Armed Forces Medicine

2016

CAPITAL PUBLISHING GROUP

Nebulized BROVANA for COPD offers:

- **Consistent 12-hour bronchodilation[1,2]**

  Some tolerance to the bronchodilator effect of BROVANA was observed after 6 weeks of dosing (at the end of the dosing interval), although the FEV_1 improvement remained statistically significant. This was not accompanied by other clinical manifestations of tolerance. BROVANA is not indicated for the treatment of acute episodes of bronchospasm, ie, rescue therapy, and does not replace fast-acting rescue inhalers.

- **Proven safety profile[1]**

  Percentage of patients reporting AEs was comparable to placebo[1]

  The five most common adverse events reported with frequency ≥2% in patients taking BROVANA, and occurring more frequently than in patients taking placebo, were pain (8% vs 5%), chest pain (7% vs 6%), back pain (6% vs 2%), diarrhea (6% vs 4%), and sinusitis (5% vs 4%).

- **Coverage under many HMOs/PPOs and Medicare Part B**

  Prior SABA use no longer required for Medicare patients*

- **Patient support**

  Sunovion Answers℠ is at your patients' service 1-844-BROVANA (1-844-276-8262) 8am-8pm ET Monday through Friday

*Not a guarantee of coverage.

Indication

BROVANA® (arformoterol tartrate) Inhalation Solution is indicated for the long-term, twice-daily (morning and evening) maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. BROVANA is for use by nebulization only.

Important Safety Information

WARNING: ASTHMA-RELATED DEATH

Long-acting $beta_2$-adrenergic agonists (LABA) increase the risk of asthma-related death. Data from a large placebo-controlled US study that compared the safety of another long-acting $beta_2$-adrenergic agonist (salmeterol) or placebo added to usual asthma therapy showed an increase in asthma-related deaths in patients receiving salmeterol. This finding with salmeterol is considered a class effect of LABA, including arformoterol, the active ingredient in BROVANA (see WARNINGS). The safety and efficacy of BROVANA in patients with asthma have not been established. All LABA, including BROVANA, are contraindicated in patients with asthma without use of a long-term asthma control medication (see CONTRAINDICATIONS).

References: 1. BROVANA [prescribing information]. Sunovion Pharmaceuticals Inc.; 2014. **2.** Baumgartner RA, Hanania NA, Calhoun WJ, Sahn SA, Sciarappa K, Hanrahan JP. Nebulized arformoterol in patients with COPD: a 12-week, multicenter, randomized, double-blind, double-dummy, placebo- and active-controlled trial. *Clin Ther.* 2007;29(2):261-278.

Please see the Brief Summary of Prescribing Information on the following pages for additional safety information. Please visit www.sunovionprofile.com/brovana for full Prescribing Information.

NEBULIZE WITH

Brovana® 15 mcg

(arformoterol tartrate) Inhalation Solution

BROVANA® (arformoterol tartrate) Inhalation Solution 15 mcg*/2 mL

*potency expressed as arformoterol

FOR ORAL INHALATION ONLY

BRIEF SUMMARY

WARNING: ASTHMA RELATED DEATH

Long-acting beta$_2$-adrenergic agonists (LABA) increase the risk of asthma-related death. Data from a large placebo-controlled US study that compared the safety of another long-acting beta$_2$-adrenergic agonist (salmeterol) or placebo added to usual asthma therapy showed an increase in asthma-related deaths in patients receiving salmeterol. This finding with salmeterol is considered a class effect of LABA, including arformoterol, the active ingredient in BROVANA (see WARNINGS). The safety and efficacy of BROVANA in patients with asthma have not been established. All LABA, including BROVANA, are contraindicated in patients with asthma without use of a long-term asthma control medication (see CONTRAINDICATIONS).

INDICATIONS AND USAGE

BROVANA (arformoterol tartrate) Inhalation Solution is indicated for the long-term, twice daily (morning and evening) maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. BROVANA is for use by nebulization only.

CONTRAINDICATIONS

BROVANA Inhalation Solution is contraindicated in patients with a history of hypersensitivity to arformoterol, racemic formoterol or to any other components of this product.

All LABA, including BROVANA, are contraindicated in patients with asthma without use of a long-term asthma control medication. (see **WARNINGS**).

WARNINGS

- **ASTHMA RELATED DEATH**

  Long-acting beta$_2$-adrenergic agonists may increase the risk of asthma-related death. The safety and efficacy of BROVANA in patients with asthma have not been established. All LABA, including BROVANA, are contraindicated in patients with asthma without use of a long-term asthma control medication (see CONTRAINDICATIONS).

– A 28-week, placebo-controlled US study comparing the safety of salmeterol with placebo, each added to usual asthma therapy, showed an increase in asthma-related deaths in patients receiving salmeterol (13/13,176 in patients treated with salmeterol vs. 3/13,179 in patients treated with placebo; RR 4.37, 95% CI 1.25, 15.34). The increased risk of asthma-related death may represent a class effect of the long-acting beta$_2$-adrenergic agonists, including BROVANA. No study adequate to determine whether the rate of asthma-related death is increased in patients treated with BROVANA has been conducted.

– Clinical studies with racemic formoterol (Foradil® Aerolizer®) suggested a higher incidence of serious asthma exacerbations in patients who received racemic formoterol than in those who received placebo. The sizes of these studies were not adequate to precisely quantify the differences in serious asthma exacerbation rates between treatment groups.

- **The studies described above enrolled patients with asthma. Data are not available to determine whether the rate of death in patients with COPD is increased by long-acting beta$_2$-adrenergic agonists.**
- **BROVANA is indicated for the long term, twice daily (morning and evening) maintenance treatment for bronchoconstriction in chronic obstructive pulmonary disease (COPD), and is not indicated for the treatment of acute episodes of bronchospasm, i.e., rescue therapy.**
- **BROVANA should not be initiated in patients with acutely deteriorating COPD, which may be a life-threatening condition. The use of BROVANA in this setting is inappropriate.**
- **BROVANA should not be used in children, as the safety and efficacy of BROVANA have not been established in pediatric patients.**
- **BROVANA should not be used in conjunction with other inhaled, long-acting beta$_2$-agonists. BROVANA should not be used with other medications containing long-acting beta$_2$-agonists.**
- **When beginning treatment with BROVANA, patients who have been taking inhaled, short-acting beta$_2$-agonists on a regular basis (e.g., four times a day) should be instructed to discontinue the regular use of these drugs and use them only for symptomatic relief of acute respiratory symptoms.**
- **See PRECAUTIONS and Information for Patients.**

Paradoxical Bronchospasm

As with other inhaled beta$_2$-agonists, BROVANA can produce paradoxical bronchospasm that may be life-threatening. If paradoxical bronchospasm occurs, BROVANA should be discontinued immediately and alternative therapy instituted.

Deterioration of Disease

COPD may deteriorate acutely over a period of hours or chronically over several days or longer. If BROVANA no longer controls the symptoms of bronchoconstriction, or the patient's inhaled, short-acting beta$_2$-agonist becomes less effective or the patient needs more inhalation of short-acting beta$_2$-agonist than usual, these may be markers of deterioration of disease. In this setting, a re-evaluation of the patient and the COPD treatment regimen should be undertaken at once. Increasing the daily dosage of BROVANA beyond the recommended 15 mcg twice daily dose is not appropriate in this situation.

Cardiovascular Effects

BROVANA, like other beta$_2$-agonists, can produce a clinically significant cardiovascular effect in some patients as measured by increases in pulse rate, blood pressure, and/or symptoms. Although such effects are uncommon after administration of BROVANA at the recommended dose, if they occur, the drug may need to be discontinued. In addition, beta-agonists have been reported to produce ECG changes, such as flattening of the T wave, prolongation of the QTc interval, and ST segment depression. The clinical significance of these findings is unknown. BROVANA, as with other sympathomimetic amines, should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension (see **PRECAUTIONS, General**).

Immediate Hypersensitivity Reactions

Immediate hypersensitivity reactions may occur after administration of BROVANA as demonstrated by cases of anaphylactic reaction, urticaria, angioedema, rash and bronchospasm.

Do Not Exceed Recommended Dose

Fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs. As with other inhaled beta$_2$-adrenergic drugs, BROVANA should not be used more often, at higher doses than recommended, or with other long-acting beta-agonists.

PRECAUTIONS

General

BROVANA Inhalation Solution should not be used to treat acute symptoms of COPD. BROVANA has not been studied in the relief of acute symptoms and extra doses should not be used for that purpose. When prescribing BROVANA, the physician should also provide the patient with an inhaled, short-acting beta$_2$-agonist for treatment of COPD symptoms that occur acutely, despite regular twice-daily (morning and evening) use of BROVANA. Patients should also be cautioned that increasing inhaled beta$_2$-agonist use is a signal of deteriorating disease for which prompt medical attention is indicated (see **Information for Patients**).

BROVANA, like other sympathomimetic amines, should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension; in patients with convulsive disorders or thyrotoxicosis; and in patients who are unusually responsive to sympathomimetic amines. Clinically significant changes in systolic and/or diastolic blood pressure, pulse rate and electrocardiograms have been seen infrequently in individual patients in controlled clinical studies with arformoterol tartrate. Doses of the related beta$_2$-agonist albuterol, when administered intravenously, have been reported to aggravate preexisting diabetes mellitus and ketoacidosis.

Beta-agonist medications may produce significant hypokalemia in some patients, possibly through intracellular shunting, which has the potential to produce adverse cardiovascular effects. The decrease in serum potassium is usually transient, not requiring supplementation. Clinically significant changes in blood glucose and/or serum potassium were infrequent during clinical studies with long-term administration of BROVANA at the recommended dose.

Information for Patients

Patients should be instructed to read the accompanying Medication Guide with each new prescription and refill. Patients should be given the following information:

1. Patients should be informed that long-acting beta$_2$-adrenergic agonists, such as BROVANA, increase the risk of asthma-related death. All LABA, including BROVANA, are contraindicated in patients with asthma without use of a long-term asthma control medication (see **CONTRAINDICATIONS**).
2. BROVANA is not indicated to relieve acute respiratory symptoms and extra doses should not be used for that purpose. Acute symptoms should be treated with an inhaled, short-acting, beta$_2$-agonist (the healthcare provider should prescribe the patient with such medication and instruct the patient in how it should be used). Patients should be instructed to seek medical attention if their symptoms worsen, if BROVANA treatment becomes less effective, or if they need more inhalations of a short-acting beta$_2$-agonist than usual. Patients should not inhale more than one dose at any one time. The daily dosage of BROVANA should not exceed one ready-to-use vial (15 mcg) by inhalation twice daily (30 mcg total daily dose).
3. Patients should be informed that treatment with beta$_2$-agonists may lead to adverse events which include palpitations, chest pain, rapid heart rate, tremor, or nervousness.
4. Patients should be instructed to use BROVANA by nebulizer only and not to inject or swallow this inhalation solution.
5. Patients should protect BROVANA ready-to-use vials from light and excessive heat. The protective foil pouches should be stored under refrigeration between 2°C and 8°C (36°–46°F). They should not be used after the expiration date stamped on the container. After opening the pouch, unused ready-to-use vials should be returned to, and stored in, the pouch. An opened ready-to-use vial should be used right away. Discard any ready-to-use vial if the solution is not colorless.
6. The drug compatibility (physical and chemical), efficacy and safety of BROVANA when mixed with other drugs in a nebulizer have not been established.
7. Women should be advised to contact their physician if they become pregnant or if they are nursing.
8. It is important that patients understand how to use BROVANA appropriately and how it should be used in relation to other medications to treat COPD they are taking.

Drug Interactions

If additional adrenergic drugs are to be administered by any route, they should be used with caution because the pharmacologically predictable sympathetic effects of BROVANA may be potentiated.

When paroxetine, a potent inhibitor of CYP2D6, was co-administered with BROVANA at steady-state, exposure to either drug was not altered. Dosage adjustments of BROVANA are not necessary when the drug is given concomitantly with potent CYP2D6 inhibitors.

Concomitant treatment with methylxanthines (aminophylline, theophylline), steroids, or diuretics may potentiate any hypokalemic effect of adrenergic agonists.

The ECG changes and/or hypokalemia that may result from the administration of nonpotassium sparing diuretics (such as loop or thiazide diuretics) can be acutely worsened by beta-agonists, especially when the recommended dose of the beta-agonist is exceeded.

Although the clinical significance of these effects is not known, caution is advised in the co-administration of beta-agonists with non-potassium sparing diuretics.

BROVANA, as with other beta$_2$-agonists, should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors, tricyclic antidepressants, or drugs known to prolong the QTc interval because the action of adrenergic agonists on the cardiovascular system may be potentiated by these agents. Drugs that are known to prolong the QTc interval have an increased risk of ventricular arrhythmias. The concurrent use of intravenously or orally administered methylxanthines (e.g., aminophylline, theophylline) by patients receiving BROVANA has not been completely evaluated. In two combined 12-week placebo controlled trials that included BROVANA doses of 15 mcg twice daily, 25 mcg twice daily, and 50 mcg once daily, 54 of 873 BROVANA-treated subjects received concomitant theophylline at study entry. In a 12-month controlled trial that included a 50 mcg once daily BROVANA dose, 30 of the 528 BROVANA-treated subjects received concomitant theophylline at study entry. In these trials, heart rate and systolic blood pressure were approximately 2-3 bpm and 6-8 mm Hg higher, respectively, in subjects on concomitant theophylline compared with the overall population.

Beta-adrenergic receptor antagonists (beta-blockers) and BROVANA may interfere with the effect of each other when administered concurrently. Beta-blockers not only block the therapeutic effects of beta-agonists, but may produce severe bronchospasm in COPD patients. Therefore, patients with COPD should not normally be treated with beta-blockers. However, under certain circumstances, e.g., as prophylaxis after myocardial infarction, there may be no acceptable alternatives to the use of beta-blockers in patients with COPD. In this setting, cardioselective beta-blockers could be considered, although they should be administered with caution.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies were conducted in mice using oral administration and rats using inhalation administration to evaluate the carcinogenic potential of arformoterol. In a 24-month carcinogenicity study in CD-1 mice, arformoterol caused a dose-related increase in the incidence of uterine and cervical endometrial stromal polyps and stromal cell sarcoma in female mice at oral doses of 1 mg/kg and above (AUC exposure approximately 70 times adult exposure at the maximum recommended daily inhalation dose). In a 24-month carcinogenicity study in Sprague-Dawley rats, arformoterol caused a statistically significant increase in the incidence of thyroid gland c-cell adenoma and carcinoma in female rats at an inhalation dose of 200 mcg/kg (AUC exposure approximately 130 times adult exposure at the maximum recommended daily inhalation dose). There were no tumor findings with an inhalation dose of 40 mcg/kg (AUC exposure approximately 55 times adult exposure at the maximum recommended daily inhalation dose). Arformoterol was not mutagenic or clastogenic in the following tests: mutagenicity tests in bacteria, chromosome aberration analyses in mammalian cells, and micronucleus test in mice.

Arformoterol had no effects on fertility and reproductive performance in rats at oral doses up to 10 mg/kg (approximately 2700 times the maximum recommended daily inhalation dose in adults on a mg/m^2 basis).

Pregnancy: Teratogenic Effects
Pregnancy Category C

Arformoterol has been shown to be teratogenic in rats based upon findings of omphalocele (umbilical hernia), a malformation, at oral doses of 1 mg/kg and above (AUC exposure approximately 370 times adult exposure at the maximum recommended daily inhalation dose). Increased pup loss at birth and during lactation and decreased pup weights were observed in rats at oral doses of 5 mg/kg and above (AUC exposure approximately 1100 times adult exposure at the maximum recommended daily inhalation dose). Delays in development were evident with an oral dose of 10 mg/kg (AUC exposure approximately 2400 times adult exposure at the maximum recommended daily inhalation dose).

Arformoterol has been shown to be teratogenic in rabbits based upon findings of malpositioned right kidney, a malformation, at oral doses of 20 mg/kg and above (AUC exposure approximately 8400 times adult exposure at the maximum recommended daily inhalation dose). Malformations including brachydactyly, bulbous aorta, and liver cysts were observed at doses of 40 mg/kg and above (approximately 22,000 times the maximum recommended daily inhalation dose in adults on a mg/m^2 basis). There are no adequate and well-controlled studies in pregnant women. BROVANA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Use in Labor and Delivery

There are no human studies that have investigated the effects of BROVANA on preterm labor or labor at term. Because beta-agonists may potentially interfere with uterine contractility, BROVANA should be used during labor and delivery only if the potential benefit justifies the potential risk.

Nursing Mothers

In reproductive studies in rats, arformoterol was excreted in the milk. It is not known whether arformoterol is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when BROVANA is administered to a nursing woman.

Pediatric

BROVANA is approved for use in the long term maintenance treatment of bronchoconstriction associated with chronic obstructive pulmonary disease, including chronic bronchitis and emphysema. This disease does not occur in children. The safety and effectiveness of BROVANA in pediatric patients have not been established.

Geriatric

Of the 873 patients who received BROVANA in two placebo-controlled clinical studies in adults with COPD, 391 (45%) were 65 years of age or older while 96 (11%) were 75 years of age or older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects. Among subjects age 65 years and older, 129 (33%) received BROVANA at the recommended dose of 15 mcg twice daily, while the remainder received higher doses. ECG alerts for ventricular ectopy in patients 65 to ≤75 years of age were comparable among patients receiving 15 mcg twice daily, 25 mcg twice daily, and placebo (3.9%, 5.2%, and 7.1%, respectively).

A higher frequency (12.4%) was observed when BROVANA was dosed at 50 mcg once daily. The clinical significance of this finding is not known. Other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

ADVERSE REACTIONS

Experience in Adult Patients with COPD

Of the 1,456 COPD patients in the two 12-week, placebo-controlled trials, 288 were treated with BROVANA Inhalation Solution 15 mcg twice daily and 293 were treated with placebo. Doses of 25 mcg twice daily and 50 mcg once daily were also evaluated. The numbers and percent of patients who reported adverse events were comparable in the 15 mcg twice daily and placebo groups.

The following table shows adverse events where the frequency was greater than or equal to 2% in the BROVANA 15 mcg twice daily group and where the rates of adverse events in the BROVANA 15 mcg twice daily group exceeded placebo. Ten adverse events demonstrated a dose relationship: asthenia, fever, bronchitis, COPD, headache, vomiting, hyperkalemia, leukocytosis, nervousness, and tremor.

Table 1: Number of Patients Experiencing Adverse Events from Two 12-Week, Double-Blind, Placebo-Controlled Clinical Trials

	BROVANA 15 mcg twice daily		Placebo	
	n	(%)	n	(%)
Total Patients	288	(100)	293	(100)
Pain	23	(8)	16	(5)
Chest Pain	19	(7)	19	(6)
Back Pain	16	(6)	6	(2)
Diarrhea	16	(6)	13	(4)
Sinusitis	13	(5)	11	(4)
Leg Cramps	12	(4)	6	(2)
Dyspnea	11	(4)	7	(2)
Rash	11	(4)	5	(2)
Flu Syndrome	10	(3)	4	(1)
Peripheral Edema	8	(3)	7	(2)
Lung Disorder*	7	(2)	2	(1)

*Reported terms coded to "Lung Disorder" were predominantly pulmonary or chest congestion.

Adverse events occurring in patients treated with BROVANA 15 mcg twice daily with a frequency of <2%, but greater than placebo were as follows:

Body as a Whole: abscess, allergic reaction, digitalis intoxication, fever, hernia, injection site pain, neck rigidity, neoplasm, pelvic pain, retroperitoneal hemorrhage

Cardiovascular: arteriosclerosis, atrial flutter, AV block, congestive heart failure, heart block, myocardial infarct, QT interval prolonged, supraventricular tachycardia, inverted T-wave

Digestive: constipation, gastritis, melena, oral moniliasis, periodontal abscess, rectal hemorrhage

Metabolic and Nutritional Disorders: dehydration, edema, glucose tolerance decreased, gout, hyperglycemia, hyperlipemia, hypoglycemia, hypokalemia

Musculoskeletal: arthralgia, arthritis, bone disorder, rheumatoid arthritis, tendinous contracture

Nervous: agitation, cerebral infarct, circumoral paresthesia, hypokinesia, paralysis, somnolence, tremor

Respiratory: carcinoma of the lung, respiratory disorder, voice alteration

Skin and Appendages: dry skin, herpes simplex, herpes zoster, skin discoloration, skin hypertrophy

Special Senses: abnormal vision, glaucoma

Urogenital: breast neoplasm, calcium crystalluria, cystitis, glycosuria, hematuria, kidney calculus, nocturia, PSA increase, pyuria, urinary tract disorder, urine abnormality.

Overall, the frequency of all cardiovascular adverse events for BROVANA in the two placebo-controlled trials was low and comparable to placebo (6.9% in BROVANA 15 mcg twice daily and 13.3% in the placebo group). There were no frequently occurring specific cardiovascular adverse events for BROVANA (frequency ≥1% and greater than placebo). The rate of COPD exacerbations was also comparable between the BROVANA 15 mcg twice daily and placebo groups, 12.2% and 15.1%, respectively.

Other adverse reactions which may occur with selective beta$_2$-adrenoceptor agonists such as BROVANA include: angina, hypertension or hypotension, tachycardia, arrhythmias, nervousness, headache, tremor, dry mouth, palpitation, muscle cramps, nausea, dizziness, fatigue, malaise, hypokalemia, hyperglycemia, metabolic acidosis and insomnia.

Drug Abuse and Dependence

There were no reported cases of abuse or evidence of drug dependence with the use of BROVANA in the clinical trials.

OVERDOSAGE

The expected signs and symptoms associated with overdosage of BROVANA (arformoterol tartrate) Inhalation Solution are those of excessive beta-adrenergic stimulation and/or occurrence or exaggeration of any of the signs and symptoms listed under **ADVERSE REACTIONS**, e.g., angina, hypertension or hypotension, tachycardia, with rates up to 200 bpm, arrhythmias, nervousness, headache, tremor, dry mouth, palpitation, muscle cramps, nausea, dizziness, fatigue, malaise, hypokalemia, hyperglycemia, metabolic acidosis and insomnia. As with all inhaled sympathomimetic medications, cardiac arrest and even death may be associated with an overdose of BROVANA.

Treatment of overdosage consists of discontinuation of BROVANA together with institution of appropriate symptomatic and/or supportive therapy. The judicious use of a cardioselective beta-receptor blocker may be considered bearing in mind that such medication can produce bronchospasm. There is insufficient evidence to determine if dialysis is beneficial for overdosage of BROVANA. Cardiac monitoring is recommended in cases of overdosage.

Clinical signs in dogs included flushing of the body surface and facial area, reddening of the ears and gums, tremor, and increased heart rate. A death was reported in dogs after a single oral dose of 5 mg/kg (approximately 4500 times the maximum recommended daily inhalation dose in adults on a mg/m^2 basis). Death occurred for a rat that received arformoterol at a single inhalation dose of 1600 mcg/kg (approximately 430 times the maximum recommended daily inhalation dose in adults on a mg/m^2 basis).

SUNOVION

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AFM 2016
FOREWORD

Army Surgeon General Receives Third Star

By J.D. Leipold

The Army formally welcomed the service's 44th surgeon general Tuesday and promoted Nadja Y. West to lieutenant general.

West became the first African American to serve as Army surgeon general when she assumed the position Dec. 11. With her promotion, she became the Army's first black woman to hold the rank of lieutenant general and the highest-ranking woman of any race to graduate from West Point.

Army Chief of Staff Gen. Mark A. Milley hosted the ceremony held on Joint Base Myer-Henderson Hall. "She has performed brilliantly in the two months she's been the surgeon general and I can personally attest to that," Milley told the audience.

Following the ceremony, West spoke with the press to provide an idea on where Army medicine would be heading.

She said her predecessor, Lt. Gen. Patricia Horoho, had brought Army medicine to the point that it is now and that one of her priorities would be to ensure that the Performance Triad — focus on sleep, nutrition and activity — continues. She said though it sounds basic, "we want to take care of ourselves in all dimensions, then to the next level."

"Gen. Milley says readiness is his No. 1 priority… and there is no other number one, so my job will be to ensure that from the health care aspect, that I can enhance the readiness of our soldiers, our families and those who are entrusted to our care," she said. "You can't lead people if you don't care about them. It has to be genuine care."

West said that her mission was to ensure medical formations are appropriately agile and adaptable to meet the needs of the entire aligned force to include the Army and the joint force.

West was raised in the nation's capital and was the youngest of 12 adopted brothers and sisters.

Before she took the oath of allegiance, her son Logan and daughter Sydney replaced their mother's two-star shoulder boards with the three-star versions gifted by her predecessor to the applause of family, friends and dignitaries. Milley then presented her with a personal three-star flag before administering the oath of office as her husband, Don, held the Bible.

Army Surgeon General Lt. Gen. Nadja Y. West

"In short, she's in charge of tens of thousands of medical professionals and she has significant responsibilities here and overseas that cover health care policies and medical material," he said. "She's in charge of organizing and integrating Army-wide healthcare assistance for about two and one-half million people. That's a lot of work, a lot of responsibility and no one is going to do it better than Gen. West… and she also manages money; she's in charge of $11.8 billion."

West next took the lectern and spoke briefly about her large family and thanked them for the support her brothers and sisters had given over the years. She said the smallest gap in ages

> "She's in charge of tens of thousands of medical professionals and she has significant responsibilities here and overseas that cover health care policies and medical material. She's in charge of organizing and integrating Army-wide healthcare assistance for about two and one-half million people. That's a lot of work, a lot of responsibility and no one is going to do it better than General West… and she also manages money; she's in charge of $11.8 billion."
>
> *Army Chief of Staff Gen. Mark A. Milley*

was between she and her next oldest sister and that was six years.

"My family was a really good team," she said. "There was a group who was all the same age and were friends in the orphanage, so they hung together and looked out for each other… that was a good environment to grow up.

"I think the message that sends is that there's no limit [to] what you can do; what you can accomplish once you put your mind to it," she continued. "No matter what your beginnings are, you can aspire to be anything you want."

West is a 1982 graduate of the U.S. Military Academy at West Point, New York, where she earned a bachelor of science in engineering. She followed up by earning her doctorate of medicine from George Washington University School of Medicine in Washington, D.C.

West flew to Fort Sam Houston, Texas, Wednesday, to formally assume command of U.S. Army Medical Command.

army.mil

> "I think the message that sends is that there's no limit [to] what you can do; what you can accomplish once you put your mind to it. No matter what your beginnings are, you can aspire to be anything you want."
>
> *Army Surgeon General Lt. Gen. Nadja Y. West*

Army Chief of Staff Gen. Mark A. Milley formally swears in Lt. Gen. Nadja Y. West as 44th Army surgeon general as her husband, Don, holds the Bible on Joint Base Myer-Henderson Hall, Va.

Army Surgeon General Lt. Gen. Nadja Y. West has her three-star shoulderboards pinned on by son, Logan, and daughter, Sydney while her husband Don looks on. West was promoted during a ceremony hosted by Army Chief of Staff Gen. Mark A. Milley on Joint Base Myer-Henderson Hall, Va.

Army Chief of Staff Gen. Mark A. Milley hosts the promotion of the 44th Army surgeon general on Joint Base Myer-Henderson Hall, Va.

Active
ADDICTION

Awards Recognize Services' Top Anti-Drug Programs

By Terri Moon Cronk, DoD News, Defense Media Activity

The military installations honored for their anti-drug program successes represent excellence, Dr. Jonathan Woodson, assistant secretary of defense for health affairs, said at the Defense Department's 25th annual Community Drug Awareness Awards ceremony in the Pentagon's Hall of Heroes today.

Woodson and Daniel P. Feehan, principal deputy assistant secretary of defense for readiness, honored an installation from each service and a military-affiliated youth organization for the best drug awareness and outreach programs in the past year in advance of the 25th annual DoD Red Ribbon Week, observed Oct. 23 to 31 this year.

Woodson said the DoD recognition honors the programs that set themselves apart in an environment where substance abuse affects national security and readiness.

"You understand that readiness is more than a concept," he told awardees. "Readiness is about our preparedness for life, [and] the readiness to assist others."

Woodson also noted that drug-positive rates in the services have averaged 0.9 percent in the past several years, which he said is well below DoD's goal of 2 percent.

The military needs service members to perform at their optimum mental and physical capabilities, he said. "We need them to be healthy. We need people who are resilient when facing adversities and … [when] operating in foreign environments."

Family members, both adults and children, also must be strong, he noted.

Jonathan Woodson, Assistant Secretary of Defense (Health Affairs)

Daniel P. Feehan, Principal Deputy Assistant Secretary of Defense (Readiness)

Leadership is Key

"Leadership means doing the right thing, even if you are in the minority, and as the department recognizes you today, you should bask in this recognition and know that your individual and organizational commitments have made a difference," Woodson said.

"It's a complicated world out there, and there are a number of things our service members have to be ready for," Feehan said, noting that some young troops are "impressionable and high-risk individuals."

Drawing on this year's Red Ribbon Week theme — "Respect Yourself. Be Drug Free" — Feehan said there is a "clear commonality with the idea that if you have a drug-free life while in uniform, you are set up for a successful life thereafter."

2015 Awards

This year's DoD Community Drug Awareness Awards were presented to:

- Army Substance Abuse Program, Army Garrison Stuttgart, Germany;
- Drug Demand Reduction Program, Marine Corps Air Station Miramar, California;
- Drug Education for Youth, Naval Computer and Telecommunications Area Master Station Atlantic, Norfolk, Virginia;
- Demand Reduction Program, 319th Air Base Wing, Grand Forks Air Force Base, North Dakota; and
- Substance Abuse Program, 5th Regiment Army, Maryland Army National Guard, Baltimore.

The Young Marines is the winner of the 2015 Fulcrum Shield Award for Excellence in Youth Anti-Drug Education. The award was presented on Thursday, October 15, 2015 at the Pentagon.

The 2015 Fulcrum Shield Award, which recognizes independent military-affiliated youth organization for its top anti-drug work in the community, was presented to the Drug Demand Reduction Program, Young Marines of the Marine Corps League.

"Today isn't a declaration of victory; but a reminder that you are doing the right things," Woodson told the awardees. He also praised them for encouraging service members and families to renew their pledges to remain drug-free. "They need people like you to stress this positive message," he added. "They are listening, … and you are succeeding."

defense.gov

Drug Demand Reduction Center Grand Opening

By Senior Airman Matthew Lotz, 31st Fighter Wing Public Affairs

The 31st Fighter Wing opened a new Drug Demand Reduction Center, March 10, 2015, at Aviano Air Base, Italy. The DDR program helps deter the use of illegal substances to better ensure Service members are capable of supporting the mission, using randomly-selected drug tests called sweeps to help eliminate drug abuse throughout the military.

aviano.af.mil

U.S. Air Force Airmen from the 31st Fighter Wing attend the grand-opening ceremony for the wing's new Drug Demand Reduction Center, March 10, 2015, at Aviano Air Base, Italy. The DDR program helps deter the use of illegal substances to better ensure Service members are capable of supporting the mission, using randomly-selected drug tests called sweeps to help eliminate drug abuse throughout the military. *(U.S. Air Force photo by Senior Airman Matthew Lotz/Released)*

Active
ADDICTION

Taking It Back: Help Prevent Prescription Drug Abuse

By Christine Cabalo

Participants nationwide are taking a stand together, Sept. 26, from 10:00am to 2:00pm, to help stop prescription drug abuse.

Marine Corps Base Hawaii will be among the thousands of locations for National Take-Back Initiative Day, when communities can drop off their old medicines for safe disposal. Prescription pills, liquids and all forms of expired medicine will be collected at a drop-off point near the Marine Corps Exchange at Mokapu Mall.

"We want to take all the drugs back," said Alton Arakaki, a manager for the MCB Hawaii Substance Abuse Counseling Center. "In particular, we want to take back opiates and ones that can cause dizziness or drowsiness. Even pain relief medicines, including over-the-counter aspirin, can cause liver damage if someone takes too many tablets or takes too many expired."

Arakaki and other representatives from Naval Health Clinic Hawaii and the Drug Enforcement Agency will be at the drop-off point to collect the medicines, including expired over-the-counter drugs.

"It's all done anonymously," said Robin Dinlocker, assistant special agent in charge of the Honolulu District Office of the DEA. "We put (what's collected) in the box, weigh it and then take it to be incinerated."

Arakaki and Dinlocker said because of the secured incineration off-base, people can drop off their medicines in the original prescription bottle or separately in another container, such as a sandwich bag.

Last year more than 35 pounds of old prescription medication were gathered at the Kaneohe Bay drop-off point, with a DEA agent sealing collection boxes and safely disposing the items. The DEA has nationally conducted the take-back initiative since 2005, according to the 2015 news release about the event from the DEA's website.

"The DEA saw an increase in prescription drug abuse, from police and emergency reports," Dinlocker said. "We wanted to do an initiative option to give people a way to properly dispose their medicines."

Both Arakaki and Dinlocker said conventional disposal methods are potentially hazardous. Old medicines that go down the sink or are flushed down the toilet risk contaminating local water sources, Dinlocker said.

Arakaki said throwing away medicines in the trash is challenging as the old prescriptions may be dug out. Arakaki said if someone is trying to dispose of medicine in the trash, it should be mixed with other unappetizing waste like coffee grinds or cat litter.

Outside of the collection days, the DEA is investigating other methods of gathering expired medication. New regulations that were implemented in October 2014 by the DEA allow the agency to nationally work with hospitals and pharmacies for voluntary collection of old prescriptions.

"Here in Hawaii, the Narcotics Enforcement Division is working on establishing drop boxes, possibly in hospitals and pharmacies, and regularly servicing them for safe disposal," Dinlocker said.

Arakaki said he's encouraging Marines and Sailors living in the barracks to participate, since they are among the more likely to have prescriptions but few have participated in the Kaneohe Bay take back. It is risky to leave expired prescription medication at home, Arakaki said, especially in a bathroom medicine cabinet.

"The bathroom is where people are most likely to be left alone," he said. "Some people don't count their medicine pills, so might not realize things are gone at first."

If people can't head to the K-Bay drop-off point, there are several other confirmed Oahu drop-off locations including Honolulu Hale, the Navy Exchange at Joint Base Pearl Harbor-Hickam and Schofield Barracks.

Arakaki said after illegal drugs like marijuana and cocaine, prescription medicines are the third type of drug most commonly abused in the Marine Corps. Service members who take controlled substances without a prescription or who give it to someone else can be investigated by the Naval Criminal Investigative Service or the U.S. Army Criminal Investigation Command.

"We have robust drug testing on base," Arakaki said. "We get results in as little as two to three days from Tripler. The testing is all computerized and get results pretty quickly. If someone tries to mask (illicit drug use), it's very difficult to do."

Dinlocker said her office has joined forces successfully with their military colleagues and hopes this year's take back efforts run just as well.

"Everyone has to join together to combat the problem, on and off base," Dinlocker said. "We can all do our part to assist in this."

marines.mil

Active
ADDICTION

Army Substance Abuse Program Supports Fort Eustis, Story Soldiers

By Staff Sgt. Teresa Cleveland

"I have an addiction and I need help getting back on my feet."

As the Fort Eustis Army Substance Abuse Program clinical director, these are words Elizabeth Calvano-Carpenter has heard multiple times throughout her career.

The ASAP mission is to strengthen the overall fitness and effectiveness of the U.S. Army's workforce, to conserve manpower and enhance the combat readiness of Soldiers.

Calvano-Carpenter and her team at the ASAP clinic work with Soldiers who struggle with substance abuse and provide flexible treatment plans to fit each Soldier's needs through counseling.

"We primarily help Soldiers who have a problem with drugs or alcohol," said Calvano-Carpenter. "Our main mission is to support the Soldiers and help them learn how to combat their issues in a healthy way and ensure they are fit for duty and mission ready."

Soldiers at Fort Eustis and Joint Expeditionary Base Little Creek-Fort Story may come to the ASAP clinic through a variety of ways, including a commander's referral if a Soldier is showing inappropriate behavior such as showing up to work under the influence or their substance abuse is interfering with work performance. Also, biochemical referrals come from a positive random urine screening, or a Soldier can self report to their primary care physician.

"We understand the stigmas behind having a substance abuse problem," said Calvano-Carpenter. "We want Soldiers to know that coming forward on their own is much better than getting in trouble and being referred to us, and we can do a lot more to help them if they want the help and aren't just forced to get help."

U.S. Army Soldiers at Fort Eustis and Joint Expeditionary Base Fort Story-Little Creek with a substance abuse problem may be referred by their commander, primary care physician or can self-refer to the Army Substance Abuse program at Fort Eustis, Va. For more information or to seek treatment, contact the Fort Eustis ASAP Clinic at 878-1674. *U.S. Air Force photo by Senior Airman Kimberly Nagle*

The clinic works with approximately 85 to 90 Soldiers annually, providing level-one treatment, which includes an evaluation, group and one-on-one therapy sessions with a licensed Virginia therapist.

Soldiers run the risk of getting into legal, physical or health problems from substance abuse, so she encourages Soldiers to seek help if they think they have a problem.

"We want to help Soldiers understand how drinking or using drugs become problematic," said Calvano-Carpenter. "We can give them skills and tools they can use to ensure they are mission ready at all times."

While most Soldiers attend both group and one-on-one therapy sessions, the clinic staff understands that some Soldiers may not be a good fit for group therapy, said Calvano-Carpenter.

"Some may have experienced significant childhood trauma, sexual or physical abuse," said Calvano-Carpenter. "Group therapy may be too overwhelming for them, so we focus primarily on individual therapy so they still get the help they need."

The clinic maintains a relationship with Naval Medical Center Portsmouth and Dwight D. Eisenhower Army Medical Center at Fort Gordon, Georgia, for Soldiers who may need level-two or level-three treatment, which may include a 21-to-28 day intensive outpatient program or a four-to-six week residential program.

Once a level-two or three treatment is complete, Soldiers return to the ASAP clinic for one year of follow-up and therapy sessions as needed.

health.mil

Active
CARDIOLOGY

Hypertension: More Soldiers Die from Silent Killer than from Combat

By Patricia Deal

Many people think that combat is the most life threatening event for Soldiers, when actually more Soldiers may die off the battlefield fighting a common enemy.

Heart disease is the leading cause of death in the United States. About every 25 seconds, an American will have a coronary event, and about one every minute will die from one, according to the Centers for Disease Control and Prevention.

Between 70 and 89 percent of sudden cardiac events occur in men, and as part of Men's Health Awareness Week June 13 through 17, 2011, the medical professionals at the Carl R. Darnall Army Medical Center want to make sure male beneficiaries know the best way to help reduce their risk.

There are several risk factors affecting heart disease. High blood pressure, also known as hypertension, is the leading cause of stroke, according to the American Heart Association.

Hypertension has been labeled "the silent killer" because there are no symptoms. It may remain unnoticed for many years.

A significant number of Soldiers are affected by hypertension, according to the Department of Defense's 2008 Survey of Health Related Behaviors. Approximately 17 percent of Soldiers have reported high blood pressure since they entered the Army.

Another 1.7 percent said they never had the condition checked, and 12.7 percent reported they didn't know or remember what their blood pressure was.

Michael Bergeron, clinical pharmacist, hooks up Sgt. David Callahaun up to an Ambulatory Blood Pressure device, which automatically records patients' blood pressure readings continually for 24 hours.

"Hypertension definitely affects the readiness of our troops. Once a Soldier is diagnosed with hypertension, our goal is to get it under control and manageable so he can deploy," said Maj. (Dr.) Alcario Serros, chief of Internal Medicine at Darnall. "The majority of the time, cases can be controlled through intervention, either with medication and/or lifestyle changes."

The key is in the diagnosis, Serros said, and fortunately for Soldiers, they have a much better chance of detecting hypertension early as they have better access to care. Soldiers are required to have a physical every year, and blood pressure checks are done at every appointment and during the pre-deployment process.

Blood pressure is measured as systolic, when the heart beats while pumping blood, and diastolic, when the heart is at rest between beats.

A normal blood pressure level is less than 120/80 mmHg. Pre-hypertension is diagnosed with readings of 120-139/80-89 mmHg and hypertension is diagnosed with readings greater than 140/90 mmHg. Higher readings are more serious, and usually require immediate intervention.

There are a number of causes of hypertension, but in 90 percent of the cases, the causes are unknown. There are several medical conditions and lifestyle choices that are known to increase a person's risk to hypertension. Most risk factors are controllable, while factors such as age and genetics are not.

Risk factors that can be controlled include cigarette smoking, poor diet, unhealthy weight/obesity, lack of physical activity and excessive alcohol use. Sleep apnea (breathing stop during sleep) is also a known cause of hypertension.

Stress is another known risk factor, and unfortunately for Soldiers, combat stress has been linked to hypertension. According to research reported in the Journal of the American Heart Association, "combat exposure may exert long-term adverse effects on cardiovascular health."

"The bad news is that the typical lifestyle of Soldiers puts them at a higher risk for hypertension and heart disease. Too often, Soldiers cope with the stress of Army life by smoking, drinking and eating unhealthy," Serros said. "The good news is though, with lifestyle changes and/or medication, you can reduce your risk."

There are a number of different types of medications that are effective in lowering blood pressure.

"It's a matter of tailoring the medication to the individual, finding which type and what dose will help. Our goal is to give the smallest amount of medication and still get the most benefit," said Michael Bergeron, clinical pharmacist at Darnall. "But medication alone is not enough to manage hypertension. You still have to make lifestyle changes to bring it under control."

Serros said that it comes down to patients taking an active role in their health care.

"Some are motivated and some are not. I try to appeal to their emotional side. Often, they have to have a traumatic event or scare to motivate them," he stated. "Even though they have high blood pressure, they aren't feeling any pain or discomfort, so it's harder for them to give up habits that they enjoy."

While most lifestyle changes are difficult, Maj. Nicole Charbonneau, chief of Nutrition Services at CRDAMC, believes that patients struggle the most with dietary changes.

"But, proper diet and exercise can do wonders to help reduce blood pressure, allowing many patients to control it without medication," she said. "We recommend the DASH (Dietary Approaches to Stop Hypertension) diet, which helps prevent or lower high blood pressure."

It's low in sodium, cholesterol and fat, and high in fruits, vegetables and low-fat dairy that provide essential minerals such as potassium, magnesium and calcium.

Getting more physical activity while on the DASH diet provides the best benefit, Charbonneau added. She suggests that even patients in the normal to pre-hypertension range follow the plan as it substantially reduces the risk of developing hypertension in the future.

"The hardest change for most people is reducing the salt in their diets. We have become so accustomed to adding salt to everything, even before tasting it. Many people believe that food just won't taste as good without salt," said Ms. Barbara Hughart, dietitian for Nutrition Services.

"You need to cut out the use of added salt to meet dietary guidelines," she explained. "Try cutting back slowly by using 'lite' or sea salts with 25-30 percent reduced sodium, then move to saltless seasonings such as spice-herb blends. It may seem hard, but your taste buds will adapt."

Current dietary guidelines for Americans recommend that adults in general should consume no more than 2,300 mg of sodium per day and adults in certain population groups should consume no more than 1,500 mg. The average American gets about 3,400 mg of sodium a day.

"It's just not table salt that's a concern," Hughart explained. "People don't realize most of our sodium intake comes from packaged foods and fast food and restaurant meals. Canned foods are especially high in sodium as are certain condiments such as soy sauce. It's best just to eat foods as close to fresh as possible."

Hughart offers more advice and tips for all beneficiaries with high blood pressure, high cholesterol, and triglycerides at her weekly Heart Healthy Eating class.

Spc. John Felt, D Company, an Abrams tank crew member, was recently diagnosed with hypertension as he was being treated for a lower back injury incurred during a deployment in 2009-2010. Felt's blood pressure was 158/128.

"I'm just 39 years old and I never had problems with my blood pressure before so I was surprised it was so high. I don't know my family history, but the doctors think it is probably genetic," he said. "I'm sure stress has a lot to do with it, too. Plus, I'm a smoker."

Felt said he learned quite a bit from Hughart's class. He's making some changes and his wife is cooking healthier now, cutting out the salt. With those changes and getting the right medication, he's happy to report that his blood pressure is lower, at 101/68.

Once patients are able to manage their high blood pressure, Serros said it is imperative that they continue to be checked and monitored.

"They may have had success in lowering their blood pressure, so they think they're out of the woods. But if they don't continue to actively take their meds or stick with their healthier habits, they're just putting themselves in more danger," he said.

To more accurately monitor blood pressure readings, Bergeron will start using an Ambulatory Blood Pressure device. The patient wears the portable device continually for 24 hours and it automatically records readings throughout the time period.

Bergeron said he also believes that follow-up care is crucial in helping patients with hypertension. He is in the process of developing a "hypertension clinic" which would devote resources to ensure proper follow-up of hypertension patients.

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Active
FIELD MEDICINE

Exercise Alamo Shield Provides Life-saving Training

By Senior Airman Bryan Swink, 433rd Airlift Wing Public Affairs

Airmen from different units of the 433rd Airlift Wing conducted an eight-day training exercise to hone their skills and prepare in case they are called into action in a deployed environment.

Alamo Shield, which was held Feb. 22-29 at Joint Base San Antonio-Lackland and Camp Bullis Training Annex, is a comprehensive training exercise designed to deploy and exercise an aeromedical evacuation system in an initial urgent response scenario.

This wartime initial contingency mission centered on the fictitious country Biloxistan, where war has broken out by a rising insurgent power and the U.S. Military has been sent to assist the country. Camp Bullis' airfield served as the country of Biloxistan with different regions surrounding the flightline simulating multiple locations down range.

Members of the 433rd Aeromedical Evacuation Squadron, 433rd Airlift Control Flight, 433rd Aeromedical Staging Squadron and 433rd Aerospace Medicine Squadron's Critical Care Air Transport Team worked together to provide the logistics and execution of evacuating injured patients out of the danger zone.

En-route Patient Staging System team members, from the 433rd Aeromedical Staging Squadron, transport a patient toward a C-130 Hercules during the Alamo Shield exercise held at Joint Base San Antonio-Lackland and Camp Bullis Training Annex, Texas Feb. 27, 2016. Alamo Shield is a comprehensive training exercise designed to deploy and exercise an aeromedical evacuation system in an initial urgent response scenario. *U.S. Air Force photo by Senior Airman Bryan Swink*

First Lt. J.C. Allen, 433rd Aeromedical Evacuation Squadron flight nurse, secures a stretcher aboard a C-130 Hercules shortly before the injured patients are brought on board during the Alamo Shield exercise at Camp Bullis Training Annex Feb. 27, 2016. Flight nurses and medical technicians are responsible for maintaining the care of patients while being transported in flight. Alamo Shield was an eight-day training exercise designed to deploy and exercise an aeromedical evacuation system in an initial urgent response scenario. *U.S. Air Force photo by Senior Airman Bryan Swink*

Two aeromedical evacuation liaison teams were spread out on different sides of the "country" and served as the first step in the process to evacuate patients out.

"We are imbedded down range with specific Army, Navy, Marine Corps or Air Force units and serve as the liaison between that unit and the aeromedical system," said Capt. Charlie South, 433rd AELT member. "We work with our communication personnel to relay the necessary information required to evacuate the patients out of the region. This exercise gives us the opportunity to truly refine our skills and make sure we have our processes as perfect as they can be."

The AELT members, consisting of a flight nurse, Medical Service Corps officer and two communication personnel, provide clinical expertise in knowing exactly what the patients need regarding aircraft specific requirements, equipment

A medical transport vehicle from the 79th Medical Wing, Joint Base Andrews, Md., loaded with patients ready for aeromedical transport raises up to the open cargo hatch of a KC-135 Stratotanker assigned to the 128th Air Refueling Wing, Milwaukee, on the ramp at JBA. The patients were transported to other military medical treatment facilities around the country by an aeromedical evacuation team demonstrating total force integration on an aeromedical evacuation mission. *U.S. Air National Guard photo by Staff Sgt. Jeremy Wilson/Released*

requirements, clinical implications of altitude and stresses of flight while preparing the patients for the flight.

With the AELT's coordination, the rest of the aeromedical evacuation teams know what they will need to do to complete the mission.

The Aeromedical Evacuation Operations Teams downrange receive the instruction from the AELTs and begin their role. The AEOTs coordinate the air crews and provide operational and mission management support by coordinating the proper equipment necessary for the mission, directs AE ground support activities like mission launch and recovery, aircraft set up and configuration, and manages medical equipment and supplies.

"We are responsible for managing the crews for our AE missions," said Lt. Col. Deborah Deja, 433rd AES flight nurse who oversaw operations for one of the two AEOT units during the exercise. "During the exercise we are only managing two crews, but we have the capability to manage up to 10 crews and launch and recover up to six missions in a 24-hour period."

During the exercise, the AEOTs ensured all the necessary equipment was ready to load onto the incoming C-130 Hercules assigned to the 908th Airlift Wing at Maxwell Air Force Base, Ala. With the exercise being simulated in an active war zone, the engines for the aircraft were continuously running, which helped maintain a high sense of urgency. As soon as the arriving aircraft came to a complete stop, the AEOT members and aircrew began loading and setting up the aircraft in the arrangement necessary to keep the patients stable.

After the equipment was loaded, patients were taken from the en-route Patient Staging System and boarded onto the aircraft. ERPSS is a staging facility that provides temporary holding capability for up to six hours for patients transiting the Air Evacuation System.

While inflight, AE crews continue care of the non-critical patients while Critical Care Air Transport Teams worked on the critical patients. CCATT teams consist of one critical care physician, a critical care nurse and a respiratory technician to ensure the best care possible is provided to those patients who need it most.

This training couldn't have come at a better time for many of the exercise participants. Some are just keeping their skills up-to-date, but many are preparing for a deployment in the upcoming months.

"I am about to deploy for the first time and this exercise couldn't have come at a better time," said Senior Airman Sarah Clark, 433rd AES medical technician. "This is an opportunity for me to learn from my mistakes so when I'm in the field, I will be sharper, quicker and more on point."

