De-implementing Inhaled Steroids to improve Care and Safety in Chronic Obstructive Pulmonary Disease (DISCuS COPD): A randomized control trial

Protocol

12/1/2021

Table of Contents

1. Abbreviations

AFO	Airflow Obstruction
CBOC	Community-Based Outpatient Clinics
CDW	Corporate Data Warehouse
COPD	Chronic Obstructive Pulmonary Disease
DISCuS COPD	De-implementing Inhaled Steroids to improve Care and Safety in Chronic Obstructive Pulmonary Disease
E-consult	Electronic Consult
ED	Emergency Department
EHR	Electronic Health Record
FEV1	Forced Expiratory Volume in 1 Second
FVC	Forced Vital Capacity
GINA	Global Initiative for Asthma
GEE	Generalized Estimating Equations
GLMM	Generalized Linear Mixed Model
GOLD	Global Initiative for Chronic Obstructive Lung Disease
ICD-9	International Classification of Diseases, Ninth Revision
ICD-10	International Classification of Diseases, Tenth Revision
ICS	Inhaled Corticosteroids
LABA	Long-acting Beta Agonist
PACT	Patient-aligned Care Team
PBM	Pharmacy Benefits Management
PCP	Primary Care Provider
QI	Quality Improvement
QUERI	Quality Enhancement Research Initiative
RE-AIM	Reach, Effectiveness, Adoption, Implementation, Maintenance Framework
SVC	Slow Vital Capacity

VA	Department of Veterans Affairs
VC	Vital Capacity
VHA	Veterans Health Administration

2. Funding/Regulatory

- Funding: Department of Veterans Affairs (VA) Quality Enhancement Research Initiative (QUERI) QUE 15-471
- Designated by the VHA Office of Specialty Care as a non-research operations activity (7/30/2015)
- Trial registration: ClinicalTrials.gov Identifier: NCT02896257

3. Study Investigators

VA Puget Sound Health Care System:
Principal Investigator
David H. Au, MD, MS
Director, Center of Innovation for Veteran-Centered and Value-Driven Care, Health Services Research & Development, VA Puget Sound HCS
Professor, University of Washington School of Medicine

Co-Investigators:
Laura C. Feemster, MD, MS
Core Investigator, Center of Innovation for Veteran-Centered and Value-Driven Care, Health Services Research & Development, VA Puget Sound HCS
Associate Professor, University of Washington School of Medicine

Christian D. Helfrich, PhD, MPH
Core Investigator, Center of Innovation for Veteran-Centered and Value-Driven Care, Health Services Research & Development, VA Puget Sound HCS
Research Associate Professor, University of Washington School of Public Health

George Sayre, PsyD MA
Core Investigator, Center of Innovation for Veteran-Centered and Value-Driven Care, Health Services Research & Development, VA Puget Sound HCS
Clinical Assistant Professor, University of Washington School of Public Health

Edith Nourse Rogers Memorial Veterans Hospital (Bedford VA):
Co-Investigators:
Renda S. Wiener, MD, MPH
Co-Associate Director, Center of Healthcare Organization and Implementation Research, Bedford VA
Associate Professor, Boston University School of Medicine

Seppo T. Rinne, MD, PhD
Investigator, Center of Healthcare Organization and Implementation Research, Bedford VA
Assistant Professor, Boston University School of Medicine

4. Background/Rationale

Chronic obstructive pulmonary disease (COPD) is among the most common medical diagnosis among Veterans.[1,2] Approximately half of those who carry a diagnosis of COPD are prescribed inhaled corticosteroids (ICS) despite having no role among those patients without fixed airflow obstruction (AFO) and a limited role among those who do.[3] Guidelines explicitly state that ICS should be limited to patients with frequent exacerbations despite long-acting bronchodilators.[4] Even this benefit comes at a cost, as ICS use has been shown in multiple randomized control trials to increase rates of pneumonia.[5-7] After prolonged exposure, ICS is also associated with higher fracture risk,[8] cataracts[9,10] and poor diabetes control.[11] Among patients without disease or with low risk of exacerbation, ICS have no demonstrated efficacy, but retain the risk of harm. For this reason, evidence-based guidelines specifically recommend against their use.[4] **We propose to improve the delivery and safety of care by de-implementing the ineffective use of ICS among Veterans with a diagnosis of COPD who otherwise lack a clinical indication for the medication. Framed in the context of the de-implementation QUERI, we will compare a substitution approach using a proactive patient-tailored electronic consult (E-consult) to usual care.** Primary care providers assigned to either treatment arm will also receive a single-session academic detailing intervention, which represents a non-intensive unlearning approach.

In collaboration with patient aligned care teams (PACT), we propose to challenge the current referral-dependent provision of specialty care by having pulmonologists assume responsibility for supporting a population of patients with COPD. Understanding how to deploy specialists to improve access, timeliness, and quality of care, using a PACT-Veteran-centric approach, is a high priority for VA and the Office of Specialty Care Services, just as decreasing ineffective medication use is a high priority for the Pharmacy Benefits Management (PBM) Services. Using a parallel cluster randomized trial design grounded in the Chronic Care Model and evaluated using the RE-AIM framework,[12-15] we propose to test an intervention that retools concepts of specialty care access and existing clinical infrastructure to align with VA operational goals to improve safety and value for Veterans with COPD.

5. Specific Aims

Primary Aim:

Among patients with a clinical diagnosis of COPD who have had spirometry and are receiving inappropriate inhaled corticosteroids:

1. Evaluate a multi-faceted intervention that seeks to decrease inappropriate use of ICS. The intervention uses a proactive E-consult approach to leverage the VA's integrated healthcare and informatics system to facilitate specialist support of primary care teams to de-implement ICS among patients with no clinical indication for the medication. Our **primary outcome** is the percentage of patients that remain off inhaled corticosteroids at six months (index date + 180 days).

Secondary Aims:

1. Assess whether the intervention is associated with:

- Unchanged rates of COPD exacerbation at 6 months [defined as (index date + 1 day) to (index date + 180 days)]
- Decreased rate of pneumonia at 6 months [defined as (index date + 1 day) to (index date + 180 days)]
- Decreased mortality at 6 months. [defined as (index date + 1 day) to (index date + 180 days)]
- Acceptance of substituted recommendations (Intervention group only).
    - Number of patients for whom recommendations were made.
    - Number of patients recommended to stop inhaled corticosteroids.
    - Proportion of recommendations accepted by primary care providers within 6 months (index date + 180 days).
- Percentage of patients where recommendations to stop inhaled corticosteroids are accepted but restarted by 6 months [defined as (index date + 1 day) to (index date + 180 days)]

2. Assess the effect of the intervention on primary care provider (PCP) burnout, professional efficacy, and perceptions of evidence for the use of ICS.

3. Assess acceptability of the intervention to PCPs and Veterans.

4. Assess implementation costs of the intervention.

6. Setting

The study will be conducted within primary care clinics located at the VA Puget Sound Health Care System (Seattle, WA) and the Edith Nourse Memorial VA Medical Center (Bedford, MA). Sites of primary care include clinics located at both academic medical centers and their associated community-based outpatient clinics (CBOCs).

7. Design

We will utilize a parallel cluster randomized trial design, with initial randomization occurring at the level of the primary care patient-aligned care team (PACT) team. Following study start, the unit of randomization will be the PCP, as described in Section 8.3. Data will be collected at the individual patient level.

8. Eligibility, Recruitment, and Consent

8.1. Eligibility

Primary Care PACT team:

Eligible primary care PACT teams will include all PACT teams located within Internal Medicine Clinics, Geriatric Clinics, Home-based Primary Care, Women's Health Clinics, and Spinal Cord Injury Clinics located at VA Puget Sound Health Care System and the Edith Nourse Memorial VA Medical Center.

Primary Care Providers:

All independently licensed providers associated with a Primary Care PACT team at each site will be eligible to participate in the study, including attending physicians, nurse practitioners and physician assistants. Physician trainees (including residents and fellows) will be eligible to participate in the study, but will not be randomized, as they practice under one or more supervising physician (attending) already eligible for randomization.

Patients:

We will utilize information from the Corporate Data Warehouse (CDW) to identify patients with a clinical diagnosis of COPD followed in primary care clinics at VA Puget Sound Healthcare System or Edith Nourse Memorial VA Medical Center who are prescribed ICS without a guideline-supported indication.

Eligible patients will meet all of the following inclusion criteria at the time of the CDW data query:

1. Veteran receiving primary care at the VA Puget Sound Healthcare System or Edith Nourse Memorial VA Medical Center.
2. Prescribed an inhaled corticosteroid within the past 180 days (**Appendix 1**)
3. Performed spirometry within the past 5 years.
4. At least one outpatient or inpatient ICD-9 or ICD-10 diagnostic code for COPD within the past 2 years
   i. ICD-9 codes: 491.XX, 492.XX, 496.XX, excluding 493.X
   ii. ICD-10 codes: J41.0, J41.1, J41.8, J42., J43.0, J43.1, J43.2, J43.8, J43.9, J44.0, J44.1, J44.9

We will exclude patients meeting **ANY** of the following criteria at the time of the CDW data query:

1. Severe fixed airflow obstruction as defined by a post-bronchodilator FEV1/VC <0.70 *and* FEV1 <30% predicted.[4] If no post-bronchodilator spirometry values are available, then pre-bronchodilator values will be substituted.
2. Severe or frequent exacerbations in the past year, defined as:[4]
   a. 1 or more inpatient COPD exacerbation defined using ICD-9 or ICD-10 diagnostic codes.
      i. Primary discharge code of COPD (ICD-9 codes: 491.XX, 492.XX, 496.XX, or 493.2; ICD-10 codes: J41.0, J41.1, J41.8, J42., J43.0, J43.1, J43.2, J43.8, J43.9, J44.0, J44.1, J44.9)

      OR

ii. Primary discharge code of acute respiratory failure (ICD-9: 518.81, 518.82, 518.84; ICD-10: J80., J96.00, J96.01, J96.02, J96.20, J96.21, J96.22, J96.90, J96.91, J96.92)
AND
Secondary discharge diagnosis code of COPD (ICD-9: 491.XX, 492.XX, 496.XX, or 493.2; ICD-10: J41.0, J41.1, J41.8, J42., J43.0, J43.1, J43.2, J43.8, J43.9, J44.0, J44.1, J44.9)

b. 2 or more outpatient COPD exacerbations, defined as:
   i. A clinic visit, ED visit or Urgent Care visit with an ICD-9 or ICD-10 code of COPD ***and*** an outpatient prescription for an oral corticosteroid **(Appendix 1)** within 2 days (before or after encounter)

