Protocol Title: Understanding perceived access and receipt of gender-affirming treatments among transgender Veterans

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Abstract

Background: Transgender people experience discord between their gender identity and birth sex, defined as gender dysphoria. Gender-affirming treatments (GATs) are medically necessary treatments to reduce gender dysphoria. However, among transgender Veterans (trans Vets) who desire GATs, not much is known about barriers and facilitators to accessing and receiving GATs in VA and VA Community Care (CC). To ensure effective and equitable GAT access for trans Vets, it is critical to understand: [1] GATs trans Vets receive and where they receive them, [2] barriers, including social determinants of health (SDOH) barriers that are highly prevalent among trans Vets, and facilitators associated with desired GAT receipt in VA and CC, [3] how barriers and facilitators influence GAT access and desire, and [4] how to improve GAT access in VA and CC.

Objectives: We propose a sequential explanatory mixed method study whose aims are to:
Aim 1. Characterize the GATs received by trans Vets in VA and/or CC (VA/CC)
Aim 2. Identify barriers and facilitators associated with desired GAT receipt in VA and CC
Aim 3: Understand trans Vet experiences related to GAT access in VA and CC.

Research Design: Aim 1: We will expand our VA cohort of 9,608 trans Vets (IIR 17-238) from 2006-18 to the data available at the time of funding. We will add CC data to determine the types of GATs received by trans Vets in VA and/or CC. Aim 2: We will survey a national sample of trans Vets identified from Aim 1. Among trans Vets who desire GATs, we will determine SDOH barriers, other barriers, and facilitators associated with desired GAT receipt. Among trans Vets who did not desire GATs, we will determine reasons for not wanting GATs. Aim 3: From Aim 2 participants, we will recruit a purposive sample of trans Vets who received all desired GAT(s), who received some desired GAT(s), and who received no desired GAT(s). We will also recruit a national sample of LGBTQ+ Veteran Care Coordinators. We will seek to understand experiences and perspectives on GAT access in VA and CC, how SDOH barriers, other barriers, and facilitators influence GAT access and desire, and how to improve GAT access in VA and CC. Informed by study findings and in partnership with our Stakeholder Advisory Group, we will develop patient-centered implementation strategies to mitigate barriers and enhance facilitators to improve GAT access in VA and CC.

Findings/Progress to Date: No findings to date.

Relevance to VA Mission

This study addresses the 2022 HSR&D priority areas of Access to Care, Health Equity/SDOH, MISSION Act, and research gap of underserved LGBTQ+ Veterans. It is also a high priority for our operational partners in VA LGBTQ+ Health Program, Pharmacy Benefits Management, Office of Integrated Veteran Care, and Office of Mental Health and Suicide Prevention. Knowledge gained from this study will ensure that GAT delivery in the VA is patient-centered and is responsive to the lived realities and needs of trans Vets.

List of Abbreviations

(CC) VA Community Care
(CDA) Career Development Awardee
(CDW) Corporate Data Warehouse
(GAT) Gender-affirming treatment
(HSR&D) Health Services Research & Development
(IIR) Investigator Initiated Research
(LGBTQ+) Lesbian, gay, bisexual, transgender, queer (or questioning) and other identities
(LGBTQ+ VCC) LGBTQ+ Veteran Care Coordinator
(Trans Vets) Transgender Veterans
(TGD) Transgender and gender diverse Veterans
(VA) Department of Veterans Affairs
(VAMC) Veteran Affairs Medical Center
(VCC) Veteran Care Coordinators
(VINCI) VA Informatics and Computing Infrastructure

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1.0 Study Personnel

Principal Investigator

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Co-Investigators

- Varsha Vimalananda, MD, varsha.vimalanada@va.gov; VA Bedford, 8/8th VA
- Christopher J. Miller, PhD, christopher.miller8@va.gov; VA Boston; 8/8th VA
- Ryann Engle, MPH, ryann.engle@va.gov, VA Boston, 8/8th VA
- Nicholas A. Livingston, PhD, nicholas.livingston@va.gov; VA Boston; 8/8th VA
- John Blosnich, PhD, john.blosnich@va.gov; VA Pittsburgh; 2/8th VA
- Rajinder "Sonia" Singh, PhD, Rajinder.singh2@va.gov; VA Central Arkansas, 8/8th VA

Investigator	Role	Site	CIRB designation	Access to PHI/Engaged in Research
Guneet Jasuja	Principal Investigator	VA Bedford	PI SC and LSI	Yes
Varsha Vimalananda	Co-Investigator	VA Bedford		No
Nicholas A. Livingston	Co-Investigator	VA Boston	LSI	Yes
Christopher J. Miller	Co-Investigator	VA Boston		Yes
Ryann Engle	Co-Investigator	VA Boston		Yes
John Blosnich	Co-Investigator	VA Pittsburgh	LSI	No
Rajinder Singh	Co-Investigator	VA Central Arkansas	LSI	Yes

2.0 Introduction

Transgender people commonly experience gender dysphoria defined as distress due to discord between their gender identity and birth sex.[1] The number of transgender Veterans (trans Vets) with gender dysphoria increased ~7-fold from 1,406 in 2006 to 9,608 in 2018 in VA.[2] Compared to non-trans Vets, trans Vets with gender dysphoria have > 2-fold hazard of suicide mortality.[3] Gender-affirming treatments (GATs; e.g. surgery, hormones)[4] are evidence-based treatments to reduce gender dysphoria, improve mental health and quality of life in trans people.[5-9] Receipt of hormones and/or surgery reduced suicidal ideation by 62% among trans people[10] with similar findings noted among trans Vets.[11] GATs are medically necessary for gender dysphoria.[4,12-14] However, not much is known about the barriers and facilitators to accessing and receiving GATs in VA and VA Community Care (i.e., care paid for by the VA in the community)[15] among trans Vets who desire GATs.

Barriers to receipt of GATs reported in a single-site VA study included delays in GAT receipt, need to travel for GATs, lack of clinician competency on trans health, discrimination, violence and lack of patient knowledge about VA GAT coverage.[16] Additional barriers suggested by non-VA studies, include low income, housing instability, and cost of GATs.[17-21] Barriers to GATs thus, reflect social determinants of health (SDOH) barriers (e.g. discrimination)[22] and other barriers (e.g. lack of patient knowledge about GAT coverage). In our ongoing IIR 17-238 using VA data, trans Vets with SDOH barriers, including housing instability, financial strain, and violence were 38% less likely to receive hormones than those without SDOH barriers.[23] Trans Vets frequently experience SDOH barriers, with 28% experiencing housing instability, 31% unemployment, and 19.5% violence.[24] Thus, targeting SDOH barriers that are especially salient in the lives of trans Vets along with other barriers are promising approaches to improving GAT access and receipt in VA and VA Community Care (CC).

