NATIONAL ACADEMY OF MEDICINE

Methadone Treatment for Opioid Use Disorder: Examining Federal Regulations and Laws—A Workshop

March 3–4, 2022

Session 4 – Expanding Access to Methadone via Regulatory Innovation

Pharmacy-Based Dispensing

Li-Tzy Wu, RN, ScD, MA
Professor
Department of Psychiatry and Behavioral Sciences &
Department of Medicine
Duke University School of Medicine
Litzy.wu@Duke.Edu

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Today's presentation

- No conflict of interest

- To present two NIDA funded clinical trials on community pharmacist-provided care services for medication treatment for opioid use disorder (MOUD): **A team-based care model**
  - Study 1: Buprenorphine (background for study 2)
  - Study 2: Methadone

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Rationale for supporting community pharmacist-provided care services for medication treatment for opioid use disorder (MOUD)

- ❑ Licensed pharmacists are medication therapy management experts.
- ❑ Community pharmacists (dispensers) are natural partners of physicians/practitioners (prescribers).
- ❑ Pharmacists are among the most trusted healthcare professionals.
- ❑ About 90% of Americans live within 5 miles of a pharmacy.
- ❑ Pharmacies are accessible even in **rural area**s with high rates of opioid overdose deaths.
- ❑ Involving community pharmacists in MOUD care services **help mitigate the shortage of physicians/addiction practitioners** (e.g., rural areas).

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Rationale for supporting pharmacist-provided care services for MOUD: Physician/practitioner shortage

- A report by Association of American Medical Colleges (AAMC): An estimated shortage of between **37,800 and 124,000 physicians by 2034**, and it impacts physicians of all types (AAMC, 2021).
- A serious shortage of addiction treatment physicians/practitioners in the US (Jones et al., 2015)


National and State Treatment Need and Capacity for Opioid Agonist Medication-Assisted Treatment

Christopher M. Jones, PharmD, MPH, Melinda Campopiano, MD, Grant Baldwin, PhD, MPH, and Elinore McCance-Katz, MD, PhD

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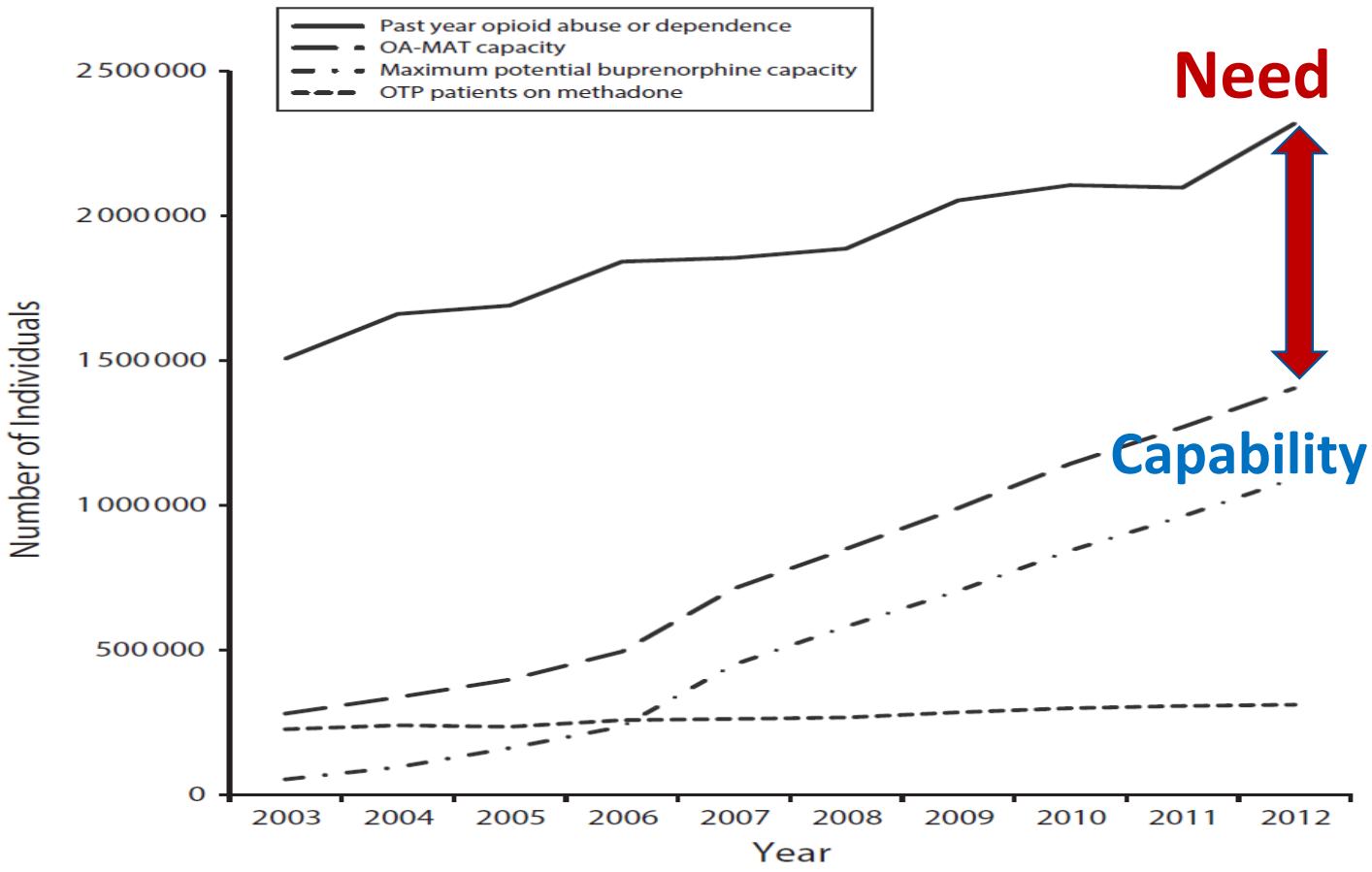
A serious shortage of addiction treatment physicians/practitioners in the US (Jones CM et al., 2015)



