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Interprofessional Communication Strategies and Tools for Improving Opioid Safety and Use

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Outline

- Disclosures
- Objectives
- The Journey and Why
- My Toolbox & Today's Focus
- Past Work on Opioids
- Current Work UCONN
  - Academic Detailing for Opioid Safety (ADOPS) Project
  - Opioid Regulation in CT Project
  - Integrated PDMP Project
- Future Directions
  - FDA Opioid Packaging Prototype
- Acknowledgements
- Questions

Disclosures

- Dr. Rickles is a consultant for Otsuka Pharmaceuticals with a primary focus as a speaker for their PsychU educational platform. This platform is a non-promotional online platform available to clinicians regarding evidenced-based concepts in mental healthcare.

- Dr. Rickles has no other potential conflicts of interests to disclose.

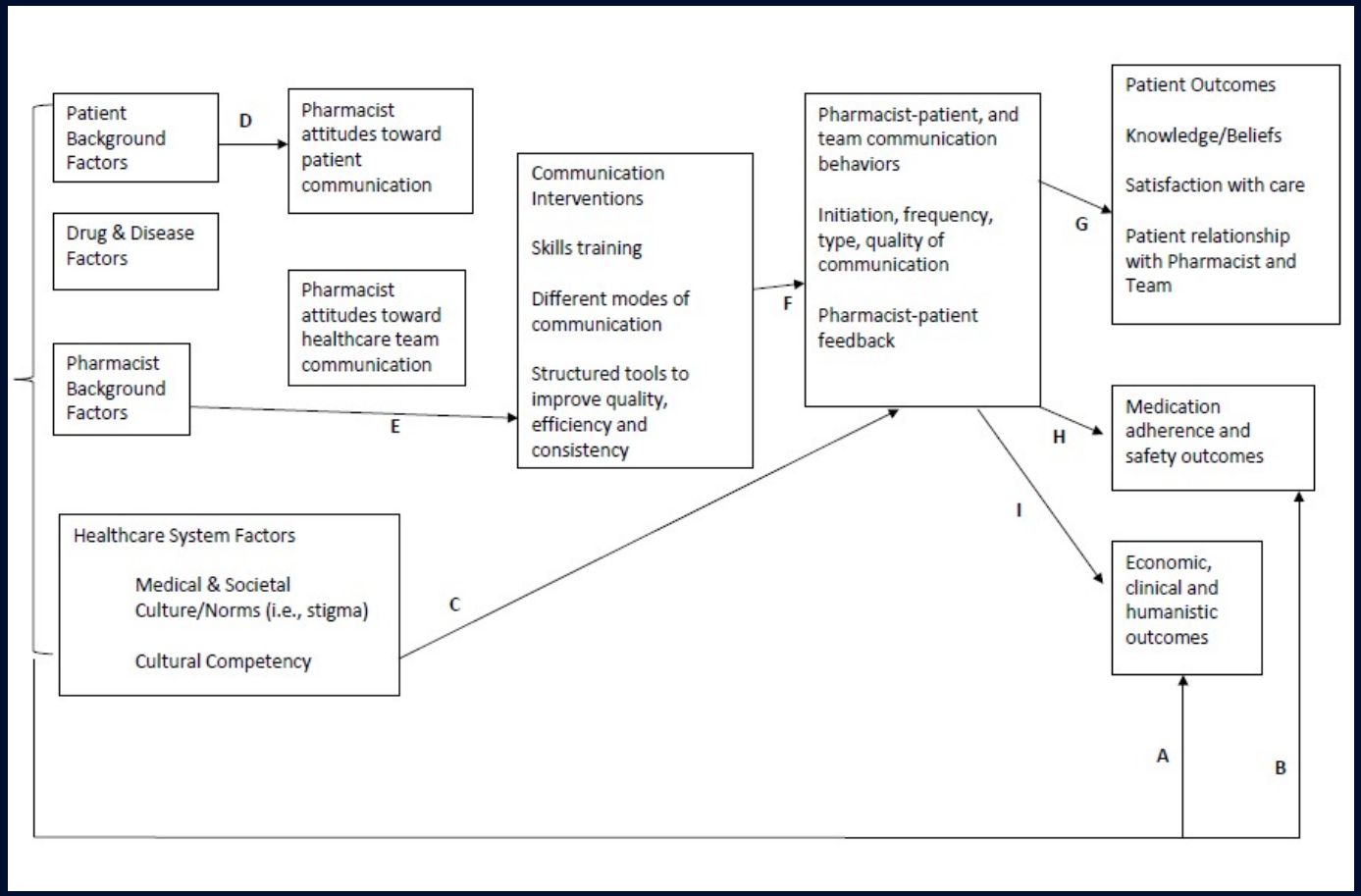
Objectives

- Review changes in health care delivery that likely impact pharmacy practice.(Q #3)
- Describe current trends in contemporary pharmacy practice as they relate to interprofessional collaboration. (Q #1)
- Discuss practice innovations designed to improve health outcomes. (Q #4)
- Discuss role delineation for pharmacists on the interprofessional health care team. (Q #2)

The Journey and Why

- Started journey with interest how intervention design can structure communications to impact pharmacist behaviors and patient outcomes.
- Recognition that intervention effectiveness is largely dependent on consistency of pharmacist behaviors.
- Overarching hypothesis of work: Improvements in intervention structure and accountability will lead to greater consistency in behaviors and improved patient outcomes.
- Structure  Process  Outcomes

