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Review of Antimicrobial Stewardship Programs in Veterans Health Administration Facilities

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Executive Summary

As directed by the Senate Appropriations Committee Report 114-57 to accompany H.R. 2029,¹ and at the request of Senator Dianne Feinstein, the Office of Inspector General reviewed Veterans Health Administration (VHA) Antimicrobial Stewardship Programs (ASPs), which are required by VHA Directive 1031.² Specifically, the Office of Inspector General was directed to:

- Review ASP implementation.
- Determine if VHA is taking sufficient and consistent steps to improve antibiotic use and reduce antibiotic-resistant infections (including the priority pathogens identified in the President's National Plan to Combat Antimicrobial-Resistant Bacteria).
- Evaluate VHA's efforts to collect and analyze data on antibiotic use and resistance.

ASPs are essential for optimal quality patient care. While antibiotics are necessary to treat infections, as they “reduce morbidity and save lives,”³ antibiotics are not without possible side effects. The overuse and misuse of antibiotics have contributed to antibiotic resistance, and the rate of secondary infections has skyrocketed. The incidence of antibiotic resistance and emergence of drug-resistant bacteria, serious side effects, and infections have increased in both inpatient and outpatient settings. Over half of antibiotic prescribing in outpatient settings is unnecessary, with most of this inappropriate use for treating acute respiratory infections.⁴ Antibiotics are also costly, and inappropriate use wastes resources.⁵

The primary goal of antimicrobial stewardship is to optimize clinical outcomes while minimizing the unintended consequences of antimicrobial use.⁶ In this respect, stewardship of antibiotics is a key function that is assessed in an ASP. Stewardship practices are evaluated by reviewing providers' antibiotic selections, dosing, and duration of treatment. All three variables should be taken into consideration when prescribing antibiotics. ASPs can monitor these elements over time and determine if prescribing practices require change.

¹ Senate Report 114-57 to accompany H.R. 2029, Military Construction, Veterans Affairs, and Related Agencies Appropriation Bill, 2016.

² VHA Directive 1031, *Antimicrobial Stewardship Programs (ASP)*, January 22, 2014.

³ CDC. “Core Elements of Hospital Antibiotic Stewardship Programs,” May 7, 2015. Accessed 7/20/15.

⁴ CDC. Get smart: know when antibiotics work. *Facts about Antibiotic Resistance*. <http://www.cdc.gov/getsmart/community/index.html>. Accessed 6/20/15.

⁵ CDC. “Core Elements of Hospital Antibiotic Stewardship Programs,” May 7, 2015. Accessed 7/20/15.

⁶ SHEA, IDSA, PIDS. Policy statement on antimicrobial stewardship. *Infect Control Hosp Epidemiol* 2012;33:322–327

We concluded that the majority of VHA facilities had established ASPs; however, we identified facility variations in VHA Directive 1031 implementation.

We found that more than 95 percent of the facilities had written ASP policies with consistency across complexity levels of facilities. However, over one third of the facilities did not conduct an evaluation of their ASPs before the deadline of January 23, 2015. We found that 84 percent of the facilities had designated provider and pharmacy champions. Additionally, facilities reported less than 50 percent, on average, compliance with the requirement for clinical and support staff education regarding the appropriate use of antibiotics.

VHA facilities utilized various interventions to improve the judicious use of antibiotics. These interventions were primarily aimed at reducing the incidence of antibiotic-resistant infections. The most commonly reported interventions included publishing antibiograms⁷ and distributing them to providers, selective reporting of antibiotic susceptibilities, requiring approval for the use of selected antibiotics to reduce the emergence of resistant organisms, and having an ASP team. Facilities reported reductions in infections due to the priority pathogens. These reductions were most often attributable to ASPs, education, and infection prevention interventions.

We determined VHA made efforts to collect and analyze data on antibiotic use and resistance. As VHA did not endorse one standard data collection tool, trends could be identified at the local level but might not be reliable for inter-facility comparisons. While not currently a requirement in VHA policy, clinical outcome reports will be required by the Joint Commission in January 2017.

We concluded that VHA facilities cannot effectively measure positive or negative national trends on antibiotic use to guide target areas for program improvement because facilities did not consistently generate clinical outcome reports on antibiotic usage. VHA must ensure that data collection efforts on antibiotic use are consistent across the system, ongoing, and relevant to clinical outcomes.

For consistency, all VHA facilities need to implement processes to ensure standardized data collection and reporting. With standardization, individual facility and system-wide trends can be analyzed. Based on the evaluations, VHA can implement appropriate actions with the goal of improving antibiotic use and reducing antibiotic resistant infections. The annual ASP evaluation needs to be based on accurate data collection and analysis.

We concluded that facility leaders need to assess adequacy of resources to achieve optimal ASPs by providing dedicated staff, administrative support, and essential tools to develop and maintain such programs.

⁷ An antibiogram is a profile of antibiotic sensitivity testing results of a specific bacterial organism to a number of antibiotic drugs. The antibiogram is a useful tool for detecting and monitoring trends in antibiotic resistance.

We recommended that the Under Secretary for Health:

- Implement procedures to ensure that facilities comply with VHA Directive 1031 requirements, including the completion of annual evaluations, designation of provider and pharmacy champions, staff education, and the provision of adequate dedicated staffing and resources.
- Require VHA facilities to track and generate clinical outcome reports on antibiotic use.
- Consider implementing standardized tools and definitions for antimicrobial stewardship data and a uniform reporting system to permit analysis of comparable information over time.

Comments

The Under Secretary for Health agreed with the findings and recommendations and provided acceptable improvement plans. (See Appendix A pages 19–23 for the full text of the comments.) We consider recommendation 3 closed. We will follow up on the planned actions for the remaining open recommendations until they are completed.



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Purpose

As directed by the Senate Appropriations Committee Report 114-57 to accompany H.R. 2029,⁸ and at the request of Senator Dianne Feinstein, Office of Inspector General (OIG) reviewed Veterans Health Administration (VHA) Antimicrobial Stewardship Programs (ASPs), which are required by VHA Directive 1031.⁹ Specifically, OIG was directed to:

- Review ASP implementation.
- Determine if VHA is taking sufficient and consistent steps to improve antibiotic use and reduce antibiotic-resistant infections (including the priority pathogens identified in the President's National Plan to Combat Antimicrobial-Resistant Bacteria).
- Evaluate VHA's efforts to collect and analyze data on antibiotic use and resistance.

