Pharmacists Can Provide MAT. Examining Innovative Models of Collaborative Care: A long-acting injectable naltrexone clinic in rural Kentucky

Gail Groves Scott, MPH, Substance Use Disorders Institute, University of the Sciences, Philadelphia, PA
Emily Blaiklok, PharmD, Director of Specialty Pharmacy, St. Matthews Community Pharmacy, Louisville, KY

USciences University of the Sciences | Substance Use Disorders Institute
EDUCATION • POLICY • RESEARCH

BACKGROUND

MAT = Medications for Addiction Treatment

Buprenorphine, methadone & long-acting naltrexone (MAT) remain underutilized in our healthcare system, despite attempts by policymakers to expand the use of these effective pharmacotherapies during a nationwide opioid overdose crisis.

BARRIERS: Especially in rural America

- Lack of treatment capacity / waiting lists
- Lack of in-network providers (take patient insurance)
- Cost: out of pocket/ deductibles/ lack of RX coverage
- Geographical distance, inflexible appointment times

PHARMACISTS:

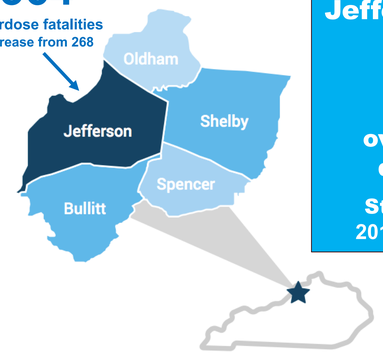
"On the front lines" of medication dispensing and "an essential part of the health care team" to address opioid addiction and overdose (CDC, 2016.)

"Unique knowledge, skills, and responsibilities for assuming an important role in substance abuse prevention, education, and assistance"(AHSP, 2016.)

Pharmacy-dispensed MAT: many countries worldwide allow administration & monitored dosing of methadone & buprenorphine by pharmacists.

Yet U.S. pharmacist's role in managing patients on addiction medications is infrequently described in the literature (Peterson, 2007.)

364
Overdose fatalities increase from 268



Clinic location: Jefferson Co. KY
#1 overdose deaths
Statewide 2015-16 data

PUBLIC HEALTH IMPLICATIONS:

Louisville, Kentucky community ⇨ high prevalence of opioid use disorders & overdose mortality ⇨ urgent need for more treatment capacity and improved patient access.

Extended-release naltrexone (Vivitrol) is:

- 1x monthly intramuscular (IM) gluteal injectable
- Approved for alcohol dependence, not actively drinking
- Approved for prevention of relapse to opioid dependence after 7-10 days opioid-free
- Must be administered by healthcare professional
- 4 mL total reconstituted suspension, refrigerated storage
- Injected w/ 20g custom supplied needles: 1.5 & 2 in.

OBJECTIVES

Pilot project: identify the benefits and limitations of implementing a pharmacist-run MAT clinic with injectable, non-opioid medication, in collaboration with a referring physician.

PROTOCOLS

St. Matthews Community Pharmacy, Louisville, KY Naltrexone Clinic

- **Fills + administers naltrexone RXs collaboratively with prescribers**
- **Also fills naltrexone (& buprenorphine) RXs for local addiction medicine providers & other clinics.**

1) *Collaborative Care Agreement* signed between prescriber & pharmacist for management of patients - includes protocol agreement & authorization for lab tests (CBC, CMP, urine drug screen)
2) Providers (inpatient & outpatient) make referrals of patients, & pharmacy appt scheduled.
3) Specialty pharmacist manages insurance prior authorizations & mail order delivery process
4) One patient hour appt w/ pharmacist includes:
   1) Patient education & relapse prevention, document engagement in psychosocial support/ counseling..
   2) Confirm negative UDS toxicology, day of injection (pharmacy can do POC test on-site
   3) Oral naltrexone dose (challenge) w/ 30 min. wait-time to confirm no allergic reaction or withdrawal symptoms.
   4) Risk-benefit review/ provide mfg. wallet card.
   5) Injection RX filled & administered to patient.
   6) Next appointment scheduled, 28 days.
5) Reminder calls to patient, follow-up

Naltrexone Clinic Collaborative Practice Agreement – Key Components:

KY law: *"Collaborative Care Agreement" establishes formal relationship*

- Can be for **groups of patients** not just individuals
- **Written agreement** between pharmacist(s) and practitioner(s) -- outlines plan of cooperative management of patients' drug-related health-care needs

✓ **Prior Authorization Protocol**
✓ **Dosing & Administration Protocol**
✓ **Patient Care Plan Flow Chart:** dictates communication between provider & pharmacist- needed for missed patient appointments in order to reconnect with care

