Quasi-Randomized Evaluation of the UCLA Next Day Clinic (NDC)

NCT ID: 24-000913

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Statistical analysis. For the primary analysis, we will compare DAOH between eligible patients in the treatment and control arms as-randomized using an instrumental variable (IV) analysis, with encouragement to refer (even/odd birth date) as the binary instrumental variable and treatment setting (NDC v. inpatient) as the exposure. Analysis will utilize a two-stage least squares approach. In the first stage, we will regress treatment setting on the instrument and all covariates. In the second stage, we will use predicted values of treatment setting to estimate differences in DAOH between arms, adjusting for the same covariates. This procedure will be repeated for the secondary outcomes of global health-related quality of life, patient experience, and the financial analysis. Covariates will include: diagnosis, comorbidity score, age, sex, insurance type, zip code, and race/ ethnicity. We will use heteroskedasticity-robust standard errors. We will evaluate the NDC's impact on health disparities by performing subgroup analyses across racial/ethnic, sex, age, and socioeconomic lines, ensuring outcomes do not differ and that all groups have equitable access to the NDC.

We will perform the following three secondary analyses:

1) Subset analysis to define a specific subgroup of patients based on the probability of being referred to the NDC. Specifically, we will use a logistic regression based on patient labs, vitals, characteristics, and comorbidities to estimate the probability of referral to NDC, and use a median split to define a threshold. We will then apply this threshold to the control group, and repeat the primary analysis of treatment v. control group only including patients above the pre-specified threshold.

2) Per-protocol analysis of eligible patients repeating the primary analysis methodology but only among patients who adhered to the assignment and treatment protocol.

3) Difference-in-differences (DiD) analysis using UCLA Santa Monica Medical Center as a control. We will compare 30-day DAOH among the eligible cohort at Ronald Reagan UCLA Medical Center to a matched eligible cohort at UCLA Santa Monica Medical Center (cohorts will be constructed using the same logic and rules). The dependent variable will be 30-day DAOH, the independent variables will be hospital location, intervention period, location x intervention interaction, and the above specified covariates.

We will also perform a formal cost-effectiveness analysis (CEA) using standard CEA methodologies to measure the incremental cost-effectiveness ratio (ICER).

For the patient-reported secondary outcomes, we will perform a complete case analysis as the primary analysis, but as a sensitivity analysis we will estimate the probability of responding to the survey using a logistic regression model informed by baseline patient characteristics, and do an inverse probability-weighted analysis to correct for non-response.

Sample size and power. Based on historical UCLA data, we expect 850 patients to be randomized in a 12-month period. Assuming similar numbers during this trial, a 1:1 randomization by birthdate would trigger the encouragement 425 times. On an as-randomized basis, two groups of 425 patients would provide 80% power to detect an effect size as small as 0.192 standard deviations (SDs) on our primary outcome, DAOH, assuming a two-sample t-test and a two-sided 0.05 significance level. If ED physicians and patients accept the 425

encouragements 50% of the time in the treatment group and there is 10% contamination in the control group (i.e., 10% of eligible patients randomized to control get referred to the NDC), then the delta effect of the instrument on referral will be 40%. Thus, the IV parameter will be 0.192 / 0.40 = 0.48 SDs. In the historical sample, mean DAOH was 26.8 with a SD of 2.2 days. We will therefore have 80% power to detect an IV effect of referral to the NDC of 2.2 * 0.48 = 1.1 days.

In this quality improvement project funded by the health system, the health system may terminate the study early at their own discretion. Should this happen, analysis will commence with the sample size enrolled at the time of termination. If this happens we will conduct a conditional power analysis to evaluate how much power we would have based on the sample size at the time of trial termination. Similarly, we will also determine power conditional on actual rates of referral to the NDC (e.g., if referral rates are below the above specified 50%, or if contamination rates are above the above specified 10%).

Additional eligibility criteria specifications:

ALL THREE CRITERION MUST BE MET FOR PATIENT TO BE NDC-ELIGIBLE (in addition to the inclusion/exclusion criteria in the NCT documentation).

