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VETERANS HEALTH CARE

Agency Efforts to Provide and Study Prosthetics for Small but Growing Female Veteran Population

GAO-21-60

GAO Highlights

Highlights of GAO-21-60, a report to congressional committees

November 2020

VETERANS HEALTH CARE

Agency Efforts to Provide and Study Prosthetics for Small but Growing Female Veteran Population

Why GAO Did This Study

Women are the fastest growing veteran subpopulation, with the number of female veterans using VHA health care services increasing 29 percent from 2014 to 2019. Female veterans accounted for an estimated 10 percent of the total veteran population in fiscal year 2019. They are eligible to receive a full range of VHA health care services, including obtaining prosthetics.

House Report 115-188 included a provision for GAO to review VHA's prosthetic services for female veterans. This report examines 1) trends in prosthetics provided by VHA to female veterans; 2) characteristics of the female veteran population with limb loss and how VHA provides prosthetic services to these veterans through its Amputation System of Care; and 3) VHA's research efforts and the challenges that exist in studying prosthetics for female veterans with limb loss.

GAO analyzed VHA documents, as well as data from fiscal years 2015 to 2019 on prosthetics and veterans with amputations. GAO interviewed agency officials from VHA central office and officials and female veteran amputees at two VA medical facilities selected for expertise in amputation care and prosthetics research activities. In addition, GAO interviewed VHA researchers conducting studies on prosthetics for female veterans.

GAO provided a draft of this report to VA. VA provided general and technical comments, which were incorporated as appropriate.

View GAO-21-60. For more information, contact Jessica Farb at (202) 512-7114 or farbj@gao.gov.

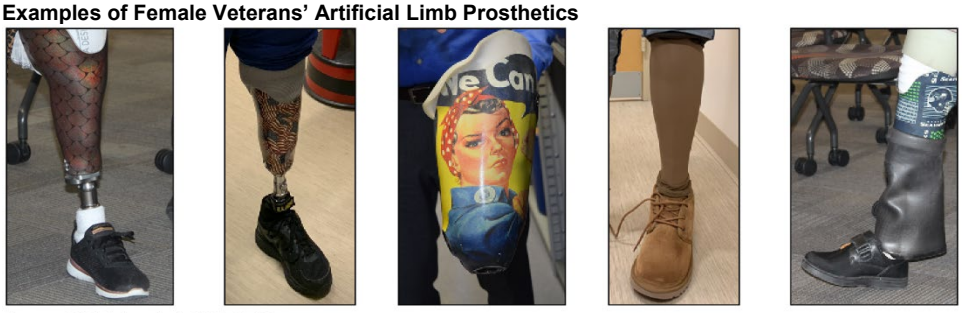
What GAO Found

The Department of Veterans Affairs' (VA) Veterans Health Administration (VHA) provides veterans with prosthetic services to assist with their mobility, vision, and hearing needs. The proportion of prosthetics VHA provided to female veterans has been small compared to the share provided to male veterans. However, in fiscal years 2015 to 2019, this proportion grew from 6.8 percent to 7.9 percent and accounted for about $889.1 million of the $15.4 billion total cost of prosthetics.

Artificial limbs comprised a relatively small number of the total prosthetics VHA provided to veterans in fiscal years 2015 to 2019; however, veterans who use artificial limbs have complex needs and are significant users of health care services. VHA provided prosthetic services to a small but growing female veteran amputee population (almost 3 percent of veteran amputees in fiscal year 2019), who were generally younger than male veteran amputees.

VHA has established an individualized patient care approach in its Amputation System of Care that seeks to address the prosthetic needs of each veteran, including accounting for gender-specific factors. VHA officials said that using a standardized, multidisciplinary approach across VA medical facilities also helps them incorporate the concerns and preferences of female veterans. For example, veterans are provided care by a team that includes a physician, therapist, prosthetist (clinician who helps evaluate prosthetic needs and then designs, fabricates, fits, and adjusts artificial limbs), and other providers as needed. Female veteran amputees GAO spoke with at one VA medical facility said they were satisfied with their VHA care. They also noted a lack of commercially available prosthetic options that VHA providers can use to meet women's needs.

Examples of Female Veterans' Artificial Limb Prosthetics



Source: GAO (photos). | GAO-21-60

Women are generally studied less than their male counterparts in prosthetic and amputee rehabilitation research. VHA designated prosthetics for female veterans a national research priority in 2017, and has funded eight related studies as of May 2020: four pertain to lower limb amputation, three pertain to upper limb amputation, and one pertains to wheelchairs. VHA officials noted the importance of this research priority and the ongoing challenge of recruiting study participants due to the small female veteran population. VHA researchers said they employ various tactics to address this challenge, such as using multi-site studies and recruiting participants from the non-veteran population.

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Abbreviations

DOD	Department of Defense
EACE	Extremity Trauma and Amputation Center of Excellence
NPPD	National Prosthetics Patient Database
ORD	Office of Research and Development
PSAS	Prosthetic and Sensory Aids Service
VA	Department of Veterans Affairs
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
Washington, DC 20548

November 12, 2020

The Honorable John Boozman
Chairman
The Honorable Brian Schatz
Ranking Member
Subcommittee on Military Construction, Veterans Affairs, and Related Agencies
Committee on Appropriations
United States Senate

The Honorable Debbie Wasserman Schultz
Chairwoman
The Honorable John Carter
Ranking Member
Subcommittee on Military Construction, Veterans Affairs, and Related Agencies
Committee on Appropriations
House of Representatives

Women are the fastest growing subpopulation of veterans, accounting for 10 percent of the total veteran population (estimated to be about 2 million of approximately 20 million veterans in fiscal year 2019). The Department of Veterans Affairs (VA) further estimates that this proportion will rise to about 16 percent over the next two decades. Female veterans are eligible to receive a full range of covered health care services, such as maternity and amputation care, through VA's Veterans Health Administration (VHA).[1] The number of female veterans who used VHA health care services increased 29 percent from 2014 to 2019.

More than half of veterans receiving care in the VA health care system, including women, rely on VHA's prosthetic services across their lifespans. The term prosthetic generally refers to any device that supports or replaces a body part or function, for purposes such as increased mobility,

[1]VA's national health care system is one of the largest in the United States and provides covered health care services to enrolled veterans—including female veterans—through its 18 regional Veterans Integrated Service Networks (VISN) containing individual VA medical facilities and health care systems made up of multiple VA medical facilities. VHA is responsible for oversight of the provision of health care at all VA medical facilities. We reported in December 2016 that VHA may not be fully meeting the health care needs of female veterans. See GAO, *VA Health Care: Improved Monitoring Needed for Effective Oversight of Care for Women Veterans,* GAO-17-52 (Washington, D.C.: Dec. 2, 2016).

vision, and hearing. Prosthetics include a wide range of items, including pacemakers, hearing aids, and diabetic socks.

Veterans seeking prosthetics due to amputation have complex needs and are significant users of health care services. Although female veterans with an amputation represent only 3 percent of all military amputees, women have unique needs when limb loss occurs. For example, one study found that 42.9 percent of women were successfully fitted with a lower limb prosthetic at discharge after amputation compared with 68.6 percent of men.[2] Additionally, women in the general population are studied less than their male counterparts in prosthetic and amputee rehabilitation research.[3] This research gap limits the availability of evidence to support clinical decision-making for female veterans.[4]

VHA has a number of ongoing efforts to consider the gender-specific prosthetic needs of female veterans.[5] For example, in 2017, VHA made prosthetics for female veterans a national research priority in response to congressional input on prosthetics research spending.[6] In addition to research efforts, VHA has a Prosthetic Women Veteran Emphasis Workgroup (hereafter, female prosthetics workgroup) to determine best practices and assess the prosthetic needs of female veterans. Nonetheless, Congress, veteran groups, and a VA advisory committee have continued to raise issues regarding female veterans' prosthetic

[2]R. Singh, J. Hunter, A. Philip, and S. Tyson, "Gender differences in amputation outcome," *Disability and Rehabilitation*, vol. 30, no. 2 (July 7, 2009).

[3]Although women make up just over half the U.S. population, their health needs have historically been underrepresented in research supported by the National Institutes of Health and others. For more information on women's participation in clinical trials funded by the National Institutes of Health, see GAO, *National Institutes of Health: Better Oversight Needed to Help Ensure Continued Progress Including Women in Health Research*, GAO-16-13 (Washington, D.C.: Oct. 22, 2015).

[4]B.J. Randolph, L.M. Nelson, and M.J. Highsmith, "A Review of Unique Considerations for Female Veterans with Amputation," *Military Medicine*, vol. 181, no. 66 (2016).

[5]For the purposes of this report, we use the term gender to encompass an individual's sex assigned at birth (i.e., male or female) or gender identity—how individuals think about their own gender, including male, female, or gender non-conforming. Prosthetics for female veterans include items for both those whose sex was assigned female at birth and those whose gender identity is female. For example, VHA policy states that it provides medically necessary prosthetics, such as wigs and chest binders, to eligible transgender veterans. See Veterans Health Administration, *Providing Health Care for Transgender and Intersex Veterans,* VHA Directive 1341(2) (May 23, 2018).

[6]Pub. L. No. 114-223, 130 Stat. 857, 871 (2016).

needs, such as the availability and selection of artificial limbs and the amount of funding for research.

House Report 115-188 accompanying H.R. 2998, a bill for the Military Construction, Veterans Affairs, and Related Agencies Appropriations Act, 2018, includes a provision for us to review the status of VHA's efforts to provide services to and study prosthetics for female veterans.[7] This report examines

1) trends in prosthetics provided by VHA to female veterans;

2) characteristics of the female veteran population with limb loss and how VHA provides prosthetic services to these veterans through its Amputation System of Care; and

3) research efforts VHA has to study prosthetics for female veterans with limb loss and the challenges that exist in those efforts.

To examine the trends in prosthetics provided by VHA to female veterans, we reviewed VHA documents, such as fact sheets and regulations, as well as agendas and meeting minutes from VHA's female prosthetics workgroup. We obtained and analyzed data from VHA's National Prosthetics Patient Database (NPPD) to provide gender-specific information and comparisons on the number, type, and cost of all prosthetics provided, as well as the trends in these data from fiscal year 2015 to fiscal year 2019.[8] We assessed the reliability of NPPD data in several ways, including electronic and manual data testing and interviews with VHA officials knowledgeable about the data. We determined that the data used in our analyses were sufficiently reliable for our reporting objectives. We interviewed officials from two key VHA program offices—Rehabilitation and Prosthetic Services and Women's Health—about

[7]H. Rept. No. 115-188, at 67 (2017).

[8]The NPPD is used by VA to administer the department's provision of all prosthetics and includes data on the binary gender of veterans in three categories: male, female, or unknown. According to VHA officials, data on gender are populated by administrative staff when a veteran first registers at a VA medical facility. As such, any data errors later corrected may not be captured by the NPPD, depending on when the data were extracted from registration information. Additionally, VA data do not account for a veteran's gender identity. We recently recommended that VHA consistently collect veterans' gender identity data within and across its record systems. See GAO, *VA Health Care: Better Data Needed to Assess the Health Outcomes of Lesbian, Gay, Bisexual, and Transgender Veterans*, GAO-21-69 (Washington, D.C.: Oct. 19, 2020).

gender-specific prosthetic needs. We also conducted two site visits to VA medical facilities with expertise in prosthetic services and interviewed knowledgeable local staff, including Women Veterans Program Managers and prosthetics officials.[9] We selected two veterans service organizations—the American Legion and Disabled American Veterans—that had publications on prosthetics or women's health issues and interviewed officials from these organizations.

To examine the characteristics of the female veteran population with limb loss and how VHA provides prosthetic services to these veterans through its Amputation System of Care, we reviewed VHA documents, such as the Amputation System of Care national policy and strategic initiatives.[10] We also reviewed documents outlining gender-specific amputation care standards, such as clinical practice guidelines and accreditation requirements.[11] We obtained and analyzed data from VHA's Amputee Data Repository to provide gender-specific information and comparisons related to patient demographics, amputation characteristics, and utilization, as well as the trends in these data from fiscal year 2015 to fiscal year 2019.[12] We assessed the reliability of Amputee Data Repository data in several ways, including electronic and manual data testing and interviews with VHA officials knowledgeable about the data. We determined that the data used in our analyses were sufficiently reliable for our reporting objectives. We interviewed Amputation System

[9]We selected the Hunter Holmes McGuire VA Medical Center in Richmond, Virginia, where the national program staff for VHA's Amputation System of Care are located. We also selected the Seattle (Washington) VA Medical Center—a facility in the VA Puget Sound Health Care System—due to its location having a VHA-funded center focusing on limb loss research and its status as one of VHA's highest level amputation care centers.