However, little is known about which GATs trans Vets receive and where they receive them, which is critical to understand how VA and CC are balanced in terms of delivering GATs. Also, among trans Vets who desire GATs, not much is known about the barriers and facilitators that influence receipt of desired GATs in VA and CC. Further, we lack an understanding of trans Vets experiences related to GAT access in VA and CC, how barriers and facilitators influence GAT access and desire and how GAT access might be improved in VA and CC.

3.0 Objectives

Specific Aims

Aim 1. Characterize the GATs received by trans Vets in VA and/or CC. We will expand our VA cohort of 9,608 trans Vets[2] (IIR 17-238) from 2006-18 to the most recent year of data available at the time of funding. We will then add CC data to characterize the GATs received by trans Vets in VA only, CC only, and VA and/or CC. We will also expand our ongoing work on receipt of hormone therapy in VA to examine it in CC as well.

4.0

Aim 2. Identify barriers and facilitators associated with receipt of desired GATs in VA and CC. We will survey a national sample of trans Vets with new gender dysphoria diagnoses identified from Aim 1. Among trans Vets who desire GATs, we will determine SDOH barriers, other barriers, and facilitators associated with receipt of desired GATs in VA and/or CC. Among trans Vets who did not desire GATs, we will determine reasons for not wanting GATs to

distinguish between trans Vets who truly do not desire GAT (e.g., due to nonbinary identity) and trans Vets who may desire GATs if certain barriers to GAT access could be addressed.
5.0
Aim 3. Understand trans Vet experiences related to GAT access in VA and CC. From Aim 2, we will recruit a purposive sample of trans Vets who received all desired GAT(s), some desired GAT(s), and no desired GAT(s). We will also recruit a national sample of LGBTQ+ Veteran Care Coordinators, who are point persons for trans Vets at VA sites.[27] Participant interviews will explore experiences and perspectives on GAT access in VA and CC, how SDOH and other barriers influence GAT access and desire, and suggestions for improving GAT access.

Relevance

Informed by study findings and in partnership with our Stakeholder Advisory Group, we will develop patient-centered implementation strategies to improve GAT access. We will deploy these strategies in a follow-up hybrid implementation effectiveness study to mitigate barriers and enhance facilitators to improve GAT access in VA and CC and promote trans health equity. This work addresses HSR&D priorities of health equity/SDOH, access to care, MISSION Act, underserved LGBTQ+ Veterans; and is informed by our ongoing IIR 17-238.

4.0 Resources and Personnel

VA Bedford

Guneet K. Jasuja, PhD, Principal Investigator: Dr. Jasuja is an epidemiologist, a CHOIR investigator, HSR&D Career Development Awardee (CDA), and health services researcher with expertise in VA data, transgender health, gender-affirming hormone therapy, and mixed methods. She is also an Assistant Professor at the Boston University School of Medicine. Dr. Jasuja will supervise all aspects of this study. She will meet regularly with study staff and investigators to successfully overcome any obstacles that present themselves during the project. Dr. Jasuja will share overall responsibility for all analyses, preparing reports and manuscripts, and disseminating findings to operational partners. In addition, she will lead Aim 1. Dr. Jasuja will have access to protected health information.

Varsha Vimalananda, MD, MPH, Co-Investigator: Dr. Vimalananda is an HSR&D CDA and practicing VA endocrinologist, who provides clinical care to transgender Veterans. She is also a CHOIR investigator and a health services researcher with expertise in mixed methods, survey methods and VA Community Care. She will participate in all three aims. Dr. Vimalananda will not have access to protected health information.

Joel Reisman, Data Analyst: The data analyst will be responsible for downloading, maintaining, and analyzing data for Aim 1 under the supervision of Dr. Jasuja. The data analyst will also be responsible for data cleaning, merging with VA data, and data analyses for Aim 2 under the supervision of Drs. Jasuja and Livingston. The data analyst will have access to protected health information.

TBN, Research Assistant: Working under the supervision of the project manager, the research assistant will assist with assist with IRB paperwork, organizing study meetings, managing correspondence, helping with data presentations, formatting and proofreading abstracts, posters, and publications. With regard to the survey aim, they will assist with survey participant recruitment, including the mailing out the recruitment letters, informed consent processes, tracking and monitoring participant activity and reimbursement, troubleshooting any technical issues with the online survey. Further, they will assist with survey data collection, including paper survey packet preparation to Veterans who ask for that option, mailings, reminder mailing and conducting telephone interviews for Veterans who ask for that option. The research assistant will have access to protected health information.

Jolie Wormwood, Statistician: The statistician will provide guidance regarding statistical and methodological issues involved in this study for quantitative Aims 1 and 2. The statistician will not have access to protected health information.

VA Boston

Nicholas A. Livingston, PhD, Co-Investigator: Dr. Livingston is a licensed clinical psychologist and Assistant Professor of Psychiatry at Boston University. He is also a Research Psychologist in the National Center for PTSD and specializes in health disparities and minority stress among sexual and gender minority Veterans. His areas of methodological expertise include multi-year survey designs, and mixed modeling techniques. He will lead the survey aim. Dr. Livingston will have access to protected health information.

Christopher J. Miller, PhD, Co-Investigator: Dr. Miller is a CHOIR investigator and Assistant Professor of Psychology in the Harvard Medical School Department of Psychiatry. Dr. Miller has extensive experience spearheading both implementation science projects and qualitative analyses in the context of implementation studies. He will lead the qualitative analysis team and the quarterly meetings with the Stakeholder Advisory Group in year 4 to develop patient-centered implementation strategies to improve access to GAT. Dr. Miller will have access to protected health information.

Ryann Engle, MPH, Co-Investigator: Ms. Engle is a Research Health Scientist at CHOIR Boston with extensive experience in qualitative data collection, management, analysis, reporting and dissemination. Ms. Engle will work closely with Dr. Miller and the project manager to recruit participants for interviews, conduct the interviews, and analyze data for the qualitative aim. Dr. Engle will have access to protected health information.

Julianne Brady, Project Manager: The project manager will coordinate all aspects of this study. They will be responsible for interacting with the IRB, compiling, drafting, and submitting IRB and other required documentation to meet research compliance standards and funding requirements, organizing study meetings, managing correspondence, helping with data presentations, formatting and proofreading abstracts, posters, and publications, and facilitating timely completion of study goals. Working under Drs. Livingston and Jasuja' s supervision, the project manager will also assist with the survey Aim 2 pilot testing and participant recruitment, including the informed consent processes, tracking and monitoring all participant activity and

reimbursement, troubleshooting any technical issues with the online survey, and following up as needed to ensure high-quality data. They will also assist with qualitative Aim 3 of the study in recruiting participants, scheduling and conducting qualitative interviews, arranging transcription of interviews, coding and analysis under the supervision of Dr. Miller and Ms. Engle. The project manager will also assist in dissemination of research findings to the Stakeholder Advisory Group. The project manager will have access to protected health information.

VA Pittsburgh

John Blosnich, PhD, Co-Investigator: Dr. Blosnich is an epidemiologist, HSR&D CDA, and health services researcher with expertise in social determinants of health, and health care disparities experienced by transgender Veterans. He also has experience in mixed methods and survey methods. He will serve as the social determinants of health expert and contribute to the analysis and interpretation of data and findings. Dr. Blosnich will not have access to protected health information.

