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# 1630016: Dissemination and Implementation of a Videoconference Antimicrobial Stewardship Team (VAST)

Funding Agency: HSR&D

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## Abstract

Antimicrobial stewardship guidelines call for a multidisciplinary team with an infectious disease (ID) physician and ID-trained clinical pharmacist as core members. Unfortunately, there are insufficient ID-trained specialists to staff on-site antimicrobial stewardship programs throughout VA.

Our goal is to implement a multidisciplinary videoconference antimicrobial stewardship team (VAST) in VAMCs using SCAN-ECHO. Our central hypothesis is that feedback reports that quantify facility-level antibiotic use will enhance the efficacy of VASTs to support antimicrobial stewardship. Our research plan includes a Type 2 hybrid effectiveness-implementation design that compares clinical effectiveness in sites that implement the VAST alone (VAST-) to sites that implement the VAST augmented by facility-level Antibiotic Use Reports (VAST+).

We will randomize rural VAMCs that do not have ID-trained professionals on staff to implement the VAST alone (VAST-) versus VAST + antibiotic use feedback (VAST+). The specific aims in the research proposal are: 1) Identify and test effective strategies for implementing the VAST; 2) Determine the influence of the VAST overall and VAST+ on the care of Veterans with suspected infections; 3) Determine the influence of the VAST overall and VAST+ on antibiotic use at each VAMC.

We describe the planned research activities as follows:

1. Determine modifications of **VAST implementation** through ongoing discussions with champions at the intervention sites and with the infectious disease experts.

2. Assess **staff perceptions** of the VAST using surveys and semi-structured interviews to gather qualitative data about what key VAST members perceive as facilitators, barriers and burden to VAST implementation.

3. Evaluate the **clinical activities** of each VAST. This evaluation will include using chart review to describe the patients discussed, including their clinical diagnoses, as well as acceptance of recommendations by providers. These activities will involve use of the VA's administrative databases as well as chart review.

4. Measure changes in overall **facility-level antibiotic use** for each VAST. These activities will involve extraction of antibiotic use and census data from the VA's administrative databases

List of Abbreviations

| | |
|---|---|
| AMDA | American Medical Directors Association—the Society for Post-Acute and Long-Term Care |
| ASI | antibiotic spectrum index |
| ASTF | Antimicrobial Stewardship Task Force |
| BIA | Budget impact analysis |
| *C. difficile* | *Clostridioides difficile* |
| CBOCs | community-based outpatient clinics |
| CDA | Career Development Award |
| CDI | *Clostridioides difficile* infection |
| CDW | Corporate Data Warehouse |
| CINCCH | Center of Innovation for Complex Chronic Healthcare |
| CLC | Community Living Center |
| COVID-19 | novel Coronavirus disease 2019 |
| DOC | days of care |
| DOT | days of therapy |
| EMR | electronic medical record |
| EMS | Environmental Management Service |
| FRAME | framework for reporting adaptations and modifications |
| FTE | Full Time Equivalent |
| ICD | International Classification of Diseases codes |
| ID | Infectious Diseases |
| IDSA | Infectious Disease Society of America |
| IT | Information Technology |
| JLV | Joint Legacy Viewer |
| LOT | length of therapy |
| NEOHCS | Northeast Ohio Healthcare System |

| | |
|---|---|
| NIDS | National Infectious Disease Service |
| OPES | Office of Productivity, Efficiency and Staffing |
| PBM | Pharmacy Benefits Management |
| PRISM | Practical, Robust Implementation and Sustainability Model |
| RE-AIM | Reach, Effectiveness, Adoption, Implementation and Maintenance |
| REDCap | Research Electronic Data Capture |
| SCAN-ECHO | Specialty Care Access Network-Extension for Community Healthcare Outcomes |
| SEIPS | extended model of the Systems Engineering for Patient Safety |
| SHEA | Society for Healthcare Epidemiology of America |
| VA | Veterans Affairs |
| VAMC | Veterans Affairs Medical Center |
| VAST | videoconference antimicrobial stewardship team |
| VAST- | VAST alone |
| VAST+ | VAST that receives a quarterly Antibiotic Use Report |
| VHA | Veterans Health Administration |
| VINCI | Veterans Affairs Informatics and Computing Infrastructure |
| VISN | Veterans Integrated Service Network |

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## 2.0 Introduction

Antimicrobial resistant and healthcare-associated pathogens cause over 3 million infections in the United States each year [1]. Over 1% of these infections end in death. The driving factor leading to the selection for antimicrobial resistant bacteria is inappropriate and unnecessary use of antimicrobials. Like all medications, antibiotics have the potential to cause direct harm to the individual taking them through allergic reactions, side effects and drug-drug interactions. Unlike most other medications, however, antibiotics may lead to unintended consequences that are temporally distant and impact both antibiotic-exposed individuals and public health. Antibiotic exposure increases an individual's risk of acquiring (and then spreading) antimicrobial resistant bacteria as well as *Clostridioides* difficile. An increase in the prevalence of antimicrobial resistant bacteria and C. difficile puts additional people at risk of acquiring these pathogens. Worldwide, health authorities recognize that antimicrobial resistance jeopardizes public health and indicate we face living in the post-antibiotic era [2–4].

Antimicrobial stewardship is an essential element for reducing the prevalence of antimicrobial resistant pathogens. Simply stated, antimicrobial stewardship seeks to minimize unnecessary and inappropriate antimicrobial use in order to decrease microbial resistance, curtail the spread of infections caused by nosocomial pathogens and ultimately, improve patient safety [5]. These efforts help decrease unnecessary days and doses of antibiotic therapy and reduce subsequent adverse events like selection for and acquisition of antimicrobial resistant and healthcare-associated pathogens. Achieving successful antimicrobial stewardship is resource intensive and requires expertise not available to every healthcare setting. Guidelines for institutional antimicrobial stewardship programs call for an infectious diseases-trained (ID) physician and clinical pharmacist as well as a clinical microbiologist, information system specialist, infection preventionist and hospital epidemiologists [6]. VHA Directive 1031 requires every VA medical facility to have an antimicrobial stewardship program, and specifies resource allocation including clinical pharmacy, ID physician, infection prevention and control, nursing, program administration and information technology support [7].