[10]Veterans Health Administration, *VHA Amputation System of Care*, VHA Directive 1172.03(1) (August 3, 2018).

[11]Jointly with the Department of Defense, VA issues clinical practice guidelines—tools that provide guidance and evidence-based recommendations to clinicians regarding the most effective interventions and services for a variety of health care topics. To develop or update a clinical practice guideline, there is a standardized process to ensure that systematic reviews of relevant research outcomes are conducted in order to formulate evidence-based recommendations for prevention, assessment, and treatment services. As of August 2020, there were 23 clinical practice guidelines, which include such topics as mental health, rehabilitation, and pregnancy.

[12]According to VHA Directive 1172.03(1), the overall goals of the Amputee Data Repository include better understanding of the demographics of the veteran amputee population and help in identifying variations in rehabilitation care. The Amputee Data Repository has information on gender using the same binary categorization as NPPD data: male, female, or unknown.

of Care officials from VHA's central office, as well as providers during our two site visits. We held discussions with six female veteran amputees in three-person groups at both site visit locations to obtain their patient experiences. We also interviewed officials from a group that accredits medical rehabilitation programs—the Commission on Accreditation of Rehabilitation Facilities—due to its amputation specialty focus area.

To assess the research efforts VHA has to study prosthetics for female veterans with limb loss and examine the challenges that exist in those efforts, we reviewed VHA documentation, such as abstracts for VHA-funded studies since this topic became a national research priority in 2017.[13] We also examined VHA's internal tracking information on rehabilitation research to identify the rate at which studies on prosthetics for female veterans generate interest and are ultimately funded by VHA. We interviewed officials from VHA central office responsible for administering rehabilitation research funding. We then identified seven VHA researchers who have funded studies on prosthetics for female veterans and interviewed them about their work, overall needs, and challenges faced in this area. During our two site visits, we interviewed local officials about research needs and challenges, including researchers at the Center for Limb Loss and Mobility in Seattle, Washington. We summarized this information and obtained illustrative examples of the challenges identified by researchers. These illustrative examples are non-generalizable to all research on this topic area. As our scope only includes VHA's intramural research program, it may omit any extramural research on this topic funded by an entity outside of VHA.[14] We also

[13]VHA's national research priority of prosthetics for female veterans was limited to studies related to limb loss due to amputation and did not include other prosthetics VHA provides, such as those for hearing or vision purposes.

[14]We recently examined VHA's efforts to prioritize and translate research into clinical practice. These efforts are specific to VHA's intramural research program, which is for research funded by and conducted within VA by VA researchers. See GAO, *VA Health Care: Efforts to Prioritize and Translate Research into Clinical Practice*, GAO-20-211 (Washington, D.C.: Jan. 23, 2020). We also conducted a review of VA's extramural research funded through other federal and non-federal sources. The agency's extramural research is administered through academic affiliates or nonprofit research and education corporations. See also GAO, *VA Research: Opportunities Exist to Strengthen Partnerships and Guide Decision-Making with Nonprofits and Academic Affiliates*, GAO-20-570 (Washington, D.C.: July 29, 2020).

interviewed officials from two medical associations with a prosthetics focus to gain their perspective on research challenges.[15]

We conducted this performance audit from August 2019 to November 2020 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

VHA's Provision of Prosthetics

VHA's Prosthetic and Sensory Aids Service (PSAS) provides prosthetics to veterans who have experienced the loss or permanent impairment of a body part or function.[16] PSAS is responsible for administering this service, including establishing national policies and procedures, allocating funding, and evaluating timely performance. Prosthetics include a variety of medical devices and equipment ranging from artificial limbs and surgical implants—such as pacemakers and hip replacements—to eyeglasses and hearing aid batteries. PSAS refers to prosthetics it provides to meet the health needs of female veterans, such as those related to breast cancer rehabilitation, pre- and post-pregnancy care, and military sexual trauma, as women's health prosthetics.

Generally, for a veteran to obtain a prosthetic, a VHA provider first determines a veteran's need and prescribes a specific item. PSAS processes the prescription and provides the prescribed prosthetic to the veteran.[17] VHA also has prosthetist and orthotist staff who provide clinical services related to the provision of artificial limbs and orthotics. For example, clinical prosthetist and orthotist staff participate in the

[15]The two medical associations with a prosthetics focus were the American Academy of Orthotists and Prosthetists and the American Orthotic & Prosthetic Association.

[16]VHA-provided prosthetics are part of a uniform set of benefits provided to all veterans who enroll in VA's health care system. Certain veterans, such as veterans needing prosthetics for service-connected disabilities, are eligible even if they are not enrolled in VA's health care system. 38 C.F.R. § 17.37 (2019).

[17]At VA medical facilities, purchasing staff generally perform the administrative actions to process prescriptions for a prosthetic, such as creating a purchase order to authorize the procurement and shipment of an over-the-counter item or the fabrication of a custom-ordered item.

evaluations of prosthetic needs for veteran amputees and subsequently design, fabricate, fit, and adjust artificial limbs and custom orthotics.

VHA's Amputation System of Care

In 2008, VHA established an Amputation System of Care to provide specialized rehabilitation, prosthetic care, and other leading practices to veterans with amputations stemming from major limb loss.[18] The Amputation System of Care is a tiered system with four levels of care into which each VA medical facility is classified. From highest to lowest level of care, there are

1) seven regional amputation centers,
2) 18 polytrauma amputation network sites,
3) more than 100 amputation specialty clinic teams, and
4) amputation points of contact responsible for consultation, assessment, and referral of veterans to a facility capable of providing the level of services required.

VHA also partners with the Department of Defense (DOD) through the joint VA/DOD Extremity Trauma and Amputation Center of Excellence (EACE) to improve amputation care and to conduct clinical research for servicemembers and veterans.

Veterans with amputations who obtain services through VHA's Amputation System of Care have varying experiences and rehabilitation needs. They may have single or multiple amputations, which may have been sustained following traumatic circumstances (e.g., combat injuries incurred during military service) or due to disease processes (e.g., diabetic complications). Not all veterans use artificial limbs or other prosthetics to meet their mobility needs. Among veterans who do, such artificial limbs may be customized with cosmetic designs or other features important to each veteran's individual quality of life.

[18]A major amputation involves a leg at or above the ankle, or an arm at or above the wrist. A minor amputation involves either all or part of the hand or foot.

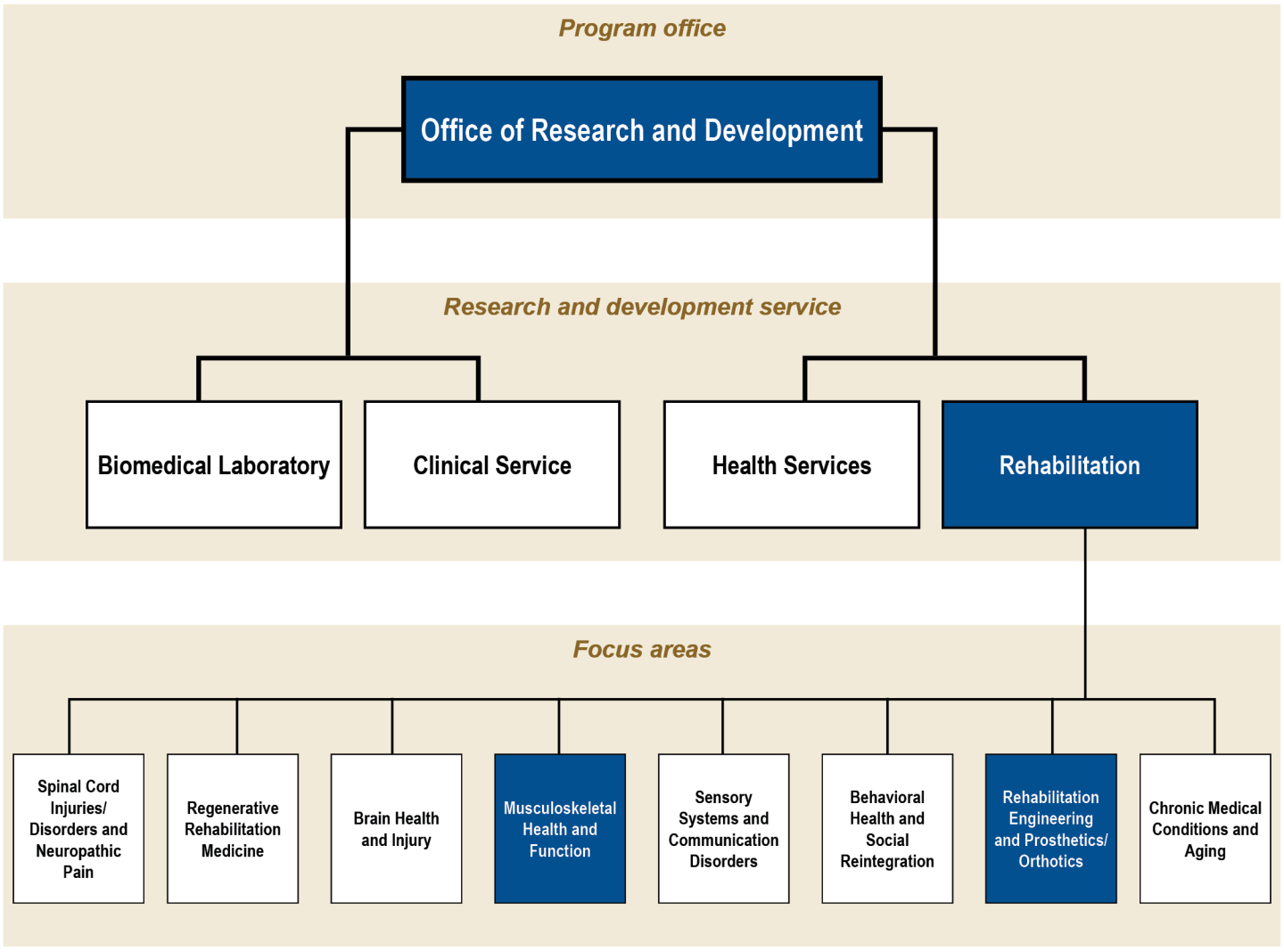
VHA's Rehabilitation Research Funding Structure

VHA's Office of Research and Development (ORD) manages the agency's intramural research program, through which VHA funds studies on a variety of topics conducted within the agency by its own investigators.[19] Within ORD, there are four research and development services—biomedical laboratory, clinical service, health services, and rehabilitation—that are responsible for program administration and support. Each service is led by a director and has scientific program managers who are responsible for specific research portfolios (or focus areas) within their service.[20] For example, the rehabilitation research and development service (hereafter, rehabilitation research service) funds studies related to advanced treatments designed to maximize recovery and minimize the long-term consequences of disabling conditions. The focus areas under the rehabilitation research service include topics such as musculoskeletal health and function and rehabilitation engineering, prosthetics, and orthotics. (See fig.1.)

[19]For more details on VHA's intramural research program, see GAO-20-211.

[20]In addition to national priorities for research funding, ORD permits its four research services to set their own service-level research priorities, which are based on the national priorities, veterans' specific needs, and other considerations.

Figure 1: VHA's Rehabilitation Research Organizational Structure



Source: GAO analysis of Veterans Health Administration (VHA) information. | GAO-21-60

Growth in Proportion of Prosthetics VHA Provided to Female Veterans Included Increased Demand for Women's Health Items

Proportion of Prosthetics VHA Provided to Female Veterans Is Small Compared to Those Provided to Male Veterans, but Grew about 1 Percentage Point from Fiscal Year 2015 to 2019

The proportion of prosthetics VHA provided to female veterans is small compared to those provided to male veterans, but grew from 6.8 percent in fiscal year 2015 to 7.9 percent in fiscal year 2019.[21] The quantity of prosthetics provided by VHA to female veterans also increased, by 41.4 percent from fiscal year 2015 to 2019, compared to a 23.9 percent increase for male veterans.[22] The types of prosthetics VHA provided to female veterans in greater quantities include items such as respiratory items (for example, ventilators), sensori-neuro aids (for example, eyeglasses and hearing aids), and medical equipment, which encompasses a broad range of items including walking aids and computer and exercise equipment. (See Table 1.)

