MI-CCSI
Center for Clinical Systems Improvement

Engaging Community Pharmacy Teams in the Management of Chronic Pain and/or Substance Use Disorder

Today's Presenter

Claire Nolan, PharmD
Program Manager for MI-CCSI's involvement in the Michigan Overdose Data to Action (MODA) program, content expert, faculty member, and participant in practice transformation initiatives. Dr. Nolan has experience in community, specialty, and ambulatory pharmacy.

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OBJECTIVES

At the conclusion of this presentation, the participant will be able to:

- Identify and proactively address potential pharmacy-level barriers to medication access, including opioid therapy and medications for opioid use disorder (MOUD).
- Apply best practices to develop and maintain relationships with community pharmacy teams.

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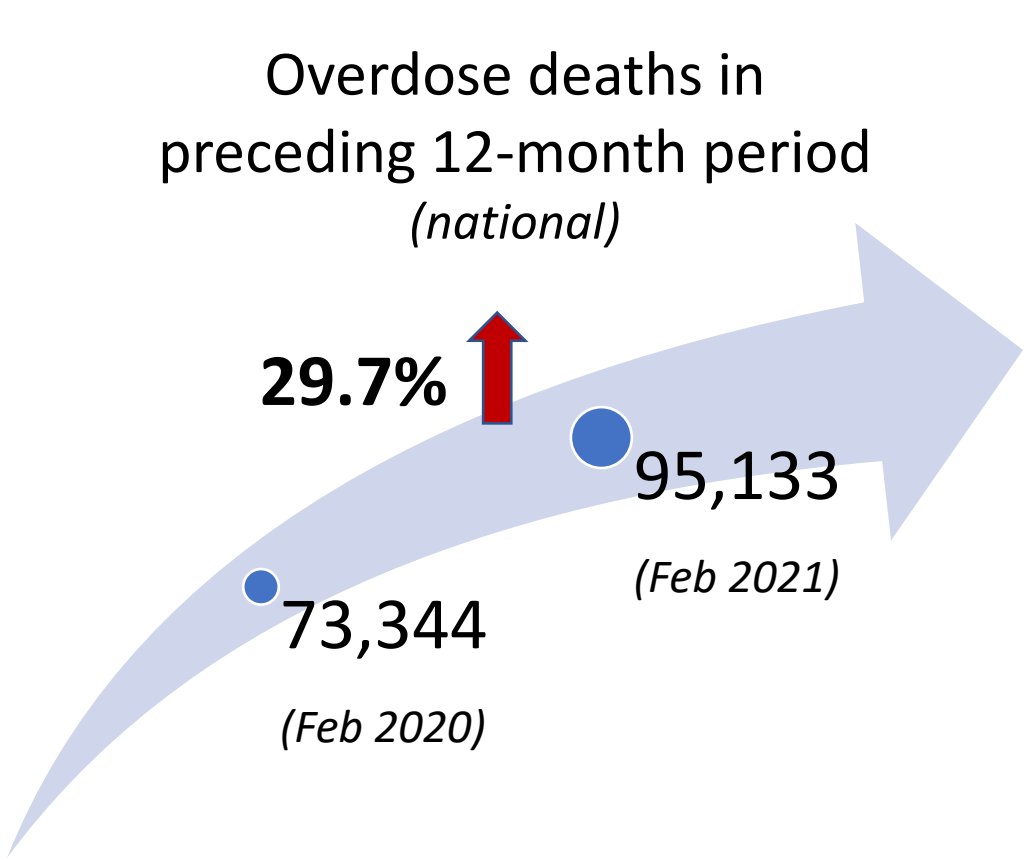
The Opioid Epidemic

National

- Overdose deaths continue to ↑
- Illicit fentanyl (+ analogs), methamphetamine, and cocaine
- Compounded by the COVID-19 pandemic



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COVID-19 Pandemic

A "Crashing of the Crises"

- Clinic closures
- Reallocation of resources to COVID-19 response
- Social isolation
- Economic insecurity

"Epidemics don't smolder during pandemics- they *ignite*."

Khatri UG and Perrone J. Opioid Use Disorder and COVID-19: Crashing of the Crises. J Addict Med. 2020;14(4):e6-7.

Macmadu A, et al. Comparison of characteristics of deaths from drug overdose before vs during the COVID019 pandemic in Rhode Island. JAMA Netw Open. 2021:4(9).