Figure 1:Research Framework



Research Framework

- A. **Personality's role in Depression/Anxiety (J Behav Health Serv Res 2020)**
- B. Socio-economic characteristics and medication adherence (Health Affairs 2014)
- C. **Opioid 3-day supply guideline research (pending submission)**
- D. Pharmacist stigma research (J Am Pharm Assoc 2010), cultural competency (Pharmacotherapy 2007 & 2009;)
- E. Pharmacist stigma research (J Am Pharm Assoc, 2010); Teaching Med Adherence US Schools of Pharmacy (Am J Pharm Educ, 2012); Consumer-led intervention on stigma (Mental Health Clinician, 2016)
- F. Pharmacist telephone antidepressant monitoring program (J Am Pharm Assoc 2005;, J Am Pharm Assoc 2006) , Student communication and medication errors (Health Comm, 2009, Am J Pharm Educ ,2010 ; Standardized Patient (SP) program evaluation (Am J Pharm Educ, 2009); Alzheimer's Screening and Referral Program (Int J Clin Pharm, 2013); Medication adherence communications (Pat Ed Counseling, 2016); **Role of Conversational Agents on Medication Safety (J Med Internet Res, 2018); Opioid dispensing algorithm (Res Soc Admin Pharm, 2018); Marijuana Dispensary Survey (Submitted to JAPhA, 2020); Academic Detailing Programs (DMHAS & DPH, 2018 to present); WISEWOMAN Medication Therapy Management (MTM) program (DPH; 2017 to present; pending submission); Long-Acting Injectable Antipsychotic Program (CPF, 2018 to present); Intervention Fidelity Review (2019 to present; pending submission); Telephone vs. Face-to-Face MTM (PCORI, 2015-2018),Opioid Packaging Prototype (FDA, 2019 to present)**
- G. Pharmacist telephone antidepressant monitoring program (J Am Pharm Assoc 2005; J Am Pharm Assoc 2006)
- H. Pharmacist telephone antidepressant monitoring program (J Am Pharm Assoc 2005; J Am Pharm Assoc 2006) Methodological assessment of adherence measures (Res Soc Admin Pharm 2007), Theoretical model relating adherence levels and outcomes (Res Soc Admin Pharm 2010;6:49-62); Medication adherence review (Pharm Pract 2010;8 :1-17); Medication adherence communications (Pat Ed Counseling, 2016); **Prescription Drug Benefits and Med Adherence (Med Care, 2017); Opioid dispensing algorithm (Res Soc Admin Pharm, 2018)**
- I. **Prescription Drug Monitoring Program and impact on time and costs (J Am Pharm, 2020)**

My Toolbox and Today's Focus

- Toolbox:
  - Survey methodology is the most common research tool utilized; some studies use qualitative/interview methods and secondary data analyses.
  - Use both quantitative and qualitative methods to analyze data at the descriptive, bivariate, and multivariate levels.
  - Theoretical Frameworks: Health Belief Model, Theory of Reasoned Action and Planned Behavior, Chronic Care Model, Health Collaboration Model, PRECEDE-PROCEED, Intervention Mapping, and RE-AIM.

Pharmacist Opioid Qualitative Study

- Aims: To develop an algorithm to guide community pharmacists in systematically approaching the detection and in store management of suspected prscription opioid misuse, and (2) to evaluate pharmacist and other stakeholders' feedback about the algorithm. Main Question: What community pharmacists and other stakeholders considered the primary steps needed to detect and intervene on prescription drug misuse.

Pharmacist Opioid Qualitative Study: Methods

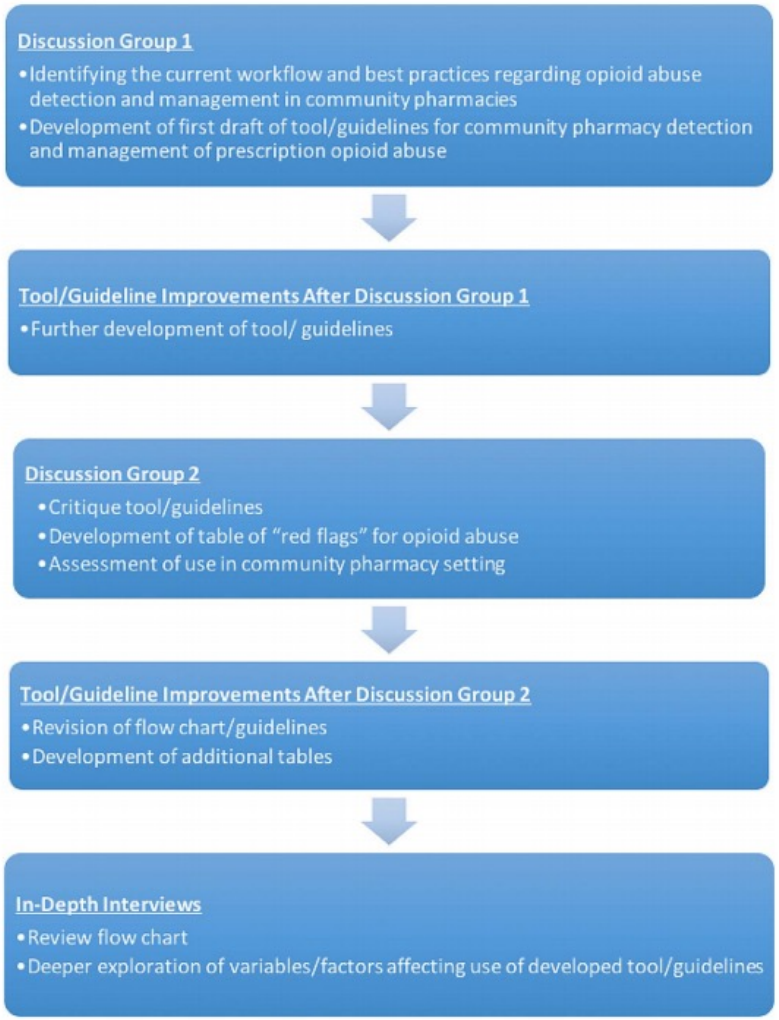


Fig. 1. Schematic of algorithm feedback process.