Note. OA-MAT = opioid agonist medication-assisted treatment; OTP = opioid treatment program.

FIGURE 1—Trends in past-year opioid abuse or dependence and opioid agonist medication-assisted treatment capacity: United States, 2003–2012.

In 2012, the difference between the number of people with past-year opioid use disorder (OUD) and combined methadone and buprenorphine treatment capacity was approximately 914,000 individuals.

Although prevalence of buprenorphine-waivered prescribers in the US increased from 3.8 in 2007 to 17.3 per 100,000 persons in 2017, the total number of waivered prescribers in 2017 still represented fewer than 10% of primary care providers (McBain et al., 2020).

Rates of opioid-involved overdose deaths have continued to escalate during the COVID-19 pandemic (e.g., stressors, limited access to care). **Annual drug overdose deaths doubled between 2015 and 2021 (CDC, 2022).**

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Provider capacity and treatment access barriers can be addressed by community pharmacists

- Physicians and pharmacists can collaborate to improve access to MOUD (buprenorphine, methadone) and allow physicians' time for other priorities.

- **Two examples: how a team-based physician-community pharmacist collaboration model may address treatment access barriers to MOUD in the US.**

Study 1: A physician-pharmacist collaboration model on **buprenorphine** treatment for MOUD

Study 2: A physician-pharmacist collaboration model on **methadone** maintenance treatment for MOUD

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Study 1

ADDICTION

SSA SOCIETY FOR THE STUDY OF ADDICTION

RESEARCH REPORT

doi:10.1111/add.15353

Buprenorphine physician–pharmacist collaboration in the management of patients with opioid use disorder: results from a multisite study of the National Drug Abuse Treatment Clinical Trials Network

Li-Tzy Wu[1,2,3,4,5], William S. John[1], Udi E. Ghitza[6], Aimee Wahle[7], Abigail G. Matthews[7], Mitra Lewis[7], Brett Hart[7], Zach Hubbard[7], Lynn A. Bowlby[2], Lawrence H. Greenblatt[2], Paolo Mannelli[1] & Pharm-OUD-Care Collaborative Investigators