VA Central Arkansas Healthcare System

Rajinder "Sonia" Singh, PhD, Co-Investigator: Dr. Singh is a clinical psychologist and investigator at the Center for Mental Healthcare and Outcomes Research at the Little Rock VA Medical Center. Dr. Singh has expertise in implementation science and health equity. Specific research interests include policy implementation to improve health equity for gender and sexual minoritized Veterans and LGBTQ+ individuals. Dr. Singh will contribute to the analysis and interpretation of data and findings, writing of papers, and will also participate in the qualitative aims of the study. Dr. Singh will have access to protected health information.

5.0 Study Procedures

5.1 Study Design

This is an observational multi-method cross-sectional study with transgender Veterans that will identify barriers and facilitators associated with GAT receipt among trans Vets who desire GATs. We will also identify patient-centered strategies to address barriers and enhance facilitators to improve GAT access. The proposed study will use a mixed-methods design, with three aims. We begin with obtaining national VA data to provide a foundational lay of the land on the GATs received by trans Vets in VA and/or CC (database Aim 1). Next, using a national cross-sectional survey, we will identify barriers and facilitators associated with receipt of desired GATs in VA and CC (survey Aim 2). Finally, by interviewing trans Vets and LGBTQ+ VCCs, we

will understand experiences and perspectives on GAT access in VA and CC, and how to improve this access in VA and CC (qualitative Aim 3).

Database Aim 1: We will expand our VA cohort of 9,608 trans Vets (IIR 17-238) from 2006-18 to the data available at the time of funding. We will add CC data to determine the types of GATs received by trans Vets in VA and/or CC. Aim 1 of the study will consist of all Veterans with documentation of a gender dysphoria (GD) diagnosis code in the VA or in CC from 1999 to the current year for which VA and CC data is available.

Survey Aim 2: We will survey a national sample of up to 1,500 trans Vets with a documentation of a gender dysphoria (GD) diagnoses identified from Aim 1 in the VA or CC in the past 2 years at the time of funding. Among trans Vets who desire GATs, we will determine barriers, and facilitators associated with desired GAT receipt. Among trans Vets who did not desire GATs, we will determine reasons for not wanting GATs. Veterans will be invited by postal mail, email, and phone to participate in a single survey. Similar to our pilot testing recruitment, we will also advertise the survey on VA's LGBTQ+ Health Office website and we will work on recruitment with LGBTQ+ Veteran Care Coordinators (VCCs). Veterans will be encouraged to complete the survey online but will have the option to complete the survey by phone or mail if desired. Data from the survey will be linked to CDW data (available through VINCI) via a study ID, and the crosswalk file will be stored in a separate secure file and will only be accessible to study team members.

Qualitative Aim 3: From Aim 2 participants, we will recruit a purposive sample of approximately 70 trans Vets. We will also recruit a national sample of approximately 20 LGBTQ+ Veteran Care Coordinators (VCCs). We will seek to understand experiences and perspectives on GAT access in VA and CC, how barriers, and facilitators influence GAT access and desire, and how to improve GAT access in VA and CC.

Risks and Benefits

Anticipated risks and protection against anticipated risks

Database Aim 1

This aim involves retrospective secondary data analyses of existing data. The principal risk to human subjects from these aims is loss of confidentiality, which will be minimized.

We will take several steps to protect participants against potential risks inherent to the proposed research in this aim. The study team has extensive experience conducting secondary data analyses that require strict data security. The Bedford VAMC healthcare systems and VINCI also have well-developed systems and training for preserving data security and confidentiality. These systems will be augmented by the additional security provided by the VINCI system. Data for all participants will be kept strictly confidential by the following means: Source data files will be stored behind the VA firewalls. These data files will be accessed only by data analysts and investigators working on this study. All investigators and project staff will have received IRB and HIPAA training prior to participation in this study. Individual patient identifier information will be removed from study data files as soon as possible after database linkage. In order to avoid any negative consequences of loss of confidentiality, clinicians and other related staff will not be privy to the individual findings, as data will be presented in aggregate in publications and presentations. Unique study-specific identifiers will be assigned to support accurate linkage of data on the same individuals across multiple data files. We will maintain an encrypted secure data dictionary linking the study identifier to the personal identifiers, which will be kept in compliance with the VA Records

Control Schedule after the IRB approval. Analysis files of de-identified data will be created by standard SAS and related analytic programs.

Survey Aim 2
Psychological risks posed by the research are primarily related to the sensitivity of some of the survey measures and interview questions. Items include thoughts, feelings, and personal difficulties that may be private, including questions about history of violence, discrimination, and mental health. These questions may make participants uncomfortable or be perceived as an intrusion on their privacy. Answers to these questions could pose a risk if the information were known and linked to identifiable individuals.

We will take several steps to protect participants against potential risks inherent to the proposed research. Potential psychological risks, including discomfort associated with disclosure of information, feelings of compromised privacy, distress caused by increased awareness of one's own behavior or symptoms, and possible short-term exacerbations of psychological distress, will be addressed in the Information Statement. Participants will be informed of potentially disturbing questions on the Information Statement during the consent process before they agree to participate to minimize the likelihood that participants will experience stress or discomfort. Participants will be encouraged to contact the study office at any time should they have any concerns about their participation or experience any distress. Initial and continuing participation will remain strictly voluntary; participants will remain free to terminate participation at any time without penalty.

Our risk management activities for the survey will also include (based on the VA Sprint Guidelines for Risk Management in Surveys (Risk Management Resources for Working with VA Research Participants):

1. We will inform patients on the survey cover page that we will not provide individual feedback on survey responses, as their surveys may not be reviewed in real time. We will encourage them to reach out to their clinician, the Veterans Crisis Line, or emergency services if they are experiencing distress or thoughts of suicide.
2. We will provide patients with resources on each survey cover that contains options for self-referral, depending on the participant's self-assessed level of need:
    - **Veterans Crisis Line:** Veterans and their loved ones can call **1-800-273-8255** and **Press 1**, chat online at VeteransCrisisLine.net, or send a text message to **838255** to receive confidential support 24 hours a day, 7 days a week, 365 days a year.
    - Emergency Services: As an alternative to calling the Veterans Crisis Line, participants may choose to call 911 in the case of an emergency.

Qualitative Aim 3
Transgender Veterans: There is a risk that transgender Veterans may feel uncomfortable sharing sensitive information with researchers about their experiences with gender affirming treatment and social determinants of health barriers. To minimize this risk, we will perform a rigorous informed consent process that stresses that participation is completely voluntary, and they can choose to skip any interview questions or withdraw from the study at any point. We will also ensure that participants know that they can decline to have their interview audio recorded.