Pharmacist Opioid Qualitative Study: Methods

Table 1: Interview Questions

1. Where do you think the pharmacist/technician divide should be?
2. What is your stance on technician PDMP use?
3. If you were to integrate this algorithm in your pharmacy, how would it affect your workflow? Could this be a realistic change?
4. Are there any deterrents (other than timeliness) for using this algorithm?
5. What other warning signs can you think of that could indicate drug abuse? For example, 100% adherence to as needed meds, patient understands how insurance works well, and frequent early fills? (Maybe we could write a list of potential “red flags”.
6. Would you prefer insurance rejection being the major indicator of drug abuse or the PDMP? What are the strengths or limitations of each approach?
7. Do you feel adequately trained for patient confrontation if drug abuse is suspected?
8. What would be a good motivator to follow and use the system? What are some practical ways the system can be enforced?
9. What are any and all changes would you make to this flow chart?

Pharmacist Opioid Qualitative Study: Results

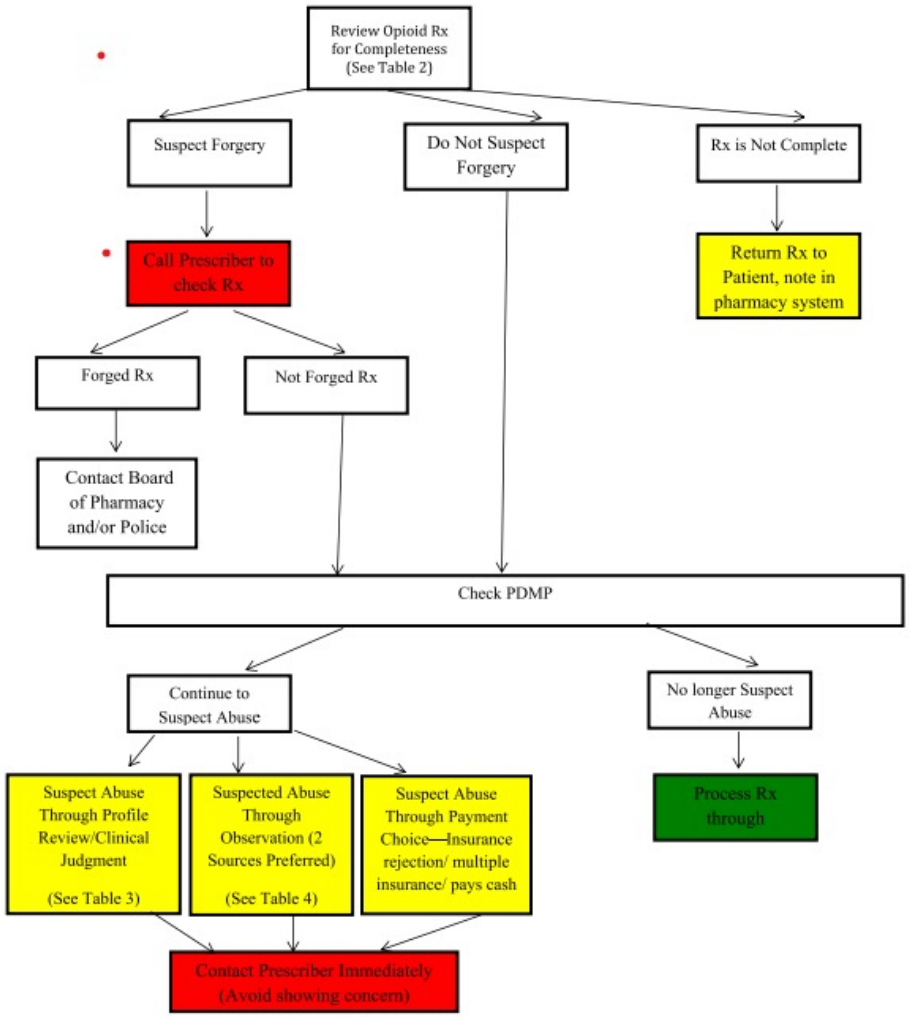


Fig. 2. Algorithm for safe opioid dispensing in community pharmacy practice.