Setting: 3 office-based buprenorphine treatment (OBBT) clinics and 3 community pharmacies in North Carolina.
Pre-implementation training: Eight 1-hour Physician and pharmacist coaching meetings.
Operational care agreement (OCA): Specifying pharmacist-provided patient care roles/responsibilities during 6 monthly pharmacy visits and to establish collaboration for three partnered clinic-pharmacy sites.
Participants: 6 buprenorphine-waivered physicians, 6 community pharmacists, and 71 patients aged ≥18 years with DSM-5 OUD on buprenorphine maintenance.
Intervention: After study screening and enrollment, eligible patients' buprenorphine care was transferred from their OBBT physician to a community pharmacist for **6 months**. Pharmacists provided Buprenorphine treatment care under remote supervision of physicians.

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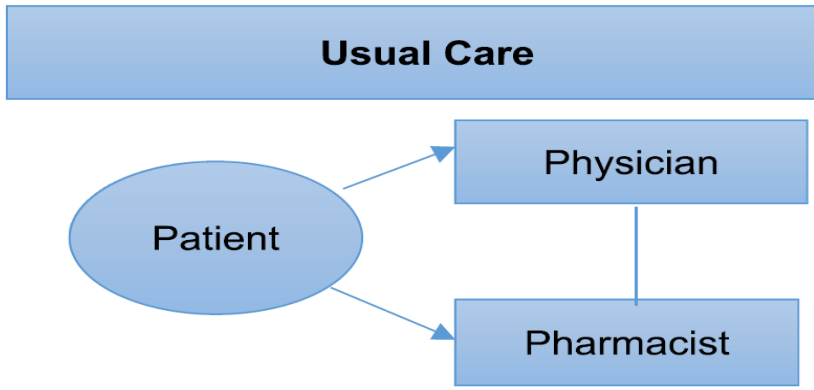
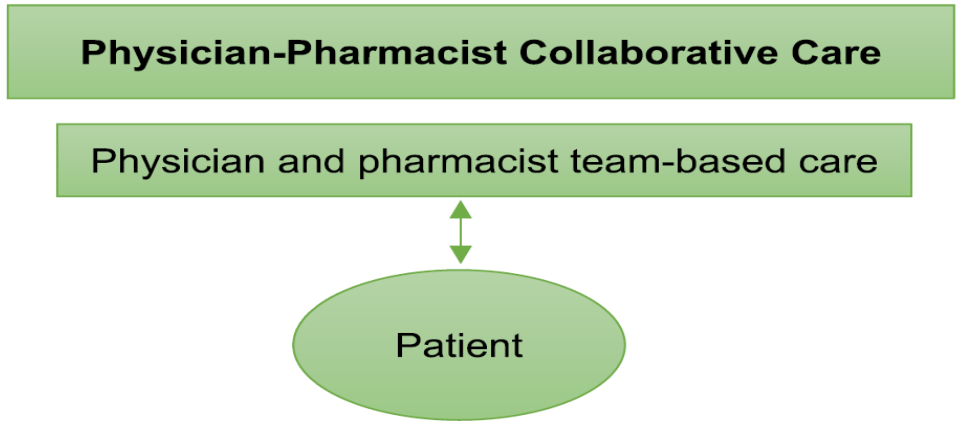
Usual care VS. A physician-pharmacist collaborative care model for MOUD

Study 1

Li-Tzy Wu et al.





▪ *Role:* Physician evaluates patient, prescribes buprenorphine, determines dosage, and monitors drug use and treatment safety. Pharmacist checks PDMP* and dispenses buprenorphine. ▪ *Visit:* Patient sees physician monthly and as needed. Patient sees pharmacist for prescription refill. ▪ *Communication:* Physician and pharmacist communicate about the prescription as needed.	▪ *Role:* Physician and pharmacist collaborate on patient's care. Physician provides clinical guidance and/or coaching to pharmacist. Physician prescribes buprenorphine and determines dosage. Pharmacist conducts dose reconciliation and patient education, and monitors drug use, treatment safety and adverse events. Pharmacist checks PDMP* and dispenses buprenorphine. Pharmacist provides feedback to physician. • *Visit:* Patient sees pharmacist monthly and as needed. Patient sees physician as needed. ▪ *Communication:* Physician and pharmacist communicate monthly or more frequently about patient's progress.

