Pragmatic evaluations of PDMP legislation to evaluate real world evidence

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Learning Objectives

1) Discuss the current **challenges to collecting data on provider PDMP use** within clinical encounters

2) Describe the **potential benefits of pragmatic trials** for PDMP interventions and legislation

3) Understand the need to ensure government agencies, public health and researchers have **access to timely and actionable data** about the impact of PDMP legislation and interventions on opioid prescribing

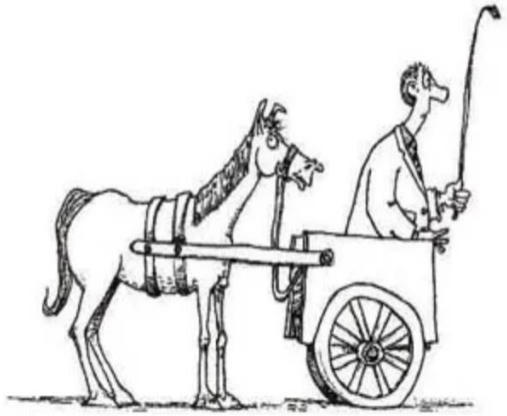
PDMP creation/implementation before ideal design

-High quality pharmacy data, but outside clinical workflows

-Legal/audit trail tracking of PDMP access, not clinical

-Limits evidence collection on mandates/policies:

-high volume actions and lack data connections

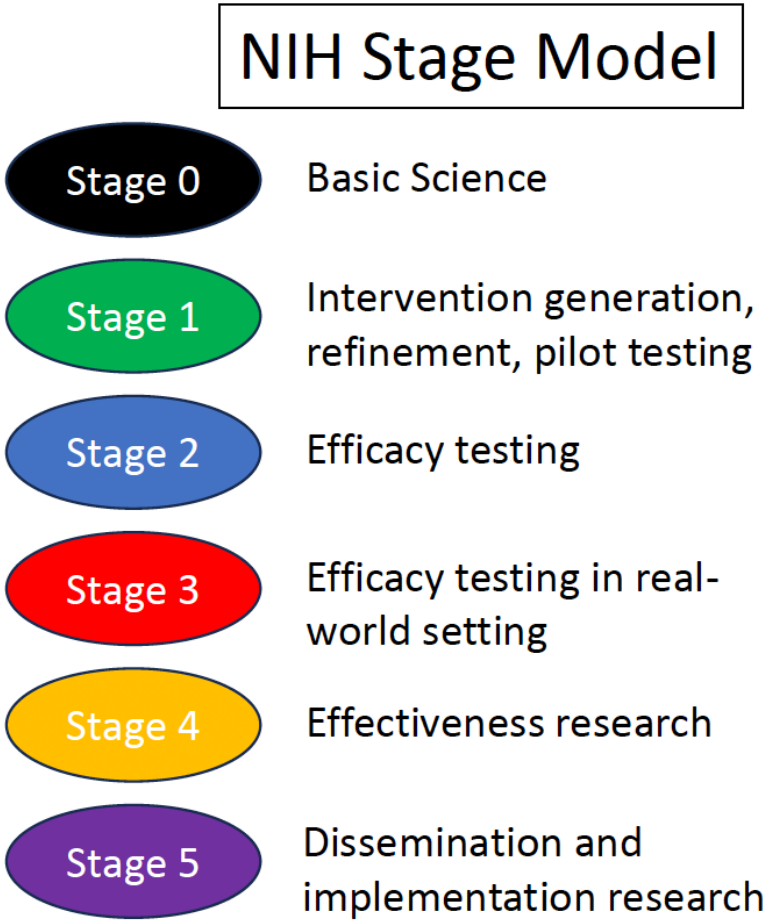


-**Need mechanisms to track “real world” PDMP use, impact on clinical decisions and patient outcomes**