Currently, the numbers of ID physicians and pharmacists are insufficient to support comprehensive antimicrobial stewardship programs. This holds true even within the Veterans Health Administration (VHA), the largest integrated health care system in the United States. Based on Specialist Provider Productivity data obtained from the VA Office of Productivity, Efficiency and Staffing (OPES) in 2019, 27% (38 of 140) of Veterans Affairs healthcare systems do not have an ID specialist. This means that over 25% of VA antimicrobial stewardship programs depend on physicians and pharmacists who are not trained in ID, let alone antibiotic stewardship. In a national assessment of 130 VA with acute care services, the presence of ID-trained physicians and pharmacists was associated with improved antimicrobial utilization measures [8]. Further, while the VA is a leader in antimicrobial stewardship [9], a multitude of studies indicate a need for

continued improvement in antimicrobial stewardship practices in the care of Veterans with an array of infectious syndromes (pneumonia, bacteriuria, skin and soft tissue infection), and settings of care (spinal cord injury, outpatient clinic, post-discharge, surgical prophylaxis) [10–16].

The opportunity to improve antimicrobial stewardship is even more pronounced in nursing homes, including VA Community Living Centers (CLCs). Increasing age, frailty, immune senescence and comorbid conditions all render nursing home residents vulnerable to infection [17]. These factors, as well as atypical signs and symptoms of infection, lower the threshold to prescribe antimicrobials to nursing home residents such that up to 75% of antimicrobial use in nursing home residents is inappropriate [18]. A retrospective chart review of antibiotics prescribed to CLC residents at our institution found that over 40% of the antibiotic days of therapy were entirely unnecessary [19]. We estimate that few VAMCs (<10%) allocate resources for the specified purpose of antimicrobial stewardship in their CLCs.

Telehealth is a feasible strategy for providing antimicrobial stewardship to VA facilities underserved by ID expertise. The Infectious Disease Society of America supports telehealth programs for antimicrobial stewardship.[20] The VA has successfully used telemedicine to increase Veterans' access to specialty care providers by providing remote training and mentoring to providers. The most notable example is the Specialty Care Access Network Extension for Community Healthcare Outcomes (SCAN-ECHO) program, which integrates patient care with provider education [21–23]. Telehealth interventions have addressed the care of people with acute infections such as community-acquired pneumonia, urinary tract infections, and skin and soft tissue infections, as well as chronic diseases such as tuberculosis, hepatitis C virus (HCV) and human immunodeficiency virus (HIV) [24].

We conducted a successful pilot study using telehealth to support antimicrobial stewardship activities at 2 rural Veterans Affairs Medical Centers (VAMCs) without local ID expertise (HSR&D Pilot Merit PPO 16-118-1). The program consisted of weekly meetings between a multi-disciplinary team at a rural VAMC with ID trained physician who joined by videoconference. Termed the VAST, for videoconference antibiotic stewardship team, at each session participants discussed patients receiving antibiotics. Team members entered the VAST's recommendations into the electronic medical record (EMR) at the rural VAMC. The ID physicians captured their clinical effort by completing interfacility consults placed using the Specialty Care Access Network Extension for Community Healthcare Outcomes (SCAN-ECHO) system. Intended to last just 6 months, the VASTs at both sites are entering their 4th year. The VAST is a successful and sustainable program that is valued by team members and resulted in statistically significant decreases in antibiotic use in the acute and long-term care units [25,26].

In our pilot study, the primary approach to antimicrobial stewardship was audit and feedback, an approach that has demonstrated effectiveness when the feedback is detailed, non-punitive, and individualized [27]. This is a common approach to antimicrobial stewardship and prospective audit and feedback demonstrated improvement in prescribing outcomes [28]. A limitation to our pilot study was a significant lag between initiating the VAST and our ability to assess changes in overall antibiotic use. Team members from both rural VAMCs indicated that more timely feedback about antibiotic use would help bolster participants' enthusiasm and leadership support for the

employee time devoted to the VAST. In response, our team successfully applied to the VA Innovators Network to use national VA data to develop a facility-level Antibiotic Use Report (Figure 2 and Appendix A). The Antibiotic Use Reports use data extracted from the BASIC Antimicrobial Use Reporting System and present it in a format suitable for front-line providers. The Antibiotic Use Report uses both text and graphics to communicate successes and improvement opportunities specific to the VAMC for which it is prepared. The graphs summarize overall antibiotic use over the previous year, with additional information regarding use of broad- and narrow-spectrum agents. Further, each Antibiotic Use Report compares or "benchmarks" the individual VAMC for which it is prepared to other VAMCs in the same Medical Complexity Group. This approach adapts and expands peer comparison, which has proven effective at reducing inappropriate antibiotic use in outpatient settings [29,30].

## 3.0 Objectives

The **purpose** of this project is to expand the VAST to additional rural VAMCs and affiliated off-site ID clinicians. We further propose to test the influence of facility-level peer comparison through the Antibiotic Use Report (VAST + feedback) to augment changes in facility-level antibiotic use beyond the influence of the VAST alone.

Our **central hypothesis** is that feedback reports that quantify facility-level antibiotic use will enhance the efficacy of VASTs to support antimicrobial stewardship. We will use the following **specific aims** as we test this hypothesis:

Aim 1: *Identify and test effective strategies for implementing the VAST*. The VAST is a complex intervention that affects individuals and systems. Using the expanded framework for reporting adaptations and modifications to evidence-based interventions (FRAME), we will assess adaptations made at intervention sites and by infectious disease experts. Methods will include process maps and semi-structured interviews to gather qualitative data about what key VAST members perceive as facilitators, barriers and burden to VAST implementation. [We will also evaluate implementation costs.] We We anticipate that VASTs that receive Antibiotic Use Reports (VAST+) will tailor their activities to address quantifiable antibiotic use metrics.

Aim 2: *Determine the influence of the VAST overall and VAST+ on the care of Veterans with suspected infections*. We will evaluate the Veteran population served, clinical activities, and user perceptions of the VAST. For a subset of patients with common infections (e.g., urinary tract infection, pneumonia, cellulitis etc.) we will assess the concordance of clinical care with recommendations from evidence-based clinical practice guidelines. User experience measures will include VAST members' perceptions of the quality and timeliness of care as well as access to input from specialty care providers. We anticipate that compared to VASTs that do not (VAST-), VASTs who receive Antibiotic Use Reports (VAST+) will report a greater perceived influence on Veteran care.