*PDMP: Prescription Drug Monitoring Program

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Study 1 Findings: A physician-pharmacist collaborative care model for MOUD (Wu LT et al., 2021)

- ✓ **Enrollment:** 93.4% (71/76) of eligible participants enrolled into the study (**high**)
- ✓ **Treatment retention:** 88.7% (**high**)
- ✓ **Treatment adherence:** 95.3% (**high**) (**100%** if the result was based on those retained in the study)
- ✓ **Opioid-positive urine drug screens (UDSs) at Month 6:** 4.9% (**low**)
- ✓ **Pharmacists checked prescription drug monitoring program (PDMP):** at 96.8% of visits (**high**)
- ✓ **Opioid-related safety events:** 0 (**none**)
- ✓ **Intervention fidelity:** 100% at all sites (based on reviews of 142 Buprenorphine Visit Checklist forms assessing a total of 2374 items) (**perfect**)
- ✓ **Patients' satisfaction:** Over 90% of patients endorsed that they were "very satisfied with their experience and the quality of treatment offered," that "treatment transfer from physician's office to the pharmacy was not difficult at all," and that "holding buprenorphine visits at the same place the medication is dispensed was very or extremely useful/convenient" (**high**)
- ✓ **Pharmacists' and physicians' satisfaction**: Similar positive findings from both pharmacists and physicians (**high**)

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Study 2: Pharmacy administration and dispensing of methadone for MOUD (Wu LT et al., 2022)

ADDICTION

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RESEARCH REPORT

doi:10.1111/add.15641

Opioid treatment program and community pharmacy collaboration for methadone maintenance treatment: results from a feasibility clinical trial

Li-Tzy Wu[1,2,3,4], William S. John[1], Eric D. Morse[5], Steve Adkins[6], Jennifer Pippin[6], Robert K. Brooner[7] & Robert P. Schwartz[8]

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Study 2: Rational for supporting pharmacy administration and dispensing of methadone for MOUD

- There are approximately **1,800 SAMHSA certified opioid treatment programs (OTPs)** across the US, which limits geographic access to methadone maintenance treatment (**MMT**) for MOUD.
- There are approximately **65,000 community pharmacies** in the US (Qato et al., 2017).
- The mean population-weighted driving time from US census tract mean center of population was **20.4 minutes to OTPs** and **4.5 minutes to pharmacies**, and that differences in driving time and distance between 1-way trips ending at OTPs and pharmacies were largest in nonmetropolitan counties (Kleinman, 2020).
- **Barriers** to attending MMT regularly: Transportation costs and long drive time, which can **reduce treatment retention, quality of life, and opportunity to keep a job**.
- Community pharmacists are well-suited for this role because of their expertise in medication therapy management and high accessibility, including rural areas (Look et al., 2019).
- Leveraging the vast network of community pharmacies **to expand the number of methadone dispensing sites** would **address the access challenge and limited capability of OTPs.**

Study 2: A proof of concept testing community pharmacy administration and dispensing of methadone +ePrescribing (Wu LT et al., 2022)

- **Design**: Nonrandomized, single-arm, open-label feasibility trial (rationale: to allow testing the feasibility in a larger sample of patients than a randomized trial given available resources).
- **Setting**: One opioid treatment program (OTP) and one community pharmacy in NC, US.
- **Participants**: One OTP physician, two pharmacists, and 20 patients receiving between 6-13 take-home methadone doses at 5-160 mg/day.
- **Intervention**: Patients' methadone administration and dispensing of take-home doses **were transferred from the OTP to the pharmacy for 3 months.**
- **Team-based care intervention model**: **adapted the physician-pharmacist collaborative care model of buprenorphine treatment (Wu LT et al., 2021):**

1. A collaborative practice agreement between pharmacists and the OTP physician.
2. Electronic prescribing of methadone from an OTP physician to a pharmacy.
3. Methadone visit checklist to document intervention and check fidelity.