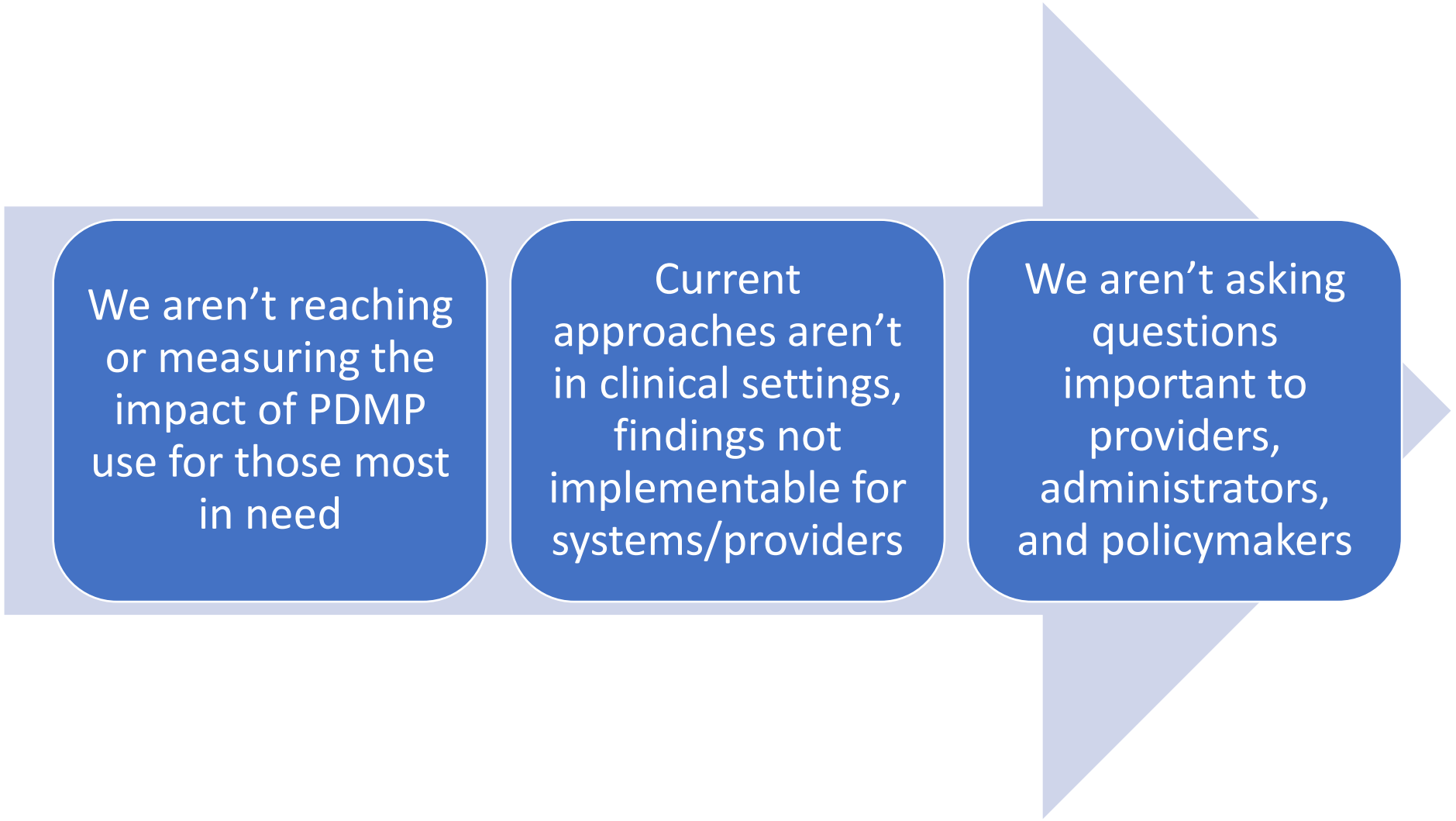
-(vs population level, observational and pre/post studies)

Challenges to traditional research methods

1) Clinical research is **slow and expensive**!
   - Only 14% of research → change practice
   - Take 17 years on avg to get into practice
2) Results often **not relevant to practice**
   - Effectiveness in selected populations and ideal conditions
3) Need mechanism to collect PDMP use and evidence in real clinical practice
   - Leverage/connect existing data streams



Why we need a new approach?



Why pragmatic research?

- Practical answers to real world questions: practice and policy
- Questions of interest to decision makers (patients, physicians, or policy makers)
- Focus on addressing real-world effectiveness
- Maximizing the chance that the results will apply to patients that are seen in practice (external validity)
- ***Does an intervention work under usual conditions?***

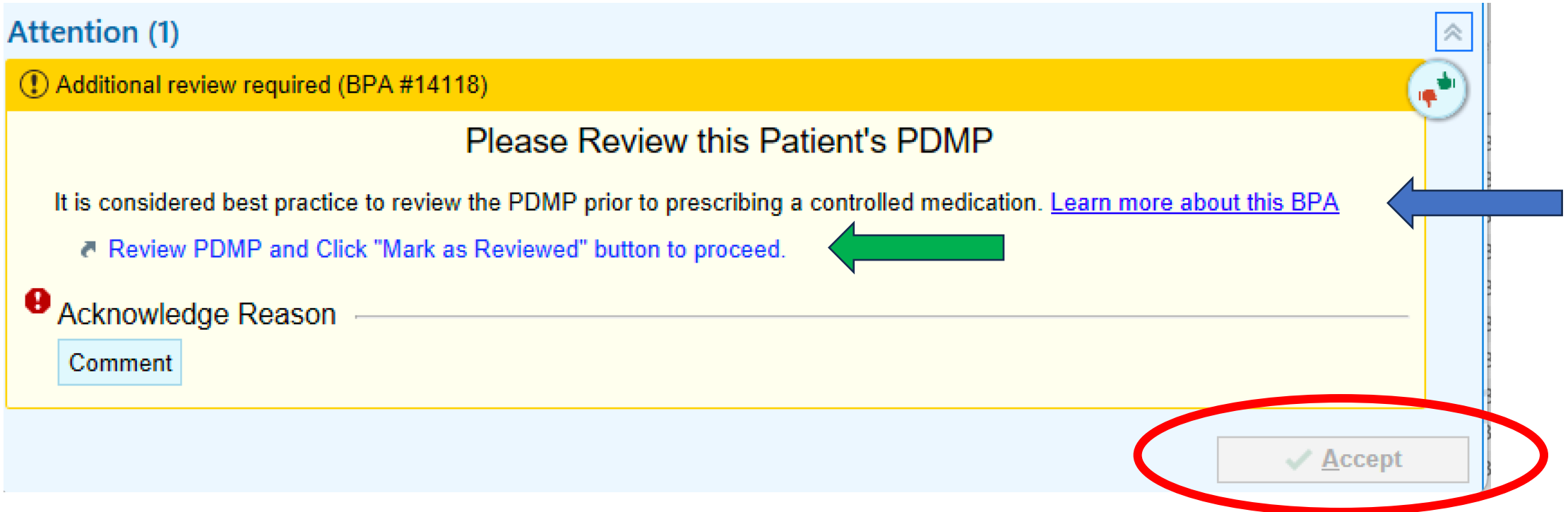
	EXPLANATORY	PRAGMATIC
Research question	Efficacy: Can the intervention work under the best conditions	Effectiveness: Does the intervention work when used in normal practice?
Setting	Well-resourced “ideal” setting	Normal care settings including primary care, community clinics, hospitals
Population	Highly selected	More representative with less strict eligibility criteria
Intervention design	Tests against placebo, enforcing strict protocols & adherence	Tests 2 or more real-world treatments using flexible protocols
Outcomes	Often short-term surrogate or process measures; data collected outside routine care	Clinically important endpoints; data collected in routine care
Clinical relevance	Indirect: Not usually designed for making decisions in real-world settings	Direct: Purposely designed for making decisions in real-world settings

