



UNDER SECRETARY OF DEFENSE

4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

PERSONNEL AND
READINESS

JUL 26 2013

The Honorable Howard P. "Buck" McKeon
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515


Dear Mr. Chairman:

The enclosed report responds to the request in Conference Report 112-705, pages 794-5, accompanying H.R. 4310, the National Defense Authorization Act for Fiscal Year 2013, "Availability of Certain Fertility Preservation Treatments for Members of the Armed Services on Active Duty." As noted in our report, the Assistant Secretary of Defense for Health Affairs issued a memorandum on April 3, 2012, that made assisted reproductive services available for seriously ill or severely injured Active Duty Service members and authorized the use of supplemental health care program funds for that purpose.

This report describes the current operational status of the program and an assessment of the feasibility and advisability of providing fertility preservation treatment for Service members. The report includes information on experience since issuance of the assisted reproductive policy, including an analysis of the types of injury or illnesses of those who sought the procedures, the procedures that were sought, what procedures or services were provided by both military treatment facilities and civilian providers, and an assessment of issues concerning quality of life and costs. A similar letter is being sent to the Chairman of the Committee on Armed Services of the Senate.

Thank you for your interest in the health and well-being of our Service members, veterans, and their families.

Sincerely,


Jessica L. Wright
Acting

Enclosure:
As stated

cc:
The Honorable Adam Smith
Ranking Member



UNDER SECRETARY OF DEFENSE

4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

PERSONNEL AND
READINESS

JUL 26 2013

The Honorable Carl Levin
Chairman
Committee on Armed Services
United States Senate
Washington, DC 20510

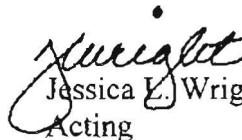
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Thank you for your interest in the health and well-being of our Service members, veterans, and their families.

Sincerely,


Jessica L. Wright
Acting

Enclosure:
As stated

cc:
The Honorable James M. Inhofe
Ranking Member

Report to Congress Availability of Certain Fertility Preservation Treatments for Members of the Armed Services on Active Duty



Office of the Secretary of Defense

June 2013

The estimated cost of report or study for the Department of Defense is approximately \$2,000 for FY13. This includes \$0 in expenses and \$2,000 in DoD labor.

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EXECUTIVE SUMMARY

The enclosed report responds to the request in Conference Report 112-705, page 794-5, accompanying H.R. 4310, of the National Defense Authorization Act for Fiscal Year 2013. The language states: “The conferees direct the Secretary of Defense to submit a report to the Committees on Armed Services of the Senate and the House of Representatives on implementation of the “Policy for Assisted Reproductive Services for the Benefit of Seriously or Severely Ill/Injured (Category II and III) Active Duty Service Members. The report shall include data on experience since issuance of the policy, including an analysis of the types of injuries or illness of those who sought the procedures, the procedures that were sought, what procedures or services were provided by both military treatment facilities and civilian providers, and an assessment of issues concerning quality of life and costs. In addition, the report shall provide an assessment of the feasibility and advisability of providing fertility preservation treatment for Service Members both in relation to deployment in support of contingency operations and as a result of illness or injury. The conferees expect the report to include recommendations for changes in policy or legislation that may be necessary to provide such services to military Service Members who, as a consequence of illness or injury, require assistance for procreative ability.”

This report analyzes implementation of the Assistant Secretary of Defense for Health Affairs ((ASD (HA)) policy memorandum “Policy for Assisted Reproductive Services for the Benefit of Seriously or Severely Ill/Injured (Category II or III) Active Duty Service Members,” issued April 3, 2012, that identifies implementation of the TRICARE benefit to provide in-vitro fertilization (IVF) services to seriously or severely ill or injured Active Duty Service members (ADSM) and their lawful spouse. In addition, the report provides an assessment of the feasibility and advisability of providing fertility preservation services for ADSMs both in relation to deployment in support of contingency operations and as a result of illness or injury. The report concludes that no additional policies or legislation are necessary at this time.

