



PERSONNEL AND
READINESS

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

NOV 04 2020

The Honorable James M. Inhofe
Chairman
Committee on Armed Services
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

The Department's response to Senate Report 116-48, page 211, accompanying S. 1790, the National Defense Authorization Act for Fiscal Year 2020, is enclosed. The Secretary of Defense is directed to provide a report on infertility in members of the Armed Forces.

Infertility impacts a significant percentage of women and men of reproductive age in the United States, and the majority of Military members serve on Active Duty during their reproductive years. The data in the enclosed report is based primarily on previously published reports of the Armed Forces Health Surveillance Branch in multiple Medical Surveillance Monthly Reports. Findings show a low incidence and prevalence of infertility among members of the Armed Forces and the ability to meet or exceed availability for provider consultation at the primary, specialty, and subspecialty levels for services covered by the TRICARE benefit.

Thank you for your continued strong support for the health and well-being of our Service members and families. I am sending an identical letter to the House Armed Services Committee.

Sincerely,

//SIGNED//

Matthew P. Donovan

Enclosure
As stated



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Report to Congressional Armed Services Committees



Study on Infertility in Members of the Armed Forces

**Requested by: Senate Report 116-48, Page 211, Accompanying S.
1790, the National Defense Authorization Act for Fiscal Year 2020**

The estimated cost of this report or study for the Department of Defense is approximately \$233,000 in Fiscal Years 2019 - 2020. This includes \$133,000 in expenses and \$100,000 in DoD labor. Generated on 2020 Aug 31 RefID: F-21CD186

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EXECUTIVE SUMMARY

This report is in response to the Senate Report 116-48, page 211, to accompany S. 1790, of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2020 which requests the Secretary of Defense to conduct a study on infertility in members of the Armed Forces¹ and provide findings for each of the elements identified below. The information in the report is based on the data available to date.

Senate Report 116-48 of the NDAA for FY 2020 requests the Secretary of Defense to provide:

- 1) Determination of the numbers of currently serving members of the Armed Forces who have been diagnosed with a common cause of infertility;
- 2) Determination of the number of Service members whose infertility has no known cause;
- 3) Determination of the incidence of miscarriage among female Service members by Service and military occupation;
- 4) Comparison of infertility rates of female Service members to the infertility rates of their civilian counterparts;
- 5) Determination of demographic information about such Service members to include race, ethnicity, sex, age, military occupation, and possible hazardous environmental exposures during service;
- 6) Determination of the availability of infertility services for those Service members who desire such treatment, including waitlist times at the military medical treatment facilities (MTFs) providing those services;
- 7) Criteria used by each of the Services to determine Service-connection for infertility, including whether screenings for environmental toxins were performed when the cause of infertility could not be determined; and
- 8) Current policies of the Department of Defense (DoD) for ensuring geographic stability during the treatment of Service members' undergoing medical treatment for infertility.

Data provided in this report for currently serving members of the Armed Forces, hereafter referred to as Active Duty Service Members (ADSMs), reflects information consistent with previously published reports on infertility by the Armed Forces Health Surveillance Branch (AFHSB) in multiple Medical Surveillance Monthly Reports (MSMRs) (Stahlman, 2019) (Williams, 2019). Supplementary data were provided by Defense Health Agency (DHA) Analytics and Evaluation Division with regard to wait times and to specify prevalence data similar to that of the United States (U.S.) Centers for Disease Control and Prevention (CDC). Data limitations, including the inability to perform statistical testing to assess differences in rates of infertility and miscarriage among subgroups of ADSMs, are detailed in Appendix 1.

According to the CDC, infertility is generally defined as not being able to get pregnant after one year of unprotected sex (CDC, 2020). CDC reports about seven percent of married women aged 15 to 44 years in the U.S. are unable to get pregnant after one year of trying (CDC, 2020). The American Society for Reproductive Medicine (ASRM) notes that infertility affects men and women (ASRM, n.d.), and there are a number of established and possible causes of infertility

¹ All methodology is described in detail in Appendix 1.

including, but not limited to genetics, aging, certain diseases, behavioral risk factors (e.g., body weight, smoking), and occupational and environmental hazards (Homan GF, 2007).

The data in this report include ADSMs of all marital statuses, based on clinically documented diagnoses of infertility and miscarriage. During the surveillance period (2013 to 2019), overall rates of infertility were 1.65 percent among female ADSMs (ADFSDMs) and 0.42 percent among male ADSMs (ADMDSMs), and the rate of miscarriage among ADFSDMs was 8.71 percent. While the rate of diagnosed infertility and miscarriage among ADSMs is low, these data likely underreport the true burden of infertility and miscarriage in the DoD. Infertility data are not directly comparable to that of CDC, which is based on self-reported survey data rather than clinical diagnosis and uses a different methodology to identify infertility. Similarly, miscarriage data are not directly comparable to that of March of Dimes or other entities, as there are many definitions and different methodologies used to determine miscarriage rates. In order to provide a more comprehensive view of infertility and miscarriage in the DoD, and to understand possible causes of the declining rate of newly diagnosed infertility among ADSMs described later in this report, more rigorous studies are needed.

Key findings for the eight elements noted above are:

1. Determination of the numbers of currently serving members of the Armed Forces who have been diagnosed with a common cause of infertility;

Between 2013 and 2019, 20,356 ADFSDMs (1.65 percent of approximately 1.2 million ADFSDMs) and 26,879 ADMDSMs (0.42 percent of approximately 6.4 million ADMDSMs) were diagnosed with infertility (Table 1). The most common diagnoses of infertility due to specific causes are related to anovulation (absence of ovulation) or tubal disease among ADFSDMs (0.28 percent and 0.19 percent, respectively), and azoospermia and oligospermia among ADMDSMs (0.04 percent and 0.06 percent). These diagnoses broadly align with the ASRM, which indicate the most common causes of infertility cases are due to ovulation problems or tubal factors among females, and azoospermia and oligospermia among males (ASRM, n.d.).

2. Determination of the number of Service members whose infertility has no known cause;

Between 2013 and 2019, 10,373 ADFSDMs (0.84 percent) and 8,249 ADMDSMs (0.13 percent) were diagnosed with infertility of no known cause (Table 1). Although not directly comparable, this is less than data provided by ASRM which suggest the cause is unknown in about ten percent or more of diagnosed infertility cases (ASRM, n.d.).

3. Determination of the incidence of miscarriage among female Service members by Service and military occupation;

Between 2013 and 2019, the prevalence (i.e., the rate of new and existing cases) of miscarriage among ADFSDMs was 8.71 percent (Table 2). Miscarriage rates for ADFSDMs by Service and military occupation were comparable, with all Services and military occupations having miscarriage rates less than ten percent. Due to the specificity of the clinical data in

this report, comparisons of data to external data should be interpreted with caution (e.g., it has been reported that in the U.S. about 10 to 15 percent of known pregnancies end in miscarriage (March of Dimes, 2017)).

4. Comparison of infertility rates of female Service members to the infertility rates of their civilian counterparts;

Between 2013 and 2019, the average prevalence of diagnosed infertility among ADFSMs was 1.65 percent (Table 1). Again, due to the specificity of the clinical data in this report, comparisons of data to external self-reported survey data should be interpreted with caution (e.g., such as that from the CDC, which reports seven percent of married women aged 15 to 44 years in the U.S. are unable to get pregnant after one year of trying (CDC, 2020)). In August 2020, DoD released the Women's Reproductive Health Survey which, when complete, may provide a better (although not exact) comparison with CDC survey methodologies and data.

5. Determination of demographic information about such Service members to include race, ethnicity, sex, age, military occupation, and possible hazardous environmental exposures during service;

By race/ethnicity, rates of newly diagnosed infertility were highest among non-Hispanic Black ADMSMs compared to men and women of other race/ethnicity groups (Table 3). By sex, rates of newly diagnosed infertility were higher among ADFSMs than ADMSMs. By age, rates of newly diagnosed infertility were higher among ADFSMs aged 35-39 years, and ADMSMs aged 30-34 years (Table 4). By military occupation, ADFSMs in health care occupations and ADMSMs in pilot/air crew occupations had the highest rates of newly diagnosed infertility (Table 5). These findings are consistent with previously published reports of infertility among ADMSMs (Stahlman, 2019) (Williams, 2019).