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Buprenorphine

Brief Overview

- Community provider access
- Multiple dosage forms available
- High-efficacy
  - ↑ treatment retention
  - ↓ opioid and overdose mortality
  - ↓ cravings
  - ↓ withdrawal
  - ↓ illicit opioid use
  - ✖ acute effects of other opioids
- Data for safe use in pregnancy

DOSAGE FORM	BRAND NAME	ACTIVE INGREDIENT(s)
Film, buccal	Belbuca®	Buprenorphine
Film, buccal	Generic only	Bup / Naloxone
Film, sublingual	Suboxone®	Bup / Naloxone
Implant, SubQ	Probuphine Implant Kit®	Buprenorphine
Patch, transdermal	Butrans®	Buprenorphine
Solution, injection	Buprenex®	Buprenorphine
Solution, SubQ PFS	Sublocade®	Buprenorphine
Tablet, sublingual	Generic only	Buprenorphine
Tablet, sublingual	Zubsolv®	Bup / Naloxone

Wakeman SE, Larochelle MR, Ameli O, et al. Comparative Effectiveness of Different Treatment Pathways for Opioid Use Disorder. *JAMA Netw Open.* 2020;3(2):e1920622. doi:10.1001/jamanetworkopen.2019.20622

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Anecdotes From Practice

Barriers

- **Prescribers…**
  - …there aren't enough of them to treat all the patients that need treatment!
  - …don't see what I see when the patient comes into the pharmacy.
  - …don't give me enough information to know if this is safe for the patient.
- **Pharmacists…**
  - …refuse to dispense or even stock buprenorphine.
  - …won't even tell you if they have it on the shelf.
  - ...are over-stepping their scope of practice.
  - ...don't understand treatment of addiction.

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Efforts to ↑ Buprenorphine Access

Prescriber-Focused

- DATA 2000
- CARA 2016
- SUPPORT Act (2018)
- Updated Practice Guideline (April 28, 2021)
  - Exemption for eligible providers from the training and certification requirement
  - 30-patient cap remains

NATIONAL ARCHIVES

FEDERAL REGISTER

The Daily Journal of the United States Government

Notice

Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder

A Notice by the Health and Human Services Department on 04/28/2021

PUBLISHED DOCUMENT

AGENCY:

Office of the Secretary, Department of Health and Human Services.

ACTION:

Notice.

SUMMARY:

The Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder provides eligible physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives, who are state licensed and registered by the DEA

DOCUMENT DETAILS

Printed version: PDF

Publication Date: 04/28/2021

Agency: Department of Health and Human Services

Dates: This guidance takes effect April 28, 2021.

Effective Date: 04/28/2021

Document Type: Notice

Cooper HLF et al. When Prescribing Isn't Enough – Pharmacy-Level Barriers to Buprenorphine Access. NEJM. 2020;383(8):703-5.

Statutes, Regulations, and Guidelines. SAMHSA. Available from: https://www.samhsa.gov/medication-assisted-treatment/statutes-regulations-guidelines#DATA-2000. Last updated June 24, 2021. Accessed October 5, 2021.

HHS Expands Access to Treatment for Opioid Use Disorder [press release]. HHS. January 14, 2021. Available from: https://www.hhs.gov/about/news/2021/01/14/hhs-expands-access-to-treatment-for-opioid-use-disorder.html. Accessed February 8, 2021.

Become a Buprenorphine Waivered Practitioner. SAMHSA. Available from: https://www.samhsa.gov/medication-assisted-treatment/become-buprenorphine-waivered-practitioner. Last updated September 20, 2021. Accessed October 5, 2021.

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Patient-Centered Treatment for Substance Use Disorder in Primary Care

MI-CCSI
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Clinical

Module	Title
1	Navigating Buprenorphine Prescribing for the Primary Care Physician
3	Buprenorphine Medical Management: Monitoring the Patient
5	Challenging Clinical Scenarios in MOUD: Early Refills and Lost or Stolen Medication
7	Complex Cases in Buprenorphine Treatment, Part 1
9	Complex Cases in Buprenorphine Treatment, Part 2
11	Pain and Addiction

