser pharmacists (95.7%, $X^2 = 6.0$, $df = 2$, $p \leq .05$) than other types of pharmacists. Consultation about the reduction of opioid misuse was more fragmented, as 74.3% of pharmacists reported being comfortable consulting with patients about opioid misuse reduction, but, in the past 2 years, only 33.0% had provided such counseling. Further, only 14.5% of pharmacists reported having provided referrals for addiction treatment, a group of which nearly half (43.2%) were independent pharmacists ($X^2 = 13.4$, $df = 3$, $p \leq .01$).

Over half (62.4%) of pharmacists believed that PharmNet was within pharmacy scope of practice. That said, pharmacist comments about the structural aspects of the practice environment reflected perceived lack of control over what happened in the pharmacy.

Nothing (about PharmNet) would need to be altered for it to be more acceptable to the pharmacy staff. The culture within retail pharmacy needs to be altered. Large pharmacy corporations are focused on saving dollars by payroll reductions. As pharmacists we simply would not have the time during a normal day to complete the screenings and assessments. (Respondent 138)

Corporate office continues to add extra steps, reports, additional immunizations and metrics we cannot reach with allotted staffing cuts- not sure how we could add more. Although I do feel this service is much more beneficial to those we serve rather than harassing our patients to see if they need sildenafil refilled. (Respondent 260)

Process

The study was conducted to inform intervention implementation planning, which is part of the domain “Process.” Other characteristics related to Process involved activities after implementation or as implementation begins. This includes engaging appropriate persons in the implementation process, the process of intervention execution, and the process of reflecting while in the midst of the intervention. The entire feasibility study was a step toward the Planning characteristic, so as to assure the advance development of the intervention as informed by implementing individuals and organizations. We also measured interest in continued planning engagement prior to implementation by asking pharmacists whether they and/or their staff might be interested in advising the continued development of PharmNet. Over one third (38.0%) of pharmacists indicated interest in advising the development of PharmNet. Of those, 82.6% believed that with training their staff could implement PharmNet or similar services ($X^2 = 19.2$, $df = 4$, $p \leq .001$).

Discussion

This study was among the first to use the CFIR framework at the development phase of a pharmacy-based intervention. This use of the CFIR framework allowed the characterization of multilevel aspects of intervention implementation at the planning stage so that the resulting intervention more precisely reflects the implementing environment, and will hopefully mitigate adoption issues. While CFIR’s measures are intentionally not optimized to summarize objective intervention feasibility, implementation researchers are able to surmise feasibility in context.

Based on reported pharmacist perceptions about intervention characteristics (complexity, cost, relative advantage and adaptability) and based on characteristics of individuals (experience with similar interventions and perceived comfort with intervention elements), we have concluded that the important components of PharmNet appear generally feasible but will need to be modified to facilitate intervention adoption. These modifications retain the core structure designed to screen, intervene, and refer; yet streamline the procedures to minimize both client and pharmacist burden, as outlined later in this section.

From the standpoint of intervention characteristics, there was widespread belief that PharmNet would benefit patients and, with adequate training, could be implemented. A majority of pharmacists had experience and were comfortable with key aspects of PharmNet, such as consulting about safe syringe use, need for naloxone and opioid misuse reduction. Most pharmacists also believed their pharmacy culture supported practice change, leadership supported ideas to improve patient health, and that their pharmacies ‘sometimes’ implemented new programs to improve patient health. Finally, many pharmacists believed there was a need for additional addiction and overdose risk screening in the community and that pharmacies should offer new services to address these risks among their patients.

