

# Reducing Care Overuse in Older Patients Using Professional Norms and Accountability

## A Cluster Randomized Controlled Trial

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**Background:** Effective strategies are needed to curtail overuse that may lead to harm.

**Objective:** To evaluate the effects of clinician decision support redirecting attention to harms and engaging social and reputational concerns on overuse in older primary care patients.

**Design:** 18-month, single-blind, pragmatic, cluster randomized trial, constrained randomization. (ClinicalTrials.gov: NCT04289753)

**Setting:** 60 primary care internal medicine, family medicine and geriatrics practices within a health system from 1 September 2020 to 28 February 2022.

**Participants:** 371 primary care clinicians and their older adult patients from participating practices.

**Intervention:** Behavioral science-informed, point-of-care, clinical decision support tools plus brief case-based education addressing the 3 primary clinical outcomes (187 clinicians from 30 clinics) were compared with brief case-based education alone (187 clinicians from 30 clinics). Decision support was designed to increase salience of potential harms, convey social norms, and promote accountability.

**Measurements:** Prostate-specific antigen (PSA) testing in men aged 76 years and older without previous prostate cancer, urine testing for nonspecific reasons in women aged 65 years and older, and overtreatment of diabetes with hypoglycemic agents in patients aged 75 years and older and hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) less than 7%.

**Results:** At randomization, mean clinic annual PSA testing, unspecified urine testing, and diabetes overtreatment rates were 24.9, 23.9, and 16.8 per 100 patients, respectively. After 18 months of intervention, the intervention group had lower adjusted difference-in-differences in annual rates of PSA testing (−8.7 [95% CI, −10.2 to −7.1]), unspecified urine testing (−5.5 [CI, −7.0 to −3.6]), and diabetes overtreatment (−1.4 [CI, −2.9 to −0.03]) compared with education only. Safety measures did not show increased emergency care related to urinary tract infections or hyperglycemia. An HbA<sub>1c</sub> greater than 9.0% was more common with the intervention among previously overtreated diabetes patients (adjusted difference-in-differences, 0.47 per 100 patients [95% CI, 0.04 to 1.20]).

**Limitation:** A single health system limits generalizability; electronic health data limit ability to differentiate between overtesting and underdocumentation.

**Conclusion:** Decision support designed to increase clinicians' attention to possible harms, social norms, and reputational concerns reduced unspecified testing compared with offering traditional case-based education alone. Small decreases in diabetes overtreatment may also result in higher rates of uncontrolled diabetes.

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Unnecessary laboratory testing may lead to clinical cascades of low clinical value exposing patients to potential harms from downstream clinical actions (1-5). Similarly, overly aggressive treatment of diabetes mellitus where harms outweigh benefits (6) are commonly observed in practice (7-9). The American Geriatrics Society (AGS), participating in the Choosing Wisely campaign of the American Board of Internal Medicine Foundation, provided recommendations on reducing overtesting and overtreatment of older adults (10).

Clinical decision support (CDS) integrated into electronic health records (EHRs) is a potential tool to address overuse but, traditionally, CDS applications

have focused on correcting clinicians' knowledge deficits. These approaches implicitly assume that rational clinicians will make correct decisions if they have accurate beliefs. If overuse stems instead from inattention, bad habits, or misaligned incentives, such approaches will be insufficient. Correcting overuse

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may require targeting clinicians' attention and motivation, using insights from social psychology and behavioral economics. In various contexts, appeals to social norms (11–14) and accountability (15) have outperformed informational alternatives; CDS that draws from these insights may effectively reduce overuse. Here, we test the hypothesis that CDS informed by behavioral science will reduce overuse more than brief online clinician education—that does not incorporate these principles—alone.

We conducted the BEAGLE (Behavioral Economic Applications to Geriatrics Leveraging Electronic Health Records) trial to test the hypothesis that point-of-care CDS leveraging behavioral principles (increasing harm salience, sharing social norms, and inducing social accountability) would reduce overuse among populations of older patients receiving ambulatory primary care. To test this hypothesis, we identified 3 clinical areas identified by the AGS Choosing Wisely statement for older patients: 1) do not recommend screening for breast, colorectal, prostate, or lung cancer without considering life expectancy and the risks for testing, overdiagnosis, and overtreatment; 2) do not use antimicrobials to treat bacteriuria in older adults unless specific urinary tract symptoms are present; and 3) avoid using medications other than metformin to achieve hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) less than 7.5% in most older adults; moderate control is generally better (10). We then built practical electronic clinical quality measures and CDS rules related to these recommendations to address: prostate-specific antigen (PSA) testing for men aged 76 years and older without a history of prostate cancer, testing for urinary tract infections in women without specific reasons, and overtreatment of diabetes to an HbA<sub>1c</sub> less than 7.0% with hypoglycemic drugs (16, 17).

## METHODS

### Design Overview

An unblinded participant, blinded outcomes assessment, pragmatic, cluster randomized controlled trial, BEAGLE was approved by the Northwestern Medicine (NM) primary care working group and Northwestern University's Institutional Review Board with a waiver of informed consent, overseen by an independent data and safety monitoring board, and preregistered at ClinicalTrials.gov (NCT04289753) (16). Sixty primary care practices, affiliated with a single regional health system, were equally randomly allocated to intervention or control. S.D.P., L.C.P., and J.Y.L. vouch for the accuracy and completeness of the results presented. Every month during a 12-month preintervention period and the 18-month intervention period, we assessed performance measures targeted at each of the 3 clinical areas. These performance measures included all patients meeting eligibility and attribution criteria for the year preceding the fixed monthly measurement date. Practices were identified in February 2020 and follow-

up was completed on 1 March 2022. The intervention was planned to begin in April 2020, but due to COVID-19, we changed the study plan. Because ambulatory medical care delivery was severely disrupted, we delayed the intervention start until 1 September 2020, and excluded data from 1 March 2020 through 31 August 2020 from the study measures.