Background

“Antibiotic stewardship is the term used to describe efforts to optimize selection of antibiotic therapy.”¹⁰ In 2015, the Centers for Disease Control and Prevention (CDC) reported that 20–50 percent of all antibiotics prescribed in U.S. acute care hospitals are either unnecessary or inappropriate, which may result in lack of clinical benefit or adverse events including hospitalization and/or death. CDC estimates that more than 2 million people are infected with antibiotic-resistant organisms, resulting in approximately 23,000 deaths annually.¹¹ In a 2006 guideline, CDC reported that the control of multidrug resistant organisms must include the judicious use of antibiotics.^{12,13}

Antimicrobial Stewardship (AS) is essential for optimal quality patient care. While antibiotics are necessary to treat infections, as they “reduce morbidity and save lives,”¹⁴ antibiotics are not without possible side effects. The overuse and misuse of antibiotics have contributed to antibiotic resistance. The rate of secondary infections, such as those caused by the overgrowth of the gastrointestinal bacterium, *Clostridium difficile*, has skyrocketed. Antibiotics are costly, and inappropriate use wastes resources.¹⁵

⁸ Senate Report 114-57 to accompany H.R. 2029, Military Construction, Veterans Affairs, and Related Agencies Appropriation Bill, 2016.

⁹ VHA Directive 1031, *Antimicrobial Stewardship Programs (ASP)*, January 22, 2014.

¹⁰ Spellberg B, Srinivasan A, Chambers H. New Societal Approaches to Empowering Antibiotic Stewardship. *JAMA* 2016;315(12):1229–1230.

¹¹ CDC. “Core Elements of Hospital Antibiotic Stewardship Programs,” May 7, 2015. Accessed 7/20/15.

¹² Ibid.

¹³ CDC. “Management of Multidrug-Resistant Organisms in Healthcare Settings, 2006.” Accessed 8/23/16.

¹⁴ CDC. “Core Elements of Hospital Antibiotic Stewardship Programs,” May 7, 2015. Accessed 7/20/15.

¹⁵ Ibid.

Our survey questions addressed key elements of ASPs as outlined by VHA in its previous survey as well as recommendations by CDC. These elements include the team's structure and facilities' interventions and outcomes of VHA facilities' ASPs.

The incidence of antibiotic resistance and emergence of drug-resistant bacteria, serious side effects, and infections have increased in both inpatient and outpatient settings. Over half of antibiotic prescribing in outpatient settings is unnecessary, with most of this inappropriate use for treating acute respiratory infections.¹⁶

The primary goal of AS is to optimize clinical outcomes while minimizing the unintended consequences of antimicrobial use.¹⁷ In this respect, stewardship of antibiotics is a key function that is assessed in an ASP. How stewardship practices are measured include providers' antibiotic selection for the appropriate drug, dosing, and duration of treatment. All three variables should be taken into consideration when prescribing antibiotics. The ASP can monitor these elements over time and determine if prescribing practices require change. For example, an ASP may recognize that broad spectrum antibiotic use is trending upward from a year ago and further analysis needs to be initiated in order to understand that trend. Analysis may indicate the need to restrict the use of broad spectrum antibiotics; however, ongoing data collection would be needed to determine the impact of interventions.

VHA facilities have varied demographics and complexity levels that can affect how and what the ASP chooses to monitor. Additionally, the trends of certain infections in the facility or the local community may influence the ASP activities.

Examples of monitoring stewardship practices by an ASP include the following:

- A tertiary VHA facility may choose to assess treatment for all healthcare-associated non-ventilator and ventilator-associated pneumonias. Specifically, an evaluation of the duration of treatment may be the focus of study.
- A predominantly VHA outpatient facility may choose to evaluate the treatment of specific outpatient infections. A subset of this evaluation may assess antibiotic use during peak flu season.
- A VHA nursing home facility may focus on long-term IV antibiotics use and the appropriateness of the initial therapy.

¹⁶ CDC. Get smart: know when antibiotics work. *Facts about Antibiotic Resistance*. <http://www.cdc.gov/getsmart/community/index.html>. Accessed 6/20/15.

¹⁷SHEA, IDSA, PIDS. Policy statement on antimicrobial stewardship. *Infect Control Hosp Epidemiol* 2012;33:322–327

VHA ASPs

In 2012, VHA conducted a survey of 140 medical facilities to obtain baseline data on ASP activities. The data provided information to the National Program Offices and VHA leadership about the status of ASP activities.¹⁸

In 2013, VHA published a summary review of VHA and non-VHA literature regarding the effectiveness of ASPs implemented in inpatient settings.¹⁹ In 2014, VHA published a similar review for ASPs in the outpatient settings.²⁰ The reviews were intended to guide clinical practice and policy within VHA.

On January 22, 2014, VHA issued Directive 1031 requiring all VHA medical facilities to establish procedures to implement and maintain an ASP. Each facility was tasked with developing and implementing an ASP with a written policy (by July 31, 2014) that included annual evaluation of ASP activities (by January 23, 2015). Elements for annual evaluation include structural and personnel resources, policies, and interventions to promote the judicious use of antibiotics and reduce the incidence of antibiotic-resistant infections.²¹

Non-VHA ASP Guidelines

In 2007, the Infectious Diseases Society of America (IDSA) and the Society for Healthcare Epidemiology of America (SHEA) published guidelines to enhance antibiotic stewardship²² as previously described by the IDSA in 1988²³ and then jointly with SHEA in 1997.²⁴ The 2007 recommendations provided the foundation for an ASP and had two core strategies that included:

- Prospective audits with intervention and feedback to the prescriber resulting in reducing the inappropriate use of antibiotics
- Formulary restriction and preauthorization requirements leading to immediate and significant reductions in antibiotic use and cost as part of a multifaceted response to a healthcare-associated infection outbreak

¹⁸ Dept. of Veterans Affairs, 2012 Survey of Antimicrobial Stewardship in VHA, May 2013.