These findings are consistent with other pharmacy studies that have examined, in isolation, one or more proposed components of PharmNet. Cochran et al. found that community pharmacy screening in two Pennsylvania community pharmacies for prescription opioid misuse was feasible,⁵⁴ as did Strand et al.’s implementation study of a prescription opioid misuse screening toolkit among 11 North Dakota pharmacists.⁴ Hagemeyer et al.’s study of factors associated with Tennessee pharmacist provision of treatment information to patients found that pharmacist characteristics, as well as having information about treatment facilities located within the pharmacy, were associated with reported provision of addiction treatment information to patients.⁵⁵

At the same time, supportive pharmacist beliefs about PharmNet benefits, adaptability, and feasibility should be balanced by concerns that PharmNet might burden both pharmacists and patients. Qualitative

feedback revealed that some pharmacists viewed their burden as partners in the healthcare relationship as disproportionate or inappropriate relative to their compensation. This is especially salient with regard to reported perceptions that current pharmacy environments function like “drive-thrus.” This has implication for pharmacist workload and patient expectation; and may also influence the types of interventions possible in the pharmacy environment. Flemming et al.’s small study of Texas pharmacists highlighted this conflict. They reported the belief that engaging patients about prescription drug misuse might cause a loss of business, despite perceived benefits to patients.⁷ Whether general perceptions of potential patient burden were due to beliefs about patient service expectations or other reasons was not clear.

Concerns of time constraints and lack of leadership support for PharmNet implementation were expressed particularly by pharmacists working in chain pharmacies. This is notable because chain pharmacists tended to report more often than their other pharmacy peers that patients asked about opioid screening, naloxone access at free or reduced cost, and syringes for non-prescription injection drug use. Being a chain pharmacy was also positively associated with naloxone stocking in our 2016 survey of Indiana managing pharmacists, at a time when fewer than 60% of Indiana community pharmacies did so.¹¹ This finding reinforces the importance of seeking leadership support above the managing pharmacist level prior to PharmNet implementation.

Study findings led us to alter the PharmNet intervention in several ways. Pharmacist reported lack of control over workflow underscores the challenge of integrating new interventions in the pharmacy setting. This reflects similar concerns expressed by managers and frontline workers in primary care.⁵⁶ Based on survey feedback, we learned that our initial screening proposal was overly ambitious given current pharmacy workflow. This study leads us to propose, instead, the use of electronic self-administration (by the client) of the 10-question Opioid Risk Tool (ORT).⁵⁷ This was developed in 2005 to identify risk among patients prescribed opioids for chronic pain. It was re-validated in 2019, reduced by one item, and response weighting was removed in order to obtain stronger predictive validity.⁵⁸ The National Institute on Drug Abuse notes that the original 10-question tool can be administered and scored in fewer than 60 seconds.⁵⁹ It is far more likely that this tool can be inserted into pharmacy workflow while retaining client privacy.

Second, the extant pharmacy system may not support even ‘brief’ (15-min) consultation with clients in many cases, though a reasonable percentage of pharmacists reported having done so at least once. This does not affect the conceptual goal of the ‘Brief Intervention.’ A driving principle of SBIRT is the appropriate pairing of identified need (via screening) to the service. The screening tool identifies risk from opioids, and in the pharmacy environment, we are particularly interested in harm reduction services – provision of naloxone and clean syringes – as a first-line response for at-risk individuals. We therefore plan to replace the ‘BI’ component with ‘Service Provision.’ Replacing the motivational interview-based BI with an alternative interaction has precedent with recent successful ‘STIRT’ work in emergency departments.^{24,25} However, patients may be ambivalent about accessing those resources (especially at cost), and pharmacists may not feel equipped to have those conversations. We therefore still feel that some level of Motivational Interviewing training is warranted to facilitate the negotiation around Service Provision. That training can also be used in larger time increments, when feasible and clinically appropriate, to address addiction treatment access, reductions in opioid use, or other pertinent consultation topics. However, the consultation is no longer the proposed emphasis of the Service Provision component of the intervention.

Third, while the ‘Referral to Treatment’ component was not substantially influenced by our findings, study findings reinforced the importance of providing pharmacies with resources to facilitate referral, including documentation, maps, lists, and even – perhaps – sponsored in-person introductions to facilities nearby the pharmacy to drive interprofessional connectedness.