   Or

   ii. A clinic visit, ED visit or Urgent Care visit with an ICD-9 or ICD-10 code of COPD ***and*** no prescription for oral corticosteroids ***but*** an outpatient prescription for an oral respiratory antibiotic (**Appendix 1**) within 2 days (before or after encounter) ***and*** no ICD-9 or ICD-10 code indicating the presence of:
      1. urinary tract infection (ICD-9: 590.X, 595.X, 597.X; ICD-10: A56.01, N10., N11.X, N12., N13.6, N15.1, N15.9, N16., N28.84, N28.85, N28.86, N30.0, N30.1, N30.2, N30.3, N30.4, N30.8, N30.9, N34.X)
      2. skin and soft tissue infection: (ICD-9: 680.X, 681.X, 682.X, 683.X, 684, 685.X, 686.X; ICD-10: B78.1, E83.2, K12.2, L01.0X, L01.1, L02.XXX, L03.XXX, L04.X, L05.0X, L05.9X, L08.0, L08.8X, L08.9, L88., L92.8, L98.0, L98.3)
      3. Acute sinusitis (ICD-9: 461.X, 473.X; ICD-10: J01.XX, J32.X)
      4. Pneumonia (ICD-9: 481.X, 482.X, 483.X, 484.X, 485.X, 486; ICD-10: ICD-10: A22.1, A37.01, A37.11, A37.81, A37.91, A48.1, B25.0, B44.0, B77.81, J13., J14., J15.XXX, J16.0, J16.8, J17., J18.0, J18.1, J18.8, J18.9)

3. Presence of likely asthma, defined as:
   a. ICD-9 or ICD-10 diagnostic code for asthma (ICD-9: 493.X; ICD-10: J45.20, J45.21, J45.22, J45.30, J45.31, J45.32, J45.40, J45.41, J45.42, J45.50, J45.51, J45.52, J45.901, J45.902, J45.909, J45.990, J45.991, J45.998)

   Or

   b. Post-bronchodilator increase in FEV1 >12% and 375 ml from pre-bronchodilator values (based on GINA guidelines that indicate a high probability of comorbid asthma)[16]

4. Deceased as of the query date

8.2. Recruitment and Consent
Primary Care Providers:

Intervention: This project was designated as a quality improvement (QI) initiative by the VA Office of Specialty Care Services. We will attempt to reach all PCPs at the VA Puget Sound Health Care System and Edith Nourse Memorial VA Medical Center. PCPs will not be provided an opportunity to opt-out of this QI initiative, though they can choose to participate or not in the survey and qualitative portions of the study.

- Prior to study start, we will query CDW to create a list of all primary care PACT teams and eligible providers, this list will be updated on a regular basis to identify PCPs that have left as well as newly eligible PCPs.
- All eligible PCPs will be included in the intervention study.

Quantitative Surveys: We will invite all eligible PCPs to participate in baseline and follow-up surveys that will provide information regarding their perception of inhaled corticosteroid use, efficacy and adverse effects.

- Approximately 1 week prior to survey recruitment start, the primary care directors at each site will send an introductory email to all eligible PCPs that includes an explanation of the project and purpose of the anticipated survey.
- PCPS will be recruited via email invitation 1-2 months prior to their planned entry into the trial (baseline survey), again at 12 months, and at study end (follow-up surveys). The email invitation will include a unique link to the online survey.
- Following the initial emailed invitation, we will mail out up to 4 additional reminder emails at 1-week intervals. The final reminder email will be accompanied by a personalized message by one or more of the study investigators.
- PCPs who do not respond after the final reminder email will be assumed to not want to participate in that survey.
- PCPs who do not respond to the baseline survey will still be eligible to complete the follow-up surveys unless they specifically request no further contact.

Qualitative Interviews: In a similar manner, we will invite eligible PCPs to participate in telephone interviews in 3 separate waves. We will attempt to recruit and interview equal numbers of providers at both sites. However, we anticipate that more VA Puget Sound providers will participate due to the significantly higher number of providers at this site.

- Wave 1: We will invite PCPs to participate in baseline interviews prior to intervention start.
- Wave 2:
    - *Intervention PCPS*: PCPs who have been "exposed" to the intervention, defined as having received 3 or more pulmonary E-consult interventions, will be invited to participate in "post-exposure" interviews. PCPs do not have to have "accepted" intervention recommendations in order to be eligible for these interviews. We will email interview invitations to PCPs withing 1-2 weeks after meeting the exposure criteria.
    - *Control PCPs*: PCPs randomized to the control group will be contacted to complete interviews using an interview guide derived from the baseline interview guide. PCPs assigned to this group who already participated in the baseline interviews will not be contacted again.

- Wave 3: All PCPs who have completed post-exposure interviews will be invited via email to participate in a "maintenance" telephone interview, timed 18-26 months following a provider's site entry date. This timeline may change based on findings from Wave 2 and/or to meeting project needs.

Patients:

Randomized Intervention Trial: The DISCuS intervention is a variant of usual-care with no direct patient interaction. All recommendations made by the intervention team for patients assigned to intervention providers are acted upon directly by the patient's primary care clinician. As a result, there will be no attempt to consent patients to participate in the quality improvement initiative.

- Once weekly, we will query CDW to create an updated list of all eligible patients and twice weekly identify patients with appointments in the next 1-3 weeks with a participating PACT provider.
- Among the eligible patients, if there are greater than 6 patients in the intervention arm, then each patient will be assigned a randomly generated number (via SQL) and only the 6 lowest-numbered intervention patients will be included in the study at that time. These patients will be assigned an index clinic date and have their charts reviewed at that week's collaborative review meeting(s). The remaining patients will re-enter the pool of eligible patients.

Qualitative Interviews: Patients of intervention-exposed PCPs will be purposively sampled and recruited to participate in qualitative interviews timed approximately 3 months post-intervention.

- To be eligible, patients: 1) will need to be identified by the DISCuS collaborative review team for the deprescribing intervention; 2) have had an order to de-implement ICS signed by their PCP; and 3) have attended their targeted clinic appointment.
- Patients will be excluded from interview recruitment after chart review if there is documentation in the medical record of active suicidal or aggressive behavior, cognitive issues, homelessness, current inpatient hospitalization, or co-occurring interventions (i.e. current enrollment in COPD research).
- Patient interview recruitment will be evenly spaced throughout the year to control for seasonal factors that may affect COPD symptoms.
- Patients will be mailed invitations. Patients not returning an opt-out card will be contacted by phone to determine interest in completing the interview.

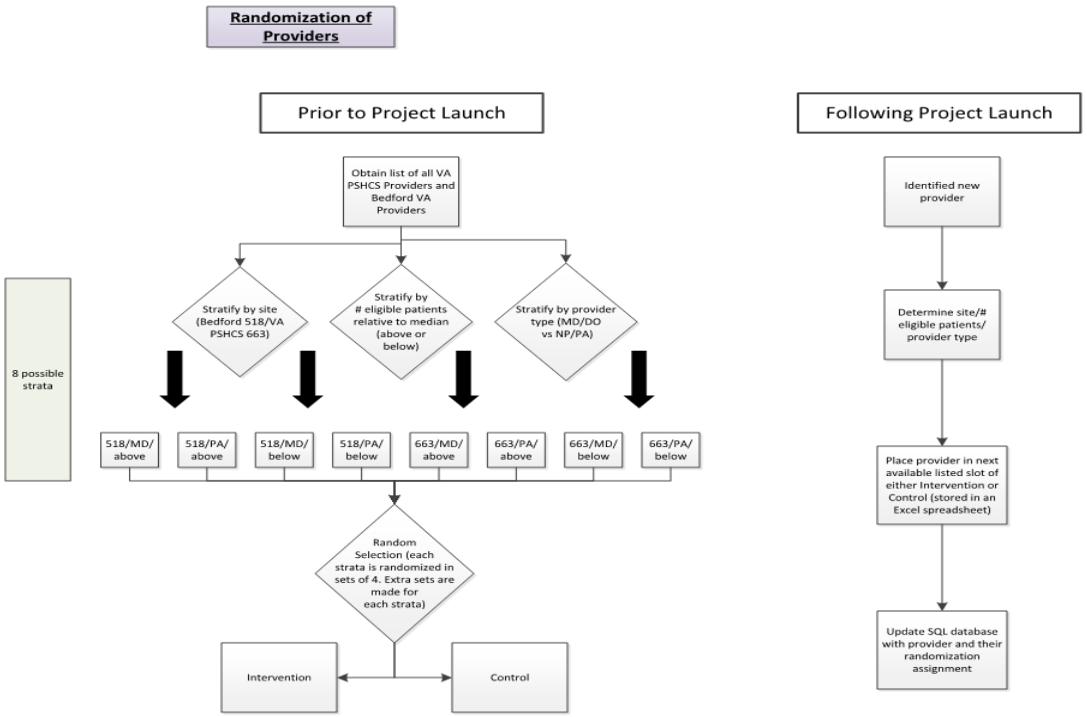
8.3. Randomization

The unit of randomization will be at the level of the primary care PACT team. Randomization will occur at the team level to help avoid issues with contamination across study arms. At study start, we will stratify PACT teams (composed of 1 or more PCPs) into eight separate strata (**Figure**). These strata will be defined by site (Seattle vs. Bedford), provider type (physician vs. advanced practice provider), and into "small" or "large" teams based on the median number of eligible patients identified. If the number of eligible patients for a PACT team is equal to the median, then the team will be randomly assigned to either the "small" or "large" stratum to help ensure balance across the eight strata. Within strata, PACT teams will then be randomly assigned in blocks of 4 to either the

intervention arm or the usual care arm of the study. These blocks will be determined using randomly generated sequences (i.e. ICIC, IICC, CIIC, etc., where I=intervention and C=usual care arm).

If a provider belongs to multiple PACT teams, their randomization will be based on their team with the most eligible patients. If there are equal number of eligible patients across their PACT teams, then the PACT team with the greatest panel size will be used for randomization. The providers' other teams will assume the same study arm. After study launch, the level of randomization will move to the level of the individual provider, and their randomization assignment will differ depending on situation.

i. If a previously randomized PCP moves to a new PACT team, they will retain their original randomization assignment.
ii. If a new PCP joins an existing PACT team that has been previously randomized, that PCP will be assigned to the same study arm as the existing PACT team providers.
iii. If a PACT is provider-less (e.g. when a PCP leaves VA), then the PACT will be re-randomized based upon the correct strata when a new PCP is assigned (i.e. defined by location, provider type and eligible patient count). The PCP (and his/her associated PACT(s)) will be added to the next available pre-randomized slot that will be created by the study biostatistician at the time of initial randomization.
iv. If a new PACT team is created for a new PCP, we will determine the correct strata for that PCP based upon their location, provider type and eligible patient count. The PCP (and his/her associated PACT(s)) will then be added to the next available pre-randomized slot that will be created by the study biostatistician at the time of initial randomization.



9. Index Clinic Date

Eligible patients with a qualifying appointment as of the time of the weekly collaborative team meeting will be assigned an index clinic date. For patients assigned to intervention PCPs, this index clinic date corresponds to the date of their scheduled primary care visit following receipt of the intervention. Patients assigned to PCPs in the usual care arm with an upcoming primary care appointment in the same week as the collaborative review meeting will also be assigned an index clinic date. Patients who are assigned to either arm who subsequently cancel, re-schedule or no-show to their clinic appointment will retain this original index date.

10. Intervention Arm

10. 1 Non-intensive unlearning:
Prior to study start, the Collaborative Review Team will attend a primary care staff meeting and provide a 10-15 minute academic detailing session that includes information about: 1) evidence for the use of inhaled corticosteroids to reduce exacerbations and symptoms among specific groups of patients with COPD; 2) risks associated with their use, and 3) distinguishing appropriate from potentially inappropriate use of ICS among patients with COPD.