¹⁹ QUERI. Antimicrobial Stewardship Programs in Inpatient Settings: A Systematic Review 2013.

²⁰ QUERI. Antimicrobial Stewardship Programs in Outpatient Settings: A Systematic Review 2014.

²¹ VHA Directive 1031, *Antimicrobial Stewardship Programs*, January 22, 2014.

²² Dellit TH, Owens RC, McGowan JE, et.al. Infectious Disease Society of America and the Society for Healthcare Epidemiology of America guidelines for developing an institutional program to enhance antimicrobial stewardship. *Clin Infect Dis*. 2007;44 153–77.

²³ Marr JJ, Moffet HL, Kunin CM. Guidelines for improving the use of antimicrobial agents in hospitals: a statement by the Infectious Diseases Society of America. *J Infect Dis* 1988;157(5):869–76.

²⁴ Shlaes DM, Gerding DN, John JF, et.al. Society for Healthcare Epidemiology of America and Infectious Diseases Society of America join committee on the prevention of antimicrobial resistance: guidelines for the prevention of antimicrobial resistance in hospitals. *Clin Infect Dis*. 1997;25(3):584–99.

In 2012, the IDSA, SHEA, and the Pediatric Infectious Disease Society issued a policy statement on AS²⁵ and made the following recommendations:

- Require AS through regulatory mechanisms.
- Monitor AS in ambulatory healthcare settings.
- Educate clinicians on AS.
- Collect and make readily available data for both inpatient and outpatient settings.
- Conduct AS research.

In May 2015, the CDC published its recommended core elements of an ASP.²⁶ These included:

- Leadership Commitment – Dedicating necessary human, financial, and information technology resources
- Accountability – Appointing a single leader responsible for program outcomes. Experience with successful programs show that a knowledgeable physician leader is effective
- Drug Expertise – Appointing a single pharmacist leader responsible for working to improve antibiotic use
- Action – Implementing at least one recommended action, such as systemic evaluation of ongoing treatment need after a set period of initial treatment (that is, “antibiotic time out” after 48 hours)
- Tracking – Monitoring antibiotic prescribing and resistance patterns
- Reporting – Regular reporting of antibiotic use and resistance information to doctors, nurses, and relevant staff
- Education – Educating clinicians about resistance and optimal prescribing

The White House National Action Plan for Combating Antibiotic-Resistant Bacteria

On September 18, 2014, President Obama issued an Executive Order establishing a task force to identify actions to facilitate and monitor implementation of the National Strategy for Combating Antibiotic-Resistant Bacteria. The task force included a representative from the Department of Veterans Affairs.²⁷ In September 2014, the task force issued the “National Strategy for Combating Antibiotic-Resistant Bacteria” to “identify priorities and coordinate investments to prevent, detect, and control outbreaks of resistant pathogens recognized by CDC as urgent or serious threats...”²⁸

²⁵ SHEA, IDSA, PIDS. Policy statement on antimicrobial stewardship. *Infect Control Hosp Epidemiol* 2012;33:322–327.

²⁶ CDC. Core Elements of Hospital Antibiotic Stewardship Programs, May 7, 2015. Accessed 7/20/15.

²⁷ Federal Register. Executive Order 13676 *Combating Antibiotic-Resistant Bacteria*, 9.18.14.

²⁸ National Strategy Plan for Combating Antibiotic-Resistant Bacteria, September 2014.

In March 2015, the task force issued the “National Action Plan for Combating Antibiotic-Resistant Bacteria”²⁹ with the following goals:

- Slow the emergence of resistant bacteria and prevent the spread of resistant infections.
- Strengthen national surveillance efforts to combat resistance.
- Advance development and use of rapid and innovative diagnostic tests for the identification and characterization of resistant bacteria.
- Accelerate basic and applied research and development for new antibiotics, other therapeutics, and vaccines.
- Improve international collaboration and capacities for antibiotic-resistance prevention, surveillance, control, and antibiotic research and development.

Since SHEA and IDSA first published guidelines to enhance antibiotic stewardship in 2007, there has been an evolution from guidelines to the new Joint Commission standard under Medication Management (MM.09.01.01). This standard will become effective January 1, 2017 and will apply to hospitals and nursing care centers and addresses AS. The elements of performance will require facilities to:

- Establish AS as an organizational priority.
- Educate staff and licensed independent practitioners.
- Educate patients and families.
- Establish multidisciplinary team.
- Include core elements such as leadership commitment, accountability, tracking and reporting.
- Use organization-approved multidisciplinary protocols.
- Collect, analyze, and report data.
- Take action on improvement opportunities.³⁰

Scope and Methodology

We conducted this review from June 12, 2015 to August 12, 2016. The review focused on facility implementation of VHA Directive 1031 and the charges set forth by the Senate Appropriations Committee report and Senator Dianne Feinstein. We addressed the following:

- ASP implementation

²⁹ National Action Plan for Combating Antibiotic-Resistant Bacteria, March 2015.

³⁰ Joint Commission Perspectives®, July 2016, Volume 36, Issue 7.

- Steps VHA has taken to improve antibiotic use and reduce antibiotic-resistant infections (including the priority pathogens identified in the President's National Plan to Combat Antimicrobial-Resistant Bacteria)
- Evaluation of VHA's efforts to collect and analyze data on antibiotic use and resistance

From October 13 to November 13, 2015, we surveyed 140 VHA medical facilities to determine the extent to which they implemented VHA Directive 1031. Using Survey Pro, a secured data exchange, we distributed survey questionnaires to 140 Facility Directors and received 100 percent response rate.

We reviewed the requirements outlined in VHA Directive 1031, the 2012 VHA Survey on Antimicrobial Stewardship,³¹ and CDC's Core Elements of ASP³² to formulate the questions for our survey. We included the requirements from VHA Directive 1031 as well as key elements—as determined by our team—from the VHA 2012 survey. We formulated the questions to address the charges from the Senate Appropriations Committee report and Senator Dianne Feinstein.