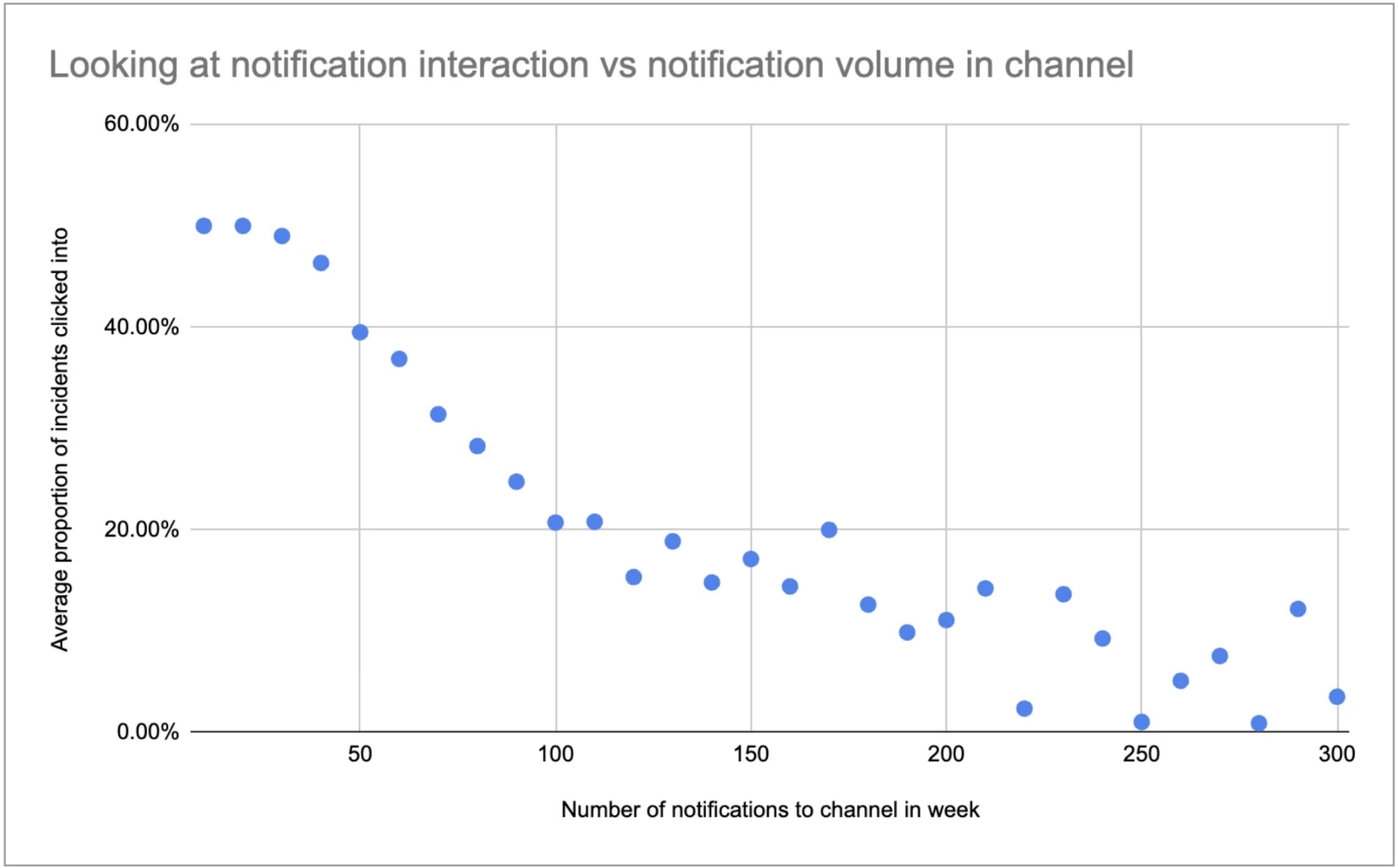
Limitations of pragmatic trials

- Routine care **data may be sparse**, few clinical variables
- Electronic health record data save's money, but it typically **inconsistent data collection and missing data (outcomes)**
- Relying on typical clinicians→ increased variability in practice and associated documentation of clinical findings
- Variation→ **reduce statistical precision** and the capability of answering the research question **unequivocally**