To date, 10 members who met the criteria under the Policy for Assisted Reproductive Services and their lawful spouses have utilized this benefit. The two most common reasons for utilizing the benefit have been trauma (blast injuries) and anticipated cancer treatment (chemotherapy/radiation therapy). All requests for IVF and services have been provided in both Military Treatment Facilities (MTF) and purchased care clinics. The use of donor sperm is not authorized in the current policy. Medical providers delivering these treatments to the ADSMs reported that members appreciate the opportunity to receive such care. Medical procedure costs were estimated to be \$7,000 per cycle at MTFs and \$12,400 in the civilian sector. Both the members and responding providers are in support of this benefit in that it improves their quality of life and psychological health. The analysis included data from April 3, 2012, to April 30, 2013.

The basic TRICARE benefit covers services and supplies required in the diagnosis and treatment of illness or injuries involving the genital system. In addition, it provides coverage for infertility testing and treatment, to include correction of any physical causes

of infertility. Specifically excluded under the basic program are all non-coital reproductive procedures, such as artificial insemination, IVF, sperm and egg cryopreservation, and all other forms of assistive reproductive technology (ART). These services are excluded because they do not meet TRICARE's definition for "medical treatment." That is, services performed in connection with the diagnosis or treatment of a disease or injury in keeping with the generally accepted norms for medical practice in the United States.

The report evaluates the potential feasibility and advisability of pre-deployment fertility preservation. Due to the short notice of deployment that members receive, there may not be sufficient time to pursue cryopreservation of sperm or eggs. Cryopreservation of sperm is a relative simple process and available in multiple locations. Freezing of eggs requires stimulation of the ovaries with medications taken over several weeks and an invasive procedure requiring conscious sedation to remove eggs from the ovaries. The potential to sustain a genitourinary injury in combat certainly exists in an environment of improvised explosive devices. The number of such injuries sustained that resulted in the complete loss of procreative ability has been small when compared to the number of Service members who have deployed in support of Operation IRAQI FREEDOM, Operation ENDURING FREEDOM, and Operation NEW DAWN. The number of Service members who would choose to participate is unknown. Fertility preservation offered to beneficiaries who are diagnosed with illness that will require treatment that is harmful to sperm or eggs such as cancers which require radiation and/or chemotherapy has greater feasibility than pre-deployment fertility preservation because it is targeted to patients with a known compromise to their fertility. However, as noted above, it is not considered to be medically necessary under the TRICARE benefit because it does not treat or diagnose a disease. The report also notes that cryopreservation of sperm or eggs may have unintended ethical and legal consequences regarding ownership of the frozen sperm and eggs, rights to use these frozen gametes to establish pregnancy and beneficiary rights for any children born following their use. Therefore, the Department of Defense (DoD) does not support this as a benefit.

On April 13, 2012, the ASD(HA) issued a memorandum that utilized section 1074(c)(4)(A) of title 10, U.S.C., to provide an Extended Care health option-like quality of life benefit for seriously or severely Ill/Injured (Category II or III) Active Duty Service members. This memorandum allows Supplemental Health Care Program (SHCP) funds to be used to pay for assisted reproductive services not covered in the basic medical benefit. The DoD believes it already has the necessary legal authority to offer ART to our serious or severely ill or injured ADSMs. Education of all of our beneficiaries regarding means of fertility preservation should be provided prior to deployment. Additionally, education regarding fertility preservation has evolved as the standard of care in oncology has changed, and survival rates and life expectancies have improved. At this time fertility preservation itself is not considered medically necessary and should not become a focus of care.

INTRODUCTION

This report is delivered in response to language in the Conference Report (House Report 112-705), to accompany H.R. 4310, the National Defense Authorization Act for Fiscal Year 2013. Specifically, the conferees directed the Secretary of Defense to submit a report to the Committees on Armed Services of the Senate and the House of Representatives on implementation of the policy for assisted reproductive services for the benefit of seriously or severely ill/injured (Category II and III) Active Duty Service members. The report shall include data on experience since issuance of the policy, including a description of the types of injuries or illness of those who sought the procedures, the procedures that were sought, what procedures or services were provided by both military treatment facilities and civilian providers, and an assessment of issues concerning quality of life and costs. In addition, the report shall provide an assessment of the feasibility and advisability of providing fertility preservation treatment for Service members both in relation to deployment in support of contingency operations and as a result of illness or injury. The conferees expect the report to include recommendations for changes in policy or legislation that may be necessary to provide such services to military Service members who, as a consequence of illness or injury, require assistance for procreative ability.