Of the 140 responses, 136 were from medical centers, and 4 were from health care centers;³³ 123 were urban facilities, while 17 were rural.³⁴ Also, 86 medical centers had community living centers. We analyzed the information provided according to the facility's complexity levels to determine if there were differences in the extent of ASP implementation: 84 facilities were level 1a, 1b, or 1c; 25 were level 2; and 31 were level 3.³⁵

We reviewed and analyzed facility survey responses related to interventions taken to improve the judicious use of antibiotics and facility improvement in prescribing practices in the five antibiotics classes that we selected based on common use (quinolones, vancomycin, extended spectrum penicillins, carbapenems, and third generation cephalosporins).³⁶

We reviewed and analyzed facility reported incidence of the healthcare-associated infections (HAIs) related to the following pathogens: carbapenem-resistant Enterobacteriaceae (CRE), methicillin-resistant *Staphylococcus aureus* (MRSA), and

³¹ Dept. of Veterans Affairs, 2012 Survey of Antimicrobial Stewardship in VHA, May 2013.

³² CDC. "Core Elements of Hospital Antibiotic Stewardship Programs," May 7, 2015. Accessed 7/20/15.

³³ Medical centers have inpatient beds and health care centers are stand-alone outpatient facilities.

³⁴ VSSC Geo-coded Rurality classifications

http://reports2.vssc.med.va.gov/ReportServer/Pages/ReportViewer.aspx?/Apps/VAST/Production/URHR_Service_and_Detail_FY2016&UserLogin=VHAMASTEROIGDALCARLIS&QuarterID=Q1FY2016&Service_Label=VA%20Medical%20Center&rs:Command=Render

http://reports2.vssc.med.va.gov/ReportServer/Pages/ReportViewer.aspx?%2fApps%2fVAST%2fProduction%2fURHR_Service_and_Summary_FY2016&rs:Command=Render accessed 6.14.16.

³⁵ VSSC Facility complexity definitions, with level 1a facilities being the most complex, and level 3 the least complex. <http://opes.vssc.med.va.gov/FacilityComplexityLevels/Pages/default.aspx> accessed 6.22.16.

³⁶ We included vancomycin, which is not technically a class of antibiotics, because it is commonly used in hospital settings for MRSA and CDI.

Clostridium difficile. We noted the March 2015 White House's National Action Plan for Combating Antibiotic-Resistant Bacteria (Plan) discussed priority pathogens in terms of the CDC's 2013 classification of 18 pathogens considered threats to public health that CDC categorized into three levels: (1) Urgent (3 pathogens), (2) Serious (12 pathogens), or (3) Of concern (3 pathogens).³⁷ CRE and *Clostridium difficile* are two of the CDC's Urgent pathogens. MRSA is classified as Serious. We included these three pathogens in our survey query because one of the goals outlined in the Plan is the prevention of "transmission of healthcare-associated infections...including multidrug resistant organisms (MDROs) such as CRE, MRSA, and *Clostridium difficile* infection (CDI), that are associated with antibiotic use...[and] can spread regionally from one healthcare facility..."³⁸ Additionally, VHA collects data and monitors CRE, MRSA, and CDI. We requested information relating to a reduction in the HAIs associated with these three priority pathogens for the year prior to and the year after the publication of VHA Directive 1031.

We also reviewed facility responses related to data collection and types of support that would be beneficial to achieve optimal antibiotic use.

We requested, received, and reviewed documents submitted to support survey responses including facility policies, clinical staff (providers,³⁹ nurses, and other clinical support) education, infection surveillance data, and specific actions taken to monitor and track prescribing practices. We also reviewed VHA and facility ASP policies.

We recognized certain limitations to the survey. We relied on self-reporting from the facilities; validating responses was beyond the scope of the survey.

We interviewed VHA and non-VHA subject matter experts and reviewed national guidelines, relevant literature, and documents/data obtained in response to the survey.

We conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

³⁷ National Action Plan for Combating Antibiotic-Resistant Bacteria, March 2015, Table 3, p. 61–3.

³⁸ National Action Plan for Combating Antibiotic-Resistant Bacteria, March 2015, p. 15.

³⁹ Physicians, nurse practitioners, and other clinical staff authorized to prescribe medications.

Inspection Results

Issue 1. ASP Implementation⁴⁰

We determined that the majority of VHA facilities had established ASPs; however, we identified facility variations in VHA Directive 1031 implementation.

VHA issued Directive 1031 in January 2014 to establish policy for the implementation and maintenance of ASPs at all VA facilities. Based on the survey responses we deployed in 2015, we found that not all surveyed facilities implemented required elements outlined in the directive. We surveyed VHA facilities to determine whether they had implemented the following required elements:

- A written ASP policy by July 31, 2014
- An evaluation of the facility's ASP by January 23, 2015
- Designation of ASP provider and pharmacist champions^{41,42}
- Education to clinicians (providers and other clinical staff) on the judicious use of antibiotics and infection prevention measures

Each of these requirements is necessary to ensure facilities have a relevant ASP. The policy serves as the template for the program and addresses what is pertinent to each facility. Each facility is unique, and the program should be tailored to the facility's needs and resources. The evaluation helps facilities evaluate their program and target areas for improvement. Leadership at the administrative level is important, but it is vital for the success of the program to have knowledgeable and vested champions to lead the program and educate the clinicians. CDC, IDSA, and SHEA recommend designating a physician and pharmacist champion to accomplish this goal. There are many ways to address education and training plans should be personalized to meet the needs of the staff. In addition to lectures and printed materials, facilities can provide education through antibiograms, antibiotic order sets, clinical guidelines, and pharmacy interventions.²⁵

Of the 140 facilities, 96 percent reported having written ASP policies with consistency across the levels of complexity. Sixty-four percent of the facilities reported that they conducted evaluations of their ASPs before January 23, 2015. More than 80 percent had designated provider and pharmacy champions. Additionally, facilities reported compliance with the requirement for clinical staff education: 56 percent for providers and 40 percent for nursing staff. Table 1 summarizes facility responses for the surveyed requirements.

⁴⁰ VHA Directive 1031, *Antimicrobial Stewardship Programs (ASP)*, January 22, 2014.

⁴¹ Provider champion: Clinical provider who is actively involved in defined components of ASP at the facility level; can advocate for and support stewardship initiatives at the facility.

⁴² Pharmacy champion: Pharmacist who can advocate for and support stewardship initiatives at the facility.