Pharmacist Opioid Qualitative Study: Results

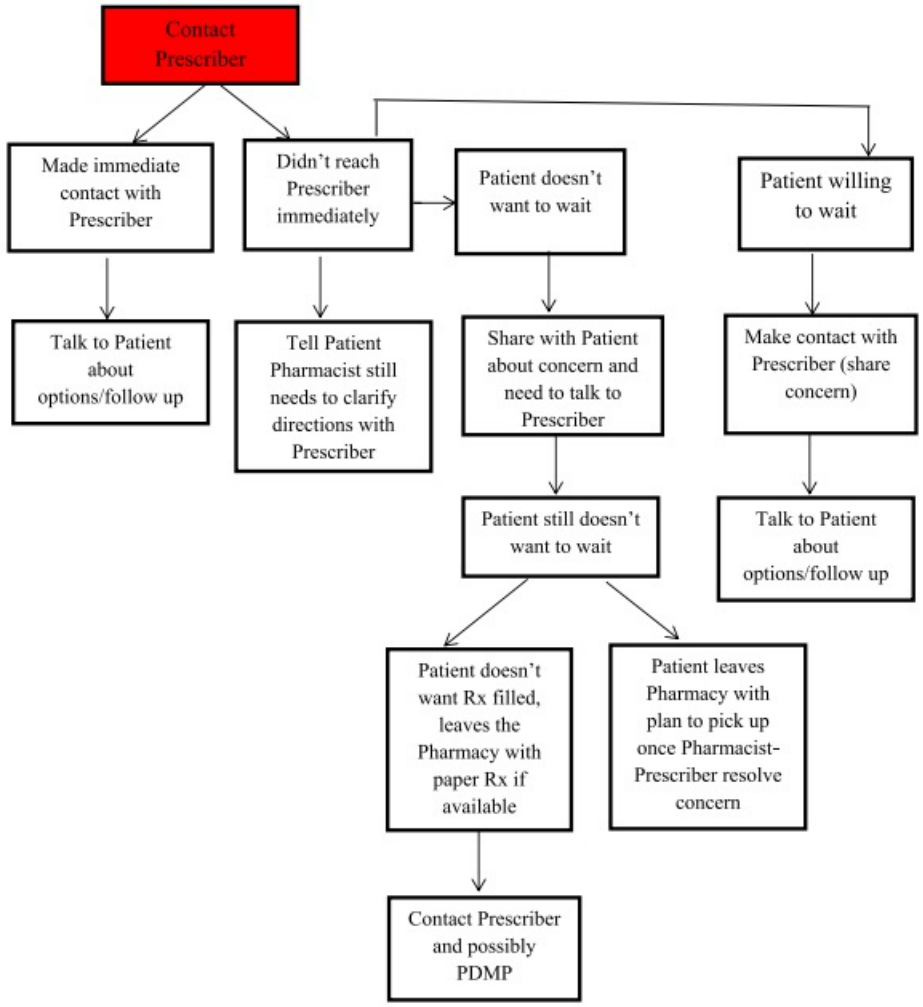


Fig. 2. (*continued*)

Pharmacist Opioid Qualitative Study: Results

Table 2: Review Opioid Rx for Completeness
General Rx completeness: NPI#, MD's name and signature, phone # and address of MD, valid prescription written within past 30 days, dosage amount and strength, directions, patient information, printed on Rx paper
Opioid Forgery check: valid DEA# **Is there a type of identification present? Is the identification valid (not expired, not fake)?** **Payment method: Is patient requesting to pay cash despite having insurance?**

Table 3: Suspected Misuse Detection Clinical/Profile Review

Is person using the same opioid Rx but obtaining from ≥ 2 prescribers during a 4 month period?
Is person using multiple opioids Rxs but obtaining from ≥ 2 prescribers during a 4 month period?
Is person using ≥ 3 pharmacies within a chain during a 4 month period?
Is person making ≥ 2 requests for early refills of opioid Rxs within a 4 month period?
Is person receiving ≥ 100 mg/day of morphine equivalent? (see link:: http://agencymeddirectors..wa.gov/mobile.html)
Is person receiving prescriptions for Benzodiazepine in addiction to narcotic prescription?

Pharmacist Opioid Qualitative Study: Results

Table 4: Suspected Misuse by Observation & Other Probes

Assess if patient appears to be exceedingly sedated, intoxicated, or in any way disoriented Examples : Nodding off, Slurred speech, Uncoordinated, Lack of logical responses, Unable to engage in a conversation
Monitor behavior for a few minutes if possible
Ask for a second individual to monitor
Ask when did they had the last dose of opioids
Ask routine questions to screen logical thought
Explore why patient or patient's delegate comes from long distance to pick up prescription at pharmacy
Explore why insurance might not be covering prescription and patient having to pay cash

Pharmacist Opioid Qualitative Study: Results

- Key Themes:
  - Opioid misuse detection starts with prescription authenticity.
  - Employ early step of utilizing the PDMP as a primary screening tool to detect those at risk for prescription opioid misuse.
  - Pharmacists should employ the additional misuse detection steps of clinical profile review and observation of the person picking up the prescription.
  - Intervention steps should involve sharing concerns with the patient, protocol of making contact with the prescriber, and/or return of the prescription if appropriate.
  - Algorithm is easy to follow and significantly enhanced with color-coding.

Pharmacist Opioid Qualitative Study: Conclusion/Future Questions

- Algorithm easy to follow; suggesting face validity.
- How might we use algorithm in practice to trigger community pharmacists to follow certain key steps and document results of using the algorithm? Integrate into software programs? Is algorithm feasible across diverse community pharmacy settings?
- Algorithm as basis for future study of pharmacist, patient, and organizational factors that influence pharmacist opioid dispensing and intervention decisions.
- More work needed to enhance development of decision support aids that guide community pharmacists in often challenging and unclear situations involving assessment and interventions of prescription opioid misuse and abuse.

Question #1:

- Based on the information learned in the pharmacist opioid qualitative study, pharmacists using the proposed algorithm can best assist prescribers by:
  - (a) calling the prescriber if the prescription appears legitimate, no flags in PDMP but patient pays cash
  - (b) calling the prescriber with assessment of patient's risk of future opioid misuse
  - (c) calling the prescriber with clinical concerns based on profile review and/or observations
  - (d) calling the prescriber after checking the PDMP as a first step in the process

Academic Detailing on Opioid Safety (ADOPS)

Research Problem:

- Prescribers and pharmacists have been inconsistent in their use of Connecticut Prescription Monitoring and Reporting System (CPMRS).[1-4]
- There lacks sufficient evidence to support pharmacist roles as detailers to their peer pharmacists and prescribers in promoting opioid safety such as greater prescription drug monitoring program (PDMP) use, naloxone prescribing and dispensing, and referral for Medication-Assisted Treatment (MAT) Opioid Use Disorders.

