

DEPARTMENT OF VETERANS AFFAIRS



Congressionally Mandated Report: Availability of Prosthetics for Women Veterans from the Department of Veterans Affairs

December 2021

CONGRESSIONALLY-MANDATED REPORT ON THE AVAILABILITY OF PROSTHETIC ITEMS FOR WOMEN VETERANS FROM THE DEPARTMENT OF VETERANS AFFAIRS

Issue: In accordance with P.L. 116-315 § 5108(b), the Johnny Isakson and David P. Roe, M.D. Veterans Health Care and Benefits Improvement Act of 2020, this report to the House and Senate Committees on Veterans' Affairs is provided on the availability, from the Department of Veterans Affairs (VA), of prosthetic devices and items made for women Veterans, including an assessment of the availability of such prosthetics at medical facilities of the Department. Requirements for this report include the following:

- (A) a list of all devices classified by the Department as prosthetic devices, including a breakdown of whether a device is considered gender-neutral or gender-specific;
- (B) for gender-neutral devices, a breakdown of sizing;
- (C) the average time it takes for a woman Veteran to receive a prosthetic device after it is prescribed, disaggregated by Veterans Integrated Service Network and medical center of the Department;
- (D) the total number of women Veterans utilizing the Department for prosthetic services, disaggregated by facility of the Department;
- (E) an assessment of efforts by the Department on research, development, and employment of additive manufacture technology (commonly referred to as 3D printing) to provide prosthetic items for women Veterans;
- (F) the results of a survey with a representative sample of not fewer than 50,000 Veterans (of which women shall be overrepresented) in an amputee care program on satisfaction with prosthetics furnished or procured by the Department that replace appendages or their function.

Discussion: VA classifies prosthetic items as any devices that support body function or replace a body part. The categories of prosthetic and rehabilitation items that VA provides include implants, mobility aids, orthotic devices, prosthetic limbs and replacement items, sensory aids (eyeglasses, hearing aids, etc.), cognitive devices, communication devices, home medical equipment, home respiratory equipment, adaptive household items and adaptive recreation equipment. As the largest and most comprehensive provider of prosthetic devices and sensory aids in the country, VA annually provides more than 22 million prosthetic items, devices and services to more than 3.5 million Veterans. Approximately 54% of all Veterans served by VA medical facilities receive prosthetic items and services from VA.

On December 28, 2020, VA published a final rule to establish and clarify eligibility for prosthetic and rehabilitative items and services available to Veterans. This rule established, for the first time, the categories of prosthetic and orthotic services, sensory aids and medical devices VA is authorized to provide to eligible Veterans as part of their active treatment and ongoing rehabilitation.

This report provides information regarding prosthetic limbs and those prosthetic devices and items provided by VA, specifically for women Veterans.

Prosthetic Devices

For fiscal year (FY) 2021, a total of 296,838 women Veterans and 3,145,011 male Veterans received prosthetic devices and items from VA. Prosthetic devices and items include both gender-neutral and gender-specific devices which encompass an array of sizes and styles to meet the individualized, unique medical needs of the Veteran. A list of items provided specifically for female Veterans, including sizing options, is in Appendix A.

Timeliness

The National Prosthetics Patient Database (NPPD) is used to identify prosthetic devices that are provided to Veterans. While this database is a comprehensive resource for products, costs and quantities provided, data regarding the delivery of prosthetic devices are limited. The timeline for when prosthetic devices are prescribed is known, although VA does not have the capability to capture when a Veteran “receives” a prosthetic device in all cases. For example, a Veteran may receive the item from the VA facility where they are seen the same day that item is prescribed. In other cases, a Veteran may receive an item dependent on when the Veteran chooses to schedule a follow-up appointment with their clinical provider. The Veteran may also request for the device be mailed to their home from VA or from the vendor. For other items that are purchased and shipped to the Veteran, VA captures the date of the purchase order and shipment but cannot record when a Veteran receives the device.

Women Veterans Utilizing Prosthetic Services

A summary of the data for the total number of women Veterans utilizing the Department for prosthetic services, disaggregated by facility of the Department, from October 1, 2020, through September 30, 2021, is provided in Appendix B.

Artificial Limbs for Women Veterans

As of FY 2021, there are 2,871 women Veterans identified in VA as having an amputation. Of those, 1,281 are identified as having a major amputation which is defined as an amputation of the ankle or above for lower limbs and the wrist or above for upper limbs. For comparison, there are 92,409 male Veterans with an amputation, of whom 42,671 have a major amputation (Source: Veterans Health Administration Support Service Center (VSSC) data repository [Amputee Cube]). The distinction of a major amputation is identified because those Veterans are potential users of an artificial limb. Prosthetic limbs or services to a prosthetic limb fall into four categories: new complete limbs, socket replacement, repair to a prosthetic limb or supplies.