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Active
FIELD MEDICINE

Belvoir Hospital Recognizes EMS Week and Emergency Personnel

By Alexandra Snyder, Fort Belvoir Community Hospital Public Affairs

At Fort Belvoir Community Hospital, a staff of approximately 30 emergency medical technicians and paramedics are on duty to ensure patients receive appropriate medical care and transport, no matter the time of day or night.

"We are here all day, every day," said Miguel Serra, supervisory medic and operations manager for Belvoir Hospital. "The team is always ready to provide world-class care, not just in the hospital, but everywhere."

At Belvoir Hospital, that care includes responding to emergency calls on base as well as inter-facility patient transfers.

"When a patient needs a level of care we cannot provide, our team takes them to where they can get it," Serra said. "For instance, we are not a stroke center. If we respond to a call where a patient is showing signs of having one, we won't bring them here, we'll take them to the closest facility equipped to treat them. We go through intensive medical training to be able to make those determinations and provide that level of expertise."

> "We rarely know when tragedy will strike and, in our most vulnerable moments, we rely on these dedicated professionals."

That type of training and sound judgement is imperative to patient care, said Dr. Daniel Gabbay, assistant chief of the Emergency Department.

"Patients need to trust that they are getting the best care available from the moment they come in contact with a provider. Our EMS team ensures that they are. The trust they're able to build with patients and the care they're able to provide is paramount."

Across the nation, for nearly 45 years, the week of May 15th through the 21st is known as EMS Week; declared by Gerald Ford as a way to recognize and celebrate the work that emergency medical service providers do on a daily basis.

President Obama, in his Presidential Proclamation for National EMS Week 2016, highlighted the risks EMS providers take on behalf of their communities. "EMS providers brave danger and uncertainty, and their efforts deserve our most profound appreciation," Obama said.

"We rarely know when tragedy will strike and, in our most vulnerable moments, we rely on these dedicated professionals. During Emergency Medical Services Week, let us celebrate and support the EMS professionals who demonstrate the values at the heart of the American spirit, and let us thank them for their heroic work."

EMS is one of the most dangerous jobs in the United States. Recent statistics show that EMTs and paramedics experience an injury rate of virtually 100 percent during the course of their careers and are twice as likely to suffer a line of duty death than any other profession.

"This job isn't easy," said Robyn Manthey, a paramedic at Belvoir Hospital. "It can be dangerous and it's certainly mentally tough. We typically see people on the worst day of their lives. People often aren't going to remember to thank you for helping them when they're having a medical emergency. And that's okay, because knowing that you've made a difference to a patient is worth it all – the risk, the lack of spoken gratitude. All of it."

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Active
FIELD MEDICINE

Brooke Army Medical Center Team Wins Regional "Best Medic" Competition

By John Franklin

As the fog permeates the darkness of the early morning hours at Camp Bullis, teams of medics from throughout the Southern Regional Medical Command compete in a 12-mile march, hauling a 35-pound pack on their back and their weapon in hand.

This was the final event in the three-day competition to earn the title, "Best Medic."

Seven teams of Soldiers from medical treatment facilities across SRMC competed Sept. 18-20 to earn the coveted title, but it was the team from Brooke Army Medical Center – Sgt. 1st Class Stephen Eisele and Spc. Garrett Woodford – who met the challenge.

"What I enjoyed most about the competition was getting out in the field and competing with great Soldiers," Woodford said.

BAMC planed, coordinated and executed the SRMC Best Medic Competition for the region.

"These competitors were challenged in a demanding, continuous and realistic simulated operational environment," said Capt. Jose Capellan, officer in charge of the competition. "In the short time they spent with us at Camp Bullis, they established lasting relationships and fostered espirit de corps. They reviewed and applied the concepts of the performance triad and continuously reflected on their role as professional Soldiers."

The Soldiers first had to complete the Army Physical Fitness Test Sept. 18 before moving to the medical lanes where they were briefed on the scenario which involved two wounded Soldiers and one possible dead in a village under hostile fire.

Each team, followed by evaluators, was scored on their tactical approach to the area and the care they provided the combat casualties they encountered while machine gun fire, mortar blasts and smoke surrounded the area. The teams had only 35 minutes to move from the start point to the village, locate the casualties, provide immediate lifesaving aid, and move them safely to an evacuation point.

"The day combat trauma lane was definitely challenging," Eisele said. "Having to maneuver tactically through the woods and the city to get to your casualties and then treat them in the allowed time given and to do it all correctly was intense. We were double checking everything we did just to make sure we wouldn't lose any points."

Teams were also tested in weapons qualification firing both an M-16 rifle and M-6 pistol from a variety of positions, night medical lanes, night land navigation, an obstacle course, a 5K buddy run and a written exam.

During the medic-style buddy run, the competitors faced some unique challenges.

Each team was required to place a 165-pound casualty on a skid and pull it several hundred meters. The teams were then required to assemble a single channel ground and airborne radio system and call in a simulated medical evacuation request before they could continue.

Near the finish line they encountered three simulated casualties which they needed to assess and load onto an ambulance before running to the finish line.

"The most challenging event was the 5K buddy run. After completing all of the other events leading up to that event we were already tired, so completing the 5K event was definitely difficult," Eisele said. "Having to pull the skid with a casualty in it as far as we did was not easy at all. And then trying to put together a radio when my arms were so tired was very interesting."

Woodford agreed, "The most challenging events were the 5K and the 12 mile ruck march."

The final day, following the 12-mile march SRMC Commander Brig. Gen. Barbara Holcomb presented Eisele and Woodford with Distinguished Service Medals for their outstanding performance and achievements during the competition. They also received the Outstanding Medic Knife and a SRMC belt buckle.

"This competition gave BAMC the opportunity to improve the organization by providing tough, realistic training in a safe manner while being fiscally responsible," Capellan said. "The execution of the events gave us an opportunity to reconnect with battlefield medicine at the point of injury. At a medical facility as big and busy as BAMC this is something that is difficult to execute.

"My team planned, coordinated and executed the competition and they had fun doing it. This is why Soldiering is our vocation," he added.

Army Spc. Garrett Woodford (left) and Army Sgt. 1st Class Stephen Eisele (right) pull a skid with a 165-pound dummy simulating a casualty during the Southern Regional Medical Command Best Medic Competition Sept. 18 at Camp Bullis. *Photo by John Franklin*

Eisele and Woodford will represent SRMC in the U.S. Army Medical Command CSM Jack L. Clark Jr. Best Medic Competition Oct. 28-30 at Camp Bullis.

"Moving into the next competition we now know what our strengths and weaknesses are and we plan to train accordingly. We have a lot of training to conduct such as learning about 25 different knots, combat water survival and, of course, maintaining and gaining more strength in the gym. The bottom line is that we plan to prepare to win the Army Best Medic Competition," Eisele said.

"I just want to be as prepared as we possibly can be going into the Army competition," Woodford added.

(Editor's note: Lori Newman from Brooke Army Medical Center Public Affairs contributed to this article)

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U.S. soldiers conduct the urban casualty evacuation lane during the European Best Squad Competition at the Grafenwoehr Training Area in Bavaria, Germany, Oct. 20, 2015. *U.S. Army photo by Gertrud Zach*

Active
FIELD MEDICINE

Army Lab Tackles Problem of Military Stress Fractures

By Curt Biberdorf, Special to American Forces Press Service

Stress fractures caused by repetitive pounding activities of physical training take a toll on enough of the military population, specifically recruits, that a major research program called "Bone Health and Medical Military Readiness" was started in 1997 to solve the problem.

With a collection of the latest research tools acquired in the past year, the U.S. Army Research Institute of Environmental Medicine's bone health and metabolic laboratory at the U.S. Army Soldier Systems Center here is ready to examine its piece of the puzzle.

"The goal of the whole program is to ultimately eliminate stress fractures," said Maj. Rachel Evans, a research physical therapist and director of bone health research. "Stress fracture cases have been reported since the late 1800s, and today are one of the most common and potentially debilitating overuse injuries seen in military recruits, particularly in women."

Stress fractures are overuse injuries that occur when muscles transfer the overload of strain to the bone, most commonly in the lower leg, and cause a tiny crack. They're tricky to see on X-rays, and they disrupt physical training, sidelining troops while costing the Defense Department as much as $100 million annually in medical costs and lost duty time, according to Evans.

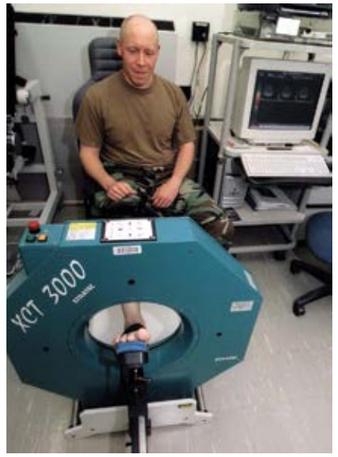
Funded in part by Congress through the advocacy efforts of the National Coalition for Osteoporosis and Related Bone Diseases and the American Society for Bone and Mineral Research, and managed by USARIEM, overall research is multi-faceted, examining factors such as gait mechanics, impact attenuation and genetics. USARIEM research physiologists are studying specifically how exercise and nutrition influence stress fractures.

"A systematic approach to the study of stress fracture was needed, but hadn't been done," Evans said. "With this focused effort, and recent breakthroughs in technology, we're hoping to come up with science-based strategies to identify individuals at risk for stress fracture, and then prevent their occurrence through innovative training interventions."

Col. Karl Friedl, USARIEM commander, led a study on bone health earlier in his career at Fort Lewis, Wash., and said the understanding of bone physiology is significantly advancing and has widespread ramifications on health.

"There has been no program in the DoD that paid attention to bone health in the past," Friedl said. "Anything we can provide has the potential to save millions of dollars and enhance readiness through reduction in lost duty time, attrition from the military and medical cost avoidance. We want to avoid occupationally- induced stress fractures now, and osteoporosis and osteoarthritis later."

Noninvasive methods of studying bone health at USARIEM started in the early 1990s with the first dual energy X-ray absorptiometry machine to measure bone density. Still in the lab, the older DEXA machines have been superseded by the superior software and scanning times in a new Prodigy fanbeam bone densitometer, according to Robert Mello, a research physiologist and the lab director.



Spc. Heath Isome is scanned for bone density and geometry on the peripheral quantitative computerized tomography machine in the bone health lab. *Photo by Sarah Underhill*

The Prodigy scans total body bone density in 5-inch instead of 1-inch increments, increasing precision and cutting scan time from 30 minutes to six minutes. Improved software provides a clearer picture of total body composition and bone mineral density.

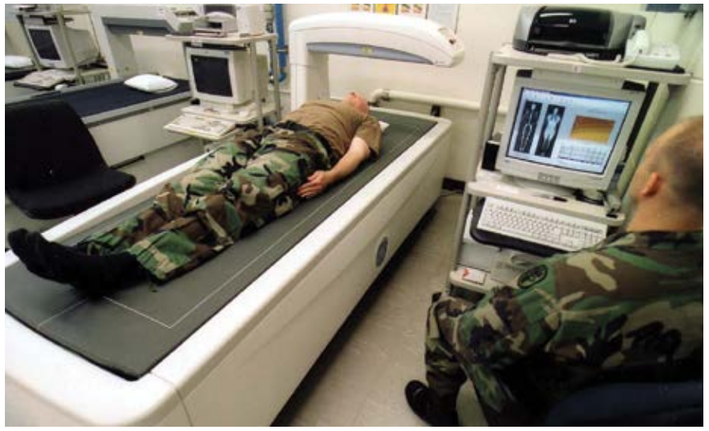
"We can look at regional areas of interest, such as sections of the tibia, forearm or hip," Mello said. "Before, you had to scan an entire area. Just to have that capability is a major advance."

The Prodigy also allows researchers to scan small animals for studies on bone health, Evans said.

While the Prodigy gives a front-to-back, two-dimensional view, the peripheral quantitative computerized tomography machine allows researchers to analyze 3-D cross sections of spongy and outer bone. It's designed to reconstruct a volumetric model of bone, from which bone density, and for the first time, bone geometry, can be determined, Evans said. "We can now look at cross-sectional images where stress fractures are most common," she said. "There's also software to quantify muscle mass at that point."

Another scanning instrument is the handheld ultrasound bone sonometer, which examines bone quality by measuring the speed of sound of ultrasonic waves axially transmitted along the bone. The results can then be used as an aid in the assessment of bone strength. "We can identify bones that may be at risk," Mello said. "The big thing is the portability so that it can easily be taken to the field."

To help understand the relationship between muscle mass and bone strength, the lab purchased an isokinetic dynamometer to assess muscle strength and endurance for the major joints of the body, except the neck.



Spc. Heath Isome is scanned on the Prodigy DEXA machine as Spc. Daniel Catrambone sits at the control station. *Photo by Sarah Underhill*

Although research is focused on preventing stress fractures in the military, Evans said the information they learn can apply to any population of physically active people to help prevent stress fractures.

Four USARIEM studies are planned in the next year to try to answer how muscle structure and function relates to bone quality. Researchers will examine whether differences in bone density and geometry exist between the right and left tibia, and then look at how that changes through physical training.

One objective is to find out the proper training balance, to see where bone strengthening ends and weakening begins. A third study will look at the effect of three 12-week exercise programs — aerobic training, strength training, and a combination of the two — against a sedentary control group.

"We want to look at what factors might build up bone," Evans said. "Maybe we can give (recruits) a program before going to basic training to ward off problems."

Building on what they've learned in the experimental study, the plan is to transfer that information to actual basic combat training units to examine what risk factors, such as slender bones or low bone density, predispose trainees to injury.

Evans and Friedl gave examples of expected outcomes from current projects that USARIEM is managing. Soldiers with high risk for fracture may simply stand on a platform for 15-minute daily treatments of low-frequency vibration to stimulate bone development.

Recruits might benefit from specific guidance on physical training, and calcium and vitamin D supplementation resulting from studies now with Navy basic trainees.

Photo Credit: U.S. Air Force photo/Airman 1st Class Xavier Lockley

Armed Forces Medicine 2016

Various studies at USARIEM could lead to new recommendations on zinc and protein content in operational rations to optimize bone health.

Even basic biology studies, such as one that demonstrated a refractory period in response of bone cells after mechanical stimulation, may affect military training with science-based advice to break up physical training into more than one session per day to maximize the benefit to bone health.

(Curt Biberdorf is editor of Warrior magazine at the U.S. Army Soldier Systems Center.)

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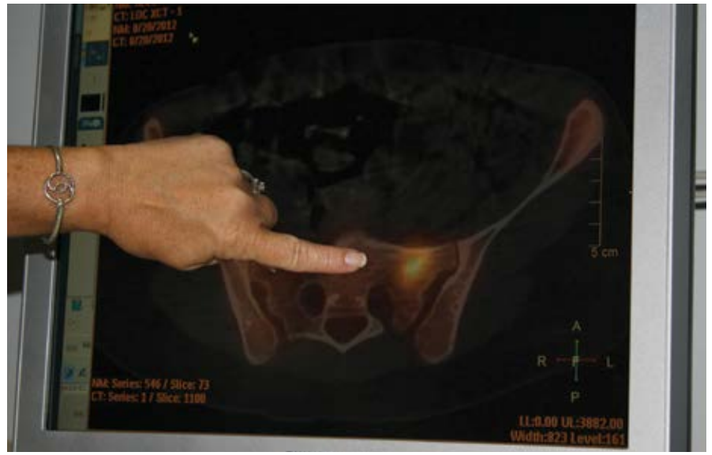

Photo Credit: John Brooks

How to avoid stress fractures

Stress fractures are common among military recruits, in about 3% of men and 9% of women, and it can take several weeks to months for stress fractures to heal. Most occur in the lower extremities, especially the lower leg and foot

A important thing to know about stress fractures is how to avoid them. A stress fracture is a tiny crack in a bone that happens when your muscles can't absorb shock and transfer stresses to the bone. Most occur in the lower extremities, especially the lower leg and foot.

A stress fracture is usually an overuse injury that develops over a long period of time — from weeks to months. They're especially common among military recruits, in about 3% of men and 9% of women. And since it can take several weeks to months for a stress fracture to heal, the best approach is to avoid getting one. Here are some tips for prevention:

Use the progression principle of training:

- Gradually increase your training intensity, usually by no more than 10% weekly if you exercise 3 or more days a week.
- Slowly incorporate higher-stress activities such as jumping and interval training into your workout.
- Set incremental goals to help you develop your training routine step-by-step.
- Check your footwear and make sure it matches your training routine.

- Replace old or worn footwear.
- Check your form. Are you moving properly when you exercise or does your form put you at risk of injury?
- Pay attention to early signs of injury. Unusual muscle soreness and other aches and pains can be a sign of injury and/or imbalances that could worsen if they aren't addressed early.
- Monitor your diet, specifically calcium and vitamin D intake.

To learn more, read the National Institute of Health's Dietary Supplement Fact Sheet on calcium and HPRC's article on vitamin D. And check out HPRC's Injury Prevention section for more on how to avoid injury.

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Active
GASTROENTEROLOGY

U.S. Naval Medical Research Unit – No. 6 (NAMRU-6) Investigators Work with Medical Staff on USNS Comfort

To Better Understand the Health Risks to Military Personnel Deployed to Latin American Countries

Travelers' Diarrhea is a frequent cause of illness and lost productivity among deployed military members.

In recent years there have been several deployments of U.S. military in the SOUTHCOM region for humanitarian assistance and disaster relief (HA/DR) missions, as well as capacity building missions, with recent examples including HA/DR missions to Haiti following the earthquake in 2010 and annual New Horizons capacity building missions in Central America.

In order to better understand the health risks to military personnel deployed to Latin American countries, researchers at the U.S. Naval Medical Research Unit - No. 6 (NAMRU-6), are leading a study titled, "Epidemiology and Etiology of Travelers' Diarrhea Among Military Personnel Deployed to Latin America," that is funded by the Armed Forces Health Surveillance Center Global Emerging Infections Surveillance (GEIS) program.

NAMRU-6 researchers Lt. Cmdr. Mark Simons, Lt. Nathanael Reynolds, and Dr. Giselle Soto, with the support of Honduran contractor Dr. Faviola Reyes, went aboard the USNS Comfort (T-AH-20) during a stop in Trujillo, Honduras, September 1.

The NAMRU-6 team met with Lt. Cmdr. David Cepeda; Lt. Cmdr. Edward Hurd; Chief Hospital Corpsman Amylyn Ross; Lt. Joel Valdez; and, Hospital Corpsman 1st Class Carrie Barnes, to discuss continued case detection of diarrhea during the Comfort's recent mission, and to implement post-deployment surveys at the end of the mission in order to better understand the burden of disease among the Sailors.

The NAMRU-6 team discusses laboratory issues and testing strategies to enhance detection of enteric pathogens from Comfort's personnel. Capturing stools and bacteria isolates is important to understand the causes of diarrhea as well as to detect antibiotic resistance, which is another focus of the NAMRU-6 mission. Pictured left to right: Lt. Cmdr. David Cepeda, HM2 Carrie Barnes, Lt. Nathanael Reynolds, Lt. Cmdr. Mark Simons.
Photo courtesy of NAMRU-6 Public Affairs

"Most people don't report to sick call when they have mild diarrhea and many of the crew were given antibiotics during their travel medicine screening," said Ross. "They usually treat themselves without seeking medical care."

In support of the under-reporting issue, Hurd and Cepeda from the ship's Department of Public Health showed Simons and his team the report reflecting a low (but steady) stream of cases reported daily throughout the deployment.

However, according to Valdez and Barnes, the laboratory received less than 10 total samples for stool culture and none were positive for enteric pathogens. Simons highlighted the inability of basic stool culture to detect pathogenic E. coli bacteria and enteric viruses, recommending that the lab freeze samples to send to NAMRU-6 for analysis using multiplex molecular methods that can provide a snapshot of the most common bacteria, viruses, and parasites.

Collectively, NAMRU-6 and the Comfort team developed a strategy for enhanced monitoring of diarrhea cases through the rest of the mission, particularly important as the crew had several port calls prior to the end of the deployment.

Additionally, the post-deployment surveys promise to provide a wealth of data on prevalence of diarrhea among the crew, common risk factors, lost duty days, and the use of self-treatment strategies versus medical care seeking behaviors, which can be used for future mission planning and improvements in force health guidelines, and enhancing case detection during future humanitarian missions.

NAMRU-6's mission is to conduct research and surveillance to diminish the threat of infectious diseases to the warfighter by developing superior prevention or therapeutic strategies; and to serve the health interests of the people of Peru and South America.

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Active
GASTROENTEROLOGY

WAMC Gastrointestinal Endoscopy Unit Receives Recognition for Excellence

Womack Army Medical Center's Gastrointestinal Endoscopy unit earned recognition status by the American Society for Gastrointestinal Endoscopy, June 1.

The ASGE Endoscopy Unit Recognition Program, the only national program of its kind, honors units that demonstrate a commitment to patient safety and quality in endoscopy. The WAMC GI Endoscopy Unit is only the second in the Department of Defense to achieve this recognition and one of only 500 organizations to receive this honor.

"The ASGE is a well-known organization and this recognition validates that we're providing high quality care," said Lt. Col. (Dr.) Viet-Nhan Nguyen, chief, Gastroenterology Service, WAMC. "The process allowed us to undergo a peer review where we were evaluated on infection control, patient care and providing quality endoscopy."

In order to be recognized, WAMC had to meet high quality measures critical to GI endoscopic patient care. According to the ASGE website, these measures include: patient assessment for procedural risk; adequacy of bowel preparation; cecal intubation rate; adenoma detection rates; adverse event tracking; and use of patient satisfaction surveys.

"We took the quality metrics looked for by the ASGE and rewrote our policy to ensure we were providing the best quality care," said Nguyen. "While we were doing endoscopy procedures appropriately before, we never really compared our data to the national data. When we did, we found that not only were we meeting the standards, we were exceeding them in some areas."

Maj. (Dr.) Michael Dann, assistant chief, Gastroenterology Service, WAMC, spearheaded the process to achieve ASGE recognition. He said that going through the evaluation has helped improve communication among all members of the team.

"It's not just the physicians who played a role in achieving this recognition," said Dann. "It's changed the way the technicians process equipment and helped create an environment where the nurses feel more comfortable coming forward if they see something wrong so it can be immediately addressed."

Members of the Womack Army Medical Center's Gastrointestinal Endoscopy unit perform an esophagogastroduodenoscopy, an upper endoscopy better known as an EGD, at Womack Army Medical Center, July 1, 2015. The clinic was recently earned recognition status from the American Society for Gastrointestinal Endoscopy for their commitment to patient safety and quality in endoscopy.
Photo Credit: Eve Meinhardt, WAMC PAO

The unit's accreditation with the Joint Commission was also instrumental in qualifying for the recognition. The recognition status is good for three years, but the WAMC GI Endoscopy Unit must continue to gather data quarterly to ensure they are continuing to meet the quality metrics.

"This isn't the end for us," said Nguyen. "By still gathering the data, it keeps us honest and ensures we remain a high-reliability organization focused on patient care. We will continue to work to improve the patient experience."

Nguyen said one of the next steps to help improve the patient experience and provide quality care is to create an all-female endoscopy team as a treatment option for patients uncomfortable with a male provider.

The WAMC GI Endoscopy Unit performs about 4,000 procedures a year. These procedures include colonoscopies, upper endoscopy, endoscopic retrograde cholangiopancreatography (ERCP), endoscopic ultrasounds, as well as other less common endoscopic procedures, as needed.

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Active
NEUROLOGY

The Naval Health Research Center Hosts Its First Insomnia Workshop

The Naval Health Research Center hosted its first insomnia workshop to bring researchers and clinicians together to discuss collaborative opportunities for addressing insomnia and sleep-related problems in service members, recently.

"The main objective for hosting this event was to discuss how we can improve the way we prevent, diagnose, and treat insomnia in our Sailors and Marines," said Dr. Rachel Markwald, sleep research physiologist and director of NHRC's sleep lab, who organized the workshop. "Perhaps, the most important aspect was getting local area military providers together and engaged about sleep issues and how they impact operational readiness."

Attendees included primary care physicians, clinical psychologists, social workers, and sleep specialists from the San Diego region including Naval Medical Center San Diego, the Concussion Care Clinic at Naval Hospital Camp Pendleton, and OASIS, a residential treatment program in San Diego for active duty patients with combat-related post-traumatic stress disorder.

"Obtaining healthy sleep is foundational to having a healthy brain," said Navy Cmdr. Paul Sargent, director of the Concussion Care Clinic. "We must use sleep to not only foster high performance, but also resilience in the face of adversity. The cognitive demands on warfighters have never been higher. Well-rested fighters will have increased vigilance, faster reaction times, and better problem- solving skills. Collaborative efforts will not only prevent disability and improve recovery times it will also lay the foundation for more effective human performance programs in the future and positively impact our ability to accomplish the challenging missions which we are assigned."

A special guest was Dr. Anne Germain, associate professor of psychiatry, psychology, and clinical and translational science at the University of Pittsburgh School of Medicine. Germain discussed her research on the mechanisms underlying sleep disturbances, especially within the context of PTSD and traumatic brain injury, and her work developing and adapting evidence-based behavioral treatments.

During the day-long workshop, participants discussed current approaches for treating insomnia and fatigue, specific barriers to treatment, evidence-based pharmacological and non-pharmacological treatment options, and better ways to provide care and treatment for patients with insomnia and sleep-related problems from initial complaint through diagnosis and treatment.

"As far as I know, this is the first time we've had people from all these different areas come together to discuss sleep problems and the way forward for helping our patients," said Navy Capt. Tony Han, physician and director of NMCSD's Sleep Lab. "Our goal was to put our minds together and look at how we can collaborate to improve treatment for insomnia. This capability affects all of our Sailors and Marines, because sleep is critical for mental resilience, physical performance, and our ability to bounce back from injuries."

According to Markwald, the workshop was instrumental in helping her and her team better understand how NHRC's sleep lab can support the different clinics and health care providers. Limited resources have prevented the traditional implementation of these treatments at most clinics; however, adapting these approaches to account for the challenges and uniqueness of each military treatment facility is possible and needed. The NHRC sleep team is currently collaborating with NMCSD's Sleep Lab to perform research that addresses these needs.

"The current practices for treating insomnia need improvement," said Markwald. "There needs to be a push to increase patient access to evidence-based, treatment options."Moving forward, we want to consider future collaborations and research projects about how we can provide better avenues for educating our Sailors and Marines about proper sleep, sleep hygiene, and the problems associated with sleep loss," said Han. "We want to improve awareness of the importance of sleep in everyday life as well as in the military."

As the DoD's premier deployment health research center, NHRC's cutting-edge research and development is used to optimize the operational health and readiness of the nation's armed forces.

In proximity to more than 95,000 active duty service members, world-class universities, and industry partners, NHRC sets the standard in joint ventures, innovation, and translational research.

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Active
NEUROLOGY

Ensuring Mission Readiness with a Few Good ZZZs

By Airman 1st Class Christopher R. MoralesJ, BER Public Affairs

According to sleepfoundation.org, 60 percent of Americans between the ages of 13 and 64 say they experience a sleep problem every night or almost every night. But only about 50 to 70 million Americans are affected by sleep disorders.

Just because people are tired or have a tough time falling or staying asleep doesn't mean they have a sleep disorder.

Many sleeping difficulties are self-induced, such as consuming caffeine after noon or staying up all night late watching a bright screen.

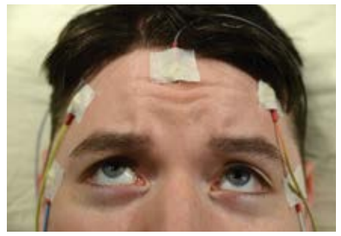
"It would be beneficial for the entire community to look at sleep and sleep habits with the same amount of focus as we look at exercise and nutrition," said Air Force Col. Teresa Bisnett, JBER hospital commander. "We are fortunate the Air Force has a sleep clinic here."

Sleep is vital because it helps recharge the brain, like taking a rest day recharges muscles after a workout. A poor sleep schedule can disrupt daily functions and worsen conditions such as hypertension, heart disease, diabetes and depression.

The JBER hospital Sleep Clinic is equipped to treat all adult military beneficiaries.

"[The SDC] is committed to readiness and seamless health service to provide high-quality health care to our mission-ready arctic warriors, dependents, veterans and retirees," said Air Force Staff Sgt. Cheryl Kuntz, 673d Medical Group SDC cardiopulmonary technician.

The center's goal is to increase overall health, daytime functions, restore regular sleep patterns and minimize risks of associated diseases.



Electrodes attached to a patient's skin are just part of the the sleep study process in the 673d medical Group Sleep Disorder Clinic at the JBER Hospital Oct. 30. During a sleep study, many wires are attached to the patient to monitor things like brain function, heart rate, temperature and movement.
U.S. Air Force photo by Airman 1st Class Christopher R. Morales

Going to the sleep clinic, just like going to behavioral health, doesn't negatively affect someone's career.

"It should improve your career to maintain your mission readiness by not struggling to stay awake," said Air Force Maj. Ross Dodge, 673d Medical Group SDC medical director.

To be admitted to the sleep clinic, a patient must be referred by their primary care manager. Depending on the symptoms, one would go to the insomnia class or schedule an appointment with the sleep clinic.

Insomnia is difficulty falling asleep or staying asleep. People with insomnia can experience fatigue, low energy, moodiness, lack of concentration and decreased performance.

The insomnia class, hosted by the Behavioral Health Optimization Program, educates participants on bad sleeping habits people have and some techniques to prepare the body for sleep. These include creating a bedtime routine and developing a sleep environment to associate the bed with sleep.

It is also recommended to have a light dinner and not to have alcohol, nicotine, an intense workout or anti-drowsy medication right before sleep.

"You don't have to have a sleep test just because you don't sleep well," Kuntz said. "You have to eliminate the factors in your control, then work on the ones outside of your control."

The sleep clinic treats out-of-control factors like chronic sleep disorders, sleep apnea, restless-leg syndrome, narcolepsy and more.

By conducting overnight sleep studies and daytime studies with multiple tools tracking breath, temperature, heart rate, noise, movement and brain functions, the sleep clinic can accurately identify the root of the medical problem.

Sleep is a personal responsibility, but maintaining mission readiness is everyone's concern.

Everyone sleeps one-third of their lives, so make it an important part of everyday — or every night to get adequate sleep.

jber.af.mil

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Active
NEUROLOGY

Construction Set to Begin on Sleep Disorder Center

By Maureen Casey, 377th Medical Group

Officials from the Air Force and New Mexico Veterans Affairs Health Care System grabbed shovels and donned hard hats and broke ground on a new site for a sleep disorder center at a ceremony Oct. 5.

The new building, expected to open in late 2016, will provide an up-to-date facility for diagnosis and treatment of sleep disorders for veterans and active-duty personnel. It will feature eight fully equipped patient sleep rooms.

The center is being built as part of the medical group's partnership with the NMVAHCS. The partnership, called Joint Venture, was developed to share resources to improve access to care for the patients of both organizations and save taxpayer dollars.

"The sleep disorder center is the latest innovation in our long-standing partnership," said Chief Master Sgt. Nathaniel Perry, 377th Medical Group superintendent. "The new center will mean better care for VA and AF patients and will save money in the process."

The NMVAHCS and 377 MDG evaluated the current and future need for sleep studies and determined that building their own sleep disorder center at the NMVAHCS would meet the two major criteria of improved patient access to care and reduced costs. The proposal was submitted and won funding in the amount of $4.9 million.

The NMVAHCS opened a temporary four-bed sleep disorder clinic in April 2013. Having an in-house facility has saved the government $2 million in cost avoidance.

kirtland.af.mil

Andrew Welch, New Mexico Veterans Affairs Health Care System director, and Col. Jeffrey White, 377th Medical Group commander, don hard hats and take shovels to break ground for a new, eight-bed sleep disorder center. Supervising is Bill Lawrence (left), VA's project manager for the construction, and Dick Hart, 377th MDG facility chief. *Photo by Jamie Burnett*

Active
NURSING

Weeklong Observance Celebrates Work of Nurses, Medical Technicians

By Robert Goetz, Joint Base San Antonio-Randolph Public Affairs

A weeklong slate of activities that begins Friday will celebrate the contributions of nurses and medical technicians at Joint Base San Antonio-Randolph's 359th Medical Group.

"Small World-Big Heart," the theme for National Nurses Week at JBSA-Randolph, represents the impact nursing service members have within the Air Force and the care and compassion they bring to their jobs, said Lt. Col. Cynthia Weidman, 359th MDG chief nurse.

"We have nurses and medical technicians working in all parts of the world delivering health care with the same compassion to ensure their patients' needs are met," she said. "They see newborn babies taking their first breaths and hold the hands of family members as their loved ones slip away. The heart of nurses is the foundation of health care."

Three events will highlight National Nurses Week, beginning with the signing of a proclamation by Col. Dana James, 359th MDG commander. Nursing's traditional passing-the-knowledge cake-cutting ceremony is set for 3 p.m.

"Last year was the first time we had this ceremony, which symbolizes the passing of knowledge from the oldest nurse to the youngest technician," Weidman said. The week will conclude with a dinner and program Thursday at the Parr Club featuring presentations by retired Army Maj. Jorge Torres, Center for the Intrepid behavioral health provider, and Army 1st Lt. John Arroyo, who was injured during the April 2, 2014, mass shooting at Fort Hood, Texas, and is undergoing rehabilitation at the CFI.

In addition to Arroyo, other wounded warriors will be honored during the event, including a Naval enlistee who died while he was training to be a Navy SEAL, but whose pledge to be an organ donor resulted in the donation of a kidney to the 12-year-old daughter of one of the 359th MDG's nurses, Weidman said. "Although he died in a training accident, he was able to save the life of another person," she said.

Also during the dinner, gifts and specially designed coins will be presented to nurses and technicians, Weidman said. The heart-shaped coins will feature the "Small World-Big Heart" theme on one side and the Air Force Nurse Corps emblem on the other side.

The conclusion of National Nurses Week marks the birthday of Florence Nightingale, founder of the nursing profession and pioneer of modern nursing, who was born May 12, 1820.

Another event during the weeklong celebration is a luncheon for nurses and technicians at 11 a.m. Tuesday.

The nursing corps at the 359th MDG comprises more than 80 active-duty members, Department of Defense civilians and contractors who serve as registered nurses, licensed vocational nurses and technicians, Weidman said. They provide care in family health, women's health, pediatrics, flight medicine and immunizations, serving active-duty members and their families as well as retirees and their families.

Education is a hallmark of nurses and technicians.

Weidman said most active-duty nurses have advanced degrees in nursing or health-care-related degrees, while technicians pursue educational opportunities such as bachelor's and master's degrees and are trained to respond to emergencies.

Master Sgt. Jose Libunao, 359th Medical Operations Squadron superintendent, said technicians play an important role in the healthcare process by preparing patients for the visits with their providers.

"Medical technicians are largely responsible for the completion of the paraprofessional portion of all medical examinations here at JBSA-Randolph," he said. "That includes the patient's health/medical history, vital signs, vision exams and immunizations.

"Medical technicians are the first in line as far as patient care is concerned," Libunao said. "Duties include doing the electrocardiograms, drawing blood for lab work, starting intravenous therapies and responding to cardiac or airway emergencies."

Technicians are also certified national registered emergency technicians, so they can respond to emergencies off the installation, he said.

National Nurses Week gives nurses and technicians the recognition they deserve for their contributions, Weidman said.

"They sometimes forget that what they do is important, but they take care of our families and warfighters so everybody can fulfill the mission," she said. "Without our nurses and technicians, healthcare doesn't function; without that team, it doesn't work."

jbsa.mil

Active
ONCOLOGY

2nd Marine Aircraft Wing Marine Runs 48.6 Miles, Raising $11,000 for Leukemia

By Cpl. N. W. Huertas

Sergeant Ashley Rowback was on her last couple of miles in the final event of the most grueling physical challenge she'd ever faced when she finally hit her wall. "What do I do now?" she asked herself. "Do I walk, do I give up?" As if an answer to her own internal turmoil, she glanced at a fellow runner and knew she had the strength to finish the race.

Amongst the crowd of runners was a woman who wore a bandana over what little hair she had on her head, and a ball cap with the word "Survivor" embroidered across the front. As the woman ran her own race in a sea of more than 35,000 fellow runners, her steady pace and obvious determination to cross the finish line gave Rowback the boost she needed to overcome her own personal struggle.

This was no ordinary road race. Rowback and the others were grinding through the final leg of a four-day race that would total nearly 50 miles — a sequential series of runs starting at 5 kilometers the first day, followed by a 10K, a half marathon, and finishing with this soul-testing full marathon over the

Sergeant Ashley Rowback poses for a photo at Marine Corps Air Station Cherry Point, N.C., Feb. 5, 2016. Rowback recently completed a 48.6 mile four event race and raised more than 11,000 dollars for leukemia and lymphoma research in memory of her late grandfather. Rowback's love for running has given her the ability to use something she enjoys as a way to raise awareness. Her passion for physical fitness has shaped her career in the Marine Corps and has paved the way for her transition into the nursing field upon her exit from the Corps. Rowback is the 2nd Marine Aircraft Wing commanding general's driver. *U.S. Marine Corps photo by Cpl. N.W. Huertas/ Released*

Carl Hornbeak-Hess, an 11-year-old from Mill Creek, Wash., stands in front of a World War II Army jeep at the USS Missouri Battleship Memorial, Feb. 15. Hornbeak-Hess, who has been diagnosed with acute lymphoblastic leukemia, dreamed of becoming a World War II Army Air Corps pilot whose aircraft is shot down and crash lands on a deserted island. He was granted his wish with the help of Marines, Sailors and the Make-A-Wish Foundation. *Photo by Lance Cpl. Nathan Knapke*

remaining three days — 48.6 miles in all. And every runner there had their own personal reasons for taking on that monstrous challenge. For Rowback, it was another stride in her marathon against the deadly ravages of leukemia and lymphoma, inspired by the memory of her late grandfather.

Rowback's love for running began at an early age, but her grandfather's brief struggle with acute leukemia nearly seven years ago spurred her to turn something she enjoys into a way to raise funds and awareness for leukemia and lymphoma research. And that focus, with its passion for physical fitness, has shaped her career in the Marine Corps and has paved the way for a planned future in the field of nursing.

"The amount of strength my grandfather had to fight his short, 17-day battle with cancer is the reason I do these races," explained Rowback. "Being able to raise money, and then put my body through pain in order to help find a cure is the only reward I will ever need. The little bit of suffering I have to go through will never compare to what a child, mother or grandfather has to go through to fight cancer, and hopefully kick cancer's butt."

As the 2nd Marine Aircraft Wing commanding general's driver, Rowback has proven to be an exemplary Marine throughout her time at Marine Corps Air Station Cherry Point. She was originally an air support network operator with Marine Air Support Squadron 1. While working under the operations officer, her squadron sergeant major nominated her for the position of the general's driver based on her strong work ethic and her reputation as a well-rounded Marine.

"I don't think you can be fully ready as a Marine if you're not physically ready," explained Rowback. "Being mentally ready is important, but if you cannot physically do something, then you are stuck. Being a well-rounded Marine means to strive to provide the best in every aspect of your life. You must know your job, be physically capable of performing, be mentally strong, and carry out beliefs and traditions."

According to Rowback, nutrition, physical activity and overall health have been a large part of her life for many years. Her drive to help others live a healthy lifestyle was initially motivated by her family's health history and the determination to be a good example for her younger family members. From there, that desire seemed to grow legs of its own.

"The first half marathon I ever ran was the Marine Corps half marathon on Marine Corps Base Camp Lejeune with my father and a friend," said Rowback. "I did not think I would be able to finish those 13.1 miles." But, said Rowback, it was a self-rewarding experience that left her addicted to running races, while fulfilling her desire to help others who need it.

Looking back to that exhausting four-day race in January, Rowback thinks of the nearly $11,000 she and her father, who ran the race with her, raised for medical research. When she had hit her personal wall, it was her father's encouragement, her grandfather's memory, and the inspiration of the other struggling runners around her that made that accomplishment possible.

Remembering the survivor who ran next to her, Rowback said, "She reminded me of the real reason I was there. I run for people who can't run, or those who can't tell their stories. This is my way of giving back to them."

2ndmawm.marines.mil

Active
ONCOLOGY

Air Force Chief's Resilience Conquers Breast Cancer

By Kevin M. Hymel, Air Force Surgeon General Public Affairs

Chief Master Sergeant Yolanda Jennings recalled that when doctors diagnosed her with breast cancer in September of 2008 she was not surprised, but she was scared.

"No one wants to hear that," Jennings, who now works at Maxwell Air Force Base's Air University, recalled. At age 37, she was below the at-risk age for cancer, but when she suspected she might have the disease after a self-diagnosis, her friends told her it was probably something else. "I kind of knew," she said.

Jennings, whose mother had died of multiple myeloma four years earlier, was diagnosed with triple-negative breast cancer, a rare and often aggressive form of breast cancer which tends to occur in younger women and African-American women, according to the Susan G. Komen organization. "It hits a lot of minorities," said Jennings, "and they don't survive."

The worst part for Jennings was the uncertainty about the future and the idea that she would never see her children. "I prayed a lot," she remembered.

Fortunately, her doctors caught the cancer early. She started her first round of chemotherapy on Halloween and

Maxwell AFB, Ala. - Chief Master Sergeant Yolanda Jennings works on a project with Senior Airman Jameka Ruta, Oct. 14, 2015. Jennings is a breast cancer survivor. *U.S. Air Force photo by Melanie Rodgers Cox/Released*

Members of the 7th Medical Group show off their pink morale shirts at Dyess Air Force Base, Texas. Members of all three squadrons within the 7th Medical Group wore pink morale shirts every Friday throughout the month of October to remind patients to schedule their mammogram screenings. *U.S. Air Force photo by Senior Airman Shannon Hall/Released*

benefitted from an accelerated program. She then went through 30 rounds of radiation, and completed her entire treatment seven months later, in April of 2009.

Through it all, she had the support of her husband and daughter. "She was my little nurse," said Jennings. Her fellow office workers at Tinker Air Force Base, Okla., also supported her as she went in every day. "I wanted to come to work,"she added. "I did not want to be 'oh woe-is-me' about it."

Working made her feel better. Her Thursday chemotherapy treatments would hit her the next day around 2 p.m. "I would tough it out until three on Fridays." Yet she did not miss any work once her chemotherapy port was placed. "I even did PT!" Her oncologist was so impressed with her condition, he told her, according to Jennings: "Whatever you're doing keep doing it."

Her wing commander was especially supportive. When her hair fell out and she had to wear an uncomfortable wig that itched, he told her to do whatever was comfortable. She took off the wig and he smiled and encouraged her to walk the office halls, pretending she didn't know she was bald. When people told her so, she would touch her head and scream, "Ahhh!" Of her time in the office she recalled, "I had fun with it."

Jennings' treatments did not limit her career either. When she learned of an open position with the Secretary of the Air Force, she wanted to apply. Even though her chemotherapy had ended, she was still receiving radiation treatments.

Her wing commander told her that he would put her in for it. She flew to Washington, D.C., and interviewed with Air Force Secretary Michael B. Donley. She wore her wig, but Donley, whose wife was an oncological nurse, told her if she was uncomfortable to take it off. She did. "It was a great interview," said Jennings. On her flight back to Tinker she learned she had the job.

Now a cancer survivor of seven years, Jennings encouraged others, "If there's something you want to do, do it, because you are not promised tomorrow." She took her own advice when her job with Secretary Donley ended and she took a job on Air Force One. "I flew around the world with the president." When she realized there were not many African-American female chiefs in the Air Force, she studied for it and achieved the rank of Chief Master Sergeant. "I did what I needed to do," she said, "and now I'm at Maxwell [Air Force Base] at an amazing job." When people ask her about retirement she says,"I'm having too much fun."

Jennings finds inspiration in events with fellow survivors and friends. At a three-day, 50-mile cancer walk, her roommate at the time, who did not have cancer, told her, "If you can do this I can do this." At a cancer run in Washington D.C., Jennings and her fellow runners cheered on an older woman who wore a t-shirt that read,"I am a 36-year survivor."

Her advice to women who suspect they might have breast cancer was direct: "Get checked. If you feel something is wrong, ask for a mammogram. I had to ask." And if someone is diagnosed with breast cancer, she encouraged: "Don't give up," adding, "fight through it whatever it is." She goes to her Medical Evaluation Board every year. "The Air Force is not looking to put you out because you're sick, they're doing it to make sure you're fit."

Today, Chief Jennings appreciates how the Air Force helped her through her diagnosis and treatment. "I'm glad I was in the military," she said of the morale and health-care support she received. "I give them 110 percent."

For more women's health information visit: http://www.breastdiseasesatoz.org/

airforcemedicine.af.mil

Active
ONCOLOGY

February is National Cancer Prevention Month

By Greg Chadwick, Air Force Materiel Command Health Wellness Team

During the month of February, Air Force Materiel Command and Hanscom Air Force Base, Massachusetts, will promote its Cancer Prevention Awareness Campaign.

The goal of the campaign is to inform members of the workforce on ways to reduce their risk of developing lung cancer and colorectal cancer. Among cancers that affect both men and women, lung cancer and colorectal cancer are the two leading causes of cancer-related death in the United States.

Throughout the month, Hanscom's Health Promotion Services offered members of the civilian workforce classes on ways to lower the risk of developing these cancers.

"The truth is, there's no sure way to prevent cancer, but there are things you can do to reduce your chances of developing cancer," said Orlagh Pawlyk, CHPS coordinator. "In this class we'll briefly review what cancer is, some facts about cancer in the United States, and several behaviors we can take to lower our cancer risk, which sometimes includes getting screened for cancer."

Lung cancer is by far the leading cause of cancer-related death for both men and women. Each year, more people die of lung cancer than of colorectal, breast, and prostate cancers combined. Overall, the lifetime probability for a man to develop lung cancer is 1 in 13; for a woman, the risk is 1 in 16.

According to the Centers for Disease Control and Prevention, personnel can lower the risk of developing lung cancer in the following ways:

- Don't smoke and avoid secondhand smoke. Cigarette smoking is linked to about 90 percent of lung cancers.
- Have a home radon test done. Radon is a naturally occurring gas that comes from rocks and dirt and can be trapped in houses and buildings. Radon is the leading cause of lung cancer among non-smokers.
- Take precautions to avoid exposure to airborne hazards such as diesel exhaust and chemicals. Follow health and safety guidelines in the workplace to reduce or eliminate the hazard.

Colorectal cancer is the second leading cause of cancer-related deaths in the United States, when men and women are combined. Colorectal cancer occurs in the colon or rectum. Sometimes it is called colon cancer. The lifetime probability of someone developing colorectal cancer is about 1 in 20.

AFMC will promote Cancer Prevention during the month of February.

The CDC lists the following ways to lower the risk of developing colorectal cancer:

- For those age 50 and older, get screened for colorectal cancer. Screening tests help prevent colorectal cancer by finding precancerous polyps (abnormal growths) so they can be removed. Screening also finds this cancer early, when treatment can be most effective.
- Maintain a healthy weight according to the Body Mass Index. Healthy weight range is 18.5 to 24.9 on the BMI height & weight chart.
- Be physically active with 150 minutes of moderate-intensity aerobic activity weekly.
- Don't smoke.
- Limit alcoholic beverage consumption to 1 drink per day for women and no more than 2 drinks a day for men.

Research is ongoing to find out if changes to diet can reduce the risk for colorectal cancer. Recent studies conducted by the World Health Organization suggest that regular consumption of processed meat such as bacon, hot dogs and sausages, can increase colorectal cancer risk.

af.mil

Active
OPHTHALMOLOGY

New Consortium to Support Vision Research

By Steven Galvan, U.S. Army Medical Research and Materiel Command

Wounded warriors with traumatic eye injuries may have a chance to see again with the support of a new research effort called the Horus Vision Restoration Project coordinated by the U.S. Army Medical Research and Materiel Command.

The project will be designed to restore sight through an artificial prosthetic eye. Researchers hope to develop a prototype within five years.

"It will take a lot of people working together to make it happen," said Dr. Kenneth Bertram, USAMRMC Principal Assistant for Acquisition.

The Horus Vision Restoration Project is the first project launched under the Medical Technology Enterprise Consortium.

MTEC is a newly established 501(c)(3) corporation created to open new avenues of opportunity for USAMRMC with large and small companies, universities, foundations and other entities to develop forward-looking medical technology solutions in an accelerated timeframe through flexible and innovative business practices.

"It is a mechanism to build partnerships [public and private entities] that will benefit warfighters and civilians," said Dr. Frazier Glenn, USAMRMC Principal Assistant for Research and Technology.

> "MTEC will improve flexibility and allow for discussions with partners that keep us moving ahead," added Glenn.

Capt. Nicholas Jones, 60th Aerospace Medicine Squadron optometry flight staff optometrist, conducts an eye examination last month at the optometry clinc at David Grant USAF Medical Center. *U.S. Air Force photo/1st Lt. Angela Martin*

Leadership held a pre-proposal conference regarding MTEC management at the Military Health System Research Symposium in Fort Lauderdale, Florida on Tuesday, Aug. 19.

A final solicitation for management is expected to be released in October 2014. The award is expected to be granted in the spring of 2015.

"This is a 10-year award," said J.B. Phillips, PhD, Office of the Principal Assistant for Acquisitions at USAMRMC. "USAMRMC would fund the first six months and up to two years if needed."

Bertram said other MTEC projects that could design and provide care during medical evacuation in high risk environments, such as under hostile fire, and reduce the cost, weight and complexity of prosthetics.

"MTEC will improve flexibility and allow for discussions with partners that keep us moving ahead," added Glenn.

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Active
OPHTHALMOLOGY

Make Eye Health a Priority during Healthy Vision Month

By Kristin Ellis, Fort Belvoir Community Hospital Public Affairs Office

Healthy Vision Month is a great opportunity to learn about eye health and promote the importance of regular, comprehensive eye exams in maintaining healthy vision, according to Fort Belvoir Community Hospital Department of Optometry.

Early detection and timely treatment of eye disease are key ways to prevent vision loss and blindness. Many people who are at risk for vision loss do not know it, and millions of people living in the United States have undetected vision problems and eye diseases and conditions.