10.2 Recommendations for discontinuation of inappropriate ICS:
Each week, for eligible patients identified with an upcoming appointment with an intervention primary care provider, we will perform the following:

Chart abstraction: A project coordinator will copy pertinent sections of the EHR into an abstraction template (**Appendix 2**). These abstractions will include smoking status, lists of current medications, discharge summaries, notes from primary care, pulmonary, and the emergency department, as well as the results of pulmonary function tests, laboratory tests, and imaging studies.

Clinical review: The collaborative review team (consisting of pulmonologists and project coordinators) will meet to review the chart abstraction, discuss the patient's history, determine if the patient is inappropriately prescribed an inhaled corticosteroid, and formulate recommendations for any changes to the patient's inhaled therapies (e.g. discontinuation of ICS and substitution of inhaled long-acting bronchodilators).

Recommendations to the patient's inhaled therapies will be categorized as followed:

1) "Recommendations" will be made when the review team feels that there is sufficient history available to endorse a specific inhaled medication regimen for a particular patient. These recommendations will be accompanied by unsigned orders for the clinician to sign/modify/or discontinue as they see fit (described below).

    a. A recommendation will be considered "conditional" if it is dependent upon a specific criteria being met (e.g. the teams' understanding that the patient has not had any recent exacerbations of their COPD).
2) "Considerations" will be made in circumstances when the review team feels they are unable to strongly endorse a specific inhaled medication regiment for a particular patient. Examples of these circumstances may include scenarios where there is insufficient history available in the chart to identify if the patient has an indication to remain on an ICS, or if a change is not necessarily appropriate now, but may be it the future.
    a. A consideration may be considered "conditional" if it is dependent upon a specific criteria being met (e.g. after a period of continued stability with no further exacerbations, it may be appropriate to discontinue the patient's ICS at a later date).

The team may also make additional recommendations relevant to the patient's pulmonary condition. For example, for patients found to have no evidence of COPD, the team may include recommendations for additional work-up or pulmonary consultation.

Entering recommendations with or without orders into the EHR: We will provide the PCP with recommendations in the form of an E-consult timed to coincide with the patient's upcoming index clinic visit (**Appendix 3**). The E-consult will be performed/signed by one of the study team pulmonologists and include:

1) A brief introductory paragraph that identifies the clinical team members, the intervention, and instructions on how to contact the study team with any questions or concerns.
2) Specific recommendations for changes to the patient's inhaled therapies and the rationale and evidence behind those recommendations.
3) Links to evidence-based guidelines that support the recommended changes to the patient's inhaled therapies.

The patient's PCP will be added as an additional signer on the E-consult note, prompting a view alert than ensures that they receive the recommendations. If the patient has a pulmonologist they will be included as an additional signer on the E-consult note as well. Clinicians will be encouraged to reach out to the study team with questions or concerns.

At the same time that the E-consult is placed in the EHR, we will enter unsigned orders on behalf of the PCP that correspond to recommendations contained within the E-consult. These unsigned orders will prompt an additional view alert to the PCP. These orders can then be signed, modified or discontinued by the PCP as appropriate based on their personal knowledge of the patient's clinical condition. This process ensures that the PCP maintains autonomous care of the patient. As noted above, if additional clinical context is needed prior to making a recommendation, we will instead offer only "considerations" and will not enter any related orders on behalf of the PCP.

10.3 Titration to wean off Inhaled Corticosteroids

Patients prescribed budesonide 160/formoterol 4.5 mcg (the most commonly used LABA/ICS in the formulary) will be provided with a titration plan to taper off inhaled corticosteroids by initiating a

once daily dose of mometasone 220 mcg for one month.[17] Note: as of March 2017, additional data has emerged that this is potentially not necessary.[18] As a result, we will now taper inhaled corticosteroids on a case by case basis (e.g. for patients with recent exacerbations and/or high respiratory symptom burden)

11. Usual Care Arm

Providers assigned to the usual care arm will attend the academic detailing session described above. We will not perform chart abstraction or formulate recommendations for patients assigned to usual care providers. Patients assigned to usual care PCPs will continue to receive inhaled medications and management of their COPD from their PCPs and/or pulmonologists.

12. Blinding

The investigators and participants will be unblinded as to intervention arm. This decision was made based on several factors, including: 1) Blinding is impractical as intervention/clinical staff and physician investigators must know the patient and provider names in the intervention group in order to access the electronic medical record to input orders and notes. Clinician participants can also not be blinded because receiving an unexplained intervention would not be acceptable in a clinical setting. 2) This is an operations project that is designed to deliver evidence-based care previously shown to be effective and the majority of our resources should be used to implement the intervention.

Data collection to assess outcomes in CDW will occur in a blinded fashion using SQL queries that do not incorporate intervention arm. This allows an unbiased assessment of our primary and secondary outcomes across the two arms. Chart abstraction will be utilized to collect data on the subset of outcomes that will be collected only among the intervention arm. This data collection will necessarily occur in an unblinded fashion.

13. Outcomes

13.1 Primary Outcome Measure: Percentage of patients with discontinued, or expired and not renewed, ICS that remain off at 6 months (index date + 180 days).

- We will assess this measure using detailed prescription data extracted from the VA Corporate Date Warehouse (CDW). All patients who no longer have an active ICS order at 6 months (defined as index date + 180 days), will be considered to be "off" ICS.
    - Percentage of patients that remain off ICS at 6 months will be calculated for each study arm as: (# of patients off ICS/# of patients) *100.
- Patients who died prior to end of follow-up are considered to be "off" ICS

13.2 Secondary Outcome Measures:

Among patients in both study arms:

- **Rate of COPD Exacerbation at 6 months** [defined as (index date + 1 day) to (index date + 180 days)]:
    - The rate of exacerbation at 6 months after index date (index date + 180 days) will be assessed for each study arm as: total #of inpatient or outpatient exacerbations participant time post index date.
    - *Inpatient exacerbations* will be defined as:
        - Primary ICD-9/ICD-10 discharge diagnostic code of COPD (ICD-9: 491.XX, 492.XX, 496.XX, 493.2; ICD-10: J41.0, J41.1, J41.8, J42., J43.0, J43.1, J43.2, J43.8, J43.9, J44.0, J44.1, J44.9)

        Or

        - Primary ICD-9/ICD-10 discharge diagnostic code of acute respiratory failure (ICD-9: 518.81, 518.82, 518.84; ICD-10: J80., J96.00, J96.01, J96.02, J96.20, J96.21, J96.22, J96.90, J96.91, J96.92) and secondary diagnosis of COPD (ICD-9: 491.XX, 492.XX, 496.XX, or 493.2; ICD-10: J41.0, J41.1, J41.8, J42., J43.0, J43.1, J43.2, J43.8, J43.9, J44.0, J44.1, J44.9)
    - *Outpatient exacerbations* will be defined as:
        - A clinic visit, ED visit or Urgent Care visit with an ICD-9 or ICD-10 code of COPD ***and*** an outpatient prescription for an oral corticosteroid within 2 days (before or after encounter)

        Or

        - A clinic visit, ED visit or Urgent Care visit with an ICD-9 or ICD-10 code of COPD ***and*** no prescription for oral corticosteroids ***but*** an outpatient prescription for an oral respiratory antibiotic within 2 days (before or after encounter) ***and*** no ICD-9 or ICD-10 code indicating the presence of:
            - urinary tract infection (ICD-9: 590.X, 595.X, 597.X; ICD-10: A56.01, N10., N11.X, N12., N13.6, N15.1, N15.9, N16., N28.84, N28.85, N28.86, N30.0, N30.1, N30.2, N30.3, N30.4, N30.8, N30.9, N34.X)
            - skin and soft tissue infection: (ICD-9: 680.X, 681.X, 682.X, 683.X, 684, 685.X, 686.X; ICD-10: B78.1, E83.2, K12.2, L01.0X, L01.1, L02.XXX, L03.XXX, L04.X, L05.0X, L05.9X, L08.0, L08.8X, L08.9, L88., L92.8, L98.0, L98.3)
            - Acute sinusitis (ICD-9: 461.X, 473.X; ICD-10: J01.XX, J32.X)
            - Pneumonia (ICD-9: 481.X, 482.X, 483.X, 484.X, 485.X, 486; ICD-10: ICD-10: A22.1, A37.01, A37.11, A37.81, A37.91, A48.1, B25.0, B44.0, B77.81, J13., J14., J15.XXX, J16.0, J16.8, J17., J18.0, J18.1, J18.8, J18.9)

- **Rate of Pneumonia at 6 months** [defined as (index date + 1 day) to (index date + 180 days)]:
    - The rate of pneumonia will be assessed for each study arm as:
        - number of new pneumonia cases/participant time post index date.
    - Inpatient pneumonia events will be defined as:

        - ICD-9 or ICD10 code: (ICD-9: 481.X, 482.X, 483.X, 484.X, 485.X, 486; ICD-10: A22.1, A37.01, A37.11, A37.81, A37.91, A48.1, B25.0, B44.0, B77.81, J13., J14., J15.XXX, J16.0, J16.8, J17., J18.0, J18.1, J18.8, J18.9)
    - Outpatient pneumonia events will be defined as:
        - ICD-9 or ICD-10 code Dx (ICD-9: 481.X, 482.X, 483.X, 484.X, 485.X, 486; ICD-10: A22.1, A37.01, A37.11, A37.81, A37.91, A48.1, B25.0, B44.0, B77.81, J13., J14., J15.XXX, J16.0, J16.8, J17., J18.0, J18.1, J18.8, J18.9)

- **Mortality at 6 months** [defined as (index date + 1 day) to (index date + 180 days)]:
    - Mortality will be assessed for each study arm as a percentage: total # deaths /# of patients *100.
    - Mortality will be determined by the presence of a date of death occurring between the (index date + 1 day) and (index date + 180 days)

Among patients in the intervention arm only:

- Among intervention patients who meet entry and exclusion criteria (collected at time of recommendations/order entry):
    - Number of participants receiving recommendations
    - Number of participants receiving recommendation to stop ICS

- Percentage of recommendations accepted by PCPs within 6 months (index date + 180 days)
    a. (Number of accepted recommendations/total recommendations made) * 100
    b. Separated by medication type: ICS recommendation & acceptance rate, LABA recommendation & acceptance rate, etc. for all meds within the study scope.
        i. Recommendation is defined as:
            1. Recommended care stated in an EHR note or consult for which an order is entered by the project team.
        ii. An accepted recommendation is defined as an order being signed by the primary care provider during the index date to (index date + 180 days).
        iii. Order data will be extracted from the VA's CDW, post-index date, to determine status (signed vs unsigned).
        iv. This data will be supplemented by data abstracted from the EHR to allow for collection of acceptance rates for recommendations other than those for medications (e.g. pulmonary referral or repeat imaging).

- Percentage of patients where recommendations to discontinue ICS are accepted but restarted by 6 months (180 days) post-index date.
    a. Among all patients where PCP accepted initial recommendation to stop ICS.
    b. Evaluate whether patient was restarted on ICS at 6 months (index date + 180 days).
    c. Pharmacy order and prescribing data will be extracted from the VA's CDW for the period between index date and (index date + 180 days) to determine status.

d. ICS is considered restarted at 6 months (180 days) if between index date and (index date + 180 days)
    i. Initial ICS order is discontinued and
    ii. A new ICS order is signed or a prescription order or dispense date exists.
e. This data will be supplemented by data abstracted from the EHR, to help determine reasons for restarting medications.