Table 1: Prosthetics the Veterans Health Administration (VHA) Provided to Female Veterans by Prosthetic Category, Fiscal Year 2015 to 2019

Prosthetic category	Quantity of prosthetics provided to female veterans	Cost of prosthetics provided to female veterans[a] (in dollars)
Accessibility items	178,180	59,760,083
Artificial limbs	47,939	18,080,658
Home dialysis	5,047	1,034,459
Home modification	2,254	8,849,932

[21]NPPD data on gender have three categories (male, female, or unknown) and do not account for a veteran's gender identity.

[22]A veteran can be prescribed multiple prosthetics of the same type. From fiscal year 2015 to 2019, the total quantity of prosthetics provided to all veterans increased from 131.6 million to 163.6 million, while the quantity of prosthetics provided to female veterans increased from 3.3 million to 4.6 million. Additionally, NPPD data on prosthetics include repair activities, which accounted for about 843,000 of the 4.6 million prosthetics VHA provided to female veterans in fiscal year 2019.

Prosthetic category	Quantity of prosthetics provided to female veterans	Cost of prosthetics provided to female veterans[a] (in dollars)
Medical equipment	2,158,252	230,608,295
Orthotic items	1,335,465	93,429,717
Other[b]	10,402,898	44,252,732
Respiratory items	3,819,423	110,171,137
Restoration items	12,413	12,673,962
Sensori-neuro aids	2,196,128	91,570,779
Surgical implants	262,481	218,699,505
Total	**20,420,480**	**889,131,259**

Source: GAO analysis of data from VHA's National Prosthetics Patient Database (NPPD). | GAO-21-60

Note: NPPD data on gender have three categories (male, female, or unknown) and do not account for a veteran's gender identity. NPPD data on prosthetics also track repair activities for each category.

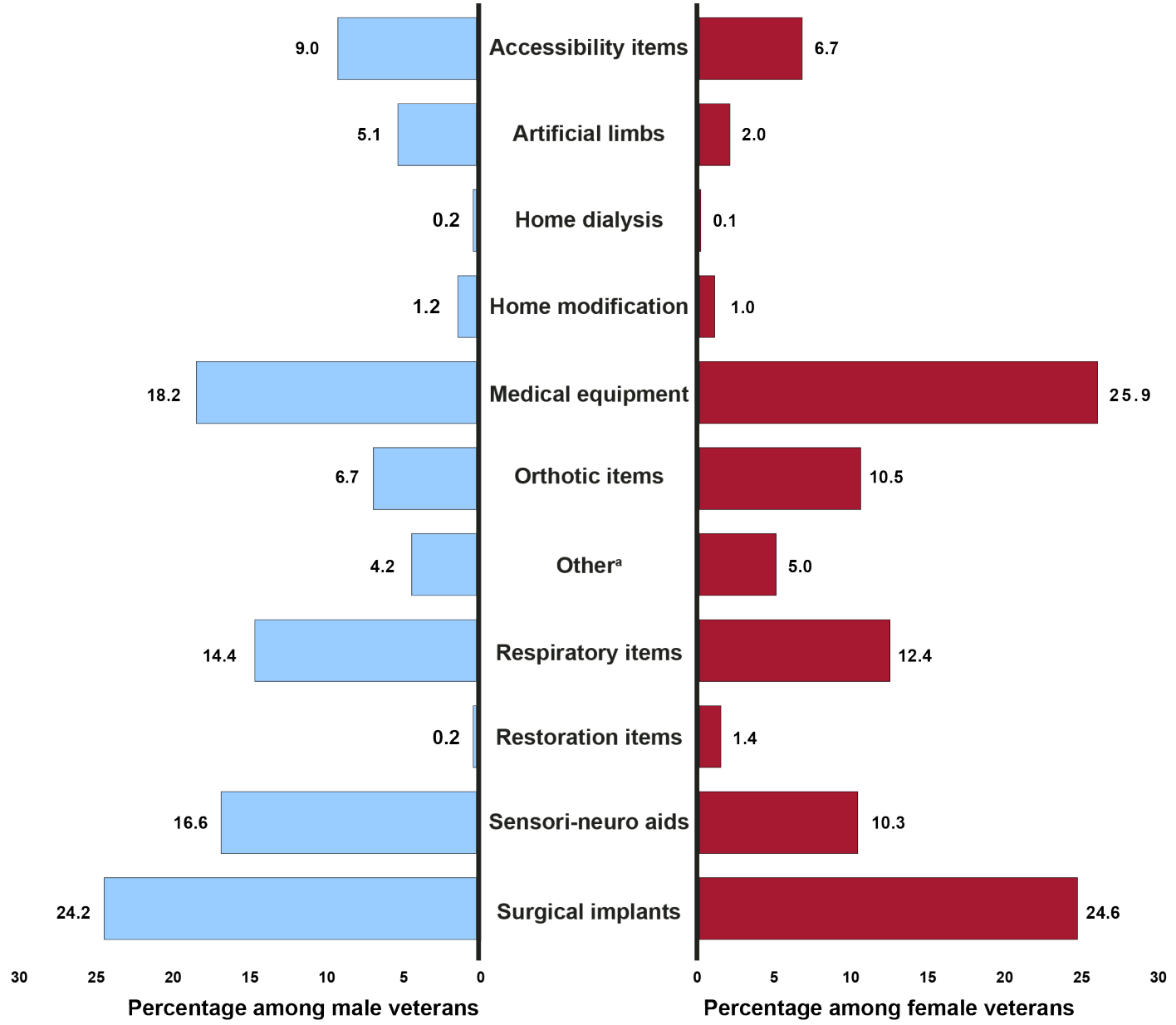
[a]We used new cost information from NPPD data to identify VHA's prosthetics costs. Officials explained that new cost information represents the cost of what VHA paid for the prosthetic and anything included in that cost, such as a commodities markup. Officials also told us this information does not include indirect administrative costs, such as the salaries of the VHA purchasing agents.

[b]Prosthetics in this category are those VHA classifies as miscellaneous and all other supplies and equipment, such as batteries and recreation equipment.

When assessing the proportion of prosthetic costs by category from fiscal year 2015 to 2019, surgical implant prosthetics represented about a quarter of all costs for both male and female veterans. (See fig. 2.) Specifically, surgical implants accounted for 24.2 percent of the costs among male veterans ($3.5 billion of $14.5 billion) and 24.6 percent of the costs among female veterans ($218.7 million of $889.1 million).[23] Two other categories that represented a higher proportion of costs among female veterans were medical equipment (25.9 percent or $230.6 million) and respiratory items (12.4 percent or $110.2 million).

[23]We used new cost information from NPPD data to identify VHA's prosthetics costs. Officials explained that new cost information represents the cost of what VHA paid for the prosthetic and anything included in that cost, such as a commodities markup. Officials told us this information does not include indirect administrative costs, such as the salaries of the VHA purchasing agents.

Figure 2: Proportion of Prosthetics Provided by the Veterans Health Administration (VHA), by Percent of Total Cost and Category, Fiscal Year 2015 to 2019



Source: GAO analysis of data from VHA's National Prosthetics Patient Database (NPPD). | GAO-21-60

Notes: Female veterans comprise a relatively small proportion of all veterans receiving prosthetics from VHA. For example, in fiscal year 2019, there was nearly a 12:1 ratio of male to female veterans receiving prosthetics.

[a]Prosthetics in this category are those VHA classifies as miscellaneous and all other supplies and equipment, such as batteries and recreation equipment.

At individual VA medical facilities, prosthetics officials are responsible for managing day-to-day operations, such as overseeing the procurement of prosthetic items.[24] At one VA medical facility we visited, prosthetics officials told us they adjust their orders accordingly if there is an influx of prosthetic requests for female veterans (e.g., whether an item is ordered 50 times vs. 1 time per month). Officials at the other VA medical facility we visited said they examine the facility's prior year prosthetics spending and the number of veterans served, then use a cost of living adjustment to plan for the following year's prosthetics budget.

Women's Health Prosthetics Had One of the Largest Growth Rates of All Types of Prosthetics VHA Provided

The number of women's health prosthetics VHA provided to veterans under the medical equipment category increased from 6,726 in fiscal year 2015 to 17,259 in fiscal year 2019.[25] This 157 percent increase was the fourth highest increase among the about 140 types of prosthetics that VHA provides. The women's health prosthetics VHA provided most commonly to female veterans were electric breast pumps and nursing bras.[26] (See Table 2.)

[24]We previously found that, in each of the fiscal years 2005 through 2009, VA's actual spending for prosthetics differed from the estimates VA reported in its congressional budget justifications for those years. See GAO, *VA Health Care: Spending for and Provision of Prosthetic Items*, GAO-10-935 (Washington, D.C.: Sept. 30, 2010).

[25]NPPD reports data by each type of prosthetic versus by individual veteran. As a result, there may be duplication across fiscal years in the data used for our analysis.

[26]Veterans whose gender is entered as male in VHA's NPPD may also obtain women's health prosthetics. However, female veterans account for the vast majority of veterans provided women's health prosthetics (i.e., about 97 percent of veterans provided these items from fiscal year 2015 to 2019).

Table 2: Most Common Women's Health Prosthetics Provided by the Veterans Health Administration (VHA) to Female Veterans, Fiscal Year 2015 to 2019

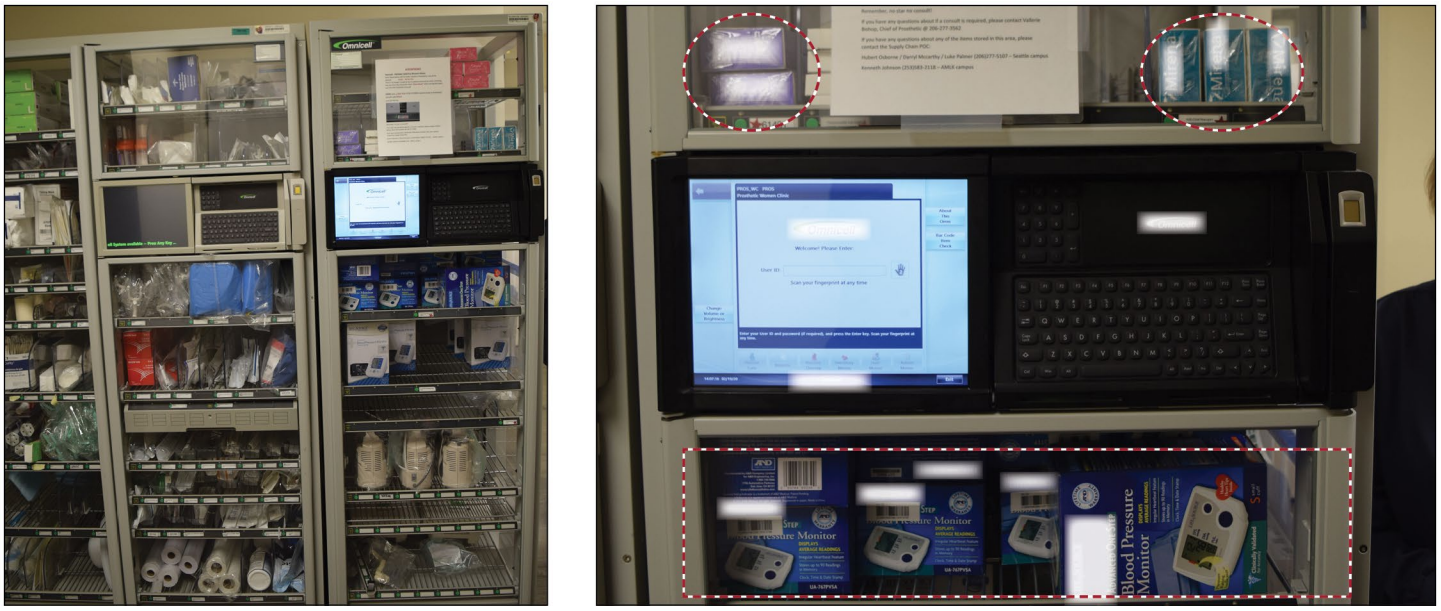
Prosthetic	Number of female veterans provided prosthetic	Cost of provided prosthetics (in dollars)	Cost per provided prosthetic (in dollars)
Electric breast pump	20,970	6,676,912	318
Nursing bra	12,913	2,371,663	184
Mastectomy bra, without form	4,429	1,076,621	243
Manual breast pump	3,461	807,924	233
Etonogestrel implant system (contraceptive)	3,345	1,802,961	539
Maternity abdominal support	3,020	222,965	74
Mirena, 52 milligrams (intrauterine device)	2,830	1,519,537	537
Intrauterine copper contraceptive	2,555	1,337,432	523

Source: GAO analysis of data from VHA's National Prosthetics Patient Database (NPPD). | GAO-21-60

Note: NPPD data on gender have three categories (male, female, or unknown) and do not account for a veteran's gender identity. In addition, NPPD reports data by each type of prosthetic versus by individual veteran. As a result, there may be duplication across fiscal years in the data used for our analysis.