The Basic Benefit

Section 1079(13) of title 10, U.S.C., states that, “Any service or supply which is not medically or psychologically necessary to prevent, diagnose, or treat a mental or physical illness, injury, or bodily malfunction as assessed or diagnosed by a physician, dentist, clinical psychologist, certified marriage and family therapist, optometrist, podiatrist, certified nurse-midwife, certified nurse practitioner, or certified clinical social worker, as appropriate, may not be provided.”

Title 32, Code of Federal Regulations (CFR), section 199.4, specifies the medical benefit under the TRICARE Basic Program for infertility diagnosis and treatment. The current benefit includes correction of a naturally occurring physical cause of infertility. Hypothalamic disease, pituitary disease, disorders of sperm transport, disorders of sperm motility or function, and/or sexual dysfunction may cause male infertility. Covered diagnostic services include semen analysis, hormone evaluation, chromosomal studies, immunologic studies, and sperm function tests and/or bacteriologic investigation. Services and supplies required in the diagnosis and treatment of illness or injuries involving the genital system are covered. Infertility testing and treatment, including correction of the physical cause of infertility are covered.

Title 32, CFR, section 199.2(b), defines medical as, “the generally used term which pertains to the diagnosis and treatment of illness, injury, pregnancy, and mental disorders by trained and licensed or certified health professionals”. For purposes of the TRICARE basic benefit, codified in the Civilian Health and Medical Program of the Uniformed Services language of the CFR, the term medical should be understood to include “medical, psychological, surgical, and obstetrical,” unless it is specifically stated that a

more restrictive meaning is intended and defines medically or psychologically necessary as the frequency, extent, and types of medical services or supplies which represent appropriate medical care and that are generally accepted by qualified professionals to be reasonable and adequate for the diagnosis and treatment of illness, injury, pregnancy, and mental disorders or that are reasonable and adequate for well-baby care.

The basic TRICARE benefit covers services and supplies required in the diagnosis and treatment of illness or injuries involving the genital system. In addition, it provides coverage for infertility testing and treatment, to include correction of any physical causes of infertility. Specifically excluded under the basic program are all non-coital reproductive procedures, such as artificial insemination, IVF, sperm and egg preservation, and all other forms of ART. These services are excluded because they do not meet TRICARE's definition for "medical treatment." No legislative or policy changes are requested at this time.

ART have been used in the United States since the early 1980's to help women become pregnant. Initially, artificial insemination was the only technology available to establish pregnancy and required that the female reproductive system be functional. Pioneers in infertility recognized the need for mechanism to move an egg to the uterus in cases where the female reproductive system was not intact due to disease or blockage of the fallopian tubes which transport eggs from the ovary to the uterus. Since the birth of the first "test tube" baby in July 1978, the use of IVF, in which eggs are fertilized in the laboratory and embryos are transferred into the uterus, has become the most commonly used ART to treat both female and male infertility. While any individual may sustain trauma that would interfere with the ability to procreate naturally, ADSMs have increased potential for exposure to trauma sustained from blast injuries impacting their ability to procreate naturally.

ART procedures involve stimulating the production of multiple eggs from the ovaries through the use of medications and then retrieving the eggs from the ovaries through trans-vaginal ultrasound guided needle aspiration. The mature eggs retrieved from the woman's ovaries are fertilized in laboratory petri dishes by combining with sperm or by injecting sperm directly into the egg (intracytoplasmic sperm injection (ICSI)) in the laboratory. The resulting embryo is then returned to the woman's body through embryo transfer. These treatments are estimated to cost approximately \$7,000 at military treatment facilities and \$12,400 in the civilian sector per cycle. The difference in costs is related to provider fees.

There has been interest in considering fertility preservation related to contingency operations (deployments). This and related legal/ethical issues are reviewed, including posthumous collection of eggs or sperm. Fertility preservation is also reviewed as it relates to an illness or injury, such as when treatments can cause damage to the glands associated with productive and viability of sperm or eggs. The Walter Reed Military Medical Center Ethics Committee reviewed ethical issues related to reproductive technologies and fertility preservation for this report.