Additional secondary outcomes:

Maintenance (to be assessed post-project intervention):

1. Assess whether PCPs prescribe ICS appropriately for new patients with COPD who do not receive our direct intervention.
    a. Use CDW to identify new cohort of patients among intervention PACTs that have not received the intervention.
        i. Study-eligible patients not under care of a study PACT/PCP during the intervention period.
        ii. Patients with COPD already under care of a study PACT/PCP that become eligible following the intervention period.
    b. Assess for temporal changes in the control group (measuring contamination).

Using a combination of surveys and qualitative interviews, the following implementation outcomes will also be assessed among PCPs: 1) burnout; 2) professional efficacy; 3) perception of evidence to support the use of ICS among patients with COPD; and 3) acceptability of the intervention. Among patients, acceptability of the intervention will also be assessed.

Adoption: The qualitative team will examine factors related to adoption, including patient and operational barriers and the fidelity of the implementation.

Implementation Costs: The economic core will develop budget impact analyses and assess the implementation costs of the intervention.

14. Additional Assessments

14.1 Baseline Characteristics

We will utilize CDW to identify the following sociodemographic information for PCPs:

- Provider type (MD vs advanced practice provider)
- Associated PACT team and location

We will utilize CDW to identify/calculate the following for eligible patients:

- Sociodemographic information (age, race, gender)
- Height, weight and body mass index
- Elixhauser Comorbidities: Collected for the year prior to the index date

- Prior inpatient and outpatient COPD exacerbations (defined above) in the year prior to index date
- Prior inpatient and outpatient pneumonia events (year prior to index date)
- Hospitalizations within the year prior to index date: including length of stay, ICU status, and use of non-invasive or invasive mechanical ventilation
- Health factors: Most recent smoking status known prior to the index date.
- Detailed prescription data for inhaled medications in the year prior to the index date
- Pulmonary clinic visits in the year prior to index date

In addition, we will utilize a combination of CDW and EHR chart abstraction to identify spirometry performed in the 5 years prior to index date.

14.2 Qualitative Interviews

We will utilize a semi-structured guides to interview primary care providers by telephone at different 3 timepoints: 1) baseline, prior to planned intervention activities (**Appendix 4**) 2) after "exposure" to the intervention, with "exposure" defined as receipt of 3 pulmonary e-consultations (**Appendix 5**) and 3) in the maintenance phase (**Appendix 6**), 18-26 months following a provider's site entry date. The interview guides are intended to explore PCP's experiences with prescribing ICS for COPD, familiarity with evidence and guidelines for prescribing ICS, and views on discontinuation of ICS. The interview guides are informed by the de-implementation and implementation literature, and include key constructs such as understanding the evidence for and against a clinical practice, [19-21] psychological reactance,[22,23] and organizational context that support clinical change.[19-22]

We will similarly utilize semi-structured guides to interview patients assigned to intervention PCPs at a single time point, approximately 3 months post-intervention (**Appendix 7**).

The interview guides for PCPs and patient participants include open ended-questions and semi-structured probes to assure uniform data collection of key topics while allowing exploration of emerging unanticipated themes. All interviews will be audio-recorded and transcribed verbatim for analysis.

14.3 Quantitative Surveys

Quantitative surveys will be administered to participating PCPs via REDCap at baseline (**Appendix 8**), 12 months following inclusion in the intervention trial (**Appendix 9**), and at the end of the study (**Appendix 10**). The surveys will be used to elicit clinician perspectives on their experience with ICS to treat patients with COPD (e.g. frequency of use, efficacy, and adverse effects), perceptions of discontinuing ICS in mild-moderate COPD, as well as their intention for use of ICS in the following 6 months to treat patients with COPD. Additional information will also be collected about leadership and management behaviors, job-related feelings, turnover intentions, and demographics. Select questions from the Maslach Burnout Inventory will be adopted,[24] in order to assess trends and

direct future quality improvement initiatives. We will have all necessary employee unions review and approve the survey instrument and interview guides prior to administration.

15. Analytic Approach

Analysis overview*:* This is a cluster-randomized trial with patients nested within individual provider who are nested within teams. This type of design invalidates many of the standard approaches to assess patient-level randomized trials because of the correlation that exists between patients cared for by one clinician within a team. It is reasonable to expect that patients within a physician's practice are likely not to be independent of one another. This effect, depending on intra-physician correlations, means that naïve model-based standard errors that assume independence between patients will be incorrect. As a result, confidence intervals and p-values based on those standard errors would not be valid. Hierarchical modeling methods, using generalized linear mixed model (GLMM), will be necessary to assess the effect of the intervention while taking into account the potential correlation between patients seeing the same physician. The primary hypothesis to be tested is that the intervention will lead to a decrease in the inappropriate use of inhaled corticosteroids (ICS).

Statistical analysis will occur in two phases. First, provider level descriptive profiles will be constructed on primary and secondary outcome variables to assess trends and identify potential outliers. Second, we will fit GLMM models and conduct hypothesis testing analyses for the specific aims as described below.

15.1. Baseline Analysis and Descriptive Statistics

Equivalence of participants and providers in the intervention and control arms will be assessed on demographic and clinical variables, including outcomes, health status, co-morbidity, and utilization variables. Because this is a randomized controlled trial, no systematic bias is anticipated. However, we will adjust for the covariates where a statistically significant difference is found and related to the primary and secondary outcomes. We will report summary statistics for all baseline covariates and outcomes (means, standard deviations, and quartiles for continuous variables; frequencies and percentages for binary variables) by randomized treatment group.

Data Analysis: **The primary outcome measure for this study will be whether or not a patient remains off ICS at 180 days post targeted PCP visit (index date)**. The important factors in the study design are: Treatment Group, PACT Team, PCP, and Patient. Initial randomization will occur at the level of the PACT, with an anticipated 1:1 relationship between PACT and PCPs. Following study start, the unit of randomization will move to the level of the PCP. PCPs with more than one PACT will have all PACTs assigned to the same study arm. For these reasons, ~~it~~ it is clustering of patients within provider that we will be primarily concerned with in this analysis, as grouping by PACTs would not provide additional meaningful information. We will use the patient as the unit of analysis, and use generalized linear mixed effect model (GLMM) to account for clustering of patients within PCP.

GLMM is an extension of traditional regression techniques that accounts for the effect of clustering as well as for important confounding factors found to not be balanced between the treatment and control groups at baseline. A GLMM approach will allow us to estimate the effect of the randomization group on patient outcome.

A multivariable model will be constructed based on the outcome of whether the given patient was not on ICS at 180 days after the targeted PCP visit, with randomization group and any variables found to be imbalanced across arms as adjustment covariates (mixed-effects logistic regression model). The intervention will be considered statistically significant if the indicator variable for the intervention group is significantly associated with a change in the odds of a patient being off ICS at 180 days after the PCP visit. The GLMM model for this analysis:

$$\ln\left(\frac{\pi_{ij}}{1-\pi_{ij}}\right) = \beta_0 + \beta_1 \text{treatment}_\text{j} + \gamma_j(1)$$

Whereπ_{ij} is the probability of patient *i* within the jth provider staying off ICS at 180 days after the targeted PCP visit, β_1 is an indicator variable equal to 1 if provider *j* is in the intervention group and 0 if the provider is in the control group, and γ_j corresponds to the random intercept for the jth provider. The random intercepts are assumed to be identically distributed independent draws from a mean-zero Normal distribution with unknown variance.

15.2 Sensitivity Analyses

In addition to the primary analyses, sensitivity analyses will be conducted using Generalized Estimating Equations (GEE) which account for clustering within the data by allowing for the specification of a correlation structure if the assumptions of GLMMs are not met.

15.3 Missing data analyses

All appropriate efforts will be made to avoid missing data. For example, accruing data will be monitored for the presence of missing values, and the study manager and coordinators will investigate causes and/or remedies for missing data. For key analysis variables that have 15% or more missing values, we will analyze patient and clinical factors that are associated with having a missing value. We will then perform our primary analyses using multiple imputation to impute these key variables to allow analysis for all subjects and reduce any bias associated with the missing data.

15.4 Secondary Analyses

Summary statistics (counts and percentages) will be computed for the following outcome variables that will be collected following baseline:

1. Number and percentage of patients that meet entry criteria
    a. Number and percentage of patients that meet entry criteria overall

b. Number and percentage of patients that meet entry criteria and are recommended to stop ICS
2. Number and percentage of patients for whom the substituted recommendations are accepted.
3. Number and percentage of patients where ICS recommendation accepted but restarted by 180 post index visit

Further data analysis will also be performed for secondary outcome measures. The procedure that is outlined above for the analysis of the primary outcome variable will be followed for the binary secondary outcome measures listed below. For each variable listed, model (1) will be modified to instead include the listed secondary variable as the outcome variable in the model.

1. COPD exacerbation within 180 days
2. Pneumonia within 180 days
3. Mortality within 180 days

We will perform additional sensitivity analysis assessing number of COPD exacerbations using mixed-effects zero-inflated Poisson regression models and time-to-COPD exacerbation and pneumonia using mixed-effects Cox proportional-hazards regression models.

Further secondary analysis will include summary statistics used to evaluate PCP burnout, professional efficacy, perceptions of evidence for the use of ICS, acceptability of the intervention to PCPs, implementation costs, and maintenance of the intervention.

15.5 Sample Size and Power

For a cluster randomized control trial, the hypothesis that will be tested is H_o: $P_1 = P_2$, where P_1 and P_2 are the population success rates in the experimental group and control groups, respectively. According to Friedman 2010,[25] the total number of subjects required for the study is

$$n = \frac{2\left[Z_{\alpha/2}\sqrt{2\bar{P}(1-\bar{P})} + Z_{\beta}\sqrt{P_1(1-P_1)+P_2(1-P_2)}\right]^2 [1+(m-1)\rho]}{(P_1-P_2)^2}, \qquad (1)$$

where ρ is the intracluster correlation, m is the number of individuals in each cluster randomly assigned either the experimental group or control group, $Z_{\alpha/2}$ is the $\alpha/2$ th quantile of the standard normal distribution function and Z_{β} is the βth quantile of the standard normal distribution function. Solving for $1-\beta$ we find the equation for power is

$$1-\beta = \Phi^{-1}\left(\frac{\sqrt{\frac{n(P_1-P_2)^2}{2(1+(m-1)\rho)}} - Z_{\alpha/2}\sqrt{2\bar{P}(1-\bar{P})}}{\sqrt{P_1(1-P_1)+P_2(1-P_2)}}\right)$$

We further define k to be the number of clusters, where $k = n/m$.

Results:

Assuming the total number of patients is ~700, two variables can vary, ρ the intracluster correlation and k the number of clusters. We see in the all scenarios (ρ varying between 0.1, 0.2, 0.3, 0.4) and with $P_1 = 1$, $P_2 = .5$, $\alpha = .05$ and k = 120, 60 or 30, that the power exceeds 99.9%.

Assuming 130 (80%) participating providers, ~700 patients, a conservative estimate of 50% of patients remaining off ICS in the intervention group, α of 0.05 , and a coefficient of variation of 0.1, we estimate our power to be in excess of 95%.