At both VA medical facilities we visited, local trends in prosthetics provided to female veterans aligned with national trends. At one VA medical facility, maternity-related items made up the majority of the women's health prosthetics provided to female veterans, with the facility providing 131 maternity abdominal support belts (for relieving pelvic pressure) to female veterans in fiscal year 2019. The facility also stocked certain prosthetics, such as intrauterine devices for the women's health clinic, in a storage unit that tracks supply and can alert logistics when stock is low. (See fig. 3.) Officials told us they provided certain prosthetics, such as maternity belts and nursing bras, to pregnant veterans as part of a lactation package. Officials at the other medical facility we visited noted that the facility has had a significant increase in demand for maternity items such as breast pumps and nursing bras. Officials said the medical facility has provided maternity items to about 55 women thus far and conducted 10 new maternity consults in the month before our visit.

Figure 3: One Veterans Health Administration Facility's Storage Unit with Women's Health Prosthetics



Left photo: a storage case containing various prosthetics.

Right photo: a close-up of prosthetics, including intrauterine devices at top and blood pressure monitors at bottom.

Source: GAO. | GAO-21-60

According to VHA officials, the agency's mechanisms and tools for capturing patient satisfaction have not identified any gender-specific issues with its prosthetic services. While there are various complaint mechanisms for female veterans to use, such as a hotline run by the department-level Center for Women Veterans, officials estimated there have been fewer than five calls per year related to prosthetics from any mechanism.[27] Although VHA also has tools to assess and compare average processing times for prosthetics across VA medical facilities, officials told us they do not generally use these tools to analyze data by gender. Officials from both veterans service organizations we spoke with said many female veterans are unaware of the broad definition VHA uses for prosthetics and of their eligibility for these items. For example, there may be a lack of understanding that VHA provides lactation and nursing

[27]Officials also told us about the VHA-level Women Veterans Call Center, which has been in place since 2013. VA- and VHA-level complaint mechanisms would not include any issues brought forward at individual VA medical facilities.

items when the veteran's maternity care is provided at a non-VA medical facility.[28]

Further, officials from one veterans service organization noted that the average size of prosthetics routinely ordered by a primary care provider may be too large for a woman. As primary care providers are main access and referral points for prosthetic care, they should be aware of women's needs and ensure that prosthetics function properly for their intended use, the officials noted. For example, VHA's female prosthetics workgroup has noted that extra-small-sized gloves for wheelchair use may be better suited to female veterans.

To increase awareness of the prosthetic services provided to female veterans, VHA has made several efforts at the national and local level. At the national level, PSAS leads the female prosthetics workgroup comprised of VHA central office representatives, including reproductive health, LGBTQ health, clinical and administrative orthotics and prosthetics, as well as representatives from VA medical facilities and veterans service organizations. The female prosthetics workgroup meets on a monthly basis to consider gender-specific prosthetic needs. For example, in its October 2019 meeting, participants discussed mastectomy and cranial prosthetics, such as wigs for individuals affected by conditions that cause hair loss.

Additionally, one of the female prosthetics workgroup's fiscal year 2019 goals was to expand a best practice identified at the local level. Specifically, one VA medical facility created a prosthetics boutique in its women's health clinic so that veterans could view gender-specific prosthetics and ask contracted vendors questions about the items.[29] Officials also told us about the female prosthetics workgroup's efforts to inform local level staff about its internal website with information on the prosthetics VHA provides. Further, Women Veterans Program Managers at both VA medical facilities we visited stated that they try to ensure female veterans are aware of all benefits for which they are eligible, such

[28]VHA covers pregnancy care typically through arrangements with community providers. VHA will pay for prenatal care, delivery, and postnatal care for eligible female veterans.

[29]A VA medical facility may choose one or more of three primary care clinic models to meet the needs of female veterans. For example, one model is structured so that primary care services are provided by a women's health primary care provider in an exclusive and separate space, including a separate entrance into the clinical area and a separate waiting room.

as by providing information about women's health services at all registration desks.[30] One of these facilities designated women's health liaisons in all specialty care areas, including rehabilitation.

VHA Promotes Individualized Prosthetics Care for Growing Population of Female Veterans with Limb Loss under its Amputation System of Care

Population of Female Veterans with Amputations Grew in Number and Proportion in Last 5 Years

According to VHA's Amputee Data Repository, the female veteran amputee population receiving care in VA medical facilities grew in number and proportion, increasing from 2,049 veterans (or 2.3 percent of the total veteran amputee population) to 2,622 veterans (or 2.7 percent of the total veteran amputee population) from fiscal year 2015 to 2019.[31] Among characteristics of female veterans:

- **Age.** Female veterans with amputations were younger compared with male veterans with amputations. For example, in fiscal year 2019, female veterans were about 61 years old while male veterans were about 69 years old.
- **Service era.** Female veterans comprised a growing proportion of all post-9/11 veteran amputees—from 66 veterans (2.9 percent of all

[30]At each VA medical facility, a Women Veterans Program Manager is designated to assist female veterans with coordinating their health care services. VHA renamed the Women Veterans Program Manager position in 2003 to emphasize the position's program management responsibilities as it had changed significantly from the prior Women Veterans Coordinator role.

[31]VHA's Amputee Data Repository data on gender have three categories (male, female, or unknown) and do not account for a veteran's gender identity. These data represent the number of veterans receiving VHA care, and may not include veterans who do not receive their care through VHA.

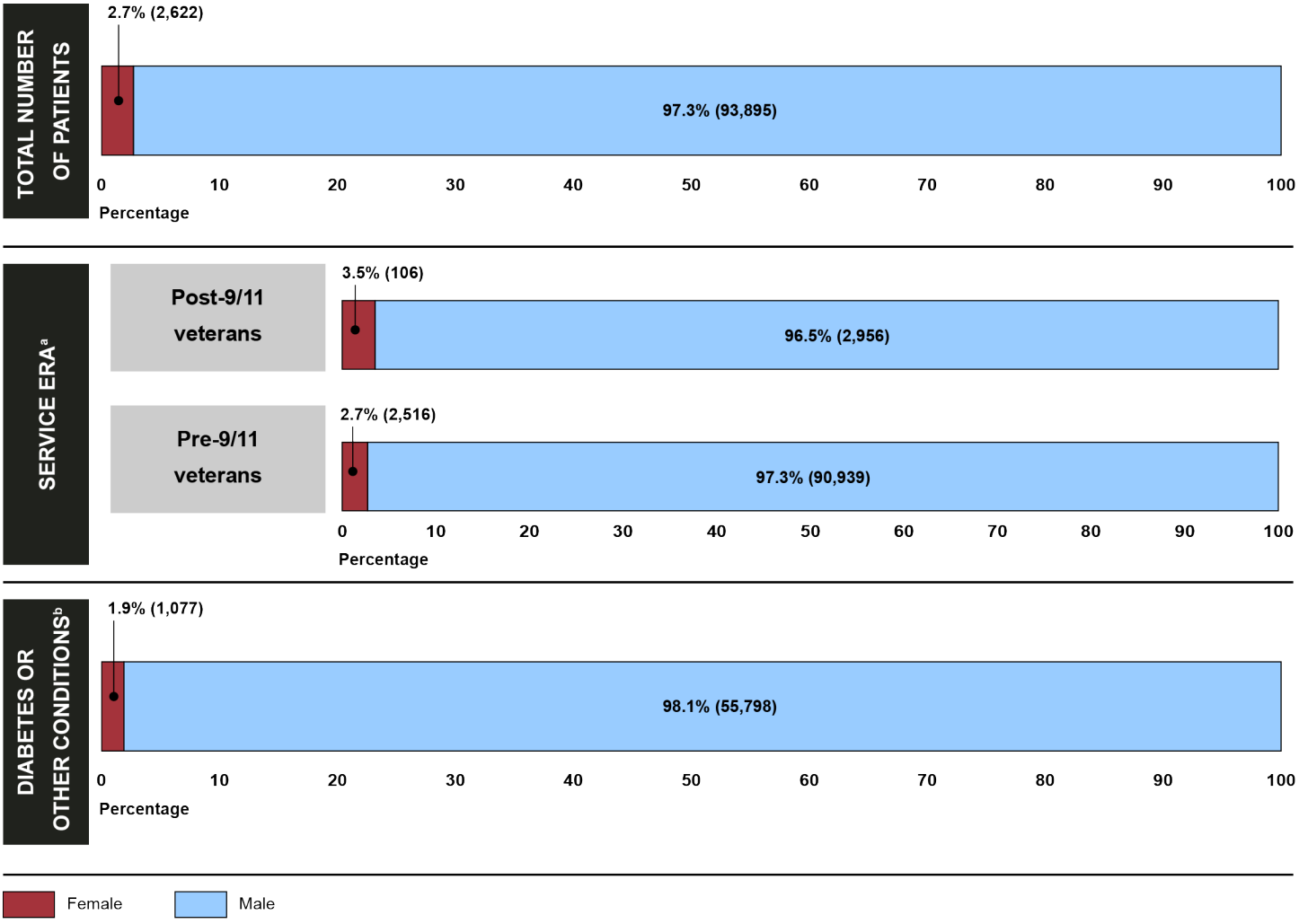
veterans with amputations) in fiscal year 2015 to 106 veterans (3.5 percent) in fiscal year 2019.[32]

- **Diabetes or other cardiovascular conditions.** Among veterans with amputations who also had diabetes or other cardiovascular conditions, the number and proportion of female veterans with amputations increased from 769 (1.5 percent) in fiscal year 2015 to 1,077 (1.9 percent) in fiscal year 2019. Among all female veterans with amputations, the proportion with diabetes or other cardiovascular conditions grew from 37.5 percent to 41.1 percent, a 3.6 percent increase during this time. In contrast, among male veterans with amputations, the proportion with these conditions increased from 56.8 percent to 59.4 percent, a 2.6 percent increase. These increases in co-morbid diagnoses are likely related to the higher average age for both female and male veteran amputees.[33] (See fig. 4.)

[32]Post-9/11 veterans served in conflicts after September 11, 2001, including Operation Enduring Freedom, Operation Iraqi Freedom, and Operation New Dawn. While the Amputee Data Repository notes veterans' service era, it does not include information on whether an amputation is directly conflict-related—resulting from an injury sustained in theater. VHA officials told us that as a result, the post-9/11 veteran population may include both veterans with conflict-related amputations and veterans with non-conflict-related amputations. VHA officials also told us that the Veterans Benefit Administration, not VHA, determines and tracks information regarding whether amputations are service-connected.

[33]While the data do not capture whether amputations are due to diabetes or other cardiovascular conditions, VHA officials told us that diabetes could be a contributing factor in veterans' amputations.

Figure 4: Certain Demographic Characteristics of the Veteran Amputee Population Receiving VHA Care, by Gender, Fiscal Year 2019



Source: GAO analysis of data from the Veterans Health Administration's (VHA) Amputee Data Repository. | GAO-21-60

Note: VHA's Amputee Data Repository data on gender have three categories (male, female, or unknown) and do not account for a veteran's gender identity. These data represent the number of veterans receiving VHA care, and may not include veterans who do not receive their care through VHA.

[a]Post-9/11 veterans served in conflicts after September 11, 2001, including Operation Enduring Freedom, Operation Iraqi Freedom, and Operation New Dawn. Pre-9/11 veterans served in prior conflicts.

[b]While the data do not capture whether amputations are due to diabetes or other cardiovascular conditions, VHA officials told us that diabetes could be a contributing factor in veterans' amputations.

Changes from fiscal year 2015 to 2019 in characteristics of female veterans' amputations and VHA prosthetic care after an amputation showed both similarities and differences from that of male veterans.