One encouraging finding was the number of pharmacists

volunteering to advise the development of the PharmNet intervention. This indicates continued interest in co-developing an evidence-based intervention that will have higher likelihood of adoption and adaptation in pharmacy settings. It also provides a larger group of advisors that will help to address larger structural questions ahead, such as remuneration and access to subsidized naloxone for lay persons.

Limitations

This study had a few limitations. First, there was a clear conflict between two disparate but widely held beliefs: that PharmNet would benefit patients and that it would burden them. We were unable to understand the meaning of these simultaneously held, yet conflicting beliefs. Additional exploratory research among pharmacists will hopefully yield helpful information.

Second, support for PharmNet in rural areas was lower; yet, the size of the rural subsample ($n = 10$) was not enough to determine whether the 40% of rural pharmacists who felt that PharmNet would not benefit patients was representative of all rural pharmacists in Indiana. Future studies among rural pharmacists would provide additional guidance about the pharmacy practice environments in rural communities, especially given the role rural pharmacies play in the health of communities.

Finally, we could not fully understand the structural environment and how it serves as a barrier to PharmNet adoption and implementation. The conflict between pharmacy practice environments and pharmacist beliefs about patient need is beyond the scope of this study; however, it is important to address if pharmacy-based interventions – of any kind – are to succeed. For example, PharmNet may be more likely to succeed if the structural barrier of service remuneration is addressed. Creating the possibility for reimbursement for screening and service provision might mitigate the economic model that many pharmacists noted – where prescriptions filled was the primary business value of the pharmacy to pharmacy owners. Moving forward with this aspect will require collective effort, as noted by Bernsten et al.’s 2010 international review of pharmacy remuneration models.⁶⁰ That said, there is little conversation about this point in the literature. Wazaify et al.’s small study of Northern Ireland pharmacists indicated support for and implementation success of motivational interviewing (MI) to reduce patient over-the-counter drug misuse without discussion of remuneration.⁶¹ Ahmad et al.’s study of MI and problem solving treatment (PST) by pharmacists during medication review among post hospitalized elderly patients also did not address funding for the additional service of MI or PST, nor have findings been published to our knowledge.⁶² Finally, Lonie et al.’s discussion of MI and even health coaching did not address pharmacist remuneration.⁶³

That said, while a majority of pharmacists believed there should be remuneration for aspects of PharmNet’s intervention, most did not state the lack of it as a barrier. It is possible that a PharmNet intervention trial should attempt to gather evidence of time spent and cost incurred in order to share with policy partners the program’s financial value. However, grantmakers simply cannot handle all implementation costs initially, particularly if naloxone is provided to patients who do not have insurance and need assistance procuring it at out-of-pocket rates. Negotiating with state governments who have access to free or subsidized naloxone for laypersons may be a solution.

Conclusions

An integrated intervention to reduce opioid overdose and related health concerns (e.g., HIV and HCV infection) in an at-risk population is likely acceptable and feasible in community pharmacies, particularly if development includes an implementation process that engages implementers themselves and attends to identified implementation barriers.

Ethics approval

This study was deemed exempt by the Indiana University Institutional Review Board. Participants were provided with study information and offered the opportunity to consent to participate.

Authors' contributions

BM and JA conceived of and directed all aspects of the study. BM led the writing of the manuscript. BM, JA and WJ conducted data analysis. AP and CS advised the development and implementation of the study and edited the manuscript. LE and TM assisted data gathering and editing the manuscript. NV and AK edited the manuscript. All authors read and approved the final manuscript.

Declaration of interest

None.

Funding

This study was funded by the Indiana University Grand Challenge: Responding to the Addictions Crisis.

Acknowledgements

Authors would like to thank the contributions of the PharmNet research team members who are not co-authors of this paper: Gregory A Carter, Jefferson Davis, Carrie A Lawrence, Scott Michael, Justin Peters.

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