Electronic Health Record (EHR) data

- Clinical decision support (technical lift)
  - Identify *when* a controlled medication order started and finished
  - Measure *if* PDMP used within encounter
  - Intervention: *Facilitate* PDMP use (risk based, mandated, informed mandated)




Looking at notification interaction vs notification volume in channel
60.00%
40.00%
20.00%
0.00%
Average proportion of incidents clicked into
50
100
150
200
250
300
Number of notifications to channel in week

Data driven, pragmatic PDMP evaluation

1. Was a controlled medication prescription considered?

Data driven, pragmatic PDMP evaluation

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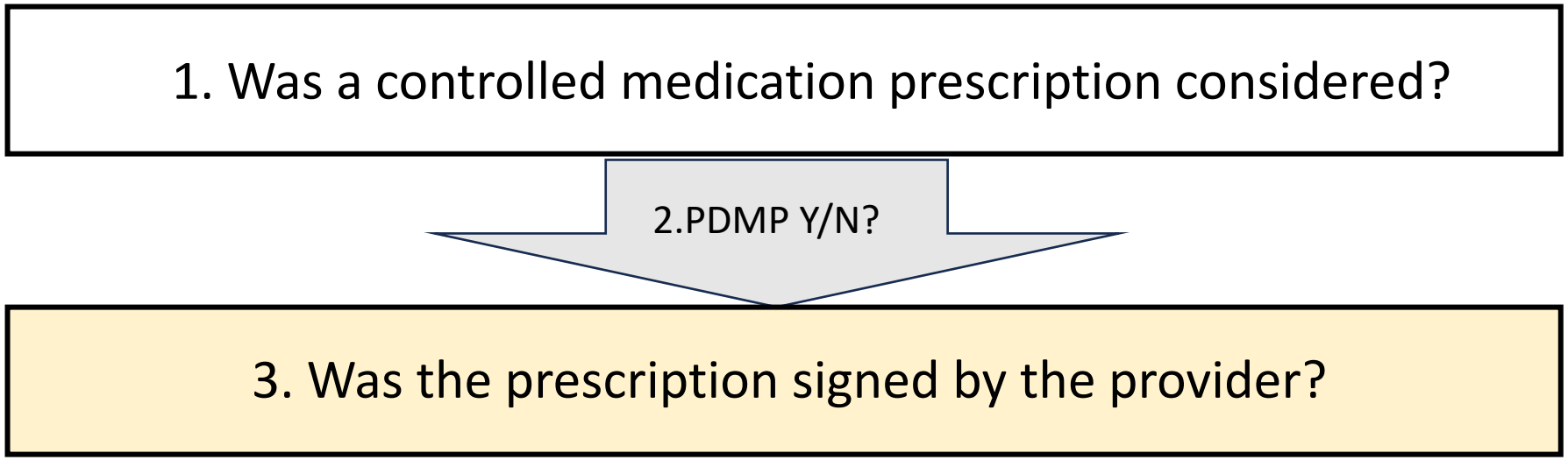
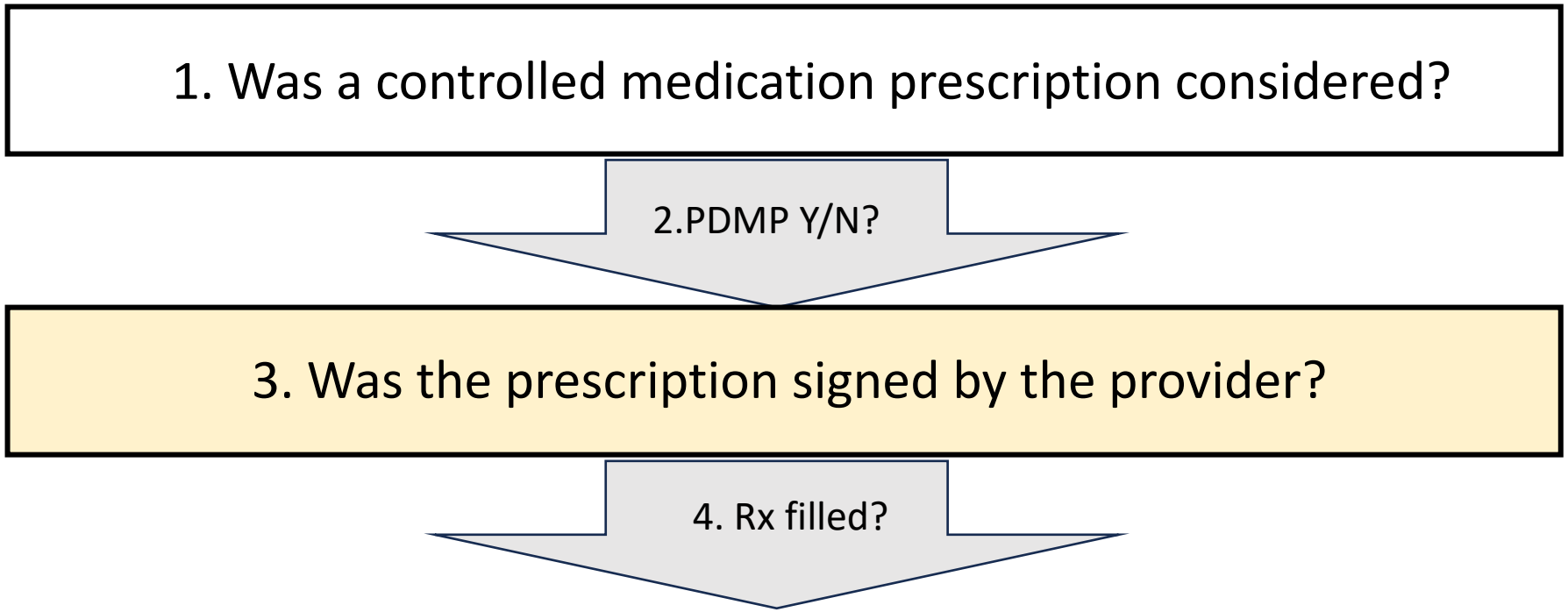
2.PDMP Y/N?

