"Prescribing Methadone for Opioid Use Disorder: An OTP Feasibility and Satisfaction Pilot Study"

Robert K. Brooner, Ph.D.
Professor Emeritus
Department of Psychiatry and Behavioral Sciences
Johns Hopkins University School of Medicine

Senior Research Scientist
Friends Research Institute

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Disclosures and Conflicts of Interest

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Conflicts of Interest: No conflicts of interest

Regulatory Restrictions Central to Talk

FDA finalized its inaugural regulations for methadone treatment in 1972 (Food & Drug Administration). These regulations made it illegal to prescribe, administer, dispense methadone for opioid use disorder outside of a specific organizational structure – opioid treatment program.

- see Code of Federal Regulations (CFR): 21 CFR – Subsections 1306 & 1307 and 42 CFR - Subsections 8.11 & 8.12

BACKGROUND/RATIONALE

Overall Goal: Increase Access to Methadone for Opioid Use Disorder (OUD)

- One approach: Utilize community pharmacies (over 60,000) to administer and dispense methadone to patients with OUD
- Critical Barrier: Illegal to prescribe methadone for OUD outside of a federally certified Opioid Treatment Program (OTP)
- Road Maps: A very small number of U.S. studies of methadone prescription and pharmacy administration and the much larger amount of international work in Canada, Europe and elsewhere
- Excellent Resource: About 1,800 OTPs in U.S., subspeciality with highly experienced methadone prescribers for OUD - natural laboratory for studies for methadone prescribing and pharmacy dispensing

EARLIEST WORK: PRE-1973

Authors (year)	Sample Size	Enrollment Status 1=unstable 2=stable	Main Findings
Brill and Jaffe (1967)	9	1	1 pharmacy-good outcomes, reduced or eliminated heroin use, no adverse events in pharmacies
Bowden, et al. (1976)*	96	1	5 pharmacies-mixed outcomes, drug use similar to baseline and similar to patients receiving methadone in OTP (72% v 78%)

* data collection complete <1973

SUBSEQUENT WORK: 45+ Years Later

Brooner, et al.	11	2	started 2018 – completed 2021 findings later in talk
Wu, et al.	20	2	started 2020 - completed 2021 findings tomorrow (Dr. Wu)

PURPOSE OF PILOT STUDY

Evaluate feasibility of OTP physician prescribing of methadone and community pharmacy administration and dispensing

Evaluate acceptability of OTP physician prescribing methadone and community pharmacy…

Evaluate satisfaction of OTP physician prescribing methadone and community pharmacy…

Evaluate participant retention and related clinical responses

APPROACH

Three-Month Non-Randomized Single-Arm Pilot Feasibility Study: Approach and Milestones

Regulatory Approvals

DEA: 05/2018 (13mo)
SAMSHA: 03/2018 (6mo)
Maryland: 10/2018

IRB Review
1st Subm: 09/2018
Final Appr: 04/2020*

* COVID-19 recruitment delay

Participant Selection

Screening:
- Initial 2018
- Rescreen 2020
- Started: 10/2020
- Completed: 01/2021

Protocol Training

- pharmacy staff
- OTP clinical staff
- research staff

3-Month Pilot Evaluation

Methadone Pharmacotherapy
- •OTP Provider Prescriptions
- •Pharmacy Administration & 13-Day Take-Home Doses

All other components of care provided in OTP
- monthly counseling services
- monthly substance use testing
- monthly protocol assessments

Return to routine methadone dispensing in OTP

*Brooner, RK, Stoller, KB, Patel, P, Yan, H, Kidorf, MS. Opioid Treatment Program Prescribing of Methadone with Pharmacy Dispensing: Pilot Study of Feasibility and Acceptability, Drug and Alcohol Dependence Reports