Aim 3: *Determine the influence of the VAST overall and VAST+ on antibiotic use at each VAMC*. The primary outcome measure will be overall rates of antibiotic use. Secondary outcomes will be changes in the rates of broad-spectrum antibiotic use and antibiotic starts, and in length of antibiotic therapy. We anticipate that antibiotic use will decrease after VAST implementation at study sites and compared to VASTs that do not (VAST), VASTs who receive Antibiotic Use Reports (VAST+) will achieve greater reduction in overall antibiotic use, and specifically in broad-spectrum antibiotics.

Relevance to Veterans and the VA

Veterans experience many of the risk factors associated with development of antimicrobial resistant and healthcare-associated infections. The unprecedented effects of the novel Coronavirus disease 2019 (COVID-19) on the health of our Veterans and on our entire healthcare system makes the demand for ID expertise even more apparent, especially in long-term care. Also, this study directly addresses the VA MISSION ACT to improve access to care, timeliness and quality of care, using telehealth services. Finally, this project is aligned with the priorities of our operation partners: VA Antimicrobial Stewardship Taskforce (ASTF), the VA National Infectious Disease Service (NIDS), VA Pharmacy Benefits Management (PBM) Services, and the Office of Rural Health.

## 4.0 Resources and Personnel

Co-Principal Investigators

**Robin Jump, MD, PhD, Co-Principal Investigator** is an infectious disease physician and member of the Geriatric Research Education and Clinical Center (GRECC) at the VA Pittsburgh Healthcare System (VAPHS)with implementing effective antimicrobial stewardship programs at the VANEOHCS Community Living Center (CLC) (2009 – 2021) as well as via telehealth with the Chillicothe VA (2017 – 2021). Dr. Jump will oversee all aspects of the work proposed including coordination of efforts among personnel from her team and that of Co-PI Dr. Evans.

**Charlesnika T. Evans, PhD, MPH, Co-Principal Investigator** is a senior investigator at the Center of Innovation for Complex Chronic Healthcare (CINCCH). She has a history of collaborating with operational partners (VA National Infectious Disease Office, MDRO Program, CDC) and with investigators at other VA facilities. She is also Co-PI of the Combatting Antimicrobial Resistance through Rapid Implementation of Available Guidelines and Evidence (CARRIAGE) Quality Enhancement Research Initiative (QUERI) Program with PIs at the Salt Lake City VA and Iowa City VA. Dr. Evans' knowledge related to infections, study design and methodological/ implementation expertise will allow her to successfully serve as co-principal investigator for this study. She will use her expertise to provide oversight of activities at the Hines VA and on epidemiological and quantitative methods.

Primary Study Team Staff

**Amy Hirsch, PharmD** is a Clinical Pharmacist trained in Infectious Diseases. She is also a research scientist with training in data analysis, assessment of the strength and quality of data, and process maps. She will assist with developing the process maps and will help to record adaptations using the process maps. She will also help interpret and disseminate results.

**Brigid Wilson, PhD, Co-Investigator** is a Senior Statistician with GRECC at the VA Northeast Ohio Healthcare System. Having worked in industry for several years, she has expertise both with statistics and data analysis. She has collaborated with Dr. Jump on several projects and has robust expertise and several years of experience working with the VA Informatics and Computing Infrastructure (VINCI). She will oversee the data

collection and analysis for Objective 3 and as well as analysis of administrative data collected for Objective 2. She will also supervise generation of Antibiotic Use Reports.

**Geneva Wilson, PhD, Co-Investigator** has a doctoral degree in Epidemiology from the University of Iowa's College of Public Health and recently joined CINCCH as a junior investigator. Her work has focused on multi-drug resistant bacterial environmental contamination in the healthcare setting. Dr. Wilson's goals are strongly rooted in antimicrobial stewardship, infection prevention, and hospital acquired infections. Dr. Wilson will be responsible for assisting with and collecting data from the facilitation calls. She will also assist with data collection and statistical analysis.

**Taissa Bej, MS, Research Coordinator** has 5 years of experience at the VA Northeast Ohio Healthcare System, where she has worked on studies within Infectious Diseases and Cardiology. She has experience managing research studies, including multi-site programs, maintaining and submitting regulatory documents, data collection, and analyzing collected data. In addition to scheduling and attending project meetings, she will submit and track regulatory requirements, assist with data collection, extraction and analysis as required.

**Amanda Vivo BS, Research Assistant** has worked with Dr. Evans for 3 years and will serve as a field research assistant for Dr. Sabzwari with responsibilities that include assisting with setting up the tele-health clinics between the Hines VAMC and the Marion VAMC in Marion, IL. She will also serve as the field research assistant for 1 additional VAST, with the ID experts and rural VAMC to be recruited during Year 1. Ms. Vivo will collect and submit data for these VASTs and also support assessment of VAST implementation as described in Aim 1. She will also assist in arranging Hines team meetings, completing and maintaining Hines IRB and R&D paperwork, assist in data documentation and support development of products including presentations and manuscripts. Ms. Vivo has extensive experience working on multisite studies and coordinating activities across facilities.

**Sunah Song, MS, Research Associate** is a data analyst who has worked with Dr. Jump and other GRECC researchers to support research informatics. She has extensive experience in research application design and development, data analysis and visualization, complex disease data modeling and data management. Her primary role will be to generate and distribute the Antibiotic use Reports; she will also assist with using VINCI to extract antibiotic use data from the Corporate Data Warehouse (CDW).

**Corinne Kowal, BS, Research Assistant** has 5 years of experience at the VA Northeast Ohio Healthcare System, where she has worked on studies in Infectious Diseases, Rheumatology, and Immunology. She has experience managing research studies, including multi-site programs, maintaining and submitting regulatory documents, data collection, and analyzing collected data. In addition to scheduling and attending project meetings, she will submit and track regulatory requirements. She will also assist with data collection as required.

**Joshua Nordman, MD** is a resident physician at the VA St. Louis Healthcare System. His clinical expertise will help with conducting chart review.

Senior Staff

**Dustin French, PhD, Co-Investigator** is a health economist at the Hines Center of Innovation for Complex Chronic Healthcare (CINCCH) and will oversee the evaluation of

implementation costs. He has over 15 years of experience evaluating health outcomes and healthcare costs, including methodological areas of comparative and cost effectiveness, health informatics, health services research, and health policy. He will participate in team meetings, oversee data collection of cost data, and conduct cost analyses.