### Setting and Participants

For cluster eligibility and inclusion, all primary care practices in internal medicine, family medicine, and geriatrics within 4 geographic regions of NM seeing patients in 2020 were eligible and were included. Physicians who piloted these interventions (17) and investigators were excluded (**Appendix Figure**, available at [Annals.org](#)). We assigned clinicians (physicians, advance practice nurses, and physician assistants) to the practice where they saw the plurality of patients between 1 March 2019 and 29 February 2020.

### Randomization and Interventions

Practices were randomized using a modified constrained process to balance groups by region, clinicians per practice, numbers of eligible patients for the 3 targets, and baseline performance rates (18–20). Details on selection of the randomization sequence are available in the Study Protocol (available at [Annals.org](#)); the study biostatistician (L.C.P.) independently generated the assignments in R v3.6.4 (R Core Team, 2020). Clinicians could not be blinded; outcome assessment was done in a blinded automated fashion. Once randomly assigned based on clinic assignment, clinicians retained the same assignment at any site where they saw patients (for example, intervention clinicians received decision support even if they also saw patients at a control group clinic). Clinicians joining practices after random assignment and the patients attributed to them were not included.

### Clinician Education (Control)

Before the intervention, regional leaders e-mailed primary care clinicians introducing the study. We then e-mailed a link to a brief, interactive, educational module covering the 3 targeted areas through case-based examples with multiple-choice answers. Case-based examples provided information on guideline recommendations and emphasized potential harms and undemonstrated benefits hosted, and participation was tracked via Research Electronic Data Capture (REDCap) (Study Protocol) (16, 21).

### Clinical Decision Support Plus Education (Intervention)

Rationale for and descriptions of the CDS have been published (16). We designed the CDS using a mixed-methods approach that included both physician interviews and feasibility piloting (17, 22). Selected information from the education material was conveyed succinctly through pop-up alerts when appropriate. We conveyed potential harms using language such as "Unindicated

testing leads to false positives, unnecessary antibiotic treatment and adverse reactions such as rashes, drug interactions, diarrhea and *C. diff* infection.” We conveyed injunctive social norms (11–14) using language such as “Danger of diabetes overtreatment in this patient. . . Reasonable glycemic targets are: 7.0–7.5 in healthy older adults with long life expectancy. . .” and descriptive social norms using language such as “Most NM PCPs use PSA rarely or not at all in men over 75 who have not already been diagnosed with prostate cancer.” At ordering, clinicians were interrupted with alerts that displayed this content. To induce feelings of social accountability (15, 23) for the PSA and urinary testing interventions, clinicians that proceeded with the order were prompted to document their rationale. This text was then visible within the chart under a heading titled “Testing Justification.” If the clinician did not enter a justification, “No justification given” was inserted similar to the approach taken in a trial that reduced antibiotic overprescribing (17, 23). There were no hard stops or restrictions to clinical decision making. Intervention group clinicians received an email link to an educational module that included the same clinical content provided to the control clinicians along with pictures and descriptions of the intervention CDS. Examples of the appearance of the CDS in the EHR and the CDS logic are included in the **Supplement Figure 1** and in the **Supplement Text** (both available at [Annals.org](#)). Interventions were activated 1 September 2020 and deactivated 1 March 2022 for intervention group clinicians. Intervention exposure was tracked using EHR data (**Supplement Table 1**, available at [Annals.org](#)).

### Outcomes and Follow-up

We measured patient characteristics and outcomes from data collected during routine care in the EHR Epic (Epic Systems), extracted from the health system’s data warehouse. Patients were attributed to the primary care clinician with whom they had the most visits (or most recent visit in the case of a tie) and only patients attributed to included clinicians were eligible. **Supplement Table 2** (available at [Annals.org](#)) provides the criteria for each of the measures used.

### Co-Primary Outcomes

There were 3 prespecified primary outcomes measured monthly during the 12-month historical control period (March 2019 through February 2020) and the 18-month intervention period (September 2020 through February 2022). Individual patients were included in all of the assessments for which they met eligibility criteria. **Supplement Figure 2** (available at [Annals.org](#)) demonstrates visually how denominator and numerator criteria were applied with respect to each measurement date.

The first primary outcome was the rate of PSA testing in men without prostate cancer. The rate was determined by the number of eligible men who received a PSA test divided by the number of eligible men overall.

Men were eligible if they were age 76 years or older, had no history of prostate cancer (determined via diagnosis or procedure code), were not taking an androgenic agent, and attended 1 or more office or telehealth visits with an included clinician in the year before the measurement date. The second primary outcome was the rate of urine testing for nonspecific reasons. The rate was determined by the number of eligible women without a diagnostic code for a specific genitourinary sign, symptom, or other potentially relevant indication (**Supplement Table 3**, available at [Annals.org](#)) for urine testing divided by the number of eligible women. Women were eligible for this measure if they were age 65 years or older and had a urinalysis and/or urine culture done in the interval from the calendar day before to the 2 days after an in-person or telehealth ambulatory care visit with an included clinician. If a woman had multiple qualifying visits in the 1-year window, only the first was included. The third primary outcome was the rate of diabetes overtreatment. The rate was determined by the number of eligible patients taking insulin, a sulfonylurea, or a meglitinide and with a most recent hemoglobin A<sub>1c</sub> less than 7.0% divided by the number of eligible patients. Patients were eligible if they had diabetes mellitus, were age 75 years or older, and attended 1 or more office or telehealth visits with an included clinician in the year before the measurement date.

### Secondary Outcomes

Prespecified secondary study outcomes included:

a. Rates of prostate biopsy, prostate magnetic resonance imaging, and new prostate cancer diagnosis in the 1-year baseline and 18-month intervention periods based on ICD10 (International Classification of Diseases, 10th Revision) or CPT (Current Procedural Terminology) codes (among eligible men without previously diagnosed prostate cancer).

b. Overall use of urinalyses and overall use of urine cultures obtained in the interval from the calendar day before to the 2 days after a clinic visit (among all women aged 65 years or older with an in-person or telehealth ambulatory care visit in the 90 days before the measurement date with a clinician included in the study: if there were multiple qualifying visits, only the first was examined), and antibiotic prescription for an oral antibiotic potentially used to treat urinary tract infection ordered in the 90 days before the measurement date (among all women aged 65 years or older with  $\geq 1$  in-person or telehealth ambulatory care visit with a participating clinician in the 3 months before the measurement date).

c. Emergency department visits or hospitalizations with hypoglycemia diagnosis (among patients with diabetes patients with a prior HbA<sub>1c</sub> less than 7.0% and treated with insulin or an oral hypoglycemic drug).