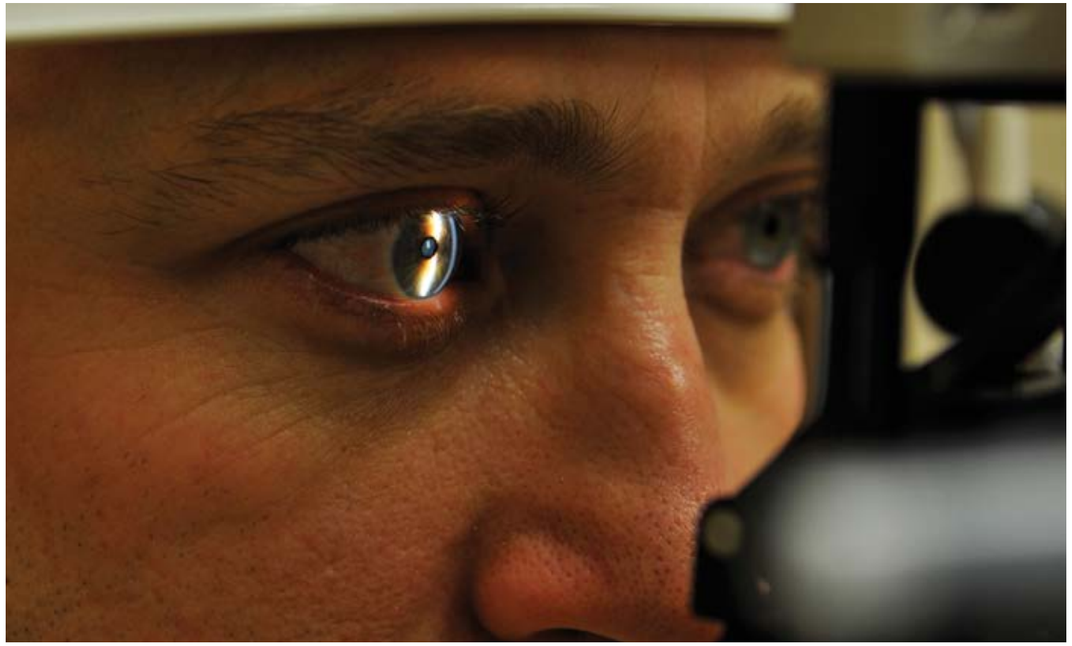
"Healthy vision starts with a healthy lifestyle," said Maj. Ginger Emig, chief of Optometry. "Patients who take an active role in their overall health will be better off in the long run."

A well-balanced diet and regular exercise can prevent diseases like diabetes and hypertension, which can cause vision loss if uncontrolled, she added. The number one preventable cause of blindness is uncontrolled diabetes.

In addition to routine annual eye exams, it is important to remember to wear proper eye protection during sports and potentially dangerous activities such as working with machinery. It is also good to wear sunglasses with UV protection whenever outdoors, as UV light can speed up the formation of cataracts, Emig said.

Belvoir hospital Optometry is self-referral and offers routine comprehensive vision evaluations to include vision checks and ocular health evaluations for diabetes, glaucoma, cataracts. The hospital also has the Warfighter Refractive Eye Surgery Program which is open to active duty Army, Navy, USCG, and Marines who qualify to be able to receive refractive eye surgery.

"Patients are commonly confused about the difference between a full eye exam



U.S. Air Force photo/Staff Sgt. Christopher Boitz

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and a vision screening," said Army Capt. Derek Black, Belvoir hospital optometrist. "An eye exam is a visual and ocular health evaluation done by either an optometrist or an ophthalmologist. A vision screening only tests one aspect of ocular health and is usually performed during a routine physical at a [primary care manager's] office."

A routine eye exam consists of a vision screening, eye pressure test, refraction (checking for glasses prescriptions), and an ocular health examination by the optometrist.

"During a routine exam we look for things like 'lazy eye in children, need for spectacle correction, glaucoma, diabetes, high blood pressure, high cholesterol, macular degeneration, cataracts, dry eye, allergies and many more ocular conditions," said Emig.

Active duty are authorized as many visits as it requires to make them "Vision Ready." TRICARE Prime patients are authorized one exam every calendar year. TRICARE Prime Retirees and their families are authorized one routine eye exam every 24 months. TRICARE Standard/Extra/For Life do not have routine eye examination coverage through TRICARE and can be seen at any Optometry office of their choice.

Patients with medical diagnosis like diabetes and other specific eye diseases are recommended to receive annual ocular health evaluations. Belvoir hospital is currently seeing active duty and TRICARE Prime patients between the ages of six and 64.

"We have state of the art equipment that can complete disease screenings in one visit and cut down the need for return appointments," said Emig.

"We also have a great co-management with pharmacy, ophthalmology, and the lab. Patients can pick up their medications in the same location as their appointment."

Other MTF optometry clinics (Bethesda, Fairfax, Dumfries, Rader, Andrews, Bolling) are seeing other populations and demographics which is why it is important for patients to utilize IRMAC for booking since they have the ability to be see and book at all Optometry clinic in the NCR, Emig said.

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Active
OPHTHALMOLOGY

Advancing Vision Care Paramount for Service Members Health

By Paul Bello, National Museum of Health and Medicine

Military personnel endure numerous attacks that potentially impair their vision, whether from a direct blast, traumatic brain injury or environmental exposure. With May designated as Healthy Vision Month, the National Museum of Health and Medicine (NMHM) seized the opportunity to welcome U.S. Navy Capt. Penny Walter, executive director, Department of Defense (DoD) Vision Center of Excellence (VCE), to its monthly Medical Museum Science Café, May 26. Her discussion included certain types of eye injuries and the treatments being developed to repair vision for service members.

Walter has served in the optometry field since being commissioned as a lieutenant in 1989. She said casualties from present conflicts are leading to changes in healthcare needs, as well as changes in research and development. She estimates that approximately 29 percent of service members sustain some type of head or neck injury. When it comes to injuries from an improvised explosive device (IED), she said most require a collaboration between multiple specialties, such as plastic surgery, neurosurgery, facial reconstruction, physical therapy, and behavioral health.

"It's not unusual for patients who suffered a blast or multiple blasts to lose consciousness or have a traumatic brain injury (TBI). It's being called the signature injury of the current war," Walter said. "Visual consequences are also quite common and have symptoms such as loss of focusing near or far, the inability to concentrate, double-vision, photo phobia (a sensitivity to light) and visual field loss." While vision itself can be good after a mild traumatic brain injury, Walter explained that visual processing is what's often impaired. Treatment can also be frustrating because not much can be done surgically or medically beyond prescribing glasses or providing supportive care. Because the role of vision therapy has not yet been proven or disproven, Walter noted there's significant interest in providing visual therapy to patients in DoD and Veteran Affairs (VA) healthcare systems.

"Since most of the patients remain on active duty, their treatment would remain within DoD facilities," Walter said. "Deactivated reservists would return home and seek therapy from VA administration or community healthcare systems."

Another group of patients exist in the middle, according to Walter. Those with a history of blast or concussive trauma, but without obvious gross ocular injuries. Many times vision impairment will not become evident until several months after the injury. These individuals may or may not have ocular syndromes, but will have significant demonstrable ocular damage, such as angle recession where the drainage angle of one's eye gets ripped. If that's damaged, the cornea will swell and everything will look blurry, Walter said.

The DoD is currently examining how blast waves affect the eyes. The organization is starting to put chips in helmets to help gauge the strength of a blast wave. Walter expects that these chips will lead to better treatment, but that much research is on the horizon before knowing more answers. (An example of one such modified helmet is on display at NMHM.

"Not long after our creation in 2008, the Vision Center for Excellence created a vision registry of data to help guide research, clinical education, to promote best practices and inform policy," Walter said. "The registry has come a long way in a short amount of time. It translates vision related data into manual information and empowers the vison care community to support vision care analysis."

Other education initiatives include the center's campaign "Shields Save Sight," which encourages service members to proactively wear eye protection, even when at home. According to Walter, almost half of all eye injuries occur around the home, most often during home improvement projects (44%) or recreational sports (14.7%), based on studies conducted by the VCE.

Inpatient and outpatient care stat sheets have also been created for patients who are blind or partially sighted. These sheets help remind staff what to do when someone comes in with this type of condition. Workshops on vision disorder are also conducted to keep providers technically competent.

"Assimilation is a proactive skill and we want people to remain fresh in that arena," Walter said. "Our mission is to enhance the quality of life for our service member and veterans."

NMHM's Medical Museum Science Cafés are a regular series of informal talks that connect the mission of the Department of Defense museum with the public. NMHM was founded as the Army Medical Museum in 1862 and moved to its new location in Silver Spring, Maryland, in 2012.

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Active
ORTHOPEDICS

Military Medicine, VA Ramp Up Sharing Patients in San Antonio

By Dewey Mitchell, Brooke Army Medical Center Public Affairs

In a move that helps veterans, and active-duty military patients and their families, local Veterans Affairs, or VA, and military medical facilities have dramatically increased their work-share agreements over the past two years and are seeking to add more.

Brooke Army Medical Center, or BAMC, the Air Force's 59th Medical Wing and the South Texas Veterans Health Care System, or STVHCS, have a combined 15 sharing agreements that give patients quicker access to health care by redirecting them to treatment facilities with convenient appointment slots.

Current agreements between BAMC and STVHCS cover a wide range of services including equipment sterilization, medical services, surgical services, the Integrated Disability Evaluation System, or IDES, transition services at the Center for the Intrepid, and ear, nose and throat, or ENT, surgery.

For BAMC, the most recently approved sharing agreement covers ENT surgical services, where the number of VA patients seen has increased dramatically since October 2013.

"The services provided and workload performed under these sharing agreements provides valuable wartime skill sustainment for DoD medical professionals, fuels 37 graduate medical education programs, enhances access to care for VA beneficiaries while simultaneously optimizing federal funding," said Col. Evan M. Renz, BAMC commander.

Agreements cover surgical services including but not limited to general surgery, ear nose and throat, gynecology and orthopedic surgery.

Similar agreements between the 59th Medical Wing and STVHCS cover blood bank services, sterilization, IDES, radiation oncology, surgical supervision, and medical services including but not limited to endoscopic ultrasound, sleep studies, dermatology laser treatments, and dialysis treatments.

Patients with access to the 59th Medical Wing's North Central Federal Clinic also benefit from the program.

"Work share agreements between the VA, BAMC and the 59th Medical Wing improves efficiency and effectiveness across a multitude of military healthcare services," said Maj. Gen. Bart Iddins, 59th Medical Wing commander.

"We are saving taxpayer dollars at a time when responsible stewardship of government resources is paramount. Appointment slots, that would otherwise remain vacant, are now filled," Iddins said. "Military medicine is focused on providing world-class, high quality, safe healthcare to our number one customer - the patient. We remain patient-centered in all we do, and work share agreements bolster this commitment."

Looking ahead, the San Antonio Military Health System, which integrates Army and Air Force health care services in the local area, is discussing several potential new agreements with local VA facilities.

These include expanded OB/GYN services — STVHCS is paying for newborn deliveries at civilian medical facilities. BAMC has the capacity to perform this work and the increased number of deliveries would be valuable for the OB/GYN residency program.

Talks are progressing. The organizations have agreed in principle and now must work out the details, draft the agreement, and submit for approval.

Other areas being discussed for possible work-sharing include radiology services, vascular surgery, inpatient behavioral health, and hyperbaric oxygen therapy.

"South Texas Veterans Health Care System has a strong partnership with DoD, and we look forward to pursuing other opportunities in the future to continue to provide the best health care possible to both VA and DoD beneficiaries," said Dr. Julianne Flynn, STVHCS chief of staff.

There are also discussions for sharing initiatives with the Texas Valley Coastal Bend Veterans Health Care System, which could potentially involve the provision of surgical and medical services to VA patients living south of San Antonio.

This VA system covers a large, mostly rural area with a shortage of civilian specialty and sub-specialty providers. Talks are still in the early stages, but BAMC has agreed to take cases as space permits on a fee-for-service reimbursement method according to federal fee schedules.

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Active
ORTHOPEDICS

Army Orthopedic Surgeon Cited as Hero for "Shining Light" on Combat Care

"More than any other crucible, war brings out the worst and best of mankind," said Vice Chief of Staff of the Army Gen. Daniel B. Allyn. "Without question, it is our military medical professionals who reflect the amazing light of creativity, compassion and exquisite care, and it is especially brilliant in these darkest moments."

Allyn was named as a "Hero of Military Medicine, Senior Leader Honoree," May 5 during the Heroes of Military Medicine Awards banquet in Washington, D.C.

"For 35 years as an infantryman, I've experienced first-hand the skill, ingenuity and passion of our medical professionals across the joint force," Allyn said. "I've seen corpsmen, medics, doctors, nurses and technicians from all services leverage their craft to save lives under the most demanding environments on the face of the Earth."

Included among those medical professionals is Army Col. Martha K. Lenhart. She is an orthopedic surgeon, has a doctorate in pathophysiology, and specializes in hand surgery. She is also responsible for publication of numerous medical books.

Lenhart was named the "U.S. Army Hero of Military Medicine" during the same event, and introduced Brig. Gen. Robert D. Tenhet, the deputy surgeon general of the Army and the deputy commanding general (support) of U.S. Army Medical Command.

"All our Soldiers, Sailors, Airmen, and Marines have the opportunity to represent our country as diplomats," Tenhet said. "During her Afghanistan deployment, Col. Lenhart recognized the need for a focused approach to management of the injuries of infants and children in combat scenarios."

Col. Martha K. Lenhart, MD, PhD, second from the left, was named the U.S. Army Hero of Military Medicine during the 2016 Heroes of Military Medicine Awards, May 5, 2016, in Washington, D.C. On stage with Lenhart are Brig. Gen. Robert D. Tenhet, the deputy surgeon general of the Army and the deputy commanding general (support) of U.S. Army Medical Command, left; John W. Lowe, president and CEO, the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., second from right; and Cynthia L. Gilman, vice president, Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. Center for Public-Private Partnerships, on the right. *Photo Credit: C. Todd Lopez*

Out of her experience there, Tenhet said Lenhart spearheaded publication of a book that would be "the first-ever pediatric military medicine book," called "Pediatric Surgery and Medicine for Hostile Environments." That book was cited by the American Medical Writers Association as "the book most likely to save a life." The book informs other doctors around the world about ways to provide better care for injured infants and children in combat environments.

"Some would question why we in Army medicine would ever have a pediatric orthopedic hand surgeon specialist in our ranks, and what possibly that could bring to the fight," Tenhet said. "Col. Lenhart's actions answered that question loud and clear. By looking at the battlefield's casualties through the lens of a pediatric hand surgeon, she viewed the chaos in ways others did not. She saw not only a medical need, but a humanitarian need as well. And she did something about it.

"There are people in Iraq and Afghanistan who noticed, and the long-range diplomatic effects can be numerous. No amount of political propaganda can displace the emotional connectives that occur when one human connects to another human in a supportive, compassionate, and caring way."

Lenhart served in Afghanistan in 2003 at Bagram Air Base, early on in the conflict, before the invasion of Iraq. "I walked into our tent hospital, our combat support hospital, and it was filled with local national children," Lenhart said. "That was my first exposure to Afghanistan, to the combat support hospital, and to our patient load — which was largely children."

Their facilities were set up then for adults — adult Soldiers. But at the time, she said, there were "very few Soldiers."

"You needed to improvise, in terms of what we did surgically," she said. "We needed to adapt some of the instruments. We also developed some ambulatory devices for some of these children. I'd draw a picture and work with our medical maintenance staff, because he would engineer it. He'd engineer this equipment."

One example, she said, was for a patient with a single-leg amputation and forearm injury who couldn't use crutches appropriately without putting inappropriate weight on the injured forearm. She said they had to adapt the crutches to make them the correct height, but also adjusted them to allow those crutches to be used to not put weight on the forearm.

Later in Iraq and Afghanistan, there was the Rapid Equipping Force that could bring gear in to make it easier to produce novel equipment, on the fly. But not back then, she said. "There was no 3-D printing then. There was no equipment like that. We were in a tent hospital. I slept in a GP medium tent."

Lack of supplies in Afghanistan was exacerbated, she said, when the war in Iraq kicked off. "At the time it was so surreal. I was in Afghanistan, watching the invasion of Iraq on TV in the morale, welfare, and recreation tent," she said. "We watched U.S. troops go into Iraq. What happened subsequently was that our supply lines were diverted. We had a difficult time getting some of the surgical supplies we needed.

Col. Martha K. Lenhart, MD, PhD, on the right, and husband, Dr. James Cox, Jr., Col., USAF (Ret), on the left, attended the 2016 Heroes of Military Medicine Awards, May 5, 2016. Lenhart was named the U.S. Army Hero of Military Medicine.
Photo Credit: C. Todd Lopez

"The junior officer who was an orthopedic surgeon and who had just graduated from his residency was my partner there," she said. "He'd been a rotor-wing pilot before he'd gone into orthopedics — a really great guy. We're standing at the scrub sink and lamenting the fact that our supplies weren't what we wanted. And I said to him 'we're going to have to improvise,' and he counters, 'we weren't already?'"

Lenhart served in both Iraq and Afghanistan, and at least two books came out of those experiences. She served as the director and editor in chief of "Pediatric Surgery and Medicine for Hostile Environments" and also as editor in chief of the award-winning "War Surgery in Afghanistan and Iraq."

On the latter, she said, in order to get that book out to medical providers as fast as possible, she worked with the Army to get the book distributed digitally into the field in advance of the availability of paper copies — though that happened too. "It was the first time they had ever transmitted a book like that through the Theater Data Medical System," she said.

For medical professionals who have never served in combat environments, she provided this advice: "You have to be very cognizant of your circumstances, use your resources wisely, and be able to improvise, but do it in a smart way. You must understand the mechanics, and understand the anatomy, and understand what it is you are trying to accomplish in those particular areas, and know that what it is you are doing in certain cases isn't the definitive surgery, but rather it is a stabilizing procedure so that you can then transport these casualties to higher levels of care."

Lenhart said she accepted the award "on behalf of thousands of heroes who have served and continue to serve our country, ensure its safety, and contribute to the welling of troops."

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Active
ORTHOPEDICS

Non-Battle Injuries Result in More Medical Evacuations Than Combat

By Veronique Hauschild, Injury Prevention Program, U.S. Army Public Health Command

If you ask Soldiers what the biggest physical health threat they face while in the Army, only a portion are aware that it has nothing to do with warfighting.

In fact, the primary health threat to troops for more than two decades has been common muscle, joint, tendon/ligament and bone injuries like knee or back pain that are caused by running, sports and exercise-related activities such as basketball and weightlifting.

These activities are not just a primary cause of injuries in stateside locations, but also in deployed locations.

"Non-battle injuries resulted in more medical air evacuations from Afghanistan and Iraq than battle injuries," said Keith Hauret, an epidemiologist at the U.S. Army Public Health Command, or USAPHC. "The leading causes of these non-battle injuries were physical training and sports."

One health provider responding to a recent USAPHC anonymous survey about injuries noted, "we spend time and money training a Soldier to become 'physically fit' — but because we don't do this right — we over-train them to the point of injury — so they are given restricted duties or medically discharged before they can ever fight our wars."

These injuries continue to cause temporary or even permanent disability and limit the physical capability of thousands of active-duty Service members each year. The impacts include millions of clinic visits annually, millions of lost or restricted duty days, as well as millions of dollars in medical costs.

Leaders need to be better educated on taking care of Soldiers

The Army places a great deal of emphasis on training Soldiers so they are fit and capable of successfully performing their physically demanding jobs. But physical training can stress the body and cause various muscle, skeletal, tendon or ligament injuries. Soldiers can also get caught up in the competitive nature of sports programs and overdo it, resulting in sprains, strains or more severe injuries.

"While participating in physical activities such as running or sports puts you at risk for an injury, the risk of injury should certainly not be interpreted as an excuse to not exercise," said Dr. Bruce Jones, injury prevention program manager at USAPHC. "Instead, high or increasing injury rates should be a wake-up call to leaders, indicating a need to adjust the physical training program to prevent over-training. This will reduce injuries and ultimately enhance fitness and physical performance."

Army medical experts say training should be conducted in a way that avoids preventable injuries.

"Fit, healthy and uninjured Soldiers are what make an exceptional Army," said Maj. Tanja Roy, an epidemiologist at the USAPHC. "Unit leaders should follow proper physical training guidance and be careful to avoid over-training Soldiers with too much running or improperly instructed exercises."

It's not just the lack of leadership awareness that prevents the Army from avoiding first-time injuries. To some health care providers it is sadly ironic that remedial physical fitness, or PT, programs often force less fit individuals to work out twice a day — which ultimately can result in injury making it more difficult to meet the standards.

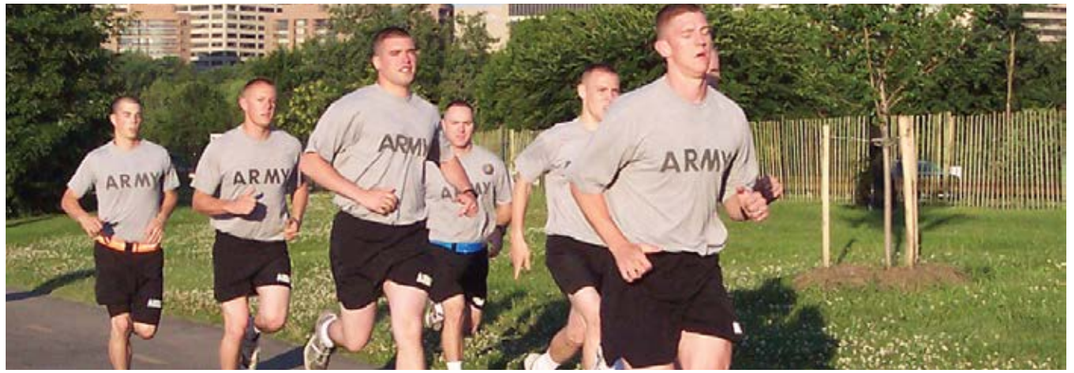
In the USAPHC anonymous survey, one Army medical provider noted, "I am currently seeing a patient for an ankle fracture. He is in a cast and on crutches, yet was forced to walk for his (physical training)."

Injury prevention experts say the lack of proper procedures increases risk of re-injuries and costly chronic conditions especially as these Soldiers age. They report that some Soldiers are forced to run every day and are plagued with lower back pain and knee pain.

So what can a Soldier do to prevent injuries?

Simply put: train smarter. There is scientifically supported guidance and doctrine that describes injury prevention to be a priority in the Army.

All Soldiers, but especially leaders, should be aware of behaviors or conditions that put individuals at increased risk of exercise-related injuries as well as training principles that can prevent them. Examples include:



The primary health threat to troops for more than two decades has been common muscle, joint, tendon/ligament and bone injuries like knee or back pain that are caused by running, sports and exercise-related activities.

- Excessive running is the most common cause of overuse injuries especially in feet, ankles or lower legs. These can be avoided by using a training regimen that incorporates alternative days of low-impact aerobic workouts (e.g. swimming, biking or rowing) and days of strength training. Running distances and durations should be slowly increased over time, and Soldiers should not be forced to run if injured. Cadence runs are not recommended as a fitness method (for esprit de corps only), and group runs should be organized by pace and distance abilities.
- Balanced physical fitness programs should include a mix of aerobic, strength and agility drills and conditioning exercises. Studies that have evaluated the effectiveness of the Army's standardized Physical Readiness Training, or PRT, program described in Army field manual 7-22 have shown that units following the PRT program had significantly lower injury rates than those following a run-centric PT regimen.
- Basketball injuries predominantly involve the foot or ankle. Scientific studies have shown that the use of semi-rigid ankle braces during basketball significantly reduces the risk of recurring ankle injury. Likewise, science has shown that wearing mouth guards during basketball reduces the number of people with broken teeth and other mouth-related injuries.
- Weight-lifting and high-intensity extreme conditioning programs most often involve the shoulders and back. These injuries are often linked to improper form and using too much weight too quickly. These injuries are not likely to be prevented with equipment. While some Soldiers choose to wear back braces during weight-lifting, substantial evaluation of this equipment has not shown them to reduce injury — in fact they may actually increase risk. Though the best physical training routine will include strength training, as with running, the physical training principles of moderation, slow progressive increases and form are important to avoid injuries.
- Military training activities other than exercise, such as parachuting and combatives have also been associated with high rates of certain types of injuries. Though not always used, some equipment has been proven to prevent these injuries. For example, mouth guards are now required during combatives, as they are proven effective at reducing painful and costly teeth and mouth injuries. Ankle braces, though not required, have also been proven as an effective tool to reduce parachuting ankle injuries.

Balancing exercise regimens and gradually building up performance levels

Through its performance triad campaign, the Army's medical community continues to encourage incorporating exercise into every Soldier's routine.

"The duration, frequency, level and type of exercise activity, however, should be balanced against known injury risks," Jones said. "Remember that regardless of how fit and how strong you are, an injured back, a sprained ankle, a stress fracture or a torn shoulder ligament can put you out of commission for days, weeks or longer. If not prevented or properly treated, an overuse injury can become a chronic debilitating condition."

By carefully following proper training techniques, avoiding over-training, and adhering to scientifically proven exercise regimens, Soldiers can help to prevent injuries and improve fitness.

NOTE: The Army's Institute of Public Health has studied Army injury trends and risk factors for years and published numerous articles and reports on these topics. Technical references can be provided by contacting the program at usarmy.apg.medcom-phc.mbx.injuryprevention@mail.mil. The program is also currently developing educational products to help increase awareness of common physical training related injuries and prevention tactics.

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Researchers Investigate Respiratory Health of Deployed Personnel during Operations

By Mr. Ronald W. Wolf (Army Medicine)

Military personnel who deployed during Operation Iraqi Freedom, or OIF, Operation Enduring Freedom, or OEF, or Operation New Dawn, or OND, were commonly exposed to airborne hazards such as dust and smoke, Army Medicine researchers say.

Some may have developed respiratory diseases and still have medical consequences as a result. Army Medicine researchers are continuing to investigate possible long-term effects of this exposure, and need your help.

Col. (Ret.) Michael J. Morris, MD, San Antonio Military Medical Center, is the lead investigator for the Study of Active Duty Military for Pulmonary Disease Related to Environmental Deployment Exposures, also known as STAMPEDE.

Dr. Morris and his team need volunteers who deployed to OIF, OEF, or OND, developed respiratory symptoms while deployed, and who still show these symptoms to assist with a research study. The STAMPEDE team aims to enroll 300 patients (from any branch of military service).

The following are study eligibility requirements for individuals who would like to be considered for STAMPEDE:

1. Deployment to OIF/OEF/OND on active-duty status;
2. Developed chronic respiratory symptoms during or soon after deployment;
3. Can exercise on a treadmill;
4. Had no history of pre-existing lung disease before deployment;
5. Are able to spend a week in San Antonio for testing procedures;
6. Can provide civilian or Veterans Affairs, or VA, medical records (if available).

Participants enrolled in the study will undergo a standardized testing protocol to include: surveys, blood work, chest imaging, echocardiography (examination of the heart), several different breathing tests, exercise testing, laryngoscopy (vocal cord examination), and bronchoscopy (airway examination).

While there is no guarantee of benefit from joining the study, it is possible that participants will benefit from identification and evaluation of shortness of breath and learning if any lung disease related to deployment is the cause of this shortness of breath.

The ongoing research of Morris and his team is important because active-duty personnel still deploy to areas where exposure to particulate matter from dust, sand storms, burn pits, explosions, and vehicle exhaust is common. This research may help build the knowledge base needed to treat Service members and veterans more effectively in the future.

A number of medical studies already have looked at the consequences of exposure to airborne dust and smoke from burn pits among Service members, going as far back as the first Gulf War. In the 1990s, the possible consequences of exposure to oil fires in Kuwait were considered. More recent studies conducted since 2000 were unable to clearly link exposure to airborne particulate matter to long-term chronic respiratory disease.

Army Medicine researchers are investigating possible long-term effects of exposure to dust and other airborne particulate matter. They are looking for volunteers who deployed to Operation Iraqi Freedom, Operation Enduring Freedom, or Operation New Dawn, developed respiratory symptoms while deployed, and are still showing symptoms.
Photo Credit: U.S. Marine photo Sgt. Brian Kester

The matter is not closed, however, and Morris and his team of experts on respiratory disease are investigating the causes and effects on individual health and how to provide the best care for those who continue to deploy where airborne particulate matter is common. Active-duty and Reserve personnel outside of the San Antonio area can contact (see information below) the Pulmonary Clinic at the San Antonio Military Medical Center to discuss possible enrollment in the study.

If a patient is accepted to the study, they must obtain permission from their unit, which will be responsible for the travel and lodging costs.

Personnel who deployed during OIE/OEF/OND and are no longer active duty (retirees and veterans) with TRICARE eligibility, will also be considered for the study. The individual will be responsible for any travel and lodging costs.

Individuals who wish to be part of the study can be evaluated at the either of two study sites: San Antonio Military Medical Center or Walter Reed Military Medical Center in Bethesda, Maryland.

army.mil

Burn Pit Registry Helps Veterans with Respiratory Conditions

By Hans Petersen

Were you exposed to burn pits while deployed?

Did you serve in Operation Enduring Freedom/Operation Iraqi Freedom/Operation New Dawn, Djibouti, Africa, Operations Desert Shield or Desert Storm or the Southeast Asia theater of operations after August, 1990?

Do you think you may have been exposed to burn pits and other airborne hazards?

Some Veterans have reported respiratory symptoms and health conditions that may be related to exposure to burn pits. The long-term health effects of exposure to burn pits and other airborne hazards are not fully understood. In an effort to better understand these health effects, VA has launched the Airborne Hazards and Open Burn Pit Registry for Veterans and Servicemembers.

"While nearly 61,000 Veterans and Servicemembers have joined the Burn Pit Registry since its launch nearly two years ago, this is only a small fraction of the estimated 3 million individuals who may be eligible to join this registry," said Dr. Stephen Hunt, National Director of VA's Post-Deployment Integrated Care Initiative. "I encourage as many eligible individuals as possible to sign up for the Burn Pit Registry."

Since the early 1980s, Dr. Hunt has conducted registry exams for the Agent Orange, Former POW, Gulf War, Ionizing Radiation, and the Airborne Hazards and the Open Burn Pit Registries. According to Dr. Hunt, the Burn Pit Registry will help Veterans in a number of ways.

The Registry gives participants an opportunity to document any concerns they may have about deployment-related exposures and provides an opportunity to obtain a free health evaluation by a VA or DoD provider. The evaluation can identify and document any problems potentially related to the exposures and ensure ongoing follow up for any existing health conditions or any additional conditions that could emerge down the road. One challenge when addressing environmental exposures is that we don't always know what the long-term health effects of those exposures may be or when those health concerns might arise. Some exposures don't lead to any long-term problems. Others, however, may have long-term or downstream health effects that aren't identifiable early on. Through the registry, if health conditions related to exposures do emerge months or years later, we will be able to identify them more quickly and to make sure that Veterans get the health care that they need in a timely manner. A common misunderstanding about the registry is that participation is required to obtain disability compensation benefits. This is not true. The burn pit registry and all other VA registries are unrelated to the disability compensation rating process. While a Registry note in your medical record summarizing your exposure concerns and related medical treatment may serve as evidence to support a claim, it is not a necessary document or step in the claims process.

The registry is open to anyone who served in:

- Operation Enduring Freedom/Operation Iraqi Freedom/Operation New Dawn
- Djibouti, Africa on or after Sept. 11, 2001
- Operations Desert Shield or Desert Storm
- Southwest Asia theater of operations on or after Aug. 2, 1990

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War Related Illness and Injury Study Center

Airborne Hazards and Open Burn Pit Registry: Introduction to Airborne Hazards for Providers

What is the Airborne Hazards & Open Burn Pit Registry?

In January 2013, Public Law 112-260[1], the "Dignified Burial and Other Veterans' Benefits Improvement Act of 2012," was enacted. Section 201 of the law requires VA to establish a burn pit registry to monitor the health of Veterans who may have been exposed to airborne hazards (e.g., air pollution), inform Veterans about the registry, and periodically notify Veterans of significant developments related to the study and treatment of conditions associated with exposures. In response, VA's Office of Public Health established a registry for individuals deployed to Southwest Asia on or after August 2, 1990, or Djibouti, Africa or Afghanistan after September 11, 2001. The registry consists of a web-based self-assessment to be completed by the eligible individual. Participants may also schedule an optional in-person clinical evaluation by a VA provider.[2] Up-to-date information about the registry and related resources are available at the Office of Public Health.

What is the concern about airborne hazards and open burn pits?

Burn pits were used in Operation Enduring Freedom and Operation Iraqi Freedom to dispose of all sorts of solid wastes. Material may have included human and medical waste, as well as substances known to generate carcinogens and other harmful substances produced in the combustion process. In addition, elevated levels of particulate matter from industrial activities, burning oil wells (particularly during and after Operation Desert Shield/Storm), and other man-made and natural sources contributed to poor air quality in many locations. Many deployed individuals wonder if these exposures affected their health.

Staff Sgt. Eric Wendt, 6253rd USAH, reviews the procedures of pulmonary function tests, using the spirometer to measure lung function, which is helpful in assessing conditions such as asthma, pulmonary fibrosis, cystic fibrosis and COPD during reserve duty at Tripler Army Medical Center on Sept. 12-24, 2015.
Photo Credit: Sgt. HoaiNam Le, 6253rd USAH, PAO

In 2011, the Institute of Medicine (IOM) reviewed the scientific literature related to the possibility of adverse long-term health effects of open burn pits. The report noted that the U.S. Department of Defense monitored air quality and measured levels of particulate matter (PM) that were higher than generally considered safe by U.S. regulatory agencies.[3] It also cited work linking high PM levels to cardiopulmonary effects, particularly in individuals at increased risk due to pre-existing conditions such as asthma and emphysema. However, the IOM concluded there is only limited evidence suggestive "of an association between exposure to combustion products and reduced pulmonary function in these populations"[4].

What are the clinical concerns?

There are published reports of higher rates of self-reported pulmonary symptoms[5], higher rates of asthma[6], and rare, unexpected conditions (e.g., eosinophilic pneumonia and constrictive bronchiolitis)[7,8] among Service members deployed to Southwest Asia. However, there are also publications that report finding no elevation in disease or symptom-reporting rates.[9] Given the different methods and conclusions of these studies, it is still unclear exactly what problems deployed individuals may develop or how widespread these problems are. However, current evidence does warrant heightened clinical attention to exposed individuals reporting cardiopulmonary symptoms.[10]

Talking About Health and Exposure Concerns

It is essential to listen to and respect the Veteran's concerns about the exposure and possible health effects. Airborne hazards exposure and possibly associated health risks are complex issues with many uncertainties. Other risk factors may be present, such as past or current cigarette smoking, civilian occupational exposures, or other inhalation exposures, which can complicate causal attribution. The complex interplay can result in disagreement about the relative contribution of various risk factors to the current health status of a patient. It is often impossible to definitively ascertain the contribution of a particular risk factor for an individual.

By taking the time to listen to the Veteran's concerns, a provider can establish trust and rapport and assess gaps in knowledge and differences of opinion. This information can be critical for making informed decisions about possible next steps or management of health concerns. Identifying areas of agreement and focusing on risk reduction and optimization of health and function may provide a constructive way forward. Health risk communication is emphasizes the importance of building trust through active listening and empathy and recognizing the relevance of perceptions of possible harm. It also acknowledges the uncertainties related to extent of exposure, relationship between exposures and possible health effects, diagnostic precision, management options, and prognosis.[11]

What initial evaluation is appropriate?

The clinician should first assess the intensity and specific focus of concern of the individual using the health risk communication approach discussed above. Patients seeking medical attention may have a variety of symptoms and exposure concerns.

At this time, there are no biomarkers specific to the environmental exposure-related health concerns of U.S. Service members deployed to Southwest Asia, Afghanistan, or Djibouti. Clinicians must rely on their own evidence-based knowledge, expertise, and skills to guide a patient-centered evaluation and management. For example, for an individual with chronic lower respiratory symptoms, such as wheezing, chronic cough, or dyspnea with exertion, the following might be appropriate initially:

- a complete blood count— to rule out anemia
- postero-anterior and lateral chest radiographs — to rule out significant structural abnormalities
- pulse oximetry— to assess for hypoxia
- spirometry with bronchodilator— to assess pulmonary function and reversibility of bronchoconstriction

Other symptoms should be evaluated according to best clinical practices, as well.

What specialty consultations are warranted?

The decision to conduct specialty evaluations should be made in the context of the individual patient's concerns and symptoms, findings on initial evaluation, and the comfort level of the primary care team. The indicated specialty evaluations are considered part of the registry evaluation and should be made available to the individual by VHA at no cost to the Veteran. Some specialties of particular relevance include:

- pulmonary (PULM)
- ear, nose and throat (ENT)
- allergy/immunology (ALL/IMM)

Consultations might result in additional assessments, such as high-resolution chest computerized tomography (CT) scan, full pulmonary function tests, assessment of vocal cord function, cardiopulmonary exercise tests, or lung biopsy[12,13].

The Veterans Health Administration maintains the Environmental Health Program with a designated Environmental Health Coordinator and Clinician at each VA medical center. Some of these clinicians may be able to provide additional information about deployment-related exposure or health concerns (see a listing of Environmental Health Coordinators by state and facility). This describes how a Veteran can apply and includes information about local benefits offices if he or she wishes to initiate the process in person.

After local evaluation is completed, some patients may still have complex, difficult-to-diagnose or medically unexplained health concerns related to airborne hazards concerns or other deployment-related exposures. For these patients, consultation with the War Related Illness and Injury Study Center (WRIISC) might be appropriate.

Service Connected Disability

In addition, Veterans may have questions about service-connected disability benefits. The clinician should acknowledge these and can refer the Veteran to the Veterans Benefits Administration for more information.

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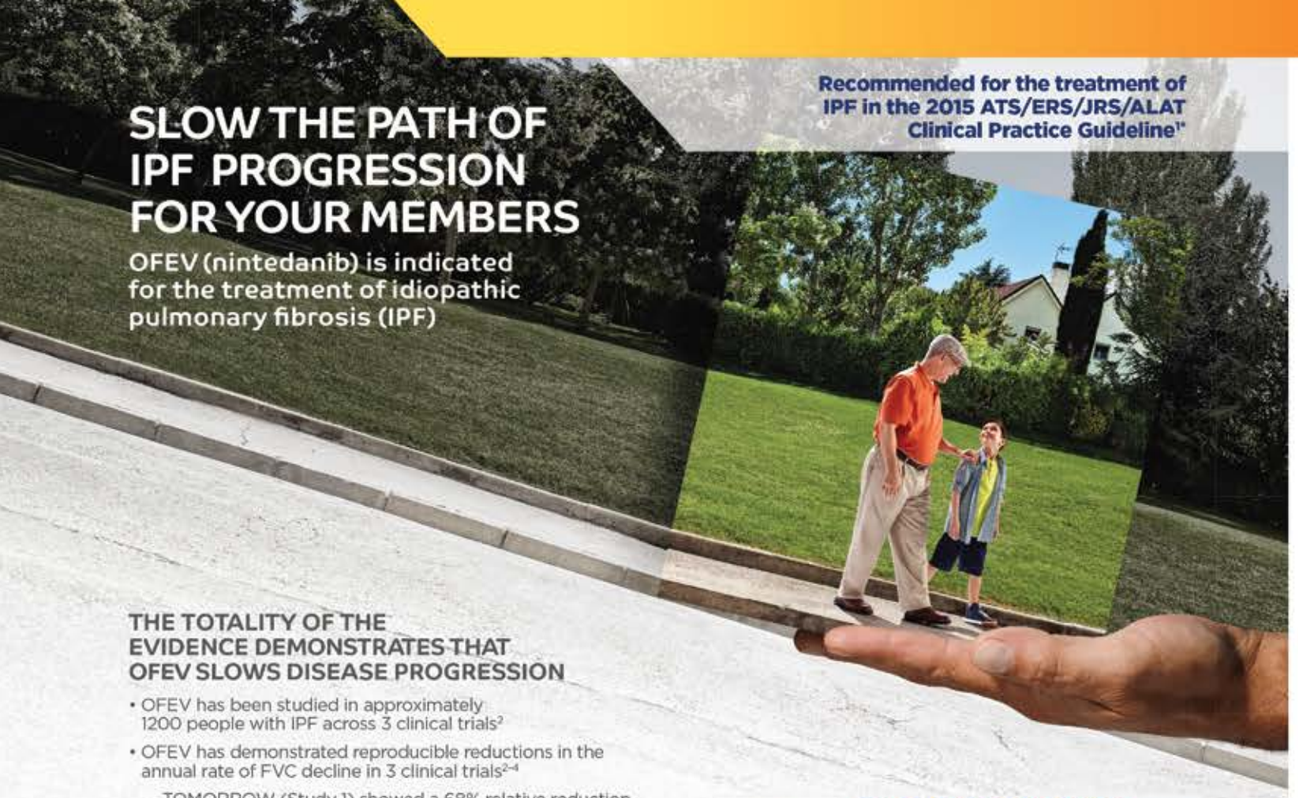
SLOW THE PATH OF IPF PROGRESSION FOR YOUR MEMBERS

OFEV (nintedanib) is indicated for the treatment of idiopathic pulmonary fibrosis (IPF)



Recommended for the treatment of IPF in the 2015 ATS/ERS/JRS/ALAT Clinical Practice Guideline[1*]

THE TOTALITY OF THE EVIDENCE DEMONSTRATES THAT OFEV SLOWS DISEASE PROGRESSION

- OFEV has been studied in approximately 1200 people with IPF across 3 clinical trials[2]
- OFEV has demonstrated reproducible reductions in the annual rate of FVC decline in 3 clinical trials[2-4]
  - TOMORROW (Study 1) showed a 68% relative reduction (-60 mL/year for OFEV [n=84] vs -191 mL/year for placebo [n=83], difference=131, 95% CI=27, 235)
  - INPULSIS®-1 (Study 2) showed a 52% relative reduction (-115 mL/year for OFEV [n=309] vs -240 mL/year for placebo [n=204], difference=125, 95% CI=78, 173)
  - INPULSIS®-2 (Study 3) showed a 45% relative reduction (-114 mL/year for OFEV [n=329] vs -207 mL/year for placebo [n=219], difference=94, 95% CI=45, 143)
- Significantly reduced the risk of time to first acute IPF exacerbation in 2 out of 3 clinical trials[2,5]
  - TOMORROW (investigator-reported): HR=0.16 (95% CI=0.04, 0.71)
  - INPULSIS®-1 (adjudicated): HR=0.55 (95% CI=0.20, 1.54; not statistically significant)
  - INPULSIS®-2 (adjudicated): HR=0.20 (95% CI=0.07, 0.56)

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*Conditional recommendation with moderate confidence in effect estimates. Interpretation of conditional recommendations for patients and clinicians: The majority of patients would want the suggested course of action, but many would not; clinicians should recognize that different choices will be appropriate for individual patients and each patient must be helped to arrive at a management decision consistent with his or her values and preferences.[1]

ALAT, Latin American Thoracic Association; ATS, American Thoracic Society; ERS, European Respiratory Society; FVC, forced vital capacity; JRS, Japanese Respiratory Society

INDICATION AND USAGE

OFEV is indicated for the treatment of idiopathic pulmonary fibrosis (IPF).

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hepatic Impairment

- OFEV is not recommended in patients with moderate (Child Pugh B) or severe (Child Pugh C) hepatic impairment. Patients with mild hepatic impairment (Child Pugh A) can be treated with a reduced dosage (100 mg twice daily). Consider treatment interruption or discontinuation for management of adverse reactions.

Elevated Liver Enzymes

- OFEV was associated with elevations of liver enzymes (ALT, AST, ALKP, and GGT) and bilirubin. Liver enzyme increases were reversible with dose modification or interruption and not associated with clinical signs or symptoms of liver injury. The majority (94%) of patients with ALT and/or AST elevations had elevations <5 times ULN. The majority (95%) of patients with bilirubin elevations had elevations <2 times ULN.
- Conduct liver function tests prior to treatment, monthly for 3 months, and every 3 months thereafter, and as clinically indicated. Monitor for adverse reactions and consider dosage modifications, interruption, or discontinuation as necessary for liver enzyme elevations.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Gastrointestinal Disorders

Diarrhea

- Diarrhea was the most frequent gastrointestinal event reported in 62% versus 18% of patients treated with OFEV and placebo, respectively. Events were primarily mild to moderate intensity and occurred within the first 3 months. Diarrhea led to permanent dose reduction in 11% and discontinuation in 5% of OFEV patients versus 0 and <1% in placebo patients, respectively.
- Dosage modifications or treatment interruptions may be necessary in patients with diarrhea. Treat diarrhea at first signs with adequate hydration and antidiarrheal medication (e.g., loperamide), and consider treatment interruption if diarrhea continues. OFEV treatment may be resumed at the full dosage (150 mg twice daily), or at the reduced dosage (100 mg twice daily), which subsequently may be increased to the full dosage. If severe diarrhea persists, discontinue treatment.

Nausea and Vomiting

- Nausea was reported in 24% versus 7% and vomiting was reported in 12% versus 3% of patients treated with OFEV and placebo, respectively. Events were primarily of mild to moderate intensity. Nausea and vomiting led to discontinuation of OFEV in 2% and 1% of patients, respectively.
- If nausea or vomiting persists despite appropriate supportive care including anti-emetic therapy, consider dose reduction or treatment interruption. OFEV treatment may be resumed at full dosage or at reduced dosage, which subsequently may be increased to full dosage. If severe nausea or vomiting does not resolve, discontinue treatment.

Embryofetal Toxicity: OFEV can cause fetal harm when administered to a pregnant woman and patients should be advised of the potential risk to a fetus. Women should be advised to avoid becoming pregnant while receiving OFEV and to use effective contraception during treatment and at least 3 months after the last dose of OFEV. Verify pregnancy status prior to starting OFEV.

Arterial Thromboembolic Events: Arterial thromboembolic events were reported in 2.5% of OFEV and 0.8% of placebo patients, respectively. Myocardial infarction was the most common arterial thromboembolic event, occurring in 1.5% of OFEV and 0.4% of placebo patients. Use caution when treating patients at higher cardiovascular risk including known coronary artery disease. Consider treatment interruption in patients who develop signs or symptoms of acute myocardial ischemia.

Risk of Bleeding: OFEV may increase the risk of bleeding. Bleeding events were reported in 10% of OFEV versus 7% of placebo patients. Use OFEV in patients with known risk of bleeding only if the anticipated benefit outweighs the potential risk.

Gastrointestinal Perforation: OFEV may increase the risk of gastrointestinal perforation. Gastrointestinal perforation was reported in 0.3% of OFEV versus in 0% placebo patients. Use caution when treating patients who have had recent abdominal surgery. Discontinue therapy with OFEV in patients who develop gastrointestinal perforation. Only use OFEV in patients with known risk of gastrointestinal perforation if the anticipated benefit outweighs the potential risk.

ADVERSE REACTIONS

- Adverse reactions reported in ≥5% of OFEV patients included diarrhea, nausea, abdominal pain, liver enzyme elevation, vomiting, decreased appetite, weight decreased, headache, and hypertension.
- The most frequent serious adverse reactions reported in OFEV patients were bronchitis and myocardial infarction. The most common adverse events leading to death in OFEV patients versus placebo were pneumonia (0.7% vs. 0.6%), lung neoplasm malignant (0.3% vs. 0%), and myocardial infarction (0.3% vs. 0.2%). In the predefined category of major adverse cardiovascular events (MACE) including MI, fatal events were reported in 0.6% of OFEV versus 1.8% in placebo patients.

DRUG INTERACTIONS

- **P-glycoprotein (P-gp) and CYP3A4 Inhibitors and Inducers:** Coadministration with oral doses of a P-gp and CYP3A4 inhibitor, ketoconazole, increased exposure to nintedanib by 60%. Concomitant use of potent P-gp and CYP3A4 inhibitors (e.g., erythromycin) with OFEV may increase exposure to nintedanib. In such cases, patients should be monitored closely for tolerability of OFEV. Management of adverse reactions may require interruption, dose reduction, or discontinuation of therapy with OFEV. Coadministration with oral doses of a P-gp and CYP3A4 inducer, rifampicin, decreased exposure to nintedanib by 50%. Concomitant use of P-gp and CYP3A4 inducers (e.g., carbamazepine, phenytoin, and St. John's wort) with OFEV should be avoided as these drugs may decrease exposure to nintedanib.
- **Anticoagulants:** Nintedanib may increase the risk of bleeding. Monitor patients on full anticoagulation therapy closely for bleeding and adjust anticoagulation treatment as necessary.

USE IN SPECIFIC POPULATIONS

- **Nursing Mothers:** Because of the potential for serious adverse reactions in nursing infants from OFEV, advise women that breastfeeding is not recommended during treatment.
- **Reproductive Potential:** OFEV may reduce fertility in females of reproductive potential.
- **Smokers:** Smoking was associated with decreased exposure to OFEV, which may affect the efficacy of OFEV. Encourage patients to stop smoking prior to and during treatment.

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Please see accompanying Brief Summary for OFEV on the following pages.

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OFEV® (nintedanib) capsules, for oral use

BRIEF SUMMARY OF PRESCRIBING INFORMATION

Please see package insert for full Prescribing Information, including Patient Information

INDICATIONS AND USAGE: OFEV is indicated for the treatment of idiopathic pulmonary fibrosis (IPF).

