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Background

- Currently marketed abuse-deterrent formulation (ADF) opioids are routinely used in patients with prior prescription opioid exposure.
- Traditional new-user design excludes patients with prior exposure to prescription opioids
 - Incident ADF users may not be representative of the overall ADF user population.
- In a prevalent new-user design:
 - Patients can be prescribed similar treatments (or potential comparators) before starting the new treatment.
 - Likely better represents the intended ADF patient population.

Objective

To evaluate the appropriateness of traditional new-user vs. prevalent new-user design for estimating post-market effectiveness of ADFs and examine patterns of ADF initiation.

Methods

Data Source & Inclusion

- Pharmaceutical claims data
- 2009-2018
- Large private insurer in North Carolina

Study Sample

- Patients aged 18-64
- Initiating an ADF opioid
- 6 months of continuous enrollment prior to first ADF claim

Measures

- Traditional new-user
 - Patients with no prescription opioid claims in a 6-month washout period prior to ADF initiation.
- Prevalent new-user
 - Patients with non-ADF opioid claims during the 6 months before ADF initiation, so long as they also had a 6-month washout period of no opioid claims prior to first non-ADF opioid claim

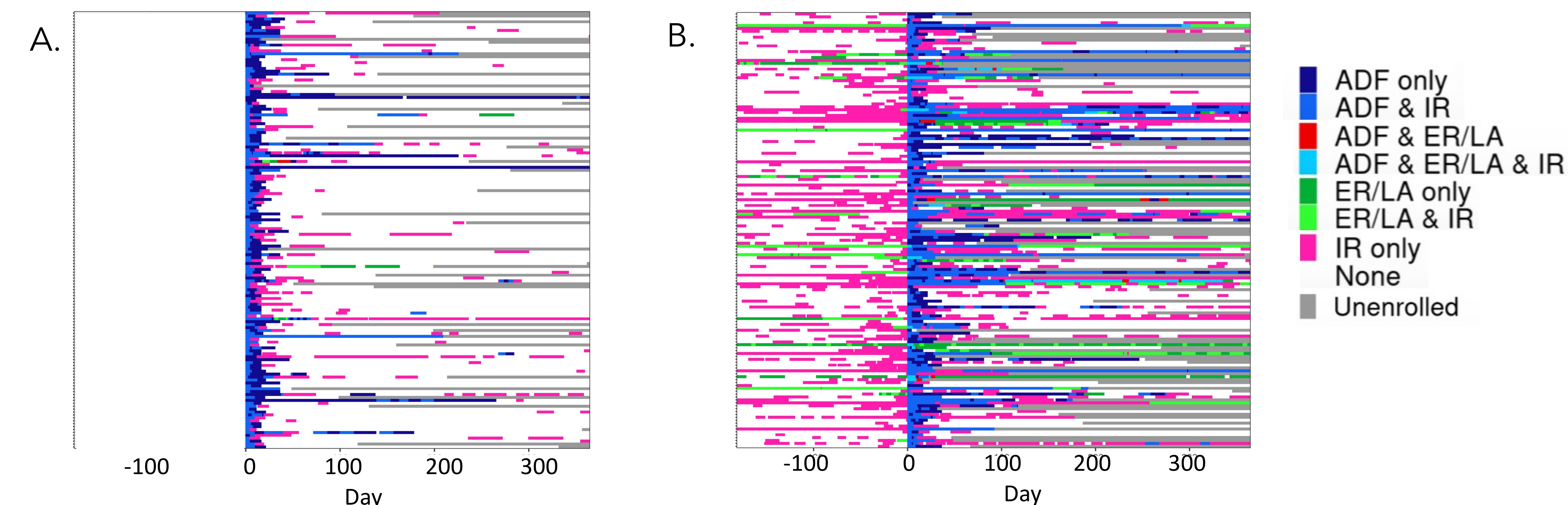
Analysis

- We compared sample sizes by study design and described ADF utilization patterns.

Results

- 8,841 eligible patients who initiated an ADF.
 - 2,332 (26%) were classified as traditional new-users
 - 6,509 (74%) were prevalent new-users with prior exposure to immediate-release (IR) or extended-release/long-acting (ER/LA) opioids
- Most traditional new-users started with an ADF and an immediate-release (IR) opioid concurrently (85%).
- Among prevalent new-users, common ADF initiation patterns were:
 - Adding an ADF to an IR opioid regimen (43%),
 - A direct switch from IR opioids to an ADF (15%),
 - Delayed switch from IR opioids to an ADF (14%)
- Prevalent new-users continued to receive opioid prescriptions after ADF initiation far more than traditional new-users (Figure 1).

Figure 1. Patterns of opioid use by (A) Traditional new-user, (B) Prevalent new-user status at ADF initiation



Conclusions

- Three-quarters of patients initiating ADFs had prior prescription opioid use and would be excluded in a traditional new-user study design.
- A prevalent new-user design would increase sample size and better capture clinically meaningful patients.
- These findings may apply to studies of other medications where prior exposure is a labeled prerequisite, such as higher dose ER opioids and second-line therapies.
- Future work will explore prevalent new user designs and consider nuances in ADF initiation such as immediate versus delayed switching by incorporating time-matching to address opioid tolerance.