There is also a risk that transgender Veterans may feel coerced to participate due to their use of VA care and the availability of compensation for their time. To minimize these risks, we will compensate participants for their time at a level consistent with other VA research studies. Participants will also receive the full compensation amount even if they choose to withdraw their participation during the interview process. Finally, we will reiterate that participation will in no way impact the care that they receive from the VA.

LGBTQ+ VCCs: As VA employees, there is the potential risk that LGBTQ+ VCCs who may not want to participate in this VA study may feel coerced to do so. We will make it clear that participation is voluntary, not mandatory, and will not impact their VA employment in any way. At any point during the subject's participation, if the participant should want a break or should want to stop participating, they will be informed that they can do so at any time without consequence.

Mishandling of research data would compromise participant confidentiality. All possible measures will be taken to assure participant confidentiality. A secure, password protected database will be constructed to record the names of study participants, with a cross-link to a unique identification number. This will be stored on a secure VA server. Audio-recorded interviews will be transferred immediately to an encrypted VA laptop and erased from the recorder.

Safety Issues. All participants will be provided with study contact information should they have any questions or concerns regarding the study and wish to speak with study staff. We will also ensure that the study office number is monitored during every business day and will return all phone calls within 48 hours. The voice message will instruct callers to hang up and dial 911 in case of an emergency and provide them with the 24-hour VA National Crisis Line, which provides confidential chat support 24 hours a day, 7 days a week. Calls received in the study office will be documented on a tracking log and participants will be provided with resources and referrals as necessary.

Confidentiality.

Database Aim 1: The study team has extensive experience conducting secondary data analyses that require strict data security. The Bedford VAMC healthcare systems and VINCI also have well-developed systems and training for preserving data security and confidentiality. These systems will be augmented by the additional security provided by the VINCI system. Data for all participants will be kept strictly confidential by the following means: Source data files will be stored behind the VA firewalls. These data files will be accessed only by data analysts or programmers and investigators working on this study. All investigators and project staff will have received IRB and HIPAA training prior to participation in this study. Individual identifier information, both patient and clinician, will be removed from study data files as soon as possible after database linkage. In order to avoid any negative consequences of loss of confidentiality, clinicians and other related staff will not be privy to the individual findings, as data will be presented in aggregate in publications and presentations. Unique study-specific identifiers will be assigned to support accurate linkage of data on the same individuals across multiple data files. We will maintain an encrypted secure data dictionary linking the study identifier to the personal identifiers, which will be kept in compliance with the VA Records Control Schedule after the IRB approval. Analysis files of de-identified data will be created by standard SAS and related analytic programs.

Survey Aim 2: All research materials will remain confidential and secure, restricted to researchers on this project who have extensive training in maintenance of privacy and

confidentiality. Upon enrollment in the study, participants will be assigned a random Subject ID number via VA Qualtrics. All data will be indexed by this ID number and stored in accordance with VA privacy and information security policies. All data collected from participants will be indexed by random Subject ID numbers and stored on secure VA Qualtrics and VA research servers, accessible only by approved study personnel. Participants will be informed that only the study team will have access to de-identified data collected in the study. No participants will be identified in any manner in publications. In addition to participants' names and email addresses, we will need to collect mailing addresses for purposes of providing payment. A separate restricted access spreadsheet will contain only this information. Access to the CHOIR building is restricted. All space accessible to the public is separated from research offices. Access to the computer systems is restricted and password protected. All research computers are located in locked rooms and data files are password protected.

Qualitative Aim 3: The research team will take all possible measures to ensure confidentiality during and following interviews. First, participants will be assured that they are free to refrain from answering any questions they do not wish to answer. In previous similar studies, we have found that participants rarely refuse to answer questions when they are collected in a clear and professional manner. Second, during interviews, participant confidentially will be protected by safeguarding names and identities of participants through the use of unique participant ID numbers, and by ensuring that phone/Microsoft Teams interviews occur at a time and place where both the researcher and participant have privacy. Following interviews, all data (audio recordings, transcripts, and researcher notes) will be coded with a unique ID number for the individual participant. The key code linking participant's name and number will be password protected and stored separately from the data, and only the study team will have access to it. All research data and any documents containing identifiers will be stored on a secure VA server or stored in a locked file cabinet in a locked office. Digital audio recordings will be transcribed using a VA-contracted secure transcription service. Recordings and transcripts will be stored onto the secure VA server as soon as possible and erased from the audio recorders. The Bedford VA servers are backed up regularly.

Results reported in presentations or publications will not contain any individual identifiers. All potential participants will be informed of any risks of participating in this research, so they can make an informed decision regarding participation.

Participant burden. To reduce participant burden, we will minimize survey items to the number necessary and scientifically justified, and by using branching logic where appropriate. Qualitative interviews will proceed at a pace comfortable for the trans Vet and LGBTQ+ VCC participants and will be completed in 45-60 and 30-45 minutes, respectively.

Benefits. There are no direct benefits to participants included in this study. Patients in the VA and in other healthcare systems may benefit from the study findings. Acquiring critical information to identify the needs, preferences, and perceived barriers and facilitators for gender-affirming treatment in this vulnerable and understudied VA population outweigh the risk of breach of confidentiality inherent in the database analyses, national survey and qualitative interviews.

5.2 Recruitment Methods

Database Aim 1
This is a secondary data analysis utilizing exclusively already collected administrative data. Subjects will be identified through VA administrative databases.

Survey Aim 2: Prior to deploying the national survey, we will pilot test the survey with approximately 5-10 transgender and/or gender diverse Veterans. Recruitment for pilot testing of the survey will consist of outreach to local LGBTQ+ Veteran Care Coordinators (VCCs) in VISN 1. We will also announce the study on the VA's LGBTQ+ Health's public-facing website where they post information about LGBTQ+ Veteran research participation opportunities. Should we need additional assistance with recruitment, we will also leverage the TGD Veteran Consultants on our advisory group and TGD veterans recruited for the pilot testing to assist in recruiting additional participating for this testing phase (i.e., snowball sampling recruitment). Last, we will reach out to local Veteran Service Organizations (VSOs) that serve LGBTQ+ Veterans. Recruitment will consist of providing the VCCs, the VA LGBTQ+ Health Office, and local VSOs with an approved survey advertisement/posting and Information Statement. The advertisement/posting and Information Statement will provide interested Veterans with the contact information for the study's project manager to "opt in" to the pilot testing phase while explaining that the survey is entirely voluntary and that if they choose not to participate or to end the survey prior to completion, there will be no penalties or loss of VA benefits. Veterans interested in participating in the pilot testing of the survey will be emailed an invitation to participate with links to the survey hosted on the Qualtrics platform. Participants in the pilot testing phase will receive a $25 gift card as an appreciation for their time. Gift cards will be procured via Purchase Order at the lead site. Once study staff receive the gift cards they will activate and then track distribution of the gift cards to participants using the gift card numbers. Once a subject completes participation study staff will mail a gift card directly to the that participant, insuring only appropriate study staff have access to PII and all information and data security protections are followed. The funds for the gift cards have been approved in the study budget by VA HSR, which is funding the study.