DOSAGE AND ADMINISTRATION: Testing Prior to OFEV Administration: Conduct liver function tests and a pregnancy test prior to initiating treatment with OFEV *[see Warnings and Precautions]*. **Recommended Dosage:** The recommended dosage of OFEV is 150 mg twice daily administered approximately 12 hours apart. OFEV capsules should be taken with food and swallowed whole with liquid. OFEV capsules should not be chewed or crushed because of a bitter taste. The effect of chewing or crushing of the capsule on the pharmacokinetics of nintedanib is not known. If a dose of OFEV is missed, the next dose should be taken at the next scheduled time. Advise the patient to not make up for a missed dose. Do not exceed the recommended maximum daily dosage of 300 mg. In patients with mild hepatic impairment (Child Pugh A), the recommended dosage of OFEV is 100 mg twice daily approximately 12 hours apart taken with food. **Dosage Modification due to Adverse Reactions:** In addition to symptomatic treatment, if applicable, the management of adverse reactions of OFEV may require dose reduction or temporary interruption until the specific adverse reaction resolves to levels that allow continuation of therapy. OFEV treatment may be resumed at the full dosage (150 mg twice daily), or at the reduced dosage (100 mg twice daily), which subsequently may be increased to the full dosage. If a patient does not tolerate 100 mg twice daily, discontinue treatment with OFEV *[see Warnings and Precautions and Adverse Reactions]*. Dose modifications or interruptions may be necessary for liver enzyme elevations. For aspartate aminotransferase (AST) or alanine aminotransferase (ALT) >3 times to <5 times the upper limit of normal (ULN) without signs of severe liver damage, interrupt treatment or reduce OFEV to 100 mg twice daily. Once liver enzymes have returned to baseline values, treatment with OFEV may be reintroduced at a reduced dosage (100 mg twice daily), which subsequently may be increased to the full dosage (150 mg twice daily) *[see Warnings and Precautions and Adverse Reactions]*. Discontinue OFEV for AST or ALT elevations >5 times ULN or >3 times ULN with signs or symptoms of severe liver damage. In patients with mild hepatic impairment (Child Pugh A), consider treatment interruption, or discontinuation for management of adverse reactions.

CONTRAINDICATIONS: None

WARNINGS AND PRECAUTIONS: Hepatic Impairment: Treatment with OFEV is not recommended in patients with moderate (Child Pugh B) or severe (Child Pugh C) hepatic impairment *[see Use in Specific Populations]*. Patients with mild hepatic impairment (Child Pugh A) can be treated with a reduced dose of OFEV *[see Dosage and Administration]*. **Elevated Liver Enzymes:** In clinical trials, administration of OFEV was associated with elevations of liver enzymes (ALT, AST, ALKP, GGT). Liver enzyme increases were reversible with dose modification or interruption and not associated with clinical signs or symptoms of liver injury. The majority (94%) of patients with ALT and/or AST elevations had elevations <5 times ULN. Administration of OFEV was also associated with elevations of bilirubin. The majority (95%) of patients with bilirubin elevations had elevations <2 times ULN *[see Use in Specific Populations]*. Conduct liver function tests (ALT, AST, and bilirubin) prior to treatment with OFEV, monthly for 3 months, and every 3 months thereafter, and as clinically indicated. Dosage modifications or interruption may be necessary for liver enzyme elevations. **Gastrointestinal Disorders:** Diarrhea: Diarrhea was the most frequent gastrointestinal event reported in 62% versus 18% of patients treated with OFEV and placebo, respectively *[see Adverse Reactions)]*. In most patients, the event was of mild to moderate intensity and occurred within the first 3 months of treatment. Diarrhea led to permanent dose reduction in 11% of patients treated with OFEV compared to 0 placebo-treated patients. Diarrhea led to discontinuation of OFEV in 5% of the patients compared to <1% of placebo-treated patients. Dosage modifications or treatment interruptions may be necessary in patients with adverse reactions of diarrhea. Treat diarrhea at first signs with adequate hydration and antidiarrheal medication (e.g., loperamide), and consider treatment interruption if diarrhea continues. OFEV treatment may be resumed at the full dosage (150 mg twice daily), or at the reduced dosage (100 mg twice daily), which subsequently may be increased to the full dosage. If severe diarrhea persists despite symptomatic treatment, discontinue treatment with OFEV. Nausea and Vomiting: Nausea was reported in 24% versus 7% and vomiting was reported in 12% versus 3% of patients treated with OFEV and placebo, respectively *[see Adverse Reactions]*. In most patients, these events were of mild to moderate intensity. Nausea led to discontinuation of OFEV in 2% of patients. Vomiting led to discontinuation of OFEV in 1% of the patients. For nausea or vomiting that persists despite appropriate supportive care including anti-emetic therapy, dose reduction or treatment interruption may be required. OFEV treatment may be resumed at the full dosage (150 mg twice daily), or at the reduced dosage (100 mg twice daily), which subsequently may be increased to the full dosage. If severe nausea or vomiting does not resolve, discontinue treatment with OFEV. **Embryo-Fetal Toxicity:** Based on findings from animal studies and its mechanism of action, OFEV can cause fetal harm when administered to a pregnant woman. Nintedanib caused embryo-fetal deaths and structural abnormalities in rats and rabbits when administered during organogenesis at less than (rats) and approximately 5 times (rabbits) the maximum recommended human dose (MRHD) in adults. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to avoid becoming pregnant while receiving treatment with OFEV and to use effective contraception during treatment and at least 3 months after the last dose of OFEV. Verify pregnancy status prior to treatment with OFEV *[see Use in Specific Populations]*. **Arterial Thromboembolic Events:** Arterial thromboembolic events have been reported in patients taking OFEV. In clinical trials, arterial thromboembolic events were reported in 2.5% of patients treated with OFEV and 0.8% of placebo-treated patients. Myocardial infarction was the most common adverse reaction under arterial thromboembolic events, occurring in 1.5% of OFEV-treated patients compared to 0.4% of placebo-treated patients. Use caution when treating patients at higher cardiovascular risk including known coronary artery disease. Consider treatment interruption in patients who develop signs or symptoms of acute myocardial ischemia. **Risk of Bleeding:** Based on the mechanism of action (VEGFR inhibition), OFEV may increase the risk of bleeding. In clinical trials, bleeding events were reported in 10% of patients treated with OFEV and in 7% of patients treated with placebo. Use OFEV in patients with known risk of bleeding only if the anticipated benefit outweighs the potential risk. **Gastrointestinal Perforation:** Based on the mechanism of action, OFEV may increase the risk of gastrointestinal perforation. In clinical trials, gastrointestinal perforation was reported in 0.3% of patients treated with OFEV, compared to 0 cases in the placebo-treated patients. Use caution when treating patients who have had recent abdominal surgery. Discontinue therapy with OFEV in patients who develop gastrointestinal perforation. Only use OFEV in patients with known risk of gastrointestinal perforation if the anticipated benefit outweighs the potential risk.

ADVERSE REACTIONS: The following adverse reactions are discussed in greater detail in other sections of the labeling: Liver Enzyme and Bilirubin Elevations *[see Warnings and Precautions]*; Gastrointestinal Disorders *[see Warnings and Precautions]*; Embryo-Fetal Toxicity *[see Warnings and Precautions]*; Arterial Thromboembolic Events *[see Warnings and Precautions]*; Risk of Bleeding *[see Warnings and Precautions]*; Gastrointestinal Perforation *[see Warnings and Precautions]*. **Clinical Trials Experience:** Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The safety of OFEV was evaluated in over 1000 IPF patients with over 200 patients exposed to OFEV for more than 2 years in clinical trials. OFEV was studied in three randomized, double-blind, placebo-controlled, 52-week trials. In the phase 2 (Study 1) and phase 3 (Studies 2 and 3) trials, 723 patients with IPF received OFEV 150 mg twice daily and 508 patients received placebo. The median duration of exposure was 10 months for patients treated with OFEV and 11 months for patients treated with placebo. Subjects ranged in age from 42 to 89 years (median age of 67 years). Most patients were male (79%) and Caucasian (60%). The most frequent serious adverse reactions reported in patients treated with OFEV, more than placebo, were bronchitis (1.2% vs. 0.8%) and myocardial infarction (1.5% vs. 0.4%). The most common adverse events leading to death in patients treated with OFEV, more than placebo, were pneumonia (0.7% vs. 0.6%), lung neoplasm malignant (0.3% vs. 0%), and myocardial infarction (0.3% vs. 0.2%). In the predefined category of major adverse cardiovascular events (MACE) including MI, fatal events were reported in 0.6% of OFEV-treated patients and 1.8% of placebo-treated patients. Adverse reactions leading to permanent dose reductions were reported in 16% of OFEV-treated patients and 1% of placebo-treated patients. The most frequent adverse reaction that led to permanent dose reduction in the patients treated with OFEV was diarrhea (11%). Adverse reactions leading to discontinuation were reported in 21% of OFEV-treated patients and 15% of placebo-treated patients. The most frequent adverse reactions that led to discontinuation in OFEV-treated patients were diarrhea (5%), nausea (2%), and decreased appetite (2%). The most common adverse reactions with an incidence of ≥5% and more frequent in the OFEV than placebo treatment group are listed in Table 1.

Table 1 Adverse Reactions Occurring in ≥5% of OFEV-treated Patients and More Commonly Than Placebo in Studies 1, 2, and 3

Adverse Reaction	OFEV, 150 mg n=723	Placebo n=508
Gastrointestinal disorders		
Diarrhea	62%	18%
Nausea	24%	7%
Abdominal pain[a]	15%	6%
Vomiting	12%	3%
Hepatobiliary disorders		
Liver enzyme elevation[b]	14%	3%
Metabolism and nutrition disorders		
Decreased appetite	11%	5%
Nervous system disorders		
Headache	8%	5%
Investigations		
Weight decreased	10%	3%
Vascular disorders		
Hypertension[c]	5%	4%

[a] Includes abdominal pain, abdominal pain upper, abdominal pain lower, gastrointestinal pain and abdominal tenderness.

[b] Includes gamma-glutamyltransferase increased, hepatic enzyme increased, alanine aminotransferase increased, aspartate aminotransferase increased, hepatic function abnormal, liver function test abnormal, transaminase increased, blood alkaline phosphatase increased, alanine aminotransferase abnormal, aspartate aminotransferase abnormal, and gamma-glutamyltransferase abnormal.

[c] Includes hypertension, blood pressure increased, hypertensive crisis, and hypertensive cardiomyopathy.

In addition, hypothyroidism was reported in patients treated with OFEV, more than placebo (1.1% vs. 0.6%).

DRUG INTERACTIONS: P-glycoprotein (P-gp) and CYP3A4 Inhibitors and Inducers: Nintedanib is a substrate of P-gp and, to a minor extent, CYP3A4. Coadministration with oral doses of a P-gp and CYP3A4 inhibitor, ketoconazole, increased exposure to nintedanib by 60%. Concomitant use of P-gp and CYP3A4 inhibitors (e.g., erythromycin) with OFEV may increase exposure to nintedanib. In such cases, patients should be monitored closely for tolerability of OFEV. Management of adverse reactions may require interruption, dose reduction, or discontinuation of therapy with OFEV. Coadministration with oral doses of a P-gp and CYP3A4 inducer, rifampicin, decreased exposure to nintedanib by 50%. Concomitant use of P-gp and CYP3A4 inducers (e.g., carbamazepine, phenytoin, and St. John's wort) with OFEV should be avoided as these drugs may decrease exposure to nintedanib. **Anticoagulants:** Nintedanib is a VEGFR inhibitor, and may increase the risk of bleeding. Monitor patients on full anticoagulation therapy closely for bleeding and adjust anticoagulation treatment as necessary *[see Warnings and Precautions]*.

USE IN SPECIFIC POPULATIONS: Pregnancy: Risk Summary: Based on findings from animal studies and its mechanism of action, OFEV can cause fetal harm when administered to a pregnant woman. There are no data on the use of OFEV during pregnancy. In animal studies of pregnant rats and rabbits treated during organogenesis, nintedanib caused embryo-fetal deaths and structural abnormalities at less than (rats) and approximately 5 times (rabbits) the maximum recommended human dose *[see Data]*. Advise pregnant women of the potential risk to a fetus. The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects is 2% to 4% and miscarriage in clinically recognized pregnancies is 15% to 20%. Data: *Animal Data*: In animal reproduction toxicity studies, nintedanib caused embryo-fetal deaths and structural abnormalities in rats and rabbits at less than and approximately 5 times the maximum recommended human dose (MRHD) in adults (on a plasma AUC basis at maternal oral doses of 2.5 and 15 mg/kg/day in rats and rabbits, respectively). Malformations included abnormalities in the vasculature, urogenital, and skeletal systems. Vasculature anomalies included missing or additional major blood vessels. Skeletal anomalies included abnormalities in the thoracic, lumbar, and caudal vertebrae (e.g., hemivertebra, missing, or asymmetrically ossified), ribs (bifid or fused), and sternebrae (fused, split, or unilaterally ossified). In some fetuses, organs in the urogenital system were missing. In rabbits, a significant change in sex ratio was observed in fetuses (female:male ratio of approximately 71%:29%) at approximately 15 times the MRHD in adults (on an AUC basis at a maternal oral dose of 60 mg/kg/day). Nintedanib decreased post-natal viability of rat pups during the first 4 post-natal days when dams were exposed to less than the MRHD (on an AUC basis at a maternal oral dose of 10 mg/kg/day). **Lactation:** Risk Summary: There is no information on the presence of nintedanib in human milk, the effects on the breast-fed infant or the effects on milk production. Nintedanib and/or its metabolites are present in the milk of lactating rats *[see Data]*. Because of the potential for serious adverse reactions in nursing infants from OFEV, advise women that breastfeeding is not recommended during treatment with OFEV. Data: Milk and plasma of lactating rats have similar concentrations of nintedanib and its metabolites. **Females and Males of Reproductive Potential:** Based on findings from animal studies and its mechanism of action, OFEV can cause fetal harm when administered to a pregnant woman and may reduce fertility in females of reproductive potential *[see Use in Specific Populations]*. Counsel patients on pregnancy prevention and planning. Pregnancy Testing: Verify the pregnancy status of females of reproductive potential prior to treatment with OFEV *[see Dosage and Administration, Warnings and Precautions and Use in Specific Populations]*. Contraception: Advise females of reproductive potential to avoid becoming pregnant while receiving treatment with OFEV. Advise females of reproductive potential to use effective contraception during treatment, and for at least 3 months after taking the last dose of OFEV. Infertility: Based on animal data, OFEV may reduce fertility in females of reproductive potential. **Pediatric Use:** Safety and effectiveness in pediatric patients have not been established. **Geriatric Use:** Of the total number of subjects in phase 2 and 3 clinical studies of OFEV, 60.8% were 65 and over, while 16.3% were 75 and over. In phase 3 studies, no overall differences in effectiveness were observed between subjects who were 65 and over and younger subjects; no overall differences in safety were observed between subjects who were 65 and over or 75 and over and younger subjects, but greater sensitivity of some older individuals cannot be ruled out. **Hepatic Impairment:** Nintedanib is predominantly eliminated via biliary/fecal excretion (>90%). In a PK study performed in patients with hepatic impairment (Child Pugh A, Child Pugh B), exposure to nintedanib was increased. In patients with mild hepatic impairment (Child Pugh A), the recommended dosage of OFEV is 100 mg twice daily *[see Dosage and Administration]*. Monitor for adverse reactions and consider treatment interruption, or discontinuation for management of adverse reactions in these patients *[see Dosage and Administration]*. Treatment of patients with moderate (Child Pugh B) and severe (Child Pugh C) hepatic impairment with OFEV is not recommended *[see Warnings and Precautions]*. **Renal Impairment:** Based on a single-dose study, less than 1% of the total dose of nintedanib is excreted via the kidney. Adjustment of the starting dose in patients with mild to moderate renal impairment is not required. The safety, efficacy, and pharmacokinetics of nintedanib have not been studied in patients with severe renal impairment (<30 mL/min CrCl) and end-stage renal disease. **Smokers:** Smoking was associated with decreased exposure to OFEV, which may alter the efficacy profile of OFEV. Encourage patients to stop smoking prior to treatment with OFEV and to avoid smoking when using OFEV.

OVERDOSAGE: In the trials, one patient was inadvertently exposed to a dose of 600 mg daily for a total of 21 days. A non-serious adverse event (nasopharyngitis) occurred and resolved during the period of incorrect dosing, with no onset of other reported events. Overdose was also reported in two patients in oncology studies who were exposed to a maximum of 600 mg twice daily for up to 8 days. Adverse events reported were consistent with the existing safety profile of OFEV. Both patients recovered. In case of overdose, interrupt treatment and initiate general supportive measures as appropriate.

PATIENT COUNSELING INFORMATION: *Advise the patient to read the FDA-approved patient labeling (Patient Information).* Liver Enzyme and Bilirubin Elevations: Advise patients that they will need to undergo liver function testing periodically. Advise patients to immediately report any symptoms of a liver problem (e.g., skin or the whites of eyes turn yellow, urine turns dark or brown (tea colored), pain on the right side of stomach, bleed or bruise more easily than normal, lethargy) *[see Warnings and Precautions]*. Gastrointestinal Disorders: Inform patients that gastrointestinal disorders such as diarrhea, nausea, and vomiting were the most commonly reported gastrointestinal events occurring in patients who received OFEV. Advise patients that their healthcare provider may recommend hydration, antidiarrheal medications (e.g., loperamide), or anti-emetic medications to treat these side effects. Temporary dosage reductions or discontinuations may be required. Instruct patients to contact their healthcare provider at the first signs of diarrhea or for any severe or persistent diarrhea, nausea, or vomiting *[see Warnings and Precautions and Adverse Reactions]*. Embryo-Fetal Toxicity: Counsel patients on pregnancy prevention and planning. Advise females of reproductive potential of the potential risk to a fetus and to avoid becoming pregnant while receiving treatment with OFEV. Advise females of reproductive potential to use effective contraception during treatment, and for at least 3 months after taking the last dose of OFEV. Advise female patients to notify their doctor if they become pregnant during therapy with OFEV *[see Warnings and Precautions and Use in Specific Populations]*. Arterial Thromboembolic Events: Advise patients about the signs and symptoms of acute myocardial ischemia and other arterial thromboembolic events and the urgency to seek immediate medical care for these conditions *[see Warnings and Precautions]*. Risk of Bleeding: Bleeding events have been reported. Advise patients to report unusual bleeding *[see Warnings and Precautions]*. Gastrointestinal Perforation: Serious gastrointestinal perforation events have been reported. Advise patients to report signs and symptoms of gastrointestinal perforation *[see Warnings and Precautions]*. Lactation: Advise patients that breastfeeding is not recommended while taking OFEV *[see Use in Specific Populations]*. Smokers: Encourage patients to stop smoking prior to treatment with OFEV and to avoid smoking when using with OFEV. Administration: Instruct patients to swallow OFEV capsules whole with liquid and not to chew or crush the capsules due to the bitter taste. Advise patients to not make up for a missed dose *[see Dosage and Administration]*.

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Active
SURGERY

Military Hospital's Surgical Care Ranks Among Best in Nation

By Elaine Sanchez, BAMC Public Affairs

San Antonio Military Medical Center ranks among the top hospitals in the nation for surgical care, according to a recent report from the American College of Surgeons.

SAMMC earned an exemplary or average rating in 180 different surgical quality variables, placing the facility in the upper half of hundreds of esteemed hospitals throughout the nation.

The report is issued by ACS' National Surgical Quality Improvement Program, or NSQIP, a voluntary program that gauges the quality of surgical programs across the nation. The aim is to help surgeons better understand their quality of care compared to similar hospitals with similar patients, according to the program's website.

"The largest and best hospitals in the U.S. are part of this program, and our percentages place us in the top half of those hospitals," said Air Force Col. Joseph Brennan, chief of SAMMC's Department of Surgery. "We are very proud of that."

Data collection is key to the program's success, Brennan noted. At SAMMC, a surgeon oversees the program and two nurses are dedicated to inputting preoperative through 30-day postoperative data into a secure, web-based platform. ACS analyzes rates of mortality and morbidity, such as pneumonia, surgical site infections, urinary tract infections, sepsis and readmissions.

S. Navy Cmdr. William Cavill examines a child before her surgery aboard Military Sealift Command hospital ship USNS Comfort during Continuing Promise 2015 in Roseau, Dominica, Aug. 3, 2015. The medical care is part of Continuing Promise, a civil-military effort that includes humanitarian-civil assistance, subject matter expert exchanges, medical, dental, veterinary and engineering support. Cavill is an anesthesiologist assigned to Naval Hospital Pensacola Fla. *U.S. Army photo by Spc. Lance Hartung*

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Personnel from the 86th Contingency Aeromedical Staging Facility load patients on a C-17 Globemaster III at Ramstein Air Base, Germany, Dec. 19, 2013. The CASF's primary role in the aeromedical evacuation mission is to evaluate patients' medical records, stage patients and secure appropriate transportation for higher-level care. *U.S. Air Force photo/Airman 1st Class Aaron Stout*

"Blinded" information is then shared with all participating hospitals, offering a snapshot of how hospitals rank according to surgical outcomes.

This data offers priceless insight, noted Army Maj. (Dr.) George Kallingal, surgeon champion for NSQIP at SAMMC. "NSQIP foremost offers us an internal metric to ensure our surgical quality outcomes continue to progress at SAMMC and sets in motion the process of continual analysis and improvement," he said.

SAMMC's surgical outcome data has been increasingly positive over the past three years, Brennan noted, an uptick he attributes directly to SAMMC's care providers and infection control, quality and process improvement teams. "As a result of the data, we've made multiple improvements to our surgical processes," he said, citing efforts to improve operating room preparations and catheter use. "And our exceptional staff did a great job pushing initiatives focused on better patient care."

While NSQIP provided the framework for analysis, "the dedication of SAMMC personnel and their commitment to quality improvement is what fostered meaningful change," Kallingal said. "It will continue to be an important tool to provide the framework for improving surgical quality outcomes in the future."

The program is an easy sell at SAMMC, added Mariea Shelton, process improvement coordinator. The aim, she said, is to always strive for "great outcomes in surgical procedures."

With an eye on further improvements, Brennan hopes to add a third NSQIP surgical clinical reviewer soon to enable more data to be inputted and more feedback to be gained. "The more numbers we can track, the better off we'll be when it comes to gauging our strengths and weaknesses," he said.

While the program is voluntary, the Department of Defense requires all military hospitals to participate in NSQIP. SAMMC has been a voluntary member of the program since 2009.

"Participation in NSQIP means there is a total commitment to deliver the highest quality surgical patient care," said Marilyn McFarland, a NSQIP surgical clinical reviewer.

"Quality patient care is priority here and it shows," added Laura Van Dyk, surgical clinical reviewer.

Brennan praised the hospital's exceptional care, citing recent successes on The Joint Commission reaccreditation survey, Level I trauma center reverification, and a Commission on Cancer silver designation for SAMMC's cancer program.

"Our focus has always been on providing the best patient care, on what's best for the patient," the colonel said. "That emphasis has never wavered. This is just a great organization, from the leadership on down."

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Active
WOMEN'S HEALTH

Womack Army Medical Center Hosts Soldiers, Families, Babies at Maternity Fair

By Sgt. Krista Rayford/10th PCH

Baby talk filled the halls of Womack Army Medical Center on Saturday as nearly 400 expecting Families attended a Maternity Fair.

In its tenth year, the fair offers information to Families who are expecting a child, new parents, or Families wishing to start a Family in the future.

"It's the quickest way to get all pertinent information out to our patients regarding pregnancy and the birthing process at Womack," said Tracey Stevens, childbirth educator, WAMC.

The event provided information on crib and car seat safety, centering programs, contraception, breastfeeding, childbirth education classes, and pregnancy and postpartum physical training.

There were also tours of the labor and delivery department at Womack and preview classes from Army Community Service New Parent Support Program.

"It is important for us to talk to expectant parents about the severity of shaken baby syndrome, crib safety and sudden infant death syndrome, or SIDS," said Bianca Gantt, licensed clinical social worker, New Parent Support Program. "We are committed to helping parents create a very safe environment for new babies."

Pregnancy can prove to be difficult or stressful for military Families due to their Family support system that may not be in town or easily accessed.

"It is a relief to know all of the support that we have because we need it," said Jessica Edmiston, military spouse, who is 28 weeks pregnant and whose family is in Oklahoma.

Tasha Felton Williams, nurse practitioner, Womack Army Medical Center, discusses options of future birth control methods to an expecting mother. WAMC offers patient education on many birth control options that will fit each individual's lifestyle. *Photo Credit: Sgt. Krista Rayford10th PCH*

She also added that given her husband and her busy work schedules, the fair was ideal and provided something other than the traditional way of distributing information.

With nearly 270 babies born at WAMC each month, there are many parents who are searching for information regarding what's available for them at the hospital.

"We want Soldiers and their Families to know that the Department of Defense has a process in place to empower them with knowledge of pregnancy," said Stevens. "My job and the fair is to reassure expecting parents that are going to be well-equipped, awesome parents."

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Active
WOMEN'S HEALTH

Contraception and Deployment

By Col. Michelle Munroe, DNP, CNM, AN, OTSG Women's Advanced Practice Nursing Consultant

Menstrual cycle and fertility control are two important issues facing reproductive age women that impact unit readiness and deployment experience. The health and quality of women's lives could be markedly improved if all women received comprehensive education, had access to a full range of contraceptive options, and actually used one of these options. Comprehensive education combined with utilization of contraceptive methods has proven to allow women to effectively control their menstrual cycles, with implications for deployment health and the rate of unintended pregnancies. This combination of education and contraception has the potential to heighten unit readiness and resilience.

Contraception and education can play a significant role in the quality of life for active duty women. Lost duty days due to difficult menstrual cycles and unintended pregnancy impacts daily mission requirements, unit readiness and morale. It is important to provide education to servicewomen in order for them to understand all their options during deployment and their careers. Providing detailed contraception education at the right time and in the right venue can have a profound impact on women's lives and mission readiness.

Unintended pregnancy rates in the United States are as high as 50-65 percent, with the Army reporting the highest rates among the branches of service. Over half of these pregnancies occurred in women who were not using any method of contraception, and most of these women were young, married or cohabitating and have lower education levels. The negative consequences associated with unintended pregnancy are decreased mission readiness, unit cohesion and morale. Providing contraceptive education to women early in their careers can combat these high unintended pregnancy rates and provide some long-term options that will benefit the individual service member and the military.

Women suffer regularly with premenstrual syndrome, mood swings, cramping, and irregular bleeding with light and heavy days. Heavy days can be associated with anemia. For some, these symptoms result in lost duty days. Many women only have a basic understanding of their menstrual cycles. There is widespread stigma that contraception is solely for "birth control" and few understand the important role that contraception can play in menstrual regulation. Contraception has other uses that are not often discussed or recognized, such as menstrual cycle control or suppression, that can increase the quality of life for women. Menstrual cycle control is when a woman uses hormones to control the number of cycles that she has per year whether that means having a cycle every month, quarterly, or none at all.

Education

Education regarding the menstrual cycle and the variety of contraceptive options available to improve menstrual cycle control should be done as early as possible in the service member's military career. Education benefits both the individual by increasing health awareness and knowledge, and the Army by decreasing the number of missed work days due to menstrual illness and unintended pregnancies. A "menstrual wellness" refresher class should be offered whenever a unit is scheduled to deploy. According toArmy research, 74 percent of women deployed in support of OIF/OEF and Afghanistan reported that they did not receive information about menstrual cycle control prior to deployment. At a minimum, the class should review menstrual cycle control/suppression options and provide women with emergency contraception to take with them on deployment should they have unprotected/unplanned intercourse or experience a sexual assault. The Tricare Formulary offers 11 different options for emergency contraception. Check your local pharmacy for specific options available to you.

Deployment Options

A study of deployed women serving in Iraq finds that contraception use by active duty women averages 69 percent overall with a decrease in use during deployment to an average of 58 percent. Women who deploy assume that they will not be

Army Staff Sgt. Bonnie Clark displays a picture of her three children while deployed to Forward Operating Base Apache in Afghanistan's Zabul province. Keeping close ties with her children is a top priority for Clark while deployed. *U.S. Army photo by Staff Sgt. Christopher Blakeslee*

sexually active therefore they choose to not use contraception without realizing the other benefits like menstrual cycle control and suppression. There are concerns about side effects like nausea, weight gain, headache and abnormal bleeding. If women do use contraception, they tend tochoose more popular options like oral contraception. Oral contraception is not necessarily the best option during deployment. Limitations with this method include lack of availability and difficulty adhering to the daily regimen due to long shifts and mission requirements.

Providers can help to overcome the issue of availability by prescribing enough packs to last the entire length of the deployment. Female Soldiers can then bring their own supply to theater. If the deployment is extended, the Soldier would have plenty of time to identify resources to refill their prescription.

Consideration of location of the deployment is important as many women have had difficulty patch adherence in extreme temperatures resulting in discontinued use. Many women are aware that a long-acting injectable reversible contraceptive option can be very effective at decreasing or eliminating menstrual bleeding, but may cause weight gain which is not a desirable side-effect for many active duty women. It also has to be injected every 12-14 weeks, which may be a problem during deployments, when geographic location or mission requirements limit access to the medication.

Other long-term options, Long-Acting Reversible Contaception (LARC) include intrauterine devices (IUD) which are excellent options for military women. Intermenstrual bleeding is a common complaint by women in the first few months of use so it should be placed well in advance of the deployment if possible. Most women have several months to prepare for deployment, offering an important window of opportunity for women to discuss the use of (IUD) prior to the deployment.

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First Sgt. Sandrea Cruz leads over 150 soldiers in the 7th Special Forces Group (Airborne)'s Sustainment and Distribution Company. Cruz is inspired by her father, a former Green Beret who served in both the 7th and 3rd Special Forces Groups. *U.S. Army photo/Staff Sgt. Bryan Henson*

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INDICATION

LILETTA is a sterile, levonorgestrel-releasing intrauterine system indicated for prevention of pregnancy for up to 3 years. The system should be replaced after 3 years if continued use is desired.

IMPORTANT SAFETY INFORMATION

Who is not appropriate for LILETTA

Use of LILETTA is contraindicated in women with: known or suspected pregnancy and cannot be used for post-coital contraception; congenital or acquired uterine anomaly, including fibroids if they distort the uterine cavity; known or suspected breast cancer or other progestin-sensitive cancer, now or in the past; known or suspected uterine or cervical neoplasia; acute liver disease or liver tumors; untreated acute cervicitis or vaginitis, including lower genital tract infections (eg, bacterial vaginosis) until infection is controlled; postpartum endometritis or infected abortion in the past 3 months; unexplained uterine bleeding; current IUS; acute pelvic inflammatory disease (PID) or history of PID (except with later intrauterine pregnancy); conditions increasing susceptibility to pelvic infection; or hypersensitivity to any component of LILETTA.

Please see additional Important Safety Information and Brief Summary of full Prescribing Information on the following pages.

IMPORTANT SAFETY INFORMATION (continued)

Clinical considerations for use and removal of LILETTA

Use LILETTA with caution after careful assessment in patients with coagulopathy or taking anticoagulants; migraine, focal migraine with asymmetrical visual loss, or other symptoms indicating transient cerebral ischemia; exceptionally severe headache; marked increase of blood pressure; or severe arterial disease such as stroke or myocardial infarction. Consider removing the intrauterine system if these or the following arise during use: uterine or cervical malignancy or jaundice. Because irregular bleeding/spotting is common during the first months of LILETTA use, exclude endometrial pathology (polyps or cancer) prior to the insertion of LILETTA in women with persistent or uncharacteristic bleeding. If the threads are not visible or are significantly shortened, they may have broken or retracted into the cervical canal or uterus. If LILETTA is displaced (eg, expelled or perforated the uterus), remove it.

Pregnancy related risks with LILETTA

If pregnancy should occur with LILETTA in place, remove the intrauterine system because leaving it in place may increase the risk of spontaneous abortion and preterm labor. Removal or manipulation may result in pregnancy loss. Evaluate women for ectopic pregnancy because the likelihood of a pregnancy being ectopic is increased with LILETTA. Tell women about the signs of ectopic pregnancy and associated risks, including loss of fertility. Women with a history of ectopic pregnancy, tubal surgery, or pelvic infection carry a higher risk of ectopic pregnancy.

Educate her about PID

Insertion of LILETTA is contraindicated in the presence of known or suspected PID or endometritis or a history of PID unless there has been a subsequent intrauterine pregnancy. IUSs have been associated with an increased risk of PID, most likely due to organisms being introduced into the uterus during insertion. About 1/3 of women diagnosed with PID developed the infection within a week of LILETTA insertion, while the remainder were diagnosed more than six months after insertion. Counsel women who receive LILETTA to notify a healthcare provider if they have complaints of lower abdominal or pelvic pain, odorous discharge, unexplained bleeding, fever, or genital lesions or sores. PID is often associated with sexually transmitted infections (STIs); LILETTA does not protect against STIs, including HIV. PID or endometritis may be asymptomatic but still result in tubal damage and its sequelae. Inform women about the possibility of PID and that PID can cause tubal damage leading to ectopic pregnancy or infertility, or infrequently can necessitate hysterectomy, or cause death.

Expect changes in bleeding patterns with LILETTA

Spotting and irregular or heavy bleeding may occur during the first 3 to 6 months. Periods may become shorter and/or lighter thereafter. Cycles may remain irregular, become infrequent, or even cease. Consider pregnancy if menstruation does not occur within 6 weeks of the onset of previous menstruation.

If a significant change in bleeding develops during prolonged use, take appropriate diagnostic measures to rule out endometrial pathology.

Be aware of other serious complications and most common adverse reactions

Some serious complications with IUSs like LILETTA are sepsis, perforation, and expulsion. Severe infection or sepsis, including Group A streptococcal sepsis (GAS), have been reported following insertion of other LNG-releasing IUSs. Aseptic technique during insertion of LILETTA is essential in order to minimize serious infections such as GAS.

Perforation (total or partial, including penetration/embedment of LILETTA in the uterine wall or cervix) may occur, most often during insertion, although the perforation may not be detected until sometime later. Perforation may reduce contraceptive efficacy. If perforation occurs, locate and remove LILETTA. Surgery may be required. Delayed detection or removal of LILETTA in case of perforation may result in migration outside the uterine cavity, adhesions, peritonitis, intestinal perforations, intestinal obstruction, abscesses, and erosion of adjacent viscera. The risk of perforation is higher if inserted in lactating women and may be higher if inserted in women who are postpartum or when the uterus is fixed retroverted.

Partial or complete expulsion of LILETTA may occur, resulting in the loss of contraceptive protection.

Delay LILETTA insertion a minimum of 6 weeks or until uterine involution is complete following a delivery or a second trimester abortion. Remove a partially expelled LILETTA. If expulsion has occurred, a new LILETTA may be inserted within 7 days after the onset of a menstrual period after pregnancy has been ruled out.

Ovarian cysts may occur and are generally asymptomatic, but may be accompanied by pelvic pain or dyspareunia. Evaluate persistent ovarian cysts.

In the clinical trial of LILETTA the most common adverse reactions (≥5% users) were vaginal infections (13.6%), vulvovaginal infections (13.3%), acne (12.3%), headache or migraine (9.8%), nausea or vomiting (7.9%), dyspareunia (7.0%), abdominal pain or discomfort (6.8%), breast tenderness or pain (6.7%), pelvic discomfort or pain (6.1%), depression or depressed mood (5.4%), and mood changes (5.2%).

Teach patients to recognize and immediately report signs or symptoms of the aforementioned conditions. Evaluate patients 4 to 6 weeks after insertion of LILETTA and then yearly or more often if clinically indicated.

Please see Brief Summary of full Prescribing Information on the following pages.

For more information about LILETTA, visit LilettaHCP.com

Liletta®
(levonorgestrel-releasing intrauterine system) 52 mg

Allergan | Medicines360

LLT60413 06/16

LILETTA (levonorgestrel-releasing intrauterine system)

Brief Summary of full Prescribing Information

Initial U.S. Approval: 2015

INDICATIONS AND USAGE: LILETTA™ is indicated for prevention of pregnancy for up to 3 years. The system should be replaced after 3 years if continued use is desired.

CONTRAINDICATIONS: The use of LILETTA is contraindicated when one or more of the following conditions exist: Pregnancy or suspected pregnancy; For use as post-coital contraception (emergency contraception); Congenital or acquired uterine anomaly, including fibroids, that distorts the uterine cavity; Acute pelvic inflammatory disease (PID) or a history of PID unless there has been a subsequent intrauterine pregnancy; Postpartum endometritis or infected abortion in the past 3 months; Known or suspected uterine or cervical neoplasia; Known or suspected breast cancer or other progestin-sensitive cancer, now or in the past; Uterine bleeding of unknown etiology; Untreated acute cervicitis or vaginitis, including bacterial vaginosis, known chlamydial or gonococcal cervical infection, or other lower genital tract infections until infection is controlled; Acute liver disease or liver tumor (benign or malignant); Conditions associated with increased susceptibility to pelvic infections *[see Warnings and Precautions]*; A previously inserted IUS that has not been removed; Hypersensitivity to any component of LILETTA *[see Adverse Reactions]*.

WARNINGS AND PRECAUTIONS: Ectopic Pregnancy - Evaluate women for ectopic pregnancy if they become pregnant with LILETTA in place because the likelihood of a pregnancy being ectopic is increased with LILETTA. Approximately half of pregnancies that occur with LILETTA in place are likely to be ectopic. Also consider the possibility of ectopic pregnancy in the case of lower abdominal pain, especially in association with missed periods or if an amenorrheic woman starts bleeding. If an ectopic pregnancy is confirmed, LILETTA should be removed. The incidence of ectopic pregnancy in the clinical trial with LILETTA, which excluded women with a history of ectopic pregnancy who did not have a subsequent intrauterine pregnancy, was approximately 0.12 per 100 women-years. The risk of ectopic pregnancy in women who have a history of ectopic pregnancy and use LILETTA is unknown. Women with a previous history of ectopic pregnancy, tubal surgery or pelvic infection have a higher risk of ectopic pregnancy. Ectopic pregnancy may require surgery and may result in loss of fertility. Tell women who choose LILETTA about the risks of ectopic pregnancy, including the loss of fertility. Teach them to recognize and report to their healthcare provider promptly any signs of ectopic pregnancy. **Intrauterine Pregnancy -** If pregnancy occurs while using LILETTA, determine if LILETTA is in the uterus. If LILETTA is in the uterus, attempt to remove LILETTA because leaving it in place may increase the risk of spontaneous abortion and preterm labor. Removal of LILETTA or probing of the uterus may also result in spontaneous abortion. In the event of an intrauterine pregnancy with LILETTA, consider the following: *Septic abortion* - In patients becoming pregnant with an IUS in place, septic abortion – with septicemia, septic shock, and death – may occur. Septic abortion typically requires hospitalization and treatment with intravenous antibiotics. Septic abortion may result in spontaneous abortion or a medical indication for pregnancy termination. Should severe infection of the uterus occur, hysterectomy may be required, which will result in permanent infertility. *Continuation of pregnancy* - If a woman becomes pregnant with LILETTA in place and if LILETTA cannot be removed or the woman chooses not to have it removed, warn her that failure to remove LILETTA increases the risk of miscarriage, sepsis, premature labor, and premature delivery. Prenatal care should include counseling about these risks and that she should report immediately any flu-like symptoms, fever, chills, cramping, pain, bleeding, vaginal discharge or leakage of fluid, or any other symptom that suggests complications of the pregnancy. **Sepsis -** Severe infection or sepsis, including Group A streptococcal sepsis (GAS), have been reported following insertion of other LNG-releasing IUSs. In some cases, severe pain occurred within hours of insertion followed by sepsis within days. Because death from GAS is more likely if treatment is delayed, it is important to be aware of these rare but serious infections. Aseptic technique during insertion of LILETTA is essential in order to minimize serious infections such as GAS. **Pelvic Inflammatory Disease or Endometritis -** Insertion of LILETTA is contraindicated in the presence of known or suspected PID or endometritis or a history of PID unless there has been a subsequent intrauterine pregnancy *[see Contraindications]*. IUSs have been associated with an increased risk of PID, most likely due to organisms being introduced into the uterus during insertion. In the clinical trial with LILETTA, pelvic infection was diagnosed in 0.6% of women. The infection was diagnosed as PID in 0.4% of women and as endometritis in 0.2% of women. About 1/3 of women diagnosed with PID developed the infection within a week of LILETTA insertion, while the remainder were diagnosed more than six months after insertion. The cases of endometritis had onset less than 40 days after LILETTA insertion. Counsel women who receive LILETTA to notify a healthcare provider if they have complaints of lower abdominal or pelvic pain, odorous discharge, unexplained bleeding, fever, or genital lesions or sores. In such circumstances, perform a pelvic examination promptly to evaluate for possible pelvic infection. Remove LILETTA in cases of recurrent PID or endometritis, or if an acute pelvic infection is severe or does not respond to treatment. Women at increased risk for PID or endometritis - PID and endometritis are often associated with a sexually transmitted infection (STI), and LILETTA does not protect against STIs. The risk of PID or endometritis is greater for women who have multiple sexual partners, and also for women whose sexual partner(s) have multiple sexual partners. Women who have had PID or endometritis are at increased risk for a recurrence or re-infection. In particular, ascertain whether the woman is at increased risk of infection (for example, leukemia, acquired immune deficiency syndrome [AIDS], IV drug abuse). Asymptomatic PID or endometritis - PID or endometritis may be asymptomatic but still result in tubal damage and its sequelae. Treatment of PID or endometritis - Following a diagnosis of PID or endometritis, or suspected PID or endometritis, perform appropriate testing for sexually transmitted infection and initiate antibiotic therapy promptly. LILETTA does not need to be removed immediately if the woman needs ongoing contraception. In the LILETTA clinical trial, 7 of the 10 women who developed PID or endometritis were successfully treated without removal of LILETTA. Reassess the woman in 48-72 hours. If no clinical improvement occurs, continue antibiotics and consider removal of LILETTA. If the woman wants to discontinue use, remove LILETTA after antibiotics have been started to avoid the potential risk for bacterial spread resulting from the removal procedure. Guidelines for PID or endometritis treatment are available from the Centers for Disease Control (CDC), Atlanta, Georgia. *Actinomycosis* - Actinomycosis has been associated with IUS use. Symptomatic women with known actinomycosis infection should have LILETTA removed and receive antibiotics. Actinomycetes can be found in the genital tract cultures in healthy women without IUSs. The significance of actinomyces-like organisms on Pap test in an asymptomatic IUS user is unknown, and so this finding alone does not always require LILETTA removal and treatment. When possible, confirm a Pap test diagnosis with cultures. **Perforation -** Perforation (total or partial, including penetration/embedment of LILETTA in the uterine wall or cervix) may occur, most often during insertion, although the perforation may not be detected until sometime later. Perforation may reduce contraceptive efficacy and result in pregnancy. The incidence of perforation during or following LILETTA insertion in the clinical trial, which excluded breastfeeding women, was 0.1%. If perforation occurs, locate and remove LILETTA. Surgery may be required. Delayed detection or removal of LILETTA in case of perforation may result in migration outside the uterine cavity, adhesions, peritonitis, intestinal perforations, intestinal obstruction, abscesses, and erosion of adjacent viscera. A large post-marketing safety study with other IUSs demonstrated an increased risk of perforation in lactating women. The risk of perforation may be increased if LILETTA is inserted when the uterus is fixed retroverted or not completely involuted during the postpartum period. Delay LILETTA insertion a minimum of six weeks or until involution is complete following a delivery or a second trimester abortion. **Expulsion -** Partial or complete expulsion of LILETTA may occur, resulting in the loss of contraceptive protection. In the clinical trial with LILETTA, an overall expulsion rate of 3.5% was reported, with a rate of 2.0% in nulliparous women and 5.6% in parous women. Expulsion may be associated with symptoms of bleeding or pain, or it may be asymptomatic and go unnoticed. LILETTA typically decreases menstrual bleeding over time; therefore, an increase in menstrual bleeding may be indicative of an expulsion. The risk of expulsion may be increased when the uterus is not completely involuted at the time of insertion. Delay LILETTA insertion a minimum of 6 weeks or until uterine involution is complete following a delivery or a second trimester abortion. Remove a partially expelled LILETTA. If expulsion has occurred, a new LILETTA may be inserted within 7 days after the onset of a menstrual period after pregnancy has been ruled out. **Ovarian Cysts -** Because the contraceptive effect of LILETTA is mainly due to its local effects within the uterus, ovulatory cycles with follicular rupture usually occur in women of fertile age using LILETTA. Sometimes atresia of the follicle is delayed and the follicle may continue to grow. Most ovarian cysts that occur during use of LNG-releasing IUSs are asymptomatic and disappear spontaneously during two to three months of observation. Cysts that cause clinical symptoms can result in pelvic or abdominal pain or dyspareunia. Symptomatic ovarian cysts occurred in 3.4% of subjects using LILETTA, and 0.3% of subjects discontinued use of LILETTA because of an ovarian cyst. Evaluate persistent ovarian cysts. Surgical intervention is not usually required, but may be necessary in some cases. Discuss this risk with patients who choose to use LILETTA. **Bleeding Pattern Alterations -** LILETTA can alter the bleeding pattern and result in spotting, irregular bleeding, heavy bleeding, oligomenorrhea, and amenorrhea. During the first three to six months of LILETTA use, the number of bleeding and spotting days may be increased and bleeding patterns may be irregular. Thereafter, the number of bleeding and spotting days usually decreases but bleeding may remain irregular. In the LILETTA clinical trial, amenorrhea developed in approximately 19% of LILETTA users by the end of the first year of use, in 26% by the end of the second year of use, and in approximately 38% of users by the end of year 3. In the trial, 1.5% of LILETTA subjects discontinued due to bleeding complaints). Table 2 shows the bleeding and spotting days based on 28-day cycle equivalents.

Table 2: Mean Number of Bleeding and Spotting Days per 28-day Cycle Equivalent

28-day Cycle Equivalent	Cycle 1 N=1,691		Cycle 4 N=1,525		Cycle 7 N=1,223		Cycle 13 N=791		Cycle 26 N=438	
Days on treatment	1-28		85-112		169-196		337-364		674-728	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Number of bleeding days	5.8	5.2	2.3	3.3	1.5	2.6	1.2	2.3	0.8	1.7
Number of spotting days	8.9	6.0	4.3	4.2	3.0	3.6	2.7	3.4	2.0	2.7

Note: Includes all LILETTA subjects.

In the LILETTA clinical trial, 248 of 255 (97.3%) of women evaluated experienced menses within 3 months after LILETTA removal. If a significant change in bleeding develops during prolonged use, take appropriate diagnostic measures to rule out endometrial pathology. Consider the possibility of pregnancy if menstruation does not occur within six weeks of the onset of a previous menstruation. Once pregnancy has been excluded, repeated pregnancy tests are generally not necessary in amenorrheic women unless indicated, for example, by other signs of pregnancy or by pelvic pain. **Breast Cancer -** Women who currently have or have had breast cancer, or have a suspicion of breast cancer, should not use hormonal contraception, including LILETTA, because some breast cancers are hormone-sensitive *[see Contraindications]*. Spontaneous reports of breast cancer have been received during postmarketing experience with another LNG-releasing IUS. Observational studies have not provided consistent evidence of an increased risk of breast cancer with use of a LNG-releasing IUS. **Clinical Considerations for Use and Removal -** Obtain a complete medical and social history, including partner status, to determine conditions that might influence the selection of an IUS for contraception. Because irregular bleeding/spotting is common during the first months of LILETTA use, exclude endometrial pathology (polyps or cancer) prior to the insertion of LILETTA in women with persistent or uncharacteristic bleeding. Special attention must be given to ascertaining whether the woman is at increased risk of infection (for example, leukemia, acquired immune deficiency syndrome [AIDS], IV drug abuse), or has a history of PID unless there has been a subsequent intrauterine pregnancy. LILETTA does not protect against HIV/STI transmission. *[See Warnings and Precautions.]* Use LILETTA with caution after careful assessment if any of the following conditions exist, and consider removal of the IUS if any of them arise during use: Coagulopathy or use of anticoagulants; Migraine, focal migraine with asymmetrical visual loss or other symptoms indicating transient cerebral ischemia; Exceptionally severe headache; Marked increase of blood pressure; Severe arterial disease such as stroke or myocardial infarction. In addition, consider removing LILETTA if any of the following conditions arise during use *[see Contraindications]*: Uterine or cervical malignancy; Jaundice. If the threads are not visible or are significantly shortened, they may have broken or retracted into the cervical canal or uterus. Consider the possibility that the IUS may have been displaced, (for example, expelled or perforated the uterus) *[see Warnings and Precautions]*. Exclude pregnancy and verify the location of LILETTA, for example, by sonography, by X-ray, or by gentle exploration of the cervical canal with a suitable instrument *[see Dosage and Administration]*. If LILETTA is displaced, remove it. A new LILETTA may be inserted at that time or during the next menses if it is certain that conception has not occurred. If LILETTA is in place with no evidence of perforation, no intervention is indicated. **Magnetic Resonance Imaging (MRI) Information -** LILETTA is MR Safe.

ADVERSE REACTIONS: The following serious or otherwise important adverse reactions are discussed elsewhere in the labeling: Ectopic Pregnancy *[see Warnings and Precautions]*; Intrauterine Pregnancy *[see Warnings and Precautions]*; Group A Streptococcal Sepsis (GAS) *[see Warnings and Precautions]*; Pelvic Inflammatory Disease or Endometritis *[see Warnings and Precautions]*; Perforation *[see Warnings and Precautions]*; Expulsion *[see Warnings and Precautions]*; Ovarian Cysts *[see Warnings and Precautions]*; Bleeding Pattern Alterations *[see Warnings and Precautions]*. **Clinical Trial Experience -** Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The data described below reflect exposure of 1,751 generally healthy 16- to 45-year-old women to LILETTA in a large, multi-center contraceptive trial conducted in the US, including 1,412 exposed for 1 year and 383 subjects who completed 3 years of use; 58% were nulliparous (mean age 25.1 ± 4.3 years) and 42% were parous (mean age 30.3 ± 6.1 years). Most women who received LILETTA were Caucasian (78.4%) or Black/African American (13.3%); 14.7% of women were of Hispanic ethnicity. The clinical trial had no upper or lower weight or BMI limit. Mean BMI of LILETTA subjects was 26.9 kg/m² (range 15.8 – 61.6 kg/m²); 25.1% had a BMI ≥ 30 kg/m², and 5.3% had a BMI ≥ 40 kg/m². The data cover more than 22,000 28-day cycles of LILETTA exposure. The frequencies of reported adverse drug reactions represent crude incidences. The most common adverse reactions during the LILETTA clinical trial (occurring in ≥ 5% users) are shown in Table 3.