**Dezon Finch, PhD, Statistician** is the Director of the Quantitative Core at CINCCH at the Hines VA Hospital. Dr. Finch is an Informatics Researcher with extensive experience in natural language processing (NLP), machine learning, and the use of VA administrative databases for predictive modeling. Dr. Finch will be responsible for creating the NLP algorithm for this project.

**Emily Budde, PhD, Study Staff** is a Health Science Specialist at the VA CINCCH at the Edward Hines Jr. VA Hospital. She has a background in social psychology and expertise in research methodology and quantitative statistics. She will assist Dr Finch with the natural language processing and machine learning methods for this project.

Local Site Investigators

**Rabeeya Sabzwari, MD, Co-Investigator** is an Infectious Disease physician at the Hines Veterans Administration Hospital and is also an Assistant Professor of Infectious Disease at the Loyola University Chicago Stritch School of Medicine. She founded Antimicrobial Stewardship Program at the Hines VA 7 years ago and continues to serve as is Director. She will serve as an Infectious Disease expert for a VAST with the Veterans Affairs Medical Center in Marion, IL, participate in meetings to discuss overall study progress, and help to interpret and disseminate results.

**Daniel Livorsi, MD, MSc, LSI** is an Infectious Disease physician and an investigator at the Center for Access and Delivery Research and Evaluation (CADRE) in the Iowa City VA Health Care System. He is an Assistant Professor of Infectious Disease at the University of Iowa Carver College of Medicine. He is the recipient of a VA Career Development Award to study antimicrobial stewardship implementation in hospitals that lack support from Infectious Diseases (ID) specialists. Dr. Livorsi will also oversee all research activities at his site. He will supervise a research assistant for local site activities, initiate and maintain local regulatory processes, and provide support for the research assistant in study implementation. He will also serve as an Infectious Disease expert for a VAST with the Royal C Johnson Veterans Memorial Hospital in Sioux Falls, SD, participate in meetings to discuss overall study progress, and help to interpret and disseminate results.

**Christopher J. Crnich, MD, PhD**, **LSI** is the Chief of Medicine as well as an Infectious Disease physician and Hospital Epidemiologist at the William S. Middleton VA Hospital and an Associate Professor of Medicine in the Division of Infectious Disease at the University of Wisconsin School of Medicine and Public Health. Dr. Crnich will oversee all research activities at his site. He will supervise a research assistant for local site activities, initiate and maintain local regulatory processes, and provide support for the research assistant in study implementation. He will also serve as an Infectious Disease expert for a VAST with the Iron Mountain Veterans Affairs Medical Center, participate in meetings to discuss overall study progress, and help to interpret and disseminate results.

**Christopher Pfeiffer, MD, MHS, LSI** is Hospital Epidemiologist and Division Chief of Infectious Diseases at VA Portland Health Care System (VAPORHCS) and Associate

Professor within the Department of Medicine at Oregon Health & Science University (OHSU). Dr. Pfeiffer is also the Medical Director for the Oregon Health Authority (OHA) Drug-Resistant Organism Prevention and Coordinated Regional Epidemiology (DROP-CRE) Network. Dr. Pfeiffer will oversee all research activities at VAPORHCS. He will supervise a research assistant for local site activities, initiate and maintain local regulatory processes, and provide support for the research assistant in study implementation. He will also serve as an Infectious Disease expert for a VAST with the Roseburg Veterans Affairs Medical Center, participate in meetings to discuss overall study progress, and help to interpret and disseminate results.

**Muthu Narayan, DO, LSI**, is a full-time staff infectious disease physician at the Minneapolis VA Healthcare System. Dr. Narayan will oversee all research activities at MVAHS. She will supervise a research assistant for local site activities, initiate and maintain local regulatory processes, and provide support for the research assistant in study implementation. She will also serve as an Infectious Disease expert for a VAST with the VA Black Hills Health Care System, participate in meetings to discuss overall study progress, and help to interpret and disseminate results.

**Federico Perez, MD, MS, LSI,** is a physician with specialty and subspecialty training in internal medicine and infectious diseases. He has expertise in the molecular mechanisms, epidemiology and clinical management of antibiotic-resistant bacterial infections. He also has a Master's degree in Clinical Research and experience in collaborative patient oriented research. He will supervise local site activities and initiate and maintain local regulatory processes.

**Andrew Webster, MD, co-LSI,** is a full-time staff infectious disease physician at the Atlanta VA Healthcare System. Dr. Epstein and Dr. Webster will oversee all research activities at AVAHS. They will supervise a research assistant for local site activities, initiate and maintain local regulatory processes, and provide support for the research assistant in study implementation. He will also serve as an Infectious Disease expert for a VAST with the Bath VA Medical Center, participate in meetings to discuss overall study progress, and help to interpret and disseminate results.

**Lauren Epstein, MD, co-LSI,** is a full-time staff infectious disease physician at the Atlanta VA Healthcare System. Dr. Epstein and Dr. Webster will oversee all research activities at AVAHS. They will supervise a research assistant for local site activities, initiate and maintain local regulatory processes, and provide support for the research assistant in study implementation. She will also serve as an Infectious Disease expert for a VAST with the Bath VA Medical Center, participate in meetings to discuss overall study progress, and help to interpret and disseminate results.

## 5.0 Study Procedures

## 5.1 Study Design

We will conduct a Type 2 hybrid effectiveness-implementation design [37], randomizing rural VAMCs that do not have ID-trained professionals on staff to implement the VAST alone (VAST-) versus VAST + antibiotic use feedback (VAST+). We propose to test the implementation strategy, specifically assessing modification and adaptations and effectiveness, measured as the VAST's influence on Veteran care and on antibiotic use.

The 4 main activities of the study are

1. Determine modifications of **VAST implementation** through ongoing discussions with champions at the intervention sites and with the infectious disease experts.

2. Assess **staff perceptions** of the VAST using surveys and semi-structured interviews to gather qualitative data about what key VAST members perceive as facilitators, barriers and burden to VAST implementation.

3. Evaluate the **clinical activities** of each VAST. This evaluation will include using chart review to describe the patients discussed, including their clinical diagnoses, as well as acceptance of recommendations by providers. These activities will involve use of the VA's administrative databases as well as chart review.