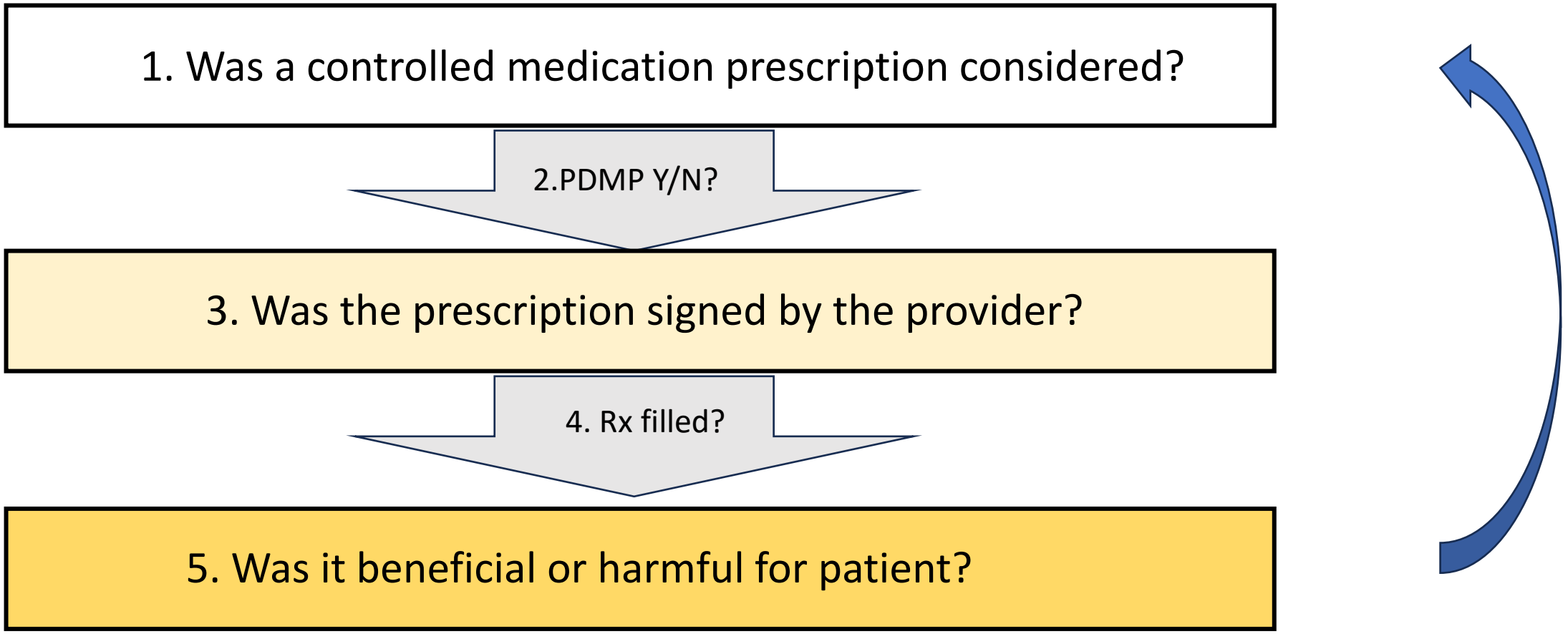
Data driven, pragmatic PDMP evaluation

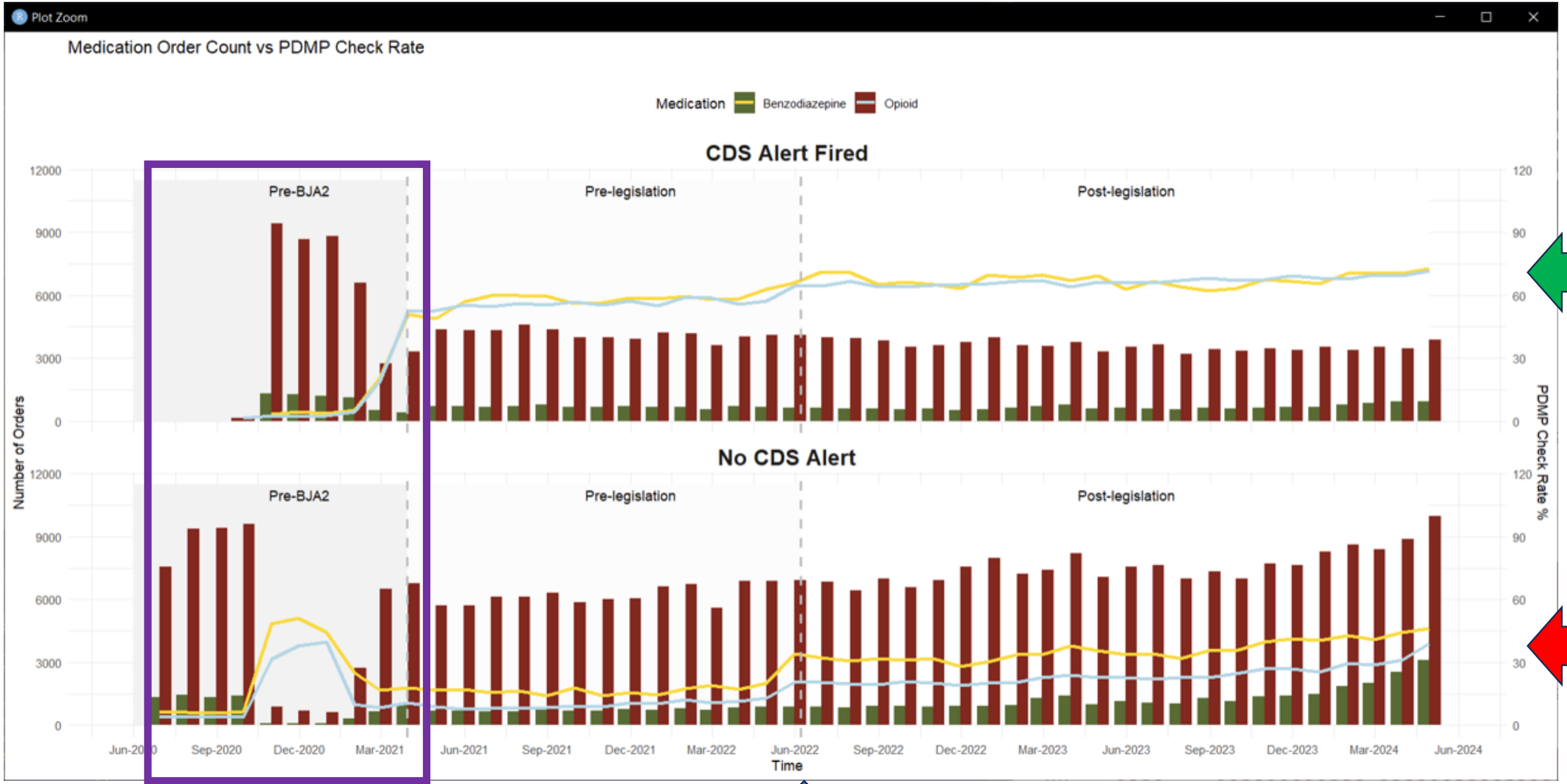


Data driven, pragmatic PDMP evaluation



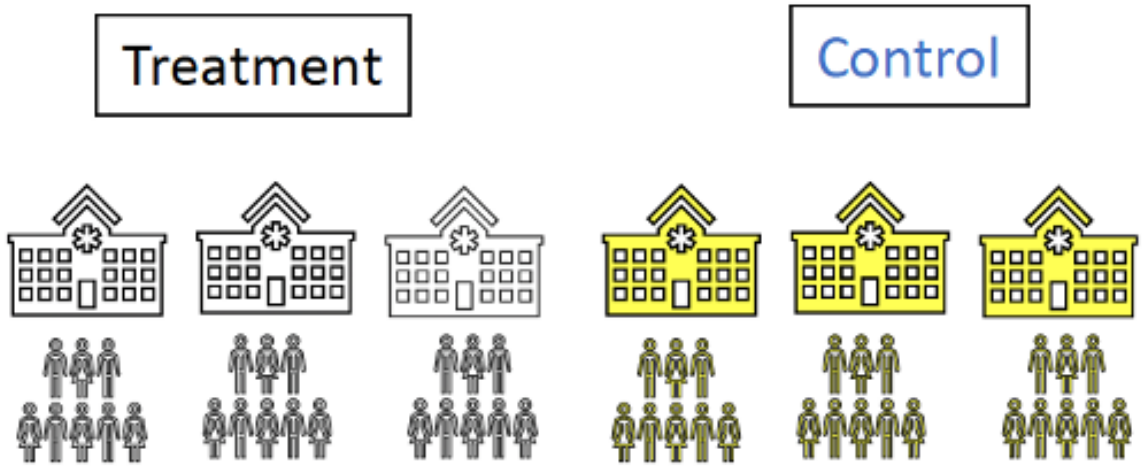
Data driven, pragmatic PDMP evaluation




Plot Zoom
Medication Order Count vs PDMP Check Rate
Medication
Benzodiazepine
Opioid
CDS Alert Fired
No CDS Alert
Pre-BJA2
Pre-legislation
Post-legislation
Number of Orders
PDMP Check Rate %
Time
12000
9000
6000
3000
0
120
90
60
30
0
Jun-2020
Sep-2020
Dec-2020
Mar-2021
Jun-2021
Sep-2021
Dec-2021
Mar-2022
Jun-2022
Sep-2022
Dec-2022
Mar-2023
Jun-2023
Sep-2023
Dec-2023
Mar-2024
Jun-2024