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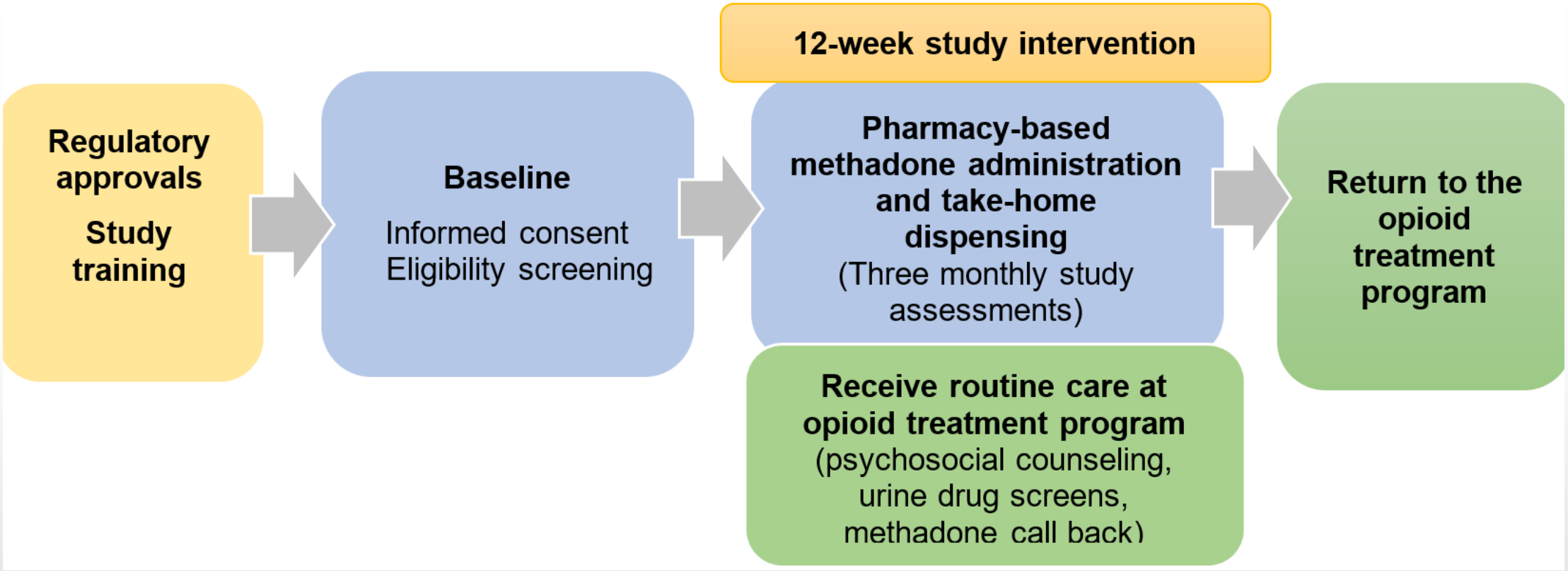
Study 2 Design diagram (Wu LT et al., 2022)



Regulatory approvals: DEA, SAMHSA, NC State Opioid Treatment Authority, NC DEA inspection, and Duke Health IRB.
PS: The study would not have been permitted under the current SAMHSA regulations and *required exemptions for PRESCRIBING.*

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Study 2 Recruitment and data collection

- **Recruitment completed successfully**

Completed it earlier than expected: within about 2 months from August 6, 2020 to October 7, 2020

- **Follow-up data collection (3 monthly follow-ups) completed successfully**

Finished all follow-up assessments on-time.

	Actual
Sample size	20
Date of first participant enrolled	08-06-2020
Date of last participant enrolled	10-07-2020
Date of last follow-up	1-5-2021