POLICY IMPLEMENTATION

Background

Title 10, U.S.C., section 1074, establishes the regulations for medical and dental care for Service members. Section 1074(c)(4)(A) states: "...coverage comparable to that provided by the Secretary under subsections (d) and (e) [Extended Care Health Option] of section 1079 of this title shall be provided under this subsection to members of the uniformed services who incur a serious injury or illness on active duty as defined by regulations prescribed by the Secretary." A serious or severe illness or injury is defined as being Category 2 or 3 in accordance with Department of Defense Instruction 1300.24, "Recovery Coordination Program (RCP)".

The Assistant Secretary of Defense for Health Affairs issued a policy memo and implementing guidance to the Services in April 2012. The intent of this policy is to provide assisted reproductive technology to enable the ADSMs in Category 2 or Category 3 and their lawful spouses to have biologic children. Payment for these services would be under the Supplemental Health Care Program for ADSMs.

Category 2:

- 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:

- Has a severe or catastrophic injury or illness.
- Is highly unlikely to return to duty.
- Will most likely be medically separated from the military.

This report responds to the request in the conference report to address the following:

1. The types of injuries/illnesses of those who sought the procedures.
2. The procedures that were sought.
3. The procedures and services provided at military treatment facilities and civilian providers.
4. An assessment of issues concerning quality of life.
5. An assessment of costs.
6. An assessment of the *feasibility* of providing fertility preservation treatment for Service members both in relation to deployment in support of contingency operations and as a result of illness or injury.
7. An assessment of the *advisability* of providing fertility preservation treatment for Service members both in relation to deployment in support of contingency operations and as a result of illness or injury.

8. Recommendations for changes in policy or legislation that may be necessary to provide such services to Service members who, as a consequence of illness or injury, require assistance for procreative ability.

DoD Response

(1) The types of injuries/illnesses of those who sought the procedures?

There have been 10 requests for treatments related to assistance with procreative abilities. The types of injuries/illnesses were either traumatic injuries to the pelvic area, spinal cord injuries, or cancer. All requests received were from male ASDMs. According to the Joint Staff there have been few genitourinary injuries sustained in female Service members in which the uterus remained intact and able to carry a pregnancy.

Of the 10 requests, 4 were for spinal cord injuries, 4 were for blast injuries that caused testicular or penile injury, and 2 were for cancer (colon cancer and medulloblastoma). There was also one waiver request for fertility preservation from a female ADSM diagnosed with breast cancer, who did not meet criteria for coverage under this policy.

(2) What procedures were sought?

All 10 requests were for IVF.

(3) What ART approved services were provided by the Military Treatment Facilities?

Three of the requested IVF procedures were performed in MTF. For care rendered at a MTF where DoD personnel perform the egg retrieval, the embryology services are provided by contracted laboratory services. In some instances, egg retrievals are performed in civilian clinics by military providers under external resource sharing agreements. Egg, sperm, or embryo storage services are provided by the contracted laboratory service providers.

(4) What services were provided by the civilian providers?

For the seven members living in remote areas, not near MTFs, services were provided by the civilian providers including the egg retrieval, fertilization, and embryo transfer procedures. These clinics also offered embryo storage capabilities. The American Society for Reproductive Medicine (ASRM) recommends transferring only one or two embryos to reduce the risk of multiple gestations including twins and triplets because of the risk that multiple gestation carries for the mother and for the babies. The ability to freeze embryos after an IVF cycle may preclude the need for additional IVF cycles with medications in the future.

(5) What is the assessment of issues concerning quality of life?

DoD contacted three providers who provided IVF services for seriously or severely ill or injured ADSMs in MTFs. Two providers responded and both had similar responses. Having access to ART services improves the quality of life for their patients, resulting in greater optimism about the future. This improvement in quality was noted even if the IVF attempts were unsuccessful. Just having the opportunity was found to be helpful. Colonel Robert Dean, the head of the Andrology Department at Walter Reed Military Medical Center said, "This is a very important issue for couples and starting a family would help reestablish normalcy and reach personal goals for having children." The miraculous advances in battlefield medical care delivery have resulted in large numbers of ADSMs surviving what would previously have been mortal wounds. Advances in post injury care such as prosthetics and tissue regeneration have allowed for significant recovery from nearly fatal wounds and return to active productive lives. Many wounded warriors achieve levels of recovery that allow them to consider having families as the next step in the process.