4. Measure changes in overall **facility-level antibiotic use** for each VAST. These activities will involve extraction of antibiotic use and census data from the VA's administrative databases

Study Population

The study will include up to 10 intervention sites, which are rural VA facilities. Infectious disease experts will serve as Local Site Investigators (LSIs). Each LSI will work with at least 1 intervention site (rural VA facility) to set up a VAST.

1. VAST Implementation

   For this study activity, study participants will include the participating sites.

2. Staff perceptions

   For this study activity, the study population will be comprised of individuals who participate in the VAST and will include VA staff members. The team members from the intervention sites will include pharmacists, infection preventionists, nurses, and prescribing clinicians. These staff are important antibiotic stewardship stakeholders. Each rural VAMC will pair with an ID expert from another VA facility to form a multidisciplinary VAST which will perform antimicrobial stewardship activities. The rural VAMCs and their affiliated ID physician will be randomized to either the VAST alone (VAST-) or VAST + feedback (VAST+), consisting of a quarterly Antibiotic Use Report describing facility level antibiotic use.

3. Evaluation of clinical activities

For this study activity, VA patients discussed during each VAST will make up the study population. Study staff will perform medical record review and utilize the VA's administrative databases to collect information about the patients. Veteran patients will not be involved in any study interventions; only chart review will be conducted.

4. Facility-level antibiotic use

We will review total antimicrobial use at the intervention sites and at control sites. These data will be accessed via VINCI.

Protection Against Risk

This is a minimal risk study. The primary risk is breach of confidentiality for patients discussed by the VAST and breach of privacy for providers who participate in semi-structured interviews.

1. VAST Implementation

For this study activity, there is no risk to patients or staff.

2. Staff Perceptions

To protect the privacy of VAST members, the semi-structured interviews will be recorded without identifying the participants by name. If, during the course of an interview, identifying information is recorded, the research team will remove those sections of the recording prior to transcribing the recorded interviews. The research team will not share any information with the intervention sites that would permit identification of the semi-structured interview participants. Aggregated themes or deidentified quotations may be shared with leadership or in research publications. The research team will indicate participants by their role only if there are sufficient numbers of people in that role to avoid attribution to specific individuals. For example, if only 1-2 pharmacists from each intervention site participates in the VAST, no specific themes or comments will be attributed to pharmacists. Participation in the semi-structured interviews will be voluntary; the research team will not share the names of individuals who decline to participate.

3. Evaluation of clinical activities

In order to determine the acceptance of the VAST recommendations by providers at the intervention site, the research team will need to record the name and medical record number (last 4 of their social security number) of patients discussed during the VAST. These records will be stored and maintained in password protected-computers in folders with restricted access, all of which will be kept behind the VA firewall. Only study staff will have access to study data No paper records recording patients' name or medical record number will be kept.

4. Facility-Level Antibiotic Use

To protect the privacy of patients when extracting facility-level antimicrobial use, all data will be stripped of patient identifying information prior to extraction from

VINCI. Our research team has experience with using VINCI and will not seek to access any patient identifying information. The research team will only note the setting (i.e. hospital or CLC) on which antibiotics were administered. Patient identifying information will be removed and replaced with a study-specific identifier in chart review data. Moreover, access to data with the study-specific identifiers will be restricted to members of the research team. Chart review data will be kept in locked cabinets only accessible to the team member doing the chart review.

Data will be kept at the VA Northeast Ohio Healthcare System (VANEOHCS),and stored such that only the primary research team will have access to all patient identifying information. Local Site Investigators and local site staff will only have access to site-specific data. Patient identifying information will be removed and replaced with a study-specific identifier in analytic datasets and chart review data. Moreover, access to data with the study-specific identifiers will be restricted to specific members of the research team. There are multiple levels of security to ensure the integrity and confidentiality of all data stored on the system. The computer system operates entirely within the VA network, which is protected by firewalls maintained by the VA Central Office. Authorized study team members are assigned an active, individually unique user identification code and an individually unique password. User identification codes limit access to specific directories and files.

***Additional Precautions.*** Appropriate precautions will be used to ensure that any risks related to invasion of privacy or breach of confidentiality is minimized. An encrypted crosswalk will be developed that links the unique patient id made with the patient identifiers that are stripped from the analytical files. All data, including study crosswalk files, are stored behind the VA firewall. There are multiple levels of security to insure the integrity and confidentiality of all data stored on the system. The computer system operates entirely within the VA network, which is protected by firewalls maintained by the VA Central Office. Authorized project team members are assigned an active, individually unique user identification code and an individually unique password. The accounts and passwords comply with existing VA policies and procedures for computer access. User identification codes limit access to specific directories and files.

As described above, each patient will be assigned a unique identifier to be used throughout this study. The study staff will be the only individuals with access to the patient key to this data. Identifiable information collected from patients will be necessary to conduct the medical chart reviews.

The potential benefit to the intervention sites is reduced use of antimicrobials, which often means decreased costs. Our long-term goal is to both maximize the benefits and minimize the risks (including adverse drug events, Clostridioides difficile infection and acquisition of drug-resistant bacteria) of antibiotic treatment. The potential benefit to VAST members is education around the topics of infectious

diseases and antimicrobial stewardship, which may influence their practice patterns. The potential benefit to veterans is increased availability of infectious disease expertise and potentially decreased exposure to systemic antibiotics, which in turn decreases their risk for acquisition of C. difficile and multi drug-resistant pathogens.

### 5.2 Recruitment Methods

1. VAST Implementation

No patient or staff populations are being recruited for this portion of the study. Rather, recruitment is at the level of VA Medical Centers. The process for recruiting VA Medical Centers is through existing professional relationships and networking as well as phone calls, emails, and teleconferencing.

We anticipate recruiting up to 10 VA Medical Centers and up to 10 ID experts to work with those sites.

2. Staff Perceptions

VAST members will be approached by email and asked to participate in a semi-structured interview conducted by a research team member distinct from those involved directly in VAST meetings. Additionally, VAST members will be asked to complete a survey using VA REDCap. VAST members will receive an email to their VA email account with a link to the survey and a brief explanation of the survey. After the initial survey email invitation, study staff will send up to 5 follow-up email reminders for completion of the survey.

None of the staff who participate in the VAST or the ID Experts will receive any payments as the activities related to this work pertain to their usual work activities.

3. Evaluation of clinical activities

This study activity will involve reviewing the medical records of Veteran patients discussed during the VAST. Patients will not be recruited for participation.

