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Background

- Abuse-deterrent formulations (ADFs) of extended-release (ER) opioids are designed to target the routes of abuse (crushing or dissolving) to reduce opioid abuse in the US
- Little is known about characteristics of patients who initiate ADF opioids, which is important to identify appropriate comparators to address confounding by indication

Objective

- To describe demographics and clinical characteristics of patients with prescribed ADF and non-ADF ER opioids

Methods

- Data source**
- Data A: A national data source from IBM MarketScan Commercial claims (2009-2018)
 - Data B: A large private insurance provider in North Carolina [USA] (2009-2018)
- Study Design:** Retrospective cohort study
- Identification of patients with ER opioids:** Patients (18-64 years-old) who initiated ER opioids (ADF and non-ADF ER opioids) with having ≥ 6 months of washout period prior to the ER initiation
- Traditional new user:** No opioid claims during 6 months prior to ER opioid initiation (i.e., washout period)
- Prevalent new user:** Allowed immediate-release (IR) opioid claims during the washout period and excluded the patients with no six-months eligibility prior to the first immediate-release (IR) opioid claim

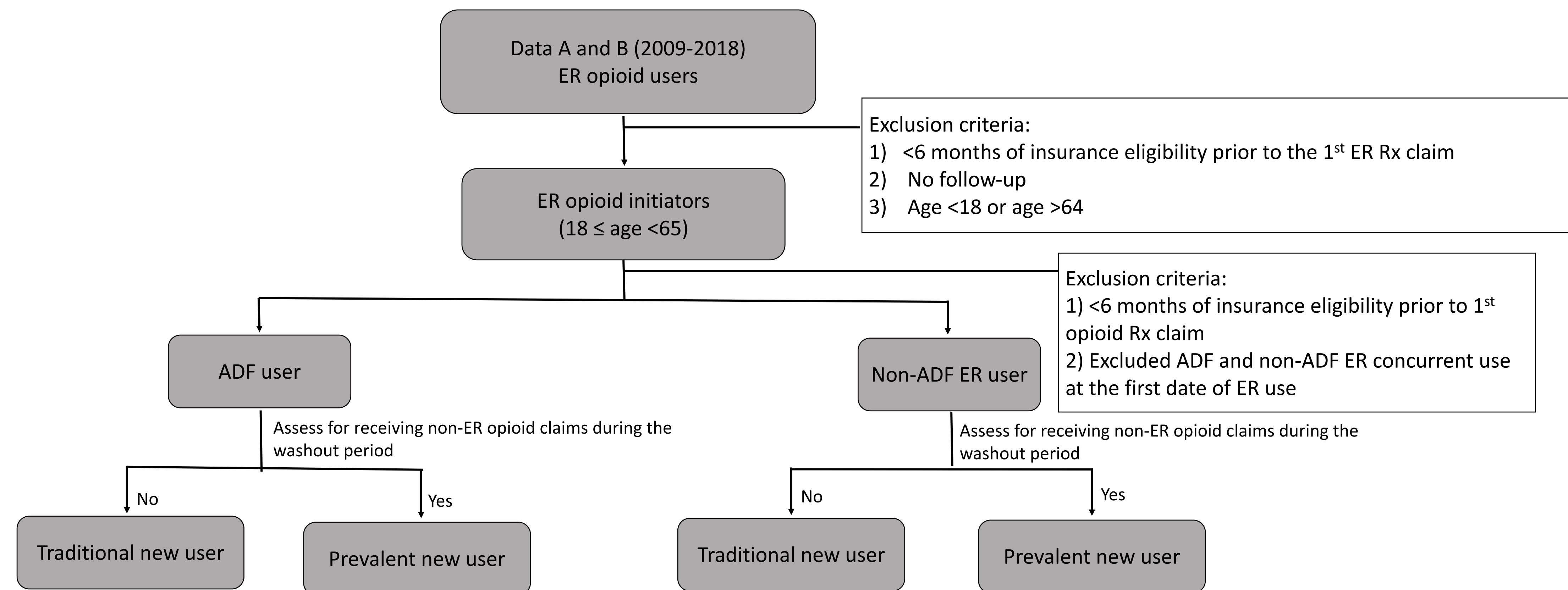


Figure 1. Flow diagram of study selection

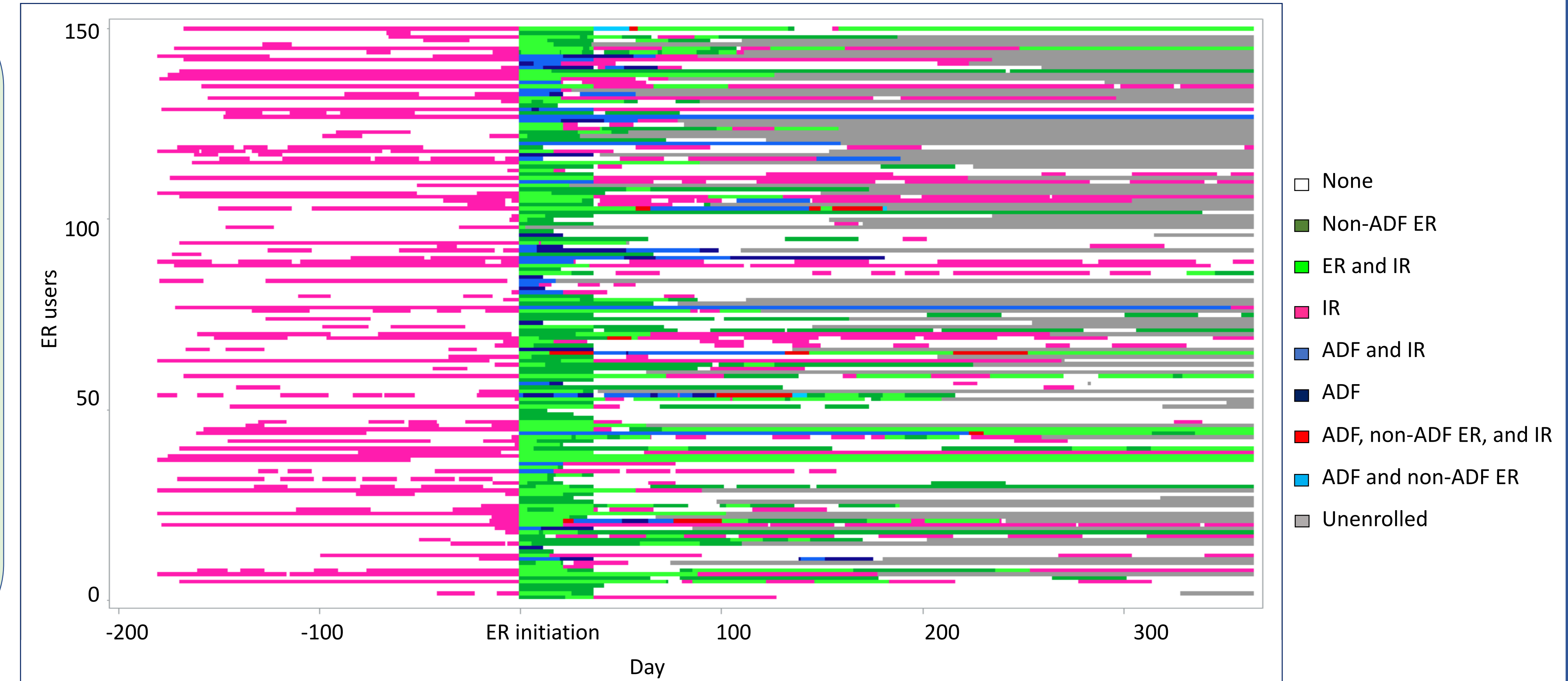
- Data analysis:** All data analyses were conducted using SAS 9.4
- Heatmap was generated to examine the patterns of opioid prescriptions in ER initiator (N=150 randomly selected from ER opioid initiator)
 - Patients characteristics: Demographics, medications (gabapentin, benzodiazepine, antidepressants, and IR opioids), pain-related symptoms (acute pain, arthritis pain, back/neck pain, chronic pain, and neuropathic pain), and cancer were measured during the washout period

Disclosure

- This study was supported by funding from the US Food and Drug Administration (FDA) under Broad Agency Announcement No. 17-00123.

Results

Figure 2. Patterns of opioid prescriptions in ER initiators (150 patients were randomly selected from ER initiators)