Inclusion and Exclusion Criteria

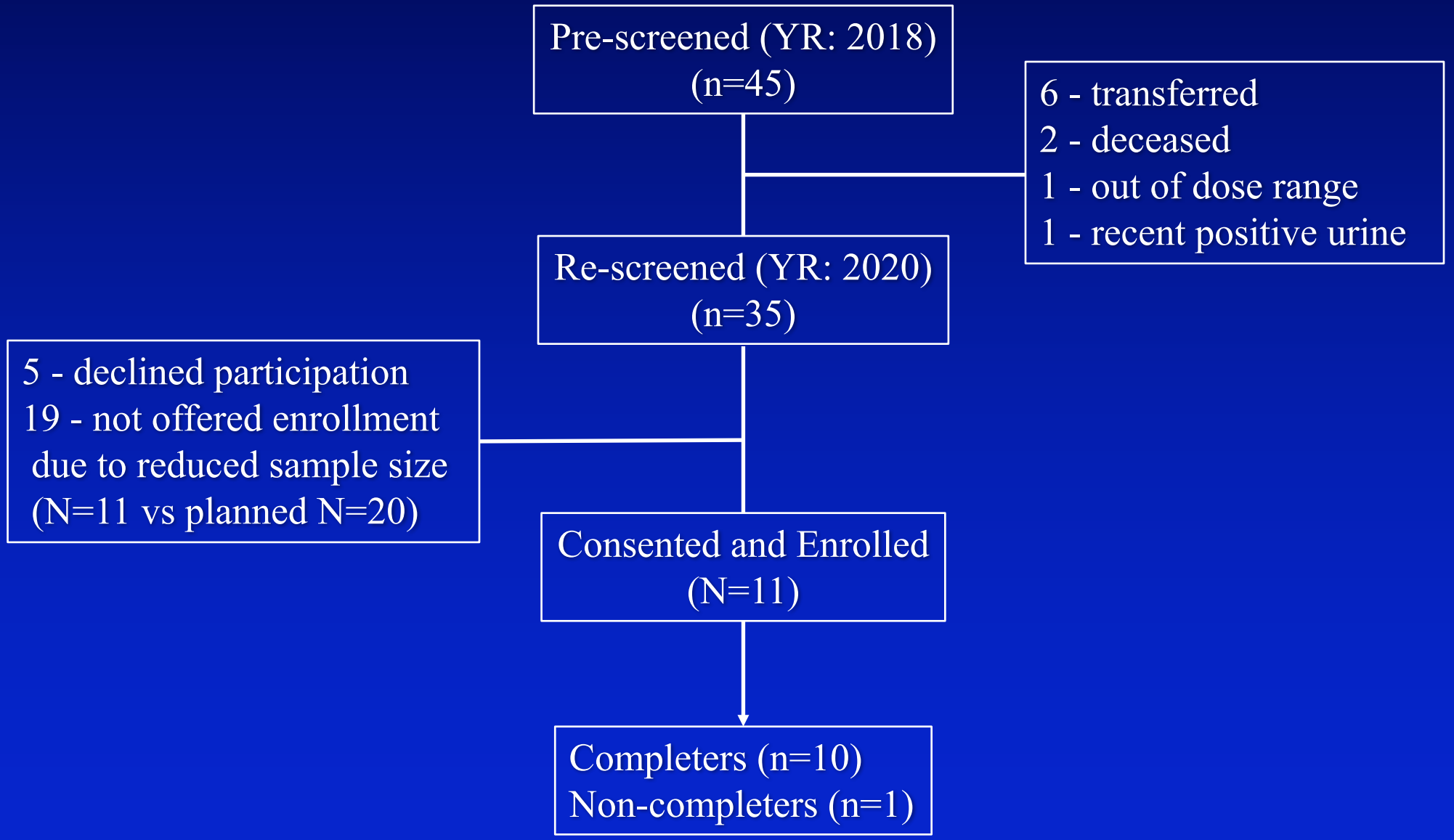
Inclusion Criteria

1. Current treatment episode of at least 6/mo
2. Stable (20–90mgs) methadone dose past 3/mo
3. Drug negative urine results past 6/mo
4. Attend ≥80% counseling sessions past 3/mo
5. Employed or community volunteer position
6. Age between 18-66 years

Exclusion Criteria

1. Unstable medical problem
2. Unstable psychiatric problem
3. Significant reading difficulties

Consort Table



PRIMARY FINDINGS

Baseline Characteristics of Participants (N=11)

Variable	
Demographic	
Female	9 (82%)
Age (mean, range)	58 (47-65 yrs)
Caucasian	8 (73%)
Education (mean, range)	12 (9-15 yrs)
Financial Supports	
Full-time employed	8 (73%)
Commercial	8 (73%)
Medicaid	3 (27%)
Monthly income (mean)	$1,555
Current Treatment Episode	
Duration of episode (mean, range)	19 yrs (3-34 yrs)
Duration of abstinence (min.)	6 months
Methadone dose (mean)	55mgs
Methadone take-home schedule	Every 2 weeks

Adherence: Scheduled Pharmacy Visits

Schedule: Once Every Two Weeks

Month 1*	Month 2	Month 3
n=11	n=10	n=10
22/22 (100%)	20/20 (100%)	20/20 (100%)

