Randomized-controlled trial to assess whether feedback on a new stewardship metric can improve antibiotic-prescribing for acute respiratory tract infections

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BACKGROUND

Urgent care clinics are a rapidly expanding provider of same-day outpatient care in the United States because they offer easier access and lower out-of-pocket costs than Emergency Departments. Antibiotics are frequently prescribed in Urgent Care settings, and a large proportion of these antibiotics are unnecessary. Unnecessary antibiotics provide no clinical benefit to the patient but increase the risk of an antibiotic-related adverse event and reinforce patients' antibiotic-seeking behavior.

Within the University of Iowa Hospitals and Clinics (UIHC) system, antibiotics were prescribed to 30% of all visits to the Urgent and QuickCare clinics during 2018-2022. One out of every two antibiotics prescribed in these settings was for a respiratory tract illness.

Our team has used an established HEDIS (Healthcare Effectiveness Data and Information Set) metric to evaluate clinicians on their antibiotic use for respiratory tract diagnoses (RTDs). This RTD metric excludes visits that are more complicated, such as repeat visits for the same complaint, visits with concomitant non-respiratory infections, and visits for patients with advanced comorbidities, such as immunosuppression. During 2018-2022, the mean frequency of antibiotic-prescribing at the clinician level for RTDs was 37.9% (standard deviation 5.4%) within the UIHC Urgent/QuickCare system. We estimate that the optimal antibiotic-prescribing frequency for RTDs should be around 28%, or roughly 25% lower than it is right now.

This protocol describes our plan to evaluate the effect of giving clinicians individualized feedback on the RTD metric. The proposed project will involve 3 Urgent Care and 4 QuickCare clinics within the UIHC system. If additional clinics come on-line during the trial, clinicians at those sites will be invited to join. Currently, clinics are staffed by approximately 40 clinicians and provide 80,000 patient-visits annually.

Objectives: To evaluate whether providing individualized feedback to clinicians on the RTD metric can safely reduce antibiotic use for qualifying respiratory tract visits across Urgent and QuickCare settings within the UIHC system.

METHODS

Trial design:

- We will perform a matched-pair randomized controlled trial to assess the effectiveness of giving individualized feedback to clinicians on the RTD metric.
- Initially we will balance allocation between the two study arms in terms of two factors:
    - Only providers who have had a qualifying RTD visit in the past 6 months will be included in this initial randomization.
    - Each provider's frequency of antibiotic-prescribing for RTD visits during the year prior to the feedback intervention starting;
    - Each provider's number of RTD visits over the year prior to the feedback intervention starting.
- Providers newly hired to UIHC after study start will also be randomized. For new hires, we anticipate 1-year historical prescribing information will not be available. We will thus randomize pairs of providers in 1:1 ratio to the two study arms.

Participants:

We will seek to enroll all active clinicians in Urgent and QuickCare settings who do not opt-out of the trial.

Inclusion criteria: Active clinician in UIHC's Urgent and QuickCare system

Exclusion criteria: None

Method of recruitment: All Urgent Care and QuickCare clinicians will be notified during both a monthly staff meeting and by e-mail of the planned randomization process outlined below approximately two weeks prior to the randomization happening. Clinicians will be given two weeks to opt-out of the study by e-mail. If clinicians do not opt-out, they will be enrolled in the randomization process. Once the intervention starts, clinic leadership will notify the study team about any new hires on a monthly basis. New hires will notified about the study by e-mail during the month prior to the next feedback point; these providers will be given two weeks to opt-out before randomization occurs.

Interventions:

Baseline activities:

At baseline, UIHC's antibiotic stewardship team has implemented antibiotic-prescribing order sets and a monthly feedback process for all Urgent/QuickCare clinicians. This feedback process involves a never-event metric, which quantifies the number of times a clinician prescribes an antibiotic for a respiratory condition that is exclusively viral in etiology. Feedback on this never-event metric will continue during the trial in both the control and experimental arms.

Intervention activities:

After the randomization is performed by the biostatistician, all clinicians who did not opt-out will be notified by e-mail of their assignment to either the control or experimental arm.