6. Determination of the availability of infertility services for those Service members who desire such treatment, including waitlist times at the MTFs providing those services;

For ADMSMs diagnosed with infertility, basic infertility services can be initiated by a Primary Care Manager, or more commonly, from a specialist such as an obstetrician-gynecologist (OB-GYN) or urologist. More advanced infertility services can be provided by a Reproductive, Endocrinology and Infertility (REI) sub-specialist. Referral wait times for these provider types are in accordance with DHA - Interim Procedures Memorandum 18-001. Assisted Reproductive Technologies (e.g., intrauterine insemination or in-vitro fertilization), are available with a patient cost-share requirement at six tertiary care MTFs² as part of their REI Graduate Medical Education (GME) program. However, due to the academic nature of the REI GME program, there is limited capacity for services, and the wait times for these programs are not tied to TRICARE appointment or referral standards.

² Walter Reed National Military Medical Center; Tripler Army Medical Center; Womack Army Medical Center; Madigan Army Medical Center; Brooke Army Medical Center; and Naval Medical Center San Diego.

7. Criteria used by each of the Services to determine Service-connection for infertility, including whether screenings for environmental toxins were performed when the cause of infertility could not be determined;

Determining Service-connection for infertility may be clear in some cases (such as with trauma or documented injury), but can be challenging when the cause of infertility is multifactorial or has no known cause. There are no current laboratory screenings performed for environmental toxins as part of the normal infertility workup that could be used to determine Service-connection. Review of the literature examining the relationship between infertility and environmental exposure among ADSMs does not currently show associations between deployment and diagnosed infertility, though these studies are few and limited (Gawron LM, 2018).

8. Current policies of the DoD for ensuring geographic stability during the treatment of Service members' undergoing medical treatment for infertility.

As of the date of this report, there are no published or anticipated DoD, DHA, or Service-level policies that provide official guidance regarding geographic stability during the treatment of ADSMs undergoing medical treatment for infertility. Individual situations and requests for geographic stability are traditionally addressed at the local command level.

SUMMARY

While the overall rate of diagnosed infertility and miscarriage among ADSMs is low, these data likely underreport the true burden of infertility in the DoD, due to the limitations noted in Appendix 1. However, there was also a decline in the number of newly diagnosed cases of infertility among ADSMs between 2013 and 2019. These findings are consistent with previously published infertility reports among ADSMs (Stahlman, 2019) (Williams, 2019). Focused studies are needed to provide a more in-depth review of the complexity of infertility and miscarriage among ADSMs, and to determine possible causes for the decline in infertility rates.

INTRODUCTION

This report responds to the Senate Report 116-48, page 211, to accompany S. 1790, the NDAA for FY 2020 (Public Law 116-92), which requests the Secretary of Defense to conduct a study on infertility in members of the Armed Forces and provides findings for each of the elements identified below, to the extent practicable.

Infertility impacts a significant percentage of women and men of reproductive age in the United States (U.S.). The majority of military members serve on active duty during their reproductive years (Pilgrim J, 2018), with over 80 percent of the military population between the ages of 17 and 35 years of age (Military One Source, 2018). However, there is no established uniform definition or measures of incidence of infertility for the U.S. population (Thoma ME, Prevalence of infertility in the United States as estimated by the current duration approach and a traditional constructed approach, 2013). Public health agencies and organizations use varied definitions and methodology, to include the following:

- Infertility, ASRM: Failure to achieve pregnancy within 12 months of unprotected intercourse or therapeutic donor insemination in women younger than 35 years or within six months in women older than 35 years;
- Infertility, CDC: Not surgically sterile and have had at least 12 consecutive months of unprotected sexual intercourse without becoming pregnant;
- Infertility, National Institutes of Health (NIH): Not being able to achieve pregnancy after one year of having regular, unprotected intercourse, or after six months if the woman is older than 35 years of age;
- Infertility, World Health Organization (WHO): A disease of the reproductive system defined by the failure to achieve a clinical pregnancy after 12 months of regular unprotected sexual intercourse.

Many physical and behavioral factors can impact fertility. According to ASRM, healthy heterosexual couples under age 30 who have sex regularly will have an approximately 20 percent chance of getting pregnant each month (ASRM, n.d.). A woman is most fertile in her early 20s; the chance a woman can get pregnant, without medical assistance, drops greatly after age 35 (and especially after age 40), when infertility and miscarriage rates increase significantly.

Established and possible causes of infertility include genetic abnormalities, aging, certain acute and chronic diseases, behavioral risk factors (e.g., body weight, smoking), iatrogenic causes, occupational and environmental hazards (e.g., reproductive or urinary tract trauma such as experienced during military deployments), infectious agents, and exposure to certain infectious agents (Homan GF, 2007). For many individuals and couples, infertility can be caused by any one or more of these factors in combination in one or both partners. Although unknown, the proportion of infertility that may be preventable is suspected to be substantial (Macaluso M, 2010).

In some cases, same-sex partners or an individual wishing to conceive without a partner may receive a diagnosis of infertility to facilitate receipt of infertility services, but may not actually be

infertile. Similarly, a woman may have an encounter for receipt of infertility services although the infertility diagnosis is with her male partner.

Among ADSMs, many lifestyle and behavioral factors which can negatively impact fertility, including tobacco use, alcohol use, and body composition (e.g., obesity), are well documented. Cigarette smoking prevalence is higher among people currently serving in the military than among the civilian population, and prevalence is even higher among military personnel who have been deployed (CDC, 2020). In addition, frequent heavy drinking is common among members of the military, particularly among men (when compared to women), non-Hispanic whites (when compared to other races), and among enlisted personnel (when compared to officers) (Schumm, n.d.). Lastly, with regard to body composition, the overall prevalence of obesity³ among ADSMs is 17.4 percent, which has increased steadily since 2014, with obesity rates higher among males (18.4 percent) compared to females (12.6 percent), and in older compared to younger Service members (AFHSB, 2019). While the data in this report are not able to provide information on the correlation between infertility and these lifestyle and behavioral factors, it does provide information regarding other known risk factors such as age, gender, and race/ethnicity.

The Military Health System's dual mission is to provide high quality health care in support of the full range of military operations, and to sustain the health of all those entrusted to its care. The data in this report are based primarily on previously published Armed Forces Health Surveillance Branch (AFHSB) reports (Stahlman, 2019) (Williams, 2019). Supplementary data were provided by DHA Analytics and Evaluation Division in order to provide prevalence data similar to that of the CDC and others. All methodology is detailed in Appendix 1. Due to the clinical data specificity in this report, data comparisons to external self-reported survey data, such as that from CDC, should be interpreted with caution. Specifically, the CDC's National Survey of Family Growth (NSFG), which collects infertility data by survey and publishes periodic reports (CDC, 2020) is sometimes used as a benchmark for infertility data, although this uses self-reported survey data rather than clinically diagnosed data, leading to the inability to have direct data comparisons. Given the limitations of the available data, no statistical testing was performed. Therefore, statistical significance of results cannot be reported.

ELEMENTS OF THE REPORT

For the purposes of this report, ADSMs include individuals who served in the active component of the Army, Navy, Air Force, or Marine Corps during the surveillance period (01 January 2013 through 31 December 2019). Specific inclusions and exclusions used in the methodology are outlined in Appendix 1. Infertility is reported in both incidence and prevalence, described in Appendix 1, where appropriate. As requested on page 211 of SASC report 116-48 of the NDAA for FY 2020, this report is outlined in eight elements:

ELEMENT 1

Determination of the numbers of currently serving members of the Armed Forces who have been diagnosed with a common cause of infertility.

³ In accordance with CDC, a body mass index ≥ 30 was considered obese (AFHSB, 2019).

Between 2013 and 2019, the most recent years for which data are available, the prevalence (i.e., rate of new and existing cases)⁴ of infertility among ADSMs shows that out of approximately 1,237,157 female ADSMs (ADFSMs), 20,356 (1.65 percent) had a diagnosed case of infertility, and out of 6,413,843 male ADSMs (ADMSMs), 26,879 (0.42 percent) had a diagnosed case of infertility (Table 1).

Infertility classification type was determined using the International Classification of Diseases (ICD) infertility codes (Appendix 1). Among ADFSMs, the most common infertility diagnoses due to specific causes were anovulation or tubal disease (0.28 percent and 0.19 percent, respectively), accounting for 5,838 of all diagnosed infertility cases among ADFSMs. Among ADMSMs, the most common infertility diagnoses due to specific causes were related to oligospermia and azoospermia (0.06 percent and 0.04 percent, respectively), accounting for 6,910 of all diagnosed infertility cases among ADMSMs. These diagnoses broadly align with the ASRM, which indicate the most common causes of infertility cases are due to ovulation problems or tubal factors among females, and azoospermia and oligospermia among males (ASRM, n.d.).