Exploratory outcomes added were antibiotic prescription specific to urinary tract infection (nitrofurantoin and fosfomicin), *Clostridioides difficile* infection

**Table 1.** Characteristics of Participating Practices and Clinicians at Randomization

Characteristics	Overall	Intervention	Control
Practices, <i>n</i>	60	30	30
Clinicians, <i>n</i>	371	184	187
Clinic characteristics			
Mean clinicians per clinic (SD), <i>n</i>	6.3 (6.1)	6.2 (5.7)	6.4 (6.5)
Mean number of patients eligible for overuse of PSA testing measure per clinic (SD)*	155.4 (167.4)	149.3 (182.1)	161.7 (153.8)
Mean overuse of PSA testing per 100 patients (SD)*, <i>n</i>	24.9 (19.1)	30.9 (23.3)	18.7 (10.8)
Mean number of patients eligible for UA/UC done without indication measure per clinic (SD)†	239.0 (304.5)	252.3 (338.3)	225.6 (271.7)
Mean UA/UC done without indication per 100 patients (SD)†, <i>n</i>	23.9 (13.7)	23.3 (13.4)	24.6 (14.1)
Mean number of patients eligible for diabetes overtreatment measure per clinic (SD)‡	117.5 (127.6)	111.8 (134.1)	123.5 (122.6)
Mean diabetes overtreatment per 100 patients (SD)‡, <i>n</i>	16.8 (9.7)	16.8 (10.3)	16.9 (9.2)
Health system region, <i>n</i> (%)			
Urban Chicago	14 (23.3)	7 (23.3)	7 (23.3)
North suburbs	8 (13.3)	4 (13.3)	4 (13.3)
Northwest suburbs	6 (10.0)	3 (10.0)	3 (10.0)
West suburbs	32 (53.3)	16 (53.3)	16 (53.3)
Clinician characteristics			
Specialty, <i>n</i> (%)			
Family medicine	121 (32.6)	64 (34.8)	57 (30.5)
Geriatrics	8 (2.2)	3 (1.6)	5 (2.7)
Internal medicine	242 (65.2)	117 (63.6)	125 (66.8)
Clinician type, <i>n</i> (%)			
Physician	318 (85.7)	163 (88.6)	155 (82.9)
Physician assistant	25 (6.7)	7 (3.8)	18 (9.6)
Advance practice nurse/nurse practitioner	28 (7.5)	14 (7.6)	14 (7.5)
Female, <i>n</i> (%)	232 (62.5)	117 (63.6)	115 (61.5)

PSA = prostate-specific antigen; UA/UC = urinalysis or urine culture.

\* Men were eligible for the PSA overtesting measure if they were aged 76 years or older and attended at least 1 in-person or telehealth ambulatory care visit between 1 March 2019 and 29 February 2020 with a clinician included in the study. Eligible patients had no history of prostate cancer (determined via diagnosis or procedure code) and were not taking an androgenic agent as of 29 February 2020. Men were considered overtreated if they received a PSA test. The unmatched PSA testing rate occurred due to a minor error in the constrained randomization process (16).

† Women were eligible for the urine testing for nonspecific reasons (UA/UC) measure if they were age 65 years or older and had an in-person or telehealth ambulatory care visit with a participating clinician between 1 March 2019 and 29 February 2020 where a UA/UC was obtained in the interval from the calendar day before to the 2 days after the visit. If a woman had multiple qualifying visits in the window, only the first was included. Women were considered overtreated if there was no diagnostic code for a specific genitourinary sign, symptom, or other potentially relevant indication.

‡ Patients were eligible for the diabetes overtreatment measure if they were age 75 years or older with a diagnosis of diabetes mellitus, and attended at least 1 in-person or telehealth ambulatory care visit between 1 March 2019 and 29 February 2020. Patients were attributed to the primary care clinician with whom they had the greatest number of visits between 1 March 2019 and 29 February 2020. Patients were considered overtreated if they were taking insulin or an oral hypoglycemic as of 29 February 2020 and their most recent hemoglobin A<sub>1c</sub> was less than 7.0%.

diagnosis, and nonspecific rash or drug eruption diagnosis based on ICD10 codes among the same denominator as the other antibiotic measure.

### Safety Outcomes

The prespecified safety outcome in the urine testing group was EHR-identified emergency department visits or hospitalizations with diagnosed urinary tract infection or sepsis in the 28 days after a primary care office visit with a clinician included in the study; in the diabetes group, it was emergency department visits or hospitalizations with a diagnosis of hyperglycemia and development of HbA<sub>1c</sub> greater than 9.0% among previously tightly controlled patients treated with a hypoglycemic medication. Safety measures were reviewed by the study's data safety and monitoring board after 6 months of intervention-period data were collected.

### Statistical Analysis

A statistical analysis plan, available in the Study Protocol, was finalized before data unblinding or analyses.

### Study Power

A priori power analysis estimated minimum detectable effect sizes from the participating practices. We used historical data to determine interclass correlations and baseline rates for each metric empirically. We determined 30 clinics in each group and a 2-sided type I error of 5% (Bonferroni-corrected to 1.7%) would have 80% or greater power to detect approximately 4% absolute differences between groups after 18 months of follow-up for each primary outcome (16).