NPPD is used to identify prosthetic devices that are provided to Veterans. While this database is a comprehensive resource for products, costs and quantities provided, data regarding the receipt of prosthetic devices by Veterans are limited. VA developed and implemented a new workflow management and reporting system called FLOW3 that provides comprehensive information on the entire process of providing limbs and custom orthotics, from prescription to delivery and final check out. FLOW3 is still being validated and adopted throughout VA.

FLOW3 was used to identify prescriptions for prosthetic limbs, sockets, repairs or supplies provided to Veterans in FY 2021. There were 517 prescriptions provided to 281 distinct women Veterans in FY 2021. The breakdown of those items along with a comparison to male Veterans is provided in the tables below. Table 1, on Page 4, shows the number of prescriptions provided to female and male Veterans.

Table 1. Prescriptions for Artificial Limbs, Repairs or Supplies Provided in FY 2021

Prescribed Item	Number Prescribed for Female Veterans		Number Prescribed for Male Veterans	
New Prosthesis	137	(26.5%)	4,393	(24.0%)
Socket Replace	132	(25.5%)	3,909	(21.4%)
Repair	67	(13.0%)	2,586	(14.1%)
Supplies	181	(35.0%)	7,397	(40.5%)
TOTAL	517		18,285	

Table 2 below shows the number of distinct Veterans who received a prescription for new prostheses, socket replacements, prosthetic repairs and supplies. While the number of women Veterans receiving artificial limbs or service to limbs is low compared to male Veterans, the relative percentages of women compared to men is proportionally comparable. It is important to understand that a distinct Veteran may receive multiple prescriptions so the total of Veterans receiving new limbs, socket replacements, repairs, and supplies in Table 2 will be greater than the total number of unique Veterans.

Table 2. Artificial Limbs, Repairs, or Supplies Provided in FY 2021 (Distinct Veterans served from all Veterans with Major Amputation)

Prescribed Item	Distinct Female Veterans Receiving Items (from total n = 1,281¹)		Distinct Male Veterans Receiving Items (from total n = 42,691¹)	
New Prosthesis	121	(9.4%)	3,822	(9.0%)
Socket Replace	99	(7.7%)	3,202	(7.5%)
Repair	52	(4.1%)	1,962	(4.6%)
Supplies	134	(10.5%)	5,523	(12.9%)

¹ Total Distinct Veterans with a Major Amputation as of FY 2021

The total number of distinct women Veterans and the prosthetic limbs and components provided, disaggregated by facility in FY 2021, is shown in Appendix C.

Additive Manufacturing Technology

VA continues to use additive manufacturing technology (i.e., 3D printing) to advance the delivery of health care and services, with more than 70 medical facilities currently leveraging 3D printing technology to deliver customized solutions to Veterans. Since 2017, VA has chartered the Advanced Manufacturing Advisory Committee to advise in areas relevant to the utilization of advanced manufacturing/3D printing technologies for medical applications. This Committee is comprised of subject matter experts who share their expertise, coordinate best practices, provide policy recommendations and develop standards that promote patient safety and consistency of patient care across VA for the use of advanced manufacturing/3D printing technologies for health care.

As of 2020, 15 VA medical facilities were leveraging 3D printing technology for orthotic and prosthetic (O/P) solutions, with 50 3D printers currently being used for O/P applications. Work

is being done across these sites to ensure the safety and performance of 3D-printed orthoses and prosthetic limbs once adopted into clinical practice. For example, the Audie L. Murphy VA Hospital in San Antonio, Texas spearheaded work with lower extremity prostheses, adapting prosthetic prototypes to incorporate higher performance materials with variable properties in strength, weight and flexibility as improvements in technology and techniques arise. VA clinicians and technical experts are creating, testing, breaking and rebuilding stronger 3D printed prototypes of weight and activity-bearing lower extremity prostheses to ensure they will be safe and high performing for Veterans. VA sites are also exploring lower-limb prosthetic sockets that can be printed and fit the same day. This will enable VA 3D printing teams to work with Veterans and their clinician to understand their O/P needs to better design and iterate a prototype for Veteran use. The digital files for a Veteran can be saved and printed for future use, decreasing travel time and allowing for replacements to be sent to the Veteran.