Across each year, the incidence (i.e., rate of new cases) of infertility declined for both ADFSMs and ADMSMs. Among ADFSMs, the rate of newly diagnosed infertility cases declined from 85.40 per 10,000 person-years (p-yrs)⁵ in 2013 to 68.02 per 10,000 p-yrs in 2019. For ADMSMs, the rate of newly diagnosed infertility declined from 35.18 per 10,000 p-yrs in 2013 to 28.70 per 10,000 p-yrs in 2019.

Consideration: While the rate of newly diagnosed infertility among ADSMs has been decreasing, these data likely underreport the true burden of infertility in the DoD. Infertility underreporting is due to the limitations noted above, as well as the fact it does not include, among others, non-Active Duty spouses or partners, or ADSMs who may self-report infertility, but did not seek a clinical diagnosis or infertility services. The decline in the rate of newly diagnosed infertility among ADSMs should be reviewed for attribution to improved health or decreased utilization of diagnostic services. Further rigorous studies are needed to provide a more comprehensive view of infertility in the DoD.

⁴ See Appendix 1 for a full definition for incidence and prevalence.

⁵ Person-years (p-yrs) is a type of measurement that takes into account both the number of people in a study and the amount of time each person spends in a study. It is an estimate of the actual time-at-risk for a disease.

Table 1: Total Diagnosed Cases of Infertility by Infertility Type Among ADSMs, Calendar Year (CY) 2013-2019

	Total		
	N	Rate [^]	Percentage ⁺⁺
Female¹	N≈1,237,157		
Total	20356	164.54	1.65%
Anovulation	3466	28.02	0.28%
Tubal origin ^a	2372	19.17	0.19%
Uterine origin ^b	344	2.78	0.03%
Other specified origin	3801	30.72	0.31%
Unspecified origin	10373	83.85	0.84%
Male	N≈6,413,843		
Total	26879	41.91	0.42%
Azoospermia	2745	4.28	0.04%
Oligospermia	4165	6.49	0.06%
Other male infertility	11270	17.57	0.18%
Infertility due to extratesticular causes	450	0.70	0.01%
Male infertility, unspecified	8249	12.86	0.13%

¹ Female of childbearing potential

^a Block, occlusion, or stenosis of the fallopian tubes

^b Structural abnormality of the uterus or non-implantation (includes fibroids)

[^] Rate per 10,000 persons

⁺⁺ Number of cases identified divided by the total ADSM's in the period, and multiplied by 100 as a standard percentage

SOURCE: DHA Analytics & Evaluation Division

ELEMENT 2

Determination of the number of Service members whose infertility has no known cause.

Infertility classification type was determined using the ICD infertility codes (Appendix 1). Infertility of no known causes was defined as “infertility of unspecified origin” or “male infertility, unspecified.” Between 2013 and 2019, 10,373 ADFSMs (0.84 percent) and 8,249 ADMSMs (0.13 percent) were diagnosed with infertility of no known cause (Table 1). Among all ADSMs, infertility of no known cause was less than one percent of all diagnosed infertility. Although not directly comparable due to differences in definition and methodology, this is less than data provided by ASRM, which suggest the cause is unknown in about ten percent or more of diagnosed infertility cases (ASRM, n.d.). However, in a much higher percentage of couples, only minor abnormalities are found that are not severe enough to result in infertility; in these cases, the infertility is referred to as unexplained (ASRM, n.d.). Infertility of no known cause is generally diagnosed after standard evaluations fail to identify an obvious reason (Practice Committee of the ASRM, 2020), or available diagnostic codes do not cover an individual's condition.

Infertility of no known cause could represent the normal distribution lower extreme of fertility when there is no defect present. It is also very likely infertility testing may miss subtle defects, such as microscopic issues within female fallopian tubes or male sperm that impacts fertilization (ACOG, 2019). In all, current testing methods may not fully capture the array of factors involved with a couple's ability to conceive (Quaas, 2008). The higher rates of infertility of no known cause diagnosed among both ADFSMs and ADMSMs may be due to multiple factors. Certain modifiable risk factors for infertility, such as smoking, heavy alcohol use, a history of sexually transmitted disease, and obesity, are conditions that impact military readiness as well as individual fertility.

According to DoD Reproductive Endocrinology/Infertility (REI) subject matter experts (SMEs), infertility of no known cause is often the first diagnosis documented until more is known with subsequent evaluation. Not uncommonly, a fertility issue may also be with the spouse or partner, but treatments and procedures for conception are part of the female partner's care, and her visit may then be coded as "other" or "unspecified." Infertility of no known cause may also be a result of provider documentation, due to the limited number of available diagnostic coding choices. Due to these known limitations, no conclusions can be drawn from these data alone.

Consideration: Infertility of no known cause is likely a combination of known and unknown causes. The complexity of coding infertility is further limited by the finite descriptions in ICD codes. Infertility of no known cause is often assigned a default diagnosis while clinical evaluation of both partners is ongoing. Additionally, same-sex partners, women without a partner, and women whose male partner has infertility may all receive a diagnosis of infertility in order to receive a referral for infertility services, although the women may not actually be infertile themselves. The exact number of ADMSMs in these populations are unknown. Individual case-level review is needed to provide a more comprehensive view of infertility of no known cause across the DoD.

ELEMENT 3

Determination of the incidence of miscarriage among female Service members by Service and military occupation.

Between 2013 and 2019, the prevalence of miscarriage determined using the pregnancy and miscarriage ICD codes, among ADFSMs was 8.71 percent (Table 2). During this time frame the prevalence of miscarriage increased each year, from 7.90 percent in 2013 to 9.35 percent in 2019, although the reasons for this prevalence change over this time period is unknown.

Miscarriage rates for ADFSMs by Service and military occupation were comparable, with all Services and military occupations having miscarriage rates less than ten percent. However, the data provided likely underreport the true burden of miscarriage in the DoD, detailed in the limitations (Appendix 1), as it does not include ADFSMs who did not seek a clinical diagnosis for their pregnancy and/or subsequent miscarriage diagnosis. Due to the specificity of the clinical data in this report, comparisons of data to external data should be interpreted with caution (e.g., it has been reported that in the U.S. that about 10 to 15 percent of known pregnancies end in miscarriage (March of Dimes, 2017)).

Consideration: Research is needed to further examine increasing overall prevalence of miscarriage in ADFSMs in the past six years, and specifically in the Army, to determine statistical significance. Future studies may be able to provide more complete information on the impact of demographic factors such as age, race/ethnicity, occupation, and rank on incidence of miscarriage among ADFSMs. In particular, rigorous studies are needed to better understand rates of different types of pregnancy loss or miscarriage (multiple miscarriages between live births over reproductive years, and/or repeated miscarriage with no live births), potential causes of miscarriage, and the overall impact of miscarriage on readiness. Additional studies are also needed to assess recurrent pregnancy loss, a disease distinct from infertility (Practice Committee of the ASRM, 2020).

Table 2: Total Diagnosed Cases of Miscarriage by Service and Occupation Among Female¹ ADSMs, CY2013-2019			
	Total		
	N	Rate[#]	Percentage⁺⁺⁺
Total	18025	87.10	8.71%
Service			
Army	7484	95.45	9.54%
Navy	4378	79.73	7.97%
Air Force	4809	83.52	8.35%
Marine Corps	1354	84.21	8.42%
Occupation			
Combat-specific ²	325	74.71	7.47%
Motor transport	625	87.54	8.75%
Pilot/aircrew	189	71.42	7.14%
Repair/engineering	3595	84.58	8.46%
Communications/intel	6311	88.98	8.90%
Health care	3402	84.21	8.42%
Other	3578	91.70	9.17%
¹ Female of Childbearing Potential			
² Infantry/Artillery/Combat Engineering/Armor			
[#] Rate per 1,000 pregnant women			
⁺⁺⁺ Number of cases identified divided by the total ADSM's in the period, and multiplied by 100 as a standard percentage			
SOURCE: AFHSB			

ELEMENT 4

Comparison of infertility rates of female Service members to the infertility rates of their civilian counterparts.

The prevalence of infertility among ADFSM between 2013 and 2019 was 1.65 percent (Table 1). However, this prevalence does not have a basis for direct comparison in with civilian benchmarks, due to the significant differences in study populations. As a health system, the DoD is able to leverage data sources and clinical diagnoses which are not generally available to CDC and other national civilian groups reporting infertility data. Specifically, the CDC's NSFG, which gathers information on family life, marriage and divorce, pregnancy, infertility, use of

contraception, and general and reproductive health (CDC, 2019), may be incorrectly seen as a possible benchmark for ADSM infertility rate comparisons.

