

Pharmacists' Role in Buprenorphine Management in Opioid Use Disorder: A Review

Dr. Jacqueline Cleary, PharmD, BCACP¹

Dr. Amanda Engle, PharmD, BCPS¹

Dr. Amanda Winans, PharmD, BCPS, CACP²

¹ Albany College of Pharmacy and Health Sciences, Albany, New York

² Bassett Medical Center, Cooperstown, New York

1

Disclosures

- Dr. Cleary: Genomind, Remitigate LLC
- Dr. Engle and Dr. Winans: nothing to disclose

2

Objectives

- Describe the role of the pharmacist in the management of buprenorphine therapy for OUD
- Discuss existing literature focusing on pharmacist involvement in buprenorphine for OUD
- Identify future opportunities for expanding access to OUD care through pharmacist collaboration

3

Accepted for Publication:

- Cleary JL, Engle AL, Winans ARM. Pharmacists' Role in Buprenorphine, Management for Opioid Use Disorder: A Narrative Review. JACCP Special Issue: The Opioid Crisis: Opportunities for Clinical Pharmacy Practice.

4

Background

- 50,000 Americans died from opioid overdose, equating to over 130 deaths, daily in 2019
- By the year 2033, there will be an estimated national shortage of primary care physicians (21,000 – 55,000)
- Rise in opioid use disorder (OUD) patient needs = care imbalance
- Pharmacists are positioned to address gaps in OUD treatment

CDC/NCHS, National Vital Statistics System, Mortality. CDC WONDER, Atlanta, GA: US Department of Health and Human Services, CDC; 2019. Association of American Medical Colleges. New report confirms growing shortage of primary care physicians. Primary Care Collaborative. Published July 10, 2020.

5

Background – Enter the Pharmacist

- Established role for treatment of primary care conditions, demonstrating improvement in clinical outcomes
 - Diabetes
 - Hypertension
 - Mental health conditions
 - Depression
 - Alcohol use disorder
- Pharmacist opportunities in OUD
 - Fill the care gap
 - Positively impact clinical outcomes
 - Reduce provider burnout

Carter BL. Evolution of Clinical Pharmacy in the USA and Future Directions for Patient Care. *Drugs Aging* 2016;33(3):169-77.
 Greer D, et al. Objective and subjective benefits of a psychiatric pharmacist–led long-acting injectable medication training at a large, multisite organization. *Ment Health Clin [Internet]*. 2020;10(5):264-9.
 Dimitropoulos E, et al. Integration of a clinical pharmacy specialist into a substance use disorder intensive outpatient treatment program to improve prescribing rates of alcohol use disorder pharmacotherapy. *Subst Abus*. 2018;39(2):190–192.

6

Role of the Pharmacist in OUD

Historical Role

- Checking Prescription Drug Monitoring Programs (PDMP)
- Medication dispensing
- Naloxone dispensing
- Patient education

Potential Role

- Initiating and modifying medications for opioid use disorder (MOUD)
- Monitoring safety & efficacy
- Referrals to adjunct services
- Patient and provider education
- Advocacy, reducing stigma

Coon SA, et al. Mobilizing pharmacists to address the opioid crisis: A joint opinion of the ambulatory care and adult medicine practice and research networks of the American College of Clinical Pharmacy. *J Am Coll Clin Pharm.* 2020; 3(8): 1493-1513.

7

Challenges to MOUD Access

- Methadone
 - Physically attend clinic on regular basis
 - Legal and regulatory barriers
- Naltrexone
 - 7-day abstinence period prior to initiation
 - Poor compliance
- Buprenorphine
 - Does not require specialized dispensing site
 - Does not require period of abstinence prior to initiation
 - Prescriber must hold DATA-2000 waiver, limitations on volume

8

Objective

- Review published literature with the aim of characterizing the current role of pharmacists in managing buprenorphine for OUD