We anticipate inviting approximately 10,000 trans Vets with a gender dysphoria diagnosis and/or self-reported gender identity as transgender and gender diverse to participate in the national survey and expect up to 1,500 will enroll and complete the survey. Recruitment for the national survey will consist of direct outreach to prospective research participants identified in Aim 1 through a mailed or emailed recruitment letter and Information Statement alerting Veterans about the survey, providing details about the individuals' rights as a research participant and inviting them to participate in the study. The letter will explain that the survey is entirely voluntary and that if they choose not to participate or to end the survey prior to completion, there will be no penalties or loss of VA benefits. The communication will make clear that the survey responses are confidential and that the Veteran's name or any other personally identifying information will not be used in any report of the survey results. The IRB's telephone number will be provided as a means for the potential participant to use to verify that the study constitutes VA research. Additionally, the study project manager's telephone number will be provided for the Veteran to call with questions about the study or if they wish to opt out of the study.

Veterans will be contacted as follows:

Contact	Method	Specifics

Contact 1	First Letter	All Veterans with a gender dysphoria diagnosis in the past 2 years and/or self-identified gender identity as transgender and gender diverse will be sent a recruitment letter via mail and/or email inviting them to participate in the study and offering the ability to opt-out, complete the survey online (either through mobile device, tablet or desktop), call in to the study project manager's number to complete the survey with the study manager or request that a paper survey is mailed to them.
Contact 2	Second letter	A second letter will be sent via mail and/or email approximately 10 days after the first letter.
Contact 3	Reminder Postcard	Approximately ten to twelve days after the second letter, we will send a reminder postcard and/or letter and/or email reinforcing basic information provided earlier and directing people to the website or to call the study project manager's number to complete the survey.
Contact 4	Telephone	Seven days after the reminder postcard is sent, study team staff will begin to make telephone calls to non-responders. Up to 3 attempts will be made, with one message left.

For individuals who are interested in participating, two automated email reminders will be sent by Qualtrics to the interested Veteran to remind them to complete the survey. For those trans Vets who do not have an email address or who prefer paper-and-pencil measures, the study project manager will mail forms along with postage-paid envelopes. Our operational partner, LGBTQ+ Health, will also help disseminate IRB approved recruitment letters to their internal and external distribution email groups to assist with recruitment of trans Vets.

Should our enrollment be lower than originally anticipated using VA Corporate Data Warehouse, we will also deploy additional recruitment methods that align with our recruitment methods used in pilot testing. These alternative recruitment methods will include posting an approved advertisement on the VA LGBTQ+ Health Office with the study information, reaching out to LGBTQ+ Veteran Care Coordinators to advertise our study and TGD Veteran Consultants on our advisory group and TGD veterans recruited for the pilot testing to assist in recruiting additional participating for this testing phase (i.e., snowball sampling recruitment). Last, we will reach out to local Veteran Service Organizations (VSOs) that serve LGBTQ+ Veterans. Recruitment will consist of providing the local VSOs with an approved survey advertisement/posting and Information Statement. In both of these recruitment methods, the interested veterans will "opt-in" to the study by contacting the study team directly. The study team will not call veterans recruited with this technique without the veteran first making contact..

Participants who complete the full survey will receive a $30 gift card. Gift cards will be procured via Purchase Order at the lead site. Once study staff receive the gift cards they will activate and then track distribution of the gift cards to participants using the gift card numbers. Once a subject completes participation (i.e., answers all questions on the survey) study staff will mail a gift card directly to the that participant, insuring only appropriate study staff have access to PII

and all information and data security protections are followed. The funds for the gift cards have been approved in the study budget by VA HSR&D, which is funding the study. If the participant does not complete the survey, we will use the information/incomplete data the participant already provided in the survey, unless they notify us that they do not want their information to be used.

Qualitative Aim 3:

Transgender Veterans: We anticipate interviewing ~ 70 trans Vets. We will seek diversity in the sample based on race, gender identity, VA region to ensure geographic representation and care received in VA vs. CC.

We will recruit qualitative interview participants from survey respondents. We will ask survey respondents in the survey if they would be willing to participate in a follow-up telephone interview. The following survey question will be reviewed for interest: “Our research team plans to interview trans Vets to learn more about their experiences accessing gender-affirming treatment in VA and VA Community Care. Would you be interested in participating?”

VA staff will mail or email potential participants a letter and an Information Statement alerting them about the interview opportunity, providing details about the individuals’ right as a research participant. The letter will explain that the survey is entirely voluntary and that if they choose not to participate or to end the interview prior to completion, there will be no penalties or loss of VA benefits. The letter will make clear that the interview responses provided are confidential and that the Veteran’s name will not be used in any report of the results. The IRB’s telephone number will be provided as a means for the potential participant to use to verify that the study constitutes VA research. Additionally, the telephone number of the study project coordinator will be provided for the Veteran to call with questions about the study or if they wish to opt out of the study.

Two weeks after the initial letter is mailed or emailed, VA research staff will begin follow-up via phone. The purpose of the phone call is to further explain the research and requirements and assess their interest in participating. Veterans will be informed that participation is fully voluntary and that their decision regarding participation will in no way affect their access to services or the quality of care they receive at the VA. Up to two additional letters and/or emails and two additional calls may be made if there is no response.

Should we experience challenges recruiting the survey respondents for the qualitative interviews, we will reach out to LGBTQ+ Veteran Care Coordinators (LGBTQ+ VCCs) to disseminate the IRB-approved recruitment letter for the interviews. The LGBTQ+ VCCs will provide the letter to all transgender Veterans at their specific sites. We will also reach out to Veteran Service Organizations (VSOs) that serve LGBTQ+ Vets, (e.g., Modern Military), to introduce the study for recruitment of trans Vets enrolled in VA care. Further, we will also post an approved advertisement on the VA LGBTQ+ Health Office for recruitment for the qualitative aim. Should we need additional assistance with recruitment, we will also leverage the TGD Veteran Consultants on our advisory group and TGD veterans recruited for the pilot testing to assist in recruiting additional participating for this testing phase (i.e., snowball sampling recruitment).

Participants will be compensated with a $25 gift card. Gift cards will be procured via Purchase Order at the lead site. Once study staff receive the gift cards they will activate and then track distribution of the gift cards to participants using the gift card numbers. Once a subject completes participation study staff will mail a gift card directly to the that participant, insuring

only appropriate study staff have access to PII and all information and data security protections are followed. The funds for the gift cards have been approved in the study budget by VA HSR&D, which is funding the study.

LGBTQ+ VCCs: We will recruit ~ 20 LGBTQ+ VCCs nationally through two approaches. First, we will recruit them through their regularly scheduled monthly calls. The VA LGBTQ+ Health Program Office will facilitate the study team's joining this call where we will announce recruitment for our study. Second, the study team potentially with the help of the VA LGBTQ+ Health Program Office will send IRB approved recruitment email and Information Statement to LGBTQ+ VCCs at all sites in which we will invite them to participate in our study. We will be limited to no more than 3 email messages to LGBTQ+ VCCs. We will use an opt-in approach, namely that we will not contact anyone by phone unless they email us back and express a willingness to participate.