Unlike the DoD's clinically diagnosed data, CDC's NSFG is a survey, conducted through voluntary and confidential in-person interviews, and with a portion of the more sensitive questions answered privately by self-administration. Additionally, CDC's NSFG defines infertility only among married women 15-49 years of age who are not surgically sterile, and have had at least 12 consecutive months of unprotected sexual intercourse without becoming pregnant. The most recent data from CDC's NSFG for 2015-2017 indicate that 8.8 percent of married women self-reported infertility, and 13.1 percent of all women self-reported impaired fecundity (i.e., who are not surgically sterile, and for whom it is difficult or impossible to get pregnant or carry a pregnancy to term) (CDC, 2020). However, as DoD data include women of all ages and marital statuses, no direct comparison can be made.

In addition, the Service Women's Action Network (SWAN) conducted an online survey in 2018, focused on reproductive health services in the military (SWAN, 2018). As findings from the SWAN survey were based on self-reported data from a very small sample which included 799 duty and retired females, of whom 262 were ADFSMs (less than one percent of the ADFSM population), findings should not be used as a benchmark, and should again be interpreted with caution. Of the few ADFSMs who answered questions about infertility, 37 percent said they had trouble getting pregnant when actively trying to do so (SWAN, 2018). However, responses did not address whether 'trouble' was current or historic, or whether respondents had accessed clinical care or obtained a diagnosis for their infertility. As noted by the findings of the SWAN study, responses were "[...] not fully representative of military women and [...] skewed toward the experiences of white officers" (SWAN, 2018). Findings may have introduced selection bias in favor of those who had negative experiences related to fertility, which would have overestimated the prevalence of infertility (Stahlman, 2019).

Consideration: In order to be able to compare infertility rates among ADFSMs and their civilian counterparts, standardization in the infertility definition and methodology used to calculate infertility will greatly assist in the ability to benchmark data. In August 2020, DoD released the Women's Reproductive Health Survey (WRHS) which, when complete, may provide a better, although not exact, comparison with CDC survey methodologies. Data from the WRHS are anticipated to be available in 2022.

ELEMENT 5

Determination of demographic information about such Service members to include race, ethnicity, sex, age, military occupation, and possible hazardous environmental exposures during service.

Military service men and women represent a demographically diverse population, with a range of backgrounds, skills, and knowledge. The DoD is uniquely positioned to offer worldwide access for ADSM infertility evaluation, diagnosis, and certain infertility services.

Race/Ethnicity: Race/ethnicity information is self-reported by ADSMs and was pulled from Defense Manpower Data Center (DMDC) records. Among ADFSMs, rates of newly diagnosed

infertility were highest among non-Hispanic Black ASFDMs (96.42 per 10,000 p-yrs) compared to women of other race/ethnicity groups (Table 3). Higher rates of newly diagnosed infertility among non-Hispanic Black ADFSMs is consistent with previous surveillance data indicating a relatively high incidence of risk factors for infertility including sexually transmitted infections, pelvic inflammatory disease, and uterine fibroids among non-Hispanics Blacks compared to those in other race/ethnicity groups (Stahlman, 2019). Among ADMSMs, rates of newly diagnosed infertility were also highest among non-Hispanic Black ADMSMs (35.89 per 10,000 p-yrs) compared to men of other race/ethnicity groups. As reported in previous MSMR articles, U.S. national surveillance data on male factor infertility by race/ethnicity are limited in the current literature (Williams, 2019). There is a need for more studies to better understand potential racial disparities that may exist among ADSM non-Hispanic Black population related to infertility.

Race/Ethnicity	Total			
	N	Rate ⁺	N	Rate ⁺
	Female ¹		Male	
Total	10367	79.58	23711	31.38
White, non-Hispanic	4252	74.22	14545	31.88
Black, non-Hispanic	3097	96.42	3890	35.89
Hispanic	1622	72.31	3086	28.36
Asian/Pacific Islander	454	78.07	718	24.24
Other/unknown	942	74.69	1472	28.02

¹ Female of childbearing potential
⁺ Rate per 10,000 person-years (p-yrs.)
 SOURCE: AFHSB

Sex/Gender & Age: Rates of newly diagnosed infertility were higher among ADFSMs (79.58 per 10,000 p-yrs) than ADMSMs (31.38 per 10,000 p-yrs). Among ADFSMs, rates of newly diagnosed infertility were highest among women aged 35-39 (154.33 per 10,000 p-yrs), which is consistent with national surveillance data that shows a diminished chance of pregnancy for females without medical assistance dropping greatly after age 35 (and especially after age 40), and consistent with natural age-related fertility decline. Among ADMSMs, rates of infertility were highest among ADMSMs aged 30-34 (58.67 per 10,000 p-yrs) (Table 4). However, there are less data on male infertility by age nationally to assist in understanding the finding of incidence being highest among ADMSM aged 30-34. While men have the potential for age-related increases in acquired medical conditions and decreases in semen quality, there remain many unknowns with regard to male aging and fertility (Harris, 2011). Among ADMSMs, it is possible this may be reflective of the age when they seek care rather than age-related decline, although the exact reasoning is unknown.

Table 4: Newly Diagnosed Cases of Infertility by Age Among ADSMs, CY2013-2019				
	Total			
	N	Rate⁺	N	Rate⁺
Age	Female¹		Male	
Total	10367	79.58	23711	31.38
<20	83	7.17	51	0.75
20-24	2216	47.25	3553	14.19
25-29	3064	89.81	7239	41.82
30-34	2801	141.57	6819	58.67
35-39	1713	154.33	4118	51.48
40-44	451	93.95	1496	34.52
45+ ²	39	19.59	435	17.90

¹ Female of childbearing potential
² For female Service members this age band includes women age 45-49; for male Service members, this is all men over age 45 (with no upper age band limit)
⁺ Rate per 10,000 person-years (p-yrs.)
SOURCE: AFHSB

Military Service/Rank/Occupation: By Service, overall rates of newly diagnosed infertility cases were highest among ADFSMs and ADMSMs in the Army compared to females and males in other Services (Table 6). The greatest decrease in infertility rates over time, however, occurred among Army ADSMs. By rank, senior officer ADFSMs had higher rates of newly diagnosed infertility (96.49 per 10,000 p-yrs) compared to other ADFSM ranks (Table 5). Senior enlisted ADMSMs had higher rates of newly diagnosed infertility (43.98 per 10,000 p-yrs) compared to other ADMSM ranks (Table 6). The data are largely in line with infertility rates by age, likely due to the fact that senior ADSMs are likely to be older than their junior counterparts.

By military occupation, ADFSMs in health care occupations had the highest rates of newly diagnosed infertility (107.42 per 10,000 p-yrs), compared to ADFSMs in other military occupations (Table 5). Among ADMSMs, those in pilot/air crew occupations had the highest rates of newly diagnosed infertility (40.63 per 10,000 p-yrs), when compared to ADMSMs in other military occupations. Previous findings suggest health care personnel may be more likely to self-diagnose or seek care and treatment, which could result in surveillance bias (Stahlman, 2019). In contrast, there is some indication pilots and flight attendants may be at higher risk for reproductive health concerns because of their job demands (Stahlman, 2019) (CDC, 2017). Appropriate medical surveillance and counseling regarding risks to health, including reproductive and developmental health, must be provided and monitored for ADSMs. Thorough, cooperative workplace evaluations for reproductive and developmental hazards by safety, industrial hygiene, and other occupational health professionals, are provided as a necessary readiness component.