15.6. Mixed-methods Analysis: Quantitative Survey and Qualitative Data Analysis

We will utilize sequential mixed methods using qualitative interview findings to inform subsequent development of quantitative survey questions. Qualitative analysis of baseline interviews will be conducted using iterative deductive and inductive content analysis methods.[26] Deductive analysis will involve application of *a priori* codes based on key construct definitions from the de-implementation literature and the interview guide questions.[19-22] Inductive content analysis will consist of open and unstructured coding to capture data that does not fit into *a priori* categories. Emergent codes will be added throughout the analysis, allowing us to identify emergent and previously unidentified or unexpected themes. Broad themes will be identified based on representative interview responses and grouped to describe distinct aspects of patient's experiences. The qualitative team will meet weekly to discuss data and reach consensus on interpretation of themes and findings. Findings will then inform adaptation of the PCP surveys.

Following survey data collection, we will use convergent mixed methods to identify qualitative data (from both patient and clinician interviews) that enhances our understating of the survey findings or indicates potential generalizability of the qualitative findings.[27]

16. Protection of Human Subjects

16.1 Quality Improvement Designation

This project was designated as a quality improvement (QI) initiative by the VA Office of Specialty Care Services. As such, we will not obtain informed consent from primary care providers or their patients as part of the clinical trial.

16.2 Data and Safety Monitoring

Adverse events: As this was a quality improvement intervention, we will not systematically assess for all adverse events. We will assess relevant safety outcomes of exacerbations (inpatient, outpatient, and combined), pneumonia events (inpatient, outpatient, and combined), and mortality.

16.3 Recommendation fidelity

At study start, all participating pulmonologists will attend joint review meetings and discussion and reach consensus about wording of recommendations, orders, and standardized language to use for the intervention. We will ensure that coordinators have detailed instructions on how to enter notes

and/or orders into the EHR for intervention patients. We will require coordinators to consult with a study clinician before entering any information in the EHR about which they have any questions.

16.4 Data management and confidentiality

This project requires the creation, maintenance, and analysis of a large, multivariate, database that includes a variety of measures from multiple sources. Recognizing that the success of this study critically depends on the quality of the data collected, systematic data collection, quality control, and data management procedures, we will implement: 1) specification and use of concise protocols; 2) rigorous training, certification, and periodic re-training of study personnel, with on-going monitoring of adherence to data collection and handling protocol; 3) validation and verification of all data, and 4) regular meetings and progress reports to provide specific, well-documented feedback to project personnel concerning potential difficulties as well as follow-up to ensure that problems are resolved quickly.

We will assign all participants a unique study ID. The master list will be stored separately from the data and accessible only by study staff. For clinical note abstractions, we will not remove identifiers because that material is copied verbatim, making it difficult to ensure that any reference to names, location, and dates were removed. We believe it is safer to acknowledge that identifiers will be present, and to carefully adhere to our strict protocol to store the abstracted notes on a secure server accessible only by authorized staff. Chart abstracted notations will not be entered into the study database.

We will store data in strong password protected environment on the secure VA network server.

For provider on-line surveys, we will e-mail a link that populates data on the VA secure server. Data will be secured at the database level, using a role-based and record-level security model.

We will store data on paper in secure, locked file cabinets within secure offices. Any communications between study staff and provider participants regarding patient care will occur via encrypted e-mail.

17. References

1. Au DH, McDonell MB, Martin DC, Fihn SD. Regional variations in health status. *Med Care*. Aug 2001;39(8):879-88.
2. Fihn SD, McDonell MB, Diehr P, et al. Effects of sustained audit/feedback on self-reported health status of primary care patients. *Am J Med*. Feb 2004;116(4):241-8. doi:S0002934303007150 [pii] 10.1016/j.amjmed.2003.10.026
3. Collins BF, Ramenofsky D, Au DH, Ma J, Uman JE, Feemster LC. The association of weight with the detection of airflow obstruction and inhaled treatment among patients with a clinical diagnosis of COPD. C*hest.* Dec 2014;146(6):1513-20. doi:10.1378/chest.13-2759
4. From the G*lobal Strategy for the Diagnosis, Management and Prevention of COPD,* Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017. Available from: http://www.goldcopd.org/.
5. Kew KM, Seniukovich A. Inhaled steroids and risk of pneumonia for chronic obstructive pulmonary disease. C*ochrane Database Syst Rev.* 2014;3:CD010115. doi:10.1002/14651858.CD010115.pub2

6. Calverley PM, Anderson JA, Celli B, et al. Salmeterol and fluticasone propionate and survival in chronic obstructive pulmonary disease. *N Engl J Med.* Feb 2007;356(8):775-89. doi:356/8/775 [pii] 10.1056/NEJMoa063070
7. Wedzicha JA, Calverley PM, Seemungal TA, et al. The prevention of chronic obstructive pulmonary disease exacerbations by salmeterol/fluticasone propionate or tiotropium bromide. Am *J Respir Crit Care Med.* Jan 2008;177(1):19-26. doi:200707-973OC [pii]10.1164/rccm.200707-973OC
8. Loke YK, Cavallazzi R, Singh S. Risk of fractures with inhaled corticosteroids in COPD: systematic review and meta-analysis of randomised controlled trials and observational studies. *Thorax. A*ug 2011;66(8):699-708. doi:10.1136/thx.2011.160028
9. Cumming RG, Mitchell P, Leeder SR. Use of inhaled corticosteroids and the risk of cataracts. *N* E*ngl J Med. J*ul 1997;337(1):8-14. doi:10.1056/NEJM199707033370102
10. Ernst P, Baltzan M, Deschênes J, Suissa S. Low-dose inhaled and nasal corticosteroid use and the risk of cataracts. *Eur Respir J. J*un 2006;27(6):1168-74. doi:10.1183/09031936.06.00043005
11. Slatore C, Bryson C, Au D. The association of inhaled corticosteroid use with serum glucose concentration in a large cohort. *Am J Med. M*ay 2009;122(5):472-8. doi:S0002-9343(08)01187-X [pii] 10.1016/j.amjmed.2008.09.048
12. Wagner EH. Chronic disease management: what will it take to improve care for chronic illness? *Eff Clin Pract. 19*98 Aug-Sep 1998;1(1):2-4.
13. Wagner EH, Austin BT, Davis C, Hindmarsh M, Schaefer J, Bonomi A. Improving chronic illness care: translating evidence into action. Research Support, Non-U.S. Gov't. *Health Aff (Millwood). No*v-Dec 2001;20(6):64-78.
14. Wagner EH, Glasgow RE, Davis C, et al. Quality improvement in chronic illness care: a collaborative approach. Evaluation Studies Research Support, Non-U.S. Gov't. *Jt Comm J Qual Improv. Fe*b 2001;27(2):63-80.
15. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health. Se*p 1999;89(9):1322-7.
16. From *the Global Strategy for Asthma Management and Prevention and the Global Strategy for the Diagnsois, Management, and Prevention of Chronic Obstructive Pulmonary Disease. D*iagnosis of diseases of Chronic Airflow Limitation: Asthma, COPD, and Asthma-COPD Overlap Syndrome 2015. Available from http://www.goldcopd.org/.
17. Magnussen H, Disse B, Rodriguez-Roisin R, et al. Withdrawal of inhaled glucocorticoids and exacerbations of COPD. *N Engl J Med. Oc*t 02 2014;371(14):1285-94. doi:10.1056/NEJMoa1407154
18. Wedzicha JA, Banerji D, Chapman KR, et al. Indacaterol-Glycopyrronium versus Salmeterol-Fluticasone for COPD. *N Engl J Med. 06* 09 2016;374(23):2222-34. doi:10.1056/NEJMoa1516385
19. Kitson AL, Rycroft-Malone J, Harvey G, McCormack B, Seers K, Titchen A. Evaluating the successful implementation of evidence into practice using the PARiHS framework: theoretical and practical challenges. Impl*ement Sci. Ja*n 07 2008;3:1. doi:10.1186/1748-5908-3-1
20. Rycroft-Malone J, Seers K, Titchen A, Harvey G, Kitson A, McCormack B. What counts as evidence in evidence-based practice? *J Adv Nurs. Ju*l 2004;47(1):81-90. doi:10.1111/j.1365-2648.2004.03068.x
21. McCormack B, Kitson A, Harvey G, Rycroft-Malone J, Titchen A, Seers K. Getting evidence into practice: the meaning of 'context'. *J Adv Nurs. Ap*r 2002;38(1):94-104. doi:10.1046/j.1365-2648.2002.02150.x
22. Morgan DJ, Brownlee S, Leppin AL, et al. Setting a research agenda for medical overuse. *BMJ. Au*g 25 2015;351:h4534. doi:10.1136/bmj.h4534
23. Helfrich CD, Rose AJ, Hartmann CW, et al. How the dual process model of human cognition can inform efforts to de-implement ineffective and harmful clinical practices: A preliminary model of unlearning and substitution. *J Eval Clin Pract. 02* 2018;24(1):198-205. doi:10.1111/jep.12855
24. Maslach C, Jackson S, Leiter M. Maslach Burnout Inventory Manual. Third Edition. Menlo Park: Mind Garden. 2010.
25. Friedman. *Fundamentals of Clinical Trials. 4th Edition.* Chapter 8. p.139, 157-158. 2010.
26. Elo S, Kyngäs H. The qualitative content analysis process. *J Adv Nurs. Ap*r 2008;62(1):107-15. doi:10.1111/j.1365-2648.2007.04569.x
27. Creswell J, Plano Clark V. Designing and conducting mixed methods research(2nd ed.). Thousand Oaks, CA: Sage; 2011.

18. Summary of Changes from Original Protocol

- 07/19/2016: Patient exclusion criteria: diagnosis of asthma
    - Clarified that asthma diagnoses identified in intervention patients at the time of chart review (in problem list or from chart abstraction) will not exclude them from the intervention; This change was made in order to ensure that patients assigned to providers in both arms are treated the same.
- 09/13/2016: Change in treatment of clinic cancellations/no-shows
    - Previously planned to not assign an index date for patients that cancelled/no-showed their clinic appointments after the collaborative review meeting, but follow them for six additional months to determine if had eligible clinic visit before permanently excluding them; Changed to assigning these patients an index date corresponding to the planned visit that was cancelled/no-showed. This change is consistent with an intention-to-treat approach, as intervention patients would have already had a note/unsigned orders placed in the chart.
- 09/20/2016: Clarification of categorization of recommendations
    - Clarified categorization of recommendations for outcome assessment into "recommendations" and "considerations", each with potential to also be "conditional."
- 10/18/2016: Frequency of data pulls and team reviews
    - Changed from interrogating EHR for upcoming primary care appointments for eligible patients from once to twice weekly.
- 12/05/2016: Patient eligibility criteria
    - Patients can be targeted for an index visit if they are found to have a scheduled appointment at least 7 days prior to the occurrence of an appointment
- 12/06/2016: Patient eligibility criteria
    - Patients assigned to intervention PCPs previously were noted to be eligible to participate in interviews 3 months following their index date. Eligibility criteria clarified to ensure that patients interviewed included only those who had had their ICS de-implemented.
- 02/01/2017: Patient eligibility criteria: Definition of fixed airflow obstruction
    - The definition of fixed airflow obstruction was changed from post-bronchodilator FEV1/FVC <0.70 to post-bronchodilator FEV1/VC <0.70, indicating that for the denominator, either the post-bronchodilator FVC or SVC could be used, whichever is greater.
- 02/07/2017: Number of eligible patients each week
    - Changed from maximum of 3 patients per arm each week to be assigned an index date to a maximum of 6 patients per arm; increased meetings of collaborative team from once to twice weekly.
- 03/14/2017: Change in recommendations to taper off ICS

- Based on re-evaluation of available evidence, Investigators decided to no longer routinely recommend tapering off inhaled corticosteroids due to its complexity and lack of known efficacy. Case by case basis used to decide if tapering appropriate (e.g. if patients had recent exacerbations and/or high respiratory symptom burden, etc.)