4. Facility-Level Antibiotic Use

Antimicrobial use data will be extracted from the VA CDW. Veteran data will be used to collect information about antibiotic use, but patients will not be recruited for participation.

### 5.3 Informed Consent Procedures

1. VAST Implementation

This study activity involves establishing a VAST at each participating site and does not require informed consent.

2. Staff Perceptions

VAST members will be asked to complete a survey using VA REDCap. VAST members will receive an email to their VA email account with a link to the survey and a brief explanation of the survey. Participation in the survey will indicate consent.

VAST members will be approached by email and asked to participate in a semi-structured interview conducted by a research team member distinct from those involved directly in VAST meetings. We have requested that participants may offer verbal consent to participate in semi-structured interviews, and offer verbal consent to audio record the interviews. We choose this approach to avoid generating informed consent documents that would become the only written link between providers and the research data.

Verbal informed consent will be obtained by trained study staff in a private setting. VAST members will be given the opportunity to ask questions before consenting to participate in semi-structured interviews.

3. Evaluation of clinical activities

   In order to conduct chart review and obtain information from the CDW, we will request a waiver of informed consent.

4. Facility-Level Antibiotic Use

   In order to obtain information from the CDW, we will request a waiver of informed consent.

### 5.4 Inclusion/Exclusion Criteria

All sites participating in the VAST will be included. Veteran patients will be discussed during VAST calls according to clinical need. Additionally, administrative data will be collected from CDW within the VINCI environment and will be used to extract and analyze age, gender, race/ethnicity, and comorbid conditions for creation of the quarterly Antibiotic Use Reports.

1. VAST Implementation

   All participating sites will be included.

2. Staff Perceptions

   All staff who participate in the VAST will be invited by email to participate in a survey and a 20-60 minute telephone semi-structured interviews.

3. Evaluation of clinical activities

   All patients discussed during the VAST will be included.

4. Facility-Level Antibiotic Use

   Information will be collected from CDW for all participating sites.

## 5.5 Study Evaluations

1. VAST Implementation

   Randomization

   To randomize rural VAMCs, we will use a matched pairs design to ensure that the total number of acute and long-term care beds is similar between the two study arms. For simplicity, if more than one rural VAMC forms a VAST with the same off-site ID expert, (e.g., both Altoona and Erie have a relationship with the Pittsburgh VAMC) we will randomize both rural VAMCs into the same arm.

   VAST Members & Activities

   Staff from acute (hospital) and long-term care (CLC) units will populate the team, with the intent of using more than one person with the same role to allow for fluidity among individual members. Each VAST will identify 2 to 3 champions, likely pharmacists and infection preventionists, with responsibilities that include identifying patients prescribed antibiotics and recording the VAST's recommendations in the electronic medical record. Contributions of the ID physician will include his or her clinical knowledge and experience with antimicrobial stewardship. The ID physician will identify 1-2 other individuals, such as an ID-trained clinical pharmacist, to also participate in the VAST. This will enhance continuity of the VAST during holidays, vacations, and travel. Each team will also include a field research assistant for the ID expert(s); field research assistants will help support VAST implementation and data collection.

   The VAST will meet for one hour each week. As a whole, team members from the rural VAMC and off-site ID experts will participate in chart review, discussion, and making recommendations regarding the need and choice of antimicrobial agent(s), length of therapy, orders for and interpretation of microbiological cultures and diagnostic tests. At each session, the field research assistant will note the names, roles, and practice setting for each of the VAST participants; this information will be shared with the primary research team.

   When feasible, the ID expert(s) will travel to the rural VAMC for a face-to-face kickoff meeting. This will facilitate team building and help set the tone for the ensuing videoconferences. Leadership support to allow time for personnel from the rural as well as the ID expert(s) VAMCs to actively engage in the VAST will be a key factor for success. Further, the presence of Chiefs or Assistant Chiefs of Staff, Medicine, Nursing, and Pharmacy from the rural VAMC, especially at the first 4 to 8 VAST sessions, will help engage other clinical staff.

   Implementation Guide and Facilitation

   The champions and ID experts will receive an implementation guide that details setting up a SCAN-ECHO clinic specific for the VAST, lays out

general recommendations for a site visit as the initial VAST session, and describes the general process for videoconference sessions.

During facilitation calls, the primary research team will review process maps (Figure 2) with champions at the rural VAMC, field research assistants, and ID experts.

- As sites adapt the intervention to suit their needs, research coordinators will work with each VAST to adjust the process maps for their site, adding or removing components as needed while also making sure each VAST retains the elements necessary for workload capture and program evaluation.
- The process maps will help the research team identify the range of adaptations used by the different VASTs as they tailor the intervention to their sites. The process maps will also help teams that are struggling to identify specific steps leading to limited success and then to develop strategies to overcome barriers.
- Once each VAST indicates it is well-established, which we expect will be around 4 months after their first session, we will re-assess the process maps quarterly and conduct a final review at the conclusion of the intervention period.

Field research assistants will use data collection forms to record and submit quantitative data describing VAST sessions and cost data. The primary research team will assess qualitative aspects of implementation and sustainability. With each facilitation call, whether scheduled or ad hoc, members of the primary research team will use field notes to log barriers and facilitators related to implementation.

2. Staff Perceptions

   a. We will conduct semi-structured interviews of the champions(s) at the rural VAMC and the ID expert(s). These will begin after their VAST is well-established, likely after 4 to 6 months. We will ask interviewees about specific goals or objectives decided on by their VAST and the rationale for those.

      Champion(s) from the rural VAMCs (2-3 per site) and ID experts (1-3 per site) will be approached by a member of the research team by email to schedule a 20 to 60-minute telephone interview. The interviews will be digitally recorded, transcribed and analyzed using Atlas.ti (Scientific Software Development GmbH; Berlin, Germany). Inductive and deductive content analysis will be used to identify salient themes, with deductive codes based on domains from SEIPS 2.0 with the additional theme of practice change.

   b. To assess user perceptions, a survey will be deployed and sent to anyone who participated in at least one VAST session. The survey will be developed and deployed using VA REDCap and distributed via VA email. The survey will query perceptions of the VAST in regard to timeliness of recommendations, access to input, influence on the quality of antibiotic use, and overall effect Veterans' care. For rural VAMCs

randomized to the VAST+, additional questions will address respondents' general perceptions of the Antibiotic Use Report as well as its potential role in helping to guide VAST activities.