Table 5: Newly Diagnosed Cases of Infertility by Service, Rank and Occupation Among ADSMs, CY2013-2019				
	Total			
	N	Rate[†]	N	Rate[†]
	Female¹		Male	
Total	10367	79.58	23711	31.38
Service				
Army	4263	99.47	10633	37.54
Navy	2665	68.69	4580	25.50
Air Force	2930	75.94	6129	35.19
Marine Corps	509	50.74	2369	19.98
Rank				
Junior enlisted (E1-E4)	3583	55.53	5948	17.93
Senior enlisted (E5-E9)	4085	96.49	12981	43.98
Warrant officer (W01–W05) ⁴	-	-	447	39.92
Junior officer (O1-O3, W01-W03)	1793	101.71	2790	39.34
Senior officer (O4-O10, W04-W05)	906	156.69	1545	33.13
Occupation				
Combat-specific ²	188	62.81	3549	28.72
Motor transport	297	70.61	683	31.37
Pilot/aircrew	194	98.20	1253	40.63
Repair/engineering	1825	66.90	7410	31.35
Communication/intel	3472	84.18	4940	33.46
Healthcare	2545	107.42	1858	35.44
Other	1846	63.93	4018	28.10
¹ Female of childbearing potential				
² Infantry/Artillery/Combat Engineering/Armor				
⁴ Warrant officer (W01-W05) data are only specified for Active Component men; for Active component women, these data are broken out between Junior Officers (O1-03 and W01-W03) and Senior Officers (O4– O10, W04–W05)				
[†] Rate per 10,000 person-years (p-yrs.)				
SOURCE: AFHSB				

Possible hazardous environmental exposures: No research has revealed direct causal relationships between deployment, combat service, and reproductive health, although limited recent studies suggest military deployments do not increase risk for miscarriage or infertility in ADSMs (Ippolito AC, 2017). While it has been hypothesized ADSMs may be at increased risk for infertility because of environmental exposures during service, there are no laboratory screening tests that can directly attribute infertility to environmental exposures in the absence of a specific known exposure (e.g., lead). DoD has a robust occupational health program to control and monitor harmful occupational exposures to meet or exceed Occupational Safety and Health Administration regulations and standards.

Consideration: By Service, research is needed to further examine any and all factors impacting both the increased infertility incidence for soldiers in the Army and an overall decrease in

infertility diagnosis for all ADSMs that occurred between 2013 and 2019. Future studies should consider adjustment for socioeconomic position (e.g., education and rank), correlation of pregnancy intent (e.g., marital status and hormonal contraceptive use), and risk factors for infertility (e.g., age, smoking, alcohol/drug use, testosterone, history of sexual transmitted infections, fibroid presence, etc.), and/or unique military occupation components or considerations. Rigorous studies are needed to evaluate fertility changes during an ADSM's career to draw conclusions on the potential risks of occupational and environmental exposures (with data to include unique or combined types of exposure, exposure time, chemical or agent exposure type, age of ADSMs, and comorbid conditions).

ELEMENT 6

Determination of the availability of infertility services for those Service members who desire such treatment, including waitlist times at the MTFs providing those services.

For ADSMs diagnosed with infertility, basic infertility services, including diagnosis and evaluation, can be initiated by Primary Care Managers (PCMs). More commonly, however, evaluation and infertility services are received after referral to a specialist, such as an obstetrician-gynecologist (OB-GYNs) or urologist. Depending on the MTF, the ability to see an OB-GYN may not require referral and/or ADFSMs may have an OB-GYN as their PCM.

Between 2016 and 2019, the average wait time (from time of referral to visit) for an ADFSM with an infertility diagnosis to see an OB-GYN was 24.55 days, and the average wait time for an ADMSM with an infertility diagnosis to see a urologist was approximately 29.76 days, although wait times vary by MTF.⁶ Depending on the specific infertility diagnosis and desired next steps for fertility services, some ADSMs may require an additional subspecialty referral to an REI provider. The average wait time for a referral to an REI sub-specialist⁷ during the report time period was 26.34 days. These wait times are in accordance with DHA-Interim Procedures Memorandum (DHA-IPM) 18-001, which directs that if no appointments are available for the patient within seven days for primary health care needs, or 28 days for specialty health care needs, an MTF will offer to defer the patient to the network. ADMSMs average wait time for a urology referral exceed the TRICARE standard by 1.76 days in excess of the DHA-IPM 18-001. Beneficiaries, including ADSMs, may choose to be referred to outside the MTF or wait for MTF-based care if wait time exceeds the TRICARE standard.

More advanced infertility services, including Assisted Reproductive Technologies (ART) such as intrauterine insemination (IUI) or in vitro fertilization (IVF) are available with a cost-share requirement at six tertiary care MTFs⁸ as part of the GME program. When care is received at an

⁶ OB-GYN wait time reflects MTF referrals that resulted in an appointment in the OB-GYN product line, with an infertility diagnosis; Urology wait time reflects MTF referrals that resulted in an appointment to a Urology Clinic (MEPRS 3 code 'BBI'), with an infertility diagnosis (males only).

⁷ Average wait time for REI subspecialists is determined by SME identification of REI providers practicing in the DoD during the timeframe, 2013 to 2019.

⁸ Walter Reed National Military Medical Center (WRNMMC), Bethesda, Maryland; Tripler Army Medical Center (TAMC), Honolulu, Hawaii; Womack Army Medical Center (WAMC), Fayetteville, North Carolina; Madigan Army Medical Center (MAMC), Tacoma, Washington; Brooke Army Medical Center (BAMC), San Antonio, Texas; and Naval Medical Center San Diego (NMCSD), San Diego, California.

MTF with an REI GME program, beneficiaries incur a cost-share requirement for some components of care not covered by the GME program (due to the elective nature of the services which are not covered by the TRICARE benefit), but at a significant discount as compared to civilian programs. In 2019, REI GME programs conducted more than 1,700 IVF cycles (note, this is not unique individuals, and is inclusive of all beneficiaries, not just ADSMs). This volume is prescribed to meet the GME program needs rather than the needs or demands of ADSMs or other beneficiaries. Access to REI GME programs offers ADSMs services that may be inaccessible if faced with cost-share requirements in the community.

ADSMs may opt to seek infertility services and treatments in the community if the wait time for ART services within the REI GME programs don't meet their personal requirements. There is no process for tracking wait time and access to infertility services not covered by the TRICARE benefit (e.g., ART procedures). If ADSMs seek services outside the TRICARE benefit, the provider selection and costs are the individual's responsibility. Anecdotal findings suggest some ADSMs are willing to wait for ART services through select GME programs due to the reduced beneficiary cost-share requirement, rather than accessing the same care at full cost in the community. The TRICARE benefit (detailed in Appendix 3) covers services and supplies required in the diagnosis and treatment of illness or injuries involving the genital system, including coverage for infertility testing and treatment, to include correction of any physical causes of infertility. TRICARE may also cover some types of assisted reproductive services, when medically necessary, and combined with natural conception. The TRICARE basic benefit covers necessary fertility diagnostic services, genetic testing and medically necessary reversal of surgical sterilization to treat disease or injury, chronic pelvic pain, or post-vasectomy pain. For infertility services not covered by TRICARE, ADSMs and their families may utilize other health insurance, and/or cover the cost-share requirement.

Consideration: Initial steps toward an infertility diagnosis and select infertility services are available from PCMs, specialists such as OB/GYNs and urologists, and REI sub-specialists, generally within TRICARE wait time standards. For services not covered by the TRICARE benefit, to include ART procedures offered by GME platforms, there is no wait time defined or monitored. The capacity of each REI GME program is based on the number of providers, fellows, students, and the requirements of the GME program. Anticipated declines in the number of REI sub-specialty providers and declining fellowship billets for training may further limit these program capabilities in the future. Rigorous studies on potential disparities in ART services related to ADSM access, rank, and sociodemographic characteristics are needed, as well as to understand the policies that provide some ADSMs with unique infertility programs (e.g., ART services for ADSMs who are severely ill or injured), described in Element 8.

ELEMENT 7

Criteria used by each of the Services to determine Service-connection for infertility, including whether screenings for environmental toxins were performed when the cause of infertility could not be determined.

Based on review of Service policies and discussions with Service consultants for Army, Air Force, and Navy/Marine Corps, there are no specific criteria related to infertility for consideration in Service-connection determination. Review of the literature examining the

relationship between infertility and environmental exposure among ADSMs does not currently show associations between deployment and diagnosed infertility, although these studies are few and limited (Gawron LM, 2018). To the extent possible, occupational health and industrial hygiene professionals develop thorough, cooperative workplace evaluations for reproductive and developmental hazards, with the intent to identify environmental toxins or other hazards to be eliminated, minimized, or controlled to the greatest degree possible.

The Annual Period Health Assessment (PHA), Pre-Deployment Health Assessment (Pre-DHA, DD Form 2795), Post-Deployment Health Assessment (PDHA, DD Form 2796), and Post-Deployment Health Re-Assessment (PDHRA, DD Form 2900) do have some questions regarding exposures, but do not include specific infertility impact correlations. Similarly, the Periodic Occupational and Environmental Monitoring Summary (POEMS), which seeks “to ensure that appropriate environmental exposure information is available should Service members as well as their providers have exposure-related concerns,” also does not include data or information related to impact on infertility issues. The PDHA, PDHRA, and POEMS, are also not generally referenced during infertility work-up by providers, and there are no established linkages between survey responses and infertility diagnoses. The most promising instrument for ADSM career exposures is expected to be realized with full implementation of the Individual Longitudinal Exposure Record (ILER).