- 05/11/2017: Patient eligibility criteria
  - ICD-9 Diagnostic code 493.2x (chronic obstructive asthma) was added to the list of exclusionary ICD-9 codes (previously missed); exclusionary code now written as 493.X
- 05/23/2017: Change in patient eligibility criteria for qualitative interview
  - Prior to this date, intervention and control patients were considered to be possibly eligible to participate in qualitative interviews. Criteria were changed so that only patients assigned to intervention PCPs were to be interviewed.
- 05/26/2017: Templated E-consult note change
  - Templated text changed to include a request that PCP discuss any medication changes with their patients at their upcoming appointment. This change was prompted by instances of orders/notes being signed by PCP and patients not being made aware of change.
- 11/28/2017: Clarification: PCP Survey Eligibility
  - Clarified that all active PCPs are eligible to receive follow-up surveys (not just those that received baseline surveys).
- 01/03/2018: Clarification of randomization process
  - Clarified that if a PCP/PACT has a number of eligible patients equal to the median # of eligible patients identified for a PACT that they would be randomly assigned to "small" or "large" stratum.
- 5/21/2018: Patient eligibility criteria
  - Changed exclusion criteria to FEV1 <30% predicted from <50% predicted based on updated GOLD guidelines (severity of airflow limitation alone no longer an indication for prescription of inhaled corticosteroids; team decided to still exclude those with very severe airflow obstruction).
  - Updated background section of protocol to reflect most recent evidence
- 10/16/2020: Outcome assessment and Analyses
  - Decided to supplement CDW data with EHR abstraction to ensure data quality of recommendation acceptance and assess non-pharmacologic recommendations
  - Changed outcome assessment period for secondary outcomes from (index date + 180 days) to (index date + 1 day) to (index date + 180 days)
  - No longer plan to stratify exacerbation rates by presence or absence of airflow obstruction
  - No longer plan to account for clustering of PCPs within PACT team within GLMM analysis. This decision was made because at the initial randomization there was 1:1 relationship between PCPs and PACTS (making them synonymous) and following initial randomization the unit of randomization was the PCP. This means that

accounting for clustering within PCP sufficiently accounts for clustering within PACT team as well; and adding the PACT team to the analysis would not add additional meaningful information.
    - We initially planned a primary analysis restricted to participants who complete the study and have fully observed outcomes and covariates (complete case analysis). However, after finding an imbalance in smoking status between groups, smoking status was included as an additional covariate in our GLMM analysis. Due to ~ 5% missingness of this covariate, we performed our primary analysis using multiple imputation with chained equations.
    - Additional sensitivity analyses added to account for counts of COPD exacerbations (using mixed-effects zero-inflated Poisson regression models) and time-to-COPD exacerbation and pneumonia (using mixed-effects Cox proportional-hazards regression models).
- 12/1/2021: Made corrections to protocol to clarify secondary outcomes
    - Rate of exacerbation: denominator changed to reflect "participant time" rather than "number of participants"
    - Rate of pneumonia: removed reference to events/patient and left only correct definition of rate (inpatient or outpatient pneumonia events/participant time since index).
    - Mortality: incorrectly labeled as rate rather than percentage; corrected.

Appendix 1: Medications

Medication Classification	Medications included
Inhaled Corticosteroids	Beclomethasone Dipropionate 40 mcg/actuation and 80mcg/actuation (oral)
	Budesonide 0.5 mg/2ml inhaled suspension (oral)
	Budesonide 90 mcg/inhalation and 200 mcg/inhalation (oral)
	Flunisolide 250 mcg/spray (oral)
	Fluticasone Propionate 220 mcg/spray (oral)
	Mometasone Furoate 220mcg/inhalation (oral)
	Triamcinolone 75 mcg/inhalation (oral)
	Budesonide 80 mcg/Formoterol 4.5 mcg/spray
	Budesonide 160 mcg/Formoterol 4.5 mcg/spray
	Fluticasone 100mcg/Salmeterol 50 mcg/spray
	Fluticasone 115mcg/Salmeterol 21 mcg/spray
	Fluticasone 250mcg/Salmeterol 50 mcg/spray
	Fluticasone 500mcg/Salmeterol 50 mcg/spray
	Formoterol 5mcg/Mometasone 100 mcg/inhalation
	Formoterol 5mcg/Mometasone 200 mcg/inhalation
Oral Corticosteroids	Cortisone Acetate 10 mg and 25 mg tablets
	Hydrocortisone 5 mg, 10 mg, and 20 mg tablets
	Methylprednisolone 2 mg, 4 mg, and 8 mg tablets
	Prednisolone Na phosphate 6.75 mg/ml oral solution
	Prednisolone 5 mg tablets
	Prednisone 5mg/5ml oral solution
	Prednisone 1 mg, 2.5 mg, 5 mg, 10 mg, 20 mg, 50 mg tablets
	Triamcinolone 2 mg and 4 mg tablets
Oral Respiratory Antibiotics	Fluroquinolones Gatifloxacin 200mg and 400 mg tablets Lomefloxacin 400 mg tablets Ofloxacin 200 mg, 300 mg, and 400 mg tablets Ciprofloxacin 250 mg, 500 mg, and 750 mg tablets Levofloxacin 250 mg, 500 mg, and 750 mg tablets Moxifloxacin 400 mg tablets Norfloxacin 400 mg tablets
	Macrolides Azithromycin 250 mg and 600 mg tablets Clarithromycin 250 mg and 500 mg tablets Erythromycin 125 mg/5ml, 200mg/5ml, 250 mg/5ml and 400mg/5ml oral suspension Erythromycin 200 mg, 250 mg and 400 mg tablets
	Sulfonamides Sulfamethoxazole 200 mg/trimethoprim 40 mg/5ml suspension Sulfamethoxazole 400 mg/trimethoprim 80 mg tab Sulfamethoxazole 800 mg/trimethoprim 160 mg tab Co-trimoxazole single strength tab
	Tetracyclines

	Demeclocycline 150 mg and 300 mg tablets Doxycycline 50 mg and 100 mg tablets Minocycline 50 mg and 100 mg capsules Tetracycline 250 mg capsules Tetracycline 125mg/5ml syrup
	Cephalosporins Cefadroxil 500 mg capsule Cephalexin 250 mg/5 ml suspension Cephalexin 250 mg and 500 mg capsules Cefaclor 250 mg capsule Cefuroxime 250 mg and 500 mg tablets Loracarbef 400 mg capsule Cefdinir 300 mg capsule Cefpodoxime proxetil 100 mg and 200 mg tablets
	Beta-Lactams Penicillin V K 250 mg tablet Penicillin V K 250 mg/5mg solution Dicloxacillin 250 mg capsule Oxacillin 250 mg capsule Amoxicillin 250 mg/5 ml suspension Amoxicillin 250 mg and 500 mg capsules Amoxicillin 250mg/Clavulanate 125 mg tablets Amoxicillin 500mg/Clavulanate 125 mg tablets Amoxicillin 875mg/Clavulanate 125 mg tablets Amoxicillin 250mg/Clavulanate 62.5 mg/5 ml suspension Amoxicillin 600mg/Clavulanate 42.9 mg/5 ml suspension Ampicillin 250 mg and 500 mg capsules Ampicillin 250mg/5ml suspension Bacampicillin 400 mg tablets

Appendix 2. Chart Abstraction Form

Date of abstraction: Click for date. **Abstractor(s):**
Links:
Patient Information
Admissions (Discharge Notes) PFTs
Primary Care Visit Labs
Pulmonary Visit Medications
ED Visit Imaging

Upcoming pulm consult or PFTs:

Patient: **Station:** Choose an item. **Last 4 SSN:**					
PCP: **Team/Location:**				**Appointment Date/Time:**	
Age:	**Sex:** Click here.	**Race:** Choose an item.	**Ht (in):**	**Wt (lbs):**	**BMI:**
Mark if Asthma is on the Problem List in the last 1 year: ☐					
Smoking Status:		**Smoking cessation counseling (last 1 year):** **Date Received:** Click to enter a date. **Provided by:** Choose an item. **Provider name:**			

Hospital Discharges: *Notes from past 1 year. Indicate if patient has history of older respiratory-related discharge notes* Back to top

Outpatient Medications: *Paste in Medication list from CPRS. Includes current, recently expired and discontinued. (Recent/current **short** course of Prednisone? Check for ED eval note). If available, include last 2 or 3 **ICS** med refill dates below the meds.* Back to top

PFT: *Collect worst and additional 2 most recent.* Back to top *LLN calculator link: http://www.biostat.jhsph.edu/courses/bio622/misc/calculate.htm*
Check box if FEV_1/FVC is below 0.7 ☐
CXR Chest 2 view: *Most recent report* Back to top
CT Scan Chest: *Most recent report* Back to top

Echo: *Most recent report* Back to top

Labs: Back to top

1. IgE (most recent)
2. White blood cell count w/differential (most recent)
   "Diff, Automated 5-Part (& Cbc)", include only values for: Wbc, NE%, Ly%, Mo%, Eo%, Ba%, Ne#, Ly#, Mo#, Eo#, Ba#
3. CO_2 (most recent)

Primary Care Visits : *Notes from past 1 year* Back to top

Outpatient Pulmonary Visits: ***most recent note. Could be listed as a Pulmonary outpatient visit or Pulmonary consult report*** **Back to top**

Emergency Department Visit : *Note from past 1 year related to ED visit for* ***COPD*** Back to top

Appendix 3: E-Consult Note Template

Pulmonary Non-visit E-Consult Note

As part of an ongoing quality improvement initiative (DISCuS COPD) within pulmonary, our team has reviewed your patient's medical record to review their use of inhaled corticosteroids. Our team from pulmonary medicine includes Drs. David Au (VAPSHCS), Laura Feemster (VAPSHCS), Renda Wiener (Bedford VA), and Seppo Rinne (Bedford VA).

We have entered any recommendations as orders for you to review, modify as you see fit and sign, if agreeable. If you have questions, please feel free to contact us by encrypted e-mail (VHAPUGSVCICS@va.gov), CPRS, Pulmonary SCAN-ECHO, or E-Consult.

RECOMMENDATIONS:
1. [*enter recommendation to stop inhaled corticosteroid if not indicated (may include taper off of ICS)*]
2. [*enter recommendation for substitution of long-acting bronchodilator(s) if indicated*]
3. [*enter any additional recommendations*]

Please discuss any medication changes that you make with this patient in their upcoming visit with you.

RATIONALE:
[*provide summary of patient's history and current inhaled medication regimen*]

[*provide rationale for recommended changes in inhaled therapies]* For example: Recent guidelines advocate that in the absence of frequent exacerbations (defined below) patients with COPD should be treated primarily with long-acting bronchodilators and to reserve the addition of inhaled corticosteroids for patients with frequent exacerbations. Inhaled corticosteroids have been shown in multiple randomized trials to increase the risk of pneumonia among patients with COPD.