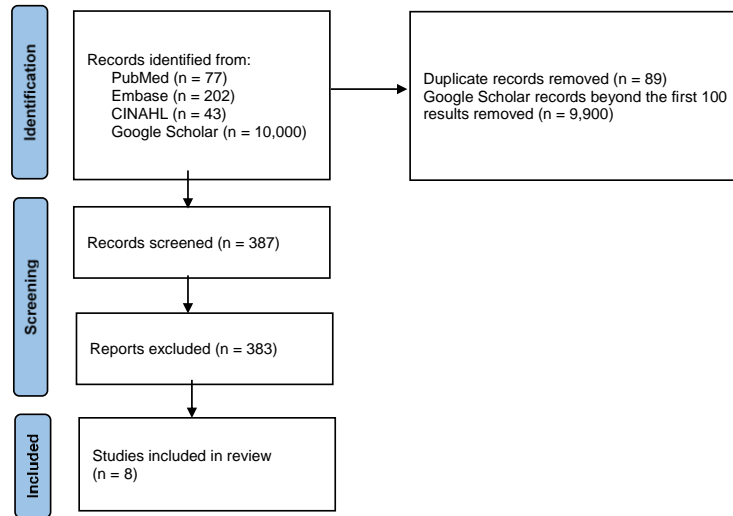
9

Methods

- Modified PRISMA approach using electronic query
 - Search terms used “buprenorphine” and “pharmacist”
- Inclusion criteria
 - Pharmacist role described by authors
 - Practice site located within United States
 - Full text available in English language
- Exclusion criteria
 - Included buprenorphine management for pain indication
 - Pharmacist role included solely order verification, dispensing, or administration
 - Primary methodology as survey or perception-based tool
 - Citation not available as full text

10

Methods



11

Results - Overall

Eight care models identified

Author, Year	Brief Reference
Dipaula, 2015	Dipaula B, Menachery E. <i>J Am Pharm Assoc.</i> 2015;55: 187-192.
Duvivier, 2017	Duvivier H, Gustafson S, Greutman M, et al. <i>J Am Pharm Assoc.</i> 2017; 57: S135-S140.
Grgas, 2013	Grgas M. <i>Mental Health Clinician.</i> 2013;3: 290- 291.
Mattle, 2021	Mattle AG, Aladeen T, Blondell RD, et al. <i>J Am Coll Clin Pharm.</i> 2021; 4: 424– 434.
Suzuki, 2014	Suzuki J, Matthews ML, Brick D, Nguyen MT, Wasan AD, Jamison RN, Ellner AL, Tishler LW, Weiss RD. <i>J Opioid Manag.</i> 2014 May-Jun;10(3):159-68.
DeRonne, 2021	DeRonne B, Wong KR, Schultz E, Jones E, Krebs EE. <i>American Journal of Health-System Pharmacy</i> , Volume 78, Issue 4, 15 February 2021, Pages 354–359.
Mailloux, 2021	Mailloux LM, Haas MT, Larew JM, DeJongh BM. <i>Ment Health Clin.</i> 2021;11(1):35-9.
Wu, 2020	Wu LT, John WS, Ghitza UE, et al. <i>Addiction</i> 2020;116: 1805-1816.

12

Results - *Overall*

- All conducted in outpatient settings
- Significant heterogeneity in program design and outcomes evaluated
 - Practice model sizes included 12-150 patients
 - Study duration 5-26 months
 - All conducted in different states
- **5 Key Categories**
 1. Pharmacist Role
 2. Clinic Setting
 3. Collaborating Prescriber Type
 4. Pharmacist Practice Type
 5. Outcomes

13

Results - *Pharmacist Role*

- No autonomous buprenorphine prescriptive authority for pharmacists
- 3 care models utilized pharmacists for buprenorphine dosing recommendations
- Most common pharmacist roles:
 - UDS review (62.5%)
 - Patient counseling/education (50%)
 - Buprenorphine dosing recommendation (37.5%)

14

Results- *Clinic Setting*

- Three Veterans Affairs (VA) clinics
- Clinic housed within mental health, primary care, or substance abuse programs
- Most variable characteristic