Table 1: Facility Responses to Surveyed VHA Directive 1031 Elements

Elements	Yes Responses (Percent)
1. ASP policy	135 (96)
2. Annual evaluation	89 (64)
3. Designated champions:	
a. ASP champion provider	117 (84)
b. ASP champion pharmacist	117 (84)
4. Education programs for	
a. Providers	79 (56)
b. Nursing staff	56 (40)

Source: VAOIG analysis of 2015 facility survey responses

Complexity level 1 facilities reported higher education percentage rates (63 percent providers and 43 percent nursing staff) than levels 2 and 3.

Developing a Written ASP Policy by July 31, 2014

All but 5 (4 percent) of the 140 facilities surveyed reported having a written ASP policy by July 31, 2014, as required by VHA. We queried these facilities to determine their ASP policy status as of August 2016. One had issued a policy in early 2016, and two had draft policies awaiting final approval from facility leadership. Two facilities had no written ASP policies. We did not assess whether facilities performed AS functions while developing their policies. See Table 2 below.

Table 2: Facilities With No Written ASP Policy by July 31, 2014

Facility	Complexity level	Written Policy by July 31, 2014	Comments – Status as of August 2016
1. Augusta, GA	1A	No	Developing program; implementation in early 2017
2. Pittsburgh, PA	1A	No	Draft awaiting final approval
3. El Paso, TX	3	No	Draft awaiting final approval
4. Roseburg, OR	3	No	<i>Policy issued in early 2016</i>
5. Big Spring, TX	3	No	Elements of program in place; activities reported to Infection Control Committee and Pharmacy and Therapeutics

Source: VAOIG analysis of 2015 facility survey responses

Of the five facilities that did not have a written ASP policy by July 31, 2014, two were complexity level 1A, and three were level 3. Complexity Level 1 facilities care for patients with more complicated conditions with higher risk for morbidity and mortality.

AS practices may require more monitoring of patients with complex diseases. Examples include caring for patients with infections on ventilators, managing the patient with sepsis, initiating antibiotics for patients with heart valve infections, selecting antibiotics for meningitis, or choosing antibiotics for patients with post-op infections. Although the AS policy requirement applied to all facilities, level 1 facilities admit and care for high-risk patients, including those who have or develop overwhelming infection during hospitalization. Level 1 facilities have more resources devoted to the management of high risk patients. An AS policy should be in place to direct stewardship practices within the facilities and ensure that resources are devoted to the program that ultimately improves care for those patients.

Performing an Annual Evaluation of the Facility's ASP by January 23, 2015

Of the 140 facilities surveyed, 89 (64 percent) reported conducting evaluations of their ASPs prior to January 23, 2015, as required. Evaluations are necessary to analyze data, assess the strengths and weaknesses of the programs, and allow for the analysis of whether the facility has reached its intended objectives. Specifically, assessments reevaluate resources devoted to achieving program objectives and may reveal best practices that should be continued and supported, or deficiencies that require further analysis for improvement. Since we relied on self-reporting, we could not determine why 36 percent of the facilities did not conduct evaluations prior to January 23, 2015.

Designating an ASP Provider and Pharmacist Champion

Of the 140 facilities surveyed, 117 (84 percent) had designated both provider and pharmacist champions. We could not determine the impact of not having designated champions; however, it is required by VHA policy and is one of the recommended core elements by the CDC for a successful program.

Providing Education to Clinicians (Providers and Other Clinical Staff) on the Judicious Use of Antibiotics and Infection Prevention Measures.

According to the California Department of Public Health, “one of the important aspects of an effective ASP is the dissemination of stewardship education and metrics data to medical staff. Practitioners are much more likely to change their prescribing habits when local data are presented that demonstrate opportunities for improvement.”⁴³

We found in the 140 surveyed facilities:

- 79 (56 percent) reported education for providers.
- 56 (40 percent) reported education for nursing staff.

⁴³ California Department of Public Health. *Antimicrobial Stewardship Program Toolkit* 2015, accessed 8/8/16.

Issue 2. VHA Steps To Improve Antibiotic Use and Reduce Antibiotic-Resistant Infections

Facilities reported having taken steps to improve the judicious use of antibiotics, which contributed to a reported reduction in the incidence of antibiotic-resistant infections.

Reported Interventions To Improve the Judicious Use of Antibiotics and Reduce Antibiotic Resistance

ASPs are one of the most effective ways to improve judicious use of antibiotics. “Their purpose is to optimize clinical outcomes, minimize unintended consequences, improve patient safety, and improve the cost-effectiveness of antibiotic use through a multidisciplinary approach.”⁴⁴ By using antibiotics judiciously, the development of antibiotic resistance can be decreased.⁴⁵

VHA Directive 1031 included an example of an ASP evaluation checklist with elements of surveillance that could promote stewardship practices. Given the range in size and complexity of care provided at each facility, a single template was not practical for all ASPs. ASP staff must take into consideration the particular needs and unique aspects of a facility. ASP staff had the option to modify the Directive’s checklist to track the effectiveness of their program and to target specific areas for resource allocation and improvements.

In their survey responses, VHA facilities reported multiple interventions to improve judicious use of antibiotics, thereby contributing to the reduction in the incidence of antibiotic-resistant infections. The most commonly reported interventions included publishing antibiograms,⁴⁶ and distributing them to providers, selective reporting of antibiotic susceptibilities,⁴⁷ requiring approval for the use of selected antibiotics to reduce the emergence of resistant organisms, and having an ASP team. Table 3 shows facility responses indicating interventions used to improve the judicious use of antibiotics and reduce antibiotic resistance.

⁴⁴ VHA Directive 1031, *Antimicrobial Stewardship Programs*, January 22, 2014.

⁴⁵ Ibid.

⁴⁶ An antibiogram is a profile of antibiotic sensitivity testing results of a specific bacterial organism to a number of antibiotic drugs. The antibiogram is a useful tool for detecting and monitoring trends in antibiotic resistance.

⁴⁷ “Selective reporting is the practice of reporting susceptibility results for a limited number of antibiotics instead of all antibiotics tested based on the organism, type of infection, and the facility antibiogram.”

