

Study Protocol

Montoy JCC, Coralic Z, Herring AA, Clattenburg EJ, Raven MC. Association of default electronic health record settings on health care professional patterns of opioid prescribing in emergency departments. *JAMA Intern Med.* Published online January 21, 2020. doi:10.1001/jamainternmed.2019.6544

Study protocol submitted to the University of California, San Francisco Institutional Review Board.

Title: Effect of defaults on opioid prescribing practices

Design: We will undertake a prospective cohort study of patients seen at the University of California, San Francisco's (UCSF) Emergency Department. The electronic medical record (EMR) will be modified such that outpatient prescriptions for opioids will be pre-populated with new, lower values than the current default. These new defaults will be changed according to the study schedule then returned to their original values. The EMR will be used to capture demographic and health variables, including procedures performed, diagnoses, and prescriptions. Quantities of opioid-containing pills per prescription will be compared across treatment groups and to the pre- and post-intervention periods.

All patients discharged from the ED are potentially eligible for the intervention. Clinicians will decide without guidance from the study for whom to prescribe opioids at time of discharge; likewise, the quantity prescribed is at the discretion of the provider and without any guidance from the study.

The dispense quantity default for ED discharge opioid prescriptions will be modified throughout the study period. The values will be changed every four weeks over a total of six months according to the study schedule, which was developed using block randomization within each opioid-containing pill. A dispense quantity of 0 provides a hard stop in the EMR and forces the provider to enter a quantity before electronically signing the prescription.

Procedures / Methods: The dispense quantity default for ED discharge opioid prescriptions will be modified throughout the study period. The values will be changed every four weeks over a total of six months according to the study schedule, which was developed using block randomization within each opioid-containing pill. A dispense quantity of 0 provides a hard stop in the EMR and forces the provider to enter a quantity before electronically signing the prescription.

Statistical Methods: The primary outcome is the dispense quantity of opioids prescribed at the time of ED discharge. We will perform an ordinary least squares multivariate analysis to test the relationship between the default number of tablets and actual number prescribed, controlling for patient characteristics, ED provider, diagnoses, and day of the week. We will conduct this analysis for all patients

prescribed opioids, regardless of previous opioid use and medical condition. These analyses will be conducted for all opioids together and separately for each medication. We will base our main analysis on the authorizing provider (the provider who authorizes the patient's chart and prescription medications – normally the attending physician), as this is the provider ultimately responsible for the prescription.

Secondary outcomes include the distribution of opioid quantities prescribed and the proportion of patients who return to the ED within seven-days of their initial visit. We will report descriptive characteristics (median, interquartile range) for each type of opioid prescribed under each treatment and during the pre- and post-intervention periods. We will also undertake secondary analysis to categorize mid-level providers (i.e., nurse practitioners and physician assistants) as if they were authorizing providers, as in practice these providers practice nearly-independently from the attending who authorizes their work. Likewise, we will investigate provider behavior at the resident level, and account for their year of training. Revisits can be used a proxy for inadequate pain control and will thus be reported in order to guide future work investigating unintended consequences of lower quantities of opioids prescribed.