Operational

Module	Title
2	Substance Use Disorder and Patient Identification
4	OBAT Eligibility, Intake and Assessment
6	Patient Support for Induction and Maintenance
8	Operationalizing Team Meetings, Systematic Case Review, & Documentation
10	Team Roles and Responsibilities
12	Supporting the Patient Beyond Buprenorphine

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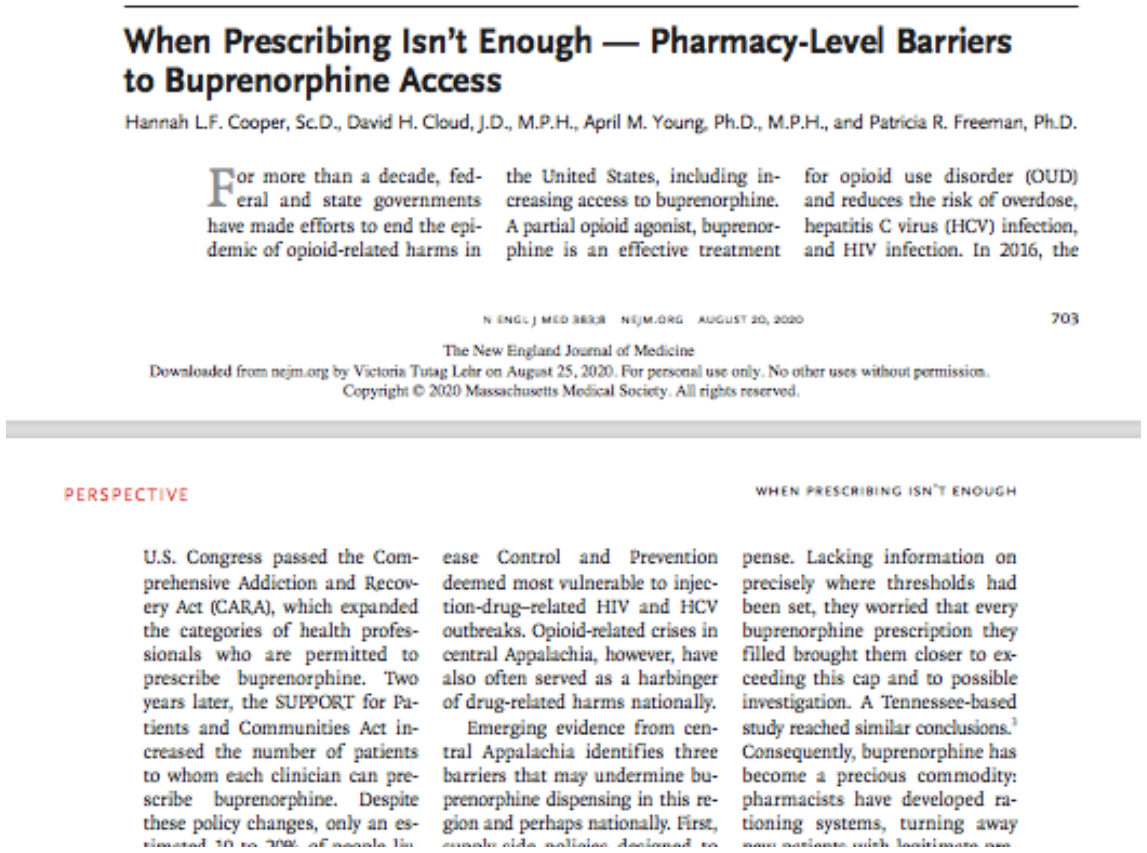
Pharmacy-Level Barriers

NEJM Perspective Piece

- Supply-side policies → rationing
- Lack of trust
  - Prescribers
  - Buprenorphine
- Stigmatizing attitudes



When Prescribing Isn't Enough — Pharmacy-Level Barriers to Buprenorphine Access

Hannah L.F. Cooper, Sc.D., David H. Cloud, J.D., M.P.H., April M. Young, Ph.D., M.P.H., and Patricia R. Freeman, Ph.D.

