Effect of TIRF-REMS on Transmucosal Fentanyl Prescribing

A Time Series Analysis

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Our Research Questions

- 1. Did TIRF-REMS implementation decrease overall TIRF prescribing?
- 2. Did TIRF-REMS decrease off-label prescribing?
- 3. Did TIRF-REMS decrease prescribing to patients not tolerant to other opioids?

Secondary questions:

 Differences by brand? By age group? # of prescribers vs # prescriptions. Did TIRF-REMS affect patients with/without cancer differently?

Methods

- Data source: Medicare Part D prescription claims
- Inclusion: all Part D prescriptions claims for opioids 2010-2014
- Exclusions
 - Abstral, Lazanda, Onsolis (already had a REMS)*
 - IV/injectable drugs

*only excluded for the prescribing rate analysis; are included in the opioid tolerance guideline adherence analysis as analysis would be invalid if some Rx excluded

Methods

- Defining cancer
 - No cancer diagnosis during prescription claim year
 - Sensitivity analysis: no cancer diagnosis during the entire study period
- Defining opioid tolerance
 - As defined in TIRF-REMS educational materials*
 - Lookback using pt's opioid prescriptions for 7/14/30/60/90 day periods
 - "non tolerant" = below tolerance threshold in ALL lookback periods

*Patients whose daily prescribed average was less than 60 MME in all of the look-back periods, and whose average daily dose of oxycodone or hydromorphone were less than 30mg and 8mg, respectively, were considered non-opioid tolerant.

Methods

- Analysis:
 - Descriptive
 - Interrupted time series analysis
- Adjustment
 - Used all-opioid prescriptions as a control
 - Sensitivity analyses excluding buprenorhphine, cold prep meds
 - Time series analyses adjusted for autocorrelation, seasonal variation, days in month

Results – descriptive

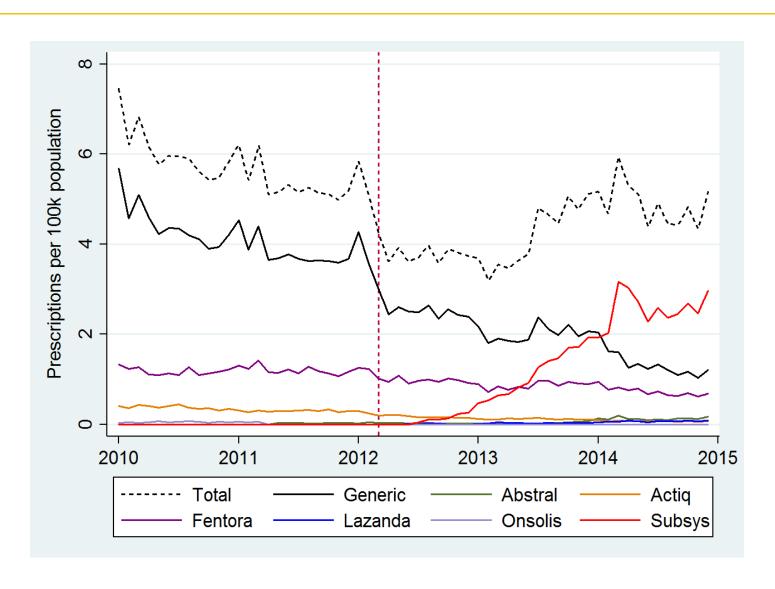
TIRF

- 99,601 prescription claims
- 8,619 clinicians
- 10,472 patients
- Average age: 56 years
- 79% of prescriptions for pts <65 yo
- 72% of prescriptions for patients without cancer

Opioids

- 372,023,319 prescription claims
- 2,001,523 clinicians
- 27,409,105 patients

Results – TIRF prescription claims 2010-2014, by brand



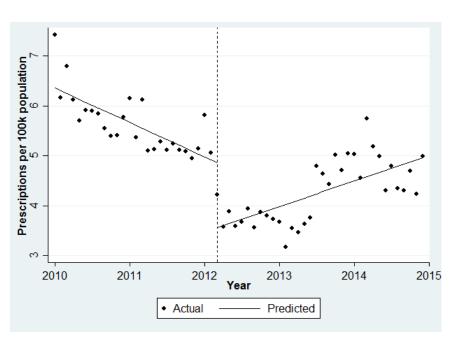
Results – TIRF & Opioid prescription claims 2010-2014