15

Results- *Collaborating Prescriber Type*

- MD trained in psychiatry most common (62.5%)
- Primary care/internal medicine MD (37.5%)
- Non-physician prescribers mentioned by Mattle et al and DeRonne et al

16

Results - *Pharmacist Practice Type*

- Most often specialty trained in psychiatry (62.5%)
- Care models included a pain management pharmacist and a community pharmacist practicing per protocol
- Pharmacists were utilized to see patients in lieu of prescriber for routine follow up for low-risk inductions
- Telemedicine utilized in Indian Health Services

17

Results - *Outcomes*

- **Treatment retention** [including medication adherence] (62.5 %) and **relapse rates** [including opioid overdose events] (25 %) most common outcomes
 - Most outcomes were improved by pharmacist involvement
 - Other concurrent confounding variables
- Other outcomes included:
 - Number of pharmacist recommendations and % implemented
 - Time spent with patients
 - Patient cravings, quality of life, psychological health, injecting risk behavior
 - Abnormal UDS
 - Criminal activity
 - Patient wait time to visit and at pharmacy
- Economic impact of pharmacist work not evaluated
 - Cost avoidance reported in one paper

18

Discussion

- Pharmacist lack of autonomy in prescribing buprenorphine and ordering labs not surprising given DATA 2000 restrictions
 - Increasing autonomy in these two areas can expand access and reduce prescriber burden
- Laboratory and urine drug screen review most common role
 - Difficult to translate to management decisions without understanding drug absorption, metabolism and elimination
 - Required for effective monitoring
- Existing collaborative care models give pharmacists autonomy-> mismatch
- Opportunity to reduce provider burnout!

19

Discussion

- Education is a central role
 - Patients and Prescribers alike
 - Complex pharmacokinetics and pharmacodynamics
 - Numerous formulations available
 - Dose titration, drug interactions, side effects
 - Reduce stigma
- Pharmacist MOUD training
 - Needed in PGY2 and PGY1 programs for clinical practice settings
 - Needed for all practicing pharmacists given prevalence of OUD in every practice setting

20

Discussion

- Outcomes of Interest
 - Patient-Centered vs Productivity-Oriented
 - Economic impact
 - Provider perception
- Increased monitoring between visits
- Key patient outcomes examples: retention and relapse

We challenge each pharmacist who has a role in buprenorphine management to report and publish on their specific care models and patient care outcomes, with the goal of elevating pharmacy practice and allowing others to replicate sustainable care models nationwide.

21

Future Opportunities

- Federal
 - Legislative changes to DATA 2000 regulations already proposed
- State
 - Focused advocacy with State legislators including collaborating prescribers
 - Include language describing the specific roles a pharmacist can have in buprenorphine prescribing to increase prescriber confidence with liability
- Local
 - Leverage strong support of physician champions to amend institution specific rules

22

Challenges

- Collaborative practice agreements are state specific and often have specific restrictions
 - Financially sustainable for a pharmacist?
- Outpatient treatment models must be standardized
- Need for inpatient treatment models
- Future work → surveying patient and provider perception of this expanded pharmacist role

Tran TH, Swoboda H, Perticone K, et al. The substance use intervention team: a hospital-based intervention and outpatient clinic to improve care for patients with substance use disorders. *American Journal of Health-System Pharmacy* 2021;78(4):345-353. doi:10.1093/ajhp/zxaa408

23

Summary/Conclusions

- Low number of published care models involved pharmacists' collaboration of buprenorphine management in the setting of OUD
- Key roles include laboratory monitoring, education, dose recommendations
- Expansion of pharmacist roles should also include increased pharmacist training
- Legislative challenges exist and pharmacists should aim to have a self-sustaining practice
- More work is needed!