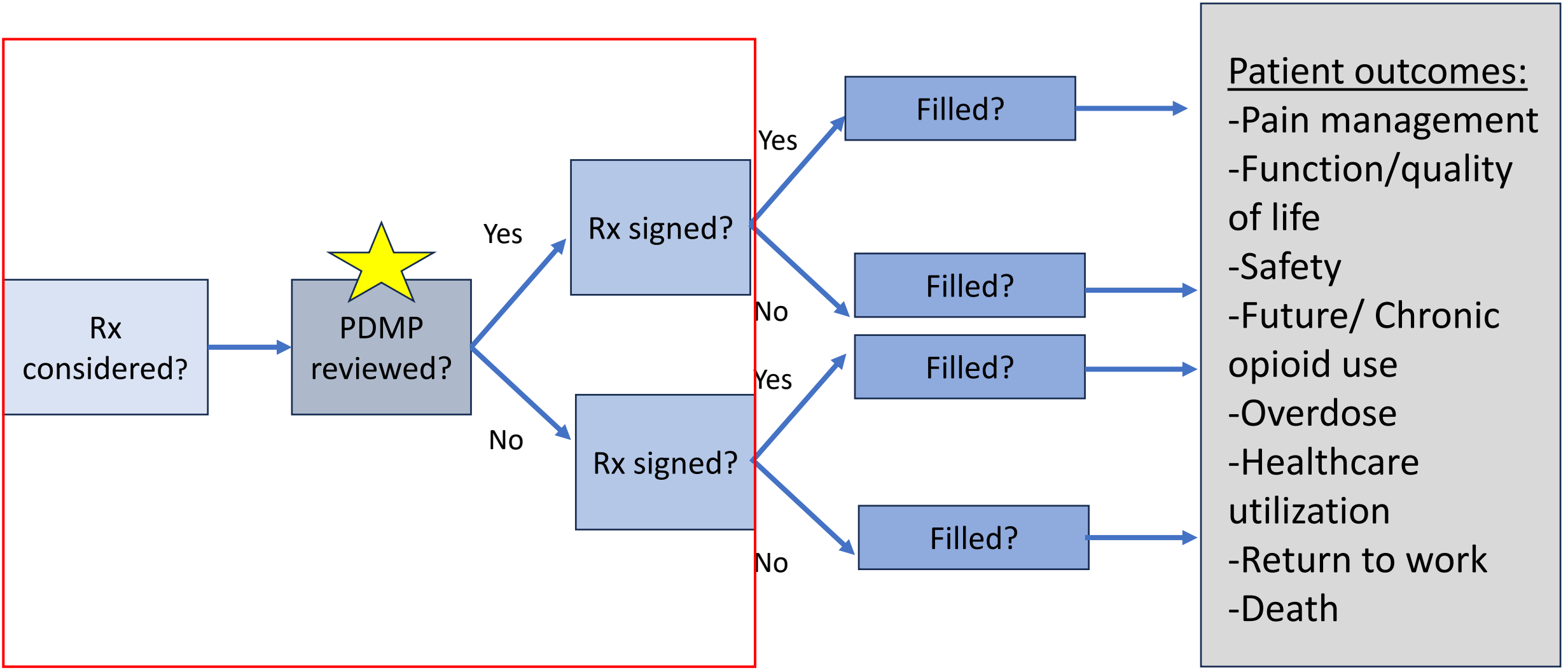
Cluster randomization

- Identify providers/settings
- Balance groups
- Assign an intervention
  - Level of assignment
- Validate data collection
- Compare risk in groups



“PDMP CDS”

“Usual care”