- Total number of ER opioid analgesics initiators
Data A: 303,014
Data B: 20,992
- Among patient initiating ER opioids, 33.4% and 34.3% initiated with ADF opioids from Data A and Data B, respectively
- Data A: 73.3% and 72.8% of ADF and non-ADF ER users were prevalent new users, respectively
- Mean age [standard deviation]: 49.0 [11.9] (Data A) and 48.4 [11.8] (Data B)
- Male (%): 49.6% (Data A) and 55.4% (Data B)

Table 1. Characteristics of patients with ADF and non-ADF ER opioid analgesics

	Data A: ER opioid initiators (N=303,014)		Data B: ER opioid initiators (N=20,992)	
	ADF users(N=101,319)	Non-ADF ER users (N=201,695)	ADF users(N=7,204)	Non-ADF ER users (N=13,788)
Age (mean (SD))	48.9 (12.2)	49.1 (11.7)	48.4 (11.8)	47.8 (11.3)
Male	53,347 (52.7)	96,867 (48.0)	3,993 (55.4)	6,950 (50.4)
Medications				
Gabapentin	9,559 (9.4)	24,909 (12.4)	1,115 (15.5)	2,356 (17.1)
Selective serotonin reuptake inhibitors	14,756 (14.6)	31,747 (15.7)	2,150 (29.8)	4,842 (35.1)
Benzodiazepine	20631 (20.4)	51,289 (25.4)	1,284 (17.8)	2,629 (19.1)
IR opioids	59,242 (58.5)	127,707 (63.3)	4,958 (68.8)	10,206 (74.0)
Diagnosis				
Cancer	27,601 (27.2)	67,795 (33.6)	1,359 (18.9)	2,924 (21.2)
Acute pain	56,904 (56.2)	83,889 (41.6)	4,087 (56.7)	5,726 (41.5)
Arthritis pain	35,813 (35.4)	40,709 (20.2)	2,622 (36.4)	3,130 (22.7)
Back/neck pain	33,634 (33.2)	82,919 (41.1)	2,848 (39.5)	7,061 (51.2)
Chronic pain	84,820 (83.7)	14,9854 (74.3)	6,447 (89.5)	11,760 (85.3)
Neuropathic pain	16,958 (16.7)	42,433 (21.0)	1,352 (18.8)	3,566 (25.9)

(All results presented are N (%) unless otherwise noted)

All results showed significant differences (p-value <0.01) between patients with ADF and non-ADF ER opioids

Conclusions

- Both data sources revealed significant differences in the selected characteristics between patients with ADF and non-ADF ER opioids
- The prevalence of several types of pain, including acute pain, arthritis pain, and chronic pain, were higher among patients with initiating ADF opioids than in patients with non-ADF ER opioids
- The implications for research design include identifying appropriate comparator groups when examining ADF opioid use related outcomes