24

References

- CDC/NCHS, National Vital Statistics System, Mortality, CDC WONDER, Atlanta, GA: US Department of Health and Human Services, CDC; 2019. Association of American Medical Colleges. New report confirms growing shortage of primary care physicians. Primary Care Collaborative. Published July 10, 2020.
- Carter BL. Evolution of Clinical Pharmacy in the USA and Future Directions for Patient Care. *Drugs Aging* 2016;33(3):169-77.
- Greer D, et al. Objective and subjective benefits of a psychiatric pharmacist–led long-acting injectable medication training at a large, multisite organization. *Ment Health Clin [Internet]*. 2020;10(5):264-9.
- Dimitropoulos E, et al. Integration of a clinical pharmacy specialist into a substance use disorder intensive outpatient treatment program to improve prescribing rates of alcohol use disorder pharmacotherapy. *Subst Abus*. 2018;39(2):190–192.
- Coon SA, et al. Mobilizing pharmacists to address the opioid crisis: A joint opinion of the ambulatory care and adult medicine practice and research networks of the American College of Clinical Pharmacy. *J Am Coll Clin Pharm*. 2020; 3(8): 1493-1513.
- Dipaula B, Menachery E. Physician- pharmacist collaborative care model for buprenorphine-maintained opioid-dependent patients. *J Am Pharm Assoc*. 2015;55: 187-192.
- Duvivier H, Gustafson S, Greeting M, et al. Indian Health Service pharmacists engaged in opioid safety initiatives and expanding access to naloxone. *J Am Pharm Assoc*. 2017; 57: S135-S140.
- DeRonne B, Wong KR, Schultz E, Jones E, Krebs EE. Implementation of a pharmacist care manager model to expand availability of medications for opioid use disorder, *American Journal of Health-System Pharmacy*, Volume 78, Issue 4, 15 February 2021, Pages 354–359, <https://doi.org/10.1093/ajhp/zxaa405>

25

References

- Grgas M. Clinical psychiatric pharmacist involvement in an outpatient buprenorphine program. *Mental Health Clinician*. 2013;3: 290- 291.
- Mattle AG, Aladeen T, Blondell RD, et al. Evaluating outcomes of a clinical pharmacist medication management program in a multidisciplinary practice for outpatient buprenorphine treatment of opioid use disorder. *J Am Coll Clin Pharm*. 2021; 4: 424– 434. <https://doi.org/10.1002/jac5.1405>
- Suzuki J, Matthews ML, Brick D, Nguyen MT, Wasan AD, Jamison RN, Ellner AL, Tishler LW, Weiss RD. Implementation of a collaborative care management program with buprenorphine in primary care: a comparison between opioid-dependent patients and patients with chronic pain using opioids nonmedically. *J Opioid Manag*. 2014 May-Jun;10(3):159-68. doi: 10.5055/jom.2014.0204. Erratum in: *J Opioid Manag*. 2014 Sep-Oct;10(5):302. Wasan, Ajay D [added]. PMID: 24944066; PMCID: PMC4085743.
- Mailloux LM, Haas MT, Larew JM, DeJongh BM. Development and implementation of a physician-pharmacist collaborative practice model for provision and management of buprenorphine/naloxone. *Ment Health Clin [Internet]*. 2021;11(1):35-9. DOI: 10.9740/mhc.2021.01.035.
- Wu LT, John WS, Ghitza UE, et al. Buprenorphine physician-pharmacist collaboration in the management of patients with opioid use disorder: results from a multisite study of the National Drug Abuse Treatment Clinic Trials Network. *Addiction* 2020;116: 1805-1816.
- Tran TH, Swoboda H, Perticone K, et al. The substance use intervention team: a hospital-based intervention and outpatient clinic to improve care for patients with substance use disorders. *American Journal of Health-System Pharmacy* 2021;78(4):345-353. doi:10.1093/ajhp/zxaa408

26

Contact Information:

Dr. Jacqueline Cleary, PharmD, BCACP

Email: Jacqueline.Cleary@acphs.edu

Dr. Amanda Engle, PharmD, BCPS

Email: Amanda.Engle@acphs.edu

Dr. Amanda Winans, PharmD, BCPS, CACP

Email: Amanda.Winans@bassett.org