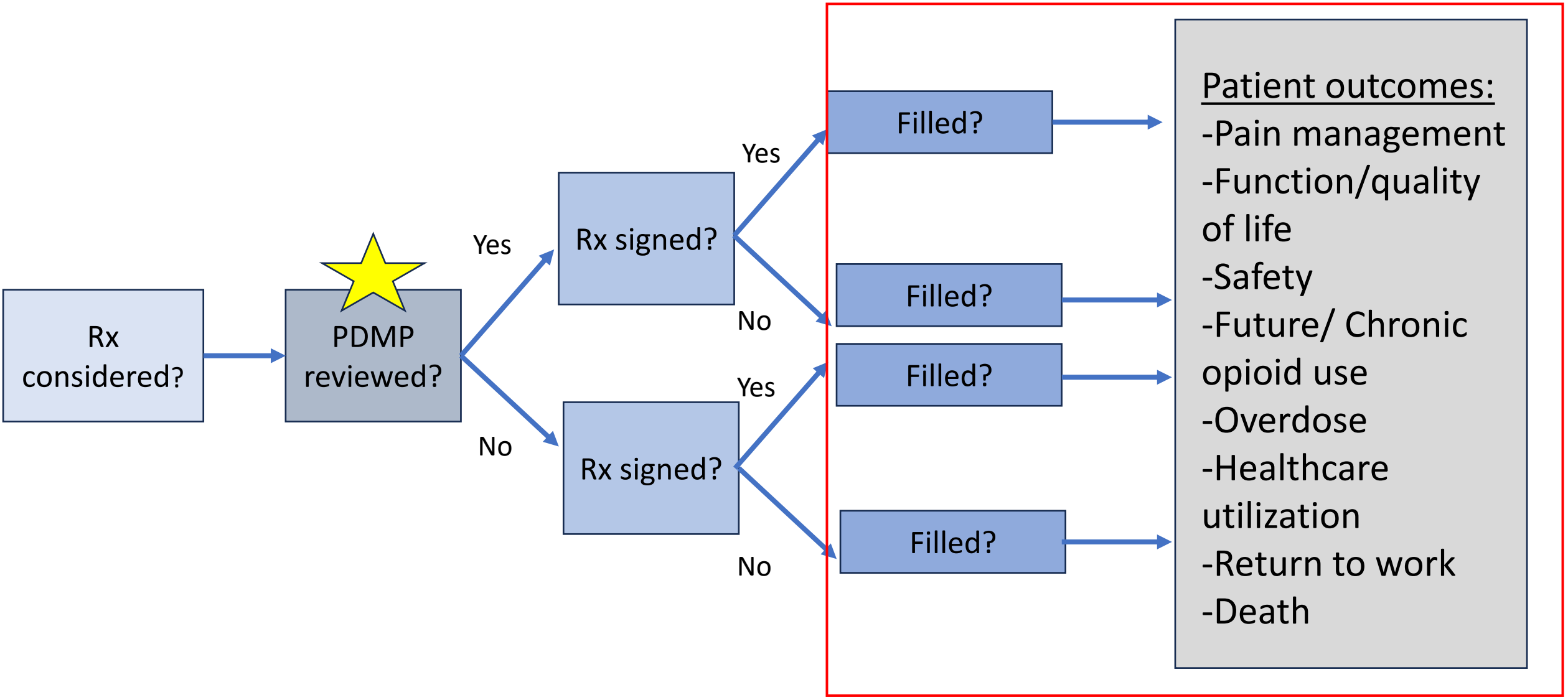

Rx considered?
PDMP reviewed?
Yes
No
Rx signed?
Rx signed?
Yes
No
Yes
No
Filled?
Filled?
Filled?
Filled?
Patient outcomes:
-Pain management
-Function/quality of life
-Safety
-Future/ Chronic opioid use
-Overdose
-Healthcare utilization
-Return to work
-Death

CDS can facilitate PDMP review (vs Control 37%)

PDMP checked	Mandated CDS	PDMP risk	PDMP+EHR risk
Yes	**95.1%**	**85.4%**	**87.7%**
No	4.9%	14.6%	12.3%

PDMP review changes opioid prescribing decisions (high risk)

Opioid Abandonment Rate by Settings	PDMP Reviewed		
	Yes	Not Reviewed	P-value*
Outpatient			
Opioid rx completed after PDMP review?			<0.0001
No (abandoned)	5.4%	3.4%	
Yes (no change)	94.6%	96.6%	
Emergency Department			
Opioid rx completed after PDMP review?			<0.0001
No (abandoned)	7.9%	3.1%	
Yes (no change)	92.1%	96.9%	
In patient			
Opioid rx completed after PDMP review?			<0.0001
No (abandoned)	11.7%	4.2%	
Yes (no change)	88.3%	95.8%	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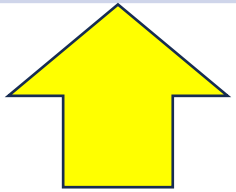
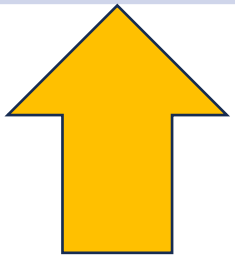
-Death

End goal

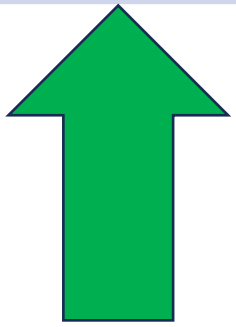
Intervention	Interruptiveness	Change in prescribing	Patient outcomes
Usual care			
Informed CDS (PDMP)			
Informed CDS (PDMP +EHR)			
Informed CDS (mandated)			
Mandated CDS			



Providers, system, alert fatigue/safety



Safety, patient, population



Patient, systems, population, policymakers, society

Pragmatic trials: key take aways

Practical	• Designed to test what will work in everyday care, with emphasis on successful implementation.
Inclusive	• PCTs study diverse populations receiving care in real-world settings using broadly inclusive criteria for study participation.
Engaged	• Health systems, providers, and patients are involved in study design, collecting data, interpreting results, and acting on findings.
Relevant	• Results designed to directly inform decision-making of administrators, providers, patients, and policymakers.

Thank you!

- Jason.hoppe@cuanschutz.edu

References available upon request