Table 3: Facility Responses: Interventions To Improve the Judicious Use of Antibiotics and Reduce Antibiotic Resistance

Intervention (N = 140)	Yes Responses (Percent)
1. Antibiograms available to prescribing providers	134 (96)
2. Laboratory selectively reports susceptibility to antibiotic agents ⁴⁸	116 (95)
3. Policy to restrict selected antibiotics	127 (91)
4. ASP team	123 (88)
5. Facility offers internal VHA inpatient Infectious Disease Consultation Service	107 (76)
6. Automatic stop orders in place for duration of antibiotics	99 (71)
7. Use of order sets (standardized orders developed for specific diagnoses)	100 (71)
8. Clinical pathways or antibiotic therapy guidelines	89 (64)
9. Policy to promote substitution of oral antibiotics for parenteral (intravenous) antibiotics	76 (54)
10. Process to limit dual anaerobic bacteria coverage (two different antibiotics for bacteria that can grow without oxygen)	69 (49)
11. Guidelines for antibiotic duration	47 (34)
12. “Timeout” clinical review at 48–96 hour to assess antibiotic choice	41 (29)
13. Policy to limit use of non- <i>CDI</i> directed antibiotic exposure (for example, Clindamycin and broad-spectrum antibiotics such as fluoroquinolones and cephalosporins)	23 (16)

Source: VAOIG analysis of 2015 facility survey responses

⁴⁸ Of the 140 facilities, 122 had onsite microbiology laboratories. Of the 122, 116 selectively reported susceptibilities to antibiotic agents. This is performed to avoid inappropriate use of antibiotic agents and subsequent development of drug-resistant bacteria.

Reported Improvements in Antibiotic Prescribing Practices

Additionally, facilities reported improvements in prescribing practices for the selected classes of antibiotics. Facility self-reported improvements are displayed in Table 4. VHA facilities can decide to follow certain antibiotics based on various factors such as their own antibiograms (antibiotic resistance patterns), community hospital resistance patterns, or specific patient populations (for example, organ transplant).

Table 4: Facility Responses: Self-Reported Improvements in Prescribing Practices Since FY 2013

Five Selected Antibiotic Classes	Yes Responses (Percent)
Quinolones	57 (41)
Vancomycin	51 (36)
Extended spectrum penicillins	46 (33)
Carbapenems	39 (28)
Third generation cephalosporins	28 (20)

Source: VAOIG analysis of 2015 facility survey responses

Reported Reductions in HAIs With Contributing Interventions

In the survey, we requested facilities’ infection surveillance data from FY 2012 and FY 2015 in order to compare pre-VHA Directive 1031 data with 1-year post-VHA Directive data. Facilities that did not report reductions in these infections reported either no change or an increase in infections. Table 5 shows facility self-reported reductions in HAIs and contributing interventions employed to effect reductions. The rate of improvement could have been affected by the baseline rate of infection for a specific organism. For instance, CRE may have had a lower overall incidence of infection than other organisms. Interventions such as infection prevention activities or antibiotic restriction can also contribute to the reductions.

Table 5: Facility Responses: Self-Reported Reductions in HAIs With Contributing Interventions

	MRSA Responses	CRE Responses	CDI Responses
HAI reduction	80	16	58
<i>Contributing Interventions to Infection Reductions*</i>			
ASP	39	16	42
Education	65	28	56
Infection prevention activities	76	30	66

*Multiple answers could be selected

Source: VAOIG analysis of 2015 facility survey responses

Issue 3. VHA Efforts To Collect and Analyze Data on Antibiotic Use and Resistance

We determined VHA made efforts to collect and analyze data on antibiotic use and resistance. VHA Directive 1031 did not endorse a standard measurement tool but allowed each facility to select a preferred tool. Without a standardized tool, facility staff could identify trends at the local level, but trends were not reliable for inter-facility comparisons of comparable information. We also found that facilities did not consistently track the use of antibiotics or generate clinical outcome reports on antibiotic use.

Data Collection Methods

When facilities reported improvement in antibiotic prescribing practices, we noted that facilities utilized a variety of data collection methods to determine improvements. Examples of the methods used included the following:

- CDC's National Healthcare Safety Network (NHSN),⁴⁹ Antibiotic Usage Module⁵⁰ (days of therapy per 1,000 bed days) (Boston, MA, Cincinnati, OH)
- Defined daily dose per 1,000 patient days⁵¹ (Columbia, SC)
- Sum of antibiotic days per 1,000 patient days (Memphis, TN)

Antibiotic Data Collection and Reporting Practices

Subsequent to our review, VHA program staff told us that VHA “has a validated, accurate program to extract and analyze antimicrobial usage at all VHA inpatient facilities. Bar Code Medication Administration data is collected on all inpatient medications, including antimicrobials.” We found that 99 (71 percent) of the facilities surveyed tracked the use of antibiotics, and 72 (51 percent) tracked the days of antibiotic therapy. Since we relied on self-reporting, we could not determine why 29 percent of the facilities surveyed reported not tracking antibiotic use and 49 percent did not track days of antibiotic therapy. Table 6 shows the reported facility antibiotic data collection practices.

We noted that nearly one third of the facilities (31 percent) did not generate clinical outcomes reports. Without monitoring clinical outcomes, facilities cannot effectively measure positive or negative trends locally to guide target areas for program improvement.

⁴⁹ CDC *About NHSN*. Accessed 7/13/16.

⁵⁰ CDC “Core Elements of Hospital Antibiotic Stewardship Programs,” May 7, 2015, Accessed 7/20/16.

⁵¹ Antibiotics that were dispensed during the given time period.

Table 6: Facility Responses: Antibiotic Use and Resistance Tracking and Reporting

Activity	Yes Responses (Percent)
1. Tracks use of antibiotic agents	99 (71)
2. Tracks days of antibiotic therapy	72 (51)
3. Facilities generate reports based on clinical outcomes related to antibiotic use. Reports results are made available to:	96 (69)
a. Infection Control Committee	90 (94)
b. Pharmacy & Therapeutics Committee	74 (77)
c. Administrative Committees	74 (77)
d. Providers	34 (35)
e. ASP Committee	6 (6)
f. Other (miscellaneous)	5 (5)
<i>Facilities may select more than one committee</i>	
4. Of the 96 facilities that generated reports, the following types of clinical outcomes reports were created	
a. <i>CDI</i> rates	91 (95)
b. Antibiotic resistance rates	72 (75)
c. Adverse drug effects	65 (68)
d. Average length of stay	19 (20)
e. Other reports	25 (26)

Source: VAOIG analysis of 2015 facility survey responses

To effect positive change in stewardship practices, facilities must ensure that data collection efforts on antibiotic use are ongoing and relevant to clinical outcomes. Standardization of data collection (for example, CDC’s NHSN program) allows for comparative analysis of comparable information and trending on a national level.