TIRF

• **Pre trend:** 1% decrease

Level: 27% decrease

Post trend: 2% monthly increase



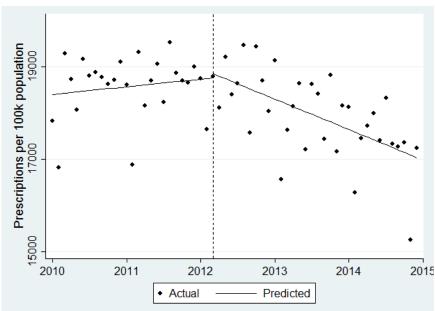
All-opioids

• Pre trend: no sig trend

• Level: no change

• **Post trend:** 0.36% monthly

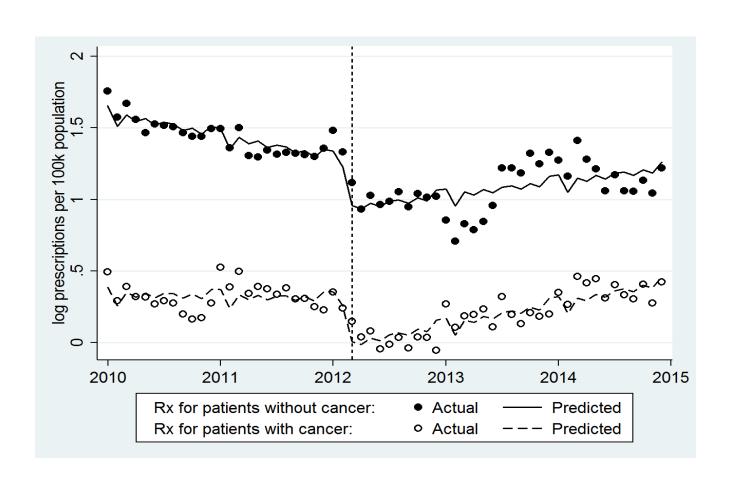
decrease



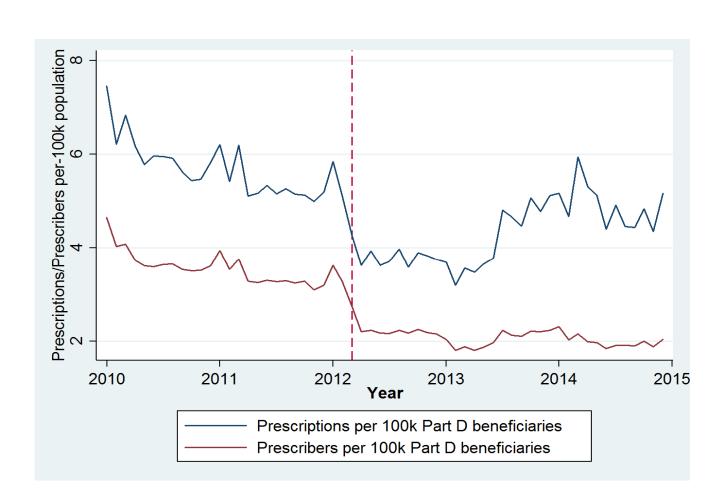
Results – TIRF & Opioid prescription claims 2010-2014

- No sig differences between over/under age 65 as a result of the intervention
- No sig differences between brands as a result of the intervention
- No sig differences when buprenorphine is excluded

Results – Overall rx to patients with/without cancer



Prescriptions and Prescribers



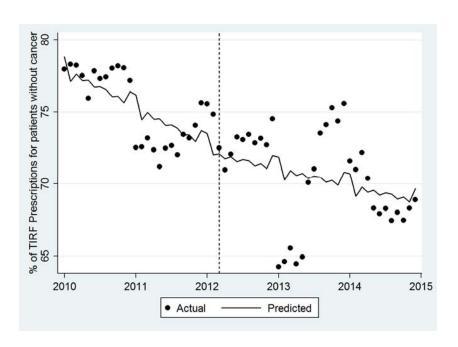
Results – Prescriptions to patients without cancer

Cancer in same year

Pre trend: 0.29% decrease

Level: no change

Post trend: no sig trend



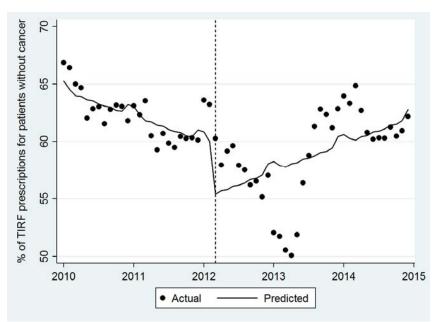
Cancer during 5 year study period

Pre trend: 0.29% decrease

• Level: 7.2% decrease

• Post trend: 0.63% monthly

increase



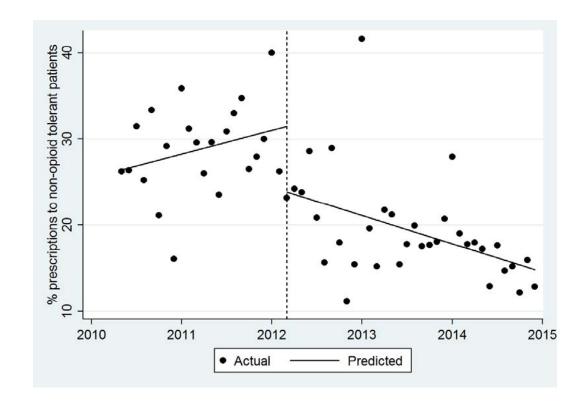
Results – Prescriptions to patients not opioid tolerant

• **Pre trend:** no sig trend

• **Level:** 23% decrease

• **Post trend:** 2% monthly

decreases



Limitations

- Only Medicare Part D beneficiaries
- No out of pocket prescriptions data
- Formulary changes a potential confounder, but are generally prohibited after January

Conclusions

- REMS implementation resulted in a temporary decline in TIRF prescriptions for Part D beneficiaries.
- Most TIRF prescriptions are for patients without cancer
- REMS implementation may have resulted in a temporary decrease in prescribing to patients without cancer
- REMS implementation resulted in a lasting decrease in TIRF prescribing to patients not yet tolerant to other opioids

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