Table 3: Adverse Reactions in ≥ 5% of LILETTA Users in Phase 3 Clinical Study

System Organ Class/Preferred Term	% LILETTA Subjects (N = 1,751)
Vaginal infections	13.6%
Vulvovaginal infections	13.3%
Acne	12.3%
Headache or migraine	9.8%
Nausea or vomiting	7.9%
Dyspareunia	7.0%
Abdominal discomfort or pain	6.8%
Breast tenderness or pain	6.7%
Pelvic discomfort or pain	6.1%
Depression or depressed mood	5.4%
Mood changes	5.2%

In the contraceptive trial, 12.3% of LILETTA users discontinued prematurely due to an adverse reaction. The most common adverse reaction leading to discontinuation was expulsion (3.5%), bleeding complaints (a total of 1.5%). The next most common adverse reactions causing discontinuation were acne (1.3%), mood swings (1.3%), dysmenorrhea (0.6%), and uterine spasm (0.6%). Two women discontinued the clinical study due to PID and one due to endometritis. In the clinical trial, serious adverse reactions included: suicidality and exacerbations of depression and bipolar disorder, ectopic pregnancy, ovarian cysts, and IUS perforation requiring a laparoscopic surgery. **Postmarketing Experience -** The following adverse reactions have been identified during post-approval use of other LNG-releasing IUSs. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure: Hypersensitivity including rash, urticaria, and angioedema; Device Breakage.

DRUG INTERACTIONS: No drug-drug interaction studies have been conducted with LILETTA. Contraceptive effect of LILETTA is mediated via the direct release of LNG into the uterine cavity and is unlikely to be affected by drug interactions via enzyme induction or inhibition.

USE IN SPECIFIC POPULATIONS: Pregnancy - Risk Summary: LILETTA is contraindicated for use in pregnant women because there is no need for pregnancy prevention in a woman who is already pregnant and LILETTA may cause adverse pregnancy outcomes. If a woman becomes pregnant with LILETTA in place, there is an increased risk of miscarriage, sepsis, premature labor, and premature delivery. Published studies report no harmful effects on fetal development associated with long-term use of contraceptive doses of oral progestins in a pregnant woman. The background risk in the U.S. general population of major birth defects is 2-4% and of miscarriage is 15-20% of clinically recognized pregnancies. Advise a woman of the potential risks if pregnancy occurs with LILETTA in place. **Lactation -** Risk Summary: Published studies report the presence of LNG in human milk. Small amounts of progestins (approximately 0.1% of the total maternal doses) were detected in the breast milk of nursing mothers who used other LNG-releasing IUSs. There are no reports of adverse effects in breastfed infants with maternal use of progestin-only contraceptives. Isolated cases of decreased milk production have been reported with another LNG-releasing IUS. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for LILETTA and any potential adverse effects on the breastfed child from LILETTA or from the underlying maternal condition. **Pediatric Use -** Safety and efficacy of LILETTA have been established in females of reproductive age. Efficacy is expected to be the same for postpubertal females under the age of 16 as for users 16 years and older. Use of this product before menarche is not indicated *[see Clinical Pharmacology in the full Prescribing Information]*. **Geriatric Use -** LILETTA has not been studied in women over age 65 and is not indicated for postmenopausal women. **Hepatic Impairment -** No studies were conducted to evaluate the effect of hepatic disease on the disposition of LNG released from LILETTA *[see Contraindications]*. **Renal Impairment -** No studies were conducted to evaluate the effect of renal disease on the disposition of LNG released from LILETTA. **Obesity -** The safety and efficacy of LILETTA have been evaluated in overweight, obese, and morbidly obese patients. There was no apparent effect of BMI or body weight on contraceptive efficacy *[see Clinical Pharmacology in the full Prescribing Information]*.

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Please also see full Prescribing Information at www.LILETTA.com

Active
WOUND CARE

Research to Control Blood Loss Underway for Enhanced Battlefield Care

By the Military Health System Communications Office

When a warfighter becomes injured on the battlefield and is bleeding uncontrollably, wounds must be treated quickly and effectively.

Statistics show that up to 90 percent of preventable combat deaths occur due to uncontrollable bleeding, and that keeping a patient alive during the first 10 minutes after injury can substantially reduce mortality rates.

The Rapid Active Injury/Distress Enhanced Recovery (RAIDER) project is looking at ways to control and stop bleeding in the field faster and save warfighter lives.

Third-year medical students at the Uniformed Services University of the Health Sciences go through an exercise on the school's campus in Bethesda, Maryland.

"RAIDER has continuously evolved since its inception. Originally created to detect severe allergic reactions, RAIDER has expanded its capabilities to stabilize trauma and wound healing," said Alan Furuno, director of the Pacific Joint Information Technology Center (JITC) Biotechnology Hui (the Hawaiian word for group or organization). "It integrates battlefield care with integrated care delivery, a major vision of the MHS for the future."

RAIDER's research goal was to build a sensing platform that could detect substances involved in adverse drug reactions. This work then led researchers to begin using the platform to detect pathogens and biomarkers of infection.

The journey has now led project team members to focus primarily on the development of wound treatments for both immediate and longer-term use to better address changing warfighter priorities.

Currently, two types of wound treatments have been developed and are currently undergoing testing. These include RAIDER therapy for immediate use on the battlefield and first aid posts to stabilize wounds; and RAIDER+ Hydrogel therapy for longer-term use at higher levels of care.

In lab tests, RAIDER therapy has been effective at clotting plasma and blood within 3 seconds. It can be used in different form factors, such as in packets or on gauze, to prevent blood loss from various types of wounds and stop bleeding faster on the battlefield.

RAIDER+ Hydrogel therapy provides physical protection while maintaining a moist environment to aid long-term healing and prevent infection. The healing gel is implanted with stem cells that encourage migration of new cells into the wound site to promote healing.

Limited pre-clinical animal experiments have demonstrated that RAIDER+ Hydrogel can accelerate wound healing on the skin by more than 100 percent.

These two types of wound treatments could significantly affect the outcome and recovery for wounded soldiers and deliver an effective way for medical personnel to provide innovative point-of-injury care when a warfighter's life is on the line.

health.mil

Active
WOUND CARE

Physician, Nurse Leaders Carve Out Time for Patient Care

By Elaine Sanchez, BAMC Public Affairs

Electrician Indalecio Morales was in a "bucket" working on power lines when 14,000 volts of electricity shot into his chest, knocking him unconscious. He doesn't recall much about the accident, but vividly recalls his flight here and the "angel" doctor who never left his side.

Morales later learned that his doctor not only is considered one of the best burn surgeons in Texas, but is the commander of the busiest hospital in the Department of Defense.

"I had the main guy for my doctor and the main guy for the hospital," said Morales, now an outpatient at the U.S Army Institute of Surgical Research Burn Center here. "What more could I ask for?"

Army Col. (Dr.) Evan Renz, commander of Brooke Army Medical Center and a trauma surgeon, is among the top hospital leaders who carve out time each week to engage in patient care. BAMC encompasses San Antonio Military Medical Center — the largest U.S. military hospital and only Level 1 Trauma Center in the DoD — six outpatient clinics across the region, and the Center for the Intrepid, an extremity injury rehabilitation center.

While his schedule is packed with meetings, briefings and visits with staff across the facilities he oversees, Renz has made it a priority to serve on call as an attending surgeon at least one day a week since he took command.

"I feel a deep sense of responsibility for knowing how medicine is practiced within our walls, for knowing if and how we are meeting the needs of our patients," he said. "The single best way for me as a physician leader to do that is to remain clinically active and see patients each week."

> "Leaders can benefit greatly from talking with patients and staff and learning their challenges," said Keenan, who also serves as chief of the Army Nurse Corps. "We can use this feedback to make changes not only at BAMC, but across Army Medicine."

Active, engaged leadership at all levels is vital to continued success for BAMC, the colonel noted.

"Our delivery of safe, quality care is greatly enhanced when leaders responsible for it remain intimately knowledgeable of the practices and processes used each and every day within our system of health," the commander said.

Time in the 'trenches'

Army Col. (Dr.) Douglas Soderdahl, deputy commander for acute care and a urologist, devotes one day a week to patient engagement. Time in the "trenches" has multiple benefits, he said. He's able to maintain continuity of care for his patients, better understand staff challenges and fast-track needed improvements for both patients and staff.

As an added bonus, Soderdahl is able to continue mentoring and training urology residents. "Teaching is a passion of mine," he said. "I hope the next generation of urologists can benefit from my experience."

Air Force Col. (Dr.) Kimberly Pietszak, interim chief, Department of Quality Services, and assistant chief, Department of Medicine, works clinical care into her daily schedule. Like Soderdahl, she appreciates the opportunity to mentor junior providers, particularly when it comes to her areas of expertise: quality and safety.

"I believe it is of the utmost importance to remain clinically active," said Pietszak, an internal medicine physician. "In my administrative job I make decisions which impact clinical care, and my clinical responsibilities give me perspective on how those decisions will affect our clinical staff."

'Suits to Scrubs'

To encourage leader-patient engagement even further, Army Col. Richard Evans, deputy commander for nursing, implemented the "Suits to Scrubs" program in March. One day a month, senior nurse leaders step away from their desks and work a shift in an inpatient ward to get a "pulse check in the organization" and experience day-to-day operations firsthand.

"It's an opportunity for leaders to role model effective patient communication," he said. "We encourage staff to establish a personal connection with patients; see them as more than just a room number or a diagnosis, but as incredible generations of service and family members."

Army Col. (Dr.) Evan Renz, Brooke Army Medical Center commander, explains the function of a vacuum-assisted closure device to Indalecio Morales in the U.S. Army Institute of Surgical Research Burn Center at San Antonio Military Medical Center, Aug. 11, 2015.
U.S. Army photo by Lori Newman

This communication can lead to improvements for both patients and staff, noted Maj. Gen. Jimmie O. Keenan, Army Medical Command's deputy commanding general (operations).

Keenan described a recent "Suits to Scrubs" shift at SAMMC in which she assisted a patient with a walk through the ward, asking about her care along the way.

Her patient pointed out the heavy weight of the telemetry monitor, a portable box that monitors heart rate and rhythm, the general recalled, while also noting marked improvements in bedside manner.

"Leaders can benefit greatly from talking with patients and staff and learning their challenges," said Keenan, who also serves as chief of the Army Nurse Corps. "We can use this feedback to make changes not only at BAMC, but across Army Medicine."

Engaged leadership and robust process improvement are vital in the journey to become a High Reliability Organization, which is an ongoing commitment to provide the safest, highest quality care possible to patients, the general said.

"At the end of the day, our patients are at the center of everything we do," she said. Army Col. (Dr.) Pedro Lucero, the new assistant deputy commander for clinical services and former chief of the Pulmonary Disease Service, said he's been able to strike a balance between his leadership role and patient care. He noted his gratitude for the "100 percent" command support of his clinical time.

"It's a privilege to be a part of this outstanding leadership team and still continue to make a difference for our patients and advocate for staff in my new role," he said.

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Armed Forces Medicine 2016

Active
WOUND CARE

Innovation Offers Hope for Burn Patients

By Crystal Maynard

Cnflicts in Iraq and Afghanistan brought a surge in burn and blast wound injuries from improvised explosive devices. Many who sustain such injuries endure years of rehabilitation and countless surgeries.

Finding innovative strategies to heal these complex wounds more quickly, with fewer complications and less long-term impact from scarring, contractures and disability is a high priority for military medicine.

In 2008, the Department of Defense established the Armed Forces Institute of Regenerative Medicine, or AFIRM, led by the Wake Forest Institute for Regenerative Medicine and Rutgers University. AFIRM was designed as a partnership between academia, industry and the government to deliver regenerative medicine therapies with the goal of restoring form and function to the most critically-injured wounded warriors.

"Regenerative medicine is a rapidly growing area of science that aims to unlock the body's own ability to rebuild, restore or replace damaged tissue and organs," said Kristi Pottol, director of the Tissue Injury and Regenerative Medicine Program Management Office. "Much of regenerative medicine research in the civilian sector is focused on finding ways to reduce the burdens of chronic illness — diabetes, heart disease and others. The DOD wants to use these technologies to treat complex traumatic injuries."

At Fort Detrick, Maryland, the Tissue Injury and Regenerative Medicine Project Management Office at the U.S. Army Medical Materiel Development Activity is monitoring the progress of two new burn treatments under development with DOD funding:

- ReCell
- StrataGraft

Skin wounds are categorized by the amount of total body surface area involved and by the layers of skin tissue involved, both of which determine how the body responds, how the wounds heal and therefore, which treatment strategies are necessary. The larger and deeper the skin injury, the less likely it is the wound will heal without intervention. That's where innovations like ReCell and StrataGraft come in, Pottol said.

The standard treatment for burn wounds is to harvest healthy skin from elsewhere on the patient's body and to use it to cover the burn wounds. This creates another wound on an already fragile body and is extremely painful for the patient.

ReCell, by Avita Medical, harnesses the skin's own regenerative properties. In the operating room, surgeons take a sample of healthy skin about the size of a postage stamp and place it into the ReCell device to create a suspension of individual skin cells.

Within 30 minutes, the resulting cell suspension can treat a skin wound, which is 80 times larger than the skin sample taken. ReCell speeds the healing process, decreases the need to harvest skin from donor sites and improves the appearance of the burn scars.

StrataGraft is for more severe burns. Developed by Stratatech Corporation, StrataGraft is a living, meshable, suturable human skin substitute that reproduces many of the structural and biological properties of normal human skin.

Patients with extensive skin injuries sometimes do not have enough remaining healthy skin to take skin grafts from to cover all of the skin injuries with one procedure. In such cases, burns are covered with cadaver skin or synthetic dressings while waiting for donor sites to heal to re-harvest the site. Unfortunately, after about two weeks, the body rejects cadaveric or synthetic coverings.

The promise of StrataGraft is that it may eliminate the need for donor sites altogether. Surgeons would have a ready supply of tissue "off-the-shelf," saving donor sites, reducing trips to the operating room and minimizing complications.

"The promise of both of these new technologies is that they could be the first substantial change in how burn and skin injuries are treated in the last half century," said Dr. Wendy Dean, Tissue Injury and Regenerative Medicine Program Management Office medical advisor. "Sparing burn patients the pain of large donor sites, or offering surgeons a ready-made, permanent option for wound coverage could lead to a paradigm shift in skin injury treatment."

health.mil

TRICARE
CARDIOLOGY

What Does a Navy Hospital Corpsman Know about the Heart?

By Navy Lt. Louis Streb, Medical Education and Training Campus

Marines know when they're sent to the front lines, a U.S. Navy corpsman will be right there with them. Hospital corpsmen, better known as "Doc," are medical specialists similar to civilian physicians' assistants, but without the years of training and under the added pressure of providing medical care in the field or anywhere else the Navy decides.

The Basic Medical Technician Corpsman Program is a 14-week introductory course in the delivery of medical care.

Students are provided formal education and training that develops them into entry-level medical technicians and corpsmen within fixed and deployable medical facilities.

They receive instruction on medical terminology, anatomy and physiology, basic life support, emergency medical technician-basic curricula, as well as various aspects of nursing and primary patient care, including nutrition, cardiac life support, first aid procedures, infection control, universal precautions, vital signs, intravenous care, wound care management, history taking and physical assessment, as well as customer service.

Corpsmen get a crash course on the cardiovascular, or circulatory system, which consists of the heart, blood, and blood vessels. They start with key terms such as atria, ventricle, artery, vein, capillary, red and white blood cells, plasma, blood pressure, hypertension, pacemaker and shock.

Students learn that the heart is a muscle about the size of your fist, located in the center of the chest; that it has four chambers, responsible for pumping blood through the heart, past multiple valves and out to the body via blood vessels. These vessels are described by their function, location and whether they carry blood away from or to the heart.

Seaman Luke Wagner, Basic Medical Technician Corpsman Program student conducts basic life support skills training during a course at the Medical Education and Training Campus on Joint Base San Antonio-Fort Sam Houston. *Photo by Lisa Braun*

Corpsmen must also understand that the heart does not work alone. It is paired closely with the lungs, and one without the other leads to death.

The functions and effects of these two systems are so intertwined that they are often referred to as the cardiopulmonary system. It becomes crystal clear that the main purpose of the heart is to deliver oxygen and nutrients to all the body's organs such as the brain, kidneys, eyes, liver and skin.

It is because of this newly obtained knowledge and hands-on training that our hospital corpsmen are then able to identify and treat cardiac emergencies, such as coronary artery disease, aneurysm, dysrhythmia, angina pectoris, acute myocardial infarction (heart attack), congestive heart failure and cardiac arrest.

As a BMTCP instructor, registered nurse and prior hospital corpsman myself, I know about the effectiveness of the training students receive in our program, but I think a student's perspective speaks volumes

"What I already knew about the heart is that without it we would die," said one Navy student. "What I didn't understand was how it was like a pump, automatic at first, but when necessary, could be run manually."

"Something which I found extremely interesting was that when you have a myocardial infarction it actually kills a little bit of your heart muscle," another Navy student noted.

"That bit of the heart is now incapable of ever functioning again and now the rest of the heart is having to compensate for normal productivity."

jbsa.mil

TRICARE
CARDIOLOGY

HAWC Shares Ways People Can Improve Their Heart Health

By Holly Logan-Arrington, Robbins AFB Public Affairs

Having a family history of heart disease places a person at higher risk, but it doesn't mean all hope for a healthy heart is lost. Heart disease has traditionally been associated with men, but the disease kills more women than all forms of cancer combined. People can cut their heart disease risk by making some lifestyle changes.

Stuart Bapties, Health and Wellness Center Flight chief, said quitting smoking reduces heart disease risk. "Smoking is the most preventable cause of premature death and it increases your risk for heart disease," he said. "In addition, when you stop smoking, you help lower your blood pressure and lower your low-density lipoprotein, or bad, cholesterol. So, if you want to live longer, stop smoking."

The HAWC offers free tobacco cessation options that include counseling and discussion, along with nicotine replacement therapy to help people kick the tobacco habit.

Secondhand smoke also raises people's heart disease risk. "We now know for a certainty that even being around smoke increases the risk for heart disease and death, even in those who have never smoked. Avoid secondhand smoke whenever possible." Bapties said.

People need to know their numbers. "You owe it to yourself to take an active role in your own health," he said. "Find out your blood pressure, cholesterol and weight and discuss those numbers with your doctor. With your doctor's help, you can monitor any changes and make informed decisions."

Civilians can contact the Civilian Health Promotion Service office at 478-327-8030 to schedule screenings in their work center or create an account on the Air Force Materiel Command Wellness site at www.afmcwellness.com. TRICARE community members can make an appointment to discuss having these tests done with their primary care manager.

Making changes that impact blood pressure, cholesterol and weight can also reduce heart disease risk, said Bapties. "Switch out one processed food a month for something you make yourself," he said. "It can be as simple as a soup. By switching from processed foods, which are usually high in sodium, you can make a difference in your blood pressure and overall health."

Angela Hawkins, Tricare representative, has her blood pressure checked by Kelley Denny, Civilian Health Promotions Services coordinator, as part of her Cardiac Risk Profile at last year's Healthy Heart Fair. February is National Heart Health Month and CHPS will be available at locations base wide throughout the month to answer questions about heart disease and other wellness concerns. *U.S. Air Force photo by Misuzu Allen*

Making other small steps can make a big difference also, he said. "Try parking further away from the office, choosing the stairs, or taking a walk after lunch," he said. "Stand up every hour at your desk to stretch. If you have a pedometer, aim for at least 10,000 steps a day."

Robins Air Force Base workers can get a free pedometer and participate in the Robins Million Steps Challenge for wellness prizes throughout the year by calling the HAWC or CHPS.

Making lifestyle changes to reduce heart disease risk can often inspire others. "Whether we're taking care of our parents, our children, our partners or looking out for friends, we have a unique ability to influence changes in diet and exercise," said Bapties. "You can impact a lot of people through your own choices."

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TRICARE
CARDIOLOGY

METC Cardiovascular Technicians Training for Healthy Hearts

By Petty Officer 1st Class Aldrin Augustus, Medical Education and Training Campus

As a Navy cardiovascular technician, or CVT, I am one of the most highly specialized, medically trained enlisted professionals in the Navy. The training I deliver at the Medical Education and Training Campus at Joint Base San Antonio-Fort Sam Houston is one of a kind.

In a matter of just 13 months, students graduate with the knowledge and skills to function in a specialized field. Our students learn both invasive and noninvasive aspects of cardiology. Our civilian counterparts have two-year associate's degree programs, but their students are only trained on either non-invasive or invasive cardiology. Navy CVTs are trained to do both.

As a CVT, I work under the direction of a cardiologist assisting with cardiac emergencies and examination studies in both diagnostic and invasive settings, so it's no secret that the training is quite demanding.

The METC CVT program is an intensive program consisting of five months of didactic Phase 1 training at the METC, followed by eight months of clinical training at Naval Medical Center San Diego.

Throughout this time, students receive training in anatomy and physiology, physics, echocardiography, advanced cardiac life support, electrophysiology and cardiac catheterization. Students are also trained to perform exercise stress testing, electrocardiograms and interpretation of the heart's rhythm. These tools allow CVTs to assist the cardiologist in diagnosis and treatment of cardiac disease before it becomes life threatening.

Petty Officer 1st Class Aldrin Augustus (center), cardiovascular technician program instructor and Navy service lead at the Medical Education and Training Campus on Joint Base San Antonio-Fort Sam Houston, instructs Navy Petty Officer 3rd Class Chessa Sheppard (left) and Army Spc. Victoria Belbusti (right) on using the cardiac catheterization simulator during a portion of their CVT didactic training. The simulator is used to demonstrate concepts learned in the classroom and exposes students to hands on training that they will be expected to perform. *Photo by Lisa Braun*

After six years as a CVT, I am proficient in recognizing cardiac rhythm disturbances that could indicate a life-threatening medical condition. Using sound waves, I am able to perform cardiac ultrasounds to visualize the heart, which provides the cardiologist with valuable information regarding the heart's structure and motion.

Standing side-by-side with an invasive cardiologist, I am able to assist with invasive diagnostic cardiac catheterization procedures that look for blockages in the coronary arteries, and if found, I play an integral part in the interventional procedure using balloons and stents to reopen the vessel.

Through mapping of the heart's electrical conduction system, the electrophysiology study will find rhythm abnormalities and correct them with specialized cardiac ablation procedures including implanting pacemakers where applicable. This specialty requires me to have a cool head and the ability to think and act quickly in critical situations.

Along with the five months of didactic training, CVT students work with some of the most technologically advanced equipment in the cardiovascular field. The program employs two state-of-the-art Laerdal SimMan 3G Advanced Cardiac Life Support simulators that are utilized during the ACLS and patient assessment portion of the curriculum.

The two simulators provide a tangible hands-on link between didactic lessons learned in pharmacology and patient assessment. It allows students to effectively practice CVT skills in a training environment.

Having this level of simulator technology allows students to learn all the different modalities of cardiovascular training that they experience throughout the course and will be exposed to upon graduation. In previous years there was no way to illustrate some of the things that a CVT will see out in the real world, like patient reaction in real time and how to treat and anticipate possible complications.

The most impressive simulation capability is during the cardiac catheterization rotation. There is a fully functional cardiac catheterization suite that allows students to practice positioning the x-ray equipment, safe patient transfer procedures, and setting up and maintaining a sterile field. It is fully stocked with the same diagnostic and interventional equipment that is used during real clinical rotations.

In addition to the cardiac catheterization laboratory, the program utilizes a Simbionix Angio-Mentor to teach invasive skills.

Students use the simulator to combine all the didactic and clinical hands on invasive techniques learned throughout the curriculum. The Angio-Mentor provides experience with basic and advanced guide wire and catheter skills, familiarity with endovascular procedures, and catherization lab team experience. Students learn how to manipulate catheters, inflate balloons and stents, and respond to complications associated with all the respective procedures.

Students receive training in anatomy and physiology, physics, echocardiography, advanced cardiac life support, electrophysiology and cardiac catheterization. Students are also trained to perform exercise stress testing, electrocardiograms and interpretation of the heart's rhythm. These tools allow CVTs to assist the cardiologist in diagnosis and treatment of cardiac disease before it becomes life threatening.

The simulator tracks X-ray exposure, contrast administration and reacts to the procedure in real time. Other skills learned include how to operate the C-arm, patient's table, and fluoroscopic screen, as well as how to read the hemodynamic monitoring and administer medications.

The simulator offers hands-on training that is designed to enhance manual dexterity and improve appropriate instrument decision making. I was able to feel the high-end sensation that provides realistic simulation of guide wire, balloon, stent and other interventional devices.

The program also conducts team training exercises to build confidence and help students understand the requirements of all the catheter lab team members. Patient safety is the primary focus of the vast curricula, and validation studies have reinforced the value of simulators in professional development.

Recently, our program director underwent one of the procedures the students learn about in the program. He had an atrial fibrillation ablation, where the cardiologist mapped the electrical conduction system of the heart to see where the abnormal impulses were coming from. Once the doctor knew the location he used a catheter to deliver extremely cold energy to that area, destroying the tissue to restore normal heart rhythm.

However, seeing this as an opportunity for more learning, the program director invited his students to observe the procedure so they could see firsthand what they will be expected to do after they graduate. In addition, the staff where the procedure was conducted included two cardiovascular technicians who were trained at METC by him.

Stories like these are the reason we take great pride in our field and why we are so dedicated to providing the highest quality training using the most advanced, cutting edge technology to produce the world's finest cardiovascular technicians.

navymedicine.navylive.dodlive.mil

TRICARE
ENDOCRINOLOGY

Retirees Receive Extra Care During Appreciation Day

By Tech. Sgt. Travis Edwards, 51st Fighter Wing Public Affairs

Retirees received some extra care and attention in the form of benefit education and health screening from Team Osan during the Retiree Appreciation Day held at the Exchange here Feb. 3, 2016.

Retirees living and working near Osan Air Base showed up to enjoy and learn about the free benefits available to retirees and veterans.

"The retired population around Osan is small, but they support big when it comes to helping the local community with projects," said Candace Ford, lead coordinator for the event. "After four years of being at Osan, I've seen that retirees have the strongest presence and the biggest hearts — so we wanted to give back."

Ford added that it isn't uncommon to see large donations from veteran and retiree-centric clubs, like the Veterans of Foreign Wars.

"We're here to help," said retired Tech. Sgt. Ron Davis, VFW senior vice commander for Korea. "Some retirees may not know how to get involved or that the VFW is here, so we're here to show them."

A total of 12 agencies came to the Exchange to support the retirees and inform them of what benefits are available to them; including The Department of Veteran Affairs.

Additionally, one doctor and a team of nurses from Hallym University Dongtan Sacred Heart Hospital, were on hand to give a free health screening, something not always available to the retirees.

"I have a strong service history with my family and I've been on two deployments to Bosnia and Kuwait, so I have a strong affiliation to those who serve, have served and retired from service," said Ford. "I really just want [retirees] to remember that they are not forgotten, we still care for them and we really appreciate the time they put into the service to help us be where we are today."

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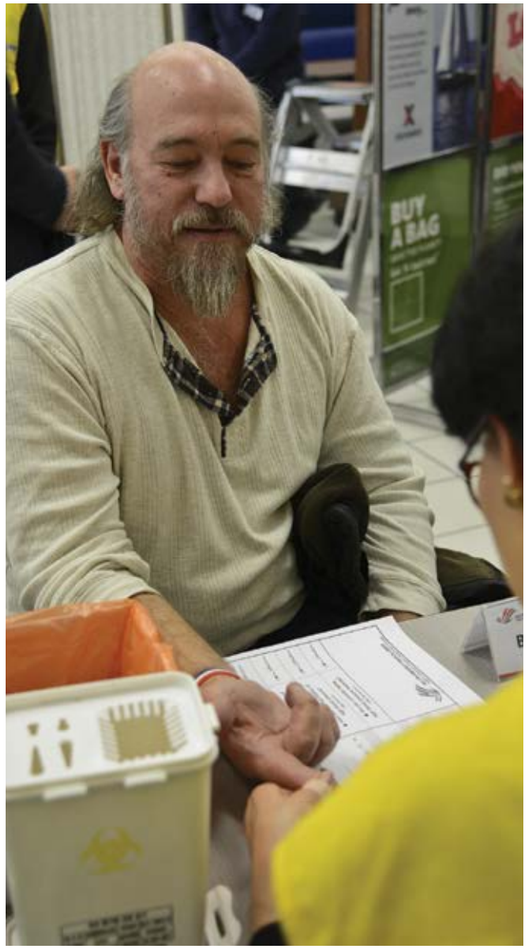

Retired Tech. Sgt. Jeff Laman, receives a blood-sugar test from a Hallym University Dongtan Sacred Heart Hospital nurse during the Retiree Appreciation Day in the Exchange at Osan Air Base, Republic of Korea, Feb. 4, 2016. Laman was one of many retirees who received some extra care, attention and appreciation during the Exchange-sponsored event. *U.S. Air Force photo by Tech. Sgt. Travis Edwards/Released*

TRICARE
ENDOCRINOLOGY

Warrior Games Athlete's Illness Strengthens Couple's Bond

By Shannon Collins DoD News, Defense Media Activity

U.S. Special Operations Command veteran Sean Walsh earned silver medals in the 100-meter freestyle, 50-meter freestyle and 50-meter backstroke and a bronze medal in the 50-meter breaststroke in swimming competition yesterday at the Freedom Aquatic and Fitness Center in Manassas, Virginia, as part of the 2015 Department of Defense Warrior Games.

He earned a bronze medal June 21 in the men's upright cycling open category, and he will compete here today in the men's 4-by-100-meter relay and the 1,500-meter run.

Walsh said doesn't really pay attention to whether he earns medals when he competes. Between competitions, he visits with his wife of six years, Caroline, and their 15-month old son, Tommy.

"It's incredible to have her out here — to have her see me race at this level in this state is absolutely incredible — so I'm very, very fortunate to have her in my life," he said.

How They Met

Walsh had just graduated from the U.S. Military Academy in West Point, New York, and was in Beijing when he met Caroline.

"We were both studying Chinese," she said. "He had just graduated from West Point, and one of his former roommates was in my language study program, so we all went out to dinner together. I always think very fondly about his friend who introduced us."

Sean Walsh swims the 50-meter freestyle category 6.0 for the U.S. Special Operations Command team during the 2015 Department of Defense Warrior Games at Freedom Aquatic and Fitness Center in Manassas, Va., June 27, 2015. He earned a silver medal in the event. *DoD photo by EJ Hersom*

U.S. Special Operations Command veteran Sean Walsh and his son, Tommy, 15 months, enjoy some time together before Walsh competes in the men's open upright cycling competition at the 2015 Warrior Games at Marine Corps Base Quantico, Va., June 21, 2015. Walsh earned a bronze medal in the event.
DoD photo by Shannon Collins

Illness

Walsh started as an infantry officer, but crossed over after four years into civil affairs. The former captain said he went out for a run while he was deployed three years ago, and he got so tired he didn't know if he would be able to make it back.

"I went from doing half Ironmans and training for a marathon and then suddenly, I couldn't run at all," he said. "I'm in the middle of nowhere, and it was like, 'I don't know if I'm going to make it back.' Unfortunately, it was the most tired I had ever been in my life."

Caroline Walsh said she was in graduate school in New Jersey, and her husband was at Fort Bragg in North Carolina after he returned from overseas, and he told her he needed to go to the doctor.

"He called me a little later that afternoon and said, 'I'm actually going to have to go into the [intensive care unit]. I've got Type 1 diabetes," she recalled. "It was just something that never crossed our minds, so I just jumped in the car and sped down. From the minute I got to the hospital, everybody was wonderful. The support was just fantastic, even though it was terrifying and [he had] a new life to adjust to.

Walsh now wears a pump that provides him with insulin 24 hours a day.

Support

Caroline helps him keep his insulin in check, Walsh said. "There's been a bunch of times where I've gotten too low, like I give myself too much insulin and my blood sugar drops, and she's been there to take care of me, and that's been incredibly supportive," he said. "I can't imagine her not being there. I would've been very lost without having her there. It would've been much tougher, because I was also part of a common identity. … I'm not a soldier [any more], but I'm still a husband, and I have to concentrate on that. She's my rock." Caroline said she is proud of how her husband is handling his illness.

"He's handling it really well. I'm really proud of him," she said. "There are hard days, and there are things that are frustrating. It just sort of adds a new level of complication to life, but he's doing great, and in some ways, I think it's made him more determined. I think it's maybe made him a more focused athlete, and it's made him more grateful for everything that he has."

The illness has made them a stronger couple, she added.

"It also made us realize that we could really deal with anything, and I think it's made us [stronger]," she added. "It happened before Tommy was born, but I think it's made us stronger parents too, because we know what we're capable of."

Pursuing Excellence

Walsh said he swam in high school and a little bit at West Point, and that he uses adaptive sports to control his illness and to reassert that control over his life by training.

"I got a coach. I got all the great things that the Military Adaptive Sports Program offers, and I was able to use that to help control my diabetes," he said. "It was really phenomenal. When I got sick, and I had to leave the military, I was like, 'This is my new identity.'

"I'm going to become the best athlete I can," he continued. "And when I say the best athlete, I don't mean about winning races — it's about being the best that you can be and pursuing excellence."

Walsh added that this has translated beyond sport, providing the drive and dedication to be a great father, a great husband and a great worker. His goal, he said, is to become elite enough to join an all-diabetic pro cycling team and join a diabetic triathlon club so he can inspire others with diabetes.

defense.gov

TRICARE
NEUROLOGY

Patient Makes Post-Stroke Strides at Brain Injury Clinic

By Elaine Sanchez, Brooke Army Medical Center Public Affairs

When Kathryn Harris arrived for her first appointment at the Brain Injury Rehabilitation Service, she was leaning heavily on a walker.

The staff told her to park it at the door next time. "They told me no walker, no wheelchair. You don't need them. You're going to walk," said Harris, who is recovering from a stroke at the clinic in San Antonio Military Medical Center. "I knew then I could achieve my goals here."

The clinic, located in SAMMC's lower level, is a one-stop shop for patients with brain injuries such as strokes, aneurisms, tumors and severe traumatic brain injuries.

Once referred, patients are assigned to a team comprising a physical medicine rehabilitation provider, occupational therapist, physical therapist, speech language pathologist, psychologist, recreational therapist and veteran benefits coordinator.

"We manage patients as a team," said Amy Bowles, the service's director. "The treatment is more comprehensive and we are able to address more global goals. It greatly benefits the patient's recovery."

Harris said she's come a long way since her two strokes last spring. The San Antonio native was driving home from seeing her husband, retired Air Force Master Sgt. Allen Harris, one day in March when a driver side-swiped her car.

She wasn't injured but felt ill as she waited for the police to arrive. That evening, her daughter, Robbie Harris, asked her a question about the accident, but didn't get a response.

"I knew something wasn't right and then I saw the left side of her face droop," Robbie said. She realized that her mother was having a stroke. Harris had a second stroke at her outpatient rehabilitation center about a week later, affecting function on her entire left side, including the vision in her left eye.

She was provided home health care, but asked to be treated at SAMMC's outpatient clinic. "I knew when I first walked in that the energy was different," Harris said. "They were caring and nurturing, and pushed me to achieve my goals."

Her goals, she added, included walking into her granddaughter's school unassisted and "getting back into the kitchen." Fortunately, the clinic is equipped with a full kitchen, along with assistance in everything from writing a grocery list to stirring a bowl with one hand.

"I made brownies here and everyone ate them up. I didn't even get one," she said with a laugh.

She's also improved her walking with help from a physical therapist and an anti-gravity treadmill. "I cried when I first used the treadmill because I could walk again," Harris said.

Harris is just one of the many motivated patients who have made progress in the clinic since it opened its doors eight years ago, said Bowles, who has been with the service since its first day.

The military initially stood up the clinic, formerly known as the Traumatic Brain Injury Service, to aid wounded service members with concussions and other brain injuries at the height of the war.

> "They told me no walker, no wheelchair. You don't need them. You're going to walk," said Harris. "I knew then I could achieve my goals here."

"We'd get patients here three days after they received a concussion or a more severe injury in Iraq or Afghanistan," the doctor recalled. The staff treated primarily active duty service members for nearly a decade but once the wars wound down, they looked to expand their scope to retirees and family members with other types of brain injuries to keep their skills sharp. They also provide frequent consults to inpatients across the hospital.

continued on page 95

continued from page 92

Leville Crowther, physical therapy assistant, explains shoulder mechanics to Kathryn Harris and her daughter, Robbie Harris, Oct. 16, 2015. Kathryn Harris suffered two strokes last spring, but has made great strides at the Brain Injury Rehabilitation Service in San Antonio Military Medical Center. *Photo Credit: U.S. Army photo by Robert T. Shields*

"The type of care they need falls right in our wheelhouse," she said. "And we got a great response when we expanded our services. There was a definite need for comprehensive brain injury care among our retirees and family members."

With every related specialty on hand, Bowles said she's proud of the holistic care they offer both military families and civilian trauma patients.

Bowles said she most enjoys seeing her patients' progress. She ran into one of her first active duty patients the other day and was glad to hear he was interviewing for a job and pursuing other interests.

"It's wonderful to see how he's building a new life," she said. "It's always deeply satisfying to see the progress our patients are making."

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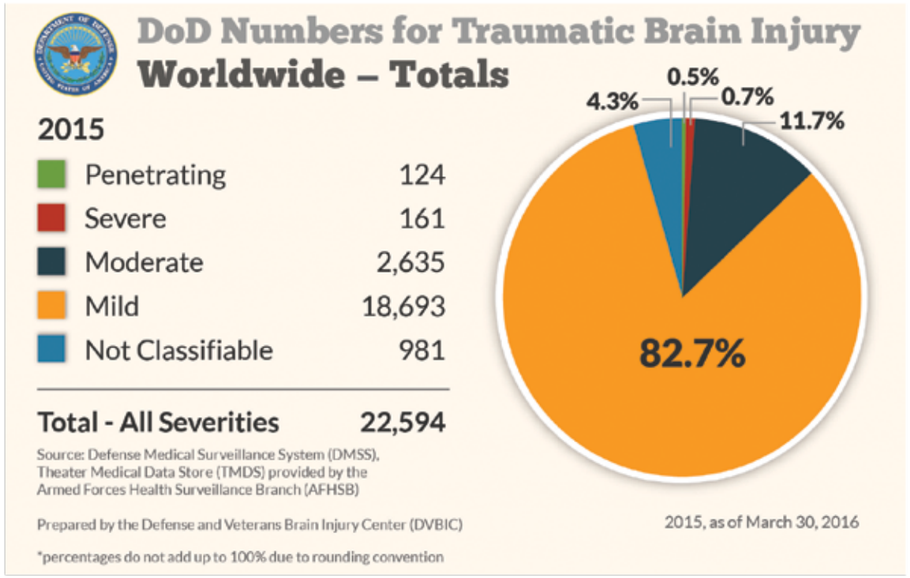
She's also improved her walking with help from a physical therapist and an anti-gravity treadmill. "I cried when I first used the treadmill because I could walk again," Harris said.



Effective October 2015, the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD) was implemented across the Military Health System (MHS). This implementation and the 2015 Assistant Secretary of Defense Memo on the TBI case definition allow for more moderate traumatic brain injuries to be captured. Please consult the Armed Forces Health Surveillance Branch (AFHSB) TBI case definition for additional information.

Worldwide numbers represent medical diagnoses of TBI that occurred anywhere U.S. forces are located including the continental United States since 2000.

Concussion/Mild TBI is characterized by the following: Confused or disoriented state which lasts less than 24 hours; or loss of consciousness for up to 30 minutes; or memory loss lasting less than 24 hours. Excludes penetrating TBI. A CT scan is not indicated for most patients with a Mild TBI. If obtained, it is normal.

Moderate TBI is characterized by the following: Confused or disoriented state which lasts more than 24 hours; or loss of consciousness for more than 30 minutes, but less than 24 hours; or memory loss lasting greater than 24 hours but less than seven days; or meets criteria for Mild TBI except an abnormal CT scan is present. Excludes penetrating TBI. A structural brain imaging study may be normal or abnormal.

Severe TBI is characterized by the following: Confused or disoriented state which lasts more than 24 hours; or loss of consciousness for more than 24 hours; or memory loss for more than seven days. Excludes penetrating TBI. A structural brain imaging study may be normal but usually is abnormal.

DoD Worldwide TBI Numbers

TRICARE
ONCOLOGY

Lung Cancer Screening Day Seeks to Heighten Awareness

By Bernard S. Little, WRNMMC Public Affairs

In keeping with Lung Cancer Awareness Month observed during November, the John P. Murtha Cancer Center (MCC) at Walter Reed National Military Medical Center (WRNMMC) hosted Lung Cancer Screening Day on Nov. 4 in the hospital.

The MCC is the only Department of Defense Cancer Center of Excellence in the Military Health System, and it has developed an effective lung cancer screening program, explained Cmdr. Elena Prezioso.

"It's important to us, especially here at Walter Reed Bethesda where we have a large population, to do as much health prevention as we can," said Prezioso, director of the lung cancer screening program. "Our lung prevention program helps us find lung cancer."

She explained the challenge with lung cancer is it usually doesn't show until it's in its later stages.

"Now that we have this screening tool available, we can identify high-risk patients early and treat them, and most of the time, it's a curative treatment," Prezioso said. She added the criteria established by the U.S. Preventive Services Task Force to be considered a high-risk patient for lung cancer, is anyone between the ages of 55 and 80 with a 30-pack-a-year history, or if the person still smokes or has quit less than 15 years ago.

Those 50 and older who have at least a 20-pack-a-year history of smoking and at least one additional risk factor, such as a family history of cancer, pulmonary fibrosis, and post exposure to toxic chemicals such as asbestos, radon, agent orange or silica/silicon, may also be considered high risk.

"They should be screened with a low-dose computerized tomography or CT scan," Prezioso said.

Carolyn Mesnak, who facilitates the tobacco cessation program for Integrated Health Services-Internal Medicine Department at WRNMMC, was also on hand at the Lung Cancer Screening Day event to provide people with helpful information concerning kicking the smoking habit and her program.

"We provide individual counseling and classes [to help people quit smoking, dipping and vaping]," Mesnak said. In addition to tobacco products, Mesnak explained people are getting nicotine through other different avenues, including vape pens, liquid nicotine and hookah pipes.

"A can of smokeless tobacco could equal to three packs of cigarettes," Mesnak continued. "People may think they are doing themselves a favor by quitting smoking, but they may be getting more nicotine from the smokeless tobacco." She added the same may be the case with cigars, which one could equal a pack or two of cigarettes depending on its size. Cigars are rolled using all tobacco leaves for use, whereas cigarettes are rolled in paper with a filter, she explained.

Mesnak said alternatives for smokers may include the use of cinnamon sticks and ginger, behavioral techniques to curb cravings, in addition to patches, gum and medications.

She added the tobacco cessation program is open to service members, their families and other TRICARE beneficiaries, as well as federal employees and contractors, although civilian employees and contractors cannot receive medication to help them quit smoking.

Mesnak added the Great American Smokeout will be on Nov. 19 to encourage smokers to give up the habit. According to the American Cancer Society, sponsor of the observance, about 42 million Americans still smoke cigarettes, and tobacco use remains the single largest preventable cause of disease and premature death in the U.S. As of 2013, there were also 12.4 million cigar smokers in the U.S., and more than 2.3 million who smoke tobacco in pipes.

The tobacco cessation program at WRNMMC is located in the America Building, second floor in the Internal Medicine Department, Integrated Health and Medicine. For more information, call 301-295-0105.

Clinical research coordinator Maggie Nellissery participated in Lung Cancer Screening Day as well. She is currently involved in two studies seeking to detect early lung cancer among military personnel. "Right now we see lung cancer in the CT scan, but the goal for this project is to detect lung cancer earlier than when you can see it on the CT scan," she explained. Nellissery said she's been working on the project for three years, and it's slated to last five years.

wrnmmc.capmed.mil

TRICARE
ONCOLOGY

Fort Belvoir Community Hospital Earns Radiation Oncology Accreditation

By Alexandra Snyder, Fort Belvoir Community Hospital Public Affairs

Affording patients the highest standards of care in the treatment of cancers and cancer-related pain, Fort Belvoir Community Hospital recently became the first military treatment facility to receive accreditation in radiation oncology by the American College of Radiology.

Radiation therapy within the Oncology field involves the careful use of high-energy radiation to treat cancer. The accreditation process, which saw an impartial peer review and evaluation of patient care, staff, equipment, and randomly selected treatment planning and records, ensures Belvoir Hospital is practicing the highest level of quality and patient safety, said Army Maj. Delnora Erickson, chief of Radiation Oncology here.

The accreditation process, which saw an impartial peer review and evaluation of patient care, staff, equipment, and randomly selected treatment planning and records, ensures Belvoir Hospital is practicing the highest level of quality and patient safety.
Photo courtesy of Fort Belvoir Community Hospital

"We have a rigorous, collaborative department," said Erickson. "All of patient cases are peer-reviewed to ensure a consensus of diagnosis from multiple experts. We work closely with other departments to make sure patients are getting treatment that is accurate, safe and tailored to them."

> "This is a team that doesn't get a day off, simply because of the nature of the treatment they provide. "Patients receiving radiation must get their treatments on a set schedule or the cancer can begin to grow back. This means that snow days, holidays, this team is here. They're dedicated, they go above and beyond every day and they deserve to be commended."

By electively obtaining ACR accreditation, the department is able to demonstrate to patients that commitment to providing the best patient care and image quality possible, said John Pacyniak, PhD, lead physicist in the Belvoir Hospital Radiation Oncology clinic.

"The accreditation team, which consisted of an outside physician, administrative member and physicist, expressed to us that they were impressed by the fact that all our records and communications are electronic, meaning patients don't have to bring a hard copy of their folder to each treatment," said Pacyniak. This allows for streamlined care through the various planning processes, he added.

"The average time it takes a facility to receive official accreditation after being reviewed is six to eight weeks," said Pacyniak. "We received ours in 10 days, which I think truly signifies we are doing the right things."

Doing the right things comes naturally to the Radiation Oncology team, said Navy Cmdr. Michael Meadows, chief, Department of Radiology at the hospital.

"This is a team that doesn't get a day off, simply because of the nature of the treatment they provide," said Meadows. "Patients receiving radiation must get their treatments on a set schedule or the cancer can begin to grow back. This means that snow days, holidays, this team is here. They're dedicated, they go above and beyond every day and they deserve to be commended."

health.mil

TRICARE
ONCOLOGY

Screening, Early Detection Help Prevent Colon Cancer

By David DeKunder, Joint Base San Antonio-Randolph Public Affairs

March is National Colon Cancer Awareness Month and Joint Base San Antonio members 50 years of age and older, or who have a family history of colon cancer are being urged to get screened for the disease to prevent it from occurring.

According to the Centers for Disease Control and Prevention, every year in the U.S. about 140,000 people are diagnosed with colon cancer and 50,000 die from the disease, making it the second leading cause of cancer deaths in the U.S. More than 90 percent of colon cancer cases occur in people ages 50 years and older.

Colon cancer occurs in the form of polyps, which are abnormal growths inside the colon or rectum that could become cancerous if not removed.

Col. Bryce Mays, chief of gastroenterology services at San Antonio Military Medical Center, said screening and early detection could stop colon cancer from developing.

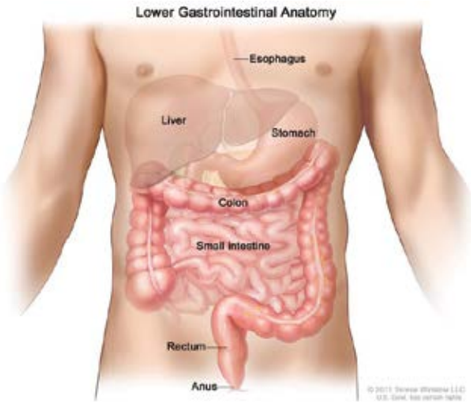
"This is a disease that is mostly preventable with appropriate screening," Mays said.

Symptoms of colon cancer include a change in normal bowel habits, including diarrhea, constipation and a change in consistency of stools; persistent abdominal pain; rectal bleeding, including blood in the stool; and fatigue, including unexplained weight loss. Patients should consult their physician as to what screening test options there are for detecting the disease, Mays said.

While it is recommended that people start getting screened for colon cancer at 50 years of age, Mays said people who are younger than 50 years of age should consider getting screened earlier if they have a family history of colon cancer or an inflammatory bowel disease.

According to the Colon Cancer Alliance, patients whose colon cancer is detected at an early stage have a five-year survival rate of 90 percent.

Priscilla King, a certified personal trainer at the JBSA-Randolph Rambler Fitness Center, was diagnosed with stage three colon cancer in 2009. King was 41 years of age at the time of her diagnosis.



Symptoms of colon cancer include a change in normal bowel habits, including diarrhea, constipation and a change in consistency of stools; persistent abdominal pain; rectal bleeding, including blood in the stool; and fatigue, including unexplained weight loss.

King said she first experienced symptoms of colon cancer three years earlier and had gone to see a physician who misdiagnosed her condition. She put off getting screened until her symptoms got worse.

After her diagnosis, King underwent 10 months of treatment, including radiation, chemotherapy and surgery. King said her colon cancer is now in remission. King said she urges anyone who has symptoms of colon cancer to get a screening as soon as possible.

"I am now an advocate of listening to your body and getting screened, if things aren't right and you have the symptoms of colon cancer," King said.

jbsa.mil

TRICARE
OPHTHALMOLOGY

Belvoir Hospital Clinic Has (20/20) Vision for the Future of our Forces

By Alexandra Snyder, Fort Belvoir Community Hospital Public Affairs

In an effort to improve troop efficiency on and off the battlefield, Fort Belvoir Community Hospital offers refractive eye surgery for all qualified active-duty service members.