5.3 Informed Consent Procedures

Database Aim 1: Informed consent will not be obtained from the study subjects, as this would not be feasible for reasons of resources and logistics. As per standard practice, we are requesting a waiver of HIPAA authorization and waiver of informed consent since this is a database study and sample will be recruited from the VA administrative data.

Survey Aim 2 and Qualitative Aim 3: For survey aim 2 (both pilot phase and national survey deployment) and qualitative aim 3 recruitment procedures, we will request a Waiver of HIPAA Authorization and an alteration of the Informed Consent process. As noted in VHA Handbook 1200.05, Appendix C, researchers may petition the IRB for a waiver of informed consent when:
(a) The research involves no more than minimal tangible or intangible risk to the subjects;
(b) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
(c) The research could not practicably be carried out without the waiver or alteration; and
(d) Whenever appropriate, the subjects must be provided with additional pertinent information after participation.

For the survey aim 2 and qualitative aim 3, we will seek a Waiver of Informed Consent Documentation. We are requesting a waiver of written documentation of consent to reduce risk and burden on participants as well as to ensure feasibility of the study, given the national scope of the aims. As part of the informed consent process, we will email and/or mail individuals an Information Statement that describes the study purpose, requirements, risks and benefits, compensation, confidentiality and privacy, who they can contact with questions, and how they can opt out of further contact. On recruitment calls completed by VA research staff, the staff member will review the Information Statement with the Veteran, prompt questions, and answer questions. The text of the Information Sheet will also be available on the survey website. Veterans will also be informed that participation is fully voluntary and that their decision regarding participation will in no way affect their access to services or the quality of care they receive at the VA.

If, during the conversation with the potential participant, the staff member has concerns that the individual does not understand the study or procedures and is perceived to be unable to provide informed consent, the staff member will consult with Dr. Jasuja, and upon agreement, either invite the individual to participate or thank the individual for their time and inform the individual that they are not eligible for the study. Answering survey and/or interview questions will constitute consent to participate.

All research staff will maintain current trainings, including CITI Human Subject Training, VA Privacy and Information Security Awareness and Rules of Behavior, VA Privacy and HIPAA Training, R&D Scope of work.

5.4 Inclusion/Exclusion Criteria

Inclusion criteria for database aim 1: Aim 1 of the study will consist of all Veterans with documentation of a gender dysphoria/gender identity disorder diagnosis code in the VA or in CC from 1999 to the current year for which VA and CC data is available. We will also request a sample of Veterans without a gender dysphoria/gender identity disorder diagnosis code in VA and/or CC or otherwise not identified as TGD through self-identified gender identity (non-TGD) to compare our TGD cohort on variables such as demographics, health condition, utilization, etc.

Inclusion criteria for survey aim 2: For survey aim 2, we will identify Veterans with a documentation of a gender dysphoria/gender identity disorder diagnoses in the VA or CC in the past 2 years at the time of funding.

Inclusion criteria for qualitative aim 3: From survey aim 2, we will recruit a purposive sample of ~70 trans Vets. We will also recruit ~ 20 LGBTQ+ VCCs.

There are no exclusion criteria for any of the aims to allow participation from the full range of trans Vets.

Rational for Involvement of Vulnerable Populations

We will not exclude VA employees, students, pregnant people, economically and/or educationally disadvantaged persons, or terminally ill patients. These participants will not be specifically targeted for recruitment; if participants happen to fall into these subcategories, it would be coincidental. The aim of the study is to examine the health of transgender Veterans – thus, exclusion criteria are minimal to approximate as generalizable a sample as possible. The study procedures would not be of elevated risk to these subpopulations as compared to the general population.

5.5 Study Evaluations

Database Aim 1. Data obtained from the VA administrative data will include identifiers (e.g., name, postal address, email address, phone number), demographics (e.g., age, sex, region, marital status, enrollment priority), vitals (e.g., weight and height), and some behaviors (e.g., smoking and alcohol misuse data) from health factors data. Participants' medical history, diagnoses, treatments, and health care utilization will also be ascertained for both VA and CC from VA administrative data.

Survey Aim 2. Measures will include demographics, setting of gender-affirming treatment receipt (VA, CC) , adverse social determinants of health (e.g., housing instability, unemployment), receipt of gender-affirming treatments (e.g. hormones, psychotherapy), barriers and facilitators to gender-affirming treatment in VA and CC, satisfaction with gender-affirming treatment, desire for gender-affirming treatment, depression, anxiety, suicide, minority stress, health conditions/comorbidities, barriers to VA care, quality of life, and smoking. For the pilot testing of the survey, we will elicit open-ended and close-ended feedback about the survey from Veterans to allow for refinement of the survey prior to national deployment of the survey.

Qualitative Interview. Data will be collected from trans Vet participants and LGBTQ+ VCCs during a 45-60-minute and a 30-45 minute telephone/Microsoft teams-based semi-structured interview. Interview guides will contain open-ended questions and areas to query. We will explore trans Vet experiences with barriers and facilitators impacting their ability and desire to access gender-affirming treatments in VA and CC. We will also query them on whether they have used any services and resources in VA and in the community to mitigate these barriers and suggestions on how gender-affirming treatment access might be improved in VA and CC. In addition, we will ask trans Vets about their awareness of gender-affirming treatment availability and coverage in the VA and differences in experiences in accessing gender-affirming treatments in VA and CC.
We will assess LGBTQ+ VCCs perspectives to understand how barriers and facilitators influence trans Vets gender-affirming treatment access in VA and CC and services and resources used by trans Vets to address these barriers. We will also elicit feedback on strategies to improve gender-affirming treatment access in VA and CC from both trans Vets and LGBTQ+ VCCs. These interview guides will be iteratively refined and revised based on database aim 1 and survey 2 findings (e.g., include questions on VA/CC coordination for GATs primarily received in CC, additional barriers identified from Aim 2, etc.) and as needed to ensure that the questions are understood as intended. Modifications may also be made during initial coding if a theme emerges that requires further exploration.

5.6 Data Analysis

Database aim 1: The data analyst under the supervision of the PI will produce summary statistics (e.g., proportions, means) for gender-affirming receipt in VA and/or CC (VA/CC). We will characterize gender-affirming receipt by: 1) patient characteristics, including demographics (e.g. race), comorbidities (e.g. mental health conditions) commonly reported by trans individuals, utilization of VA care (e.g. primary care), 2) site (e.g. region, rural/urban) and 3) setting (VA/CC). As appropriate, two-sided chi-square test (categorical variables), t-test (continuous variables) or their nonparametric equivalent tests will be used to test for the statistical significance of the associations of these patient and site characteristics with gender-affirming receipt. We will also compare the characteristics of patients receiving gender-affirming treatment through VA vs. CC.