### Primary and Secondary Analyses

All analyses were performed according to the intention-to-treat principle. We assessed the 3 primary outcomes using patient-level data with separate piecewise, hierarchical, mixed-effects logistic regression models, including time as a linear term with a knot at the intervention start and random effects for clinicians. As clinicians' clinic assignment remained constant through the study, we adjusted all models for the clinic-level variables included in the constrained randomization, and did not include clinic-

**Table 2.** Eligible Population Counts and Rates of Co-Primary Outcomes Before and at the Completion of the Intervention Periods

Outcome	Intervention			Control			Comparative Effectiveness 18-mo Differences in Annual Rates per 100 Eligible Patients (95% CI)†
	Measurement Date		Difference From End of Baseline to End of Intervention Period in Annual Rate per 100 Patients (95% CI)‡	Measurement Date		Difference From End of Baseline to End of Intervention Period in Annual Rate per 100 Patients (95% CI)‡	
	End of Baseline, February 2020*	End of Intervention, February 2022*		End of Baseline, February 2020*	End of Intervention, February 2022*		
<b>Overuse of PSA testing</b>							
Eligible persons in prior 1 y, n‡	4054	4811	-	4221	5169	-	-
Persons who experienced PSA testing overuse in prior 1 y, n	1299	1373	-	1191	1675	-	-
Unadjusted annual rate per 100 eligible patients (95% CI)§	32.0 (30.6 to 33.5)	28.5 (27.3 to 29.8)	-	28.2 (26.9 to 29.6)	32.4 (31.1 to 33.7)	-	-
Effect estimates (95% CI)	-	-	-0.4 (-1.4 to 0.5)	-	-	8.2 (7.0 to 9.4)	-8.7 (-10.2 to -7.1)
<b>Urinalysis or urine culture done without indication</b>							
Eligible persons in prior 1 y, n‡	5893	4264	-	5158	4535	-	-
Persons who experienced UA/UC without indication in prior 1 y, n	1985	1032	-	1406	1127	-	-
Unadjusted annual rate per 100 eligible patients (95% CI)§	33.7 (32.5 to 34.9)	24.2 (22.9 to 25.5)	-	27.3 (26.0 to 28.5)	24.9 (23.6 to 26.1)	-	-
Marginal model-based effect estimates (95% CI)	-	-	-6.2 (-7.4 to -4.7)	-	-	-0.7 (-1.9 to 0.4)	-5.5 (-7.0 to -3.6)
<b>Diabetes overtreatment</b>							
Eligible persons in prior 1 y, n‡	2745	3624	-	2808	3781	-	-
Persons who experienced diabetes overtreatment in prior 1 y, n	550	605	-	446	603	-	-
Unadjusted annual rate per 100 eligible patients (95% CI)§	20.0 (18.5 to 21.5)	16.7 (15.5 to 17.9)	-	15.9 (14.5 to 17.2)	15.9 (14.8 to 17.1)	-	-
Effect estimates (95% CI)	-	-	-2.3 (-3.3 to -1.2)	-	-	-0.9 (-1.9 to 0.2)	-1.4 (-2.8 to -0.03)

PSA = prostate-specific antigen; UA/UC = urinalysis or urine culture.

\* February 2020 represents outcome measures (with a 1-year lookback period) from the last month of the baseline period. February 2022 represents outcome measures (with a 1-year lookback period) from the last month of the intervention period.

† Marginal group-specific absolute differences in annual rates per 100 eligible patients and differences in 18-month changes in annual rates per 100 patients representing intervention effects at 18 months were calculated from piecewise, hierarchical, logistic regression models (coefficients reported in Supplement Tables 8-10), adjusted for clinic-level characteristics included in constrained randomization. The 95% CIs were calculated via a nonparametric bootstrap from 1000 balanced resamples done at the cluster level within study groups.

‡ Men were eligible for the PSA overtreatment measure if they were age 76 years or older and attended at least 1 visit in the 1 year before the measurement date with a clinician included in the study. Eligible patients had no history of prostate cancer and were not taking androgen therapy as of the measurement date. Men were considered overtreated if they received a PSA test.

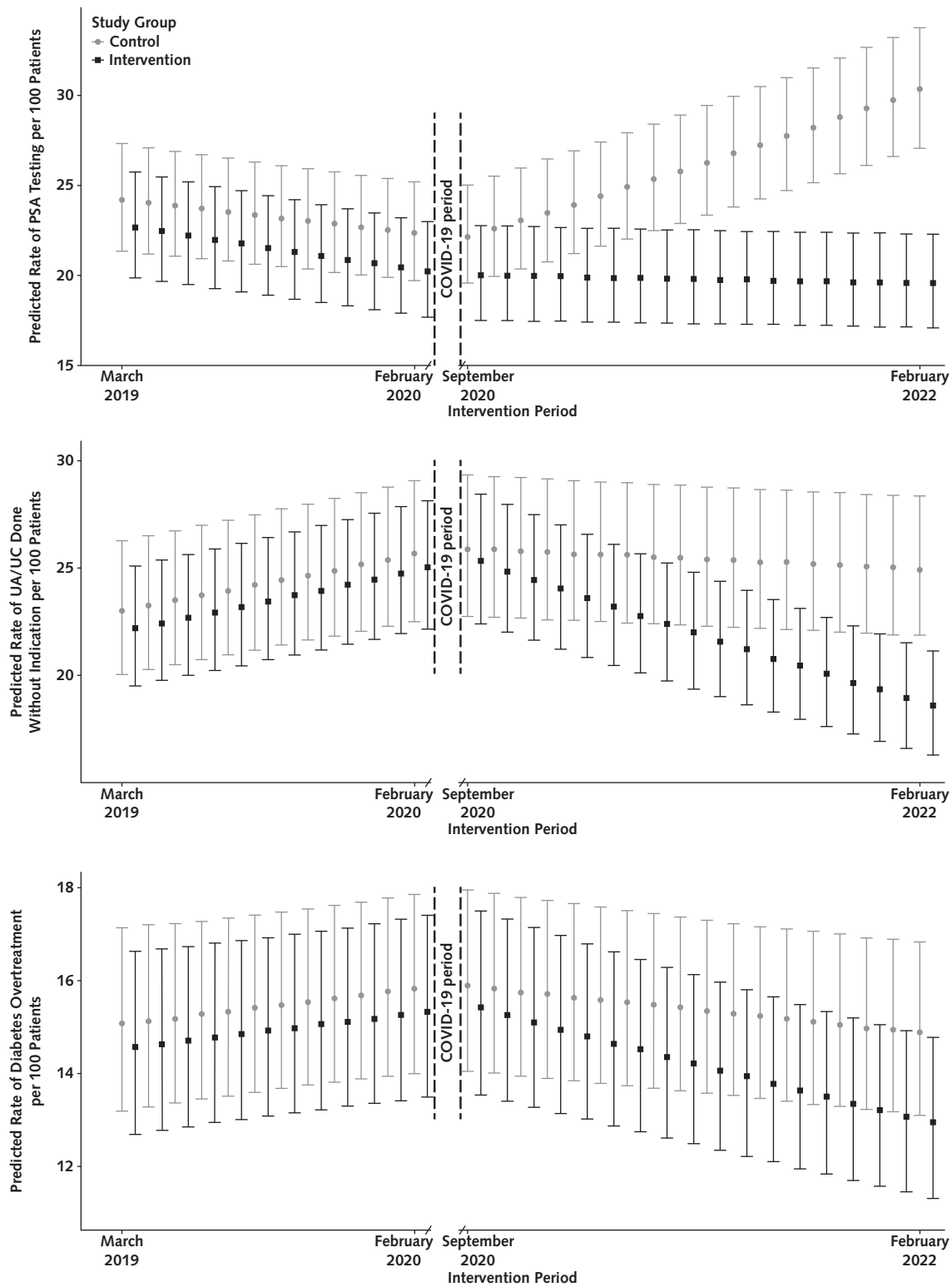
Women were eligible for the urine testing for nonspecific reasons measure if they were age 65 years or older and had an in-person or telehealth ambulatory care visit with a participating clinician in the 1 year before the measurement date where a urinalysis and/or urine culture was obtained in the interval 24 hours before the 48 hours after the visit. If a woman had multiple qualifying visits in the 1-year window, only the first was included. Women were considered overtreated if there was no diagnostic code for a specific genitourinary sign, symptom, or other potentially relevant indication.