The provision of prosthetic services to women Veterans is being amplified through 3D printing by offering solutions that are not readily available through commercial off-the-shelf products for women. Recent examples are provided below with regard to how VA facilities are creating 3D printed prosthetic devices to meet individual women Veteran's requirements and preferences, and personalizing those devices in sizing and function:

- Minneapolis VA Medical Center Adaptive Design and Engineering Program is collaborating with the industry to create a prosthetic ankle that can interface with 3D-printed feet, allowing women Veterans with amputations to choose nearly any shoe they want to wear with the prosthesis. This product, developed in response to Congressional interest to improve prostheses for women Veterans, is licensed to UNYQ with a planned product release to occur in late 2021.
- Advanced Manufacturing Network members are exploring 3D printed breast prostheses for cancer patients, post-mastectomy, as an alternative to reconstructive surgery (not implanted but used within clothing/swimsuit/undergarments to restore symmetry and aesthetics).
- New Orleans VA Medical Center is working with Tulane University students to develop a 3D printed socket that will be used for Aqua Therapy. This will allow a physical therapist to rotate the fin in different directions with different size fins to increase resistance and direction during therapeutic exercises.
- The Hunter Holmes McGuire VA Medical Center (Richmond, Virginia) Advanced Technologies Lab has utilized 3D printed solutions to personalize and assist women Veterans with their health care needs, such as producing a self-catheterization mirror for a Veteran with a spinal cord injury or a makeup brush and holder for a female Veteran to achieve her goal of putting on makeup using her universal cuff.

The Department is also engaged in research, development and interagency collaborations to employ 3D printing to provide prosthetic items to Veterans. As results of new research emerge, VA identifies new applications and technology as they are introduced to industry to determine how best to incorporate them within the VA health care system. Recent examples of such efforts include:

- VA formed interagency collaborations with the Food and Drug Administration (FDA), National Institutes of Health, the Department of Defense and America Makes to increase the reach and impact of advanced manufacturing technologies, such as

developing mechanisms to evaluate community and commercial designs for novel personal protective equipment; supporting domestic manufacturing and health networks; developing a scalable 3D printing consortium with a single, intergovernmental 3D printing quality system meeting FDA and International Organization for Standardization standards to expand the number of patients who receive 3D printed health care solutions.

- Three VA medical centers (in Charleston, South Carolina; Richmond, Virginia; and Seattle, Washington) are registered with the FDA as medical device manufacturers, allowing for on-site research, development and medical device manufacturing to meet the unique needs of Veterans.
- Teams of VA medical center clinicians, researchers and engineers created a rapid response network to address the design, prototyping, regulation and fabrication of critically-needed products.
- VA is exploring the applications of bioprinting in the following five core clinical areas: bone, vasculature, nerves, skin and complex structures.
- The Advanced Manufacturing Advisory Committee is considering how 3D printing can be utilized for Veterans seeking to undergo gender-affirming surgeries.
- VA is also partnering with universities to deploy training programs that allow students to engage in the design and iteration process of developing 3D-printed orthotic and prosthetic solutions for Veteran-specific needs. Such partnerships will help to promote a comprehensive training and workforce development program for hospital-based 3D printing.

Patient Satisfaction with Amputation Care

As the specific details of the survey on Veterans' satisfaction with prosthetics furnished or procured by the Department were not detailed in P.L. 116-315 § 5108(b)(2)(F), clinicians in VA's Amputation System of Care, in collaboration with a team of researchers from the Seattle-Denver Center of Innovation, set out to learn more about the Veteran population living with limb loss. The aims were to: 1) describe general demographics and amputation characteristics of Veterans with limb loss receiving care in VA; 2) describe overall satisfaction with amputation care, prosthetic devices and quality of life of patients with limb loss receiving care in VA; and 3) identify gender differences in satisfaction with amputation care, prosthetic devices and quality of life among patients with limb loss receiving amputation care in VA. A copy of the survey is provided in Appendix D.

Survey development

A survey was created with questions regarding general demographics, prosthesis procurement and use of a prosthetic device followed by questions from validated instruments assessing:

- satisfaction with the prosthetic device;
- satisfaction with quality of life;
- satisfaction with prosthesis-related care;
- importance of cosmetic considerations related to the prosthesis;
- comfort with prosthesis use in intimate relationships;
- satisfaction with the time required for Veterans to receive their prosthetic limb; and

- satisfaction with the extent to which the prosthesis reflected the Veteran’s self-identified gender.

Veterans were asked to answer questions based on their most recent amputation. The survey was piloted and tested and later translated into Spanish as a language option. See Appendix D for the complete survey.

Cohort selection

Using the VSSC Amputee Data Cube, the Department first identified all Veterans with a major limb amputation (defined as amputation at or above the ankle or wrist) who had received any type of care in VA in FY 2020. In an attempt to fully comply with the requirement to reach the target of 50,000 Veterans, the Department included Veterans with minor limb amputation (as defined as partial hand or foot amputations and finger or toe amputations) although this population does not commonly use a prosthesis. The final cohort of 46,613 Veterans excluded Veterans who are known to be deceased.