For more than a decade, federal and state governments have made efforts to end the epidemic of opioid-related harms in the United States, including increasing access to buprenorphine. A partial opioid agonist, buprenorphine is an effective treatment for opioid use disorder (OUD) and reduces the risk of overdose, hepatitis C virus (HCV) infection, and HIV infection. In 2016, the

N ENGL J MED 383;8 NEJM.ORG AUGUST 20, 2020

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U.S. Congress passed the Comprehensive Addiction and Recovery Act (CARA), which expanded the categories of health professionals who are permitted to prescribe buprenorphine. Two years later, the SUPPORT for Patients and Communities Act increased the number of patients to whom each clinician can prescribe buprenorphine. Despite these policy changes, only an estimated 10 to 20% of people liv-

ease Control and Prevention deemed most vulnerable to injection-drug–related HIV and HCV outbreaks. Opioid-related crises in central Appalachia, however, have also often served as a harbinger of drug-related harms nationally.

Emerging evidence from central Appalachia identifies three barriers that may undermine buprenorphine dispensing in this region and perhaps nationally. First, supply-side policies designed to

pense. Lacking information on precisely where thresholds had been set, they worried that every buprenorphine prescription they filled brought them closer to exceeding this cap and to possible investigation. A Tennessee-based study reached similar conclusions.[3] Consequently, buprenorphine has become a precious commodity: pharmacists have developed rationing systems, turning away new patients with legitimate pre-

Cooper HLF et al. When Prescribing Isn't Enough – Pharmacy-Level Barriers to Buprenorphine Access. NEJM. 2020;383(8):703-5.

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Pharmacy-Related Access Barriers

A Nationwide Audit

- 20% of pharmacies reported that they would not dispense buprenorphine
  - Independent > chain
  - Southern states > West, Midwest, or Northeast

Contents lists available at ScienceDirect

Drug and Alcohol Dependence

journal homepage: www.elsevier.com/locate/drugalcdep

Pharmacy-related buprenorphine access barriers: An audit of pharmacies in counties with a high opioid overdose burden

Neda J. Kazerouni [a], Adriane N. Irwin [a], Ximena A. Levander [b], Jonah Geddes [a], Kirbee Johnston [a], Carly J. Gostanian [a], Baylee S. Mayfield [a], Brandon T. Montgomery [a], Diana C. Graalum [c], Daniel M. Hartung [a,*]

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ARTICLE INFO

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Community pharmacies
Buprenorphine
Access
Opioid-related disorders

ABSTRACT

Background: Pharmacies sometimes restrict access to buprenorphine-naloxone (buprenorphine) for individuals with opioid use disorder. The objective of this study was to quantify the frequency of barriers encountered by patients seeking to fill buprenorphine prescriptions from pharmacies in United States (US) counties with high opioid-related mortality.

Methods: To characterize buprenorphine availability, we conducted a telephone audit ("secret shopper") study using a standardized script in two randomly selected pharmacies (one chain, one independent) in US counties reporting higher than average opioid overdose rates. Availability across pharmacy type (chain versus independent), county characteristics (rurality, region, overdose rate), and day of week were analyzed using univariate tests of categorical data. Independent predictors of buprenorphine availability were then identified using a multivariable binomial regression model.

Results: Among 921 pharmacies contacted (467 chain, 454 independent), 73 % were in urban counties and 42 % were in Southern states. Of these pharmacies, 675 (73 %) reported being able to dispense buprenorphine. There were 183 (20 %) pharmacies that indicated they would not dispense buprenorphine. Independent pharmacies (adjusted prevalence ratio [aPR], 1.59; 95 % CI 1.21–2.08) and pharmacies in Southern states (aPR 2.06; 95 % CI 1.43–2.97) were significantly more likely to restrict buprenorphine.

Kazerouni NJ, Irwin AN, Levander XA, et al. Pharmacy-related Buprenorphine Access Barriers: An audit of pharmacies in counties with a high opioid overdose burden. *Drug and Alcohol Dependence*. 2021;224:108729. doi:10.1016/j.drugalcdep.2021.108729

