Federal Mandates and Trends in Acetaminophen-Opioid Combination Product Supratherapeutic Ingestions at a Large Urban Safety-Net Hospital From 2011-2020

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Introduction

- During the opioid epidemic, people misusing acetaminophen-opioid combination products resulted in supratherapeutic acetaminophen ingestions and cases of hepatotoxicity
- In 2014, the FDA limited the amount of acetaminophen in combination products to 325 mg, and the DEA changed hydrocodone/acetaminophen from schedule III to schedule III.
- This study highlights the association of federal mandates with changes in acetaminophen-opioid supratherapeutic ingestions at a large Texas county hospital from 2011-2020.

Methods

- From our electronic health record, we identified emergency department (ED) encounters between 1/1/2011-12/31/2020 of patients ≥ 18 years old with a detectable acetaminophen concentration (> 10 mcg/mL).
- Using a standardized abstraction form, trained chart abstractors manually reviewed these charts to identify encounters involving acetaminophen-opioid supratherapeutic ingestions and extracted demographics, laboratory values, product(s) patient reported ingesting, intent, amount, and disposition.
- We defined supratherapeutic ingestions as >10 mcg/mL serum acetaminophen concentration with patient report of taking more than a therapeutic dose.

Figure 1

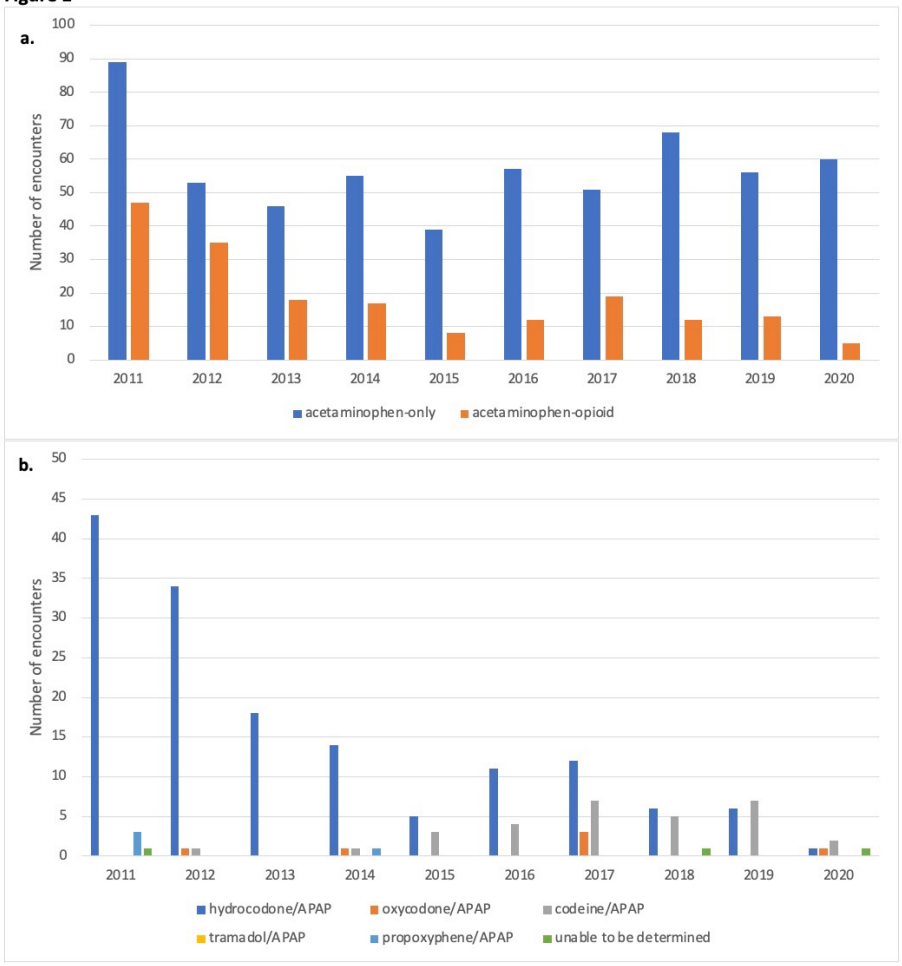

Figure 1: Trends in acetaminophen and acetaminophen-opioid ingestions per year.
a. Number of encounters per year of acetaminophen-only and acetaminophen-opioid supratherapeutic ingestions.
b. b. Number of encounters per year of each acetaminophen-opioid combination product.

Results

- Of 760 encounters, 186 (25%) involved APAP-opioid combination products. Most patients were Caucasian (83%), non-Hispanic (76%), and female (54%).
- The number of supratherapeutic APAP-opioid ingestions decreased over the 10-year period (Fig.1a). Most ingestions were acute (64%) and with intent at self-harm (57%). Most patients were discharged from the Emergency Department (37%) and not treated with N-acetylcysteine (65%). Five developed acute liver failure, with no fatalities.
- The most used combination product was hydrocodone/APAP (80%). A downtrend in hydrocodone/APAP accompanied a relative increase in codeine/APAP ingestions from 2015 onwards (Fig.1b).

Discussion

- Our study shows a decline in acetaminophen-opioid combination product supratherapeutic ingestions at our institution.
- As hydrocodone/acetaminophen supratherapeutic ingestions declined, codeine-acetaminophen, which remained schedule III, may have replaced some hydrocodone-acetaminophen prescriptions.
- This experience at one large safety net hospital suggests a beneficial impact of the FDA ruling in reducing likely unintentional acetaminophen supratherapeutic ingestions, carrying a risk of hepatotoxicity, in the setting of intentional opioid ingestions.