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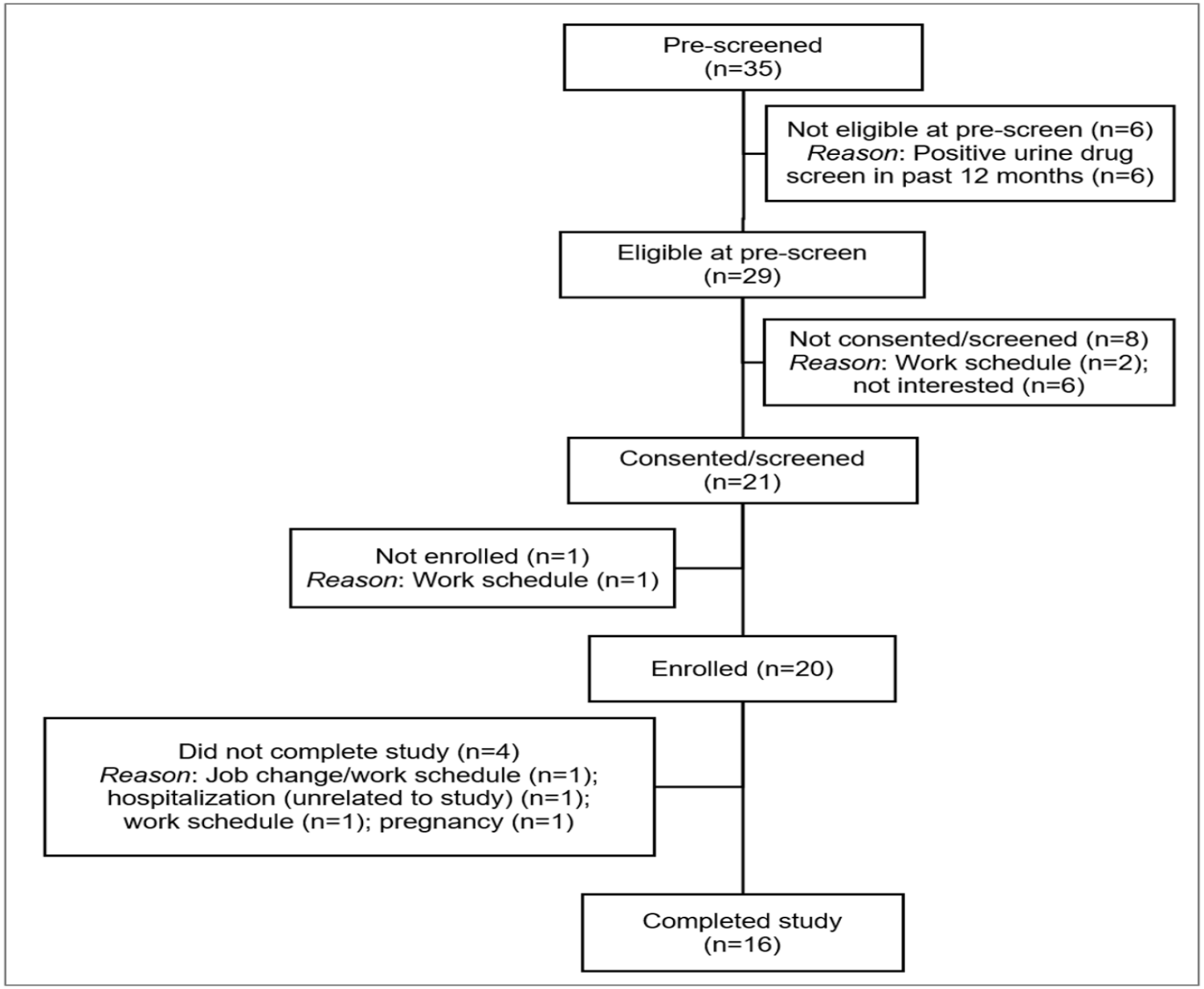
Study 2 CONSORT flow diagram



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Study 2 Medication adherence: 100%

- **Medication adherence: Pharmacy visit adherence among participants who retained in the study**

Month 1[a]	Month 2	Month 3	Overall
n=19	n=17	n=16	n=19
77/77 (100%)	66/66 (100%)	64/64 (100%)	207/207 (100%)

- **Treatment adherence (additional measure): Methadone call-back results**

	n (%)
Participant attended the scheduled call-back visit[1]	
No	0 (0%)
Yes	17 (100%)
Evidence of medication tampering/diversion	
No	17 (100%)
Yes	0 (0%)

[1]One methadone call-back assessment was randomly scheduled for each participant during the course of the 3-month study period; methadone all-back was not completed for 3 participants due to early study termination.