With great success in reducing dependence on glasses and contact lenses and a short wait time, the Warfighter Refractive Eye Surgery Program and Research Center aims to enhance a service member's readiness and battlefield performance. By improving their vision- Soldiers are able to perform tasks they currently must use contacts or glasses to perform, said Lt Col. Bruce Rivers, the program director.

"Imagine being able to deploy without glasses, or inserts in your gasmask," said Rivers. "These surgeries allow us to improve upon the already able warrior by making their vision more reliable, and therefore, making that service member more combat effective." Furthermore, when wearing ballistic eye protection, the decreased dependence on glasses eliminates additional degradation of vision caused by interface and fit issues. Dr. Rivers had refractive surgery prior to deploying in 2006 and feels that "it is one of the best military enhancements the military has to offer its service members."

The WRESP-RC offers several options for reducing one's dependency on prescription glasses and corrective lenses.

"Our goal is to offer corrective surgeries to everyone eligible, minimize risks and review alternatives with patients who should not have surgery" said Rivers. "Because of the numerous vision correction options we're able to offer here, we are able to take care of populations who previously wouldn't have qualified because of thin corneas or very high prescriptions."

There are several forms of laser refractive surgery currently available and the most commonly performed procedures, such as are photorefractive keratectomy (PRK) and laser-assisted in situ keratomileusis (LASIK), use a laser to change the shape of the cornea to correct vision or "refractive error."

An optimal refractive candidate has a stable eyeglass prescription and no underlying eye conditions such as glaucoma, cataracts, or corneal diseases, Rivers said. For patients who may not qualify due to thin corneas, underlying medical conditions, or higher levels of correction, the clinic offers implantable contact lenses. These lenses are more invasive, but offer the same corrective results as LASIK or PRK. Patients are only considered candidates for ICL's when PRK or LASIK is not a safe option, said Rivers.

Prior to surgery, a comprehensive eye exam that includes measurements of the corrective error, topographical mapping of the corneas, measurement of eye pressure, and a complete dilated exam will be performed on each candidate to determine which procedure best fits their vision goals.

As the surgery is elective, patients should only participate once they are satisfied with having all of their questions and concerns answered, said Maj. Samantha Rodgers, a refractive eye surgeon in the clinic.

"Refractive surgery is not for everybody, but if you are tired of wearing glasses or contacts, then you should come in for a consultation," said Rodgers. "In most cases, the results are dramatic and patients are very happy with the results."

The WRESP-RC also serves as a U.S. Army Research Center for refractive surgery. Investigators at the WRESP-RC currently enroll subjects in several approved research protocols. Studies focus on safety, efficacy and visual performance after laser refractive surgery with particular regard to aspects of military importance. Part of the research effort is geared toward developing treatment strategies that will improve a service member's mission readiness and advancing wound healing.

Studies of Refractive Surgery in the U.S. Army have found (Hammond et al.) improved overall individual and unit readiness after refractive surgery. Furthermore, studies of military performance after refractive surgery (Bower et al. Subramanian et al.) support the operational benefits of refractive surgery.

"We have excellent, highly-skilled staff and state-of-the-art equipment, Rivers said. "Most of our surgeons have undergone refractive surgery and are more than happy to give you their personal as well as their professional opinion about the procedure. Our experience as clinicians in the field means the service we provide is unrivaled. It's a privilege to take care of our nation's heroes and ensure that they're fit to fight, every day."

Though the WRESP-RC can accommodate up to 40 patients a week, refractive eye surgeries are not currently offered to retirees or the family members of service members.

There is no referral needed for patients wishing to have the procedure; however, command approval is required.

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TRICARE
ORAL HEALTH

Dental Health and Heart Health

By Lt. Cmdr. Jeffrey Wessel, DDS, MS, Diplomate, American Board of Periodontology

The mouth has been described as a gateway to the rest of the body. Poor dental health can not only lead to tooth decay and gum disease but it can also have an impact on your overall health.

Gum disease, or periodontitis, is a common dental disease caused by oral bacteria and is associated with chronic inflammation. It causes loss of the bone that supports the teeth and is the most common cause of tooth loss. But did you know that gum disease not only affects your teeth, it can also have an increasing effect on your heart health?

The oral bacteria that cause gum disease can enter the blood stream following routine activities such as chewing and brushing your teeth. These bacteria can negatively affect your heart and blood vessels. The chronic inflammation caused by gum disease has also been associated with an increased risk for heart disease.

As a board-certified Periodontist and current faculty member for the Periodontics Residency Program at the Naval Postgraduate Dental School, I see patients on a daily basis who have been affected by gum disease and the negative impacts the disease, and associated tooth loss, can have on their dental health, systemic health and overall quality of life.

Recent estimates indicate more than 47% of American adults, almost 65 million people, have gum disease. Take the steps now to ensure that you maintain not only your dental health but your heart health by preventing gum disease.

Here are a few ways you can maintain optimal dental health and heart health:

The chronic inflammation caused by gum disease has also been associated with an increased risk for heart disease. Help prevent gum disease by getting regular dental exams and cleanings and performing proper daily brushing and flossing. *U.S. Navy photo*

Help prevent gum disease by getting regular dental exams and cleanings and performing proper daily brushing and flossing.

If you have a family history of gum disease or early tooth loss, tell your dental care provider.

If you notice bleeding, sore or swollen gums or loose teeth it is important to see your dental care provider. Gum disease often does not hurt, especially in its early stages, so it is important not to ignore these symptoms. Gum disease is easier to treat early.

Dentists in your Navy dental treatment facilities check your gums during your annual dental exams. Cleanings recommended by your dentist can help prevent gum disease. Patients with gum disease can also obtain referrals to a gum disease specialist, or Periodontist, for more advanced care.

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TRICARE
ORAL HEALTH

Celebrating 103 Years of the U.S. Navy Dental Corps

By VADM Matthew L. Nathan, Surgeon General of the Navy

This year marks 103 years of committed and honorable service of the U.S. Navy Dental Corps. On behalf of Navy Medicine, I would like to express my gratitude to the Dental Corps for ensuring dental readiness and optimizing dental health of our Sailors, Marines, and families.

Established in 1912, the history of the Dental Corps dates back to before World War I, when the Corps, then comprised of 30 dental surgeon assistants, first deployed with the Marines.

Since World War I, the Dental Corps has been a part of every wartime effort and has grown significantly in strength and numbers. Their addition to Navy Medicine allowed the Navy to recruit new Sailors and Marines who would have otherwise been rejected due to dental treatment needs.

Today, the Dental Corps continues to ensure high operational readiness for our Sailors, Marines, and their families. They serve Sailors and Marines on the battlefield and aboard ships, performing medical duties beyond the scope of a typical dental practice.

Through the Navy's annual humanitarian missions, such as Continuing Promise and Pacific Partnership, as well as deployed mobile units used in fleet support areas and on the battlefield, they are truly capable of providing world-class dental care, anytime, anywhere.

Their dedication to the readiness and health of our Sailors, Marines, and families, as well as those in need around the globe, has deemed the Dental Corps an essential part of our force readiness, and has earned them a prominent spot in the history of the United States Navy.

To the more than 1,300 active duty and reserve members of the Navy Dental Corps, I commend you for 103 years of dedicated service and sacrifice. Happy Birthday Dental Corps!

navymedicine.navylive.dodlive.mil

TRICARE
ORTHOPEDICS

TRICARE Benefit Expands to Now Cover New Hip Surgery

Starting in January 2016, TRICARE beneficiaries with a diagnosis and referral will be eligible for surgical treatment of a hip condition called femoroacetabular impingement, or FAI, according to a TRICARE news release issued December 4, 2015.

The FAI surgery is the first treatment to be evaluated and approved under the 2015 National Defense Authorization Act's provisional coverage program, which allows TRICARE to provide coverage for emerging treatments and technologies, the release said.

The hip condition can occur when the bones of the hip are abnormally shaped and therefore rub against each other and cause damage to the joint, the release said. Symptoms include pain in the hip or groin area, which limits or hinders mobility, the release added.

As of Jan. 1, 2016, eligible beneficiaries with FAI will be able to get the surgery from any TRICARE-authorized orthopedic surgeon. Costs will vary by plan, the release said, but will be lower when using network providers.

Lt. Col. John Cletus Paumier (center, facing camera) and his team perform total hip replacement surgery on a patient at the Salem Regional Medical Center in Ohio. Paumier is an orthopedic surgeon, officer-in-charge of the Army Reserve Marksmanship Program and command surgeon to the 416th Theater Engineer Command, headquartered in Darien, Ill. *Photo Credit: Sgt. 1st Class Michel Sauret*

Lt. Col. John Cletus Paumier, holds a patient's femural head while conducting a total hip replacement surgery at the Salem Regional Medical Center in Ohio, Sept. 10, 2014. Paumier is an orthopedic surgeon, officer-in-charge of the Army Reserve Marksmanship Program and command surgeon to the 416th Theater Engineer Command, headquartered in Darien, Ill. *Photo Credit: Sgt. 1st Class Michel Sauret*

The surgery must be pre-authorized by the beneficiary's regional contractor, which lets providers present additional information for review by TRICARE and its contract partners.

There is no retroactive preauthorization or coverage prior to Jan. 1, 2016.

The release referenced information from the American Orthopaedic Society for Sports Medicine, which explained that some people may have FAI their entire lives and never have any problems.

However, if symptoms develop, the TRICARE release said, it usually means there is damage to the cartilage, and the condition is likely to worsen.

"TRICARE can now review emerging health care products and services that are not currently covered under the TRICARE program but may provide a benefit to patients under a provisional coverage status," Dr. James Black, medical director for the clinical support division of the Defense Health Agency, said in the release. "We will evaluate other emerging treatments and technologies for consideration and make public announcements when additional ones are approved."

defense.gov

TRICARE
PAIN MANAGEMENT

Thomas, Schoomaker Recognized for Pain Management Efforts

By Military Health System Communications Office

To Military Health System leaders earned a national award for their work providing new alternatives in pain management to warfighters.

Army Maj. Gen. Richard Thomas of the Defense Health Agency and Dr. Eric Schoomaker of the Uniformed Services University of the Health Sciences received the Philipp M. Lippe, MD, Award March 21, 2015 from the American Academy of Pain Medicine.

The award recognizes outstanding contributions to the social and political aspects of pain medicine, and was presented during the academy's annual meeting at National Harbor, Maryland.

"This is not an individual award. This is recognition of the team effort," said Thomas, head of health care operations at the Defense Health Agency. "Techniques to manage pain learned over the last 10 years or so are good examples of the innovations that come out of our combat experience."

Thomas said the military is now more open to methods other than narcotic-based medicines when treating a warfighter struck with pain.

"It's opened the possibilities for our patients and improved their management of pain problems. People can perform better and get their lives back together quicker, optimizing their recovery and life after injury," he said.

The award also highlights the work the military has done with the civilian and academic communities, such as the Uniformed Services University, to promote changes in the practice of medicine.

Army Maj. Gen. Richard Thomas (left) and Dr. Eric Schoomaker (center) accept their Philipp M. Lippe, MD, Awards from American Academy of Pain Medicine (AAPM) president Dr. Sean Mackey at the AAPM annual meeting at National Harbor, Maryland, on March 21, 2015

"This award recognizes that the problems of our warriors — our soldiers, sailors, airmen, Marines, coast guardsmen and their families — are being listened to by practitioners across the country," said Schoomaker, a former Army surgeon general. "If there's any good to come out of war, it's that we get insights into problems plaguing mankind for millennia."

health.mil

"It's opened the possibilities for our patients
and improved their management of pain problems.

People can perform better and get their lives back together quicker,
optimizing their recovery and life after injury."

TRICARE
WOMEN'S HEALTH

New Moms Give High Marks to SAMMC for Labor, Delivery Care

By Elaine Sanchez, Brooke Army Medical Center Public Affairs

San Antonio Military Medical Center remains the Defense Department's highest-rated facility for maternal-child satisfaction, according to TRICARE Inpatient Satisfaction Surveys.

This means new moms are continually giving high marks to SAMMC for their labor, delivery and post-partum care, explained Army Col. Scott Kambiss, chief, Department of Obstetrics and Gynecology.

"We provide compassionate, state-of-the-art care every step of the way," he said. "We feel like we have the best to offer our active duty, retirees and veterans."

Kambiss credits the standout survey results to a highly qualified staff and top-notch amenities and services.

"Our staff is one of the most diverse groups of OB/GYNs I've seen," he said. "We have a mix of seasoned veterans who bring education and a vast amount of knowledge to the table, as well as recent graduates who bring with them the most modern approaches in the field." Additionally, as a teaching hospital, SAMMC hosts Army and Air Force residents and medical students on clinical rotations, he added.

The robust team also includes obstetricians and certified midwives. This mix of specialties enables expectant moms to

Air Force 2nd Lt. Auriel Vokolek, (left), a nurse, takes newborn Isabella's temperature as her mom, Air Force Staff Sgt. Keri Sorsby, holds her in the post-partum unit at San Antonio Military Medical Center, Jan. 25, 2016. *Photo by Robert T. Shields*

Air Force Maj. Nicholas Carr, a neonatologist, takes a break from his paternity leave to give Air Force Staff Sgt. Keri Sorsby a sleep sack for her newborn Isabella in the post-partum unit at San Antonio Military Medical Center, Jan. 25, 2016. SAMMC is partnering with Bexar County on the Safe to Sleep campaign, which encourages parents to place babies on their backs on a firm surface free of pillows, crib bumpers and loose bedding. *Photo by Robert T. Shields*

customize their birthing plan, whether they're set on natural childbirth or open to pain relief interventions, noted Army Col. Elizabeth Murray, chief of Maternal-Child Nursing.

"We are very involved in collaborating with patients regarding their birth plans and supporting them as much as possible," she said.

The labor and delivery environment is an extension of that support, the colonel said. With glossy wood floors and inviting colors, the unit has a home-like feel from the moment a family enters the double doors.

Expectant moms and their families stay in large, private rooms from labor throughout the postpartum experience. "We really try to provide a family centered experience in an environment that reminds them of home," Murray said.

The unit is collocated with Pediatrics' neonatal intensive care unit, which ensures state-of-the-art care for babies with health issues or born on the earliest side of maturity. "We work hand in hand with the Pediatrics Department," Kambiss said. "We wouldn't be able to do what we do without their great assistance."

Throughout the department, lactation consultants are on hand to encourage and facilitate breastfeeding for new moms, Murray added, noting SAMMC's commitment to breastfeeding initiatives.

SAMMC is the Defense Department's first designated Texas Ten Step facility, meaning it has shown an exemplary effort to promote and educate patients on breastfeeding.

Both pre- and post-partum, patients have access to one of the city's only women's health physical therapists. Patricia Rodriguez treats pelvic floor dysfunctions, such as urinary incontinence, chronic pelvic pain and a host of other women's issues.

"One of my main goals is to teach patients how to take care of themselves," she said. "The more you understand about your body, the more effective you can be in taking care of it at every stage of life."

Air Force Col. Brian York, assistant chief, Department of OB/GYN, calls it a "true honor" to work at SAMMC.

"We have the privilege of helping our patients bring a new life into their family," York said. "It's quite an honor to be a part of that."

Air Force Capt. Tiffany Prochaska, assistant team lead in the Emergency Department, also has high praise for SAMMC's childbirth services. She has the distinction of delivering the hospital's first baby of 2016: 9-pound, 2-ounce Evelyn Rose.

"Everyone was wonderful; very compassionate," she said. "I knew a lot of the people taking care of me which took a lot of the anxiety away. I'm thrilled to work and receive care here."

Obstetric services are open to all TRICARE beneficiaries.

Additionally, thanks to a new Veterans Affairs sharing agreement, VA beneficiaries are now welcome to give birth at SAMMC.

"We have a long-standing agreement with the VA to take care of veterans with gynecological issues," Kambiss said. "This new agreement in obstetrics will enable us to offer more services to our female veterans. We are excited to care for this deserving population."

Murray said she's proud to work at a facility that always puts the patients first. "When I ask the staff what they enjoy most about working here, I hear nearly the same answer across the board," she said. "It's the emphasis on safety and quality care that draws them to the organization. And if our staff is happy, our patients are happy."

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TRICARE
WOMEN'S HEALTH

Resources Help New Military Moms Gain Resiliency Against Post-Partum Depression

New moms have a lot going on. Dramatic changes in daily schedules that cut into sleep, learning to meet the needs of a new baby, as well as body and hormonal changes, can wreak havoc with emotions after a baby is born. All of these factors can contribute to post-partum blues, commonly experienced by new mothers, where feelings of sadness and tears come unexpectedly.

"There is a normal emotional roller coaster within the first three to 10 days after a baby's birth when many women will feel overwhelmed," said Dori Rogut with the Defense Health Agency's Clinical Support Division. "But for about 15 percent of new moms, those feelings continue.

Symptoms can become more severe and develop into post-partum depression, when women report feelings of extreme sadness, insomnia, fatigue and difficulty thinking. If the feelings of being overwhelmed continue to the point that even talking to family or friends is just too much effort, that's when a new mom should get help and support."

The challenges of military family life can make the post-partum period especially difficult for new mothers. The Military Health System tries to keep new mothers from progressing into post-partum depression through enhanced support to new mothers and immediate mental health care to those who develop post-partum depression.

"For our beneficiaries, one of the biggest challenges is the lack of proximity of family," said Theresa Hart, a nurse consultant and manager for Perinatal, Pediatrics and Special Medical Programs at DHA. "Do you have folks around who you can reach out to? Do you have a support network?"

A recent move to support mothers and families is the Department of Defense's change of maternity leave for active-duty mothers to 12 weeks. Partners of new moms also get paternity leaves of 14 days. That puts another person at home to share the workload during that immediate post-partum period. Add it all up, and everyone gets extra time to adjust to new and expanding roles and responsibilities, especially for those who might not have family close by, before heading back to work.

Hart also said it's important to recognize hormonal changes and sleep deprivation, which can affect mood and can possibly make moms more vulnerable to post-partum depression.

"Every mom is going to have hormonal changes, but every mom is also going to react differently," said Hart. "If moms have a history of depression, often this hormone change will bring the whole issue up again. New moms need to try to be aware of how they are feeling and what is going on within their bodies."

Military health providers, including pediatricians, obstetricians and midwives, are trained to check in with new mothers about how they are doing when they come to the clinic for appointments for themselves or their baby. This is especially important during pediatric visits as most mothers are scheduled for a check-up by their obstetrician six weeks after delivery, whereas a new baby's first appointment is often from two days to two weeks after birth.

"Our people in our pediatric clinics are doing post-partum depression screenings. This isn't just a mother's issue; it's a whole family issue. We want to make sure a mother has what she needs in order to make sure the baby and the family have what they need," said Hart.

Another good resource is the 24-hour/seven days a week Nurse Advice Line (1-800-TRICARE, option 1), helping any parent who feels at the end of their rope.

Other resources specific to the Military Health System are hospital, clinic or installation family resource centers, chaplains, spouses and co-workers, all of great help. Hart wants to make sure no mom feels any kind of stigma for reaching out.

"Especially for military moms, they don't want to be seen as weak. But that attitude can be a real detriment. We are building resilience in our mothers and families," said Hart. "We want moms to be aware that if they aren't feeling well, physically or emotionally, that's going to impact their baby. They need to think about starting the baby's life as strong as possible, and that means making sure the mom is as strong as possible."

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TRICARE
WOMEN'S HEALTH

Smoking Poses Major Risks to Women's Reproductive Health

The risks to human health from smoking are well documented: damage to the lungs and heart, increased chances of stroke and various cancers throughout the body. Women face additional, unique health risks. Dr. Angeline Lazarus, staff pulmonologist at Walter Reed National Military Medical Center, said the most obvious risk to women is in reproduction.

Women who smoke may have fertility issues, because smoking can affect their ability to conceive. It can also cause premature birth or low birth weights, certain birth defects, such as cleft pallets and complications with the placenta that passes nutrients from mother to child.

"People who smoke may have fertility issues, because smoking can affect their ability to conceive," she said, adding that smoking also affects their babies if they are able to get pregnant. "It can cause premature birth or low birth weights, certain birth defects, such as cleft pallets and complications with the placenta that passes nutrients from mother to child."

Lazarus, a retired Navy doctor now working as a civilian, said there are more women in the military than when she entered 40 years ago. As with men in the military, women's smoking rates are higher than their civilian counterparts. Lazarus said that could be due to the peer pressure women in the military get from the overall higher smoking instances for all military members. She said the key is education and the earlier the better.

"Education [is important] right from the time they get into the military," she said. But too often, when women give up smoking for a pregnancy, they unfortunately take it up again after the baby is born. "Then they are exposing the baby to secondhand smoke, and that has a long-term effect on the child."

There are resources available to help women and men to stop smoking. The military's ucanquit2.org website provides a variety of stop smoking tools, including information about local tobacco cessation programs and even a 24/7 live support chat option. Lazarus also pointed out that women need to be aware of challenges their own bodies might pose in trying to quit smoking.

"The timing of starting a smoking cessation program is important," said Lazarus, recommending women start after their latest period. "It's very difficult during the menstrual cycle or pre-menstrual cycle because of hormonal challenges."

Lazarus added that women need to be aware that quitting smoking could prompt them to eat more and gain weight, which can serve as a major disincentive for quitting smoking. Diets need to be adjusted accordingly.

She noted women can be more receptive to counseling and support, perhaps because of the impact of smoking on reproduction for women.

Once anyone quits smoking, there are improvements in his or her health. Lazarus said those who quit smoking can see improvements in lung function within six months, as well as reducing risks of cardio-vascular disease over a longer period of time. She said it's just a matter of starting and sticking with it.

"The earlier women quit smoking the better it is for them in the long run," said Lazarus. "We just need to educate them early of the dangers."

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Veterans
SPECIAL FEATURES

VA Announces New Leaders

Among Moves, the Vacant Director Position in Erie, PA, to Be Filled

The Department of Veterans Affairs has announced four senior leader appointments at facilities in Indiana, Ohio and Pennsylvania.

"At VA, we are constantly seeking ways to improve, and these personnel moves make us better across the board," said VA Undersecretary for Health Dr. David J. Shulkin. "Each individual is a proven leader who will be a strong advocate for Veterans."

John A. Gennaro, the current Director of the Cincinnati VA Medical Center, has been selected to fill the vacant Director's position atthe Erie VA Medical Center in Pennsylvania. In the new role, Mr. Gennaro will oversee a staff of more than 700 who provide health careservices to 22,000 Veterans and a budget of $144 million.

Mr. Gennaro brings extensive experience and leadership to the new post. Prior to the new assignment, he oversaw the delivery of health care to more than 43,000 Veterans, a staff of 2,000 and an annual budget of approximately $387 million at the Cincinnati VA Medical Center. During his time there, Mr. Gennaro led the facility through numerous improvements, most notably achieving a 5-star rating. Prior to that, he served in a similar capacity for VA's Butler Healthcare.

He began his career with the Department of Veterans Affairs in the Research Foundation at the Cincinnati VA Medical Center. When he takes over duties in Erie, he returns to that facility where he once served as its Associate Director.

Glenn Costie, the current Medical Center Director in Dayton, will fill the role of Acting Director in Cincinnati. He brings more than 30 years' experience to the post, having worked at VA Medical Centers in Chicago, IL; West Haven, CT; Cleveland, OH; Baltimore, MD; and Poplar Bluff, MO. Mr. Costie is expected to fill the Acting Director's role until a permanent director is hired; nationwide recruitment for the position has begun.

Mark Murdock, who has been on a temporary assignment the past six months as the Acting Director at the Northern Indiana Health Care System, will return to the Dayton VA Medical Center as its Acting Director. Before his temporary assignment at the Northern Indiana Health Care System, IN, Mr. Murdock was the Associate Director for the Dayton facility. Mr. Murdock brings more than a decade of leadership experience in healthcare delivery services.

Jay Miller, Associate Director for the Northern Indiana Health Care System, will assume the position as Acting Medical Center Director for that facility while a permanent Director is sought. Mr. Miller has 25 years of leadership experience within VA, which includes VA Ann Arbor Healthcare System, MI; Battle Creek VA Medical Center, MI; VA Central Alabama Healthcare System, AL; Aleda E. Lutz VA Medical Center, MI; and North Chicago VA Medical Center, IL.

The Erie VA Medical Center is a Joint Commission accredited, complexity level three facility serving Veterans in northwestern Pennsylvania and northeastern Ohio. The medical center's mission is to Provide Exceptional Health Care to Veterans. The two highest volume services provided include Primary Care and Behavioral Health. For more information about the Erie VA Medical Center, visit www.erie.va.gov.

The Cincinnati VA Medical Center provides care to more than 43,000 Veterans living in 17 counties in southwest Ohio, northern Kentucky and southeast Indiana.

The facility is a two-division campus located in Cincinnati, Ohio and Fort Thomas, Kentucky, with six community-based outpatient clinics (in Bellevue, KY; Florence, KY; Lawrenceburg, IN; Hamilton, OH; Clermont County, OH; and Georgetown, OH). For more information about the Cincinnati VA Medical Center, visit www.cincinnati.va.gov.

The Dayton VA Medical Center is a state of the art teaching facility that has been serving Veterans for 148 years, having

accepted its first patient in 1867. The Dayton VA Medical Center provides a full range of health care through medical, surgical, mental health (inpatient and outpatient), home and community health programs, geriatric (nursing home), physical medicine and therapy services, neurology, oncology, dentistry and hospice.

For more information about that facility, visit www.dayton.va.gov/about/index.asp

The VA Northern Indiana Health Care System was formed in 1995 by the integration of the VA Medical Centers in Fort Wayne and Marion, Indiana. The Fort Wayne Campus offers primary and secondary medical and surgical services, and the Marion Campus offers a full range of psychiatry services, nursing home care and extended care services.

Primary care clinics are available at both campuses and at Community Based Outpatient Clinics (CBOCs) located in Peru, Goshen, South Bend and Muncie, Indiana. For more information, visit
www.northernindiana.va.gov.

va.gov

Oldest Living Female WWII Veteran Turns 108

By Dwayne Wingfield

World War II Veteran Alyce Dixon, affectionately known as "Queen Bee" by those who know her and care for her at the Washington, D.C., VA Medical Center, is now 108-years young.

Cpl. Dixon has quite a story and quite a personality. Rocking a tiara on top of her head for the occasion, she was queen for the day at the D.C. VAMC.

Fellow Veterans, volunteers, staff and family members celebrated her life at a special ceremony held Sept.11.
"God has been so good," Dixon said. "He left me here with all these lovely people and all these nice things they're saying. I hope they mean it."

Dixon is now the oldest living female World War II veteran according to VA records. She joined the military in 1943 and was stationed in both England and France with the postal services.

She was one of the first African-American women in the Army as part of the 6888th Central Postal Directory Battalion — the only unit of African-American women in the WAC to serve overseas during WWII.

"This has been a marvelous day. I feel real special," Dixon said regarding the celebration that included flowers and gifts from family and friends.

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Veterans
SPECIAL FEATURES

Swimmer Asks Prince Harry to Give Gold Medal to Hospital that Saved Her Life

After Britain's Prince Harry presented Army Staff Sgt. Elizabeth Marks with the four gold medals she had earned in swimming at the 2016 Invictus Games here May 11, Marks asked him to present one to the Papworth Hospital in London, where the staff saved her life two years ago while she was there to compete in the inaugural Games.

"It was my chance to thank everybody. They ultimately saved my life," said Marks, who earned gold medals in the 50-meter backstroke, 50-meter breaststroke, 50-meter freestyle and 100-meter freestyle.

During the closing ceremony for the Invictus Games, Prince Harry said he was inspired by athletes like Marks who showed courage to make it to the starting line and give it their all.

"The competition has been fierce, with performances at the highest international standard across a number of events, but what inspired me was the courage to make it to the starting line, to take to the field or to dive into that pool, motivated by the goal of giving your all, medal or no medal," he said to the athletes. "You showed your families, your friends and yourselves just how far you've come regardless of the results. I know by your nature you all want to win, but these games are so much more than that. Invictus is so much more than that.

"What is the force that drives Elizabeth Marks to return to these games after nearly dying two years ago to compete now at the highest level in a sport that renders her blind and faint, Invictus," he continued. "You are all Invictus. You are all now ambassadors of the spirit of these games. Never stop fighting, and do everything you can to lift everyone around you."

Prince Harry presents a gold medal to U.S. Army Sgt. Elizabeth Marks at the 2016 Invictus Games in Orlando, Fla., May 11, 2016. Marks won the gold medal with a time of 42:67 seconds. *U.S. Air Force photo by Staff Sgt. Carlin Leslie*

When Marks had landed in London for the 2014 inaugural Invictus Games, she had gone into respiratory failure and had been put on life support. She was put on a machine known as ECMO — extracorporeal membrane oxygenation, which works as an external lung — for 10 days. She was put into an induced coma.

Her older brother, Jacob Marks, was there by her side.

"It was terrifying," he said. "I felt very lucky to be there, though, to be there by her side. I will be forever grateful. There was a huge team around her, and she received great care at Papworth. I don't know anywhere else where she would've gotten that kind of care. I feel very lucky she was where she was and got the care she got. She may not have made it in a lot of other places."

Marks said she was so grateful for the care she received that she asked Prince Harry if he would present one of her gold medals to the hospital.

"It's the only way I could really thank them for saving my life," she said. "These gold medals are a direct reflection of all the love and support I've had. It's not so much that I've earned them, but that the Invictus team has earned them as a whole."

Invictus Games, Take 2

Marks said getting to compete in Invictus this time was a chance for her to thank her friends and family for the love and support they've shown her throughout her recovery.

"When I was on life support, they took the time to send me pictures and to send me love," she said. "When I woke up off life support and out of my coma, it meant everything to me, and I cried like a baby. It felt like I wasn't absent from it. It felt like a part of me was there, because I was there with my friends and the people I love. I consider them my family. It means everything to me to be able to do that again."

Army Sgt. Elizabeth Marks competes in the women's breaststroke swimming finals during the 2016 Invictus Games in Orlando, Fla., May 11, 2016. Marks won the gold medal with a time of 42:67 seconds. *DoD photo by Edward Joseph Hersom II*

U.S. Army Sgt. Elizabeth Marks, right, appears with Prince Harry on an ESPN broadcast discussing the 2016 Invictus Games. Marks made international headlines Wednesday after asking the British royal to give one of her gold medals to the English hospital staff that saved her life two years ago. *Photo courtesy of the U.S. Army World Class Athlete Program*

Marks said athletes from many nations have supported her on her journey.

"Athletes from every country have supported me. The French have been super supportive, the Netherlands, the [United Kingdom], they've all reached out and shared love with me on my whole athletic journey and my journey through recovery," she said. "There's no country or service branch barrier. It's just, 'You're a soldier, and we love you. We hope you're OK,' and that's meant the world to me."

Family Support

Marks's sister, Maggie Cook, said it was a treat to see her sister compete professionally for the first time. "It was indescribable," she said. "It's a huge treat, and with the Invictus spirit in the air, she's just really incredible."

Cook said she's proud of how far Marks has come since London. "She's really pushed hard and done a good job," she added.

Marks said she was happy to have her family in the stands, cheering her on. "At the last Invictus Games, my brother had to watch me in [the intensive care unit] on life support, so this was nice for him to get to see that I'm OK," she said. "And it's wonderful because my sister is pregnant, so my beautiful baby niece got to come and see her aunt swim. It's really nice I got to share what I actually do for a living now."

Jacob Marks said he's proud of his baby sister, and that sometimes it feels like she's the older sister. "I look up to her like she's my older sister — she's a great mentor," he said. "She's always working so hard and stays positive. It makes me want to be a better person."

Road to Rio

Marks originally injured her hips during a deployment to Iraq in 2010, while serving as a medical assistant. She's had three hip surgeries, and due to decreased mobility in her legs, she is Paralympic-eligible.

Since London, Marks broke her own American record in the 200-meter breaststroke and won four gold medals and two silver medals at the California Classic meet. In addition to setting the world record in the 50-meter breaststroke in January, she also broke the American and Pan American records in the 200-meter breaststroke with a time of 3:17.89. She broke Jessica Long's SB7 world record in the 50-meter breaststroke with a time of 41.21 seconds.

She was also the first swimmer and first woman in the Army's World Class Athlete Program. She encourages others to join the program. "Now that we have a route, I want more people to come down to it with me. It's life-saving, life-changing and it's beautiful. I want to share it," she said.

In September, Marks said, she hopes to represent the Army and her country at the 2016 Paralympic Games in Rio de Janeiro, which has been her goal since the very start of her Paralympic swimming career.

"I have the trials at the end of June, and I'm very nervous," she said. "Hopefully, I'll be able to earn a slot. I've been training very hard and trying very hard to get to Rio. Hopefully along that path, I'll be able to encourage more soldiers to get into the pool because everyone's welcome."

Marks said she encourages all disabled service members and veterans to give adaptive sports a try. She said she continues to swim as a way to thank her fellow service members for their service.

"There's not a second I get into that pool or under the block that you guys aren't on my mind," she said. "Every time I swim, it's quite painful, but the pain is nothing compared to the sacrifice that my brothers and sisters make every day, so it's my way to carry them with me. You guys push me and drive me and make me believe in what I'm doing. It's not for a medal or a time. It's for a lot more than that."

Marks said she thanks everyone who has supported her and continues to support her on her journey.

"I'd just like to thank Prince Harry for the Invictus Games," she said. "I'd like to thank the U.S. Army for standing behind every second of every recovery I put you through, and for all of the veterans who maybe haven't come out yet. I want to thank you for your service, for your dedication, for your country. I love you and care about you, and I hope you can come join me."

health.mil

Hundreds of Injured Military Veterans from Around the Globe Come to Orlando to Compete in the 2016 Invictus Games

VA to provide onsite medical and mental health support to international athletes

The Department of Veterans Affairs (VA) is proud to support the over 500 ill and injured military Veterans from 15 Nations who have come to Orlando, Fla. to compete in the 2016 Invictus Games taking place May 8-12, 2016 at the ESPN Wide World of Sports Complex at Walt Disney World Resort in Orlando.

"These Games highlight the perseverance and determination of so many of our allied nations' disabled and injured military Veterans," said Secretary of Veterans Affairs Robert A. McDonald. "This competition shows exactly how Adaptive Sports greatly improves the quality of life of these heroes and VA is proud to be a part of this movement. We wish all the competitors good luck."

Britain's Prince Harry greets competitors from the United States while observing the final practice sessions before the start of the 2014 Invictus Games

During the 5-day event, athletes will compete in 10 sporting events. They will compete not only in the spirit of the cordial competition, but also engage in the camaraderie among the competitors and nations. VA will also provide onsite medical and mental health support during the week of competition.

The Invictus Games originated after Britain's Prince Harry returned from the 2013 USA Warrior Games. Prince Harry realized how the power of sport could physically, psychologically, and socially help an injured service member and created the Invictus Games. "Invictus" means unconquered in Latin. The Games harness the power of sport to inspire recovery, support rehabilitation and generate a wider understanding and respect for those who serve their countries.

VA has led the way in providing Adaptive Sports for over 30 years, teaching Veterans with disabilities about adaptive sports at VA Medical Centers across the country. VA also holds annual rehabilitation programs which are open to U.S. military Veterans with traumatic brain injuries, spinal cord injuries, orthopedic amputations, visual impairments, certain neurological problems and other disabilities, who receive care at a VA medical facility or military treatment center. Also, VA has provided over $47.3 Million in Adaptive Sport Grants to national and community programs all across the country.

To find out more about VA sponsored adaptive sports in your community, visit: http://www.va.gov/adaptivesports/ or see the national calendar of events at: http://go.activecalendar.com/adaptivesports

For more information, on the 2016 Invictus Games, visit www.invictusgames2016.org

Max Rohn, a retired Navy petty officer 3rd class, winds up to throw a discus during training.

va.gov

Veterans
SPECIAL FEATURES

Care and Benefits for Veterans Strengthened by $182 Billion VA Budget

In his FY 2017 budget, President Obama is proposing $182.3 billion for the Department of Veterans Affairs (VA). Funding will continue to support the largest transformation in VA history; expand access to timely, high-quality health care and benefits; and advance efforts to end homelessness among Veterans.

"VA has before it one of the greatest opportunities in its history to transform the way it cares for our Veterans who nobly served and sacrificed for our Nation," said VA Secretary Robert A. McDonald. "As we work to become a more efficient, effective and responsive, Veteran-centric Department, we can't do it alone; we need the help of Congress. This year, VA submitted over 100 legislative proposals, including 40 new proposals to better serve Veterans. Our goal is provide the best care to our Veterans while removing obstacles or barriers that prevent them from getting the care they deserve."

Highlights from the President's 2017 Budget request for VA

The FY 2017 budget includes $78.7 billion in discretionary funding, largely for health care and $103.6 billion for mandatory benefit programs such as disability compensation and pensions. The $78.7 billion for discretionary spending is $3.6 billion (4.9 percent) above the 2016 enacted level, including over $3.6 billion in medical care collections from health insurers and Veteran copayments. The budget also requests $70.0 billion, including collections, for the 2018 advance appropriations for medical care, an increase of $1.5 billion and 2.1 percent above the 2017 medical care budget request.

The request includes $103.9 billion in 2018 mandatory advance appropriations for Compensation and Pensions, Readjustment Benefits and Veterans Insurance and Indemnities benefits programs in the Veterans Benefits Administration.

Health Care

With a medical care budget of $68.6 billion, including collections, VA is positioned to continue expanding health care services to its millions of Veteran patients. Health care is being provided to over 922,000Veterans who served in Operation Enduring Freedom/Operation Iraqi Freedom/Operation New Dawn/Operation Inherent Resolve (OIR) and Operation Freedom's Sentinel (OFS). Major spending categories within the health care budget are:

- $12.2 billion for care in the community;
- $8.5 billion for long-term care;
- $7.8 billion for mental health;
- $1.6 billion for homeless Veterans;
- $1.5 billion for Hepatitis-C treatments;
- $725 million for Caregivers;
- $601 million for spinal cord injuries; and
- $284 million for traumatic brain injuries.

Expanding Access

The President's Budget ensures that care and other benefits are available to Veterans when and where they need them. Among the programs that will expand access under the proposed budget are:

- $12.2 billion for care in the community compared to $10.5 billion in 2015, a 16 percent increase;
- $1.2 billion in telehealth funding, which helps patients monitor chronic health care conditions and increases access to care, especially in rural and remote locations;
- $515 million for health care services specifically designed for women, an increase of 8.5 percent over the present level;
- $836 million for the activation of new and enhanced health care facilities;
- $900 million for major and minor construction projects, including funding for seismic corrections, two new cemeteries, and two gravesite expansions; and
- $171 million for improved customer service by providing an integrated services delivery platform.

Improving the Efficiency of Claims Processing

The President's Budget provides for continued implementation of the Veterans Benefits Administration's (VBA) robust Transformation Plan — a series of people, process, and technology initiatives — in 2017. This plan will continue to systematically improve the quality and efficiency of claims processing.

Major claims transformation initiatives in the budget invest $323 million to bring leading-edge technology to claims processing, including:

- $180 million ($143 million in Information Technology and $37 million

Secretary Bob McDonald outlines the "Road to Veterans Day"

in VBA) to enhance the electronic claims processing system — the Veterans Benefits Management System (VBMS); and

- $143 million for Veterans Claims Intake Program (VCIP) to continue conversion of paper records, such as Veterans' medical records, into electronic images and data in VBMS.

In addition, the President's Budget supports increasing VBA's workforce to address staffing needs so it can continue to improve the delivery of benefits to Veterans. As VBA continues to receive and complete more disability compensation rating claims, the volume of non-rating claims correspondingly increases. The request for $54 million for 300 additional full-time equivalent employees (FTE) and claims processing support will allow VBA to provide more timely actions on non-rating claims.

Appeals Reform

The current appeals process is complicated and ineffective, and Veterans on average are waiting about 5 years for a final decision on an appeal that reaches the Board of Veterans' Appeals, with thousands waiting much longer. The 2017 Budget proposes a Simplified Appeals initiative — legislation and resources — to provide Veterans with a simple, fair, and streamlined appeals process in which they would receive a final appeals decision within one year from filing an appeal by 2021. The Budget requests $156 million and 922 FTE for the Board, an increase of $46 million and 242 FTE over 2016, as a down payment on a long-term, sustainable plan to improve services to Veterans.

Ending Veterans Homelessness

The Administration has made the ending of Veteran homelessness a national priority. The Budget requests $1.6 billion for programs to prevent or reduce Veteran homelessness, including:

- $300 million for Supportive Services for Veteran Families (SSVF) to promote housing stability;
- $496 million for the HUD-VASH program, wherein VA provides case management services for at-risk Veterans and their families and HUD provides permanent housing through its Housing Choice Voucher program; and
- $247 million in grant and per diem payments that support temporary housing provided by community-based organizations.

MyVA

The 2017 budget continues the largest Department-wide transformation in VA's history through the MyVA initiative, which is changing VA's culture, processes, and capabilities to put the needs, expectations and interests of Veterans and their families first. MyVA has developed five objectives fundamental to the transformation of VA: 1) improving the Veterans' experience; 2) improving the employee experience; 3) improving support service excellence; 4) establishing a culture of continuous performance improvement; and 5) enhancing strategic partnerships.

To aid in this transformation, the Department established the Veterans Experience Office (VEO). The VEO will represent the voice of Veterans and their families in Departmental governance; design and implement customer-centric programs to make interactions with VA easier; and support VA's "mission owners" in carrying out MyVA improvements across the system.

Veterans Choice Act

The Veterans Choice Act provides $5 billion to increase Veterans' access to health care by hiring more physicians and staff and improving the VA's physical infrastructure. It also provides $10 billion through 2017 to establish a temporary program (the Veterans Choice Program) to improve access to health care by allowing eligible Veterans who meet certain wait-time or distance standards to use eligible health care providers outside of the VA system.

In 2017, VA will use the Choice Act funds in concert with annual appropriations to meet VA staffing and infrastructure needs and expand non-VA care to Veterans who are eligible for the Veterans Choice Program. VA plans to spend $1.4 billion in 2016 and $853 million in 2017 to support more than 9,700 new medical care staff hired through the Choice Act; $980 million in 2016 and $116 million in 2017 to improve VA facilities.

Other Key Services for Veterans

- $286 million to administer VA's system of 134 national cemeteries, including additional funding for operations of new cemeteries and the National Shrine program to raise and realign gravesites;
- $4.3 billion for information technology (IT), including investments to strengthen cybersecurity, modernize Veterans' electronic health records, improve Veterans' access to benefits, and enhance the IT infrastructure; and
- $125 million for state cemetery grants and state extended care grants.

Enhanced Oversight of VA's Programs

The 2017 budget requests an additional $23 million and 100 FTE for the Office of Inspector General (OIG) to enhance oversight and assist the OIG in fulfilling its statutory mission and making recommendations that will help VA improve the care and services it provides.

VA operates the largest integrated health care system in the country; the tenth largest life insurance program in the Nation, with $1.3 trillion in coverage; monthly disability compensation, pensions, and survivors benefits to 5.3 million beneficiaries; educational assistance or vocational rehabilitation benefits and services to nearly 1.2 million students; mortgage guaranties to over 2 million homeowners; and the largest cemetery system in the Nation.

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"VA has before it one of the greatest opportunities in its history to transform the way it cares for our Veterans who nobly served and sacrificed for our Nation.

As we work to become a more efficient, effective and responsive, Veteran-centric Department, we can't do it alone; we need the help of Congress.

This year, VA submitted over 100 legislative proposals, including 40 new proposals to better serve Veterans.

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VA Secretary Robert A. McDonald

Veterans
ADDICTION

Atlanta VA Medical Center Aims to Reduce Long-Term Opioid Use

The Atlanta VA Medical Center (VAMC) began its 12th 10-week education and therapy program designed to improve the quality of life for veterans with chronic pain.

The Empower Veterans Program (EVP) was established in FY14 following a $2 million grant by the Veterans Health Administration's (VHA) Southeast Region (VISN7) to VHA's Stepped Approach to Pain Management.

Pain is real, no matter its source, and veterans with chronic pain deserve better care. For the past 15 years to help manage chronic pain, various opioid medications, commonly referred to as narcotics, have been the mainstay of management for patients with chronic pain. However, long-term use of opioids, even in small amounts, can be too risky for many patients, said Dr. Michael Saenger, director of Atlanta VAMC's Empower Veterans Program.

Licensed Clinical Social Worker Symeon Burholt conducts a Whole Health class at the Atlanta VA Medical Center's new Atlanta Outpatient Clinic. The class is designed to address lifestyle issues which impact Veterans' health — to include spiritual, diet, healing of relationship to name a few.

"In addition certain types of pain, such as low back pain, may be "opioid resistant," and long-term opioid therapy (LTOT) can even worsen other kinds of pain like migraines and fibromyalgia," Saenger said.

To address these risks, VHA launched the Opioid Safety Initiative (OSI) nationwide in late 2013. OSI is a comprehensive effort to improve the safety and quality of life for the hundreds of thousands of veterans suffering from chronic pain.

The OSI directs each Primary Care teamlet to review medications and if needed, make gradual adjustments for safety of the patient.

> EVP's goals are for each veteran to experience and practice new ways of thinking and acting, to make steps toward their own goals in life, and not feel "stuck" in chronic pain.

EVP consists of three-hour sessions each week for 10 weeks where 12 veterans learn as a group to meet each individual's whole health and wellness goals through coaching by a team of behavioral health therapists, chaplains, and physical therapists. EVP's goals are for each veteran to experience and practice new ways of thinking and acting, to make steps toward their own goals in life, and not feel "stuck" in chronic pain.

Twenty-four veterans have graduated the program since its inception in January 2015, to include eight veterans in March from Atlanta VAMC's East Point site of care.

The latest Empower Veteran Program class began June 19, 2015, at the new Atlanta Clinic — which is the latest addition to Atlanta VAMC's 14 sites of care and will be officially dedicated at a July 10, 2015, ceremony.

For more information on this program or how to enroll please contact Natasha Ewell at 404-229-3978 or 404-321-6111, ext 1-3344.

dvidshub.net

Veterans
CARDIOLOGY

Getting Back on Your Feet After a Cardiac Event

Taking an active role in your health care and working with the right team of providers can make a big difference after suffering a heart attack or enduring a heart procedure. During National Cardiac Rehabilitation Week, VA Palo Alto Health Care System wants to share what it is doing to help you get back on your feet after a cardiac event.

For over twenty years, Dr. Jonathan Myers, a research scientist and the principle investigator for many cardiac studies, has conducted several clinical studies that gain valuable research data while offering a great cardiac rehabilitation program for Veterans.

His studies use everything from wearable devices that monitor the heart and blood pressure to good old-fashioned exercise.

"The devices are great but our golden rule is always logging regular physical activity," said Dr. Myers, explaining how the devices do not always give the best measurement or motivation.

Whichever a Veteran uses to log their physical activity, just getting up and moving their body seems to be the best way to combat heart disease. Studies show anywhere from 20-40 percent reduction in adverse reactions when a patient enters cardiac rehabilitation.

Unfortunately, many of these programs are based on referrals from a doctor, which is not always the first thing that comes to mind during an office visit.

"We see about 10-15 percent of people who are eligible still not participate because they just don't know about the program," said Dr. Myers.

Getting up and moving the body is the best way to combat heart disease.

Other factors also play into this issue, including funding and the tendency for prescribing pharmaceutical alternatives by doctors.

Fortunately for Dr. Myers and his colleague Dr. Khin Chan, also a research health scientist and clinical coordinator for renal studies, they both work at VAPAHCS where the second largest VA research program resides.

The PCI Alternative Using Sustained Exercise, or PAUSE, study is run by Dr. Myers and his team, with the help of referrals from primary care doctors and co-investigators from other programs.

Dr. Chan runs the Protein-Signaling Exercise in Renal Failure: A Clinical Trial, or PERFACT, which uses the same type of physical activity goals to help Veterans suffering from renal failure.

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Veterans
CARDIOLOGY

Make a Date During Heart Health Month

By Dr. Sally Haskell, Deputy Chief Consultant for Women's Health Services

As VA Goes Red for heart health month, women Veterans are encouraged to work with their primary care providers to make a personal plan for heart healthy living.

If women Veterans haven't had a primary care visit in a year, they are encouraged to "make a date."

Heart disease is the number one killer of women and high blood pressure, diabetes, high cholesterol, or smoking can increase your risk of heart disease.

Ignore the myths — Here are the facts

- Heart disease affects women of all ages. For younger women, the combination of birth control pills and smoking boosts heart disease risks by 20 percent.
- Even if you're a yoga-loving, marathon-running workout fiend, your risk for heart disease isn't completely eliminated. Factors like cholesterol, eating habits and smoking can counteract your other healthy habits.
- Sixty-four percent of women who die suddenly of coronary heart disease had no previous symptoms. Because these symptoms vary greatly between men and women, they're often misunderstood.
- Media has conditioned us to believe that the telltale sign of a heart attack is extreme chest pain. But in reality, women are more likely to experience shortness of breath, nausea/vomiting, back or jaw pain, and sometimes unexplained excessive fatigue.

Reviewing Heart Health with your Primary Care Provider

At your check up with your primary care provider you should have a discussion about your cardiovascular health and risk factors. Since heart disease is the number one killer of women, and kills more women than all forms of cancer combined, your primary care visit will emphasize cardiovascular risks and making a personal plan for heart healthy living.

The American Heart Association estimates that 80 percent of all cardiovascular disease may be preventable, and it's always better to prevent it than treat it after it becomes life threatening.

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VA Goes Red for Women

February is American Heart Month and VA facilities across the nation are working to ensure Veterans get the message that it's important to take care of your heart.

While heart disease is a major cause of death for men, it is the number one killer of women in the U.S. It's also the number one killer of women in Kentucky and an event this week at the Lexington VA Medical Center aimed to reach out directly to those it effects — women Veterans.

Wednesday's event was the first time the facility hosted a "VA Goes Red for Women" heart health fair, and the first time the facility teamed up with the Central Kentucky Chapter of the American Heart Association. Heart health experts, VA healthcare enrollment specialists, women Veterans advocacy groups and others were on hand to answer questions and provide information to the Veterans attending and their feedback."