Patients were eligible for the diabetes overtreatment measure if they were age 75 years or older with a diagnosis of diabetes mellitus. Patients were attributed to the primary care clinician with whom they had the greatest number of visits in the 1-year window. Patients were considered overtreated if they were taking insulin or an oral hypoglycemic as of the measurement date and their most recent hemoglobin A<sub>1c</sub> in the 730 days before the measurement date was less than 7.0%.

§ 95% CIs for unadjusted rates were calculated using the binomial approximation to a normal distribution.

|| 95% CIs for model-based estimates were Bonferroni-corrected for the 3 co-primary outcomes to 98.3%.

**Figure.** Model-based monthly rates of PSA overtesting, urinalysis, or urine culture done without indication, and diabetes overtreatment before and during the behavioral economic applications to geriatrics leveraging EHR trial intervention.



Results are the marginal predictions from hierarchical logistic regression models of intervention effects with clinician random effects, adjusted for historical performance and size of eligible population on all 3 outcome measures, clinic region, and number of clinicians. Baseline data were collected from 1 March 2019 to 29 February 2020, and the intervention period ran from 1 September 2020 to 28 February 2022. Difference from end of baseline to end

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**Figure—Continued.**

of intervention period in annual rate per 100 patients at the end of the intervention period is available in **Table 2**. Model coefficients are available in **Supplement Tables 8–10** (available at [Annals.org](https://annals.org)). Black font represents the intervention group; gray represents the control group. The 95% CIs are Bonferroni-corrected to reflect  $\alpha$  of 0.017. DM = diabetes mellitus; EHR = electronic health record; PSA = prostate-specific antigen; UA/UC = urinalysis or urine culture.

**Top.** Men were eligible for the PSA overtesting measure if they were age 76 years or older and attended at least 1 visit in the 1 year before the measurement date with a clinician included in the study. Eligible patients had no history of prostate cancer (determined via diagnosis or procedure code) and were not taking an androgenic agent as of the measurement date. Men were considered overtested if they received a PSA test.

**Middle.** Women were eligible for the urine testing for nonspecific reasons (UA/UC) measure if they were age 65 years or older and had an in-person or telehealth ambulatory care visit with a participating clinician in the 1 year before the measurement date where a urinalysis and/or urine culture was obtained in the interval from the calendar day before to the 2 days after the visit. If a woman had multiple qualifying visits in the 1-year window, only the first was included. Women were considered overtested if there was no diagnostic code for a specific genitourinary sign, symptom, or other potentially relevant indication (**Supplement Table 3**).

**Bottom.** Patients were eligible for the diabetes overtreatment measure if they were age 75 years or older with a diagnosis of diabetes mellitus. Patients were attributed to the primary care clinician with whom they had the greatest number of visits in the 1-year window. Patients were considered overtreated if they were taking insulin or an oral hypoglycemic as of the measurement date and their most recent hemoglobin A<sub>1c</sub> prior to the measurement date was less than 7.0%.

level random effects. The models included monthly data from 12 measurements during the historical control period (1 March 2019 through 29 February 2020) and 18 measurements during the intervention period (1 September 2020 through 28 February 2022). The estimates of interest for the intervention effects were intervention group  $\times$  time  $\times$  intervention period, representing the monthly differences in the log-odds of the annual rates of each measure within the intervention period between intervention and control groups. We standardized these estimates to generate model-based marginal predicted annual rates (reported as 18-month differences in annual rates per 100 eligible patients). Statistical significance was set at  $\alpha = 0.05$  and conservatively Bonferroni-corrected to 0.017. Ninety-five percent CIs (Bonferroni-corrected to 98.3% CIs) were calculated using a nonparametric bootstrap with 1000 resamples.

We conducted prespecified subgroup analyses by race and ethnicity and age for all co-primary outcomes as well as sex (for diabetes). For safety outcomes and subgroup analyses, we collapsed data from months to quarters (or pre/during intervention periods) due to paucity of outcomes. Analyses used SAS 9.4 (SAS Institute).