Frequent exacerbations are defined as 2 or more outpatient exacerbations in the past year **AND/OR** 1 or more inpatient exacerbations in the past 1 year. For patients with COPD that are not controlled with one long-acting bronchodilator, combination LABA/LAMA is preferred therapy over LABA/ICS combinations.

Additional information can be found at:

WISDOM Trial
http://www.nejm.org/doi/full/10.1056/NEJMoa1407154

FLAME Trial:
http://www.nejm.org/doi/full/10.1056/NEJMoa1516385

*GOLD guidelines 2017, available from:
http://goldcopd.org/gold-2017-global-strategy-diagnosis-management-prevention-copd/

*VA/DOD Clinical Practice Guideline for the Management of Outpatient Chronic

Obstructive Pulmonary Disease, Version 3.0, 2014, available from:
http://www.healthquality.va.gov/guidelines/cd/copd/
Summary:
http://www.healthquality.va.gov/guidelines/CD/copd/VADoDCOPDClinicianSummary.pdf
Pocket Card:
http://www.healthquality.va.gov/guidelines/CD/copd/VADoDCOPDPocketCard.pdf

End of note

Appendix 4: Baseline Provider Interview Guide

Grounded prompts: If responses are limited or require clarification, probes may be used to elicit more detailed responses. Probes should use words or phrases presented by the participant using one of the following formats:

What do you mean by _____?
Tell me more about _____?
Can you give me an example of _____?
Tell me about a time when _____?
Can you tell me who _____?
Can you clarify the type of inhaler _____?

Throughout the interview we'll be referring to inhaled corticosteroids as ICS. Is this okay?

- What is your current position?
  [If needed] What are your main responsibilities?
  [If needed] When did you start this role?

- How do you define mild COPD?
  [*If needed*] How do you define moderate COPD?

- Tell me about your experience prescribing ICS for mild COPD.

- Tell me about your experience prescribing ICS for moderate COPD.

- Have you had patients who have ICS prescriptions from other providers?
  [If Yes] Tell me about discontinuing ICS with these patients.
  [If needed] Have you had patients who request ICS prescriptions based on recommendations from non-VA providers?
  [If needed] When another provider has prescribed ICS, how do you decide whether to discontinue a prescription?

- Tell me about the evidence related to prescribing ICS for mild COPD.
  [If needed] Tell me about the evidence related to prescribing ICS for moderate COPD.

- How clear are the guidelines for prescribing ICS for COPD?

This study is looking at improving patient safety through De-Implementing ICS for Mild COPD by recommending that providers discontinue prescribing ICS for mild-to-moderate COPD.

- Are you familiar with this recommendation?

- What is your impression of this recommendation?

- Tell me about the evidence related to discontinuing the prescribing of ICS for mild-to-moderate COPD.
- Who should be involved in reducing unnecessary prescribing of ICS in patients with mild-to-moderate COPD?
  [If needed] How should they be involved?

- Please describe the patient's role in discontinuing ICS.
  [If needed] What attitudes or preferences do patients express regarding ICS for mild-to-moderate COPD?

- How do you think your patients with mild-to-moderate COPD would respond to discontinuing ICS?
  [If needed] Can you give me an example of a time when you discontinued ICS with a patient, and the discussion you had with the patient?

- Do you have any questions for us, or is there anything else you would like to add?

Appendix 5: "Exposed" Provider Interview Guide

Grounded prompts: If responses are limited or require clarification, probes may be used to elicit more detailed responses. Probes should use words or phrases presented by the participant using one of the following formats:

What do you mean by _____?
Tell me more about _____?
Can you give me an example of _____?
Tell me about a time when _____?
Can you tell me who _____?
Can you clarify the type of inhaler _____?

We will be referring to the program as DISCUSS.

- What is your current position?
  [If needed] What are your main responsibilities?
  What is your role with discontinuing ICS?
  When did you start this role?

- Please tell me about your experience prescribing ICS for mild to moderate COPD.

- Please tell me about your experience with the DISCUSS program.
  How satisfied have you been with the DISCUSS program?
  Have you received recommendations regarding inhalers from other providers?
  [As needed] How well does DISCUSS fit with your practice?

- How aware do you think other prescribers at your site are regarding the recommendations to stop using ICS?
  Who else at your site do you discuss reducing the use of ICS with?
  How receptive do you think other providers at your site have been to reducing the use of ICS?

- *[As needed]* How easy or difficult has it been to follow through recommendations to stop prescribing ICS for mild to moderate COPD?
  Were there any challenges to following through on recommendations to stop using ICS?
  What, if anything, made following through on recommendations to stop using ICS easier?

- Was there anything that surprised you about stopping the use of ICS?

- Have you had patients who have ICS prescriptions from other providers?
  [If yes] Tell me about discontinuing ICS with these patients.
  Have you had patients who request ICS prescriptions based on recommendations from non-VA providers?
  When another provider has prescribed ICS, how do you decide whether to discontinue a prescription?

- Tell me about the effect of discontinuing ICS on patient care.
  Tell me about the patient experience of de-implementing ICSs.

- Please describe the evidence related the use of ICS for mild to moderate COPD?
  What are the risks associated with ICSs?
  What alternatives to ICSs are available?
  [If needed] Please describe the evidence related to not using ICS for mild to moderate COPD?

- How useful was the training for de-implementing ICS?

- What types of unintended consequences have you noticed from discontinuing ICS?

- Please describe the patient's role in determining ICS use?
- What attitudes or preferences do patients express regarding ICS use?
- How do you think your patients with mild to moderate COPD would respond to discontinuing ICS?
  Can you give me an example of a time when you discontinued ICS with a patient, and the discussion you had with the patient?
- How have you felt about receiving these orders from Pulmonology? [Feasibility & Sustainability]
- Would you like to see pulmonologists continue to provide this kind of proactive outreach in the form of unsigned orders?
- At your facility, how involved has leadership been in the DISCUSS program?
- Is there anything else you would like us to know about these practices changes? Is there anyone else you would suggest we talk to regarding this project?
- Do you have any questions for us?

Appendix 6: "Maintenance" Provider Interview Guide

[Grounded prompts: If responses are limited or require clarification, probes may be used to elicit more detailed responses. Probes should use words or phrases presented by the participant using one of the following formats:
1. What do you mean by _____?
2. Tell me more about _____?
3. Can you give me an example of _____?
4. Tell me about a time when _____?
5. Can you tell me who _____?
6. Can you clarify the type of inhaler _____?

We will be referring to the program as DISCUSS.

The DISCUSS COPD intervention involved Pulmonology initiating e-consults to PCPs with ICS treatment recommendations for Veterans with mild-to-moderate COPD.

- Please tell me about your experience with the DISCUSS program.
    a. How satisfied have you been with the DISCUSS program?
    b. Have you received recommendations regarding inhalers from other providers?
    c. Have you received any additional orders from Pulmonology?

- *[As needed]* How well does DISCUSS fit with your practice? [Acceptability]
    a. How aware do you think other prescribers at your site are regarding the recommendations to stop using ICS?
    b. Who else at your site do you discuss reducing the use of ICS with?
    c. How receptive do you think other providers at your site have been to reducing the use of ICS?

- *[As needed]* How easy or difficult has it been to follow through recommendations to stop prescribing ICS for mild to moderate COPD? [Feasibility]
    a. Were there any challenges to following through on recommendations to stop using ICS?
    b. What, if anything, made following through on recommendations to stop using ICS easier?

- After receiving a few of these orders, how has this influenced your approach to using ICS with other patients [with mild-to-moderate COPD]?

- Tell me about the effect of discontinuing ICS on patient care.

- Have you had patients who have ICS prescriptions from other providers?
    a. [IF Yes] Tell me about discontinuing ICS with these patients.
    b. Have you had patients who request ICS prescriptions based on recommendations from non-VA providers?
    c. When another provider has prescribed ICS, how do you decide whether to discontinue a prescription?

- How are patients with mild to moderate COPD responding to discontinuing ICS?
    a. Can you give me an example of a time when you discontinued ICS with a patient, and the discussion you had with the patient?
    b. What attitudes or preferences do patients express regarding ICS use?

- Was there anything that surprised you about stopping the use of ICS?

- What types of unexpected changes have you noticed from discontinuing ICS?

- How did you feel about getting the notes and suggestions as pre-completed orders from the pulmonologists? [Feasibility & Sustainability]

- If this program were to continue in the future, would you like to see pulmonologists continue to provide this kind of proactive outreach in the form of unsigned orders?
    a. What do you think could be changed or improved?

- How has this program been received?

- How has leadership been involved in the DISCUSS program.

- Is there anything else you would like us to know? Is there anyone else you would suggest we talk to regarding this project?

- Do you have any questions for us?

Thank you very much for your time.

Appendix 7: "Exposed" Patient Interview Guide

Grounded prompts: If responses are limited or require clarification, probes may be used to elicit more detailed responses. Probes should use verbatim words or phrases presented by the participant using one of the following formats:

What do you mean by _____?
Can you tell me more about _____?
Can you give me an example of _____?
Can you tell me about a time when _____?

- Do you see a doctor about your breathing?
- Do you use any inhalers for your breathing?

[If yes]

a. What is the type or name of the inhalers you use?
b. Under what circumstance do you use your inhalers(s)?
c. How often do you use your inhaler?

[If no]

a. Have you used inhalers in the past?
b. What type or name of the inhalers did you use?
c. Under what circumstance did you use your inhalers(s)?
d. When did you stop using your inhaler?

- Has there been a time you wanted an inhaler and you did not have it?
- Has your inhaler prescription changed within the last few months?

[If yes] Tell me about the change.

- Can you tell me about a time when you got too much care?
- Can you tell me about a time when you didn't get enough care?
- Is there anything we should have asked you about inhalers that we did not?
- Do you have any questions for us, or is there anything else you would like to add?

DISCUSS COPD Baseline Provider Survey

Please complete the survey below for the De-implementing Steroids to Improve Care and Safety in COPD (DISCUSS COPD) project. Thank you!

Inhaled corticosteroids (ICS) are recommended to treat some patients with chronic obstructive pulmonary disease (COPD). We want to better understand VA providers' perspectives on ICS use for patients with mild to moderate COPD.

1. In the past month, I have prescribed an inhaled corticosteroid for one or more primary care patient with mild to moderate COPD.
   - ◯ Yes
   - ◯ No

Experience

This section asks about the use of ICS by patients with mild to moderate COPD.

		Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree	Don't Know/Not Applicable
2.	Use of long-acting muscarinic antagonist (LAMA) or long-acting beta agonist (LABA) is as effective as use of ICS in reducing risk of COPD exacerbation.	◯	◯	◯	◯	◯	◯
3.	Use of ICS by patients with COPD results in higher risk of pneumonia than use of a LAMA and/or LABA.	◯	◯	◯	◯	◯	◯
4.	Use of LAMA and/or LABA by patients with mild to moderate COPD has a higher cardiovascular risk than use of an ICS.	◯	◯	◯	◯	◯	◯
5.	COPD should be treated the same as asthma.	◯	◯	◯	◯	◯	◯
6.	I am unlikely to take a patient off of ICS if another provider wrote the prescription.	◯	◯	◯	◯	◯	◯
7.	Reducing use of ICS by patients with mild to moderate COPD is supported by my clinical experience.	◯	◯	◯	◯	◯	◯
8.							