3. Evaluation of clinical activities

Clinical activities will be assessed by the field research assistants and the primary research team. Field research assistants will record the infectious diagnosis discussed and determine the acceptance of recommendations made by the VAST which the primary research team will validate using administrative data. To describe the clinical activities of each VAST, the field research assistants will use a Case Report Form to record the patients discussed, their diagnoses, the recommendations made, and the acceptance of those recommendations. Field research assistants will upload their Case Report Form to a shared research drive which will be reviewed by the primary research team. For a subset of patients, the primary research team will use chart review to assess the concordance of recommendations made by each VAST with evidence-based clinical practice guidelines.

4. Facility-Level Antibiotic Use

Antimicrobial use data will be extracted from the VA CDW, which permits attribution of medication administration to specific units. The champions at each intervention site will provide their field research assistant with names for acute and long-term care units. We use four metrics to quantify changes in antibiotic use and will use them to assess changes in antibiotic use in acute care as well as well as the long-term care settings.]

1. The first metric, days of antibiotic therapy per 1000 days of care (DOT/1000 DOC), measures the overall rate of antibiotic use and is a common metric that accounts for dose adjustments, including for people who receive dialysis. Administration of any dose of an antimicrobial on a given day represents a single DOT for that agent, regardless of the number of times the doses are administered or the dose strength.
2. Second, we will specifically examine the rate of broad-spectrum antibiotics, defining broad-spectrum agents as those with an Antibiotic Spectrum Index (ASI) score of ≥ 8. This scale ranges from 1 to 13.
3. The third metric is the rate of antibiotic starts (new prescriptions), calculated as the number of starts per 1000 DOC.
4. The fourth metric is the length of antibiotic therapy in days.
    a. For people on hemodialysis, up to 72 hours may occur between doses of specific agents (e.g. vancomycin, aminoglycosides, several cephalosporins); these will be considered as a single course.

For each site, we will calculate these statistics at monthly intervals for the 12 months prior to and the 15 months following the first VAST session, allowing for a 3-month wash-in period, to generate descriptive summaries of changes in acute care and in long-term care over time, understand month-to-month variability in these metrics, and to flag any issues with data availability or validity in the course of the

intervention given operational shifts occurring at facilities around COVID-19 treatment or the rollout of the Cerner electronic medical record across the VA.

Additionally, we will use CDW data to determine the antibiotic prescribing patterns for respiratory tract infections and urinary tract infections (UTI) at VAST sites beginning January 1, 2019. We will then conduct a thorough medical record review on patients identified using CDW. Using this data, we will explore system factors, including prescriber specialty, to predict the rate of prescribing of antibiotics by race and ethnicity.

### 5.6 Data Analysis

1. VAST Implementation

   The primary research team will assess qualitative aspects of implementation and sustainability. With each facilitation call, whether scheduled or ad hoc, members of the primary research team will use field notes to log barriers and facilitators related to implementation. The research team will use process maps to record adaptations. Changes from the initial map will be categorized as major or minor. Further, the number of weeks each VAST required to achieve their final process map will be noted. Together, these assessments will be used to assess fidelity of implementation and to transform the Implementation Guide into a final, robust Implementation Playbook.

2. Staff Perceptions

   Once the intervention period for all VASTs is complete, we will assess for differences in the VAST- vs VAST+ arms on perceived influences on Veteran care, proportion of VAST recommendations accepted, and the user experience survey.

3. Evaluation of clinical activities

   Characteristics of each facility including number of beds, number of CLC beds, medical complexity group, attendance of leadership at VAST sessions and the mean number of cases discussed per session will also be compared. If significant differences are seen between VAST- and VAST+ sites, additional multivariable analyses will be conducted.

4. Facility-Level Antibiotic Use

   To assess for impact of VAST on antibiotic use, we will summarize the 4 antibiotic use metrics for each site, comparing the pre- and post-implementation periods for the acute and long-term care units. Rates of overall antibiotic use (DOT/1000 DOC), broad-spectrum antibiotic use (DOT/1000 DOC) and antibiotic starts (new prescriptions/1000 DOC) will be calculated with 95% confidence intervals based on exact Poisson distributions. To summarize length of therapy in the pre- and post-implementation periods, we will calculate means and 95% confidence intervals.

   To assess for differences between the VAST- and VAST+ study arms, we will use a multi-level Poisson regression model in which facilities will be

parameterized as random effects and study arm and time (year before vs. year of implementation) as fixed effects, with their interaction as the estimated effect of interest. This model will yield estimated rate ratios for overall antibiotic use, use of broad-spectrum agents (ASI ≥ 8), and antibiotic starts for each intervention arm. Length of therapy can be modeled as continuous outcomes in similarly parameterized models, with the interaction of arm and study year as the effect of interest.

Qualitative data will be analyzed in aggregate by the research team for each study activity and shared with the primary research team. We will use data describing specific goals or objectives for the VAST to assess our hypothesis.

Additionally, we will summarize and compare patient characteristics for patients with RTI or UTI. For patients in this cohort, we determine provider and facility factors that are predictive of over, under, or guideline-concordant prescribing for each diagnosis. Information collected from the CDW will be used to develop and pilot a natural language processing algorithm that detects UTIs using provider documentation. This algorithm will be developed using medical record note text stored in the CDW.

### 5.7 Withdrawal of Subjects

1. VAST Implementation

   This study activity involves establishing a VAST at each participating site. Sites may choose to discontinue involvement in the study at any time.

2. Staff Perceptions

   During the verbal consent process, participants (VAST members) will be informed they may withdraw from the study at any time without penalty or loss of benefits to which they are otherwise entitled. Additionally, participants may choose to end the interview or survey at any point. At the time of withdrawal, any data, including PHI, will cease immediately; however, any data already collected as part of the study up to the time of withdrawal may be retained and analyzed. We do not anticipate that the study will impose a participant withdrawal without their consent.

3. Evaluation of clinical activities

   In order to conduct chart review and obtain information from the CDW, we will request a waiver of informed consent.

5. Facility-Level Antibiotic Use

   In order to conduct chart review and obtain information from the CDW, we will request a waiver of informed consent.

## 6.0 Reporting

The Co-Principal Investigators will be jointly responsible for ensuring that the study adheres to the reporting requirements of the VA CIRB, local R&D Committee(s), and VA/VHA requirements (e.g., VHA Handbook 1200.12 and VHA Handbook 1058.01).