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## RESULTS

### Participants

Baseline characteristics of participating practices were assessed as of 29 February 2020 and used in the constrained randomization process (**Appendix Figure**, available at [Annals.org](https://annals.org)). The intervention stopped as planned after the end of the 18-month intervention period at which point 3 of the clinics (10%) had closed and 43 of the clinicians (11.5%) had departed (10% intervention and 13% control). The intervention group had slightly greater rates of PSA testing (16). This was mitigated by

adjustment for baseline clinic characteristics including PSA testing rates. Otherwise, characteristics of practices and the clinicians attributed to them were generally well balanced at baseline (**Table 1**) and remained so through the end of the intervention period (**Supplement Table 4**, available at [Annals.org](https://annals.org)).

### Primary Efficacy Outcomes

**Table 2** displays unadjusted rates of each co-primary outcome in February 2020, preceding the intervention start, and February 2022 at the end of the intervention period and adjusted differences-in-differences (aDID) in annual rates per 100 eligible patients to measure the comparative effectiveness of the intervention. Over the intervention period, PSA testing among men aged 76 and older without prostate cancer fell from 32.0 per 100 patients to 28.5 in the intervention group and rose from 28.2 to 32.4 in the control group (aDID,  $-8.7$  [95% CI,  $-10.2$  to  $-7.1$ ];  $P < 0.001$ ). Urine testing for nonspecific reasons fell from 33.7 to 24.2 in the intervention group and from 27.3 to 24.9 in the control group (aDID,  $-5.5$  [CI,  $-7.0$  to  $-3.6$ ];  $P < 0.001$ ). Diabetes overtreatment fell from 20.0 to 16.7 in the intervention group and remained at 15.9 in the control group (aDID,  $-1.4$  [CI,  $-2.8$  to  $-0.03$ ];  $P = 0.005$ ). Model-based monthly marginal rates per 100 eligible patients for these measures in the baseline and intervention periods are shown in the **Figure**.

In subgroup analyses (**Supplement Table 5**, available at [Annals.org](https://annals.org)), the intervention effect on the PSA testing was greatest for men aged 76 to 79 years in absolute and relative terms compared with older men, and effect on urine testing for nonspecific reasons was greatest in women aged 85 years and older. Other subgroup differences were small.

### Secondary Outcomes

Of the secondary outcomes, the intervention had the greatest effect on the rate of urinalyses testing in women aged 65 years and older (**Supplement Table 6**, available at [Annals.org](https://annals.org)) (aDID,  $-1.0$  [CI,  $-2.0$  to  $-0.2$ ] per 100 patients). The effect of the intervention on all other secondary outcomes was small and not statistically significant.

**Table 3.** Eligible Population Counts and Rates of Safety Outcomes Before and at the Completion of the Intervention Period, Stratified by Treatment Assignment

Safety Outcomes	Intervention			Control			Comparative Effectiveness 18-mo Differences in Annual Rates per 100 Eligible Patients (95% CI)†
	Measurement Date		Difference From End of Baseline to End of Intervention Period in Annual Rate per 100 Patients (95% CI)	Measurement Date		Difference From End of Baseline to End of Intervention Period in Annual Rate per 100 Patients (95% CI)	
	End of Baseline, February 2020*	End of Intervention, February 2022*		End of Baseline, February 2020*	End of Intervention, February 2022*		
<b>Safety outcomes related to testing for bacteriuria‡</b>							
Eligible women, <i>n</i>	26 405	30 842	–	27 698	32 749	–	–
EHR-identified ED or hospital care possibly due to UTI or sepsis among women 65 y and over after an office visit, <i>n</i> (%)	172 (0.65)	228 (0.74)	–	129 (0.47)	199 (0.61)	–	–
Effect estimates (95% CI)	–	–	0.03 (–0.06 to 0.1)	–	–	0.08 (0.01 to 0.16)	–0.05 (–0.17 to 0.07)
<b>Safety outcomes related to diabetes mellitus</b>							
Hyperglycemia requiring ED or hospital care§							
Eligible patients, <i>n</i>	493	782	–	395	667	–	–
EHR-identified ED or hospital care possibly due to hyperglycemia among previously tightly controlled, <i>n</i> (%)	4 (0.8)	10 (1.3)	–	1 (0.3)	19 (2.8)	–	–0.04 (–0.53 to 0.31)
Effect estimates (95% CI)	–	–	–0.04 (–0.53 to 0.31)	–	–	0.41 (–0.01 to 1.11)	–0.45 (–1.38 to 0.11)
Poor diabetes control							
Eligible patients, <i>n</i>	499	782	–	406	668	–	–
Patients with poor diabetes control among individuals with previously tightly controlled HbA <sub>1c</sub> , <i>n</i> (%)	5 (1.0)	22 (2.8)	–	10 (2.5)	11 (1.6)	–	0.39 (–0.002 to 1.01)
Effect estimates (95% CI)	–	–	0.39 (–0.002 to 1.01)	–	–	–0.07 (–0.44 to 0.18)	0.47 (0.04 to 1.20)

ED = emergency department; EHR = electronic health record; HbA<sub>1c</sub> = hemoglobin A<sub>1c</sub>; UTI = urinary tract infection.

\* February 2020 was the month before the start of the intervention. February 2022 was the last month that the intervention was live. Reported numbers may span different periods of time for each secondary outcome as specified in subsequent footnotes.

† Marginal group-specific absolute differences in annual rates per 100 eligible patients and differences in 18-month changes in annual rates per 100 patients representing intervention effects at 18-months were calculated from piecewise, hierarchical, logistic regression models, adjusted for clinic-level characteristics included in constrained randomization. The 95% CIs were calculated via a nonparametric bootstrap from 1000 balanced resamples done at the cluster level within study groups.