Surveys were distributed by email, text message and U.S. Postal Service, and a second attempt was made using an alternate method when email or text messages were returned as undeliverable. Two random samplings of women were selected to increase response rate among women Veterans: 200 women received personal phone calls, and 400 women received personalized emails.

Results – Data Tables included in Appendix D

General Demographics of Survey Respondents (Appendix D, Table 1)

- Total number of Veterans surveyed: 46,613 (45,257 men, 1,356 women)
- Total number of respondents: 4,981 (4,804 men, 177 women)
- Total percentage of respondents: 10.7 (11.3% men, 13.1% women)

General Demographics/Amputation and Prosthesis Characteristics (Appendix D, Table 2)

Gender Identification

- Male: 4151 (83.3%)
- Female: 158 (3.1%)
- Non-binary or self-described: 22 (0.4%)
- Did not respond to gender identification: 649 (13%)

Service Era

- Percentage of those classified as Operation Enduring Freedom/Operation Iraqi Freedom service era: 4.1% (4.1% of men, 4.4% of women, 4.3% non-binary/self-describe)

Race

- White: 77.1 %
- Black: 12.3%
- Asian: 0.4%

Level of Amputation (Calculated on the entire sample, but data are missing from 374 participants who did not respond to this variable.)

- Lower extremity: 86.2%
 - Transfemoral (Above-knee): 31.3%
 - Transtibial (Below-knee): 45.9%
 - Partial foot or toes: 14%
- Upper extremity: 8.6%
 - Transhumeral (Above-elbow): 7.5%
 - Transradial (Below-elbow): 3.4%
 - Partial hand or fingers: 3%

Cause of Amputation - (multi-selection was possible for cause of amputation)

- Infection: 31.2%
- Non-combat trauma: 29.3%
- Diabetes: 20.3%
- Vascular disease: 20.0%
- Combat injured: 17.7%

Prosthesis Use Findings (Appendix D, Tables 2 and 3)

- Respondents who reported current use of prosthesis: 87.7%
 - 89.1% reported use of lower limb prosthesis
 - 73.6% reported use of upper limb prosthesis
- Intensity of use:
 - Prosthesis use of 12 or more hours/day: 44.4%
 - Prosthesis use of 2 hours or less/day: 4.9%
- Frequency of use:
 - Prosthesis use of 7 days/week: 71.7% (74.6% of men, 54.8% of women)
 - Prosthesis use of less than 1 day/week: 1.7%

Satisfaction and Quality of Life

Prosthesis Satisfaction

The Trinity Amputation and Prosthesis Experience Scales, as noted in Appendix D, Table 4, was used to assess various aspects of prosthetic device satisfaction among the survey respondents and is scored from 1-5 (1=not at all satisfied and 5=very satisfied). Scores ranged from 2.5 to 2.9.

- 68% reported being mostly or very satisfied with their prosthetic device overall.
- 19.3% rated it as somewhat or very important to have the ability to wear jewelry or accessories.
- 80.2% rated it as somewhat or very important that prosthesis not restrict clothing or shoes.
- 38.2% are comfortable or very comfortable using a prosthesis for intimate contact.
- 26.8% responded the prosthesis reflects their gender.

Prosthetic Limb Services Satisfaction

Participants were asked to rate their level of satisfaction with services received related to their prosthesis, as noted in Appendix D, Table 5, on a scale of 1 to 5 where 1=very dissatisfied and 5=very satisfied. Ratings of prosthesis-related services ranged from 3.5 to 4.4.

- 15.3% of respondents reported that the time from prosthesis prescription to delivery was shorter than expected.
- 59.2% reported that the time was about what was expected.

General Life Satisfaction and Quality of Life

Participants were surveyed on general life satisfaction and overall quality of life, as noted in Appendix D, Table 6, with a scale from 1 to 10, 1=extremely dissatisfied and 10=extremely satisfied.

- Average general life satisfaction score was 6.7.
 - Female respondents scored 6.1 compared to 6.7 in male respondents.
- Average quality of life score was 6.7
 - Female respondents scored 6.2 compared to 6.8 in male respondents.

Survey Overview

Veterans who responded to the survey appear to reflect the population of Veterans with amputation who currently receive amputation care and prosthetic services within VA based on gender, age, era of service and diagnoses of diabetes (described in Appendix D, Table 1). Survey methods used to assess female Veterans with amputation resulted in a higher response percentage as compared to their male counterparts.

Most survey respondents reported being mostly or very satisfied with their prosthetic limb overall. Overall, satisfaction was scored above the mean in survey ratings related to prosthetic limb care services, general life satisfaction, overall quality of life and expected timeliness of prosthetic limb delivery.

In conclusion, VA continues to provide women Veterans and all cohorts of Veterans with high-quality, comprehensive prosthetic devices, items and services in a timely manner, both from within the Department and through partnerships with contracted community providers.

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