Criterion #1: Patient has even birth date (e.g., December 2nd, 4th, 6th).

Criterion #2: All of the following clinical criteria are met (using most recent labs/vitals):

- Sodium between 129-150
- Potassium between 2.9-5.9
- WBC ≤ 16k
- O2 sat ≥ 89%
- Heart rate between 50-110
- Respiratory rate < 30
- Systolic blood pressure between 90-190

Criterion #3: Plan to Admit order placed with one of the following ICD-10 codes:

Cellulitis

- ICD-10 wildcards
    - L01, L02, L03, L04, L05, L98
- ICD-10 exact matches
    - L00, L08.89, L08.9, L30.3, H60.10, K12.2, N73.0, N73.1, N73.2, T14.8XXA, I96
- SmartSets to suggest to ED providers
    - NDC Cellulitis
    - NDC Diabetic foot/osteomyelitis

Diabetic foot infection

- ICD-10 wildcards
    - E10.62, E11.62
- ICD-10 exact matches

    - E10.610, E11.610
- SmartSets to suggest to ED providers
    - NDC Diabetic foot/osteomyelitis

Osteomyelitis

- ICD-10 wildcards
    - M46.2, M46.3, M46.4, M46.5
- ICD-10 exact matches
    - M46.1
- SmartSets to suggest to ED providers
    - NDC Cellulitis
    - NDC Diabetic foot/osteomyelitis

Syncope

- ICD-10 wildcards
    - T67.1
- ICD-10 exact matches
    - R55, R42, R05.4, G90.01
- SmartSets to suggest to ED providers
    - NDC Syncope

AKI

- ICD-10 wildcards
    - N17, S37.00
- ICD-10 exact matches
    - N19
- SmartSets to suggest to ED providers
    - NDC AKI

CKD

- ICD-10 wildcards
    - N18.3
- ICD-10 exact matches
    - N18.1, N18.2, N18.4, N18.9
- SmartSets to suggest to ED providers
    - NDC AKI

CHF

- ICD-10 wildcards
    - I50, I42, I13, I11, E87.7
- ICD-10 exact matches
    - I09.81, I25.5

- SmartSets to suggest to ED providers
    - NDC CHF

Pyelonephritis

- ICD-10 wildcards
    - N10
- ICD-10 exact matches
    - A02.25
- SmartSets to suggest to ED providers
    - NDC Pyelonephritis/UTI

Acute cystitis

- ICD-10 wildcards
    - N30
- ICD-10 exact matches
    - N34.1, N34.2, N34.3, R30.0, R30.9, R82.71, R82.81
- SmartSets to suggest to ED providers
    - NDC Pyelonephritis/UTI

Hematuria

- ICD-10 wildcards
    - R31
- ICD-10 exact matches
    - R82.3
- SmartSets to suggest to ED providers
    - NDC Pyelonephritis/UTI

Pneumonia

- ICD-10 wildcards
    - J12, J14, J15, J16, J18, J22
- ICD-10 exact matches
    - A01.03, A02.22, A21.2, A22.1, A31.0, A37.11, A37.91, A41.0, A43.0, A48.1, A54.84, A70
- SmartSets to suggest to ED providers
    - NDC Pneumonia

Dyspnea

- ICD-10 wildcards
    - R06
- ICD-10 exact matches
    - None 👎
- SmartSets to suggest to ED

    - NDC Pneumonia
    - NDC CHF

Obstructive lung disease

- ICD-10 wildcards
    - J20, J40, J41, J42, J43, J47, J98
- ICD-10 exact matches
    - J44.0, J44.1, J44.9
- SmartSets to suggest to ED
    - NDC Pneumonia
    - NDC CHF

Dehydration

- ICD-10 wildcards
    - E86
- ICD-10 exact matches
    - None!
- SmartSets to suggest to ED providers
    - NDC AKI

Urinary retention

- ICD-10 wildcards
    - R33, N40
- ICD-10 exact matches
    - None!
- SmartSets to suggest to ED providers
    - NDC AKI