Objective: To determine if an academic detailing program delivered directly on site to prescribers and pharmacies is a feasible and effective approach to change knowledge and promote positive clinical behaviors that advance opioid safety.

Academic Detailing on Opioid Safety (ADOPS)

- Goal: To pilot the feasibility and effectiveness of an academic detailing program, ADOPS, used by health district staff to promote opioid prescribing and dispensing best practices among opioid prescribers and pharmacies in target health districts in CT. Academic Detailing is:

  - An interactive educational outreach to physicians to provide unbiased, non-commercial, evidence-based information about medications and other therapeutic decisions, with the goal to improve patient care.

  - Based on effective communication/ behavior change/marketing approaches used by pharmaceutical industry sales representatives to increase use of products.

  - Needed since Clinicians have difficult time staying on top of newest information, resources, and opportunities to help improve safe & effective use of opioids.

Academic Detailing on Opioid Safety (ADOPS)

- We have trained 9 health district staff in academic detailing (involved districts: North Central District Health Department, East Shore District Health Department, Torrington Area Health District, Ledge Light Health District, Uncas Health District).
- Two modules have been developed: 1 on the CPMRS and 1 on Naloxone. Both have been approved for 1.5 hours of continuing education credits for pharmacists and prescribers. Another has been recently developed on MAT.
- Detailing packets have been provided to each detailer along with portfolio cases, pens, and other small gifts. Packets include: a letter describing the project, an action plan to use to guide and track visits, flyer to promote project, prescriber/pharmacist resources for to use on each module, and information resources to distribute to patients. Detailers were also given flash disks of all content to give each person detailed and for themselves.

ADOPS Action Plan

Pharmacist/Prescriber Academic Detailing Session 1 Action Plan

Pharmacist/Prescriber:_____

Academic Detailer Name (Print):_____ Academic Detailer (Signature):_____

Learning Objectives:

1. Discuss the benefits of the Connecticut Prescription Monitoring and Reporting Program (CPMRS).
2. Identify the presence individual and practice-level facilitators and barriers to the use of the CPMRS consistently at time of new and continued users of controlled substances.
3. Describe the key components of the prescriber reports sent by the Department of Drug Control. (Prescriber Objective only)
4. Identify resources to assist with greater use of CPMRS, and engaging in safe opioid and other controlled substance prescribing and/or dispensing.
5. Outline an action plan for continued and increased use of the CPMRS.

To achieve Learning Objective 1-Review/Reinforce the following key messages (Use CPMRS Brochure):

(check the appropriate box (V1 or V2 or V3) if the information is covered during *Visit 1 or Visit 2 or Visit 3*)

V1	V2	V3	CPMRS provides CT prescribers and pharmacists dispensing of Controlled Substances II-V
V1	V2	V3	Access to comprehensive controlled substance prescription records.
V1	V2	V3	Access to controlled substance history report from other states.
V1	V2	V3	Ability to review prescribing history reports to identify possible forgeries and detect potential abuse.
V1	V2	V3	Access to unsolicited clinical alerts.

To achieve Learning Objectives 2 & 5, engage in the following need assessments:

V1	V2	V3	Explore facilitators to CPMRS use. List:
V1	V2	V3	Explore barriers to CPMRS use. List:
V1	V2	V3	Discuss the use of a delegate to look up in the CPMRS

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Academic Detailing on Opioid Safety (ADOPS)

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ADOPS Update

- Detailers started detailing in November 2019. the detailers have completed modules on approximately 12 prescribers and 9 pharmacists.
- COVID-19 created delays given restrictions. All current detailers have been provided materials on how to conduct virtual visits and several detailers attended webinars held by the National Resource Center for Academic Detailing (NaRCAD) on best practices on how to conduct virtual visits. 1-2 detailers have conducted visits virtually and shared their positive experiences with the project team.
- We have also conducted interim analyses of data from the action plans, and prescriber and pharmacist evaluation data. Responses very positive reflecting knowledge gained during visits, positive experiences during visits, and identification of key concerns around CPMRS and naloxone use.

Question #2

- Through academic detailing, pharmacists can:
  - (a) facilitate prescriber awareness and behavior change of key opioid safety concepts
  - (b) help change patient opioid use behaviors
  - (c) engage in similar roles as prescribers
  - (d) require prescribers to accept new opioid safety behaviors

Impact of an Opioid Regulation in CT

Research Problem:

- CT passed regulation in July 2016 that allowed prescribers to NOT have to search the CPMRS prior to opioid prescribing if they prescribe less than a 72-hr amount of opioids. Prescribers might be encouraged to prescribe less if they don't have to spend the time accessing the CPMRS.
- Little evaluation research on how the avoidance of one negatively perceived clinical behavior can lead to the promotion of a positively perceived and valued clinical behavior.

Objectives: (1) To explore how opioid prescription volume, benzodiazepine, morphine milligram equivalents (MME), and opioid days supply changed from pre to post regulation. (2) To explore how CPMRS search rates change from pre to post regulation.

Opioid Regulation in CT Hypotheses

- Opioid regulation would be associated with a decrease in opioid prescription volume, MME, days supply, and prescriber search rates.
- Opioid regulation would be associated with no changes in benzodiazepine prescription volume or days of supply.

Opioid Regulation in CT Methods

- The data (obtained from APRISS, vendor for CPMRS) included:
  - Prescription volume of Schedule II-V Opioids
  - Prescription volume of benzodiazepines
  - Average MME of Schedule II-V Opioids
- The data was reported per CT zip code and then further organized into CT counties
- Significant data cleaning was required
- Differences were explored between “pre-regulation” and “post-regulation”
  - “Pre-regulation” was from January 2016 to July 2016
  - “Post-regulation” was from August 2016 to August 2017
- Parametric, Paired T-tests were run against the data to calculate the difference between the data from the pre to post-guideline periods.