(6) What is the assessment of issues concerning cost?

The cost is approximately \$7,000 per IVF cycle at MTFs. If the couple requires the six maximum attempts at IVF, then the cost is roughly \$42,000.

In the civilian sector, the ASRM estimates the average costs per IVF cycle as follows:

IVF:	\$8,158
ICSI:	\$1,544
Medications (per cycle)	\$3,000-\$5,000

A couple requiring the six maximum attempts at IVF in the civilian sector could be as high as \$58,212. Medications for all IVF patients may be provided through an MTF or the mail order pharmacy.

FEASIBILITY AND ADVISABILITY OF PROVIDING FERTILITY PRESERVATION TREATMENT

DoD Response

(7) What is the feasibility of providing fertility preservation?

For contingency deployment:

While participation in such a program is feasible for both men and women, there are additional challenges facing women. Female Service members must undergo 2 to 3 weeks of hormonal therapy followed by an invasive procedure requiring conscious sedation (with its inherent risks) which would make them temporarily unfit for deployment. According to the DoD Health Support Division (J4), fertility preservation would cost, on average, about \$2,982 per member (\$885 per male and \$15,250 per female). For a single individual to benefit from such a program, 16,000 samples would need to be collected from Service members (based on 128,000 deployed in 2010 who sustained 8 cases of unrecoverable reproductive loss). Members given short notice of deployment may not have sufficient time to utilize such a benefit, and it is unknown how many might actually participate. Storage facilities would need to be created or rented from a civilian provider. Civilian cryopreservation banks are widely available to store sperm and eggs and many offer reduced costs for ADSMs facing deployment.

Related to Illness:

Cancer treatments are the most common medical procedures altering one's fertility. Infertility is a risk associated with radiation therapy or gonadotoxic chemotherapy (having a deleterious effect on a gland that produces sperm or eggs [testis or ovary]). The best available model for the Active Duty population based on expected rates of cancer diagnoses, predicts 600 new cancer cases (430 males and 170 females) where treatment may affect fertility for members less than 40 years old. Collecting sperm and eggs for these members and storing to age 40 would cost approximately \$16.9 million, in total, from Fiscal Year (FY) 2013 until FY 2018 inclusive, if fully implemented.

Included in treatments where fertility preservation may be needed are due to side effects: chemotherapy, radiation, and surgery (<http://www.jnccn.org/content/>):

- Chemotherapy Males; loss or damage of developing sperm/reduction of testosterone
Females; reduced ovarian reserve and premature ovarian failure

- Radiation Males; loss or damage of developing sperm/reduction of testosterone
Females; reduced ovarian reserve/premature ovarian failure/uterine

fibrosis and vascular insufficiency/endometrial
damage/inability to support embryo implantation
Both; disruption of hormone production

- Surgery
Males; erectile or ejaculatory dysfunction/damage to the ductal
system/impaired transport of sperm
Females; loss of ovaries or uterus
Both; disruption of hormone production

Fertility preservation in any of these situations should be considered. If the beneficiary is female there are several alternatives. The first is to complete an IVF cycle requiring the use of 2 weeks of medication to stimulate production of eggs in the ovary and an invasive procedure to retrieve the eggs. Egg banking is an evolving and accepted practice not yet widely available. Embryo banking is much more common but requires presence of a male partner or the use of donor sperm to create the embryos. A second alternative, though not well proven, is the removal and cryopreservation of ovarian tissue that can later be returned to the patient after treatments are completed. Few successful pregnancies have been reported using this method. For cancers requiring radiation therapy, the ovaries can be moved out of the range of radiation and shielded, which decreases the risk of premature ovarian failure.

For male beneficiaries, the ability to bank sperm is widely available. For male patients, there may also be issues that interfere with the ability to ejaculate. For these individuals, there are mechanisms to retrieve sperm through electroejaculation or through sperm aspiration directly from testicular tissue. Either of these procedures require, at a minimum, conscious sedation and more likely, anesthesia.