‡ In-office or telehealth patient encounters were eligible for the bacteriuria-related safety outcome if the woman was age 65 years or older at the qualifying encounter, which must have occurred in the prior 12 months (for example, February 2020: eligible encounters occurred between 1 March 2019 and 29 February 2020). Patient encounters contributed to the numerator if a woman had an EHR-identified ED or hospital care visit possibly due to UTI or sepsis within 28 days of the eligible encounter. Marginal group-specific absolute differences in annual rates per 100 eligible patients and differences in 18-month changes in annual rates per 100 patients representing intervention effects at 18 months were calculated from piecewise logistic regression models, adjusted for clinic-level characteristics included in the constrained randomization; modeled data were aggregated by quarter.

§ Patients were eligible for the hyperglycemia requiring ED or hospital care safety outcome if they were age 75 years or older with a diagnosis of diabetes mellitus, attended at least 1 in-person or telehealth visit in the 1 year before the measurement date, had insulin or a hypoglycemic medication on the active medication list at the qualifying visit, and their most recent hemoglobin A<sub>1c</sub> was less than 7.0% before the visit. Patients were attributed to the primary care clinician with whom they had the greatest number of visits in the 1-year window. Patients contributed to the numerator if they had an ED or inpatient encounter for hyperglycemia (identified via ICD-10 codes) within 1 to 90 days after the qualifying visit. Marginal group-specific absolute differences in annual rates per 100 eligible patients and differences in 18-month changes in annual rates per 100 patients representing intervention effects at 18 months were calculated from piecewise logistic regression models, adjusted for clinic-level characteristics included in the constrained randomization; modeled data were aggregated to the historical baseline (1 March 2019 to 29 February 2020) and intervention periods (1 September 2020 to 28 February 2022).

|| Patients were eligible for the poor diabetes control safety outcome if they were age 75 years or older with a diagnosis of diabetes mellitus, attended at least 1 in-person or telehealth visit in the 1 year before the measurement date, had insulin or a hypoglycemic medication on their active medication list before the visit, and their most recent hemoglobin A<sub>1c</sub> was less than 7.0% in the 730 days before the visit. Patients contributed to the numerator who had an HbA<sub>1c</sub> greater than 9.0% from any bloodwork taken after the qualifying visit. Marginal group-specific absolute differences in annual rates per 100 eligible patients and differences in 18-month changes in annual rates per 100 patients representing intervention effects at 18 months were calculated from piecewise, hierarchical, logistic regression models with random intercept for clinician department, adjusted for clinic-level characteristics included in the constrained randomization; modeled data were aggregated to the historical baseline (1 March 2019 to 29 February 2020) and intervention periods (1 September 2020 to 28 February 2022).



## Safety Outcomes

There were no clinically important or statistically significant differences between study groups in EHR-assessed measures of emergency department visits or hospitalizations for urinary tract infection or sepsis among women aged 65 years and over or for hyperglycemia among previously tightly controlled patients treated with hypoglycemic medications. The percentage of previously tightly controlled patients treated with hypoglycemic medications who subsequently developed HbA<sub>1c</sub> more than 9.0% was greater in the intervention than control group (aDID, 0.47 per 100 patients [CI, 0.04 to 1.20]) (Table 3).

## DISCUSSION

In this pragmatic clinic-randomized trial, point-of-care CDS designed to increase attention to harms and draw on social and reputational concerns reduced PSA testing in men without prostate cancer and urinary testing for nonspecific reasons with a smaller reduction in overtreatment of diabetes. These findings suggest that point-of-care behaviorally informed interventions can reduce overtesting and overuse among older patients of primary care clinicians while preserving clinician discretion. Although no differences were seen for emergency visits related to urinary tract infections, more patients with previously controlled diabetes had HbA<sub>1c</sub> more than 9.0%. Clinics and health systems considering implementation of behavior-change point-of-care tools should consider the potential effects of clinician behavior change.

The BEAGLE trial represents a large, adequately powered trial that adds support to the importance of clinician-directed interventions to reduce overuse to curb low value, potentially harmful care (23–30). Interventions to increase clinician attention to Choosing Wisely recommendations and reduce low-value care have been attempted, though most previous studies had methodological limitations and did not directly apply behavioral principles (28, 29). Only 1 of 8 randomized trials in a review by Cliff et al on interventions to promote Choosing Wisely recommendations used a behavioral nudge. That trial found a small but unsustainable benefit for 1 of 3 outcomes using a behavioral nudge intervention that asked clinicians to commit to reducing low-value care (imaging for low back pain or uncomplicated headache and antibiotic for acute sinusitis) then reminding them of their commitment at the point of care (27). More recently, an uncontrolled pilot study of interventions using EHR nudges and e-mail that incorporated behavioral principles such as framing, social norms, accountability, and competition improved adherence to diabetes-related Choosing Wisely recommendations (24). Our observed intervention effects are generally consistent with this study but did not require complex multi-component interventions such as those used by Belli et al (24) and was done using a straightforward implementation

strategy that was not resource intensive (Supplement Table 7, available at [Annals.org](https://annals.org)).

This study did not compare CDS interventions applying behavioral principles with one that did not, so it is not clear whether any differences found reflect the use of a CDS tool itself, or the specific language and principles used to develop the CDS intervention. A trial by Ho and colleagues addressed 5 Choosing Wisely recommendations including PSA screening using interruptive alerts and CDS methods similar to BEAGLE, but alert contents were merely statements of Choosing Wisely recommendations (injunctive norms), and did not make harms salient, signal that behaviors deviated from descriptive social norms, or solicit accountable justifications before the clinician overrode a recommendation. Although this study did not show significant reductions in overuse (26), a nonrandomized study of a simple CDS intervention targeting PSA screening in men aged 75 years and older in the Veterans Affairs Greater Los Angeles Healthcare System with a simple recommendation against screening significantly reduced PSA testing using time-series analysis (25). Understanding which elements of this pragmatic low-resource intensive intervention are most effective for behavior change may be an area for future research.