RESULTS

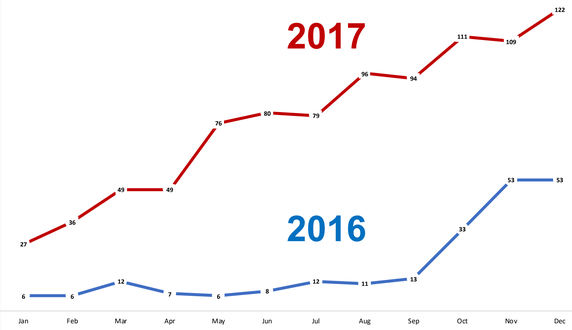
2 Years

273 RX fills administered in office

455 RX fills for partnering prescribers

AVERAGE FILLS PER PATIENT
6.7 av. Transferred cohort (combined management)
3.5 av. pharmacy cohort only
2.1 av. outside clinic cohort only

Increase in RX fills



One pharmacist gained experience

➢ **1200 naltrexone injections (3 years)**

- Patient satisfaction observed w/ pharmacist administration model & pharmacist skill with injection /administration.
- Pharmacist clinic model supported via PharmD residency program staffing, dispensing fees, patient fees.
- Insurance reimbursement from dispensing fees not adequate to fund pharmacist model.
- Lack of provider status for pharmacist precludes billing for patient management & counseling.

EMERGING POLICY INNOVATION:

- **March 2018 -** KY Board of Pharmacy established new protocols for **pharmacists *to initiate* patient therapy** (with physician sign-off, training, & protocol review)
- **Innovation transfer:** Presentation to Ohio Board of Pharmacy April 2018 on Kentucky protocols

Warnings /Precautions reviewed with patients

- **Vulnerability to Fatal Opioid Overdose**
- **Injection Site Reactions: Can be severe, or require surgical intervention.**
- **Precipitation of Opioid Withdrawal**
- **Hepatotoxicity**
- **Depression and Suicidality**
- **When Reversal of Blockade Is Required for Pain Management: regional anesthesia or local anesthetics may be required.**

RESULTS

Benefits identified:

- Increased patient access to community treatment & ability to find healthcare provider.
- Navigating insurance benefits process for patient is key factor in adherence. Pharmacist also able to facilitate access to patient assistance programs, co-pay cards.

Challenges Identified:

Managed Care: BILLING: Pharmacists can not bill insurance for appointments, counseling, on-site UDS, clinic had to fund w/ fees from patients ($50/ $20.)

MEDICAID: Difficult to find prescribers in-network to RX for Medicaid patients even w/ collaborative agreement.

DELAYS in Treatment Initiation, due to:

- Mandatory mail-order re: specialty pharmacy carve-outs
- Prior authorizations

Clinical: Early break-through cravings seen day 23 to 25 (est. 1 in 5 pts). Pharmacist adopted protocol: oral naltrexone 5-7 day dosing/ Early fill if allowed by plan.

Medical vs. Pharmacy Benefits

Naltrexone-ER injectable only covered by medical not RX benefit = barrier to fill & administration in local pharmacy.

CONCLUSIONS

Pilot suggests that community pharmacists in collaborative care models with prescribers can:

- Increase treatment capacity, esp. in rural communities
- Provide high-quality care, improve compliance
- Reduce patient barriers to access, cost, convenience
- Meet public health needs, integration of OUD into mainstream healthcare

Policymaker role: Pharmacist-run clinic model *not* currently sustainable business model without grant funding. Policies must address:

- Reimbursement / Regulatory
- Pharmacist scope of practice

Research gaps: Outcomes studies comparing models of care are needed.

Limited to no examination of treatment of break-through craving protocols for IM naltrexone in clinical literature.

SELECTED CITATIONS

- Kentucky Office Of Drug Control Policy. 2016 Overdose Fatality Report.1-27
- Food & Drug Admin., Vivitrol Medication Guide, Highlights of Prescribing Information 3 (Oct. 2010),
- Gastfriend, D.R. (2014) A pharmaceutical industry perspective on the economics of the treatments for alcohol & opioid use disorders. Ann NY Acad Sci.1327.112-130

ACKNOWLEDGEMENTS

Sullivan University College of Pharmacy; Chris Harlow, PharmD; Talya Burnett, PharmD. Poster presented in 3/2018 (AATOD conference, NYC) ; Oral abstract in 11/2018 (AMERSA conference, San Francisco). Correspondence: g.scott@usciences.edu