"As the health promotion and disease prevention program manager, I am committed to empowering Veterans to take an active role in their health," said Christy Taulbee who helped coordinate the event. "I strongly believe that events such as [this] align with the VA's commitment to provide women Veterans personalized, proactive and patient driven care."

blogs.va.gov

Veterans
CARDIOLOGY

Transcatheter Valve Therapy at Washington, DC VA Medical Center

A little over a year ago, many DC-area Veterans who were considered to have high risk or inoperable valvular heart disease had very few options and a dim prognosis. This changed when the Washington DC Veterans Affairs Medical Center expanded their established Valve program to offer Transcatheter Valve Therapy (TVT) to suitable Veteran candidates.

The VA transcatheter aortic valve replacement (TAVR) program allows surgeons from the Veterans Affairs Medical Center's Valve Clinic to offer TVT, a new minimally invasive procedure. With TVT, the replacement valve is positioned by a puncture in the groin and a small incision in the chest wall rather than an open heart procedure.

So far, the results are phenomenal. Of the 14 Veterans who have had the procedure, all have survived for over a year. The excellent outcomes are attributed to the Valve Clinic's team-base approach to patient analysis and follow-up.

Marine Corps Veteran Michael Sebastion has nothing but praise for the Valve Clinic and his heart surgeons. "Before the surgery, I couldn't make it from the parking lot to the hospital without stopping twice. Now, I feel great."

Mr. Sebastion has been receiving health care at the medical center for more than 35 years. "The VA saved my life twice, how can you argue with that?"

According to Dr. Gregory Trachiotis, Chief, Cardiac Surgery and Director of the Heart Center, "TVT is a potential game changer for some Veterans who are considered too high-risk for traditional valve replacement therapy." He warns the procedure is not without risk and is not for every patient.

Potential TVT candidates undergo a rigorous evaluation, diagnostic testing, and preparation performed in the VA medical center's Valve Clinic.

If deemed a candidate for TVT, the procedure is performed at The George Washington University Hospital by VA surgeons (through an affiliation agreement); the same surgeons and structural heart cardiologists whom the Veteran sees as part of the care team.

Gregory Trachiotis, Chief, Cardiac Surgery and Director of the Heart Center, discusses Marine Corps Veteran Michael Sebastion's latest test results in the Washington, DC Veterans Affairs Medical Center's Valve Clinic.

Although the procedure is fairly new, Dr. Trachiotis anticipates the program will continue to expand, as a state-of–the-art TVT Hybrid Operating Room is in the planning stage to be constructed at the VA facility.

Veterans and health care providers, or facility leaders can reach the Valve Clinic via phone 202-745-4967; or an interfaculty consult to the DC Valve Clinic, or via email to Drs. Trachiotis or Greenberg (Gregory.Trachiotis@va.gov, michael.greenberg@va.gov)

va.gov

The VA transcatheter aortic valve replacement (TAVR) program allows surgeons from the Veterans Affairs Medical Center's Valve Clinic to offer TVT, a new minimally invasive procedure.

Veterans
IMMUNOLOGY

Vets Have Improved Access to Treatment for Hep C

VA Nebraska-Western Iowa Health Care System

By André Kok

Physicians and other care team members are taking advantage of new medication and dedicated financial resources to reach out and educate Veterans about Hepatitis C treatment options leading to high treatment and cure rates for Veterans residing in Veterans Integrated Service Network 23, which includes VA Nebraska-Western Iowa Health Care System. The Centers for Disease Control and Prevention identify Hepatitis C as a liver infection caused by the blood-borne Hepatitis C virus (HCV).

For some people, hepatitis C is a short-term illness but for 70 to 85 percent of people who become infected, it becomes a long-term, chronic infection, with an estimated 2.7 to 3.9 million chronic cases in the United States. Due to increased efforts in identifying Veterans who have the infection, the total number of patients identified with Hepatitis C has gone up in the network, from 4,824 in March of 2015 to 5,096 in February of 2016.

When Veterans are identified as testing positive for the Hepatitis C Virus, they are triaged into different categories for treatment based on the severity of their illness.

A blood test called the Fibrosis-4 produces a FIB score, which can help quantify the impact of the disease on the health of Veterans by estimating the amount of scarring on their liver. Veterans with an FIB greater than 3.25 are at increased risk of poor health outcomes. This group of patients was targeted for aggressive case management. Of the 1,022 patients in this group in March 2015, 265 have been successfully treated and have improved liver function, 221 are under active treatment. Of the remaining patients, only 26 percent remain to be contacted to ensure they are aware of their current options for care.

"Our VISN goal is to offer treatment to all Veterans in this highest risk group for whom it is medically appropriate within the next six months," said Dr. Brian L. Cook, Acting Chief Medical Officer, VISN 23. Those Veterans with FIB levels between 2.5 and 3.25 are also considered at increased risk of poor health outcomes, but less so than those with levels of 3.25 or higher.

These Veterans will be the next group to have their cases aggressively managed. "While we are concentrating our efforts on the patients who have the greatest immediate need, our goal is to offer all patients with Hepatitis C infection treatment over the next one and a half years," said Dr. Cook.

Significant progress has already been made for all Veterans who have the virus, with the total number of those requiring intervention decreasing from 3,724 in March of 2015, to 1,671 in February of 2016.

Successful treatment can rid the Veteran of the virus, significantly improving their quality of life. VA researchers indicate that for every 100 patients who are treated and have the virus eliminated 9-10 deaths attributable to chronic liver damage and 3-4 deaths attributed to liver cancer are prevented.

During the last fiscal year, the network has spent $80 million on this effort, with another $31 million planned for this year. Veterans should consult with their primary care managers if they would like to know more about being tested for Hepatitis C and options for treatment.

Dr. Jeffrey Albrecht, gastroenterologist at Minneapolis VA Health Care System talks with a Veteran about his health care.
VA Photo by April Eilers

The Veterans Affairs Midwest Health Care Network (VISN 23) serves more than 440,000 enrolled Veterans residing in the states of Iowa, Minnesota, Nebraska, North Dakota, South Dakota and portions of Illinois, Kansas, Missouri, Wisconsin and Wyoming.

Through an integrated system of 9 hospitals, 66 community based outpatient or outreach clinics, 8 community living centers and 4 domiciliary residential rehabilitation treatment programs the network aims to fulfill President Lincoln's promise, "To care for him who shall have borne the battle, and for his widow, and his orphan," by serving and honoring the men and women who are America's Veterans.

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...Require **Real-world** Treatment Choices

Discover the possibilities with VIEKIRA PAK

NON-CIRRHOTIC GT1b CHRONIC HCV

100% — **OVERALL SVR_{12} RATE**

Treatment-naïve and pegIFN/RBV-experienced

VIEKIRA PAK ⊖ RBV

for 12 weeks

*Cure (virologic cure): sustained virologic response (SVR_{12}); HCV RNA <25 IU/mL 12 weeks after the end of treatment.

Study Design: 2 randomized phase III clinical studies (PEARL II and III) evaluated 300 non-cirrhotic GT1b treatment-naïve and -experienced (pegIFN/RBV) patients who received VIEKIRA PAK without RBV for 12 weeks.

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ombitasvir, paritaprevir and ritonavir tablets; dasabuvir tablets

INDICATION[1]

VIEKIRA PAK™ (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets), with or without ribavirin (RBV), is indicated for the treatment of adult patients with genotype 1 (GT1) chronic hepatitis C virus (HCV) infection, including those with compensated cirrhosis.

IMPORTANT SAFETY INFORMATION[1]

Risks Associated with RBV Combination Treatment

If VIEKIRA PAK is administered with RBV, the contraindications, warnings and precautions (particularly pregnancy avoidance), and adverse reactions for RBV also apply to this combination regimen. Refer to the RBV prescribing information.

CONTRAINDICATIONS

VIEKIRA PAK is contraindicated:

- in patients with moderate to severe hepatic impairment (Child-Pugh B and C) due to risk of potential toxicity.
- with drugs that are highly dependent on CYP3A for clearance and for which elevated plasma levels are associated with serious and/or life-threatening events; moderate or strong inducers of CYP3A and strong inducers of CYP2C8, which may lead to reduced efficacy of VIEKIRA PAK; and strong CYP2C8 inhibitors, which may increase dasabuvir levels and the risk of QT prolongation.
- with the following drugs: alfuzosin HCL; colchicine; carbamazepine, phenytoin, phenobarbital; gemfibrozil; rifampin; ergotamine, dihydroergotamine, ergonovine, methylergonovine; ethinyl estradiol-containing medicines, such as combined oral contraceptives; St. John's Wort (*Hypericum perforatum*); lovastatin, simvastatin; pimozide; efavirenz; sildenafil (when dosed as Revatio* for pulmonary arterial hypertension); triazolam and oral midazolam.
- in patients with known hypersensitivity (e.g., toxic epidermal necrolysis or Stevens-Johnson syndrome) to ritonavir.

WARNINGS AND PRECAUTIONS

Risk of Hepatic Decompensation and Hepatic Failure in Patients with Cirrhosis

- Hepatic decompensation and hepatic failure, including liver transplantation or fatal outcomes, have been reported mostly in patients with advanced cirrhosis prior to initiating therapy. Reported cases typically occurred within one to four weeks of initiating therapy.
- For patients with cirrhosis: monitor for clinical signs and symptoms of hepatic decompensation; perform hepatic lab testing, including direct bilirubin levels, at baseline and during the first 4 weeks of starting treatment and as clinically indicated; discontinue treatment in patients who develop evidence of hepatic decompensation.

Increased Risk of ALT Elevations

- Elevations of ALT to >5x the upper limit of normal (ULN) occurred in 1% of all subjects in clinical trials and were significantly more frequent in females using ethinyl estradiol-containing medications. In female patients, discontinue ethinyl estradiol-containing medications prior to starting therapy and use alternative methods of contraception during therapy. Use caution when co-administering VIEKIRA PAK with estrogens other than ethinyl estradiol, such as estradiol and conjugated estrogens.
- Perform hepatic lab testing on all patients during the first 4 weeks of treatment and as clinically indicated thereafter. If ALT is elevated above baseline levels, repeat testing and monitor closely. Patients should be instructed to consult their doctor without delay if they have onset of fatigue, weakness, lack of appetite, nausea and vomiting, jaundice, or discolored feces. Consider discontinuing VIEKIRA PAK if ALT levels remain persistently >10x the ULN. Discontinue VIEKIRA PAK if ALT elevation is accompanied by signs or symptoms of liver inflammation or increasing conjugated bilirubin, alkaline phosphatase, or INR.

Risk of Adverse Reactions or Reduced Therapeutic Effect Due to Drug Interactions

- The concomitant use of VIEKIRA PAK and certain other drugs may result in known or potentially significant drug interactions, some of which may lead to loss of therapeutic effect of VIEKIRA PAK and possible development of resistance, or clinically significant adverse reactions from greater exposures of concomitant drugs or components of VIEKIRA PAK.

HCV/HIV-1 Coinfected Patients: Risk of HIV-1 Protease Inhibitor Drug Resistance

- The ritonavir component of VIEKIRA PAK is an HIV-1 protease inhibitor and can select for HIV-1 protease inhibitor resistance. To reduce this risk, HCV/HIV-1 coinfected patients should also be on a suppressive antiretroviral drug regimen.

ADVERSE REACTIONS

Most common adverse reactions observed:

- VIEKIRA PAK with RBV (>10% of subjects): fatigue, nausea, pruritus, other skin reactions, insomnia, and asthenia.
- VIEKIRA PAK without RBV (≥5% of subjects): nausea, pruritus, and insomnia.

*Revatio® is a trademark of its respective owner and not a trademark of AbbVie Inc. The makers of this brand are not affiliated with and do not endorse AbbVie Inc. or its products.

References: 1. VIEKIRA PAK [package insert]. North Chicago, IL. AbbVie Inc.

Please see accompanying Brief Summary on the adjacent pages for more information.

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VIEKIRA PAK™

(ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets)
co-packaged for oral use

PROFESSIONAL BRIEF SUMMARY
CONSULT PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

INDICATIONS AND USAGE

VIEKIRA PAK with or without ribavirin is indicated for the treatment of patients with genotype 1 chronic hepatitis C virus (HCV) infection including those with compensated cirrhosis.

CONTRAINDICATIONS

- VIEKIRA PAK is contraindicated in patients with moderate to severe hepatic impairment (Child-Pugh B and C) due to risk of potential toxicity *[see Warnings and Precautions and Use in Specific Populations]*.
- If VIEKIRA PAK is administered with ribavirin, the contraindications to ribavirin also apply to this combination regimen. Refer to the ribavirin prescribing information for a list of contraindications for ribavirin.
- VIEKIRA PAK is contraindicated with:
  - Drugs that are highly dependent on CYP3A for clearance and for which elevated plasma concentrations are associated with serious and/or life-threatening events.
  - Drugs that are moderate or strong inducers of CYP3A and strong inducers of CYP2C8 and may lead to reduced efficacy of VIEKIRA PAK.
  - Drugs that are strong inhibitors of CYP2C8 and may increase dasabuvir plasma concentrations and the risk of QT prolongation.

Table 1 lists drugs that are contraindicated with VIEKIRA PAK *[see Drug Interactions]*.

Table 1. Drugs that are Contraindicated with VIEKIRA PAK

Drug Class	Drug(s) within Class that are Contraindicated	Clinical Comments
Alpha1-adrenoreceptor antagonist	Alfuzosin HCL	Potential for hypotension.
Anti-gout	Colchicine	Potential for serious and/or life-threatening reactions in patients with renal and/or hepatic impairment.
Anticonvulsants	Carbamazepine, phenytoin, phenobarbital	Ombitasvir, paritaprevir, ritonavir and dasabuvir exposures may decrease leading to a potential loss of therapeutic activity of VIEKIRA PAK.
Antihyperlipidemic agent	Gemfibrozil	Increase in dasabuvir exposures by 10-fold which may increase the risk of QT prolongation.
Antimycobacterial	Rifampin	Ombitasvir, paritaprevir, ritonavir and dasabuvir exposures may decrease leading to a potential loss of therapeutic activity of VIEKIRA PAK.
Ergot derivatives	Ergotamine, dihydroergotamine, ergonovine, methylergonovine	Acute ergot toxicity characterized by vasospasm and tissue ischemia has been associated with co-administration of ritonavir and ergonovine, ergotamine, dihydroergotamine, or methylergonovine.
Ethinyl estradiol-containing products	Ethinyl estradiol-containing medications such as combined oral contraceptives	Potential for ALT elevations *[see Warnings and Precautions]*.
Herbal Product	St. John's Wort *(Hypericum perforatum)*	Ombitasvir, paritaprevir, ritonavir and dasabuvir exposures may decrease leading to a potential loss of therapeutic activity of VIEKIRA PAK.
HMG-CoA Reductase Inhibitors	Lovastatin, simvastatin	Potential for myopathy including rhabdomyolysis.
Neuroleptics	Pimozide	Potential for cardiac arrhythmias.
Non-nucleoside reverse transcriptase inhibitor	Efavirenz	Co-administration of efavirenz based regimens with paritaprevir, ritonavir plus dasabuvir was poorly tolerated and resulted in liver enzyme elevations.
Phosphodiesterase-5 (PDE5) inhibitor	Sildenafil when dosed as REVATIO for the treatment of pulmonary arterial hypertension (PAH)	There is increased potential for sildenafil-associated adverse events such as visual disturbances, hypotension, priapism, and syncope.
Sedatives/hypnotics	Triazolam Orally administered midazolam	Triazolam and orally administered midazolam are extensively metabolized by CYP3A4. Coadministration of triazolam or orally administered midazolam with VIEKIRA PAK may cause large increases in the concentration of these benzodiazepines. The potential exists for serious and/or life threatening events such as prolonged or increased sedation or respiratory depression.

- VIEKIRA PAK is contraindicated in patients with known hypersensitivity (e.g. toxic epidermal necrolysis (TEN) or Stevens-Johnson syndrome) to ritonavir.

WARNINGS AND PRECAUTIONS

Risk of Hepatic Decompensation and Hepatic Failure in Patients with Cirrhosis

Hepatic decompensation and hepatic failure, including liver transplantation or fatal outcomes, have been reported postmarketing in patients treated with VIEKIRA PAK. Most patients with these severe outcomes had evidence of advanced cirrhosis prior to initiating therapy with VIEKIRA PAK. Reported cases typically occurred within one to four weeks of initiating therapy and were characterized by the acute onset of rising direct serum bilirubin levels without ALT elevations in association with clinical signs and symptoms of hepatic decompensation. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

VIEKIRA PAK is contraindicated in patients with moderate to severe hepatic impairment (Child-Pugh B and C) *[see Contraindications, Adverse Reactions, and Use in Specific Populations]*.

For patients with cirrhosis:

- Monitor for clinical signs and symptoms of hepatic decompensation (such as ascites, hepatic encephalopathy, variceal hemorrhage).
- Hepatic laboratory testing including direct bilirubin levels should be performed at baseline and during the first 4 weeks of starting treatment and as clinically indicated.
- Discontinue VIEKIRA PAK in patients who develop evidence of hepatic decompensation.

Increased Risk of ALT Elevations

During clinical trials with VIEKIRA PAK with or without ribavirin, elevations of ALT to greater than 5 times the upper limit of normal (ULN) occurred in approximately 1% of all subjects *[see Adverse Reactions]*. ALT elevations were typically asymptomatic, occurred during the first 4 weeks of treatment, and declined within two to eight weeks of onset with continued dosing of VIEKIRA PAK with or without ribavirin.

These ALT elevations were significantly more frequent in female subjects who were using ethinyl estradiol-containing medications such as combined oral contraceptives, contraceptive patches or contraceptive vaginal rings. Ethinyl estradiol-containing medications must be discontinued prior to starting therapy with VIEKIRA PAK *[see Contraindications]*. Alternative methods of contraception (e.g., progestin only contraception or non-hormonal methods) are recommended during VIEKIRA PAK therapy. Ethinyl estradiol-containing medications can be restarted approximately 2 weeks following completion of treatment with VIEKIRA PAK.

Women using estrogens other than ethinyl estradiol, such as estradiol and conjugated estrogens used in hormone replacement therapy had a rate of ALT elevation similar to those not receiving any estrogens; however, due to the limited number of subjects taking these other estrogens, caution is warranted for co-administration with VIEKIRA PAK *[see Adverse Reactions]*.

Hepatic laboratory testing should be performed during the first 4 weeks of starting treatment and as clinically indicated thereafter. If ALT is found to be elevated above baseline levels, it should be repeated and monitored closely:

- Patients should be instructed to consult their health care professional without delay if they have onset of fatigue, weakness, lack of appetite, nausea and vomiting, jaundice or discolored feces.
- Consider discontinuing VIEKIRA PAK if ALT levels remain persistently greater than 10 times the ULN.
- Discontinue VIEKIRA PAK if ALT elevation is accompanied by signs or symptoms of liver inflammation or increasing direct bilirubin, alkaline phosphatase, or INR.

Risks Associated With Ribavirin Combination Treatment

If VIEKIRA PAK is administered with ribavirin, the warnings and precautions for ribavirin, in particular the pregnancy avoidance warning, apply to this combination regimen. Refer to the ribavirin prescribing information for a full list of the warnings and precautions for ribavirin.

Risk of Adverse Reactions or Reduced Therapeutic Effect Due to Drug Interactions

The concomitant use of VIEKIRA PAK and certain other drugs may result in known or potentially significant drug interactions, some of which may lead to:

- Loss of therapeutic effect of VIEKIRA PAK and possible development of resistance
- Possible clinically significant adverse reactions from greater exposures of concomitant drugs or components of VIEKIRA PAK.

See Table 4 for steps to prevent or manage these possible and known significant drug interactions, including dosing recommendations *[see Drug Interactions]*. Consider the potential for drug interactions prior to and during VIEKIRA PAK therapy; review concomitant medications during VIEKIRA PAK therapy; and monitor for the adverse reactions associated with the concomitant drugs *[see Contraindications and Drug Interactions]*.

Risk of HIV-1 Protease Inhibitor Drug Resistance in HCV/HIV-1 Co-infected Patients

The ritonavir component of VIEKIRA PAK is also an HIV-1 protease inhibitor and can select for HIV-1 protease inhibitor resistance-associated substitutions. Any HCV/HIV-1 co-infected patients treated with VIEKIRA PAK should also be on a suppressive antiretroviral drug regimen to reduce the risk of HIV-1 protease inhibitor drug resistance.

ADVERSE REACTIONS

If VIEKIRA PAK is administered with ribavirin (RBV), refer to the prescribing information for ribavirin for a list of ribavirin-associated adverse reactions.

The following adverse reaction is described below and elsewhere in the labeling:

- Risk of Hepatic Decompensation and Hepatic Failure in Patients with Cirrhosis *[see Warnings and Precautions]*
- Increased Risk of ALT Elevations *[see Warnings and Precautions]*

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in clinical trials of VIEKIRA PAK cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety assessment was based on data from six Phase 3 clinical trials in more than 2,000 subjects who received VIEKIRA PAK with or without ribavirin for 12 or 24 weeks.

VIEKIRA PAK with Ribavirin in Placebo-Controlled Trials

The safety of VIEKIRA PAK in combination with ribavirin was assessed in 770 subjects with chronic HCV infection in two placebo-controlled trials (SAPPHIRE-I and -II). Adverse reactions that occurred more often in subjects treated with VIEKIRA PAK in combination with ribavirin compared to placebo were fatigue, nausea, pruritus, other skin reactions, insomnia, and asthenia (see Table 2). The majority of the adverse reactions were mild in severity. Two percent of subjects experienced a serious adverse event (SAE). The proportion of subjects who permanently discontinued treatment due to adverse reactions was less than 1%.

Table 2. Adverse Reactions with ≥5% Greater Frequency Reported in Subjects with Chronic HCV GT1 Infection Treated with VIEKIRA PAK in Combination with Ribavirin Compared to Placebo for 12 Weeks

	SAPPHIRE-I and -II	
	VIEKIRA PAK + RBV 12 Weeks N = 770 %	Placebo 12 Weeks N = 255 %
Fatigue	34	26
Nausea	22	15
Pruritus*	18	7
Skin reactions§	16	9
Insomnia	14	8
Asthenia	14	7

*Grouped term 'pruritus' included the preferred terms pruritus and pruritus generalized.

§Grouped terms: rash, erythema, eczema, rash maculo-papular, rash macular, dermatitis, rash papular, skin exfoliation, rash pruritic, rash erythematous, rash generalized, dermatitis allergic, dermatitis contact, exfoliative rash, photosensitivity reaction, psoriasis, skin reaction, ulcer, urticaria.

VIEKIRA PAK with and without Ribavirin in Regimen-Controlled Trials

VIEKIRA PAK with and without ribavirin was assessed in 401 and 509 subjects with chronic HCV infection, respectively, in three clinical trials (PEARL-II, PEARL-III and PEARL-IV). Pruritus, nausea, insomnia, and asthenia were identified as adverse events occurring more often in subjects treated with VIEKIRA PAK in combination with ribavirin (see Table 3). The majority of adverse events were mild to moderate in severity. The proportion of subjects who permanently discontinued treatment due to adverse events was less than 1% for both VIEKIRA PAK in combination with ribavirin and VIEKIRA PAK alone.

Table 3. Adverse Events with ≥5% Greater Frequency Reported in Subjects with Chronic HCV GT1 Infection Treated with VIEKIRA PAK in Combination with Ribavirin Compared to VIEKIRA PAK for 12 Weeks

	PEARL-II, -III and -IV	
	VIEKIRA PAK + RBV 12 Weeks N = 401 %	VIEKIRA PAK 12 Weeks N = 509 %
Nausea	16	8
Pruritus*	13	7
Insomnia	12	5
Asthenia	9	4

*Grouped term 'pruritus' included the preferred terms pruritus and pruritus generalized.

VIEKIRA PAK with Ribavirin in Subjects with Compensated Cirrhosis

VIEKIRA PAK with ribavirin was assessed in 380 subjects with compensated cirrhosis who were treated for 12 (n=208) or 24 (n=172) weeks duration (TURQUOISE-II). The type and severity of adverse events in subjects with compensated cirrhosis was comparable to non-cirrhotic subjects in other phase 3 trials. Fatigue, skin reactions and dyspnea occurred at least 5% more often in subjects treated for 24 weeks. The majority of adverse events occurred during the first 12 weeks of dosing in both treatment arms. Most of the adverse events were mild to moderate in severity. The proportion of subjects treated with VIEKIRA PAK for 12 and 24 weeks with SAEs was 6% and 5%, respectively and 2% of subjects permanently discontinued treatment due to adverse events in each treatment arm.

Skin Reactions

In PEARL-II, -III and -IV, 7% of subjects receiving VIEKIRA PAK alone and 10% of subjects receiving VIEKIRA PAK with ribavirin reported rash-related events. In SAPPHIRE-I and -II 16% of subjects receiving VIEKIRA PAK with ribavirin and 9% of subjects receiving placebo reported skin reactions. In TURQUOISE-II, 18% and 24% of subjects receiving VIEKIRA PAK with ribavirin for 12 or 24 weeks reported skin reactions. The majority of events were graded as mild in severity. There were no serious events or severe cutaneous reactions, such as Stevens Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), erythema multiforme (EM) or drug rash with eosinophilia and systemic symptoms (DRESS).

Laboratory Abnormalities

Serum ALT Elevations

Approximately 1% of subjects treated with VIEKIRA PAK experienced post-baseline serum ALT levels greater than 5 times the upper limit of normal (ULN) after starting treatment. The incidence increased to 25% (4/16) among women taking a concomitant ethinyl estradiol containing medication *[see Contraindications and Warnings and Precautions]*. The incidence of clinically relevant ALT elevations among women using estrogens other than ethinyl estradiol, such as estradiol and conjugated estrogens used in hormone replacement therapy was 3% (2/59).

ALT elevations were typically asymptomatic, generally occurred during the first 4 weeks of treatment (mean time 20 days, range 8-57 days) and most resolved with ongoing therapy. The majority of these ALT elevations were assessed as drug-related liver injury. Elevations in ALT were generally not associated with bilirubin elevations. Cirrhosis was not a risk factor for elevated ALT *[see Warnings and Precautions]*.

Serum Bilirubin Elevations

Post-baseline elevations in bilirubin at least 2 x ULN were observed in 15% of subjects receiving VIEKIRA PAK with ribavirin compared to 2% in those receiving VIEKIRA PAK alone. These bilirubin increases were predominately indirect and related to the inhibition of the bilirubin transporters OATP1B1/1B3 by paritaprevir and ribavirin-induced hemolysis. Bilirubin elevations occurred after initiation of treatment, peaked by study Week 1, and generally resolved with ongoing therapy. Bilirubin elevations were not associated with serum ALT elevations.

Anemia/Decreased Hemoglobin

Across all Phase 3 studies, the mean change from baseline in hemoglobin levels in subjects treated with VIEKIRA PAK in combination with ribavirin was -2.4 g/dL and the mean change in subjects treated with VIEKIRA PAK alone was -0.5 g/dL. Decreases in hemoglobin levels occurred early in treatment (Week 1-2) with further reductions through Week 3. Hemoglobin values remained low during the remainder of treatment and returned towards baseline levels by post-treatment Week 4. Less than 1% of subjects treated with VIEKIRA PAK with ribavirin had hemoglobin levels decrease to less than 8.0 g/dL during treatment. Seven percent of subjects treated with VIEKIRA PAK in combination with ribavirin underwent a ribavirin dose reduction due to a decrease in hemoglobin levels; three subjects received a blood transfusion and five required erythropoietin. One patient discontinued therapy due to anemia. No subjects treated with VIEKIRA PAK alone had a hemoglobin level less than 10 g/dL.

VIEKIRA PAK in HCV/HIV-1 Co-infected Subjects

VIEKIRA PAK with ribavirin was assessed in 63 subjects with HCV/HIV-1 co-infection who were on stable antiretroviral therapy. The most common adverse events occurring in at least 10% of subjects were fatigue (48%), insomnia (19%), nausea (17%), headache (16%), pruritus (13%), cough (11%), irritability (10%), and ocular icterus (10%).

Elevations in total bilirubin greater than 2 x ULN (mostly indirect) occurred in 34 (54%) subjects. Fifteen of these subjects were also receiving atazanavir at the time of bilirubin elevation and nine also had adverse events of ocular icterus, jaundice or hyperbilirubinemia. None of the subjects with hyperbilirubinemia had concomitant elevations of aminotransferases *[see Warnings and Precautions and Adverse Reactions]*. No subject experienced a grade 3 ALT elevation.

Seven subjects (11%) had at least one post-baseline hemoglobin value of less than 10 g/dL, and six of these subjects had a ribavirin dose modification; no subject in this small cohort required a blood transfusion or erythropoietin.

Median declines in CD4+ T-cell counts of 47 cells/mm^3 and 62 cells/mm^3 were observed at the end of 12 and 24 weeks of treatment, respectively, and most returned to baseline levels post-treatment. Two subjects had CD4+ T-cell counts decrease to less than 200 cells/mm^3 during treatment without a decrease in CD4%. No subject experienced an AIDS-related opportunistic infection.

VIEKIRA PAK in Selected Liver Transplant Recipients

VIEKIRA PAK with ribavirin was assessed in 34 post-liver transplant subjects with recurrent HCV infection. Adverse events occurring in more than 20% of subjects included fatigue 50%, headache 44%, cough 32%, diarrhea 26%, insomnia 26%, asthenia 24%, nausea 24%, muscle spasms 21% and rash 21%. Ten subjects (29%) had at least one post-baseline hemoglobin value of less than 10 g/dL. Ten subjects underwent a ribavirin dose modification due to decrease in hemoglobin and 3% (1/34) had an interruption of ribavirin. Five subjects received erythropoietin, all of whom initiated ribavirin at the starting dose of 1000 to 1200 mg daily. No subject received a blood transfusion.

Post-Marketing Adverse Reactions

The following adverse reactions have been identified during post approval use of VIEKIRA PAK. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Immune System Disorders: Hypersensitivity reactions (including angioedema).

Hepatobiliary Disorders: Hepatic decompensation, hepatic failure *[see Warnings and Precautions]*.

DRUG INTERACTIONS

See also Contraindications and Warnings and Precautions.

Potential for VIEKIRA PAK to Affect Other Drugs

Ombitasvir, paritaprevir, and dasabuvir are inhibitors of UGT1A1, and ritonavir is an inhibitor of CYP3A4. Paritaprevir is an inhibitor of OATP1B1 and OATP1B3 and paritaprevir, ritonavir and dasabuvir are inhibitors of BCRP. Co-administration of VIEKIRA PAK with drugs that are substrates of CYP3A, UGT1A1, BCRP, OATP1B1 or OATP1B3 may result in increased plasma concentrations of such drugs.

Potential for Other Drugs to Affect One or More Components of VIEKIRA PAK

Paritaprevir and ritonavir are primarily metabolized by CYP3A enzymes. Co-administration of VIEKIRA PAK with strong inhibitors of CYP3A may increase paritaprevir and ritonavir concentrations. Dasabuvir is primarily metabolized by CYP2C8 enzymes. Co-administration of VIEKIRA PAK with drugs that inhibit CYP2C8 may increase dasabuvir plasma concentrations. Ombitasvir is primarily metabolized via amide hydrolysis while CYP enzymes play a minor role in its metabolism. Ombitasvir, paritaprevir, dasabuvir and ritonavir are substrates of P-gp. Ombitasvir, paritaprevir and dasabuvir are substrates of BCRP. Paritaprevir is a substrate of OATP1B1 and OATP1B3. Inhibition of P-gp, BCRP, OATP1B1 or OATP1B3 may increase the plasma concentrations of the various components of VIEKIRA PAK.

Established and Other Potential Drug Interactions

If dose adjustments of concomitant medications are made due to treatment with VIEKIRA PAK, doses should be re-adjusted after administration of VIEKIRA PAK is completed. Dose adjustment is not required for VIEKIRA PAK.

Table 4 provides the effect of co-administration of VIEKIRA PAK on concentrations of concomitant drugs and the effect of concomitant drugs on the various components of VIEKIRA PAK. See *Contraindications* for drugs that are contraindicated with VIEKIRA PAK. Refer to the ritonavir prescribing information for other potentially significant drug interactions with ritonavir.

Table 4. Established Drug Interactions Based on Drug Interaction Trials

Concomitant Drug Class: Drug Name	Effect on Concentration	Clinical Comments
ANTIPSYCHOTIC		
quetiapine*	↑ quetiapine	• Initiation of VIEKIRA PAK in patients taking quetiapine: Consider alternative anti-HCV therapy to avoid increases in quetiapine exposures. If coadministration is necessary, reduce the quetiapine dose to 1/6th of the current dose and monitor for quetiapine-associated adverse reactions. Refer to the quetiapine prescribing information for the recommendations on adverse reaction monitoring. • Initiation of quetiapine in patients taking VIEKIRA PAK: Refer to the quetiapine prescribing information for initial dosing and titration of quetiapine.
ANTIARRHYTHMICS		
amiodarone*, bepridil*, disopyramide*, flecainide*, lidocaine (systemic)*, mexiletine*, propafenone*, quinidine*	↑ antiarrhythmics	Caution is warranted and therapeutic concentration monitoring (if available) is recommended for antiarrhythmics when co-administered with VIEKIRA PAK.
ANTIFUNGALS		
ketoconazole	↑ ketoconazole	When VIEKIRA PAK is co-administered with ketoconazole, the maximum daily dose of ketoconazole should be limited to 200 mg per day.
voriconazole*	↓ voriconazole	Co-administration of VIEKIRA PAK with voriconazole is not recommended unless an assessment of the benefit-to-risk ratio justifies the use of voriconazole.
CALCIUM CHANNEL BLOCKERS		
amlodipine	↑ amlodipine	Consider dose reduction for amlodipine. Clinical monitoring is recommended.
CORTICOSTEROIDS (INHALED/NASAL)		
fluticasone*	↑ fluticasone	Concomitant use of VIEKIRA PAK with inhaled or nasal fluticasone may reduce serum cortisol concentrations. Alternative corticosteroids should be considered, particularly for long term use.
DIURETICS		
furosemide	↑ furosemide (C_{max})	Clinical monitoring of patients is recommended and therapy should be individualized based on patient's response.
HIV-ANTIVIRAL AGENTS		
atazanavir/ritonavir once daily	↑ paritaprevir	When coadministered with VIEKIRA PAK, atazanavir 300 mg (without ritonavir) should only be given in the morning.
darunavir/ritonavir	↓ darunavir (C_{trough})	Co-administration of VIEKIRA PAK with darunavir/ritonavir is not recommended.
lopinavir/ritonavir	↑ paritaprevir	Co-administration of VIEKIRA PAK with lopinavir/ritonavir is not recommended.
rilpivirine	↑ rilpivirine	Co-administration of VIEKIRA PAK with rilpivirine once daily is not recommended due to potential for QT interval prolongation with higher concentrations of rilpivirine.
HMG CoA REDUCTASE INHIBITORS		
rosuvastatin	↑ rosuvastatin	When VIEKIRA PAK is co-administered with rosuvastatin, the dose of rosuvastatin should not exceed 10 mg per day.
pravastatin	↑ pravastatin	When VIEKIRA PAK is co-administered with pravastatin, the dose of pravastatin should not exceed 40 mg per day.
IMMUNOSUPPRESSANTS		
cyclosporine	↑ cyclosporine	When initiating therapy with VIEKIRA PAK, reduce cyclosporine dose to 1/5th of the patient's current cyclosporine dose. Measure cyclosporine blood concentrations to determine subsequent dose modifications. Upon completion of VIEKIRA PAK therapy, the appropriate time to resume pre-VIEKIRA PAK dose of cyclosporine should be guided by assessment of cyclosporine blood concentrations. Frequent assessment of renal function and cyclosporine-related side effects is recommended.

(continued)

Table 4. *continued*

Concomitant Drug Class: Drug Name	Effect on Concentration	Clinical Comments
IMMUNOSUPPRESSANTS		
tacrolimus	↑ tacrolimus	When initiating therapy with VIEKIRA PAK, the dose of tacrolimus needs to be reduced. Do not administer tacrolimus on the day VIEKIRA PAK is initiated. Beginning the day after VIEKIRA PAK is initiated; reinitiate tacrolimus at a reduced dose based on tacrolimus blood concentrations. Typical tacrolimus dosing is 0.5 mg every 7 days. Measure tacrolimus blood concentrations and adjust dose or dosing frequency to determine subsequent dose modifications. Upon completion of VIEKIRA PAK therapy, the appropriate time to resume pre-VIEKIRA PAK dose of tacrolimus should be guided by assessment of tacrolimus blood concentrations. Frequent assessment of renal function and tacrolimus related side effects is recommended.
LONG ACTING BETA-ADRENOCEPTOR AGONIST		
salmeterol*	↑ salmeterol	Concurrent administration of VIEKIRA PAK and salmeterol is not recommended. The combination may result in increased risk of cardiovascular adverse events associated with salmeterol, including QT prolongation, palpitations and sinus tachycardia.
NARCOTIC ANALGESICS		
buprenorphine/naloxone	↑ buprenorphine ↑ norbuprenorphine	No dose adjustment of buprenorphine/naloxone is required upon co-administration with VIEKIRA PAK. Patients should be closely monitored for sedation and cognitive effects.
PROTON PUMP INHIBITORS		
omeprazole	↓ omeprazole	Monitor patients for decreased efficacy of omeprazole. Consider increasing the omeprazole dose in patients whose symptoms are not well controlled; avoid use of more than 40 mg per day of omeprazole.
SEDATIVES/HYPNOTICS		
alprazolam	↑ alprazolam	Clinical monitoring of patients is recommended. A decrease in alprazolam dose can be considered based on clinical response.

The direction of the arrow indicates the direction of the change in exposures (C_{max} and AUC) (↑ = *increase of more than 20%*, ↓ = *decrease of more than 20%*, ↔ = *no change or change less than 20%*).

*not studied.

Drugs without Clinically Significant Interactions with VIEKIRA PAK

No dose adjustments are recommended when VIEKIRA PAK is co-administered with the following medications: digoxin, duloxetine, emtricitabine/tenofovir disoproxil fumarate, escitalopram, methadone, progestin only contraceptives, raltegravir, warfarin and zolpidem.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category B

Pregnancy Exposure Registry

There is an Antiretroviral Pregnancy Registry that monitors pregnancy outcomes in women who are HCV/HIV-1 co-infected and taking concomitant antiretrovirals. Physicians are encouraged to register patients by calling 1-800-258-4263.

Risk Summary

Adequate and well controlled studies with VIEKIRA PAK have not been conducted in pregnant women. In animal reproduction studies, no evidence of teratogenicity was observed with the administration of ombitasvir (mice and rabbits), paritaprevir, ritonavir (mice and rats), or dasabuvir (rats and rabbits) at exposures higher than the recommended clinical dose [see Data]. Because animal reproduction studies are not always predictive of human response, VIEKIRA PAK should be used during pregnancy only if clearly needed.

If VIEKIRA PAK is administered with ribavirin, the combination regimen is contraindicated in pregnant women and in men whose female partners are pregnant. Refer to the ribavirin prescribing information for more information on use in pregnancy.

Data

Animal data

In animal reproduction studies, there was no evidence of teratogenicity in offspring born to animals treated throughout pregnancy with ombitasvir and its major inactive human metabolites (M29, M36), paritaprevir, ritonavir, or dasabuvir. For ombitasvir, the highest dose tested produced exposures approximately 28-fold (mouse) or 4-fold (rabbit) the exposures in humans at the recommended clinical dose. The highest doses of the major, inactive human metabolites similarly tested produced exposures approximately 26-fold the exposures in humans at the recommended clinical dose. For paritaprevir, ritonavir, the highest doses tested produced exposures approximately 98-fold (mouse) or 8-fold (rat) the exposures in humans at the recommended clinical dose. For dasabuvir, the highest dose tested produced exposures approximately 24-fold (rat) or 6-fold (rabbit) the exposures in humans at the recommended clinical dose.

Nursing Mothers

It is not known whether any of the components of VIEKIRA PAK or their metabolites are present in human milk. Unchanged ombitasvir, paritaprevir and

its hydrolysis product M13, and dasabuvir were the predominant components observed in the milk of lactating rats, without effect on nursing pups.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VIEKIRA PAK and any potential adverse effects on the breastfed child from VIEKIRA PAK or from the underlying maternal condition.

If VIEKIRA PAK is administered with ribavirin, the nursing mothers information for ribavirin also applies to this combination regimen (see prescribing information for ribavirin).

Pediatric Use

Safety and effectiveness of VIEKIRA PAK in pediatric patients less than 18 years of age have not been established.

Geriatric Use

No dosage adjustment of VIEKIRA PAK is warranted in geriatric patients. Of the total number of subjects in clinical studies of VIEKIRA PAK, 8.5% (174/2053) were 65 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger subjects, but greater sensitivity of some older individuals cannot be ruled out.

Hepatic Impairment

No dosage adjustment of VIEKIRA PAK is required in patients with mild hepatic impairment (Child-Pugh A). VIEKIRA PAK is contraindicated in patients with moderate to severe (Child-Pugh B and C) hepatic impairment *[see Contraindications and Warnings and Precautions]*.

Renal Impairment

No dosage adjustment of VIEKIRA PAK is required in patients with mild, moderate or severe renal impairment. VIEKIRA PAK has not been studied in patients on dialysis. For patients that require ribavirin, refer to the ribavirin prescribing information for information regarding use in patients with renal impairment.

Other HCV Genotypes

The safety and efficacy of VIEKIRA PAK has not been established in patients with HCV genotypes other than genotype 1.

OVERDOSAGE

In case of overdose, it is recommended that the patient be monitored for any signs or symptoms of adverse reactions and appropriate symptomatic treatment instituted immediately.

PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

Inform patients to review the Medication Guide for ribavirin *[see Warnings and Precautions]*.

Risk of ALT Elevations or Hepatic Decompensation and Failure

Inform patients to watch for early warning signs of liver inflammation or failure, such as fatigue, weakness, lack of appetite, nausea and vomiting, as well as later signs such as jaundice, onset of confusion, abdominal swelling, and discolored feces, and to consult their health care professional without delay if such symptoms occur *[see Warnings and Precautions and Adverse Reactions]*.

Pregnancy

Advise patients to avoid pregnancy during treatment with VIEKIRA PAK with ribavirin. Inform patients to notify their health care provider immediately in the event of a pregnancy. Inform pregnant patients that there is an Antiretroviral Pregnancy Registry that monitors pregnancy outcomes in women who are HCV/HIV-1 co-infected and taking concomitant antiretrovirals *[see Use in Specific Populations]*.

Drug Interactions

Inform patients that VIEKIRA PAK may interact with some drugs; therefore, patients should be advised to report to their healthcare provider the use of any prescription, non-prescription medication or herbal products *[see Contraindications, Warnings and Precautions and Drug Interactions]*.

Inform patients that contraceptives containing ethinyl estradiol are contraindicated with VIEKIRA PAK *[see Contraindications and Warnings and Precautions]*.

Hepatitis C Virus Transmission

Inform patients that the effect of treatment of hepatitis C virus infection on transmission is not known, and that appropriate precautions to prevent transmission of the hepatitis C virus during treatment should be taken.

Missed Dose

Inform patients that in case a dose of ombitasvir, paritaprevir, ritonavir is missed, the prescribed dose can be taken within 12 hours.

In case a dose of dasabuvir is missed, the prescribed dose can be taken within 6 hours.

If more than 12 hours has passed since ombitasvir, paritaprevir, ritonavir is usually taken or more than 6 hours has passed since dasabuvir is usually taken, the missed dose should NOT be taken and the patient should take the next dose as per the usual dosing schedule.

Instruct patients not to take more than their prescribed dose of VIEKIRA PAK to make up for a missed dose.

Manufactured by AbbVie Inc., North Chicago, IL 60064.

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Veterans
IMMUNOLOGY

VA Expands Hepatitis C Drug Treatment

Expanded funding now allows VA to provide increased drug therapy at VA facilities nationwide

The Department of Veterans Affairs (VA) today announced that it is now able to fund care for all Veterans with hepatitis C for Fiscal Year 2016 regardless of the stage of the patient's liver disease. The move follows increased funding from Congress along with reduced drug prices.

"We're honored to be able to expand treatment for Veterans who are afflicted with hepatitis C," says VA Under Secretary for Health Dr. David Shulkin. "To manage limited resources previously, we established treatment priority for the sickest patients. Additionally, if Veterans are currently waiting on an appointment for community care through the Choice Program, they can now turn to their local VA facility for this treatment or can elect to continue to receive treatment through the Choice Program."

VA has long led the country in screening for and treating hepatitis C. VA has treated over 76,000 Veterans infected with hepatitis C and approximately 60,000 have been cured.

In addition, since the beginning of 2014, more than 42,000 patients have been treated with the new highly effective antivirals. In fiscal year 2015, VA allocated $696 million for new hepatitis C drugs (17 percent of the VA's total pharmacy budget) and in fiscal year 2016, VA anticipates spending approximately $1 billion on hepatitis C drugs. VA expects that with the expansion, many more Veterans will be started on hepatitis C treatment every week this fiscal year.

In addition to furnishing clinical care to Veterans with hepatitis C, VA Research continues to expand the knowledge base regarding the disease through scientific studies focused on effective care, screening, and healthcare delivery including to female Veterans and Veterans with complicated medical conditions in addition to hepatitis C.

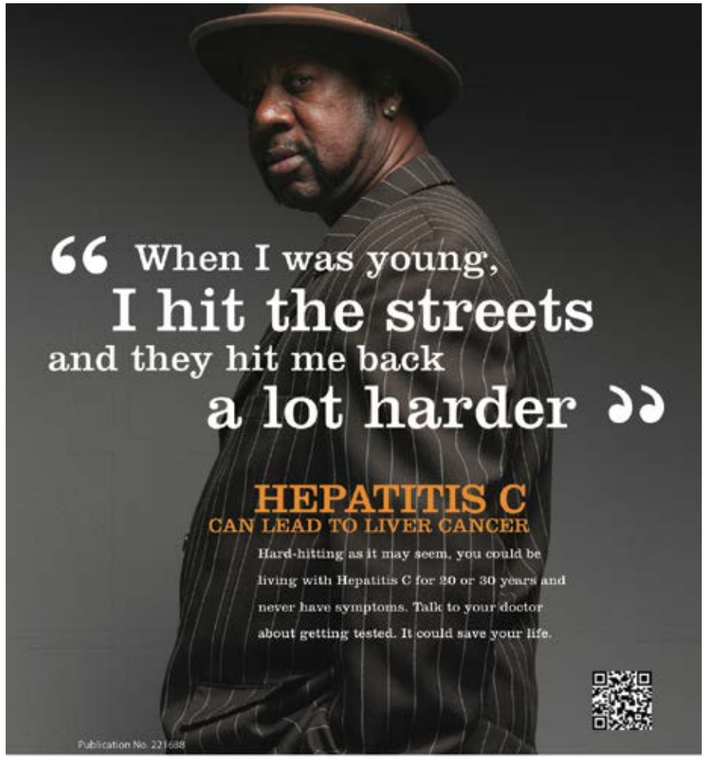
va.gov

Veterans
IMMUNOLOGY

New Hepatitis C Treatments Have High Cure Rates for African Americans

By Camilla Graham, MD, MPH, Co-Director, Viral Hepatitis Center, Division of Infectious Disease, Beth Israel Deaconess Medical Center, Boston, Massachusetts

The epidemic of chronic hepatitis C virus (HCV) infection impacts over 3 million individuals in the United States, and over 50% of infected people are undiagnosed. In an effort to increase the number of people who are aware of their HCV infection and link them to care, in 2012 the U.S. Centers for Disease Control and Prevention (CDC) recommended that all persons born from 1945 through 1965 be tested for HCV, given that this group currently accounts for more than 75% of adults infected with hepatitis C in the U.S. and are five times more likely to be infected than other adults. Subsequently, in 2013, the U.S. Preventive Services Task Force also recommended a one-time HCV screening for adults born between 1945 and 1965.



Hepatitis C among African Americans

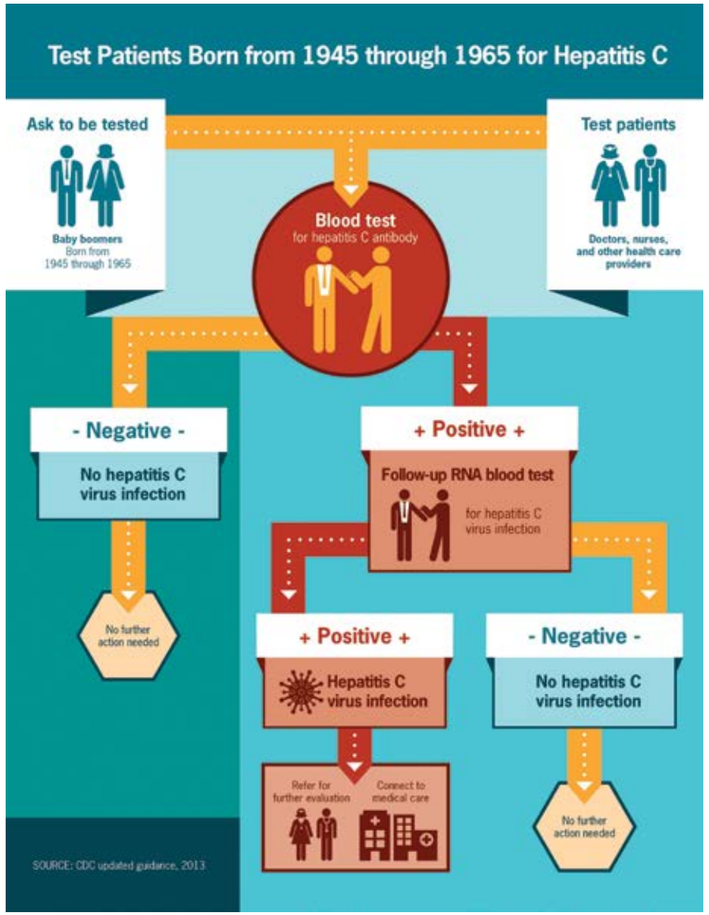
These screening guidelines are especially important for African Americans, a group that is disproportionately affected by HCV infection. An estimated 1 in 12 African-American men born from 1945 through 1965 have been exposed to HCV (Armstrong, et al. 2006) Exit Disclaimer. African Americans experience high rates of death due to cirrhosis and liver cancer, often related to chronic HCV infection (Ly, et al. 2014) Exit Disclaimer.