Survey aim 2: Our analytical goal is to identify barriers and facilitators associated with receipt of desired gender-affirming treatments in VA and/or CC. In keeping with this goal, the data analyst under the supervision of the PI, will conduct the following analyses:
Descriptive analyses: We will obtain summary statistics (e.g., proportions, 95% confidence intervals, etc.) of the distribution of each gender-affirming treatment, degree of receipt of desired gender-affirming treatments, barriers, and facilitators of gender-affirming treatment. We will characterize the degree of receipt of desired gender-affirming treatments in VA and/or CC. We will also characterize barriers and facilitators by degree of receipt of desired gender-affirming treatments in VA and/or CC, recognizing that trans Vets who received all desired gender-affirming treatments could encounter barriers in receipt of these gender-affirming treatments and trans Vets who received no desired gender-affirming treatments could encounter facilitators in trying to receive gender-affirming treatments. We will also characterize the degree of receipt of desired gender-affirming treatments, barriers and facilitators by age, race/ethnicity, gender identity (transfeminine, transmasculine, non-binary), and region.
Primary analyses: We will conduct bivariate analysis to assess the unadjusted relation of barriers and facilitators with the dependent variables, receipt and desire of gender-affirming treatments in VA and CC. As appropriate, two-sided chi-square tests (categorical variables) or their equivalent non-parametric tests will be used to test the significance of any group differences. We will obtain odds ratios (ORs) and 95% confidence intervals (CI) from separate multivariable logistic regression models, to assess associations between barriers and facilitators for the dependent variables**.** A multinomial logistic regression model will be used to evaluate associations of barriers and facilitators with the ordinal dependent variable: degree of receipt of desired gender-affirming treatments**.** These models will adjust for covariates, such as age, race/ethnicity and gender identity. Further, depending on the distribution of respondents across sites, we will examine the distributions of the independent and dependent variables as well as the respondents' characteristics across sites. If there is substantial variation across sites and there are adequate number of respondents (at least 5) in each site, we will adjust for clustering of respondents within sites in the analyses. We will combine sites with small sample sizes into a single cluster for the analyses.
Secondary analyses: To assess interrelationships between barriers, we will examine the overlap of barriers by ascertaining the proportion of trans Vets with various combinations of barriers. To examine this overlap, we will create two variables: 1) a categorical variable, indicating combinations of different barriers (e.g., housing instability only, housing instability and employment, housing instability, unemployment and need to travel for gender-affirming treatments, etc.); 2) number of barriers. We will also explore the effects of these variables in models described in the primary analyses.
Missing data: In a cross-sectional survey, we expect non-response to the entire survey (unit non-response) or to certain questions in the survey (item non-response). We will try to reduce unit non-response by sending two automated email reminders to Veterans to complete the survey. If we have >=10% unit non-response, we will examine the distribution of characteristics between respondents and non-respondents on measures (e.g., age, race/ethnicity, comorbidities, etc.) available in VA data. If necessary, we will create a weight as the inverse of the probability of response from a logistic regression model that predicts response and include these measures as independent variables. These weights will be used in all analyses to reduce bias due to unit non-response. To mitigate item non-response, we will use validated measures, improve the clarity of questions, and use survey branching logic to reduce response burden. Our primary analysis will assume that data are missing completely at random (MCAR) and include only subjects with complete information or computable variables. For items that have >=10% of missing data, we will examine patterns and predictors of missingness and conduct a sensitivity analysis by

imputing the values under the assumptions of missing at random conditional on the observed data. Comparing results from these analyses to that under the MCAR assumption will allow us to assess the amount of bias due to missing data. We will then adjust final models by including predictors of missingness accordingly.

All analyses will be conducted in SAS (SAS, Cary, NC) on complete data. Our tests of significance will be adjusted for multiple testing using the Benjamini-Hochberg procedure to control for the False Discovery Rate.

Qualitative aim 3. We will use a directed content analysis approach. The initial codebook will include a priori codes based on elements of the conceptual model. The qualitative team will come to consensus on codebook definitions in an iterative fashion, adding emergent codes as needed based on newly identified themes and patterns present in the data. To ensure coding consistency, 20% of transcripts will be double-coded and the team will meet periodically during the coding process to resolve any discrepancies through consensus discussion. The resulting coded data will be analyzed to determine domains related to barriers and facilitators around gender-affirming treatment access and desire. Analysis will employ established qualitative techniques, including the constant comparative method, which identifies key themes and concepts from the data to generate meaningful categorization. From the resulting domains, we will develop case studies to further describe the influence barriers and facilitator experiences may have on desire and receipt for trans Vets gender-affirming treatment. Case studies will also note the differences in these barriers to gender-affirming treatment access in VA vs. Summaries of interview findings with both trans Vets and VCCs will be integrated with the survey Aim 2 findings to inform the development of patient-centered strategies.

5.7 Withdrawal of Subjects

The survey aim 2 and qualitative aim 3 do not involve any follow-up. Thus, if participants consent to participate, they will be included. Participants may elect to stop study participation at any time (e.g., during an interview or part-way through the survey).

If a participant wants to stop study participation, we will continue to use information that has already been collected. The study may collect information from their VA medical record up to that date, but no further information will be collected after that date. However, if an individual provides a request in writing to completely withdraw from the study, including having their data withdrawn, we will do so.

6.0 Reporting

If a serious adverse event (SAE) occurs, the research team will follow the policy and procedures established by the IRB: https://www.research.va.gov/programs/pride/cirb/CIRB-Table-of-Reporting-Requirements.pdf. Specifically, the PI, Dr. Jasuja will report all SAEs to the CIRB and local Research and Development Office within five working days. SAEs will be reported even if the PI believes that the adverse events are unrelated to the protocol. If a study participant reports a SAE to a research team member, the team member will contact Dr. Jasuja. Unexpected (but not serious) adverse events that are related to participation in the protocol will be reported to the CIRB by Dr. Jasuja within 10 working days. All AEs and SAEs will be kept in

a log. Because this is an observational cross-sectional study with no intervention and no invasive procedures, we will not have a Data Safety Monitoring Board.

During the course of a phone call, if a Veteran is in extreme distress or says anything related to hurting themselves or others, a safety protocol will be implemented. If warranted, we will conduct a warm transfer from the interviewing station directly to the Veteran's Crisis Line. If the Veteran hangs up during the process, then we call the Veteran's Crisis Line and provide information for them to follow-up with the Veteran. No information relating to the use of the safety protocol will be saved with participant data.

7.0 Privacy and Confidentiality

Protected Health Information (PHI)

Database Aim 1: This aim involves retrospective secondary data analyses of existing data. We will only request the minimum amount of PHI necessary to conduct this study aim. The principal risk to human subjects from these aims is loss of confidentiality, which will be minimized. No personal identifying information will leave the Bedford VAMC study site and/or the VINCI environment. Data will remain solely within secured VA servers. Moreover, we will not perform any case studies; all data results will be presented in aggregate to prevent risk of nefarious reductive interpretations aimed at trying to ascertain identifying characteristics of individual Veterans.