*1 participant withdrew at end of first month

Counseling Attendance and Drug Use

Counseling Attendance

- Scheduled Sessions 31
- Attended Sessions 31

Adherence Rate: 100%

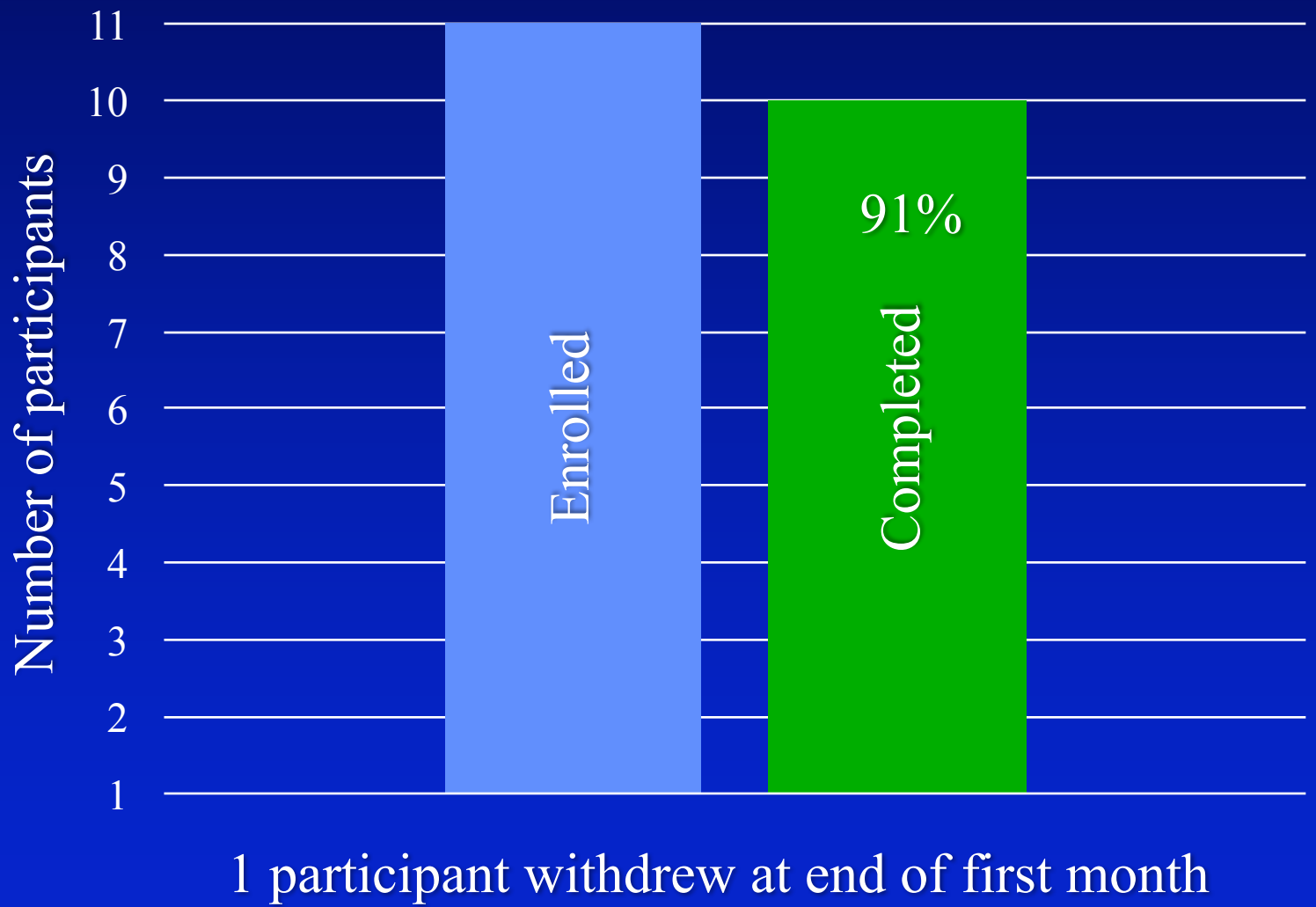
Opioid Use - Data Collected Monthly

- Self-reported days of opioid use: 0/31 assessments (**0%**)
- Opioid positive urine specimens: 0/33 specimens (**0%**)

Participant Satisfaction with Pharmacy Services

Monthly Satisfaction Summary	Ratings
Satisfaction with quality of services received at pharmacy?	Excellent (80%), Good (20%)
Satisfaction with amount of help received at pharmacy ?	Excellent (80%), Good (20%)
Would you prefer pharmacy methadone dosing?	Yes (90%) or Not Sure (10%)
Satisfaction with convenience of pharmacy dosing	Very (88%) or Mostly (12%)
Satisfaction with privacy you received at pharmacy?	Very (92%) or Mostly (8%)
Behavioral Choice Procedure (Pay $0 to $50 more weekly, $5 increments)	
Would you pay more weekly for pharmacy dosing ?	Yes (100%) How much? $9.00/week

Study Retention



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Findings Summary

Feasibility and acceptability:

- success receiving DEA exceptions and SAMHSA waiver
- rapid recruitment of patients, 91% completers

Shifting methadone from OTP to pharmacy had no negative impacts on:

- medication adherence: 100% adherence to pharmacy visits, high satisfaction
- counseling adherence: 100% attendance to sessions generated from OTP
- drug abstinence rates: 100% opioid negative urine specimens, no days of self-reported use

Proposed Next Steps

Obtain federal and state approvals for extension of this work to other OTPs using a collaborative approach between DEA, SAMHSA, and the states allowing providers to submit exception/waiver requests directly to the state's methadone authority to:

- conduct demonstration projects and trials for patients with shorter periods of stability, with telehealth evaluations and counseling and behavioral interventions
- extend this approach with methadone to office-based buprenorphine practices and projects evaluating safety, implementation and efficacy
- work with Medicaid, Medicare and commercial insurers to recognize prescribed methadone for OUD an accepted benefit in pharmacy coverage plans