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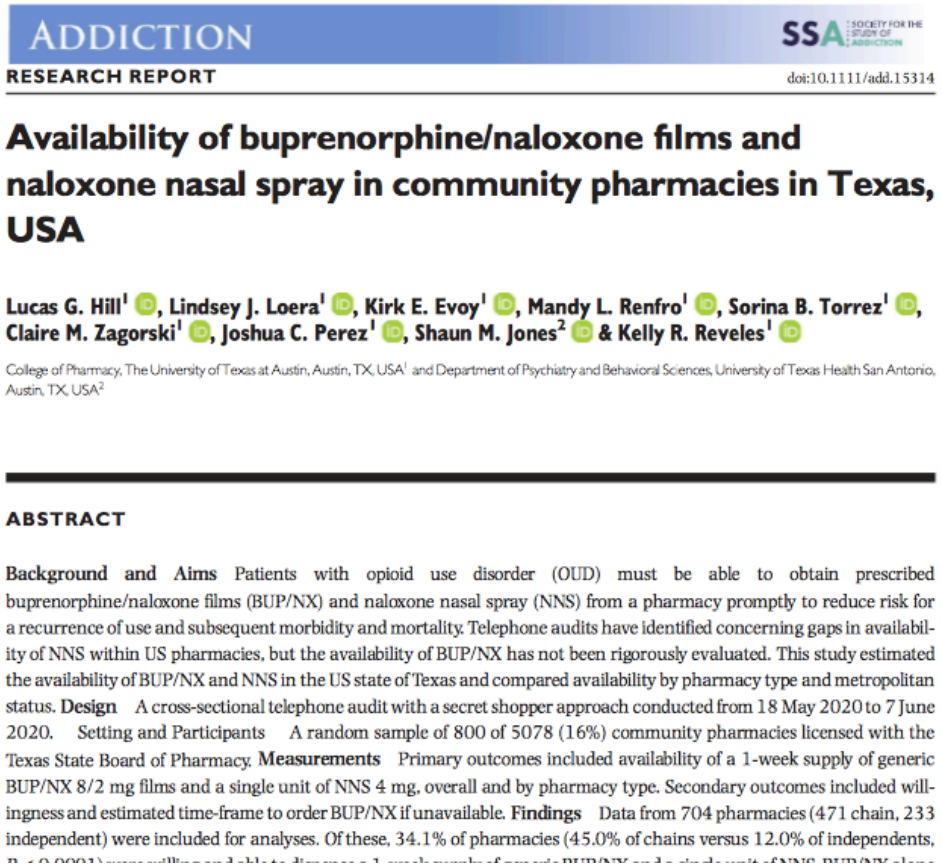
Product Availability - Texas

Statewide Audit

- 34.1% of pharmacies willing and able to dispense
  - 1-week supply of generic buprenorphine/naloxone
  - Single unit of naloxone nasal spray



ADDICTION

SSA SOCIETY FOR THE STUDY OF ADDICTION

RESEARCH REPORT

doi:10.1111/add.15314

Availability of buprenorphine/naloxone films and naloxone nasal spray in community pharmacies in Texas, USA

Lucas G. Hill[1], Lindsey J. Loera[1], Kirk E. Evoy[1], Mandy L. Renfro[1], Sorina B. Torrez[1], Claire M. Zagorski[1], Joshua C. Perez[1], Shaun M. Jones[2] & Kelly R. Reveles[1]

College of Pharmacy, The University of Texas at Austin, Austin, TX, USA[1] and Department of Psychiatry and Behavioral Sciences, University of Texas Health San Antonio, Austin, TX, USA[2]

ABSTRACT

Background and Aims Patients with opioid use disorder (OUD) must be able to obtain prescribed buprenorphine/naloxone films (BUP/NX) and naloxone nasal spray (NNS) from a pharmacy promptly to reduce risk for a recurrence of use and subsequent morbidity and mortality. Telephone audits have identified concerning gaps in availability of NNS within US pharmacies, but the availability of BUP/NX has not been rigorously evaluated. This study estimated the availability of BUP/NX and NNS in the US state of Texas and compared availability by pharmacy type and metropolitan status. **Design** A cross-sectional telephone audit with a secret shopper approach conducted from 18 May 2020 to 7 June 2020. Setting and Participants A random sample of 800 of 5078 (16%) community pharmacies licensed with the Texas State Board of Pharmacy. **Measurements** Primary outcomes included availability of a 1-week supply of generic BUP/NX 8/2 mg films and a single unit of NNS 4 mg, overall and by pharmacy type. Secondary outcomes included willingness and estimated time-frame to order BUP/NX if unavailable. **Findings** Data from 704 pharmacies (471 chain, 233 independent) were included for analyses. Of these, 34.1% of pharmacies (45.0% of chains versus 12.0% of independents,

Hill LG, Loera LJ, Evoy KE, et al. Availability of buprenorphine/naloxone films and naloxone nasal spray in community pharmacies in Texas, USA. *Addiction*. 2020;116(6):1505-1511. doi:10.1111/add.15314