Reducing use of ICS for patients with mild to moderate COPD takes into consideration the needs and preferences of my patients and their family members.	○	○	○	○	○	○

Intention

In the next 6 months, for patients with mild to moderate COPD, I will:

		Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree	Don't Know/Not Applicable
9.	Make greater use of LAMAs and/or LABAs.	○	○	○	○	○	○
10.	Make efforts to reduce ICS prescriptions.	○	○	○	○	○	○
11.	Find ways of managing breathing issues with approaches other than medications.	○	○	○	○	○	○

Context

In the past year, how frequently have you observed the following sets of behaviors in senior leadership or clinical management (e.g., Clinic Director, Chief of Staff, Director) in your clinic?

		Very Infrequently	Infrequently	Neither Frequently Nor Infrequently	Frequently	Very Frequently	Don't Know/Not Applicable
12.	Reward clinical innovation and creativity to improve patient care.	○	○	○	○	○	○
13.	Promote team building to solve clinical care problems.	○	○	○	○	○	○
14.	Establish clear goals for patient care processes and outcomes.	○	○	○	○	○	○
15.	Encourage and support changes in practice patterns to improve patient care.	○	○	○	○	○	○

The following questions are about improving care for primary care patients.

		Very Infrequently	Infrequently	Neither Frequently Nor Infrequently	Frequently	Very Frequently	Don't Know/Not Applicable
16.	How frequently have you observed your colleagues from the clinic exhibit a sense of personal responsibility for improving patient care and outcomes?	○	○	○	○	○	○
17.	When change needs to happen to improve patient care, how frequently have you or your colleagues had the necessary resources such as budget, training, staffing, facilities or protected time?	○	○	○	○	○	○

Work Life

This section contains statements about job-related feelings. Please check the appropriate box to tell us how frequently you feel this way.

		Never	A Few Times Per Year	Once a Month or Less	A Few Times Per Month	Once a Week	A Few Times Per Week	Every Day
18.	I feel burned-out from my work.	○	○	○	○	○	○	○
19.	I worry that this job is hardening me emotionally.	○	○	○	○	○	○	○
20.	I have accomplished many worthwhile things in this job.	○	○	○	○	○	○	○

Turnover

		Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree	Don't Know/Not Applicable
21.	If I were able, I would leave my current job.	◯	◯	◯	◯	◯	◯
22.	I plan to leave my job within the next six months.	◯	◯	◯	◯	◯	◯

About You

23. How long have you been with VA?

- ◯ Less than 6 months
- ◯ Between 6 months and 1 year
- ◯ Between 1 and 2 years
- ◯ Between 2 and 5 years
- ◯ Between 5 and 10 years
- ◯ Between 10 and 15 years
- ◯ Between 15 and 20 years
- ◯ More than 20 years

24. What is your level of supervisory responsibility?

- ◯ None
- ◯ Team Leader (informal; not responsible for performance ratings)
- ◯ First Line Supervisor (formal; rates performance, e.g.: Foreman, Section Chief)
- ◯ Manager (formal; rates performance e.g.: Division/Department/Service/Care Line managers)
- ◯ Executive (formal; rates performance e.g.: Associate Director, Chief of Staff, Program Director, Nurse Executive)
- ◯ Senior Executive (formal; rates performance e.g.: Network Director, Facility Director, Chief Medical Officer, Chief Officer, Deputy)

25. Is there anything else you would like us to know?

_____

Thank you for your assistance in completing this survey.

For further questions, please contact:

Christian Helfrich, MPH PhD at
christian.helfrich@va.gov

DISCUSS COPD Follow up Provider Survey

Please complete the survey below for the De-implementing Inhaled Steroids to Improve Care and Safety in COPD (DISCUSS COPD) project. Thank you!

In the past 12 months, you may have received information and advice about the potential value of reducing the use of inhaled corticosteroids in patients with chronic obstructive pulmonary disease (COPD) for whom this therapy may not be the best practice. Included in the information you received were details about the benefit of changing this prescribing practice for some patients, and the potential reduction in pneumonia among this population.

We want to better understand VA providers' perspectives on inhaled corticosteroids (ICS) use for COPD.

Experience

The first questions ask about use of ICS by patients with mild-to-moderate COPD.

In the past month, I have prescribed an inhaled corticosteroid for one or more primary care patient with mild-to-moderate COPD.	◯ Yes ◯ No

---

	Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree	Don't Know/Not Applicable
Use of a long-acting muscarinic antagonist (LAMA) and/or long-acting beta agonist (LABA) is as effective as use of ICS in reducing risk of COPD exacerbation.	◯	◯	◯	◯	◯	◯
Use of ICS by patients with COPD results in higher risk of pneumonia than use of a LAMA and/or LABA.	◯	◯	◯	◯	◯	◯
Use of LAMA and/or LABA by patients with mild to moderate COPD has a higher cardiovascular risk than use of an ICS.	◯	◯	◯	◯	◯	◯
COPD should be treated the same as asthma.	◯	◯	◯	◯	◯	◯
I am unlikely to take a patient off of ICS if another provider wrote the prescription.	◯	◯	◯	◯	◯	◯
Reducing use of ICS by patients with mild to moderate COPD is supported by my clinical experience.	◯	◯	◯	◯	◯	◯

Reducing use of ICS for patients with mild to moderate COPD takes into consideration the needs and preferences of my patients and their family members.	○	○	○	○	○	○

Patient Response

In the past 6 months, have you proposed discontinuing or reducing an ICS prescription for one of your patients with mild-to-moderate COPD

○ Yes
○ No

	Very Receptive	Somewhat Receptive	Neither Receptive nor Unreceptive	Somewhat Unreceptive	Very Unreceptive	Don't Know/Not Applicable
If YES, how did the patient respond?	○	○	○	○	○	○

	Continued	Reduced Dosage	Switched to another medication	Discontinued
For this patient was the medication	○	○	○	○

Comments: _____

In the past 6 months, have you proposed discontinuing or reducing other prescriptions for one of your patients?

○ Yes
○ No

	Very Receptive	Somewhat Receptive	Neither Receptive nor Unreceptive	Somewhat Unreceptive	Very Unreceptive	Don't Know/Not Applicable
If YES, how did the patient respond?	○	○	○	○	○	○

	Continued	Reduced Dosage	Switched to another medication	Discontinued
For this patient was the medication	○	○	○	○

Comments: _____

Provider Response

If you received information and advice about the potential value of reducing the use of inhaled corticosteroids in patients with COPD, did you feel:

	Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree	Don't Know/Not Applicable
Irritated	○	○	○	○	○	○
Angry	○	○	○	○	○	○
Annoyed	○	○	○	○	○	○

	No, Strongly Disagree	No, Disagree	Neither Agree nor Disagree	Yes, Agree	Yes, Strongly Agree	Don't Know/Not Applicable
Did you criticize information you received about efforts to reduce ICS use among patients with COPD?	○	○	○	○	○	○
Can you think of points that go against efforts to reduce ICS use among patients with COPD?	○	○	○	○	○	○
Are you skeptical of efforts to reduce ICS use among patients with COPD	○	○	○	○	○	○

Is there anything else you would like us to know?

Thank you for your assistance in completing this survey.

For further questions, please contact:

Christian Helfrich, MPH PhD at
christian.helfrich@va.gov

DISCUSS COPD Provider Survey

Please complete the survey below for the De-implementing Inhaled Steroids to Improve Care and Safety in COPD (DISCUSS COPD) project. Thank you!

In the past 12 months, you may have received information and advice about the potential value of reducing the use of inhaled corticosteroids in patients with chronic obstructive pulmonary disease (COPD) for whom this therapy may not be the best practice. Included in the information you received were details about the benefit of changing this prescribing practice for some patients, and the potential reduction in pneumonia among this population.

We want to better understand VA providers' perspectives on inhaled corticosteroids (ICS) use for COPD.

Use of inhaled corticosteroids (ICS) by patients with mild-to-moderate COPD:

In the past month, I have prescribed an ICS for one or more primary care patient(s) with mild-to-moderate COPD.

◯ Yes
◯ No

	Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree	Don't Know/Not Applicable
Use of a long-acting muscarinic antagonist (LAMA) and/or long-acting beta agonist (LABA) is as effective as use of ICS in reducing risk of COPD exacerbation.	◯	◯	◯	◯	◯	◯
Use of ICS by patients with COPD results in higher risk of pneumonia than use of a LAMA and/or LABA.	◯	◯	◯	◯	◯	◯
Use of LAMA and/or LABA by patients with mild to moderate COPD has a higher cardiovascular risk than use of an ICS.	◯	◯	◯	◯	◯	◯
COPD should be treated the same as asthma.	◯	◯	◯	◯	◯	◯
I am unlikely to take a patient off of ICS if another provider wrote the prescription.	◯	◯	◯	◯	◯	◯
Reducing use of ICS by patients with mild to moderate COPD is supported by my clinical experience.	◯	◯	◯	◯	◯	◯

Reducing use of ICS for patients with mild to moderate COPD takes into consideration the needs and preferences of my patients and their family members.	◯	◯	◯	◯	◯	◯

Discontinuing or reducing an ICS prescription and patients' emotional reactance to the precription change:

In the past 6 months, have you proposed discontinuing or reducing an ICS prescription for one of your patients with mild-to-moderate COPD

◯ Yes
◯ No

	Very Receptive	Somewhat Receptive	Neither Receptive nor Unreceptive	Somewhat Unreceptive	Very Unreceptive	Don't Know/Not Applicable
If YES, how did the patient respond?	◯	◯	◯	◯	◯	◯

	Continued	Dosage Reduced	Switched to another medication	Discontinued
For this patient was the medication	◯	◯	◯	◯

Comments: _____

In the past 6 months, have you proposed discontinuing or reducing other prescriptions for one of your patients?

◯ Yes
◯ No

	Very Receptive	Somewhat Receptive	Neither Receptive nor Unreceptive	Somewhat Unreceptive	Very Unreceptive	Don't Know/Not Applicable
If YES, how did the patient respond?	◯	◯	◯	◯	◯	◯

	Continued	Dosage Reduced	Switched to another medication	Discontinued
For this patient was the medication	◯	◯	◯	◯

Comments: _____

We are trying to gauge emotional reaction to receiving information and advice about the potential value of reducing the use of ICS in patients with COPD.

If you received information and advice about the potential value of reducing the use of ICS in patients with COPD, did you feel:

	Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree	Don't Know/Not Applicable
Irritated	○	○	○	○	○	○
Angry	○	○	○	○	○	○
Annoyed	○	○	○	○	○	○

	No, Strongly Disagree	No, Disagree	Neither Agree nor Disagree	Yes, Agree	Yes, Strongly Agree	Don't Know/Not Applicable
Did you criticize information you received about efforts to reduce ICS use among patients with COPD?	○	○	○	○	○	○
Are you skeptical of efforts to reduce ICS use among patients with COPD	○	○	○	○	○	○
Can you think of points that go against efforts to reduce ICS use among patients with COPD?	○	○	○	○	○	○

Is there anything else you would like us to know?

_____

You missed a question! Please complete the question(s) or click Submit.

Thank you for your assistance in completing this survey.

For further questions, please contact:

Christian Helfrich, MPH PhD at
christian.helfrich@va.gov