Primary study team staff and local site staff will be jointly responsible for reporting problems involving adverse events and/or risks to participants or to research staff, as well as protocol deviations, violations, and noncompliance and information security incidents. All such reports will be completed in compliance with applicable VA/VHA reporting requirements (e.g., VA CIRB Table of Reporting Requirements, VHA Handbook 1200.12, and VHA Handbook 1058.01). All information security and privacy incidents – such as theft or loss of data, unauthorized access of sensitive data or non-compliance with security controls – will be reported to the local site facility's ISSO and PO in accordance with VA/VHA requirements. Event reports will be communicated promptly in the most expeditious method available; reports that contain PHI will be communicated securely (i.e., via encrypted email). Education on the responsibilities regarding these requirements will be provided by the coordinating center. The Coordinating Center will ensure that study personnel follow the VA CIRB reporting requirements and will keep the Co-Chairs (or designee) informed as appropriate.

There are no anticipated serious adverse events or problems, as the study is minimal risk; however, any unanticipated serious adverse events or problems that are related to study procedures will be collected via case report forms at the time of occurrence. Any serious adverse events or unanticipated problems related to study procedures involving risks to subjects or others will be promptly reported to the VA CIRB. Unanticipated problems that don't involve risks to subjects or others will be summarized in narrative format and submitted to the VA CIRB at the time of continuing review.

The study will not have a Data Monitoring Committee.

## 7.0 Privacy and Confidentiality

1. VAST Implementation

   The work proposed is a standard quality improvement approach. The recommendations made as a result of the work proposed will result from a multidisciplinary team with each member working within their professional scope of practice.

2. Staff Perceptions

   This is a minimal risk study. The primary risk is breach of privacy for providers who participate in semi-structured interviews.

   To protect the privacy of VAST members, the semi-structured interviews will be audio recorded without identifying the participants by name. Interviews will be conducted by select members of the primary research team; study members conducting interviews will use a coded list to assign a study ID to providers who participate in interviews. Only study staff directly involved in conducting interviews will have access to this data. If, during the course of an interview, identifying information is recorded, the research team involved in conducting interviews will remove those sections of the recording prior to transcribing the recorded interviews. The research team conducting interviews will not

share any information with the intervention sites, Local Site Investigators, or rest of the primary research team that would permit identification of the semi-structured interview participants. Aggregated themes or deidentified quotations may be shared with leadership or in research publications. The research team conducting and analyzing the interview data will indicate participants by their role and site only if there are sufficient numbers of people in that role to avoid attribution to specific individuals. For example, if only 1-2 pharmacists from each intervention site participates in the VAST, no specific themes or comments will be attributed to pharmacists. Participation in the semi-structured interviews will be voluntary; the research team will not share the names of individuals who decline to participate.

3. Evaluation of clinical activities.

   This is a minimal risk study. The primary risk is breach of privacy for patients discussed by the VAST. In order to determine the acceptance of the VAST recommendations by providers at the intervention site, the research team will need to record the name and medical record number (last 4 of their social security number) of patients discussed by the VAST. These records will be stored and maintained in password protected-computers in folders with restricted access, all of which will be kept behind the VA firewall. No paper records recording patients' name or medical record number will be kept.

4. Facility-Level Antibiotic Use

   To protect the privacy of patients and providers when extracting facility-level antimicrobial use, all data will be stripped of identifying information prior to extraction from VINCI. Our research team has experience with using VINCI and will not seek to access any patient identifying information. The research team will only note the setting (i.e. hospital or CLC) on which antibiotics were administered. Patient and provider identifying information will be removed and replaced with a study-specific identifier in chart review data. Moreover, access to data with the study-specific identifiers will be restricted to members of the research team.

All information security/privacy incidents – such as theft or loss of data, unauthorized access of sensitive data or non-compliance with security controls – will be reported to the primary study team and the local site facility's ISSO and PO in accordance with VA/VHA requirements.

## 8.0 Communication Plan

The primary study team will obtain all local site approvals before informing a site they may start conducting study procedures. There are no VHA facilities where research is being conducted but the facility is not engaged.

When applicable, the study will be conducted in accordance with the current version of the CSP Guidelines, Staff Administrative Guide, and Standard Operating Procedures. VA Central Office establishes overall policies and procedures that are applied to all VA

Cooperative Studies through the Study Chair's Office, CSP Coordinating Center, and CSP Clinical Research Pharmacy Coordinating Center, and other CSP Centers. Participating VA medical centers delegate responsibility for global monitoring of the ongoing study to the primary study team. The primary study team will prepare interim and final progress reports at intervals determined by study leadership; however, the R&D Committee, its subcommittees (e.g., IRB), and the Research Compliance Officer may require the LSI to submit annual and final progress reports concerning the status of the study at the medical center for local monitoring purposes

Site Training and Performance Monitoring

The primary study team will direct and support all phases of the research project, including study implementation, approved-protocol implementation, central coordination of study conduct, data collection and management, interim statistical analyses, study progress monitoring, compliance, and final analyses for study publications.

A training session will be held at each study site prior to initiating enrollment for personnel involved in the conduct of the study to provide guidance on participant management, data collection and other study procedures, and monitoring and reporting adverse events and unanticipated problems. The LSIs will be responsible for ensuring the training of all other personnel listed on the Delegation of Responsibilities Log. All site personnel must be trained on the protocol prior to engaging in research activities. Site personnel should be trained on the version of the protocol that is current at the time of their training. In addition, LSIs will be required to document all personnel who are trained when a new version of the protocol or operations manual is issued.

The primary study team will track and obtain R&D and IRB approvals and ensure that all sites and all personnel are informed of changes to the protocol, operations manual, recruitment materials, consent documents, and data collection instruments. Version control mechanisms will be used on study documents as appropriate. Any adverse events, unanticipated problems, protocol deviations, violations, and noncompliance must be reported to the primary study team. Key study personnel will meet on a regular schedule and agenda items will include site progress, any problems encountered, and IRB and other regulatory issues.

Study Meetings

The primary study team will meet throughout the study to review the progress of the study, discuss any problems the investigators have encountered, and provide suggestions for improving how the study is conducted. Study leadership will meet regularly to monitor the performance of the study sites and oversee publication and presentation of all study data.

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