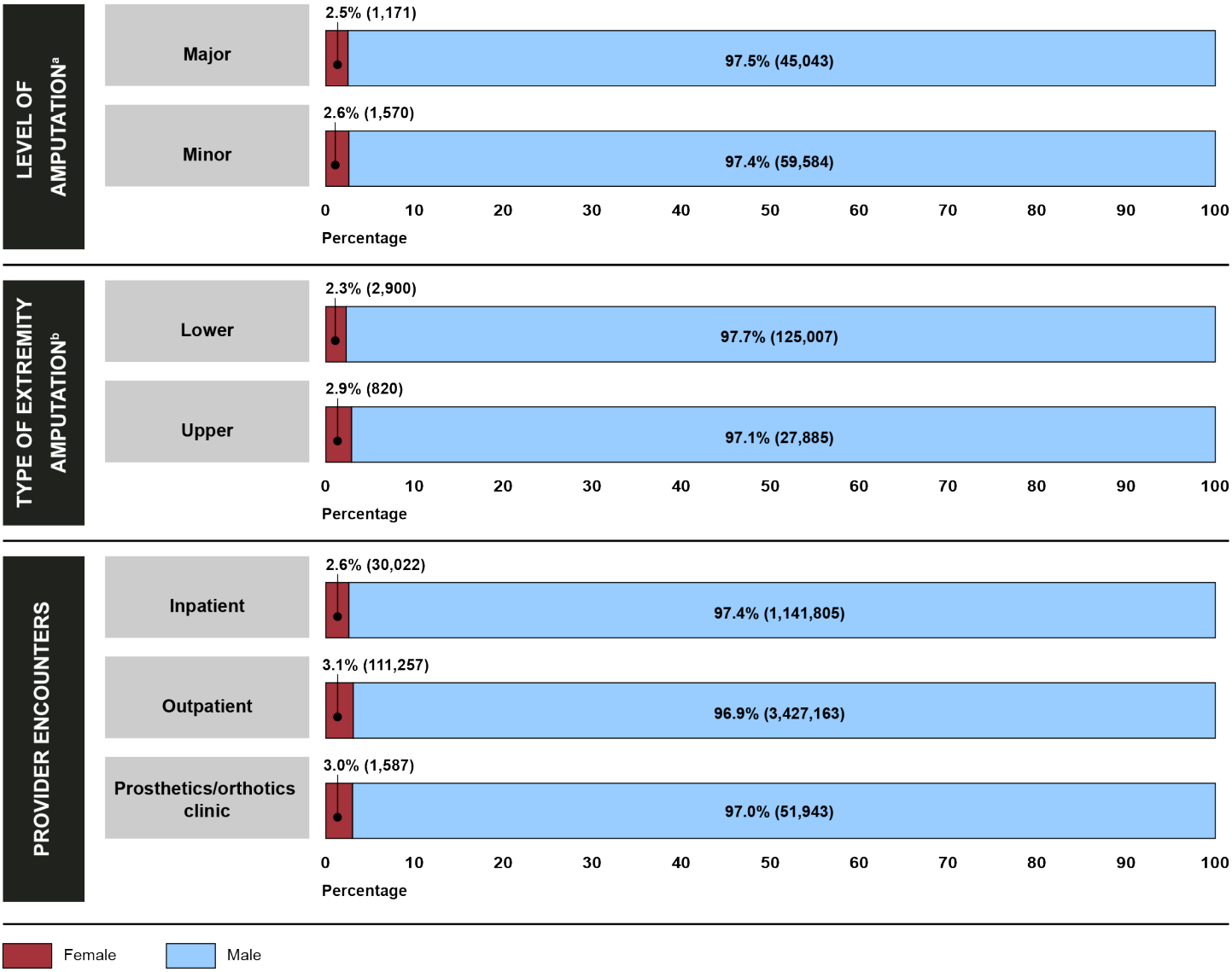
- **Level of amputation.** The number and proportion of female veterans with major amputations grew from 902 (2.1 percent of all major amputations) to 1,171 (2.5 percent of all major amputations) from fiscal year 2015 to 2019.[34] Similarly, the number and proportion of female veterans with minor amputations also grew from 1,206 (2.3 percent of all minor amputations) to 1,570 (2.6 percent of all minor amputations) during this period. Of all female veteran amputees in fiscal year 2019, 39.8 percent had at least one major amputation and 53.4 percent had at least one minor amputation. Similarly, of all male veteran amputees in fiscal year 2019, 39.5 percent had at least one major amputation and 52.3 percent had at least one minor amputation.
- **Type of extremity amputation.** More male and female veterans had lower extremity amputations than upper extremity amputations, and the number of male and female veterans with lower extremity amputations increased from fiscal year 2015 to 2019.[35] The most common amputation type for all veterans each year was a lower digit amputation (a partial or complete amputation of one or more toes) and the second most common amputation type was a transtibial amputation (a partial to complete amputation anywhere below the knee). For example, in fiscal year 2019, 934 female veterans and 36,334 male veterans had a diagnosis of a lower digit amputation, while 728 female veterans and 32,992 male veterans had a diagnosis of a transtibial amputation. The number and proportion of female veterans with upper extremity amputation diagnoses also grew from 653 (2.6 percent of all upper amputations) to 820 (2.9 percent of all upper amputations). See appendix I for more information on the types of extremity amputation diagnoses, by gender.
- **Provider encounters.** The number and proportion of inpatient and outpatient visits increased among female veteran amputees from fiscal year 2015 to 2019. Specifically, the number and proportion of visits to a prosthetics/orthotics clinic made by female veteran

[34]A major amputation involves a leg at or above the ankle, or an arm at or above the wrist. A minor amputation involves either all or part of the hand or foot.

[35]A lower extremity amputation includes any full or partial removal of any area between the pelvis to the tips of the toes. An upper extremity amputation includes any full or partial removal of any area between the shoulder to the tips of the fingers.

amputees increased from 973 female veterans (2.2 percent of all visits to a prosthetics/orthotics clinic) to 1,587 (3.0 percent of all visits to a prosthetics/orthotics clinic). In addition, the number of visits to a prosthetics/orthotics clinic increased from 475 per 1,000 female veteran amputees to 605 visits per 1,000 female veteran amputees from fiscal year 2015 to 2019, representing a 27.4 percent change. In contrast, the number of visits to a prosthetics/orthotics clinic increased from 509 visits per 1,000 male veteran amputees to 553 visits per 1,000 male veteran amputees from fiscal year 2015 to 2019, representing an 8.6 percent change. (See fig. 5.)

Figure 5: Amputation and Prosthetic Services Characteristics, by Gender, Fiscal Year 2019



Source: GAO analysis of data from the Veterans Health Administration's (VHA) Amputee Data Repository. | GAO-21-60

Note: VHA's Amputee Data Repository data on gender have three categories (male, female, or unknown) and do not account for a veteran's gender identity. These data represent the number of veterans receiving VHA care, and may not include veterans who do not receive their care through VHA.

[a]A major amputation involves a leg at or above the ankle, or an arm at or above the wrist. A minor amputation involves either all or part of the hand or foot.

[b]A lower extremity amputation includes any full or partial removal of any area between the pelvis to the tips of the toes. An upper extremity amputation includes any full or partial removal of any area between the shoulder to the tips of the fingers.

Providers in VHA's Amputation System of Care Incorporate Female Veterans' Prosthetic Goals as Part of an Individualized Care Approach for All Veterans

VHA has established an individualized patient care approach in its Amputation System of Care that seeks to address the prosthetic needs and goals of all veterans, including female veterans. VHA uses several documents to guide Amputation System of Care providers across VA medical facilities, including a national policy directive establishing the system and two joint VA/DOD clinical practice guidelines on amputation care.[36]

VHA's national policy directive states that the Amputation System of Care provides "patient-centered, gender-sensitive, lifelong, holistic care and care coordination for the Veteran or Servicemember who have undergone amputation." However, the directive does not directly expand on what gender-sensitive care entails. VHA officials we spoke with clarified that standardizing care across VA medical facilities through a multidisciplinary team approach helps them to incorporate the individual concerns and preferences of veterans, including female veterans. For example, veterans are provided care by a team that includes a physician, therapist, prosthetist, and other providers as needed.

In addition to a multidisciplinary team approach, VHA uses tele-rehabilitation services—conducted through VA's video conferencing system at a local facility or through the veteran's equipment at home—to provide clinical access between veterans and providers.[37] VHA can use tele-rehabilitation services to provide access to rural areas and to consult with smaller facilities without specialized amputation care. VHA officials we spoke with said that tele-rehabilitation has expanded the services they are able to provide. An Amputation System of Care official at one VA medical facility we visited explained that tele-rehabilitation enabled the facility to participate in a greater number of multidisciplinary appointments for veterans at other facilities within their region. For example, a specialty

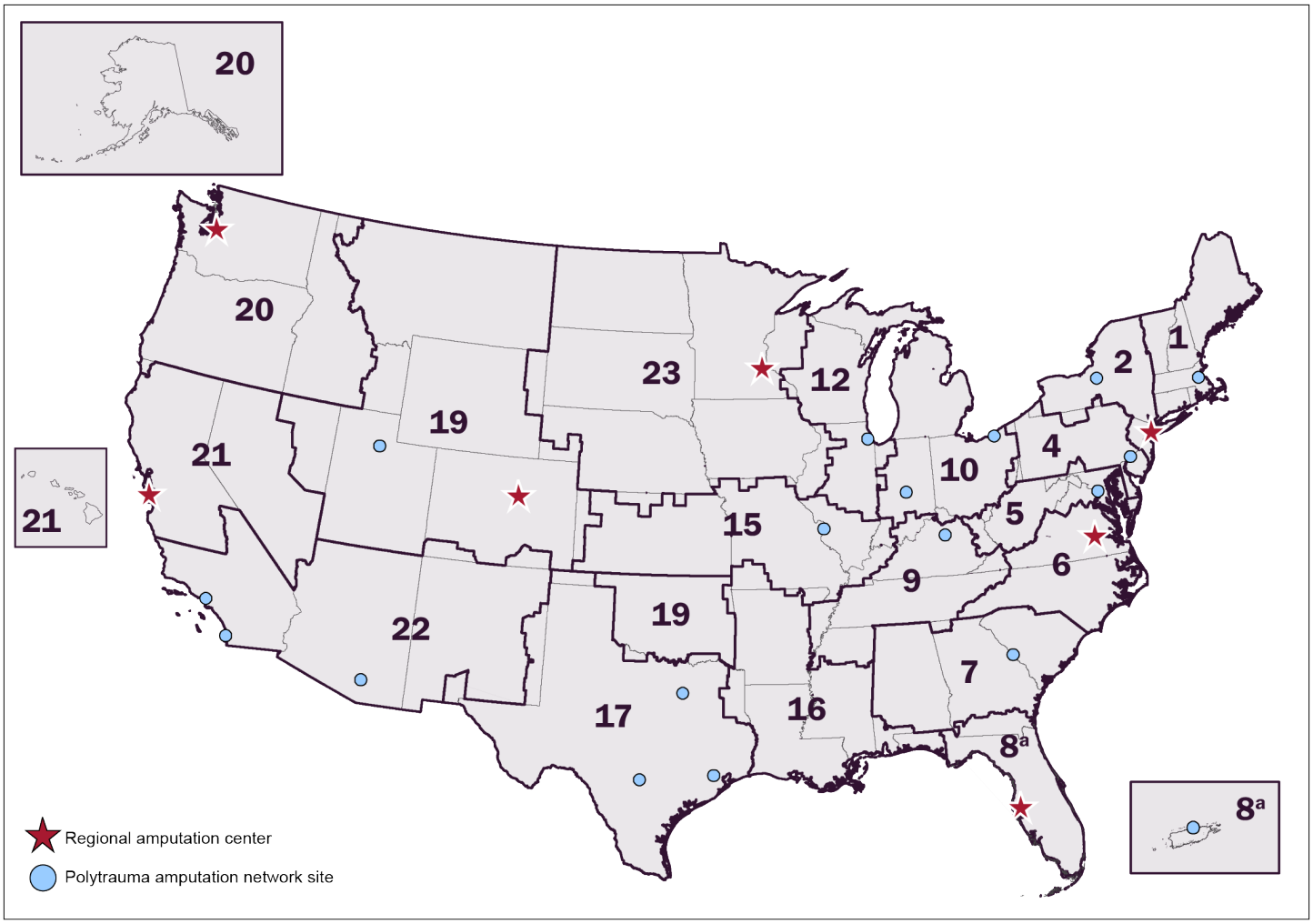
[36]The stated mission of the Amputation System of Care is to (1) provide care to veterans across the VA system, (2) maximize the health and independence of veterans through a team approach and coordination of care, and (3) be the provider of choice for veterans with amputations. See VHA Directive 1172.03(1). The clinical practice guideline for lower limb amputations was issued in 2007 and updated in 2017. The clinical practice guideline for upper limb amputations was issued in 2014.