From that point forward, an e-mail will be sent to the clinicians in the experimental arm every two months describing their performance on the RTD metric. If a clinician had more than 20 qualifying RTD visits within the prior two months, his/her performance will be compared to peers, both in words and graphically. The e-mail will also direct clinicians to visit a dashboard in the electronic medical record where they can review the patient visits captured by the metric in greater depth.

Any clinician assigned to the control arm will not receive these e-mails but will continue to be informed of their never-event metric, as outlined above.

Antibiotic-prescribing data for both experimental and control clinicians will be collected both retrospectively (beginning in January 2022) and prospectively through the end of the 18-month trial. Data on all clinicians will be identifiable but will be kept strictly confidential.

Outcomes:

We will use the RE-AIM framework to assess our pilot trial, as outlined on page 5.

Primary outcome: The primary outcome of effectiveness will be the frequency at which antibiotics are prescribed for qualifying RTD visits.

Secondary outcomes: To ensure that this intervention is safe, we will measure the following outcomes: antibiotic prescriptions written after but within 30-days of the index clinic visit, 30-day return visits to an Urgent/QuickCare clinic or the Emergency Department, 30-day hospital admission rate, and 30-day *C. difficile* testing and infection rate. We will also track the proportion of monthly Urgent/QuickCare visits within tiers 1, 2 and 3 to ensure that diagnostic shifting does not occur over time. Finally, we will track total antibiotic prescriptions per 1,000 patient visits. Because clinicians may stop using RTD-related diagnostic codes once they know they are being tracked on this metric, quantifying total antibiotic use will provide another way for us to determine whether changes in antibiotic-prescribing have occurred.

Process measures and qualitative outcomes: During the trial, we will track dashboard visits. A qualitative researcher (K. Dukes) will design a post-trial electronic survey or semi-structured interview guide that we will use to evaluate clinician perceptions of the RTD metric and the dashboard after this pilot study ends.

Sample Size: Our power calculation was based on the following assumptions: 25,000 RTD visits per year across 38 clinicians, a baseline antibiotic prescription rate of 35%, and 18-months of data for the baseline and intervention periods. Using an interrupted time series model with~~in~~ indicators for implementation, time, and the interaction of the two and a type I error rate of 5%, we calculated more than 90% power to detect a 4% absolute difference in antibiotic prescribing between the experimental and control arms.

Blinding: None

Unit of Analysis: Each participating clinician

Statistical Methods: After the 18-month intervention period, we will perform an intention to treat analysis. We will use logistic regression to perform a stratified interrupted time series (ITS) analysis to assess the level and slope change for antibiotic use between the intervention and baseline periods within the experimental and control arms. We will use a general linear mixed model with log link and Poisson distribution accounting for clinician clustering to assess differences between study arms before and after implementation of the intervention. This analysis will be performed in two ways: 1) all providers randomized, and 2) only the initial set of providers randomized. We will perform similar statistical analyses for each secondary outcome.

Applying the RE-AIM implementation framework to our evaluation of this pilot study's findings

Dimension	Definition[1]	Measurement
Reach	The absolute number, proportion and representativeness of individuals who are willing to participate in a given initiative or program, and reasons why they do or do not participate. Who actually participates or is exposed to the initiative?	Record the # of clinicians who choose not to opt-out of the trial. Monitor the number of clinicians in the experimental arm who acknowledge receipt of their feedback e-mail.
Effectiveness	The effect of an intervention on important individual outcomes, such as clinical events, quality of life, and economic outcomes	See primary and secondary outcomes, as listed above
Adoption	The absolute number, proportion and representativeness of settings and agents who are willing to start a program and why they are willing to start it. Where is the program applied and who applied it?	Describe the location and complexity of the clinic sites. Explain why clinic leadership wanted to participate in this project.
Implementation	Fidelity to the key elements of an evidence-base practice, including consistency of delivery as intended and the time and cost of the program. How consistently was the program delivered? How was it adapted to each setting? How much did it cost? Why did it achieve the observed result?	Measure fidelity by tracking the number of audits performed and feedback reports distributed. Measure acceptability with a post-intervention survey/interview of frontline prescribers.
Maintenance	The extent to which a program or policy becomes institutionalized or part of the routine organizational practices and policies. *How long are the results of the program or policy sustained?*	Assess whether clinic leadership wants to maintain the dashboard and, if so, how it is sustained.

1. All definitions are taken from https://www.re-aim.org