Survey aim 2 and qualitative aim 3: PHI is collected in survey aim 2 and qualitative aim 3 to enable processing of study payments. We will take stringent precautions to protect the confidentiality of participants' PHI. All study participants will be assigned a random-digit Study ID Number to prevent their research data from being identifiable. PHI collected will be stored separately from all other research and survey data. A crosswalk file that links the Study ID Number to the participant's name will be securely stored behind the VA firewall in the study's drive folder. Only research staff approved by the IRB can access the study's secure drive. In accordance with 38 USC 7332, this information will be kept confidential and will not be disclosed in presentations, publications, or any other dissemination of the study results, or to anyone outside of the IRB-approved study team.
Trainings. All research staff will maintain current trainings, including CITI Human Subject Training, VA Privacy and Information Security Awareness and Rules of Behavior, VA Privacy and HIPAA Training, R&D Scope of work.

8.0 Communication Plan

VA team. Dr. Jasuja will meet weekly with project staff to review study aims and progress. Regular meetings with key team members will be held to ensure that:

- All required approvals are obtained, and the IRB is notified of any modifications;

- All are knowledgeable about the protocol including the informed consent process and informed of changes to the protocol and informed consent process;
- All are aware of any Serious Adverse Events, Unanticipated Problems, or interim results that may impact conduct of the study;
- The study is being conducted according to the IRB-approved protocol.

Data Sharing with VA Research Facilities. So that they may perform data analysis, co-investigators at VA Boston and the Little Rock VAMC will access data directly on the shared folder on the secure VA CHOIR drive, VINCI, or by receiving the data via a VA encrypted email. No data analyses will be performed by co-investigator, Dr. John Blosnich, at VA Pittsburgh.

9.0 References

1. American Psychiatric Association. Diagnostic and statistical manual of mental disorders (5th ed.). Arlington, VA: American Psychiatric Association; 2013.
2. Wolfe HL, Reisman JI, Yoon S, et al. Validating data-driven methods to identify transgender individuals in the Veterans Affairs. *Am J Epidemiol.* 2021 Apr 12: kwab102.
3. Boyer TL, Youk AO, Haas AP, et al. Suicide, Homicide, and All-Cause Mortality Among Transgender and Cisgender Patients in the Veterans Health Administration. *LGBT Health.* 2021 Apr;8(3):173-180.
4. https://transcare.ucsf.edu/guidelines/overview
5. White Hughto JM, Reisner SL. A systematic review of the effects of hormone therapy on psychological functioning and quality of life in transgender individuals. *Transgender Health.* 2016;1(1):21-31.
6. Nguyen HB, Chavez AM, Lipner E, et al. Gender-Affirming Hormone Use in Transgender Individuals: Impact on Behavioral Health and Cognition. *Curr Psychiatry Rep*. 2018;20(12):110.
7. Branstrom R, Pachankis JE. Reduction in Mental Health Treatment Utilization Among Transgender Individuals After Gender-Affirming Surgeries: A Total Population Study. *The American Journal of Psychiatry*. 2020;177(8): 727-34.
8. Hughto JMW, Gunn HA, Rood BA, et al. Social and Medical Gender Affirmation Experiences Are Inversely Associated with Mental Health Problems in a U.S. Non-Probability Sample of Transgender Adults. *Arch Sex Behav*. 2020;49(7):2635-2647.
9. Glynn TR, Gamarel KE, Kahler CW, et al. The role of gender affirmation in psychological well-being among transgender women. *Psychol Sex Orientat Gend Divers*. 2016;3(3):336-344.
10. Bauer GR, Scheim AI, Pyne J, Travers R, Hammond R. Intervenable factors associated with suicide risk in transgender persons: a respondent driven sampling study in Ontario, Canada. *BMC Public Health.* 2015;15:525.
11. Tucker RP, Testa RJ, Simpson TL, et al. Hormone therapy, gender affirmation surgery, and their association with recent suicidal ideation and depression symptoms in transgender veterans. *Psychol Med.*2017;48(14):2329 -36.
12. Coleman E, Bockting W, Botzer M, et al. Standards of care for the health of transsexual, transgender, and gender-nonconforming people, version 7. *Int J Transgenderism*. 2012; 13:165–232.

13. World Professional Ass'n for Transgender Health, Standards of Care Version 7 (2018). Available at https://www.wpath.org/publications/ soc.
14. Wylie Hembree, et al., Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *J Clinical Endocrinology & Metabolism,* 2017, 11, 3869-903.
15. https://sgp.fas.org/crs/misc/R45390.pdf
16. Rosentel K, Hill BJ, Lu C, et al. Transgender Veterans and the Veterans Health Administration: Exploring the Experiences of Transgender Veterans in the VA Healthcare System. *Transgend Health.* 2016;1(1):108-116.
17. White Hughto JM, Rose AJ, Pachankis JE, Reisner SL. Barriers to Gender Transition-Related Healthcare: Identifying Underserved Transgender Adults in Massachusetts. *Transgend Health*. 2017;2(1):107-118.
18. Martinez-Velez JJ, Melin K, Rodriguez-Diaz CE. A Preliminary Assessment of Selected Social Determinants of Health in a Sample of Transgender and Gender Nonconforming Individuals in Puerto Rico. *Transgend Health*. 2019;4(1):9-17.
19. Clark K, Fletcher JB, Holloway IW, Reback CJ. Structural Inequities and Social Networks Impact Hormone Use and Misuse Among Transgender Women in Los Angeles County. *Arch Sex Behav*. 2018;47(4):953-962.
20. Garcia J, Crosby RA. Social Determinants of Discrimination and Access to Health Care Among Transgender Women in Oregon. *Transgend Health*. 2020;5(4):225-233.
21. Lee H, Park J, Choi B, et al. Experiences of and barriers to transition-related healthcare among Korean transgender adults: focus on gender identity disorder diagnosis, hormone therapy, and sex reassignment surgery. *Epidemiol Health.* 2018 Feb 27;40.
22. Social Determinants of Health | Healthy People 2020
23. Wolfe HL, Vimalananda VG, Wong DH, et al. Patient Characteristics Associated with Receipt of Gender-Affirming Hormone Therapy in the Veterans Health Administration. *Revise and Resubmit.*
24. Blosnich JR, Marsiglio MC, Dichter ME, et al. Impact of Social Determinants of Health on Medical Conditions Among Transgender Veterans. *Am J Prev Med.* 2017 Apr;52(4):491-498.
25. Gelberg L, Andersen RM, Leake BD. The Behavioral Model for Vulnerable Populations: application to medical care use and outcomes for homeless people. *Health Serv Res*. 2000;34(6):1273-1302.
26. Fetters MD, Curry LA, Creswell JW. Achieving integration in mixed methods designs—principles and practices. *Health services research.* 2013;48(6pt2):2134-2156.
27. Department of Veterans Affairs VHA. VHA Directive 1341(2): Providing health care for transgender and intersex Veterans. 2018.