Opioid Regulation in CT Results

- (1) Opioid prescription volume Pre-Post change
  - Results: **Statistically significant decrease of 71.244** [t (186) = -8.72, p -value < 0.05]
- (2) Benzodiazepine prescription volume Pre-Post change
  - Results: **Statistically significant decrease of 27.275** [t (186) = -7.42, p-value < 0.05]
- (3) Opioid MME Pre-Post change
  - Results: no statistically significant change [t(186) = 1.25, p-value = 0.2115]
- (4) Opioid and Benzodiazepine days supply
  - Results: no statistically significant changes for either
  - Opioids: t(185) = 0.32, p-value = 0.7474
  - Benzodiazepines: t (185) = -0.32, p-value = 0.7496

Opioid Regulation in CT Results/Conclusions

- (5) Prescriber CPMRS Search Rates
  - Mean diff: 0.015, 95 CI (0.2, 3.43). Search rates pre regulation was significantly higher than post regulation.
- Conclusions:
  - Support: Opioid Prescription Volume and prescriber search rates both declined; Benzodiazepine days supply no change
  - Rejection: No change with opioid prescription days supply and MME, and benzodiazepine days of supply; significant decrease in benzodiazepine prescription volume
  - Findings suggest prescribers may have reacted to regulation by looking up the CPMRS less and prescribing less but no changes in days supply. Could this be changing prescriber perceptions of what is really needed for days supply coverage? MME standardization may have influenced variability in prescribing changes.
  - Decrease in benzodiazepine use might reflect overall state efforts to decrease both benzodiazepines and opioid use.

Use of Integrated CPMRS Study

Research Problem:

- Medical marijuana dispensing information enables clinicians to make more informed decisions when prescribing and dispensing all controlled substances. CPMRS is a unique platform that provides clinicians access to both medical marijuana and controlled substance information.
- It is unknown how community-based pharmacists (CBPs) and medical marijuana dispensary pharmacists (MMDPs) use this integrated PDMP and perceptions of its value.

Objective: (1) Identify ways CT pharmacists use the CPMRS when dispensing opioid medications and/or medical marijuana products, (2) determine pharmacists' perceived value of the CPMRS when dispensing opioids or medical marijuana, and (3) compare practices and perceived value of the CPMRS among CBPs and MMDPs.

Integrated CPMRS Study Methods

- An online survey was administered in May and June 2019 to community-based (n=178) and marijuana dispensary (n=12) pharmacists.
- The survey consisted of 31 questions (27 close-ended/multiple choice and 3 open-ended) and took approximately 10 -15 minutes to complete.
  - Key Sections: Survey Eligibility Screening (3 items), Demographics (4 items), Professional Background (9 items), and Use of the CPMRS (14 items).
  - The survey was developed using the online platform SurveyMonkey and began with asking respondents to consider activities that had occurred in the past 12 months when responding to the survey. Respondents were given the option to enter into a drawing to win one of five $50 gift cards for participating in the survey.

Integrated CPMRS Study Results

- Never Use CPMRS to make such decisions as:
  - CBPs- > 45%: determining if a patient is using medical marijuana, (2) referring a patient to substance misuse support, and (3) prescribing naloxone
  - MMDPs- >50%: when dispensing/prescribing naloxone
  - More MMDPs (80%) than CBPs (38.1%) reported always using the CPMRS to determine if a patient is taking an opioid.
- Top Reasons for Using CPMRS
  - CBPs: patient has opioid presciption, patient paying cash, following a pharmacy-developed dispensing protocol
  - MMDPs: state regulations, patient has opioid prescription, and following a pharmacy-developed dispensing protocol
- Both groups reported less use of the CPMRS for clinical value such as drug interactions, risk of side effects, and patient has complex medical conditions.

Integrated CPMRS Study Results

- A similiar percentage of CBPs and MMDPs use CPMRS for opioid information and other patient concerns.
- A greater percentage of MMDPs than CBPs use the CPMRS for both opioid and marijuana information.
- MMDPs saw greater usefulness in using the CPMRS than CBPs.
- A much higher percentage of MMDPs (36.4%) than CBPs (5.1%) used the CPMRS with every patient.
- A greater percentage of MMDPs than CBPs use the CPMRS when referring patients to substance use support, and prescribing and dispensing naloxone.

Integrated CPMRS Study Results

- Few CBPs and MMDPs reported having contact with prescribers and caregivers about medical marijuana and opioid medication use.
- Both groups indicated their sites need to integrate CPMRS into workflow and pharmacy technicians being involved in conducting CPMRS searches.
- Respondents indicated the need for CPMRS improvements like more rapid updating of opioid dispensing information, the clarity of where opioids were dispensed, and the specificity of the medical marijuana information (THC content, strain) and diagnoses for use.

Integrated CPMRS Study Conclusions

- First known study exploring differences in perceptions of CBPs and MMDPs regarding their use of an integrated marijuana and opioid PDMP.
- Despite the availability of medical marijuana information in an integrated PDMP, fewer CBPs than MMDPs indicate using the system for such information.
- CBPs use the PDMP mainly as an additional source of opioid use information that goes beyond what they have in their medication profile systems.
- MMDPs do not have such opioid information and thus rely on the integrated PDMP for both medical marijuana and opioid dispensing information.

Integrated CPMRS Study Conclusions

- Need to educate CBPs on the clinical value of using the integrated PDMPs to identify critical drug safety and efficacy concerns
- Integrated PDMPs should aim to expand the nature and extent of medical marijuana information within their systems.
- These combined enhancements involving greater awareness in the value of an integrated system, system efficiency, and medical marijuana content hopefully will yield greater use of an integrated PDMP and subsequently contribute to greater opioid and medical marijuana safety.