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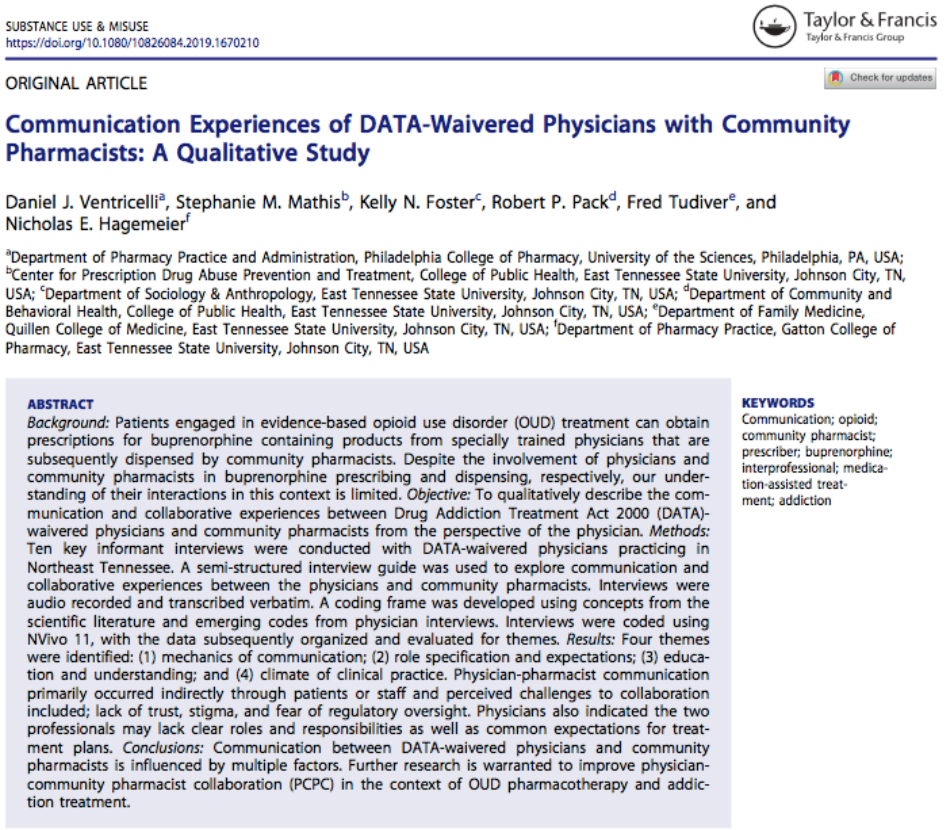
Communication Experiences

A Quantitative Study

- Direct communication between prescribers and pharmacists is infrequent
- Proactive communication provides benefits
- Physicians identify the primary role of pharmacists as ensuring the prescription "gets filled"
- Perception that pharmacists do not fully understand "recovery"
- Fear and stigma influence pharmacist behavior



SUBSTANCE USE & MISUSE
https://doi.org/10.1080/10826084.2019.1670210

Taylor & Francis
Taylor & Francis Group

ORIGINAL ARTICLE

Check for updates

Communication Experiences of DATA-Waivered Physicians with Community Pharmacists: A Qualitative Study

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ABSTRACT

Background: Patients engaged in evidence-based opioid use disorder (OUD) treatment can obtain prescriptions for buprenorphine containing products from specially trained physicians that are subsequently dispensed by community pharmacists. Despite the involvement of physicians and community pharmacists in buprenorphine prescribing and dispensing, respectively, our understanding of their interactions in this context is limited. *Objective:* To qualitatively describe the communication and collaborative experiences between Drug Addiction Treatment Act 2000 (DATA)-waivered physicians and community pharmacists from the perspective of the physician. *Methods:* Ten key informant interviews were conducted with DATA-waivered physicians practicing in Northeast Tennessee. A semi-structured interview guide was used to explore communication and collaborative experiences between the physicians and community pharmacists. Interviews were audio recorded and transcribed verbatim. A coding frame was developed using concepts from the scientific literature and emerging codes from physician interviews. Interviews were coded using NVivo 11, with the data subsequently organized and evaluated for themes. *Results:* Four themes were identified: (1) mechanics of communication; (2) role specification and expectations; (3) education and understanding; and (4) climate of clinical practice. Physician-pharmacist communication primarily occurred indirectly through patients or staff and perceived challenges to collaboration included; lack of trust, stigma, and fear of regulatory oversight. Physicians also indicated the two professionals may lack clear roles and responsibilities as well as common expectations for treatment plans. *Conclusions:* Communication between DATA-waivered physicians and community pharmacists is influenced by multiple factors. Further research is warranted to improve physician-community pharmacist collaboration (PCPC) in the context of OUD pharmacotherapy and addiction treatment.