Issue 4. Program Support

We found that facilities identified additional support that would be beneficial for their ASPs.

VHA Directive 1031 outlines administrative support and responsibilities essential for ASP. Facilities surveyed identified additional types of support that would be beneficial to achieve optimal ASPs. Facility leaders play a critical role in the success of ASP by providing the support and tools to develop and maintain such programs. “For an ASP to

be successful, active leadership and ongoing maintenance is required.”⁵² VHA Directive 1031 is explicit in its recommendation for adequate dedicated multidisciplinary staffing and resources for a successful ASP. CDC⁵³ and IDSA⁵⁴ recommendations also emphasize the importance of providing staffing and support. The 2015 VHA survey of ASPs reported comparable results regarding the types of support that would be beneficial.⁵⁵ More than half of the facilities responded that additional Information Technology/data tools support would be beneficial. Table 7 lists the predominant areas facilities selected for additional support.

Table 7. Facility Responses: Types of Support That Would Be Beneficial

Type of Support	Yes Responses (Percent)
Information technology/data tools support	79 (56)
Educational tools support	52 (37)
Administrative support	48 (34)
Infectious Disease Physician support	47 (34)
Provider/prescriber buy-in	45 (32)
Pharmacy support	43 (31)
Guidelines support	41 (29)
Multiple answers could be selected	

Source: VAOIG analysis of 2015 facility survey responses

Conclusions

We concluded that the majority of VHA facilities had established ASPs; however, we identified facility variations in VHA Directive 1031 implementation. More than 95 percent of the facilities had written ASP policies with consistency across complexity levels of facilities. However, over one third of the facilities did not conduct an evaluation of their ASPs before the deadline of January 23, 2015. We found that 84 percent of the facilities had designated provider and pharmacy champions. Additionally, facilities reported less than 50 percent, on average, compliance with the requirement for clinical and support staff education.

⁵² VHA Directive 1031, *Antimicrobial Stewardship Programs (ASP)*, January 22, 2014.

⁵³ CDC. “Core Elements of Hospital Antibiotic Stewardship Programs,” May 7, 2015. Accessed 7/20/16.

⁵⁴ Dellit TH, Owens RC, McGowen JE, et.al. Infectious Disease Society of America and the Society for Healthcare Epidemiology of America. Guidelines for developing an institutional program to enhance antimicrobial stewardship. *Clin Infect Dis.* 2007;44. 153–77.

⁵⁵ Chou AF, Graber CJ, Jones N, et.al. Characteristics of Antimicrobial Stewardship Programs at Veterans Affairs Hospitals: Results of a Nationwide Survey. *Infection Control and Hospital Epidemiology* 2016;37(6): 647–564.

VHA facilities utilized various interventions to improve the judicious use of antibiotics aimed at reducing the incidence of antibiotic-resistant infections. The most commonly reported interventions included publishing antibiograms and distributing them to providers, reporting of selected antibiotic susceptibilities, requiring approval for the use of selected antibiotics to reduce the emergence of resistant organisms, and having an ASP team. Facilities reported infection reductions due to the priority pathogens, and most often attributed these reductions to ASP, education, and infection prevention interventions.

VHA made efforts to collect and analyze data on antibiotic use and resistance but did not endorse one standard data collection tool. As a result, trends can be identified at the local level but may not be reliable for inter-facility comparisons.

VHA reported that the Bar Code Medication Administration program collects data on all inpatient medications, including antimicrobials. However, nearly one third of the facilities surveyed did not consistently track the use of antibiotics or generate clinical outcome reports on antibiotic use.

We concluded that VHA cannot effectively measure positive or negative trends on antibiotic use to guide target areas for program improvement because facilities did not consistently generate clinical outcome reports on antibiotic usage. VHA must ensure that data collection efforts on antibiotic use are consistent across the system, ongoing, and relevant to clinical outcomes.

For consistency, all VHA facilities need to implement processes to ensure standardized data collection and reporting. With standardization, individual facility and system-wide trends can be analyzed. Based on the evaluations, VHA can implement appropriate actions with the goal of improving antibiotic use and reducing antibiotic resistant infections. The annual ASP evaluation needs to be based on accurate data collection and analysis. The CDC NHSN program is an example of a federal standardized reporting system used by medical facilities in the US to track healthcare-associated infections. The NHSN Antibiotic Use Module is one portion of the program to specifically track antibiotic usage.⁴⁹ This could facilitate standardized reporting of infections, antibiotic usage and resistance and enable inter-facility comparisons.

We concluded that facility leaders need to assess adequacy of resources to achieve optimal ASPs by providing dedicated staff, administrative support, and essential tools to develop and maintain such programs.

Recommendations

1. We recommended that the Under Secretary for Health implement procedures to ensure that facilities comply with Veterans Health Administration Directive 1031 requirements, including the completion of annual evaluations, designation of provider and pharmacy champions, staff education, and the provision of adequate dedicated staffing and resources.

2. We recommended that the Under Secretary for Health require that Veterans Health Administration facilities track and generate clinical outcome reports on antibiotic use.
3. We recommended that the Under Secretary for Health consider implementing standardized tools and definitions for antimicrobial stewardship data and a uniform reporting system to permit analysis of comparable information over time.