Additionally, VHA issued a fiscal year 2020 strategic plan for the Amputation System of Care with 11 strategic initiatives, including an initiative to improve systemwide collection and utilization of standardized outcomes data in veterans with amputations. None of the 11 strategic initiatives included a focus on female veterans.

[37]In May 2018, VA issued final regulations that, among other things, allowed VHA providers to deliver telehealth services outside of VA medical facilities. See 83 Fed. Reg. 21,897 (May 11, 2018).

provider such as a prosthetist based at a regional amputation center would be able to provide care to veterans for the Veterans Integrated Service Networks (VISN) it serves. The largest number of veteran amputees, including female veteran amputees, received prosthetic care in VISN 8, where the Tampa, Florida regional amputation center is located. (See fig. 6 for the distribution of female veterans with amputations by VISN, and table 5 in appendix II for the location of all veterans with amputations by VISN.)

Figure 6: Female Veterans with Amputations, by Veterans Integrated Service Network (VISN), Fiscal Year 2019



1 Number/percentage of female veterans: 94 / 3.3%	5 Number/percentage of female veterans: 117 / 4.1%	8a Number/percentage of female veterans: 278 / 9.7%	12 Number/percentage of female veterans: 109 / 3.8%	17 Number/percentage of female veterans: 198 / 6.9%	21 Number/percentage of female veterans: 149 / 5.2%
2 Number/percentage of female veterans: 106 / 3.7%	6 Number/percentage of female veterans: 212 / 7.4%	9 Number/percentage of female veterans: 118 / 4.1%	15 Number/percentage of female veterans: 116 / 4.1%	19 Number/percentage of female veterans: 156 / 5.4%	22 Number/percentage of female veterans: 195 / 6.8%
4 Number/percentage of female veterans: 141 / 4.9%	7 Number/percentage of female veterans: 214 / 7.5%	10 Number/percentage of female veterans: 217 / 7.6%	16 Number/percentage of female veterans: 184 / 6.4%	20 Number/percentage of female veterans: 163 / 5.7%	23 Number/percentage of female veterans: 99 / 3.5%

Source: GAO analysis of data from the Veterans Health Administration's (VHA) Amputee Data Repository. | GAO-21-60

Notes: VISNs are regional networks containing individual Department of Veterans Affairs (VA) medical facilities or groups of VA medical facilities, known as health care systems. VHA previously

realigned some of its VISN boundaries in 2002 and 2015, decreasing the number of VISNs from 23 to the current 18. Percentages reflect the proportion of female veterans treated in each VISN.

VHA's Amputation System of Care is a tiered system with four levels of care within which each VA medical facility is classified. From highest to lowest level of care, there are 1) seven regional amputation centers, 2) 18 polytrauma amputation network sites, 3) more than 100 amputation specialty clinic teams, and 4) amputation points of contact responsible for consultation, assessment, and referral of veterans to a facility capable of providing the level of services required.

VHA's Amputee Data Repository data on gender have three categories (male, female, or unknown) and do not account for a veteran's gender identity. These data represent the number of veterans receiving VHA care, and may not include veterans who do not receive their care through VHA.

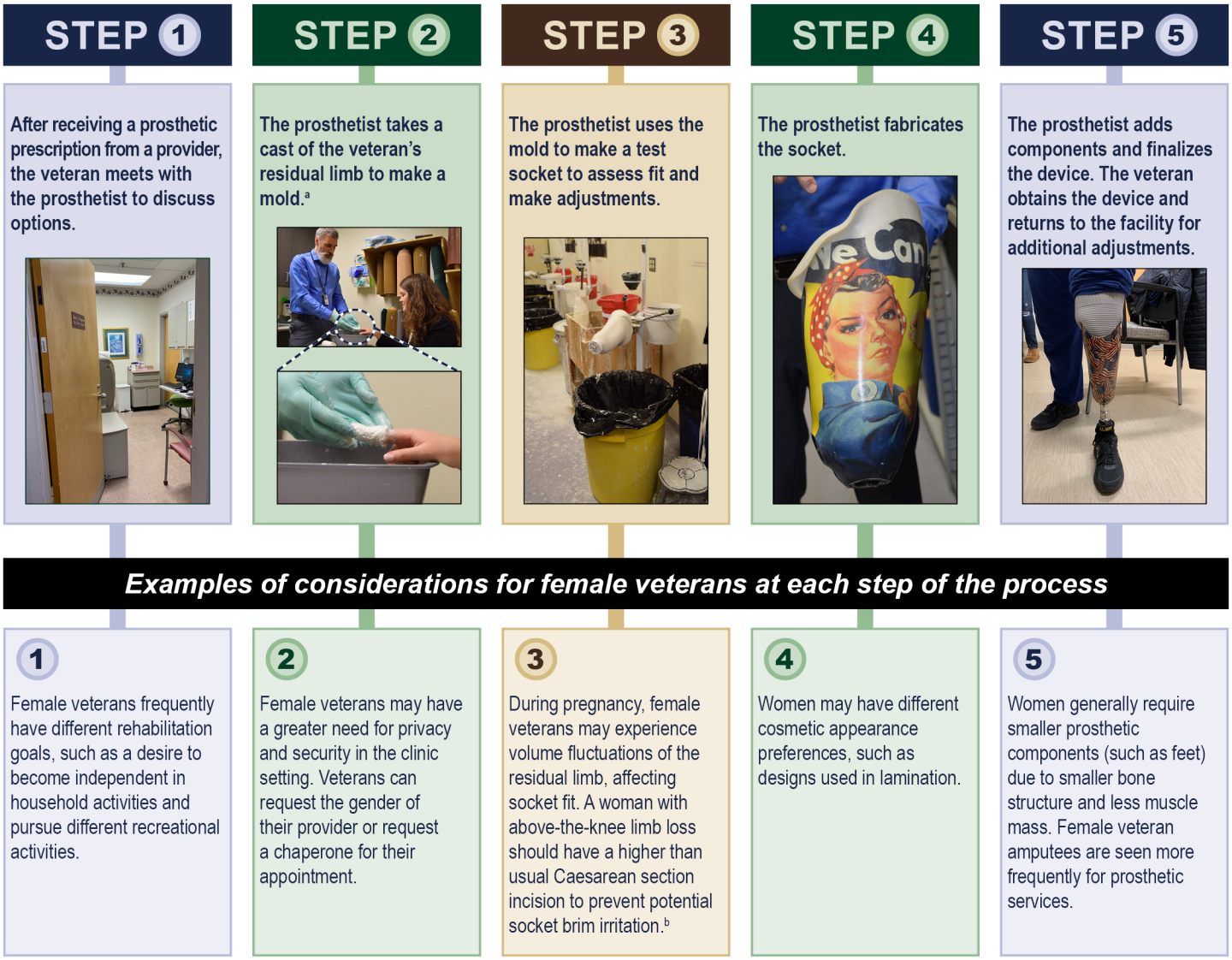
[a]Totals for VISN 8 include San Juan, Puerto Rico, which treated 16 female veteran amputees.

The two clinical practice guidelines on amputation care state that communication between the provider and patient should be supported by evidence-based information tailored to the patient's needs. The most recent guideline also notes that an "empathetic and non-judgmental approach facilitates discussions sensitive to gender, culture, and ethnic differences" and recommend that providers consider the patient's sex assigned at birth and gender identity in developing individualized treatment plans. In particular, providers should be aware of specific areas in which studies reviewed for the clinical practice guidelines indicated that there are significant differences between male and female patients based on sex assigned at birth, including

- **successful fitting of a prosthetic.** Male patients are more likely to experience successful fitting of their prosthetics than female patients. Satisfaction with prosthetics includes socket comfort, function, and the ability of the prosthetic to accommodate clothes and shoes, which can be particularly challenging for women. In addition, the size and weight of prosthetics made for men may be too heavy or oversized for some women.
- **time in rehabilitation.** Female patients spend more time in rehabilitation after a successful fit of a prosthetic leg than male patients, which presents concerns given that female patients generally have less social support following rehabilitation.
- **experience with pain.** Female patients express and experience pain differently than male patients. For example, female patients are more likely to have transfemoral (above the knee) amputations than male patients. Such higher levels of amputation are associated with more complicated care and greater difficulty with socket fit, contributing to an increased level of pain.

Before receiving a prescription for an artificial limb prosthetic, the veteran undergoes pre-prosthetic training on their residual limb for purposes such as increasing flexibility and strength. (See fig. 7 for the steps involved in making an artificial limb prosthetic with examples of considerations for female veterans.)

Figure 7: Steps Involved in Making an Artificial Limb Prosthetic with Examples of Considerations for Female Veterans



Source: GAO analysis of Veterans Health Administration (VHA) information; GAO (photos). | GAO-21-60

[a]A residual limb is the part of the body that remains after an amputation has been performed. For example, for an above-the-knee amputation, the part of the thigh that remains after the amputation is the residual limb.

[b]Women with lower limb amputations also report more skin problems. One female veteran we spoke with developed an allergic reaction to an adhesive commonly used in some prosthetic liners.

The clinical practice guideline for lower limb amputations also states that it is unknown whether gender differences are attributable to sex assigned

at birth or gender-based cultural factors. As a result, providers are directed, for transgender female veterans, to consider risk and resilience factors associated with both sex assigned at birth and gender identity, as research that includes both is limited. VHA officials we spoke with said they did not differentiate care provided to veterans with amputations by gender. They explained that because care is highly individualized to each patient, providers accommodate patient needs, including those related to the veteran's gender.

Additionally, the clinical practice guidelines recommend that providers offer peer support interventions for those with amputations, including visitation by a certified peer visitor, as early as feasible, and throughout the rehabilitation process. The literature suggests that peer visits work best when age, gender, and amputation level are considered and matched. VHA's Amputation System of Care directive requires that a peer visitation support program be maintained at the highest level amputation care locations—regional amputation centers and polytrauma amputation network sites. (See table 6 in appendix II for the distribution of veterans by Amputation System of Care location type in fiscal year 2019.)

VHA officials told us that they have several informal means of assessing patient satisfaction with amputation care in accordance with inpatient rehabilitation accreditation requirements.[38] According to officials at one VA medical facility we visited, patient satisfaction with prosthetic care is not included in VHA's larger patient survey system; however, the Amputation System of Care has created its own informal survey to assess patient satisfaction, which a couple of female veterans have participated in. The three female veteran amputees we spoke with at one facility said they were satisfied with their VHA care, but noted a lack of commercially available prosthetic options for women's needs. For example, one veteran reported that while her providers did their best to accommodate her needs, the prosthetics available are generally sized for men, and it was very difficult to find a pair of shoes that would fit her very narrow remaining foot as well as her much wider prosthetic foot. In addition, two

[38]The Commission on Accreditation of Rehabilitation Facilities has accreditation standards for inpatient amputation care and notes that providers treating patients in rehabilitation settings should consider the patient's gender (which may include both gender identity and expression), among other areas, in that treatment. VHA requires that all regional amputation centers and polytrauma amputation network sites maintain this accreditation for their rehabilitation facilities.

veterans told us that obtaining a prosthetic that accurately matches their darker skin tone has been a challenge.[39]

VHA Has Funded Eight Studies on Prosthetics for Female Veterans, but Participant Recruitment Is an Ongoing Research Challenge

VHA's Eight Funded Studies on Prosthetics for Female Veterans Focus on Outcomes and Device Development Research Needs

Since making prosthetics for female veterans a national research priority in 2017, VHA has funded eight studies on this topic as of May 2020.[40] The funded studies vary in several ways, such as the award mechanism used. Specifically, ORD's primary award mechanism funds up to 4-year studies with a maximum amount of $1.2 million per award and accounts for the majority of VHA-funded research studies. ORD also has a short-term award mechanism, which is for pilot or exploratory studies to determine if additional research in an area should be conducted.[41] The funded studies also vary by the extremity the research is focused on, and

[39]The Amputee Data Repository does not have data on veterans' race. We previously identified opportunities for VA to better identify and address racial and ethnic disparities. See GAO, *VA Health Care: Opportunities Exist for VA to Better Identify and Address Racial and Ethnic Disparities*, GAO-20-83 (Washington, D.C.: Dec. 11, 2019).