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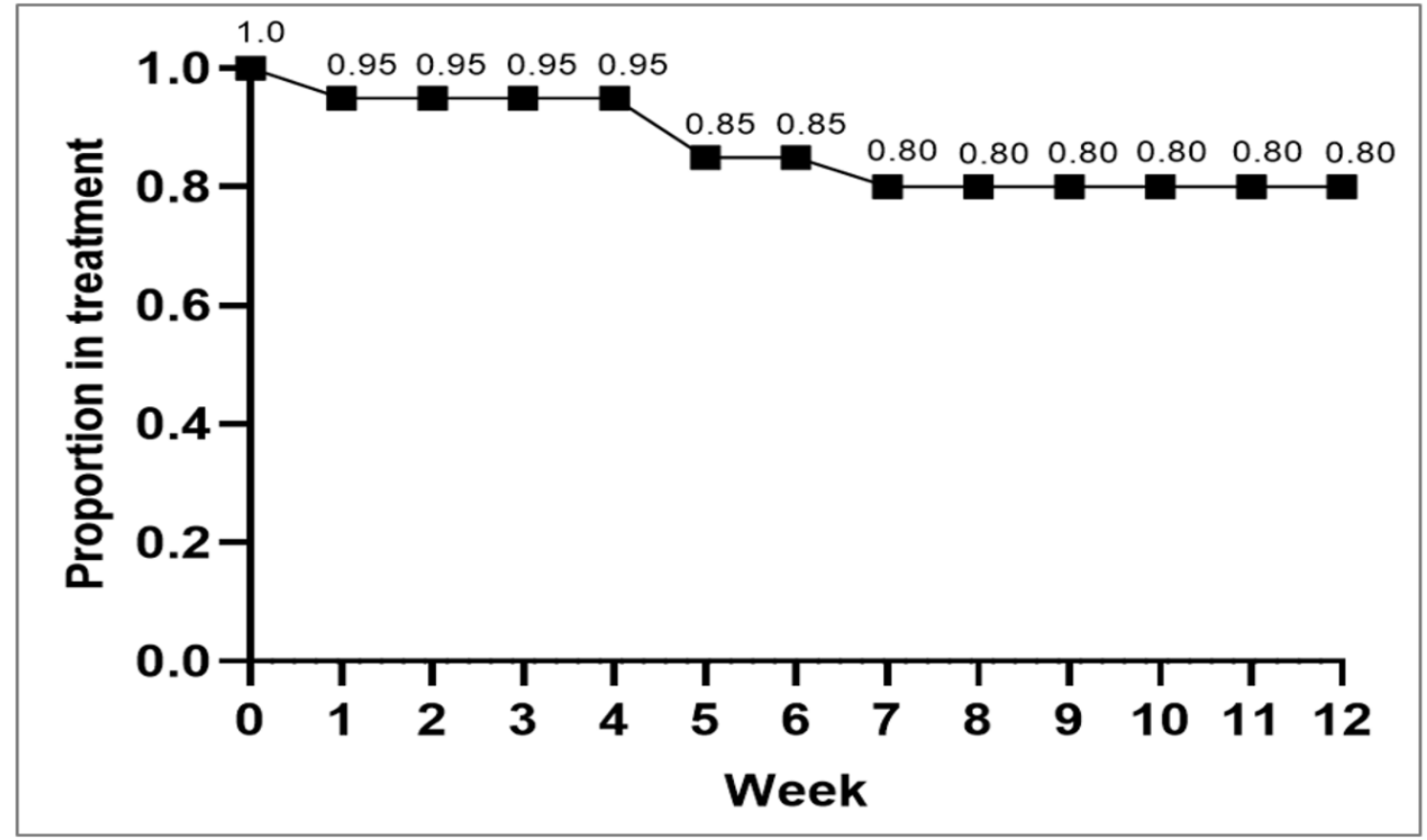
Study 2 Treatment retention: 80%

(4 patients with early termination: 2 patients due to work/job schedule change, 1 patient due to pregnancy, and 1 patient due to the non-study related hospitalization)