Under Secretary for Health Comments

**Department of
Veterans Affairs**

Memorandum

Date: November 22, 2016

From: Under Secretary for Health (10)

Subj: **Healthcare Inspection—Review of Antimicrobial Stewardship Programs in VHA Facilities**

To: Assistant Inspector General for Healthcare Inspections (54)
Director, Management Review Service (VHA 10E1D)

1. Thank you for the opportunity to review the Office of Inspector General draft report: Healthcare Inspection, Review of Antimicrobial Stewardship Programs in Veterans Health Administration Facilities. I concur with the findings in the draft report and provide the attached action plan to address recommendations 1 through 3.
2. The Veterans Health Administration (VHA) has a long-standing commitment to antimicrobial stewardship and through VHA Directive 1031 became one of the first health care systems in the country to require development of antimicrobial stewardship programs at every medical center.
3. Antimicrobial use is one of the strongest risk factors for the development of antimicrobial-resistant infections and may also lead to unintended consequences such as adverse drug events and infection due to *Clostridium difficile*. Antimicrobial stewardship programs strive to optimize antimicrobial use to avoid unintended consequences and improve clinical outcomes.
4. The VHA National Antimicrobial Stewardship Initiative, established in March 2011, is a highly successful, enterprise-wide effort to support local development and augmentation of stewardship programs with the ultimate goals of optimizing antimicrobial use and improving the care of the Nation's Veterans.

5. VHA is dedicated to sustained improvement in the Government Accountability Office high risk areas. The recommendations in this draft report apply to high risk areas 1 (ambiguous policies and inconsistent processes) and 2 (inadequate oversight and accountability). VHA's action plan will not only reinforce the importance of adhering to all aspects of VHA Directive 1031, but also monitor facility compliance and consistent implementation.
6. If you have any questions, please email Karen Rasmussen, M.D., Director, Management Review Service at VHA10E1DMRService@va.gov.



David J. Shulkin, M.D.

Under Secretary for Health Comments to Office of Inspector General's Report

The following comments are submitted in response to the recommendations in the Office of Inspector General's report:

OIG Recommendations

Recommendation 1. We recommended that the Under Secretary for Health implement procedures to ensure that facilities comply with Veterans Health Administration Directive 1031 requirements, including the completion of annual evaluations, designation of provider and pharmacy champions, and staff education and the provision of adequate dedicated staffing and resources.

Concur

Target date for completion: March 2017

Facility response: This recommendation is related to Government Accountability Office (GAO) High Risk Area 1 (ambiguous policies and inconsistent processes). VHA agrees that compliance with VHA Directive 1031 is very important and will reinforce the importance of completing annual Antimicrobial Stewardship Program evaluations, providing staff education and providing adequate dedicated staffing and resources.

The Inspector General's (OIG) survey was distributed to the field in October 2015 which identified some deficiencies in facilities having designated provider and pharmacy champions for stewardship. After the OIG Stewardship Survey was completed, the Veterans Health Administration (VHA) Healthcare Analysis and Information Group (HAIG) conducted an additional, comprehensive survey at the request of the VHA National Antimicrobial Stewardship Taskforce. This second survey was previously scheduled as a follow up to the HAIG 2012 Antimicrobial Stewardship Survey. Results from the second HAIG survey, completed in January 2016, revealed improvements from OIG's October 2015 data: 93 percent (up from 84 percent) of VHA facilities had identified a provider champion for antimicrobial stewardship and 96 percent (up from 84 percent) had identified a pharmacy champion for stewardship. The improvements made demonstrate a marked increase in overall compliance with the Directive.

VHA concurs that compliance with the remaining elements of the Directive: completion of annual evaluations, staff education and the provision of adequate dedicated staffing and resources need improvement. The Office of the Deputy Under Secretary for Health for Policy and Services and the National Infectious Diseases Service (10P4E) will draft a memorandum for dissemination by the Office of the Deputy Under Secretary for Health for Operations and Management emphasizing the need for compliance with VHA Directive 1031. The memo will reinforce the importance of completing annual evaluations, staff education and provision of staffing and resources for antimicrobial stewardship, as well as require a plan from those facilities that are non-compliant with those elements.

Recommendation 2. We recommended that the Under Secretary for Health require that Veterans Health Administration facilities track and generate clinical outcome reports on antibiotic use.

Concur in Principle

Target date for completion: March 2017

Facility response: This recommendation is related to GAO High Risk Area 2 (inadequate oversight and accountability). VHA agrees with the need for VHA stewardship programs to track and generate clinical outcomes reports and is currently 100 percent compliant. The OIG's draft report revealed a failure in communicating these activities within the program.

While there is no national consensus or any evidence-based studies that identify the most appropriate clinical outcomes for antimicrobial stewardship, hospital-acquired *Clostridium difficile* infection (CDI) is considered one of the most appropriate measures to monitor because of the direct correlation of antibiotic use and CDI. For a number of years, VHA facilities have been required to report on several health-care associated infections including CDI through local Infection Prevention and Control Programs and Multi-Drug Resistant Organism Program mechanisms, to the VHA's Inpatient Evaluation Center (IPEC).

One hundred percent of acute care facilities are compliant with reporting CDI to IPEC. According to the OIG finding, 31 percent of VHA facilities reported they did not generate clinical outcomes reports for stewardship, which appears to reveal a failure in communication. Antimicrobial stewardship programs should be multi-disciplinary in order to facilitate inter-disciplinary communications for more comprehensive stewardship reports. The Office of the Deputy Under Secretary for Health for Policy and Services and the National Infectious Diseases Service (10P4E) memorandum will include a reminder of the current policy specifying the multidisciplinary nature of antimicrobial stewardship programs.

Recommendation 3. We recommended that the Under Secretary for Health consider implementing standardized tools and definitions for antimicrobial stewardship data and a uniform reporting system to permit analysis of comparable information over time.

Concur

Target date for completion: Complete

Facility response: This recommendation is related to GAO High Risk Area 2 (inadequate oversight and accountability). VHA has considered the importance of implementing standardized tools for antimicrobial stewardship data and agrees that standardized definitions are imperative for reporting and analyzing comparative information over time.

In recognizing the importance of standardization in antimicrobial use data, VHA has been actively engaged with the Centers for Disease Control and Prevention since 2012 in developing mechanisms to assist VHA with electronic reporting of antimicrobial use data to the Center for Disease Control's National Healthcare Safety Network's Antimicrobial Use (AU) Option. At present, 79 of VHA acute care facilities have already engaged in the process to submit antimicrobial use to the AU Option.

OIG Contact and Staff Acknowledgments

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