[40]VHA sets national research priorities based on various factors, including input from Congress. Specifically, the prosthetic needs of female veterans was identified by Congress as a research need for fiscal year 2017. In 2019, VHA broadened the description of prosthetics for female veterans to include "other assistive technology." VHA officials told us they made this change to align with the broad definition of prosthetics used by the agency that includes various medical devices and equipment. Other assistive technology could therefore include prosthetic attachments to bones (known as osseointegration) and the size and design of wheelchairs. As of May 2020, VHA had received one application using this new definition, which it funded.

[41]Combined, the primary and short-term award mechanisms accounted for 97 percent of studies funded in fiscal year 2018.

the study's aim for the research to be conducted (see table 3). The earliest study completion date is March 2021.[42]

Table 3: Information on VHA's Eight Funded Studies on Prosthetics for Female Veterans

Funded study title	Award mechanism[a]	Extremity focus	Study aim
Needs, Preferences, and Functional Abilities of Veterans and Service Members with Upper Limb Amputations	Primary	Upper limb	Improving outcomes
Validation of Patient-Reported Outcomes for Female Veterans with Upper-Limb Amputation	Primary	Upper limb	Improving outcomes
Artificial Digit Replacements for Women Veterans with Individual Digit Loss	Primary	Upper limb	New device development
Understanding Prosthetic Needs and Outcomes in Women Veterans with [Lower Limb] Amputation	Primary	Lower limb	Improving outcomes
Lower limb Prostheses for Individuals who Carry Infants, Toddlers, and Other Loads	Primary	Lower limb	Improving outcomes
Improving Footwear Options for Women Veterans with Amputations	Primary	Lower limb	New device development
Are Women at Increased Risk of Developing Secondary Physical Conditions Associated with Lower-Limb Amputation and Long-Term Prosthesis Use?	Short-term	Lower limb	Improving outcomes
Assessing Women Veterans' Needs for Mobility Devices	Short-term	Other[b]	Improving outcomes

Source: GAO analysis of Veterans Health Administration (VHA) information. | GAO-21-60

[a]VHA has two award mechanisms under which it made prosthetics for female veterans a national research priority in 2017—a primary award mechanism and a short-term award mechanism. Combined, these two award mechanisms accounted for 97 percent of studies funded in fiscal year 2018.

[b]In 2019, VHA broadened the description of prosthetics for female veterans to include "other assistive technology." Under this new definition, VHA funded a short-term study on wheelchairs.

The funded studies help address two knowledge gaps concerning female veterans identified by VHA officials and others we interviewed: 1) understanding their unique prosthetic needs and 2) designing and customizing prosthetics for them. For example, one VHA researcher noted that little is known about female veterans' prosthetic needs, and that the funded study on understanding prosthetic needs and outcomes in female veterans with lower limb amputations will be foundational. That

[42]ORD officials told us that the earliest study's completion date, originally September 2020, was given a 6-month extension to March 2021 due to the COVID-19 pandemic. Officials also noted that the completion dates of other studies may also be extended, as necessary.

study will assess outcomes by gender, such as prosthetic prescription rates, prosthetic use, prosthetic satisfaction, and mobility.

Additionally, VHA officials said there is little incentive for prosthetic companies to invest in products for which the target pool of customers is small, such as for female veterans.[43] While women are estimated to comprise about a third of amputees in the general population, one researcher explained that most prosthetics have been designed for men and scaled down for women as opposed to purposefully designed for women. This knowledge gap is also noted in a recently published study's conclusion that efforts to develop cosmetically acceptable, lightweight, and functional upper limb prosthetics for female veterans are needed.[44] Two VHA-funded studies focus on this knowledge gap by developing prosthetics for female veterans. (See fig. 8.)

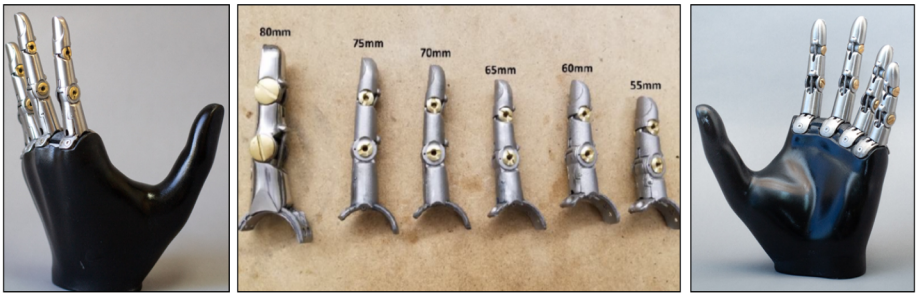
[43]According to VHA, compared with male veterans, female veteran amputees face ill-fitting prosthetics that are mostly designed for men (e.g., nearly all of the hundreds of commercially available prosthetic feet are male, which are larger and wider than female feet). See, VA, Advisory Committee on Women Veterans Meeting Minutes (Washington, D.C.: May 8-10, 2018). All three female veterans at one VA medical facility we visited agreed that research on foot designs for women would be helpful as there is a lack of smaller and narrower prosthetic foot options that may fit women better.

[44]L.J. Resnik, M.L. Borgia, and M.A. Clark, "A National Survey of Prosthesis Use in Veterans with Major Upper Limb Amputation: Comparisons by Gender," *American Academy of Physical Medicine and Rehabilitation* (Feb. 24, 2020).

Figure 8: Information on VHA-Funded Studies Focused on Developing Prosthetic Devices for Female Veterans

Appropriately sized mechanical prosthetic finger

Due to the lack of commercially available prosthetic fingers that are sized appropriately for the full range of female hand sizes, one study aims to develop a mechanical prosthetic finger at various lengths. Using advanced metal 3D printing technology, the finger can be operated with one hand through a ratcheting mechanism.



From left to right: Back view of hand with prosthetic fingers; display showing size of smallest current prosthetic finger followed by range of 3D metal prototypes being developed; frontal view of hand with prosthetic fingers.

Prosthetic footwear options

Because the majority of prosthetic feet are specific to a shoe's heel height with none that adjust to different shoe widths, one study aims to develop a prosthetic ankle-foot system that allows female veterans to more easily change footwear with different heel heights. Using this modular ankle-foot system would allow the female veteran to easily switch custom footwear without needing to change the alignment of the prosthetic.

Source: GAO summary of Veterans Health Administration (VHA) information; VHA (photos). | GAO-21-60

VHA awards funding in rehabilitation research focus areas in four award cycles each year—two in its primary award mechanism and two in its short-term award mechanism.[45] Under its primary award mechanism, VHA-funded studies on prosthetics for female veterans represented about one third of selected applications on the topic of prosthetics within the rehabilitation research focus areas of musculoskeletal health and function and rehabilitation engineering, prosthetics, and orthotics. However, letters of intent and submitted applications for studies on prosthetics for female veterans have shown an overall decline from 2017 to May 2020.[46] ORD officials told us that the overall response from researchers to this priority area has been positive but that obtaining adequate applications is subject to participant recruitment challenges, also seen in conducting the research. The seven VHA researchers we spoke with all noted that the addition of the priority area on prosthetics for female veterans influenced their decision to apply for funding to study the issue. For example, one VHA researcher said that he had an idea for studying this population that he did not consider submitting until the priority area was included in VHA's request for applications.

Under its short-term award mechanism in the same time frame, VHA received fewer total applications for the two rehabilitation research focus areas through which studies on prosthetics for female veterans are funded. Three of the 16 total submitted applications since 2017 were for research on prosthetics for female veterans; two of the three submitted applications received funding. Combined with the primary award mechanism, VHA-funded studies on prosthetics for female veterans represented 40 percent of selected applications on the topic of prosthetics as of May 2020.

[45]The selection process consists of a panel of reviewers under each ORD research service that evaluate and score research proposals by their scientific merit. To assess scientific merit, reviewers use a range of review criteria, such as the proposals' significance to veterans' health, feasibility, innovation, and the experience of the researchers who would conduct the study. Research proposals are then ranked according to their scores and the directors of the research services decide which proposals to fund. The number and type of proposals funded can depend on a range of factors, such as the amount of available funding.

[46]Before submitting an application for a primary or short-term award in a rehabilitation research focus area, researchers first submit a letter of intent with a broad outline of their study goals and parameters. VHA must approve the researcher's letter of intent in order for the researcher to submit a full funding application.

VHA Researchers and Others Identified Participant Recruitment as the Greatest Challenge to Studying Prosthetics for Female Veterans

The ability to recruit female veteran participants is the greatest ongoing challenge in studying prosthetics for this small population, according to VHA officials in research positions and in its central office, as well as officials from two medical associations we interviewed. Of the eight studies VHA funded, the number of needed participants varied by the aim of the research. In general, research on outcomes requires more participants to obtain an adequate study size, while research on device development requires far fewer participants. For example, one VHA-funded study planned to conduct a longitudinal survey of 400 female and male respondents, while another study required six individuals (three men and three women) to test a prosthetic device. (See text box below for selected examples of the challenges VHA researchers told us about.)

Selected Examples of Participant Recruitment Challenges in Studying Prosthetics for Female Veterans

VHA researchers we spoke with identified challenges with recruiting female veterans. For example, in a study on

- **developing smaller mechanical prosthetic fingers**, the VHA researcher described having success recruiting male veterans and non-veteran women with partial hand loss, but not female veterans with partial hand loss. Further, the challenge has been in identifying female veterans with partial hand amputations in the local area even though partial hand amputations generally outnumber all other levels of upper limb amputations.
- **use of prosthetics for upper limb amputation**, a total of 138 female veterans who obtained care at VA medical facilities nationwide were identified as having an upper limb amputation.[a] However, only 21 of the 138 female veterans were ultimately eligible to participate in the study's survey. Of the remaining 117 female veterans, 57 were excluded, 50 were found to be ineligible, and 10 were not recruited. The various reasons for individuals who were excluded or found to be ineligible included being deceased or having an inaccurate upper limb amputation diagnosis in VHA's central patient database.
- **improving prosthetic footwear options**, the study goal was to recruit three female veterans with lower limb amputations in the local area. However, the VHA researcher told us there were only two female veterans locally who fit the inclusion criteria.

[a]L.J. Resnik, M.L. Borgia, and M.A. Clark, "A National Survey of Prosthesis Use in Veterans with Major Upper Limb Amputation: Comparisons by Gender," *American Academy of Physical Medicine and Rehabilitation* (Feb. 24, 2020).

Source: GAO summary of Veterans Health Administration (VHA) information. | GAO-21-60

To address recruitment challenges, the seven VHA researchers we spoke with said they employ various tactics, such as using multi-site studies and recruiting participants from the non-veteran population. However, these tactics may add complexity, time, and resources to completing the research and meeting study aims, according to VHA researchers and other officials. For example, it can be challenging to identify the necessary principal investigators and other research staff at each site of a multi-site study, which may in turn increase the time needed for data collection and the research cost. Extra steps may be required for

recruiting non-veterans, such as demonstrating that recruiting enough veterans is not possible. Further, there is also a challenge of whether researchers can then generalize the results to the veteran population.

ORD officials told us that there is no agency guidance on strategies to enhance recruitment of small populations in research studies. Instead, officials communicate with researchers on a case-by-case basis to identify strategies to increase recruitment when challenges arise. The main tool ORD officials told us they use to keep track of recruitment challenges is a spreadsheet that documents the participants needed for screening and enrollment to reach adequate study results. The spreadsheet tracks participant numbers at each individual study site and overall, with alerts for when recruitment has fallen below a certain threshold that might indicate the need for the researcher to adjust recruitment strategies.

