

Nudging Primary Care Providers toward Guideline-Recommended  
Opioid Prescribing through Easier and More Convenient EHR  
Information Design

**R33 Clinical Trial**

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## CT. Gov: Statistical Analysis Plan

**Study title:** Nudging Primary Care Providers toward Guideline-Recommended Opioid Prescribing through Easier and More Convenient EHR Information Design

To assess the OneSheet effects on guideline-concordant care, we collected data from participating clinicians' visits with patients meeting several criteria described below. The criteria were: 1) 18+ years old; 2) no cancer diagnosis in the prior 3 years; 3) meet the following indications of chronic pain over the most recent 24 months:

- a. 3+ unique\* instances of a qualifying pain diagnosis (either billed diagnosis or problem list) OR
- b. 3+ unique\* prescriptions for one or more of the following drugs: an opioid (“opioid agonist,” “opioid partial agonist,” “opioid combinations”), Tramadol, Nortriptyline, Amitriptyline, Gabapentin, Pregabalin, Duloxetine, desipramine, milnacipran, tapentadol OR
- c. 2 unique\* instances of a qualifying pain diagnosis AND 2+ unique\* pain medication prescriptions containing one or more of the drugs listed in b.

\*“unique”, for Diagnoses and medications was defined as separated by at least 30 days from any previous qualifying diagnosis or prescription.

Because chronic pain treatment is often discussed during visits not explicitly identified as related to chronic pain, any visit that a qualifying patient has with a participating primary care clinician was considered as a qualifying visit for the trial. The data for qualifying visits was collected one year before OneSheet access was granted (October/November 2019) to May 2022 (18 months of the trial period).

**Outcomes:** We constructed six visit-level binary outcomes that could be measured with electronic health record (EHR) data and reflected recommendations in the 2016 CDC opioid prescribing guideline: 1) recording pain-related goals in the last 90 days; 2) recording pain and function via the Pain, Enjoyment, and General (PEG) assessment in the last 90 days; 3) checking the prescription drug monitoring program (PDMP) in the last 90 days; 4) assessing UDS results in the last calendar year; 5) ordering medications for opioid use disorder (MOUD) within seven days of the visit; and 6) ordering Naloxone within seven days of the visit.

Each outcome was set to 1 if the patient met the lookback criteria outlined above (e.g., 90 days for pain-related goals, PEG, and PDMP; 1 year for UDS, seven days for MOUD and Naloxone), or if the provider completed a given task one week following the visit (a 7-day grace period). For PDMP review, there was no one-week grace period because PDMP review is recommended by the CDC (and mandated by many states) to occur at the time of opioid prescribing.

The outcomes of pain-related pain and function goals and PEG assessments were evaluated for all patients with chronic pain, while the CDC recommendations for PDMP checking, UDS review, MOUD ordering, and Naloxone ordering only apply to patients on long-term opioid therapy (LTOT). We identified visits for patients on LTOT as those involving an opioid analgesic prescription lasting at least 28 days, per the Agency for Healthcare Research and Quality's CDS Connect recommendation for assessing opioid therapy (Agency for Healthcare Research and Quality, 2018).

As an example outcome, if a patient on LTOT had not had a UDS result in the last calendar year, but the provider ordered a UDS on the day of the visit, the outcome would be set to 1 (guideline-concordant). Similarly, if the patient had a UDS result in the last calendar year, the outcome would be set to 1 because at the time of the visit, the clinician was concordant with the CDC guideline recommendations for UDS review. If both a) a UDS had not been completed in the last year and b) the clinician did not order a UDS within one week of the visit, the outcome would be set to 0 (non-concordant).

**Statistical Analysis:** We used descriptive statistics to compare the demographic characteristics of clinicians assigned to the intervention group versus the control. We computed our outcomes at the patient-visit level for visits by qualifying patients with study providers for the 12 months before the OneSheet went live (the baseline period) and 18 months following OneSheet go-live. We excluded patients from the sample who had visits during the study period with both treatment and control clinicians to ensure that outcomes were not compared across trial arms for the same patient. To estimate the effect of OneSheet on our outcomes, we used a multi-level linear probability model including patient demographics, clinician random effects, and indicator variables for a) site; b) treatment and control clinicians; and c) pre-/post-OneSheet go-live. We included an interaction term for treatment and post-OneSheet go-live, the coefficient for which estimates the causal effect of OneSheet on our outcomes of interest. Statistical tests were 2-tailed, and p-values < 0.05 were considered statistically significant. Data analyses were performed from November 2022 to September 2023 using *tidyverse*, *lubridate*, *fixest*, and *lme4* R packages in RStudio (Bates et al., 2015; Berge, 2018; Grolemund et al., 2011; Wickman, 2017).

## References:

Agency for Healthcare Research and Quality, 2018. Recommendation 7: Opioid therapy risk assessment. Retrieved March 1, 2024, from <https://cds.ahrq.gov/cdsconnect/artifact/recommendation-7-opioid-therapy-risk-assessment>

Wickham H. The tidyverse. R package ver 1.1.1 [Internet]. 2017; Available from: [https://slides.nyhackr.org/presentations/The-Tidyverse\\_Hadley-Wickham.pdf](https://slides.nyhackr.org/presentations/The-Tidyverse_Hadley-Wickham.pdf)

Grolemund G, Wickham H. Dates and Times Made Easy with lubridate [Internet]. Vol. 40, Journal of Statistical Software. 2011. p. 1–25. Available from: <https://www.jstatsoft.org/v40/i03/>

Bergé L (2018). "Efficient estimation of maximum likelihood models with multiple fixed-effects: the R package FENmlm." CREA Discussion Papers.

Bates D, Mächler M, Bolker B, Walker S (2015). "Fitting Linear Mixed-Effects Models Using lme4." *Journal of Statistical Software*, 67(1), 1–48. doi:10.18637/jss.v067.i01.