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Study 2 additional outcomes

- **Urine drug screen results: No** illicit opioid use
- **Compliance with psychosocial counseling attendance:** All participants attended their scheduled psychosocial counseling sessions at the OTP (**100%**)
- **Pharmacists' use of the PDMP:** Pharmacists used the PDMP in **100%** of pharmacy visits (207/207 visits). There were no issues of other opioid prescriptions, unauthorized benzodiazepine prescriptions, or other controlled medication use reported for all visits where the PDMP was consulted.
- **Participant Safety:** No safety events**.** There were **no** substance-related overdoses and hospitalizations. There was only one participant hospitalized for abdominal pain **(unrelated to the study**) who was removed from the study (i.e., early termination).
- **Intervention fidelity: 100%**

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Study 2 Treatment delivery satisfaction (patients)

All 16 participants who remained in the study for 3 months completed a self-administered satisfaction survey at Month 3. Among them,

- **87.5%** were very satisfied with their **overall experience** in this study.
- **87.6%** were either satisfied (6.3%) or very satisfied (81.3%) with the **quality of treatment** offered in this study.
- **93.8%** reported that treatment **transfer from the OTP to the pharmacy was not difficult** at all.
- **87.5%** reported that **receiving methadone doses at the pharmacy** was either **extremely useful/convenient** (62.5%) or very useful/convenient (25.0%).
- **100%** endorsed that they would definitely **choose to participate in the study again** if given the opportunity. Reasons for influencing their decision to participate in a future study were:

➢ **"My participation may help to improve and expand treatment delivery/options" (100%).**

➢ **"Pharmacy is the right location for this type of treatment" (100%).**

➢ **"The treatment offered at the pharmacy was of better quality than the usual treatment** (i.e., at the OTP)" (**86.7%**).

➢ **"It was easy to understand/distinguish patient, physician, and pharmacist roles" (93.8%).**

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Study 2 Summary

- This pilot study was conducted in the “real-world” setting of a community pharmacy partnered with a non-academic OTP.
- Participant recruitment was completed efficiently and successfully.
- Both indicators of medication adherence and intervention fidelity were successful.
- **The OTP-pharmacy collaboration** to establish **electronic prescribing of methadone from an OTP physician to a pharmacy** to improve MMT access **is feasible and acceptable**.

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Study 2 Next steps

- **RCTs:** Efficacy, Effectiveness, and Implementation (+economic analysis)
- **Models of pharmacy dispensing of methadone**:
  - Electronic prescribing of methadone from an OTP physician to a pharmacy (current study model)
  - Pharmacy based methadone medication units (based on federal regulations)
- **Opioid Use Disorder treatment providers/prescribers**:
  - OTP physicians (current study model)
  - Buprenorphine-waivered physicians
- **MMT Patients**:
  - Stable patients (current study model),
  - Newer patients (e.g., stabilized on MMT for ≥3 months)
- **Pharmacy locations:**
  - Suburban and rural areas
- **Policy and institutional/organizational support** for pharmacy-based administration and dispending for methadone for MOUD: such as
  - **Pharmacy/pharmacist training (e.g., accreditation)**
  - **Payment for pharmacist-provided care services for MOUD**
  - **Electronic prescribing of methadone from an OTP physician to a pharmacy**

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THANK YOU

Wu LT, John WS, Morse ED, Adkins S, Pippin J, Brooner RK, Schwartz RP. **Opioid treatment program and community pharmacy collaboration for methadone maintenance treatment: results from a feasibility clinical trial.** Addiction. 2022 Feb;117(2):444-456.

Wu LT, John WS, Ghitza UE, Wahle A, Matthews AG, Lewis M, Hart B, Hubbard Z, Bowlby LA, Greenblatt LH, Mannelli P; Pharm-OUD-Care Collaborative Investigators. **Buprenorphine physician-pharmacist collaboration in the management of patients with opioid use disorder: results from a multisite study of the National Drug Abuse Treatment Clinical Trials Network**. Addiction. 2021 Jul;116(7):1805-1816.

- **Contact:**

Li-Tzy Wu, RN, ScD, MA

Litzy.wu@Duke.Edu

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