KEYWORDS
Communication; opioid; community pharmacist; prescriber; buprenorphine; interprofessional; medication-assisted treatment; addiction

Ventricelli DJ, Mathis SM, Foster KN, Pack RP, Tudiver F, Hagemeier NE. Communication experiences of data-waivered physicians with Community Pharmacists: A qualitative study. *Substance Use & Misuse*. 2019;55(3):349-357. doi:10.1080/10826084.2019.1670210

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Addressing Pharmacy-Level Barriers

Cases and Strategies

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Case 1

Pharmacist Refuses Fill

- Patient scheduled for induction in 7-days
- Prescription sent to pharmacy closest to his house (about 45 min from practice)
- Patient calls your practice later that day and tells you that the pharmacy won't fill his prescription

What do you do?

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Case 1

Option 1

- Contact the pharmacy
- The pharmacist states that they are “already at their wholesaler max”
  - Have a conversation with the pharmacist about clinical rationale for this patient
  - Suggest contacting the wholesaler to address threshold

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Case 1

Option 2

- Consider outreach to an alternative pharmacy
- If the patient insured by Medicaid – consider mail order pharmacy option

Image available from: https://www.sutterhealthplus.org/newsroom/signing-up-for-mail-order-pharmacy. Accessed October 11, 2021.

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Case 2

Establishing Relationships

- You have a newly established practice and are planning to prescribe buprenorphine
- You want to build relationships with your local pharmacy

What do you do?

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Establishing Relationships

Ideas for Practice

- **Reach out!**
  - Call
  - Drop in
  - Schedule time
  - Introduce members of your team
  - Describe the services you will provide
  - Explore options for collaboration – buprenorphine and beyond

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Establishing Relationships

Roles for Community Pharmacists

- Naloxone access
- MOUD – buprenorphine, naltrexone
- Routine health maintenance - immunizations, screening
- Addressing other aspects of care (e.g., nicotine replacement)
- Patient education

Giannitrapani KF, et al. Expanding the role of clinical pharmacists on interdisciplinary primary care teams for chronic pain and opioid management. BMC Fam Pract. 2018;19(1):107.
Chisholm-Burns, et al. The opioid crisis: Origins, trends, policies, and the roles of pharmacists. Am J Health Syst Pharm. 2019;76(7):424-435.