This approach is also supported by a VA/DOD collaboration guidebook for health care research, which suggests using professional networks to identify collaborators who have time to devote to research activities.[47] VHA researchers we spoke with identified various approaches the agency could take to help address recruitment challenges. For example:

- **Helping fund participant travel** for prosthetic fitting and testing. One VHA researcher described being involved in past studies that were not successful in recruiting because they could not pay for participant travel with a limited budget. ORD officials explained that researchers can request a waiver to go above the study budget cap.
- **Making the Amputee Data Repository more accessible** to researchers looking to recruit participants nationwide, as it compiles veterans' amputation diagnosis codes. According to Amputation System of Care officials, VHA researchers must request access

[47]Department of Veterans Affairs, *VA/DOD Collaboration Guidebook for Healthcare Research* (Aug. 30, 2013).

through the process that applies to obtaining information from any internal agency database.[48]

- **Using joint VA/DOD EACE funding** for VHA research personnel at each regional amputation center would enable VHA to do more research and address expensive research coordination. EACE officials explained that VHA's role in the EACE is supportive to DOD, as VHA already had the research infrastructure and clinical expertise at the time the EACE was created.[49]

In addition to participant recruitment, some VHA researchers identified a few other challenges in studying prosthetics for female veterans. For example, one VHA researcher said there is a need for a small business incentive program to encourage companies to produce more feminine prosthetic components, such as foot shapes, because the market size is small. ORD does not participate in such small business incentive programs as it only conducts intramural research. Another researcher said that, despite increased attention on this topic, there is a lack of understanding from some reviewing VHA research applications of the need for gender-specific clinical tools. Specifically, there is a need to further develop the evidence base so that clinicians can develop effective treatment plans for the rising number of women with limb loss in the VHA system and in the general population. VHA officials noted that it is the responsibility of the applicant to make a clear case to reviewers that their proposed research will make a positive difference on VA's health care services.

Agency Comments

We provided a draft of this report to VA for review and comment. In its response (reproduced in appendix III), VA noted its continued efforts to

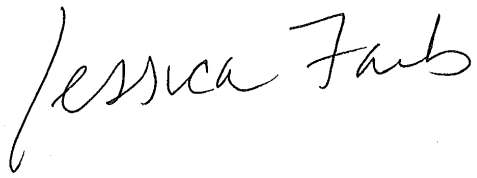
[48]Once a project is approved for research, VA has a centralized data repository—the VA Informatics and Computing Infrastructure—for VA and affiliated researchers to request and receive access to various internal VA databases. Amputation System of Care officials told us there are staff who will then assist the researchers with their data extraction, such as pulling the appropriate records, in order to optimize the efficiency of the request. However, one VHA researcher said that the Amputee Data Repository is easier to use and has already assembled the desired data. On the other hand, VHA researchers from the Center for Limb Loss and Mobility told us they maintain a local registry of potential veteran and non-veteran female research participants in the Seattle, Washington area that is approved for research purposes.

[49]The joint VA/DOD EACE conducts research and surveillance to complement DOD, VA, and academic research programs in four key research focus areas, including advanced prosthetic and orthotic technologies. As of 2016, the EACE included 37 staff members in DOD medical facilities and four staff members in VA. VHA officials told us that there is a large amount of joint research conducted through the EACE that has included female veterans, but its research is not specifically focused on the population.

address the prosthetic needs of the female veteran population with respect to prosthetic size, fit, and cosmetic appearance. VA also provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the appropriate congressional committees, the Secretary of Veterans Affairs, and other interested parties. In addition, the report will be available at no charge on the GAO website at http://www.gao.gov.

If you or your staffs have any questions about this report, please contact me at (202) 512-7114 or farbj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix IV.



Jessica Farb
Director, Health Care

Appendix I: Types of Veteran Amputations

Table 4 describes the distribution of veterans' amputations by gender, with information on amputation type, level, and extremity affected.

Table 4: Distribution of Amputation Types by Veteran Gender, Fiscal Year 2019

				Number of veterans with type of amputation		
Type of amputation	**Description of amputation**	**Level of amputation[a]**	**Type of extremity[b]**	**All**	**Female**	**Male**
Ankle disarticulation	Full or partial amputation at the ankle	Major	Lower	3,500	70	3,430
Digit lower	Full or partial amputation of a portion of one or more toes	Minor	Lower	37,268	934	36,334
Digit upper	Full or partial amputation of a portion of one or more fingers	Minor	Upper	19,784	534	19,250
Elbow disarticulation	Full or partial amputation at the elbow level	Major	Upper	328	12	316
Forequarter	Amputation at the forequarter, which includes the arm, scapula, clavicle, and pectoral muscles	Major	Upper	21	0	21
Hip disarticulation	Full or partial amputation at the hip joint	Major	Lower	1,397	49	1,348
Knee disarticulation	Full or partial amputation at the knee	Major	Lower	7,292	155	7,137
Lower extremity (not otherwise specified)	Major or minor lower extremity amputation that is not specified	N/A	Lower	8,263	158	8,105
Partial foot	Full or partial amputation of a portion of one or both feet	Minor	Lower	15,483	300	15,183
Partial hand	Full or partial amputation of a portion of one or both hands	Minor	Upper	1,162	35	1,127
Shoulder disarticulation	Full or partial amputation at the shoulder	Major	Upper	418	22	396
Transfemoral	Full or partial amputation of the femur, between the hip and knee	Major	Lower	20,970	505	20,465
Transhumeral	Full or partial amputation of the humerus, between the shoulder and elbow	Major	Upper	1,737	48	1,689
Transradial	Full or partial amputation of the radius, between the elbow and wrist	Major	Upper	3,176	99	3,077
Transtibial	Full or partial amputation of the tibia, between the knee and ankle	Major	Lower	33,720	728	32,992
Upper extremity (not otherwise specified)	Major or minor upper extremity amputation that is not specified	N/A	Upper	1,571	47	1,524
Wrist disarticulation	Full or partial amputation at the wrist	Major	Upper	508	23	485

Source: GAO analysis of data from the Veterans Health Administration's (VHA) Amputee Data Repository. | GAO-21-60

Note: Veterans may have more than one amputation. To protect patient confidentiality, we excluded data on one type of amputation—a hemipelvectomy, which is an amputation at the hindquarter and includes the partial removal of the pelvis and attached leg—because the number of cases among female veterans was less than 11.

VHA's Amputee Data Repository data on gender have three categories (male, female, or unknown) and do not account for a veteran's gender identity. These data represent the number of veterans receiving VHA care, and may not include veterans who do not receive their care through VHA.

[a]A major amputation involves a leg at or above the ankle, or an arm at or above the wrist. A minor amputation involves either all or part of the hand or foot.

[b]A lower extremity amputation includes any full or partial removal of any area between the pelvis to the tips of the toes. An upper extremity amputation includes any full or partial removal of any area between the shoulder to the tips of the fingers.

Appendix II: Locations of Veterans with Amputations

Table 5 describes the distribution of veteran amputees by gender and VISN location, while table 6 describes the distribution of veteran amputees by gender and type of facility under VHA's Amputation System of Care.

Table 5: Distribution of Veteran Amputees, by Veterans Integrated Service Network (VISN) and Gender, Fiscal Year 2019

VISN	All veterans	Female veterans	Male veterans
1	3,797	94	3,703
2	4,267	106	4,161
4	5,325	141	5,184
5	3,877	117	3,760
6	6,594	212	6,382
7	6,606	214	6,392
8[a]	9,021	278	8,743
9	5,048	118	4,930
10	8,860	217	8,643
12	4,616	109	4,507
15	4,183	116	4,067
16	6,946	184	6,762
17	6,091	198	5,893
19	5,155	156	4,999
20	5,108	163	4,945
21[b]	6,094	149	5,945
22	7,427	195	7,232
23	4,788	99	4,689
Total[c]	**96,517**	**2,622**	**93,895**

Source: GAO analysis of data from the Veterans Health Administration's (VHA) Amputee Data Repository. | GAO-21-60

Notes: VISNs are regional networks containing individual Department of Veterans Affairs (VA) medical facilities or groups of VA medical facilities, known as health care systems. VHA previously realigned some of its VISN boundaries in 2002 and 2015, decreasing the number of VISNs from 23 to the current 18.

VHA's Amputee Data Repository data on gender have three categories (male, female, or unknown) and do not account for a veteran's gender identity. These data represent the number of veterans receiving VHA care, and may not include veterans who do not receive their care through VHA.

[a]Totals for VISN 8 include San Juan, Puerto Rico, which treated 16 female veteran amputees.

[b]Totals for VISN 21 include Manila, Philippines, which treated male veteran amputees, but not female veteran amputees.

[c]Totals represent unique veterans, and include veterans being treated at facilities in U.S. territories or overseas bases—including Puerto Rico and the Philippines. Veterans at these facilities represent less than 0.1 percent of all veteran amputees. Veterans may receive prosthetic care at more than one VA medical facility or VISN.

Table 6: Distribution of Veteran Amputees, by VHA Amputation System of Care Facility Type and Gender, Fiscal Year 2019

Facility type	All veterans	Female veterans	Male veterans
Regional amputation centers	10,395	323	10,072
Polytrauma amputation network sites	22,327	632	21,695
All other Amputation System of Care locations	73,414	1,947	71,467
Total Amputation System of Care locations	**96,517**	**2,622**	**93,895**

Source: GAO analysis of data from the Veterans Health Administration's (VHA) Amputee Data Repository. | GAO-21-60

Notes: VHA's Amputation System of Care is a tiered system with four levels of care into which each VA medical facility is classified. From highest to lowest level of care, there are 1) seven regional amputation centers, 2) 18 polytrauma amputation network sites, 3) more than 100 amputation specialty clinic teams, and 4) amputation points of contact responsible for consultation, assessment, and referral of veterans to a facility capable of providing the level of services required. Totals represent unique veterans. Veterans may receive prosthetic care at more than one medical facility.

VHA's Amputee Data Repository data on gender have three categories (male, female, or unknown) and do not account for a veteran's gender identity. These data represent the number of veterans receiving VHA care, and may not include veterans who do not receive their care through VHA.

Appendix III: Comments from the Department of Veterans Affairs

DEPARTMENT OF VETERANS AFFAIRS
Washington DC 20420

October 27, 2020

Ms. Jessica Farb
Director
Health Care
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Ms. Farb:

The Department of Veterans Affairs (VA) reviewed the Government Accountability Office (GAO) draft report, ***"VETERANS HEALTH CARE: Agency Efforts to Provide and Study Prosthetics for Small but Growing Female Veteran Population"*** (GAO-21-60).

The enclosure contains general and technical comments to the draft report. VA appreciates the opportunity to comment on the draft report.

Sincerely,

Brooks D. Tucker

Brooks D. Tucker
Assistant Secretary for the Office of
Congressional and Legislative Affairs
Performing the Delegable Duties of the
Chief of Staff

Enclosure

Enclosure

Department of Veterans Affairs (VA)
Response to Government Accountability Office (GAO) Draft Report
"VETERANS HEALTH CARE: Agency Efforts to Provide and Study Prosthetics for Small but Growing Female Veteran Population"
(GAO-21-60)

General Comments

The Veterans Health Administration (VHA) offers exceptional artificial limb care to both the male and female population. Although the female population needs for a prosthetic device is much lower than the male population, VHA continues to develop research projects to evaluate potential opportunities into the future. VHA continues to evaluate and address the needs and interest of the female population, noting the variety of interests and needs which are different from the male population, to include size, cosmetic finishing and adjustable heel foot.

- **Preparing for future readiness because:**
  - More females are in front line and potential combat roles presenting the potential for greater need of prosthetic limb care for females.

- **Providing access to females based upon needs, preferences, desires and goals depending on:**
  - Injury level,
  - The individual, and
  - Roles, interests.

- **Providing services to the female Veteran population that may not be available in the community because:**
  - Commercial insurance may not reimburse for all componentry, and
  - There may be less opportunity to participate in research in the community.

- **Providing greater opportunity for improved fit options:**
  - Adjustable heel foot, and
  - Changeable/exchangeable componentry for multiple functions and situations, such as from formal dress shoe to athletic or other footwear.

- **Meeting psychosocial needs of female Veterans to maximally integrate into society such as:**
  - Variable dress options to support multiple societal roles (i.e. family, work, recreation, formal dress, etc.).

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact

Jessica Farb, (202) 512-7114 or farbj@gao.gov

Staff Acknowledgments

In addition to the contact named above, Raymond Sendejas (Assistant Director), E. Jane Whipple (Analyst-in-Charge), Alison Granger, and Giao N. Nguyen made key contributions to this report. Also contributing were Jennie F. Apter, Jacquelyn Hamilton, and Vikki Porter.

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