Question #3

- The following statement BEST reflects how the integrated CPMRS system has changed pharmacy practice? CBPs= Community-based Pharmacists, MMDPs= Medical Marijuana Dispensary Pharmacists

  - (a) More CBPs than MMDPs use the integrated system for the marijuana information.
  - (b) MMDPs use the integrated system for access to the opioid information.
  - (c) The integrated system has provided a rich source of patient counseling information such strain, THC content of product, and diagnoses for marijuana use.
  - (d) Most CBPs and MMDPs in the study report the CPMRS has been well integrated into their workflow.

Opioid Packaging Prototype (OPP) Study

Research Problem:

- There have been many initiatives to reduce opioid prescribing, misuse, and abuse.
- Despite these initiatives, there remains a great need to identify other prescribing and diversion interventions that can create additional infrastructure and ensure greater consistency in appropriate opioid prescribing. Such additional interventions can complement and enhance ongoing efforts to avoid excessive prescribing and aid in reducing diversion.
- FDA would like to consider the value of using fixed dose packages as a way to restrict prescribing.

Objective: Using a randomized, controlled cross-over design to determine the effectiveness of a packaging prototype on prescribing, dispensing, and patient use of a Scheduled II opioid. Using survey and qualitative research methods, determine the feasibility of the packaging prototype for prescribers, pharmacists, and patients.

OPP Study Aims

- Aim 1: To evaluate the effectiveness of OPP on prescribing, dispensing, and patient use of oxycodone among orthopedic surgery patients receiving post-operative outpatient oxycodone for post-surgical pain.
- Aim 2: To determine the feasibility of OPP for orthopedic surgery prescribers, pharmacists, and orthopedic surgery patients. Such data can be used to further optimize packaging and labeling design, help patients and caregivers utilize their medication and packaging correctly, and improve prescribing and dispensing habits.
- Central hypothesis: OPP will be more effective than the amber vial in efforts to reduce oxycodone prescribing among patients receiving treatment for post orthopedic surgery pain.

OPP Study Design

- Seven orthopedic surgeons (UCONN Health) will be randomly assigned to the OPP or usual care (amber vials of any amounts of oxycodone 5 mg) during Phase 1 of the study.
- Thirty patients of the 7 orthopedic surgeons will be randomly selected to be included in the study (210 patients) and will receive oxycodone in whatever packaging as designated by the surgeon's arm of the study for post surgical pain.
- In Phase 2 of the study, the arms will be switched and 30 additional patients per surgeon will be randomly selected to receive that surgeon's Phase 2 designated arm.
- Sixty patients per surgeon will be recruited for a total study sample of 420 patients.

OPP Study Eligibility Criteria

- 18 years or older
- No prior history of Opioid Use Disorder
- Patient of one of the participating surgeons
- Willingness to receive oxycodone 5 mg
- Willing to receive medication at the study pharmacy (located at UCONN Health)
- Ability to read/understand English

OPP Study Design

- For Aim 1, researchers will use descriptive, bivariate, and multivariate statistics to examine differences in the following variables among study groups across Phases 1 and 2:
  - the average MME
  - the number of tablets of oxycodone 5 mg prescribed to study participants at baseline, one week and one-month post-surgery;
  - amount of time required to dispense product to study participant, patient report of awareness of doses taken and consistent access to oxycodone medication information.
  - We also compare the prescribing outcomes of OPP and usual care groups to historical control groups of patients seen by the study's surgeons 6 months prior to the start of the study.

OPP Study Design

- For Aim 2, we will conduct in-depth semi-structured interviews with all the study's orthopedic prescribers involved with the OPP prescribing and pharmacists involved in the OPP dispensing.
- To elicit patient feedback about the OPP, a survey will be administered to all those who received the OPP.
- Prescribers, pharmacists, and patients will be asked to report benefits and weaknesses of the OPP design, interest in prescribing, dispensing, and suggestions for OPP improvements in the future.
- OPP patient survey data will be analyzed using descriptive, bivariate, and multivariate analyses of survey's closed-ended items. Open-ended questions will be thematically analyzed in a similar fashion as interview data.