The ILER is being developed to create a historical record of an ADSM’s occupational and environmental health exposures over the course of his or her career, and may eventually be able to identify a relationship between potential exposures and later diagnoses. The ILER, currently in initial operating capability, is able to identify specific populations with suspected environmental exposures. However, it is limited in that current exposure information is essentially qualitative. Once mature and in full operating capability (anticipated 2023), ILER could be used as a source to identify, with a higher degree of certainty, occupational exposures, occupations, assignment locations and deployment history. The future may provide the potential for environmental and occupational exposures studies of identified populations. The exposures in the ILER will be used to distill and report an individual’s relevant known and reported exposure events or incidents, assumed, unknown or known. Exposure events or incidents that are ‘assumed exposures’ present as an ecologic risk of exposure during deployment (assumed to be exposed); ‘unknown exposures’ are unidentified, and ‘known exposures’ are those exposures identified through specific incidents and events. Future ILER development and maturation may address many of these challenges and limitations with proposed capabilities for alignment with new individual level exposure monitoring capabilities and record keeping policies and procedures. The ILER will also provide insight on potential exposure pathways for future research.

Consideration: Infertility diagnoses are multifactorial, and occupational exposure connection may provide some fidelity to the consideration of infertility as a Service-connected injury or conditions. Rigorous studies are needed to better understand potential alignment of the information in the PDHA, PDHRA, and POEMS. Leveraging a mature ILER, after 2023, could eventually address gaps in tracking occupational and environmental exposures.

ELEMENT 8

Current policies of the Department of Defense for ensuring geographic stability during the treatment of Service members' undergoing medical treatment for infertility.

As of the date of this report, there are no published or anticipated DoD, DHA, or Service-level policies that provide official guidance regarding geographic stability during the treatment of ADSMs undergoing medical treatment for infertility. Requests for geographic stability are traditionally addressed on an individual basis to the local command level and adjudicated at the command's discretion. As command consideration for geographic stabilization or compassionate reassignment may consider infertility treatment 'elective' rather than medically necessary, it may not be considered a valid reason for granting geographic stability. Infertility as elective versus medically necessary may create an inherent bias, and may contribute to the lack of inclusion of infertility services in many policies or guidance.

Infertility can also impact both parties of a couple, of which the partner may not be an ADSM, but for which the treatment modalities may require both partners to be geographically co-located. The Exceptional Family Member Program, DoD Instruction 1315.19, provides criteria for enrollment of an ADSM dependent, who is experiencing a "chronic (duration of six months or longer) medical or physical condition requiring specialty care." This program can be used to enroll an ADSM spouse/partner for the consideration of geographic stability to support a family member diagnosed with the chronic disease of infertility. The Services' personnel guidance further references compassionate reassignments to support family members.

Consideration: A review of infertility recognition by TRICARE and the Services is needed to implement processes that treat infertility as a medical diagnosis, and treatment as medically necessary, rather than elective. Rigorous study to understand the impact of infertility ART procedures on retention and readiness is needed to provide a more comprehensive view of the full impact of infertility diagnosis, treatment, and procedures on the ADSM and family.

CONCLUSION

The findings of this report show a low incidence and prevalence of infertility among ADSMs, and demonstrate the DoD's capabilities to provide infertility diagnosis and select infertility services to ADSMs. The DoD has the ability to meet, and in many cases exceed (in a positive direction), availability for provider consultation at the primary, specialty, and sub-specialty levels, for services covered by the TRICARE benefit. For infertility services outside the scope of the TRICARE benefit, ADSMs can access these services through the capabilities of MTFs with REI GME programs, or seek services in the community, although both involve a cost-share requirement. However, REI GME programs offering ART procedures are limited by provider capacity, and may require additional wait times. For ADSMs who opt to pursue infertility services not covered by the TRICARE benefit in the community, these services cannot be tracked by the DoD, limiting the view and understanding of the utilization and wait time ADSMs may experience to access these services.

Continued standardized reporting by AFHSB, and leveraging of other research components (e.g., Uniformed Services University of the Health Sciences), will provide ongoing surveillance and

research data on infertility, pregnancy, and birth outcomes and miscarriage among ADSMs. Until such time as a single, standardized, and validated definition of infertility is made available, DoD data will not be comparable to CDC, ASRM, or SWAN findings due to differences in data collection (i.e., self-reported versus diagnosed and differences in sample population). Further rigorous studies are needed to provide a more comprehensive view of infertility in the DoD, and to better understand disparities and the impact of demographic factors such as age, race/ethnicity, occupation, and rank on incidence of infertility and miscarriage among ADSMs.

APPENDIX 1: METHODOLOGY OVERVIEW

Armed Forces Health Surveillance Branch (AFHSB)

Overview: Data in this report were primarily provided by the AFHSB, the central epidemiologic resource for the U.S. Armed Forces, responsible for conducting medical surveillance to protect those who serve the nation in uniform and allies who are critical to national security interests. AFHSB provides timely, relevant, actionable and comprehensive health surveillance information to promote, maintain, and enhance the health of military and military-associated populations. AFHSB health surveillance resources support worldwide disease surveillance and public health activities to improve the U.S. Military's Force Health Protection program. AFHSB has previously published reports on infertility in members of the Armed Services in several MSMRs, provided in the references.

Data: All data have been rounded to the nearest hundredth decimal point where applicable. All case definitions were based on AFHSB literature review and discussion/consultation with DoD physicians.

Population: As reported in the MSMRs and this report, data reflect the 'active component' population, which includes individuals serving in the Army, Navy, Air Force, or Marine Corps during the surveillance period (01 January 2013 through 31 December 2019). This excludes Reserve Component (Reserve and National Guard) Service members who have been activated, as well as members of Space Force, Coast Guard, United States Public Health Service Commissioned Corps, and National Oceanic and Atmospheric Administration Commissioned Officer Corps. For the purposes of this report, these previously published MSMR data points have been updated and refreshed using the same methodology.

Diagnosis criteria: Infertility rates were based on encounter data and diagnoses codes from records routinely maintained in the Defense Medical Surveillance System (DMSS) for health surveillance purposes. Diagnoses were ascertained from administrative records of all medical encounters of individuals who received care in fixed (i.e., not deployed or at sea) medical facilities of the DoD or civilian facilities in the private care system.

DHA J5/Analytics & Evaluation Division: Prevalence data in Table 1 were calculated by DHA J5/Analytics & Evaluation, using the same methodologies identified by AFHSB and outlined below. Additionally, DHA J5 provided wait time data as described in Element 6.

Incidence: The incidence rate is the number of *new* cases (numerator) identified during the period of observation (denominator). It describes how quickly disease occurs in a population. The incidence can be specified as person-years as a measurement that takes into account both the number of people in the study and the amount of time each person spends in the study. For the purposes of this report, incidence includes the following:

- Women aged 17-49 years without any history of hysterectomy or permanent sterilization (defined by having a qualifying diagnostic or procedural code for hysterectomy or permanent sterilization in any position of an inpatient or outpatient record); infertility defined by having at least two outpatient medical encounters with an infertility diagnosis (International

Classification of Diseases, 9th Revision [ICD-9] code 628.*; International Classification of Diseases, 10th Revision [ICD-10] code N97.*, outlined below) in the first or second diagnostic position or by having an inpatient encounter with an infertility diagnosis in the first diagnostic position;

- Men serving in active component, of any age; infertility defined by any infertility diagnosis (ICD-9 code 606.*; ICD-10 code N46.*, outlined in Appendix 1) in the first diagnostic position of a record of an inpatient or outpatient medical encounter.

Prevalence: The prevalence rate is the number of *new and existing* cases (numerator) identified in the population of interest during the period of observation (denominator). For the purposes of this report, prevalence includes the following:

- For women, the inclusion criteria for clinical diagnosis were as follows:
 - 1. Two infertility diagnoses (see ICD 9/10 list below) in an outpatient facility, in the first or second position, or one infertility diagnosis in an inpatient facility in the first position in the year of interest OR
 - 2. Infertility diagnosis (see ICD 9/10 list below) in the first position in either inpatient or outpatient facility, in any prior year, with at least one infertility diagnosis, in any position, in the year of interest.
 - The denominator for infertility prevalence calculations was the total number of women of childbearing potential in active component service during that year.
- For men, the inclusion criteria for clinical diagnoses were as follows:
 - 1. Infertility diagnosis (see ICD 9/10 list below) in the first position in either inpatient or outpatient facility, in the year of interest OR
 - 2. Infertility diagnosis (see ICD 9/10 list below) in the first position in either inpatient or outpatient facility, in any prior year, with at least one infertility diagnosis, in any position, in the year of interest.
 - The denominator for infertility prevalence calculations was the total number of men age 17 and above in active component service during that year.
- Prevalence rates for miscarriage were calculated per 1,000 pregnant women. Pregnant women were defined as those who had an inpatient or outpatient encounter with a pregnancy diagnosis in any diagnostic position. One pregnancy per year was counted.