If fertility preservation is not available or the timing of beginning medical treatment is critical and cannot be delayed to allow for one of these methods of fertility preservation, the use of donor eggs or donor sperm is an alternative. The use of gestational carriers or surrogates is also available to help patients achieve much desired families.

(8) What is the advisability of providing fertility preservation?

In summation, the monetary cost, fitness for duty, ethical, and legal implications of fertility preservation makes this inadvisable as a DoD benefit. The DoD believes there should be a focus instead on AD/SM education which addresses this issue as a pre-deployment option for consideration. Pre-deployment preparation should include realistic assessment of expectations for injury and available services to preserve eggs or sperm, if desired.

There are many logistical and legal concerns related to fertility preservation that would make implementation difficult, especially as related to timing of deployment. For example, storage of specimens, timing of fertility preservation requests (especially for women because of the required ovarian stimulation cycle and recovery period after egg

retrieval), and specimen ownership in cases of death, injury, or divorce are complex and laws on these issues vary by state. It is noted that any laboratory that freezes eggs or sperm has specific consent documents that are required to define ownership of gametes, rights to use gametes, and intent for disposal of gametes. Therefore, pre-deployment and non-medically necessary fertility preservation is not advisable at this time.

With respect to fertility preservation due to illness, while targeted to beneficiaries who are likely to lose reproductive capability, it is not considered medically necessary care and is not advised at this time.

In addition to reviewing reports from the Ethics Committee of American Society for Reproductive Medicine, we contacted the Ethics Committee of Walter Reed Military Medical Center. Some of the ethical/legal considerations are outlined below. These concerns should be considered carefully before drafting new benefits and as any implementing guidance is issued.

Fertility in cancer patients is often reduced by exposure to gonadotoxic treatment. Cancer patients should be informed of options for fertility preservation and future reproduction prior to cancer treatment. Consideration should also be given for heritable cancers. The issue of ownership of gametes, rights of use, and survivorship are generally covered within the consent process with any organization that can successfully freeze and store gametes.

Current DoD policy is to provide assistive reproductive technologies in seriously or severely injured ADSMs and is consistent with existing ethical and legal principles

(9) What changes to policy or legislation may be necessary to provide such services to military Service members who, as a consequence of illness or injury, require assistance for procreative ability?

If the Services wish to offer cryopreservation of sperm or eggs prior to deployment because of concerns for potential toxic exposures or genitourinary injury, no legislative changes would be required. However, the cost of this cryopreservation would have to be borne as a Service cost, not a Defense Health Program cost since cryopreservation of sperm and eggs does not qualify as medically necessary care.

Improved survival rates for patients with cancer diagnoses have resulted in consideration of fertility preservation becoming the standard of care in many cancer treatment protocols. The decision to offer a benefit for cryopreservation of eggs or sperm prior to cancer treatment would require a change to the CFR to include fertility preservation as medically necessary care.

CONCLUSION

TRICARE has the authority to correct physical causes of infertility and to provide IVF treatments for seriously or severely ill or injured ADSMs. Ten seriously ill or injured

ADSMs have utilized the IVF benefit and the participating members and responding providers are in support of this benefit in that it improves their quality of life.

DoD believes that pre-deployment fertility preservation would be expensive, difficult to implement, and may have ethical and legal unintended consequences currently unforeseen. The number of Service members who have lost reproductive capability is very small when compared to the number of Service members who have deployed. If the Member is a seriously or severely ill or injured ADSM with a lawful spouse, the member would be eligible for the IVF benefit. Donated sperm, eggs, surrogacy, or gestational carriers, however, are not authorized for coverage.

Fertility preservation related to illness, involving treatments that are harmful to glands that produce sperm or egg, has not previously been considered medically necessary care under the TRICARE basic benefit. Fertility preservation is rapidly evolving as the standard of care for certain cancers. Sperm cryopreservation has been recognized for decades and egg cryopreservation has recently been designated as no longer experimental by ASRM.

DoD believes it already has the necessary legal authority to offer assisted reproductive technologies to our serious or severely ill or injured ADSMs. Education of our beneficiaries about fertility preservation both prior to deployment and as it relates to treatment of illness should be provided. DoD will consider drafting a CFR change to include fertility preservation as a medically necessary part of the standard of care for cancer treatment.