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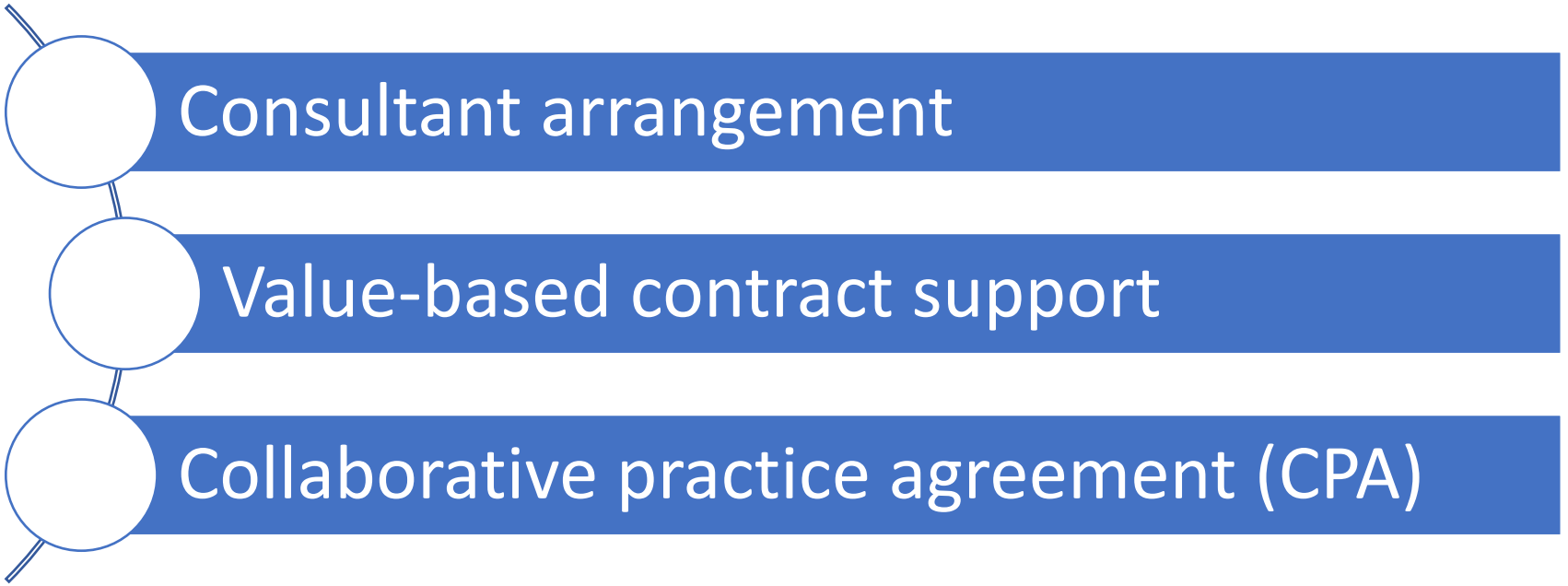
Establishing Relationships

Collaboration Opportunities

- Consider a business agreement that facilitates pharmacist involvement



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Case 3

The Request for More Info

- Patient scheduled for buprenorphine induction
- Prescription sent to local pharmacy
- The next day, you receive a note that the pharmacist is requesting a call back “to verify” the prescription

What do you do?

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Corresponding Responsibility

Code of Federal Regulations Part 1306

"A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. ***The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription****. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (****21 U.S.C. 829****) and* ***the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances****."*

Title 21 Code of Federal Regulations. DEA, Drug Control Division. Available from: https://www.deadiversion.usdoj.gov/21cfr/cfr/1306/1306_04.htm. Accessed September 15, 2021.

Burke J. Be Aware of Corresponding Responsibility. Pharmacy Times. 2019. 85(5). Available from: https://www.pharmacytimes.com/view/be-aware-of-corresponding-responsibility-. Accessed September 15, 2021.

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Oath of the Pharmacist

"…apply my knowledge…to assure optimal outcomes…"

"I promise to devote myself to a lifetime of service to others through the profession of pharmacy. In fulfilling this vow:

- I will consider the welfare of humanity and relief of suffering my primary concerns.
- ***I will apply my knowledge, experience, and skills to the best of my ability to assure optimal outcomes for my patients.***
- I will respect and protect all personal and health information entrusted to me.
- I will accept the lifelong obligation to improve my professional knowledge and competence.
- I will hold myself and my colleagues to the highest principles of our profession's moral, ethical and legal conduct.
- I will embrace and advocate changes that improve patient care.
- I will utilize my knowledge, skills, experiences, and values to prepare the next generation of pharmacists.

I take these vows voluntarily with the full realization of the responsibility with which I am entrusted by the public."

Oath of A Pharmacist. American Pharmacists Association. Available from: https://pharmacist.com/About/Oath-of-a-Pharmacist. Accessed September 29, 2021.

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Case 3

Responding to the Request

- Provider outreach, if possible
- Speak directly with the pharmacist
- Fill in gaps in the information the pharmacist has access to
- Use the opportunity to establish a relationship

Image available from: https://www.vectorstock.com/royalty-free-vector/phone-call-to-doctor-linear-icon-vector-28416987. Accessed October 11, 2021.

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Case 3

Avoiding Future Need

- **Provide the diagnosis code.**
- **Include notes about the care plan.**
  - *Taper in progress.*
  - *We are aware that the patient filled a prescription for [X] on [X/XX/XXXX] – the patient has been counseled not to take these medications together.*
  - *Please cancel the previous prescription for [X].*
  - *Feel free to call with any questions.*
  - *If a PA is required , please [X].*
  - *Induction in progress. Dose may change.*

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Thank You

Please email Claire.Nolan@miccsi.org with any questions.

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