Limitations:

- *Statistical significance:* The data made available by AFHSB and DHA Analytics and Evaluation were summarized as frequency data, and not raw data. Therefore, statistical testing could not be performed, and statistical significance cannot be determined.
- *Infertility:* The data provided herein reflects only the incidence and prevalence of infertility among ADSMs (cases of new or cases of new and existing infertility that occurred during a given year). The data may underreport ADSMs who may have left service or conceived during the observed time period and those who may have had an infertility diagnosis prior to 2013. Furthermore, the data provided within this report only account for individuals who were diagnosed with infertility through evaluation and/or treatment. There would be no data for ADSMs who did not see medical care, or in seeking medical care were not diagnosed with infertility. If an ADSM or their spouse self-referred to a civilian provider for services not covered by TRICARE, there would be no record of the visit or the diagnosis. The data

do not address the actual proportion of infertility cases that eventually achieved pregnancy, just the initial diagnosis of infertility.

- *Miscarriage* identification is underreported in that this report requires a diagnosis of miscarriage. Many women experience miscarriage prior to ‘official’ medical diagnosis of pregnancy. Miscarriage data also do not account for a woman who may have had more than one pregnancy loss within a given year.

Data Sources:

- *Limitations:* For 2017-2019, medical data from MTFs using MHS GENESIS are not available in DMSS. These sites include Naval Hospital Oak Harbor, Naval Hospital Bremerton, Air Force Medical Services Fairchild, and Madigan Army Medical Center. Therefore, medical encounter data for individuals seeking care at any of these facilities during 2017-2019 were not included in the analysis.
- **International Statistical Classification of Diseases:** In October 2015, the U.S. transitioned from the ICD-9-CM to the ICD-10-CM diagnosis coding system for most inpatient and outpatient medical encounters, and the ICD-10-PCS (procedure coding system) for inpatient hospital procedures. This transition had a direct impact on the reporting of medical services and health services research, as the transition included a shift from 13,000 medical codes to more than 68,000 medical codes, among other changes. These changes directly impacted the ability to report on infertility data (ICD-09 and ICD-10). All coding is dependent on the accuracy of a provider-assigned and diagnostic coding.
 - Those with a history of diagnoses for male factor infertility in female patient (ICD-10: **Z31.81**) were not excluded; numbers for women may also include male infertility cases and may thus be higher than actual.
 - The data excluded those who had prior documented sterilization procedure codes, although did not exclude **ICD10 Z98.51**, history of tubal ligation or **Z98.52** vasectomy status/history of vasectomy. Infertility data may have included Service members with history of tubal ligation or vasectomy procedures done outside the DoD or prior to service.
 - **N46.8** “other male infertility” became a new code in ICD-10 on October 1, 2015, and ICD-9 code “infertility due to extra-testicular causes” was retired. Conditions coded “infertility due to extra-testicular cause” in 2013-2014 under ICD-9 may have begun to be coded as “other male infertility” in 2015. “Other male infertility” increased as “infertility due to extra-testicular cause” decreased. If combined, the most common diagnosis would be “other male infertility” and not “azoospermia.”

ICD-9/ICD-10 Codes for Infertility Used by AFHSB			
	ICD-9	ICD-10	Description
Female infertility	628.0	N97.0	Infertility associated with anovulation
	628.2	N97.1	Infertility of tubal origin (block, occlusion, stenosis of fallopian tubes)
	628.1, 628.4, 628.8	N97.8	Infertility of other specified origin (pituitary-hypothalamic, cervical or vaginal, age-related, etc.)
	628.9	N97.9	Infertility of unspecified origin

ICD-9/ICD-10 Codes for Infertility Used by AFHSB			
Male infertility	606	N46	male infertility
	606.0	N46.0	azoospermia
		N46.01	organic azoospermia
		N46.02	azoospermia due to extratesticular causes
		N46.021	azoospermia due to drug therapy
		N46.022	azoospermia due to infection
		N46.023	azoospermia due to obstruction of efferent ducts
		N46.024	azoospermia due to radiation
		N46.025	azoospermia due to systemic disease
		N46.029	azoospermia due to other extratesticular causes
	606.1	N46.1	oligospermia
		N46.11	organic oligospermia
		N46.12	oligospermia due to extratesticular causes
		N46.121	oligospermia due to drug therapy
		N46.122	oligospermia due to infection
		N46.123	oligospermia due to obstruction of efferent ducts
		N46.124	oligospermia due to radiation
		N46.125	oligospermia due to systemic disease
	N46.129	oligospermia due to other extratesticular causes	
	606.8	--	infertility due to extratesticular causes
606.9	N46.9	male infertility, unspecified	
	N46.8	other male infertility	

ICD-9/ICD-10 Codes for Pregnancy and Miscarriage Used by AFHSB	
Pregnancy ICD codes (Miscarriage Denominator for Element 3)	
ICD-9 Codes	ICD-10 Codes
V220 Supervision of normal first pregnancy V221 Supervision of other normal pregnancy V222 Pregnant state, incidental V23* Supervision of high-risk pregnancy V27* Outcome of delivery V72.42 Pregnancy examination or test, positive result 630*-633* Ectopic and molar pregnancy 634*-639* Other pregnancy with abortive outcome 640*-649* Complications mainly related to pregnancy 650*-659* Normal delivery, and other indications for care in pregnancy, labor, and delivery 660*-669* Complications occurring mainly in the course of labor and delivery 670*-677* Complications of the puerperium 678*-679* Other maternal and fetal complications	Z34* Encounter for supervision of normal pregnancy Z33* Pregnant state O09* Supervision of high risk pregnancy Z37* Outcome of delivery Z32.01 Encounter for pregnancy test, result positive O00*-O08* Pregnancy with abortive outcome O10*-O16* Edema, proteinuria and hypertensive disorders in pregnancy, childbirth and the puerperium O20*-O29* Other maternal disorders predominantly related to pregnancy O30*-O48* Maternal care related to the fetus and amniotic cavity and possible delivery problems O60*-O77* Complications of labor and delivery O80, O82 Encounter for delivery O85*-O92* Complications predominantly related to the puerperium O94*-O99*, O9A* Other obstetric conditions, not elsewhere classified
Miscarriage ICD codes	
ICD-9 Codes	ICD-10 Codes
634* Spontaneous abortion	O03* Spontaneous abortion
Prevalence Rules	

Pregnancy:

- A woman is considered pregnant if she has any inpatient or outpatient encounter with a pregnancy diagnosis in any diagnostic position (see ICD 9 and 10 above).
- The earliest encounter per year per woman is taken.
- Pregnancies numbers were used as the denominator for the rate calculation.

Miscarriage:

- A miscarriage is defined as any inpatient or outpatient encounter with a miscarriage ICD code any diagnostic position (see ICD 9 and 10 above).
- The earliest miscarriage encounter per year per woman is taken.
- Miscarriage numbers were used as the numerators for the rate calculation.

Miscarriage prevalence rules:

- Miscarriage prevalence is calculated as the number of miscarriage cases divided by the total number of pregnancies during the specified calendar year.
- Prevalence rate is calculated per 1,000 pregnant women.

APPENDIX 2: GLOSSARY OF TERMS

- **American Society of Reproductive Medicine (ASRM):** (formerly the American Fertility Society or AFS) Large multidisciplinary organization serving as a platform for new ideas, education, and advocacy in fertility and reproductive medicine issues.
- **Assisted Reproductive Technologies (ART):** ART includes all fertility treatments in which both eggs and embryos are handled. In general, ART procedures involve surgically removing eggs from a woman's ovaries, combining them with sperm in the laboratory, and returning them to the woman's body or donating them to another woman, in order to establish a pregnancy.
- **Azoospermia:** A complete absence of sperm from the fluid ejaculated during orgasm (semen).
- **Endocrinology:** The study of hormones, their function, the organs that produce them and how they are produced.
- **Insemination:** Transfer of semen or sperm for the purpose of establishing a pregnancy.
- **Intrauterine Insemination (IUI):** A fertility treatment that involves placing sperm inside a woman's uterus to facilitate fertilization. The goal of IUI is to increase the number of sperm that reach the fallopian tubes and subsequently increase the chance of fertilization
- **In Vitro Fertilization (IVF):** An assisted reproductive technology (ART) commonly referred to as IVF. IVF is the process of fertilization by extracting eggs, retrieving a sperm sample, and then manually combining an egg and sperm in a laboratory dish to permit fertilization. The embryo(s) is then transferred to the uterus or stored for future pregnancy.
- **Oligospermia:** Anything less than 15 million sperm per milliliter, or 39 million sperm per ejaculate, is considered low sperm count.
- **Semen Analysis:** The microscopic examination of the ejaculate to determine the number of sperm, their shapes (morphology), and their ability to move (motility).