OPP Study Outcomes

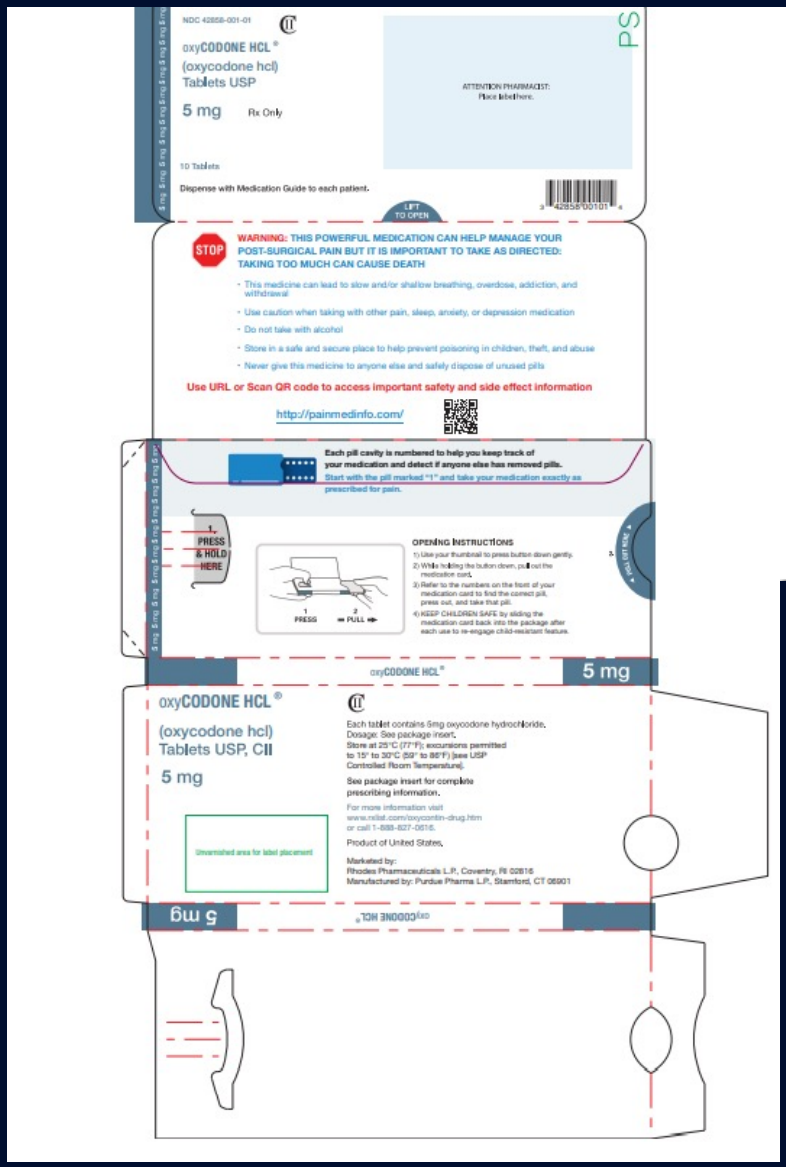
	Pre-Op	1 Week	4 Week	12 Week
Pain Medication Attitudes	✓	✓	✓	
Background Information Demographics Prior opioid use Prior pain management approaches	✓			
Knowledge of oxycodone	✓	✓		
PCS	✓		✓	✓
Pain Level PEG	✓	✓	✓	✓
PHQ-9	✓	✓	✓	
SANE	✓	✓	✓	✓
Peri-Operative Opioid-Related Symptom Distress Scale (OR-SDS)		✓	✓	
Tabs Used (since surgery) Visual Inspection		✓	✓	
Ease of Tab Removal (1-5; 1 easy, 5 hard)		✓		
Confidence No Dispensing Errors		✓		
Awareness of Tabs Used		✓	✓	
Awareness of Diversion		✓	✓	
Awareness and Consistency of Access to Oxycodone Medication Information		✓	✓	
Additional Prescriptions Requested		✓	✓	✓
OTC Products		✓	✓	
CT Prescription Monitoring and Reporting System (CPMRS)				✓
Self-report opioid-use data from all participants?		✓	✓	✓

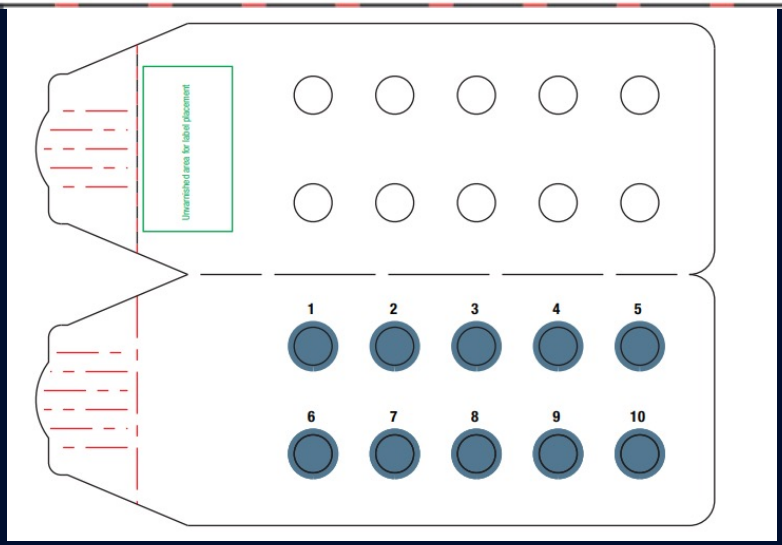
- Researcher will obtain historical control group 6 mo prior to start of study to compare baseline oxycodone prescribing with study oxycodone prescribing

OPP Study: Update

- We have gone through consumer testing (n=19) of a finalized/locked OPP that has been vetted by a large advisory panel of various stakeholder.
- Surveys for baseline, 1 week post surgery, 4 and 12 weeks post surgery developed.
- Received IRB approval.
- Hired a Clinical Research Associate
- Website on OPP developed.
- OPP being manufactured and target delivery date of May 15.
- Target start enrollment date mid to late May.

OPP Locked Design





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FDA U.S. FOOD & DRUG ADMINISTRATION

My Journey's Impact

- Fostering new understanding for how the structure of pharmacist communication with patients, peers, and other team members impact pharmacist behaviors and subsequent patient outcomes.
- Building new conceptual frameworks to provide the theoretical and practical infrastructure for innovations in pharmacy practice.
- Advancing the evaluation of pharmacist roles in substance use disorders and the care of vulnerable populations.
- Promote awareness and patient, pharmacist, and prescriber action to engage in target behaviors to ensure medication safety and enhance patient outcomes.

Question #4

- Which of the following BEST describes a key PATIENT outcome being explored in the current FDA trial on the Opioid Packaging Prototype (OPP):
  - (a) prescriber communication about opioids
  - (b) patient feedback about opioid use experiences
  - (c) patient use of opioids
  - (d) pharmacist opioid dispensing time

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Questions??

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