The present study has several limitations. The reduction in urinalysis or urine culture done without indication among women getting a urine test showed that the intervention reduced underdocumentation but not necessarily overtesting. However, in the secondary outcomes, we did see some reductions in the rate of total urinalyses and total urine cultures among all women, which provides some evidence that some of the difference may be related to reduced total testing. Although we were interested in PSA screening, we did not distinguish whether men with PSA testing had signs, symptoms, or other clinical indications for testing. The trial was conducted in a single health system with a common EHR. Generalizability to other settings is unknown. Owing to disruptions that occurred in 2020 due to COVID-19, there was a large reduction in ambulatory care use and we chose to alter our study plan to address this. Outcome assessment was limited to data available within 1 system. Lastly, we did not have sufficient follow-up duration for a meaningful safety measure to assess unintended consequences of reducing PSA testing, or relaxed diabetes control, which if present, we would expect to unfold over many years.

In primary care, point-of-care CDS designed to increase clinicians' attention to possible harms and to draw on social and reputational concerns to reduce overuse and overtreatment in older patients reduced PSA testing and urinary tract infection testing for nonspecific reasons. Small decreases in diabetes overtreatment may also result in higher rates of uncontrolled diabetes with subsequent HbA<sub>1c</sub> elevation over 9.0%. Other health systems can consider whether this type

of intervention would be appropriate to adopt to their system.

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**Data Sharing Statement:** The following data will be made available with publication: Deidentified participant data and a data dictionary (requests should be sent to the corresponding author, Dr. Persell, at [spersell@nm.org](mailto:spersell@nm.org)). The following supporting documents will be made available with publication: Statistical/analytic code (supporting documents are included in the **Supplement Text**). Given the nature of these data and the fact they were collected during the course of routine care delivery and used for study purposes with a HIPAA authorization waiver, we will restrict access to the study data file to by-request only. We will permit access to the data on the basis of the experience and scientific qualifications of the investigator(s) and their agreement to not reproduce or share the data with others and to not attempt to determine the identities of clinicians, patients, or clinical locations. Data use agreements will be executed as necessary for access to the limited data set, for any purpose described in the data use agreement, with a signed data access agreement (restrictions: see above). Additional context: The study data file (available by request) will include much of the data needed to replicate study outcomes reported on in peer-reviewed manuscripts from the trial. However, due to the published lookback periods being more specific than calendar year, we will be unable to create a fully deidentified data set that could be made publicly

available without restrictions. It would necessarily include elements of "dates of service" protected health information (PHI). Given this, the available-by-request data set will include demographic characteristics of enrolled patients and clinicians and aggregated variables but would not be sufficient to replicate all study outcomes. The limited data set that would include these indirect "dates of service" variables could be made available if data use agreements were executed with Northwestern Medicine.

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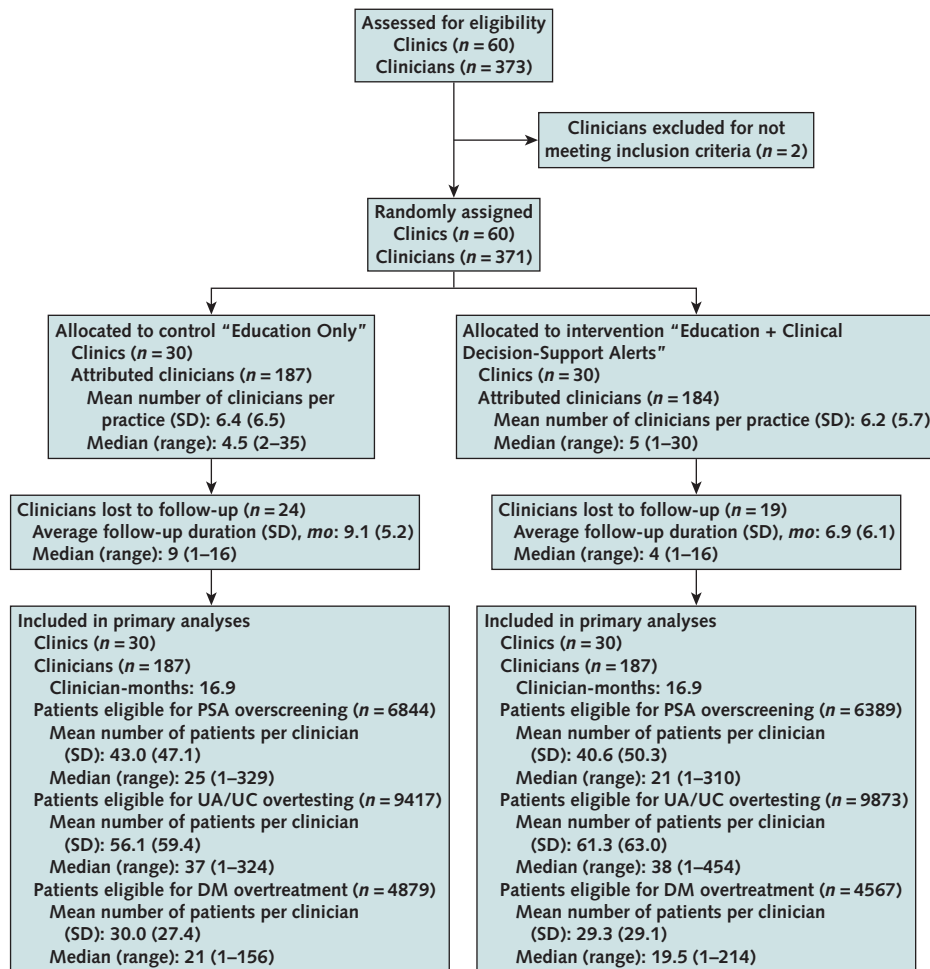
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**Appendix Figure.** Selection of clinics and clinicians into the BEAGLE study.



Nineteen clinicians were excluded since they participated in the pilot study or were investigators. No clinics were lost to follow-up. Clinicians were lost to follow-up if they stopped practicing at Northwestern Medicine before the end of the study (28 February 2022). These numbers reflect the number of patients eligible for each co-primary outcome analysis during the intervention period (1 September 2020 to 28 February 2022). DM = diabetes mellitus; PSA = prostate-specific antigen; UA/UC = urinalysis or urine culture done for nonspecific reasons.