- **Unexplained Infertility/ Infertility of no known cause:** Inability to conceive where no cause has been found despite routine testing of semen, ovulation, and pelvic anatomy by laparoscopy.

APPENDIX 3: TRICARE BENEFIT ELIGIBILITY & INFERTILITY COVERAGE

TRICARE is a set of health care benefits defined by statute, and the DoD meets the medical needs of enrolled beneficiaries through a comprehensive worldwide health care system that combines the best of military medicine and community medical resources, and specific health care benefits defined by statute under TRICARE. The purpose of the TRICARE program as set forth in Chapter 55 of Title 10, U.S. Code (U.S.C.) is to provide a uniform program of medical and dental care (10 U.S.C. . §1071) and pharmacy benefits (10 U.S.C. §1074g) for members and certain former members of the uniformed services, and for their dependents.

The DoD is composed of both care provided in MTFs (direct care [DC]), and care provided through a network of participating community providers/facilities (private sector care [PSC]). TRICARE contracts with Managed Care Support Contractors (MCSCs) and civilian providers to expand and augment the scope of care available to beneficiaries. It is the combination and collaboration of DC and PSC that provides the comprehensive network of health care resources necessary for the DoD to meet the health care needs of military members and their beneficiaries. ADSMs are auto enrolled into TRICARE Prime, and assigned to an MTF unless stationed in a location without an MTF. Other beneficiaries make health care choices that include their preference for care delivery location and cost-sharing. Enrollment choices define the access to benefits and any cost-shares associated with exercise of the benefits.

When possible, ADSMs use DC, with PSC capabilities available as needed. ADSMs are entitled to the same health benefits as civilians under the TRICARE program unless specifically excluded in policy; e.g., bariatric surgery. TRICARE offers services for the diagnosis or treatment of an illness or injury based on medical necessity, which encompasses diagnosis and specific treatments for infertility in both males and females. Infertility diagnosis and treatment may include review of a previous illness or injury of the male or female reproductive system, of the correction of some physical cause of infertility, as well as diagnostic services such as semen analysis or hormone evaluation. Once diagnosis and all treatments are completed, restored fertility could be possible and demonstrated through coitus (male to female heterosexual copulation).

TRICARE excludes coverage for non-coital (not involving heterosexual copulation) methods of infertility treatment in accordance with the TRICARE Policy Manual (TPM) Chapter 4, Section 17.1, Female Genital System, paragraphs 5.4 and 5.5 by excluding from coverage: Artificial insemination, including any costs related to donors and semen banks; IVF; Gamete Intrafallopian Transfer (GIFT); Zygote Intrafallopian Transfer (ZIFT); Tubal Embryo Transfer (TET); and, all other non-coital reproductive procedures, including all services and supplies related to, or provided in conjunction with, those technologies. Additional exclusions under TPM Chapter 4, Sec. 15.1, para. 5.11 include Penial Vibratory Stimulation (PVS) devices, such as Feticare Personal 2 medical Vibrator. May be used to achieve conception via coitus

after a traumatic injury. Utilization of non coital methods for IVF is an individual choice. Beneficiaries, including ADSMs, may self-pay for these treatment modalities.

A full outline of coverage and limitations for male and female infertility testing and treatment are outlined in the TPM, Chapter 4, Sections 15.1 and 17.1. Additionally, TRICARE covers genetic tests to diagnose the cause of male infertility including Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) or gene testing and Y Chromosome Microdeletion Analysis. These tests can be found in the TRICARE Operations Manual (TOM), Chapter 18, Section 3.

APPENDIX 4: ASSISTED REPRODUCTIVE TECHNOLOGY BENEFITS

Cryopreservation is the process of freezing eggs, sperm or embryos to sub-zero temperatures for later use. When the eggs, sperm or embryos are needed, they are thawed and fertilized or used in a fertility treatment cycle.

Assisted Reproductive Services Benefit for Seriously Ill or Injured ADSMs

The National Defense Authorization Act for Fiscal Year 2008, Section 1633, codified at Title 10, United States Code, Sec. 1074(c)(4), provided an Extended Care Health Option-like quality of life benefit for severely or seriously ill/injured ADSMs. Under this authority, assisted reproductive technology is available to qualified seriously ill or injured ADSMs. A serious or severe illness or injury is defined as being Category 2 or 3 in accordance with Department of Defense Instruction 1300.24 and is defined in the box below.

SERVICE MEMBER CARE COORDINATION CATEGORIES	
Category 2 (CAT 2)	<ul style="list-style-type: none"> - Has a serious injury or illness - Is unlikely to return to duty within a time specified by his or her Military Department - May be medically separated from the military
Category 3 (CAT 3)	<ul style="list-style-type: none"> - Has a severe or catastrophic injury or illness - Is highly unlikely to return to duty - Will most likely be medically separated from the military

On April 3, 2012 the Assistant Secretary of Defense, Health Affairs (ASD[HA]), issued policy and implementation guidance providing assisted reproductive services to enable ADSMs (Category 2 or Category 3) with urogenital trauma and their lawful spouse who are unable to conceive naturally to have biologic children.

The policy includes the following:

- Up to six initiated and three completed IVF cycles may be provided for the lawful spouse of the seriously or severely ill/injured Service member.
- Cryopreservation and storage of viable embryos.
- Artificial insemination such as intrauterine insemination and intracervical insemination.

Oncofertility

On April 17, 2017, this authority was expanded to seriously ill ADSMs and their lawful spouse with a diagnosis of cancer and who were undergoing gonadotropic therapy with radiation and/or chemotherapy. The ADSM must be either Category 2 or 3, as defined above, as a result of their cancer at the time of retrieval. Males must be 61 or under at the time of retrieval, females 49 or under. This new benefit included cryopreservation of sperm and oocytes along with ART. The benefit is available for 36 months from the date of sperm or oocyte retrieval. Policy guidance was published in the TRICARE Operations manual on February 2, 2018, with an effective date of April 17, 2017.

Section 8129 of the FY19 Appropriations Act removed the application of the three-year coverage limitation on embryo cryopreservation and storage that was in the April 2012 policy and implementation guidance. Changes to the TRICARE Operations Manual implementing this section have been published with the effective date the date the legislation was signed, September 28, 2018.

On February 22, 2019 the Principal Deputy ASD(HA) approved coverage of transportation and shipping costs of cryopreserved sperm and oocytes retrieved from qualified ADSMs diagnosed with cancer. Changes to the TRICARE Operations Manual implementing this decision have been published with the effective date the date of approval, February 22, 2019.

The policy has the following coverage exclusions:

- Donated semen/eggs; surrogacy; gestational carriers, cryopreservation of gametes in anticipation of deployment.

Oncofertility Extension During Coronavirus Disease 2019 (COVID-10) Pandemic: Since the COVID-19 pandemic limited access to elective services such as Oncofertility for beneficiaries, on July 15, 2020 the ASD(HA) approved temporarily waiving the 36 month limit for all qualified ADSMs whose coverage ended or would have ended between the dates of March 01, 2020, the date of the declaration by President Trump of the COVID-19 national emergency, until 90 days following the declared end of the national emergency.

Force for the Future: In 2016, then-Secretary of Defense Ashton Carter also declared that DoD would support the capability of troops to freeze their oocytes and sperm, ensure ovum and sperm were available for a future family or additional children. This effort was targeted to promote senior troop retention and make the military more family friendly. The Assistant Secretary of Defense for Health Affairs was directed to develop and execute a two-year demonstration pilot. The pilot was to be designed wherein ADSMs with no pending deployment would be allowed up to three attempts to successfully collect, freeze, and store their own eggs or sperm using resources in the TRICARE Network at zero out-of-pocket expense. The DoD cost was projected at \$56.9M for the full featured, two-year demonstration pilot, through September 30, 2018. The Department placed program implementation on hold in July 2016 because it was unfunded. The Department decided not to fund the program and canceled it in December 2017 (House Report, Pages 145–146).

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