However, some people may be reluctant to be tested or seek treatment because of serious and often debilitating side effects associated with the previous standard of care for treating HCV, which included injections of interferon-alfa. Furthermore, interferon-based treatment resulted in cure rates among African Americans that were significantly lower than among Caucasian populations, highlighting the need for new treatment options to increase the possibility of cure for all patients. This blog will summarize the recent rapid advances in HCV treatment that now allow most patients, including African Americans, to be treated and cured without interferon.

HCV Treatment History

Pegylated interferon-alfa (Peg-IFN) and ribavirin (RBV) were used to treat genotype 1 HCV from 2002 until 2011. This combination cured about 40% to 50% of Caucasians, but only 19% to 21% of African Americans, so there was reluctance among many African American patients to take injections of Peg-IFN, with many difficult side effects, for 48 weeks, with only a 1 out of 5 chance of being cured

Armed Forces Medicine 2016



Exit Disclaimer. For years, it was unclear why African Americans did not respond well to interferon. Finally, in 2009, it was discovered that African Americans are much less likely to inherit genes (IL28B polymorphisms) that allow Peg-IFN to work by helping liver cells eliminate the HCV (Ge, et al. 2009) Exit Disclaimer. It was clear that in order to improve HCV cure rates for African Americans, alternative treatments would be needed.

New HCV Treatments: Faster, Better Tolerated, Higher Cure Rates for All

The past four years have seen significant advances in HCV treatment, with several new drugs coming to market that can now cure HCV in a shorter period of time and with fewer side effects. The first oral, direct-acting antiviral drugs, telaprevir and boceprevir, were approved by the Food and Drug Administration (FDA) in 2011 and increased cure rates but still required co-administration with Peg-IFN. Clinical trials using boceprevir or telaprevir showed that African Americans had increased cure rates of 53% to 62%, but these rates were still lower Exit Disclaimer than the 68% to 78% cure rate seen for Caucasians.

In October 2014, the combination of sofosbuvir plus ledipasvir (Harvoni™) received FDA approval. This treatment represented a dramatic shift in the approach to HCV therapy as it is a single pill taken once a day that effectively blocks HCV replication. The treatment course lasts from 8 to 24 weeks, depending on if a patient was previously treated unsuccessfully for HCV or if cirrhosis of the liver is present. Furthermore, it can be used for people who have HIV-HCV coinfection, cirrhosis, liver failure, and liver transplant, and it is very well tolerated. Researchers studied 308 people who identified as Black in clinical trials of Harvoni™.

The cure rate was 95% in Black/African American patients compared with 97% in non-Black patients. This is the first time we have seen a study in which nearly all African Americans were cured of their HCV infection (Jeffers, et al. AASLD 2014 Abstract #237) Exit Disclaimer.

In December 2014 another new HCV therapeutic regimen, this one containing paritaprevir, ritonavir, ombitasvir and dasabuvir (Viekira Pak™), taken with or without RBV, was approved by the FDA. While clinical trials for Viekira Pak™ included a relatively small number of African Americans, cure rates for African Americans are also similar compared with Caucasians (Vierling, et al. AASLD 2014 Abstract #1968) Exit Disclaimer.

With more new therapies still in development, it is important that African Americans are included in ongoing trials of both newly approved drugs and drugs in development so that we can improve our understanding about which are most effective in this disproportionately affected population.

While the substantial increase in cure rates have delivered great promise for addressing the HCV epidemic, the cost of these new treatments presents access and affordability challenges for many people. Now that patients, providers, and insurers have two highly effective regimens from which to choose, the price of these regimens has decreased substantially since their initial launch.

We are now paying the lowest price per cure of genotype 1 hepatitis C infections in history. However, since there are several million people in the U.S. who need to be diagnosed and treated for HCV, the overall costs are still large. Because of this, some insurance companies and

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state Medicaid programs are prioritizing paying for treatment of people who already have severe liver disease or other complications that require urgent treatment. Hopefully, as treatment prices pose less of a barrier, everybody who seeks treatment for HCV will be able to achieve a cure.

Curing HCV is the most effective way to decrease the likelihood that a person will die from liver cancer or liver failure. African Americans have nearly twice the death rate Exit Disclaimer from HCV as Caucasians, so our nation has an urgent need to find people who are infected, link them into care, and evaluate their need for antiviral treatment.

As the baby boomer population continues to age, and many remain unaware of their HCV infections, we have a narrow window of time to prevent unnecessary deaths from this curable infection. By raising greater awareness in African-American communities and making best use of these new curative treatments we can decrease or eliminate the health disparities faced by African Americans living with HCV.

Editor's Note: April is Minority Health Month, bringing a national focus on advancing health equity and ending health disparities. During April we will be sharing several blog posts about responding to viral hepatitis disparities among minority communities.

va.gov

VA Launches Hepatitis C–Advanced Liver Disease Disparities Dashboard

Dashboard Bolsters VA Efforts to Identify and Treat Veterans With Hep C and Liver Disease

The Department of Veterans Affairs (VA) is stepping up its efforts to accelerate treatment for Veterans with hepatitis C and advanced liver disease (ALD) through the creation of a Hepatitis C–ALD dashboard.

The dashboard works by using a set of criteria, including age, gender, geography, service era along with and race and ethnicity, to distinguish Veteran groups at highest risk for ALD as a result of hepatitis C.

"The dashboard is a powerful data tool to help VA identify Veteran groups disproportionately affected by Advanced Liver Disease and to ensure they receive the appropriate health care," said Dr. David Shulkin, VA's Under Secretary for Health. "VA will provide data directly to facilities for any of the vulnerable groups identified by the dashboard and support outreach efforts to Veteran populations disparately impacted and not currently served by VA health care. This is an important step in assuring all Veterans with ALD receive timely, appropriate care."

VA's Veterans Health Administration's Office of Health Equity developed the dashboard as part of its efforts to target and accelerate care of Veterans with this serious disease. The new resource promotes equitable diagnosis and treatment of underserved Veterans with hepatitis C and ALD nationally and compliments existing clinical hepatitis and liver disease dashboards available in some Veterans Integrated Service Networks or VISNs.

Chronic hepatitis C virus (HCV) infection is the most common blood-borne infection in the world. Complications that result from untreated HCV infection include progressive liver damage leading to cirrhosis, primary cancer of the liver, liver failure and death.

Although many of these complications are treatable or even preventable, three-quarters of the individuals with HCV infection in the U.S. are unaware they are infected. VA leads the country in hepatitis screening, testing, treatment, research and prevention.

Veterans
IMMUNOLOGY

Curing Hepatitis C: Not Just a Dream Anymore

By Lt. Cmdr. Brent Lacey, Gastroenterologist, Naval Hospital Pensacola

Are you between 50 and 70 years old? If so, you need to get screened for Hepatitis C.

An estimated three to four million people in the United States are chronically infected with Hepatitis C and 80 to 90 percent of people have no symptoms and therefore have no idea that they have the infection (www.ncbi.nilm.nih.gov).

The highest risk population in the U.S. includes people born between 1945 and 1965. People born between those years grew up during a time when we didn't know about Hepatitis C and had no way to screen for it.

Hepatitis C is a virus that causes chronic liver disease that can lead to cirrhosis and liver cancer. It is spread primarily through the bloodstream but can also be spread through sexual contact, though it is not spread through other forms of physical touch. Common methods of transmission include blood transfusions, tattoos, needle sticks (esp. healthcare workers), intravenous drug use (even once in your life) and sharing a toothbrush or razorblade with an infected person.

For a couple of decades, the diagnosis of chronic Hepatitis C was devastating, carrying a high likelihood of progression to cirrhosis (advanced liver disease), liver cancer and possibly liver transplant. The treatments we had for many years had a low rate of curing the infection and were incredibly difficult to tolerate.

Treatment often made people feel like they had the flu every day for most of a year. Since the fall of 2014, a handful of outstanding medications have been developed that are well tolerated and highly effective.

The treatments can be as short as eight weeks for some patients, but others may require longer treatment courses of 12 to 24 weeks. The medications that we have available for genotype 1, the most common strain of the virus, achieves a cure rate greater than 95 percent. It is even successful with people who have previously failed treatment, and there are almost no significant side effects from the medications.

The only way to know if you have Hepatitis C is with a laboratory screening. Remember, most people have no symptoms

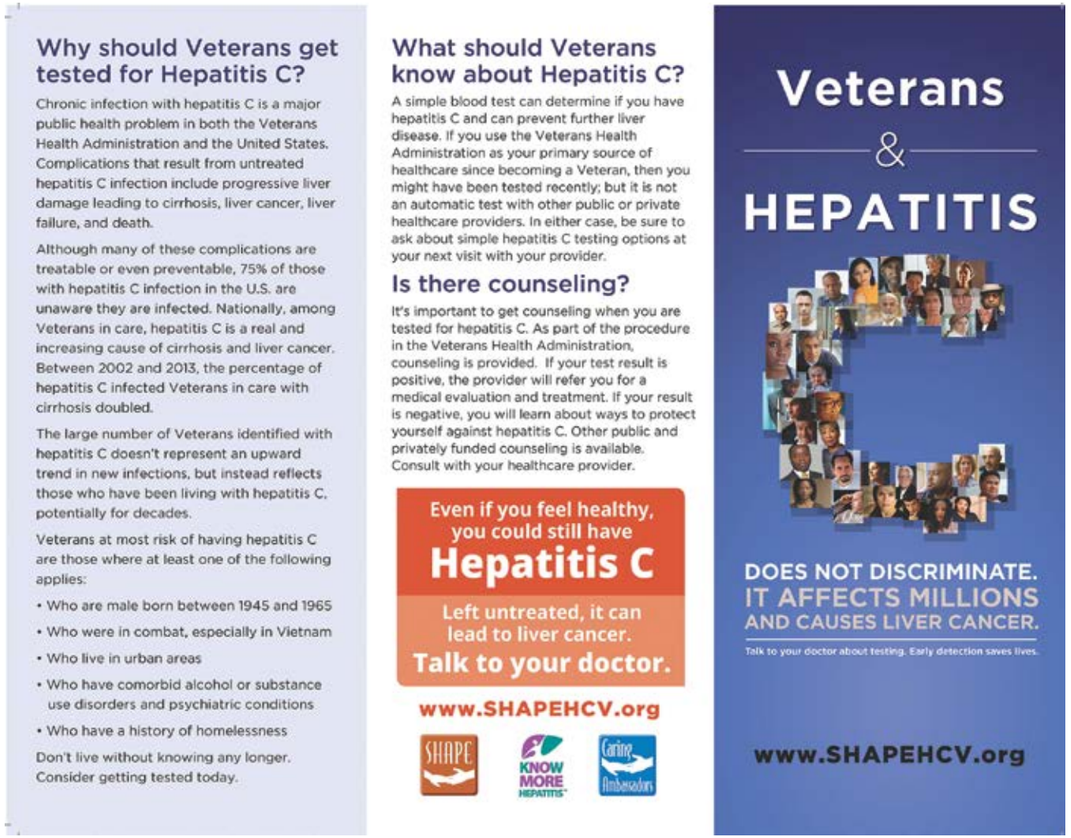
Lt. Cmdr. Brent Lacey, gastroenterologist, Naval Hospital Pensacola, consults with patient about Hepatitis C and Liver Cancer. *Photo by Jason Bortz*

to tell them that something might be wrong. At Naval Hospital Pensacola, we are leading the way for the Navy in terms of screening at-risk patients and getting them treatment if they turn out to be infected.

We have developed the first hospital-wide comprehensive screening program for Hepatitis C in the Navy. The program has been incredibly successful so far, and we've already had over 1,100 people get screened in just the first two months of the program.

Patients enrolled at NHP can visit the NHP Lab without an appointment to have the Hepatitis C screening done. You do not have to fast for this test, and you will be contacted with the results of your test within a couple of weeks. TRICARE beneficiaries not enrolled at NHP should contact their primary care manager to inquire about getting a screening.

Here are some of the most commonly asked questions about the program:



I've already had the hepatitis vaccines. Do I still need screening for Hepatitis C?

Yes, you do. There are a two shot series for Hepatitis A and a three shot series for Hepatitis B, but there is not yet a vaccine for Hepatitis C. Any hepatitis vaccines you received were probably Hepatitis A or B (or both).

I'm 100 percent sure that I've had the screening test for Hepatitis C at another facility. Do I still need to be screened?

No, you only need to be screened once in your life as long as you are not at high risk for contracting Hepatitis C. High risk behaviors warranting annual screening include intravenous/intranasal drug use, sharing infected needles and getting tattoos with unsterile tools.

If you are enrolled to NHP and are sure you have had the blood test to check for Hepatitis C, please call the NHP Gastroenterology Clinic at 850-505-6649 to let us know so that we can remove you from the list of patients who need screening.

What if I choose not to get screened?

You are within your rights to decline this screening test. The chance of having Hepatitis C is about 1 to 1.5 percent based on your age. However, if you have Hepatitis C and do not get treated, you have a high risk of progressing to severe liver disease (cirrhosis) during your lifetime.

What if I have more questions?

Your primary care manager is the best initial resource for determining whether you need to get screened. If you have additional questions or concerns, the Gastroenterology Clinic staff is available to answer your questions at 850-505-6649.

At NHP, we are excited about the opportunity to participate in this program, which has already led to the successful treatment of people who were unaware they had the infection. Help us make Hepatitis C a thing of the past by getting screened. The cure is here!

navy.mil

Veterans
MENTAL HEALTH

Preventing Veteran Suicide: A Call to Action

As a national leader in suicide prevention, VA understands that more needs to be done and we cannot do it alone. Nearly 200 mental health professionals, caregivers, veterans and their families, veteran service organizations, members of Congress and experts from other federal agencies answered the call to action this week, a call to end the tragedy of Veteran suicide. It was a day dedicated to listening, getting to know each other and learning. It was a day of reflection, hope, inspiration and idea generation.

We pulled this together in record time — 30 days from conception to execution. The reason for the urgency was because this is truly urgent and when there is a crisis– it is important to act as if there is a crisis. We cannot accept Veteran suicides as inevitable and we cannot accept the status quo.

Among the attendees at yesterday's summit on "Preventing Veteran Suicide — A Call to Action," were Susan and Richard Selke. Their son, Clay Hunt, was a Marine Corps Veteran of Iraq and Afghanistan who took his own life in 2011. Their moving story and inspiring call for improving mental health care for Veterans like their son was an emotional reminder of how Veteran and Servicemember suicide impacts all Americans and needs to be addressed in a coordinated effort with government and community stakeholders.

Dr. Howard and Jean Somers, parents of Sgt. Daniel Somers, also spoke on learning from their son's suicide. "We must insist on a refocus on VA health care to become a center of excellence for war related injuries." I couldn't agree more.

Both of these families turned their grief into action — to give hope to the hopeless, and to save others from knowing the pain they have known. I am grateful to them for their courage and perseverance and for sharing their story.

President Obama joined us by video and re-emphasized that "Caring for our Veterans is a national mission. So long as any Veteran is hurting and needs help our work is not done."

We had the benefit of hearing from Army Veteran Brent Rice and Air Force Veteran John Heitzman. They shared their very personal experiences. Rice shared that volunteering to help others is what helped him recover. For Heitzman, he explained

Under Secretary for Health Dr. Shulkin and Secretary McDonald speak with participants at Preventing Veteran Suicide: A Call to Action

it was the VA who helped him through his difficult time. As Dr. Thomas Joiner, Professor of Psychology at Florida State University told us, "Only care and follow up is proven to completely stop suicidal tendencies." He went on to say, "One solution is a hope box that reminds people of what they have to live for — we have to get better at learning how to motivate people to take up offers of connection."

While we had a conversation in D.C., thousands joined the conversation across the nation. In fact, #PreventVetSuicide was recognized as a Twitter trending topic for the day and was the top trending hash-tag in more than 10 U.S. cities. Many positive comments came from the online discussion, along with some very personal sharing from those who knew people who succumbed to suicide. Here is a collection of some of the more prevalent social media posts.

I'm grateful to all of our speakers and to everyone that attended. We met because suicides are an unacceptable crisis in our Veterans' lives. VA depends so much on the work of others to accomplish our mission — on their research, their expertise, their insight, and their commitment to suicide prevention.

Yesterday's summit is a starting point. Now we need to work together to end this crisis and help the men and women who are now serving and have served their country. Thank you for all you do for Veterans each and every day.

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Veterans
MENTAL HEALTH

Achieving New Mental Health Treatment Goals for Veterans, Servicemembers and their Families

Dr. Robert Petzel, VA Undersecretary for Health

Jonathan Woodson, Assistant Secretary of Defense for Health Affairs

Pam Hyde, Administrator Substance Abuse and Mental Health Services Administration

The Departments of Veterans Affairs, Defense and Health and Human Services are working hard every day to implement the president's Aug. 31, 2012, executive order by removing barriers, improving access and investing in research to improve the science and understanding of mental health care and treatment for Veterans, Servicemembers and their families.

As part of the efforts related to this executive order, VA has hired more than 1,600 new clinicians and over 800 peer specialists, bringing its total mental health staff to more than 20,000. VA has also increased the capacity of the Veterans Crisis Line by more than 50 percent. In a related effort, DoD has hired more than 9,400 mental health professionals, launched the largest study of mental health risk and resilience ever conducted among military personnel and expanded the Military Crisis Line to Europe, Afghanistan and Korea. DoD has also added over 10,000 mental health providers in the TRICARE purchased care network and embedded mental health professionals into our military treatment facility primary care settings.

VA, DoD and HHS have jointly implemented a national suicide prevention campaign to connect Veterans and Servicemembers with evidence-based mental health and substance use treatment resources. VA has worked with community clinics to expand the number of locations where Veterans can receive mental health treatment and has hosted 152 summits across the United States in the past year to increase collaboration and coordination with resources in the community that support our nation's Veterans.

HHS worked closely with the VA to implement community pilots to increase or supplement VA capacity in geographical areas where VA facilities are not located close by. Likewise, HHS has now brought together teams from 46 states, four territories and the District of Columbia in policy academies to develop and implement plans to ensure timely access to and quality of the behavioral health needs for military service personnel, Veterans and their families.

Our agencies have also worked closely together to begin implementation of a National Research Action Plan to inform federal research in post-traumatic stress disorder, traumatic brain injury and other critical behavioral health issues. Through the cutting-edge research that will support this plan, we will gain answers to the crucial questions about how best to prevent and treat conditions related to mental health and traumatic brain injury.

The new Cross Agency Priority goal recently announced builds on these efforts and expands our focus in order to find new ways to further:

- Reduce barriers to seeking care
- Enhance access to and improve the quality of mental health care
- Support innovative research on mental health and substance use care and treatment.

Only by working together can we continue to fulfill the president's commitment to those who serve and support our country, and the administration will continue to ensure a spotlight remains on these important public health issues. We know that treatment works, and with effective mental health and substance use treatment, we can meet the mental health needs of Veterans, Servicemembers and their families.

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The VA hired 782 psychologists and psychiatrists in 2014 as well as 257 other mental health providers, such as social workers, nurses and licensed professional counselors, and 45 mental health administrative support employees. These professionals are filling new positions and existing vacancies to meet the growing requirements for mental health services.

New VA Education and Training Initiative Creates Pipeline to Hire Mental Health Counselors

As part of the Department of Veterans Affairs' (VA) recruitment plan to hire additional mental health care professionals, a new training initiative has been funded to attract Licensed Professional Mental Health Counselors (LPMHC). LPMHCs are an important aspect of the mental health treatment team and VA plans to continue to increase hiring in this profession.

"By building a pipeline of highly-trained Licensed Professional Mental Health Counselors, VA will ensure that these important mental health clinicians are available to treat the Veterans we serve today and those we will serve in the future," said Dr. Robert L. Jesse, Director, VA Office of Academic Affiliations. "Through the ongoing expansion of mental health education and training programs, VA will be better positioned to attract the most qualified and skilled professionals to treat our Veterans."

To support hiring efforts, VA has announced new clinical training opportunities for LPMHC students for the upcoming 2015-2016 academic year. Eighteen pre-degree internship positions were awarded to seven VA medical centers to provide clinical experiences within VA's interprofessional mental health teams.

The VA anticipates an expansion of these positions in coming years to assist with future workforce needs.

Through its network of academic affiliations and VA-sponsored programs, VA provides clinical education and training programs for approximately 120,000 health care professionals each year.

Licensed Professional Mental Health Counselors contribute substantially to VA's ability to deliver high-quality patient care for Veterans.

Recognizing that VA's health professions training programs are a key resource for recruitment of healthcare professionals with high-level Veteran-centric skills, VA invests $100 million annually to pay stipends for these developing clinicians in key mental health professions including LPMHC, nursing, psychiatry, psychology, and social work.

Sixty percent of VA psychiatrists, 70 percent of psychologists, and 35 percent of social workers have previously participated in VA's own training programs.

We are optimistic that LPMHCs training in VA will be interested in returning to VA for future employment.

"VA is a leader in defining the education of future health care professionals to meet the changing needs of U.S. health care delivery," said Under Secretary for Health, Dr. David J. Shulkin. "Licensed Professional Mental Health Counselors contribute substantially to VA's ability to deliver high-quality patient care for Veterans.

Now we are developing a group of highly skilled trainees to ensure future growth in this important mental health profession."

Interested mental health care providers can find additional information about VA careers and apply for jobs online at www.vacareers.va.gov.

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Program Focuses on Safe Psychiatric Medication

Helping improve quality of care for Veterans with mental health problems

Ensuring Veterans receive safe, effective, and evidence-based treatments for their mental health problems is a top priority for the Veterans Health Administration (VHA). For many Veterans, this treatment includes the use of psychiatric medications.

Over 1.8 million Veterans currently have an active prescription filled by VA pharmacy for a psychiatric medication, which highlights how important it is to ensure those medications are being used in a manner that maximizes the benefit to Veterans and minimizes potential harms.

We recently reviewed the impact of the Psychotropic Drug Safety Initiative (PDSI), a program that focuses on safe psychiatric medication use across VHA, and I'm pleased to share that the program has had a positive impact on the care provided to Veterans.

First, let me tell you a little bit more about the PSDI program. VHA launched PDSI back in December 2013 in order to foster the highest quality of treatment with medications for Veterans with mental health problems. PDSI is a nation-wide quality improvement (QI) program in which every VHA facility across the country participates.

Metrics of mental health treatment with psychiatric medications

Each facility chooses an area of prescribing on which to focus its local QI efforts and develops their own local plan for improvement. The national PDSI program office supports these local QI efforts by providing data, informatics tools, trainings and educational resources, and feedback and

technical assistance. PDSI data include facility and national scores reported quarterly on prescribing metrics that address a variety of aspects of mental health treatment with psychiatric medications.

PDSI informatics tools help facilities identify individual Veterans who might benefit from changes to their current medications. The data in these tools are updated nightly to ensure the most actionable data is shared with facilities every day.

PDSI has also developed trainings for providers and supports the development of educational materials for patients about the safe and effective use of psychiatric medications. PDSI leaders conduct national conference calls twice a month to bring facility workgroups together to share in their success and learn from one another's challenges.

Program having positive impact on care of Veterans

Since its implementation, the PDSI program has had a robust and positive impact on the care of Veterans. Out of the 20 prescribing metrics tracked in the initial phase of the program, 16 showed improvement in the national score.

There are several areas of prescribing that showed especially strong improvements. Across the system we have decreased use of potentially harmful medications in patients with Posttraumatic Stress Disorder (PTSD), including decreased use of benzodiazepines, antipsychotics and the use of complex, multiple-drug regimens. We have also decreased the use of benzodiazepines among vulnerable populations, such as Veterans with PTSD, dementia, and the elderly, as well as decreased the use of complex, multiple-drug regimens for patients with depression.

We have also successfully increased the use of evidence-based medications for treatment of substance use disorders, particularly in Veterans with alcohol and opioid addiction. These improvements have directly and positively impacted the care of thousands of Veterans.

As the PDSI program moves forward, we are now specifically focusing on ensuring safe, effective use of psychiatric medications among older Veterans. We are confident that the success from our initial efforts will continue, and we are excited to have this opportunity to improve the quality of care we provide our older Veterans.

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Veterans
NEUROLOGY

Identification of Pseudobulbar Affect Symptoms in Veterans with Possible Traumatic Brain Injury

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Abstract — Pseudobulbar affect (PBA), a neurological syndrome characterized primarily by involuntary episodes of laughing and crying, can develop secondary to neurological conditions including traumatic brain injury (TBI). Veterans of the wars in Afghanistan and Iraq have an unprecedented risk for TBI, primarily from blast-related munitions. In this cross-sectional study with linkage to Department of Veterans Affairs (VA) clinical data, Veterans screening positive for TBI on the VA TBI screen (N = 4,282) were mailed packets containing two PBA symptom assessments: a single PBA symptom screen question and the Center for Neurologic Study-Lability Scale (CNS-LS) questionnaire. Seventy percent (n = 513) of the 728 Veteran respondents screened positive for PBA symptoms with a CNS-LS score of 13 or greater.

There was strong concordance between PBA symptom prevalence measured with the single screening question and CNS-LS, with high sensitivity (0.87) and positive predictive value (0.93) and moderate specificity (0.79). Posttraumatic stress disorder (54% vs 32%), major depression (35% vs 22%), and anxiety disorder (20% vs 13%) were more common for Veterans with PBA symptoms than for those without. PBA symptoms were common in this Veteran cohort, were detected using simple screening tools, and often co-occurred with other psychiatric disorders common in Veterans.

Key words: cross-sectional surveys, depression, emotional lability, lability scale, nervous system diseases, pseudobulbar affect, pseudobulbar syndromes, PTSD, traumatic brain injuries, Veterans.

Abbreviations: ALS = amyotrophic lateral sclerosis, AUC = area under the ROC curve, CDW = Corporate Data Warehouse, CNS-LS = Center for Neurologic Study-Lability Scale, ICD-9 = International Classification of Diseases-Ninth Revision, MS = multiple sclerosis, NewGen = New Generation of U.S. Veterans, OEF = Operation Enduring Freedom, OIF = Operation Iraqi Freedom, OND = Operation New Dawn, PBA = pseudobulbar affect, PLC = pathological laughing and crying, PPV = positive predictive value, PTSD = posttraumatic stress disorder, ROC = receiver operating characteristic, SD = standard deviation, Se = sensitivity, Sp = specificity, SSN = Social Security number, TBI = traumatic brain injury, TRACTS = Translational Research Center for TBI and Stress Disorders, VA = Department of Veterans Affairs, VHA = Veterans Health Administration, VISN = Veterans Integrated Service Network.

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INTRODUCTION

Pseudobulbar affect (PBA), a neurological syndrome characterized by involuntary, uncontrollable, exaggerated, and often inappropriate outbursts of crying and/or laughing, can cause severe distress, embarrassment, and social dysfunction [1]. This syndrome develops in the context of numerous neurological conditions, including stroke, multiple sclerosis (MS), amyotrophic lateral sclerosis (ALS), Parkinson disease, Alzheimer disease, and traumatic brain injury (TBI) [2–4]. PBA is believed to be caused by disruption or damage to the neural circuitry between the cerebellum and frontal cerebral cortex, which modulates emotional expression [1,4–7]. In the PBA Registry Series, a large (N = 5,290) clinical sample of patients with neurological conditions associated with PBA, the prevalence of PBA symptoms as defined by a score of 13 or greater in the Center for Neurologic Study-Lability Scale (CNS-LS) [5] was approximately 37 percent [2]. The prevalence of moderate or severe PBA symptoms, defined as CNS-LS score = 21, was 9 percent and the highest among the 590 patients with TBI (n = 96, 16%). This rate was similar to what was reported by Tateno et al. regarding the prevalence of pathological laughing and crying (PLC), an alternate term for PBA [8]. PLC following TBI was reported in approximately 11 percent of a sample of patients admitted for a closed head injury. Furthermore, patients with PLC had more depressive, anxious, and aggressive behaviors than patients without PLC. PLC was also associated with anxiety disorder and disruption of frontal lobe function [8].

Servicemembers returning from Operation Iraqi Freedom (OIF), Operation Enduring Freedom (OEF), and Operation New Dawn (OND) in Iraq and Afghanistan have been exposed to unprecedented risk for TBI due primarily to high rates of exposure to blast-related munitions. Blasts and explosions are the most common cause of injury for U.S. military personnel engaged in OIF/OEF/OND [9], and the reported incidence of TBI in OIF/OEF/OND Veterans ranges from 9 to 39 percent [10–13]. It is currently unknown whether these cases of TBI are associated with the development of PBA symptoms.

The current study had two primary aims: first, to estimate the occurrence of PBA symptoms in OIF/OEF/OND Veterans using two survey instruments mailed to Veterans who screened positive for TBI, and second, to evaluate the concordance between the two survey instruments used to assess the occurrence of PBA symptoms—a single PBA screen question [5] and the CNS-LS questionnaire [6]. To date, there is not a standard method to screen for PBA specifically in TBI.

METHODS

Study Population

Our study population consisted of OIF/OEF/OND Veterans in the Department of Veterans Affairs (VA) New England Healthcare System, Veterans Integrated Service Network (VISN)-1, who screened positive for TBI on the Veterans Health Administration (VHA) four-item TBI screen between April 2007 and April 2013. We excluded Veterans who had an International Classification of Diseases-Ninth Revision (ICD-9) diagnosis code for bipolar disorder (296.0, 296.1, and 296.4–296.8), schizophrenia, or other psychiatric disorder (293.81, 293.82, 295, and 297–298) recorded at any time in their VA medical record. Veterans with a diagnosis of psychosis not otherwise specified due to trauma-related hallucinations (293.9) were retained in the study.

Procedure

We obtained names and mailing addresses from the VA Corporate Data Warehouse (CDW) Patient Data Domain. All Veterans in our study population were mailed a packet that included a cover letter, two questionnaires, and a pre-addressed, postage-paid return envelope. The cover letter included all elements of consent, informing the Veteran that completion of the questionnaire was considered implied consent. The first questionnaire included the seven-item CNS-LS, supplemented with a single additional PBA screening question (see "Measures" section). The EuroQol 5-dimension 5-level questionnaire was also included as a health status measure (subject of future publication). Each survey contained a unique study code to maintain confidentiality. Survey responses were hand-entered into a database and further verified for quality assurance. The survey data were linked to the VHA files using a crosswalk file that contained the study code and scrambled Social Security number (SSN), which is a unique identifier for each Veteran.

Baseline demographic and clinical characteristics were obtained from the VHA electronic medical data sets during VA fiscal year 2012 (October 1, 2011–September 30, 2012). Data for inpatient hospitalizations and outpatient visits were extracted from the National Patient Care Database, which includes patient demographic information, the name of the clinic where the service was provided, and up to 13 ICD-9 coded diagnoses. Pharmacy data were extracted from the VA Decision Support System pharmacy files, which include all outpatient prescription orders filled at a VA pharmacy or consolidated mail outpatient pharmacy. Laboratory data were extracted from the VA CDW, which includes the laboratory test name, result, and unit. All files were merged by scrambled SSN. All procedures were approved by the VA Boston Institutional Review Board. Burden of disease and comorbidities, quality of life, and costs in patients with PBA symptoms will be reported elsewhere.

Measures

Traumatic Brain Injury Assessment

The VA TBI screen, instituted in April 2007, is a one-time mandatory screening for all Veterans entering the VA medical system who served in OIF/OEF/OND [14]. This screen, which is based on the Brief Traumatic Brain Injury Screen [15], consists of four sequential questions assessing—

1 Events associated with the risk for TBI (e.g., blast, fall).

2. Immediate symptoms following the event (e.g., confusion, being dazed).

3. New or worsening symptoms following the event (e.g., dizziness, headaches).
4. Symptoms within the past week (e.g., headaches, sleep problems).

Results from the screen are recorded in the VA CDW Patient Data Domain, from which we identified OIF/OEF/OND Veterans who screened positive on the VHA 4-item TBI screen. Recently, Fortier et al. reported high sensitivity (Se = 0.85) and specificity (Sp = 0.82) of the VA screen for predicting probable cases of TBI when administered for research purposes, although sensitivity was lower when compared with a semi-structured clinical interview (Boston Assessment of Traumatic Brain Injury-Lifetime) [10]. The VA screen has also been shown to have high internal consistency and reliability [16].

If a Veteran answers affirmatively to all four questions on the screen, he or she is classified as probable TBI and referred for a comprehensive, secondary screening. The secondary screen follows a standard protocol administered by a clinician, with questions about the mechanism (e.g., blast or blunt trauma) and severity of the injury, as well as current neurobehavioral symptoms and psychiatric history. At the end of examination, the clinician is required to confirm or rule out a TBI diagnosis [14].

Assessment of Pseudobulbar Affect Symptoms

We assessed the presence of PBA symptoms using the CNS-LS questionnaire supplemented with a single PBA screening question. The 7-item CNS-LS is a quantitative measure of the frequency and severity of involuntary or excessive laughing and crying symptoms [6]. Possible responses to each question are as follows: (1) applies never, (2) applies rarely, (3) applies occasionally, (4) applies frequently, and (5) applies most of the time. The total score is the sum of the individual question responses and ranges from 7 (no symptoms) to 35 (highest frequency/severity). The CNS-LS was also divided into laughing and crying subscales. The laughing subscale consists of four questions, and the crying subscale consists of three questions [6]. The CNS-LS has been validated as a measure of PBA symptoms in patients with ALS and MS [5–6,17]; however, it has not been specifically validated in patients with TBI. The single PBA symptom screening question was included to assess the CNS-LS performance. The PBA symptom screening question asks the Veteran, "Have you ever experienced involuntary episodes of crying and/or laughing that were exaggerated or even contrary to how you felt at the time?" Possible responses for this screening question are "yes," "no," and "unsure." The single question was used in a recently published PBA symptom prevalence survey [5]. In that study, of the respondents with a CNS-LS score of 13 or greater, 70 percent answered "yes" to the symptom screening single question.

Statistical Analyses

The presence of PBA symptoms was assessed separately using the two screening instruments. Veterans were categorized as screening positive with symptoms for PBA if they had a CNS-LS score of 13 or greater or if they answered "yes" on the single PBA screening question. We assessed the concordance between the two survey instruments to determine the proportion that screened positive for PBA symptoms on both measures. Additionally, Veterans were categorized as screening positive for moderate or severe PBA symptoms if they had a CNS-LS score of 21 or greater. We characterized the study population overall and by PBA symptom screening status (positive and negative for symptoms by each of the two screening instruments) by demographic, clinical, and TBI characteristics obtained from the previous fiscal year (October 1, 2011–September 30, 2012). The descriptive statistics included means and standard deviations (SDs) for continuous variables and frequencies and percentage for categorical variables.

The distribution of CNS-LS responses was tabulated and stratified by CNS-LS subscale and PBA symptom single screening question response. The mean and SD for the CNS-LS total score and frequency and percent for the PBA symptom screening question were computed. Statistical significance of the difference in CNS-LS total score between Veterans with positive and negative PBA symptom screening responses was determined using a t-test. Linear trends of CNS-LS question responses with PBA symptom single screening question responses were tested using Pearson correlation coefficient and log-linear association models [18] for each of the CNS-LS questions separately. A significant, positive trend test indicates that the proportion who responded "yes" on the PBA symptom single screening question increases linearly with increasing CNS-LS category responses.

Analogs of sensitivity and specificity of the CNS-LS total scores at various thresholds relative to the PBA symptom screening question were determined and used to develop the receiver operating characteristic (ROC) curves. True measures of sensitivity and specificity are not calculable because neither the CNS-LS nor the single PBA symptom screening question are validated measures of PBA symptoms in a population with TBI. The area under the ROC curve (AUC) is an index of the accuracy of the dichotomous test on a probability scale of 0 to 1. An AUC of 1 indicates a perfect test, and an AUC of 0.5 indicates a test with no ability to discriminate positive from negative results [19]. Separate ROCs were constructed using the CNS-LS total score and the laughing and crying subscales. The analogs of sensitivity, specificity, and positive predictive value (PPV) are reported for each ROC analysis.

Analyses were conducted using SAS (version 9.3; Cary, North Carolina) software. All statistical tests were two-sided, using $p < 0.05$ as the cutoff for reporting statistically significant results.

RESULTS

Demographic and Clinical Characteristics

Veterans with Positive Traumatic Brain Injury Screen

We identified 33,487 OIF/OEF/OND Veterans in the VISN-1 who received the VA primary TBI screen between April 2007 and April 2013, of whom 4,837 (14%) screened positive for TBI. We excluded 437 Veterans with a diagnosis for bipolar disorder or schizophrenia and 118 with incomplete or duplicate demographic information. Our final sample was 4,282 Veterans who screened positive for TBI.

Our study population was predominantly male (95%), with an average age of 34.5 ± 8.8 yr. This sample closely resembles the demographic characteristics of the National Health Study for a New Generation of U.S. Veterans (NewGen), which is a national cohort of OIF/OEF Veterans and nondeployed Veterans who served during the same era [20]. The key difference was that our sample had a higher proportion of males than the NewGen cohort (95% vs 88%). The complete demographic characteristics are presented in Table 1.

In the screened TBI study population, about half had at least one current type of pain condition, with back and neck pain (32%), other arthropathies (31%), and headaches and migraines (17%) as the most common (Table 2). Current mental health conditions were highly prevalent in this population, including posttraumatic stress disorder (PTSD) (46%), major depression (26%), and anxiety disorders (17%). Within the year 2012, more than a third of the population had at least one prescription for an antidepressant (37%), 16 percent for a sedative or hypnotic agent, and 7 percent for an antipsychotic (in spite of psychosis being an exclusion criterion) (Table 2).

Blast or explosion was the most common mechanism of injury (84%) reported on the TBI screen among Veterans who screened positive for TBI, followed by fall (46%), other mechanism (46%), and vehicle accident (42%). It is important to note that the mechanisms of injury are not mutually exclusive; a Veteran could report more than one mechanism on the VHA TBI screen if he or she experienced more than one probable TBI, or more than one mechanism of injury could be reported for a single TBI event (e.g., blast and fall). The number of possible TBI events is not assessed in the screen. Finally, in the subset of 2,467 (58%) who completed the secondary TBI evaluation, 1,311 (53%) had a confirmed TBI. The majority of the confirmed TBIs were mild (89%).

Comparison of Respondents and Nonrespondents

There were 758 Veterans (19%) who completed the survey among the subset of 3,954 (92%) who had accurate mailing addresses. Compared with nonrespondents, respondents were more likely to be older, white, married, and college graduates (Table 1). Respondents had a higher prevalence of depression and were more likely to have a prescription for antidepressants than nonrespondents. Additionally, respondents were more likely to have a prescription for antiepileptics than nonrespondents (Table 2). Finally, respondents also had a higher prevalence of pain-related diagnoses, mostly due to higher prevalence of osteoarthritis and other arthropathies. Respondents were similar to nonrespondents for all other comorbid conditions and biomedical characteristics, including PTSD, anxiety disorders, substance abuse, and headaches/migraines (Tables 2 and Appendix Table S1, available online only).

Center for Neurologic Study-Lability Scale Overall Score

Nearly all respondents (97%) completed every item on the CNS-LS questionnaire. Of these, the average CNS-LS score was 16.0 ± 5.7, with the majority of Veterans (70%) screening positive for PBA symptoms with a CNS-LS score of 13 or greater and 22 percent screening positive for moderate or severe PBA symptoms (CNS-LS = 21; n = 165). For the PBA symptom screening single question, 60 percent answered "yes," 20 percent answered "no," 14 percent answered "unsure," and 6 percent did not answer.

In the subset of 591 respondents (78%) with complete data for the CNS-LS questions and a "yes" or "no" answer for the PBA symptom screening question, 62 percent screened positive and 20 percent screened negative for PBA symptoms on both measures; 21.3 percent had a CNS-LS score of 21 or greater and a "yes" response on the screening question. Greater than 99 percent (126/127) of those with CNS-LS score of 21 or greater answered "yes" to the screening questions. Those who responded "yes" on the PBA symptom screening question had a significantly higher average CNS-LS score than those who answered "no" (18.4 ± 5.0 vs 10.1 ± 3.4, respectively; $p < 0.001$). All CNS-LS questions showed a significant increasing linear trend of symptom frequency with a "yes" response on the PBA symptom screening question ($p < 0.001$; Appendix Table S2).

Evaluation of Center for Neurologic Study-Lability Scale Questionnaire and Pseudobulbar Affect Symptom Screening Question

The ROC analysis indicated that the optimum analogs of sensitivity and specificity occurred at the CNS-LS total score of 12 (Se = 0.87, Sp = 0.79, PPV = 0.93; Table 3). The AUC was 0.914, indicating that the single PBA symptom screening question discriminates very well between those with and without PBA symptoms as determined by the CNS-LS.

CNS-LS responses showed that reported crying symptoms outweighed laughing symptoms (Table 4). The study population weighted mean score (laughing scores weighted by 0.75) for the CNS-LS crying questions (questions 1, 3, and 6) was significantly higher than the weighted mean score for the laughing questions (questions 2, 4, 5, and 7) (7.5 ± 3.1 vs 6.4 ± 2.7, respectively; $p < 0.001$).

The ROC analyses indicate that the PBA symptom single screening question discriminates CNS-LS crying-related symptoms better than it does CNS-LS laughing-related symptoms (AUC = 0.908 and 0.806, respectively).

DISCUSSION

Self-report of PBA symptoms was common among OIF/OEF/OND Veterans who screened positive for TBI and responded to our survey. There was high concordance between the PBA symptom single screening question and PBA symptoms measured on the CNS-LS 7-item rating scale. The ROC analysis indicated that a CNS-LS threshold of 12 provided optimal discrimination between positive and negative responses on the PBA symptom screening question, with high sensitivity and

PPV and moderate specificity. The CNS-LS has been validated as a measure of PBA symptoms in patients with ALS and MS [5–6,17]. In ALS patients, a CNS-LS score of 13 or greater provided the highest incremental validity for physician diagnosis of PBA with a sensitivity of 0.84 and specificity of 0.81. Among MS patients, the optimal threshold corresponding to physician diagnosis of PBA for the CNS-LS was reported as 17 or greater [17]. For both ALS and MS patients, a threshold of CNS-LS = 13 was found to provide good predictive value (PPV = 0.82 and 0.78, respectively) and good sensitivity (Se = 0.84 and 0.96, respectively) [6,17] but poor specificity in the MS patients (Sp = 0.55). In this study, the analogs of sensitivity and specificity were not significantly different when using a threshold of CNS-LS = 13 (Se = 0.82, Sp = 0.83), rather than the optimal threshold of CNS-LS = 12, and were very similar to those reported for ALS patients [6]. This consistency across populations suggests that the CNS-LS is a reliable screen for PBA symptoms, as shown in other studies [6,17] and further, that the PBA symptom single screening question can be used in Veterans as a sensitive and specific screening tool for CNS-LS–defined PBA symptoms.

The CNS-LS has not been validated in a population with TBI and may not be sufficiently specific to discriminate PBA from other concomitant disorders that can be associated with affective lability or crying, such as PTSD or depression, which are highly prevalent in this study population. Given the high occurrence of PBA symptoms in this study, it may be that the CNS-LS is not sufficiently specific to be diagnostic for PBA symptoms in this population. The single screening question, inquiring about the hallmark symptoms of PBA, was included in the survey, in part to assess specificity of the CNS-LS for PBA symptoms. So it is encouraging that the large majority of those with CNS-LS = 13 also answered "yes" to this question. Future studies should evaluate the presence of clinically diagnosed PBA in those with positive screen.

In order to maximize the number of respondents for the PBA symptom questionnaire, this study included all Veterans who screened positive on the VA primary TBI screen. False positive screens for TBI may occur if the Veteran has other conditions, including PTSD or other conditions that have concussion-like symptoms, such as hearing loss and vestibular changes [21]. The proportion of screened TBI Veterans who completed a secondary TBI assessment and subsequently received a physician diagnosis of TBI was 53 percent, which is consistent with the proportion of approximately 60 percent found in other studies [22–23]. The reported symptom prevalence was similar in both the screened TBI and the confirmed TBI groups (70% vs 72%). Parallel analyses in the subset of Veterans with definitive TBI confirmed by a follow-up neuropsychiatric examination yielded very similar results to those reported in this larger sample of Veterans who screened positive for TBI based on the four-question screen (data not shown).

To our knowledge, this is the first study to evaluate the occurrence of PBA symptoms in a Veteran population with possible and confirmed TBI. The high prevalence of PBA symptoms in this cohort was surprising, especially given that the majority of TBIs in the current Veteran population are mild in severity. PBA symptoms are not routinely assessed in patients with mild TBI, but these data suggest that they should be, because this problem may be even more common than other comorbidities, including PTSD, depression, and anxiety disorders. Not all Veterans who screened positive for TBI were confirmed through secondary screening to have TBI (47%), and it may be that PBA symptoms are also highly prevalent in Veterans with whom TBI is suspected but not diagnosed. As noted previously, our study found similar results in both the confirmed and unconfirmed TBI cases, suggesting that the population of Veterans of concern for PBA symptoms may be broader than just those with confirmed TBI.

Symptoms of PBA can be extremely disabling in any clinical population but perhaps even more so in Veterans who are, by their nature, very proud and confident individuals. Our data indicate that Veterans who expressed symptoms of PBA also experienced a lower quality of life and higher costs than Veterans without such symptoms (subject of future publication). We further speculate that not being in control of the basic emotional expressions of laughing and, especially, crying may be particularly distressing in this population and may add to the risk of well-documented self-destructive behaviors, including substance abuse, dangerous driving, and suicide, all of which have increased incidence in this cohort of OIF/OEF/OND Veterans [24–25]. The data here suggest that clinicians should regularly screen for PBA if there is even a possibility that the Veteran may have sustained a TBI while in service, because over half of Veterans were found to have symptoms of PBA. Our data indicate that a simple question asking a patient about involuntary episodes of laughing or crying was equally effective in assessing the presence/absence of PBA symptoms as the CNS-LS. Thus, a simple question can potentially detect the presence of a debilitating disorder that Veterans may be reluctant to talk about with a healthcare provider. When a patient answers "yes" to this question, the clinician can conduct a more in-depth probe to determine the presence and severity of potential PBA diagnosis.

It is important to recognize that TBI rarely exists in isolation in the OIF/OEF/OND Veteran. The majority of TBIs are the result of exposure to explosive munitions, which are simultaneously physically and psychologically traumatic, leading to polymorbid psychological and physical injuries. Following deployment, this is reflected in the fact that those with a history of TBI are commonly diagnosed with other conditions, including PTSD, depression, pain, and sleep disturbance [26]. To this list we now add symptoms of PBA. Because these disorders share highly interactive underlying neurological circuitry, including frontal lobe executive systems (controlling decision making, impulsivity, addiction behaviors, etc.) [27] and cerebellar modulating systems (associative learning, emotional regulation) [28], it is likely that treatment must be multifaceted and not targeted to a single condition. We suspect that this may be the reason that a substantial proportion of Veterans report PBA symptoms despite use of antidepressant medications. It is essential to treat the "whole" Veteran if clinicians are going to be effective. Gaining a better understanding of how one condition interacts with or compounds the burden of another will be critical to designing effective—i.e., individualized—treatments for returning servicemembers and Veterans.

This study employed a cross-sectional study design, and thus we are unable to determine the causal directional of the association between TBI and PBA symptoms. However, this study is able to minimize potential retrospective reporting biases common to cross-sectional studies by obtaining clinical and TBI information from electronic medical records and standardized TBI reports.

Another limitation of this study was the inclusion of OIF/OEF/OND Veterans who received care at a VA facility in the New England region only. Nevertheless, this sample closely resembles the demographic characteristics of a national cohort of younger U.S. Veterans [20]. Thus, results could be generalized to a national sample of OIF/OEF/OND Veterans who screened positive for TBI.

Finally, the population prevalence cannot be estimated with this study design because the responding population may not be representative of the broader TBI population, which constitutes the desired denominator. Our results depend on the subjects accurately completing and returning the surveys. The responding population may be drawn more heavily from those who are more motivated to respond due to presence of PBA symptoms or other mental health comorbidities. While there were some demographic difference between the responding and nonresponding populations and the respondents were more likely to have a diagnosis and prescriptions for depression, the prevalence of other mental health comorbidities determined from clinical records (PTSD, anxiety disorder) were similar between respondents and nonrespondents. Furthermore, respondents and nonrespondents were very similar on clinical characteristics unrelated to PBA (e.g., hypertension and hyperlipidemia), suggesting that the potential biases are minimal.

CONCLUSIONS

There is a high occurrence of PBA symptoms in OIF/OEF/OND Veterans who screen positive for TBI. It is another piece of a very complicated puzzle of trying to understand the mental and physical needs of our returning servicemembers and Veterans. Our findings are important, highlighting the presence of PBA symptoms in addition to other comorbidities. The inability to control one's emotional expressions, such as laughing and crying out of social or emotional context, may be particularly debilitating in this population who are normally proud and confident individuals. This study suggests that clinicians should regularly screen for PBA symptoms in Veterans who may have sustained a TBI while in service. To that end, having a simple question asking about involuntary episodes of laughing and crying, which was equally as effective as assessing the presence or absence of PBA symptoms using the 7-item CNS-LS questionnaire, may help with feasibility of screening in everyday clinical practice. Additionally, the single question may provide signals for required differential diagnosis. Thus, clinicians can potentially detect this debilitating disorder using this simple screening question and conduct a more thorough neuropsychiatric evaluation, including the use of a measure like the CNS-LS to gauge the frequency and severity of PBA symptoms.

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Author Contributions:

Significant contribution to study design: C. Yonan, R. E. McGlinchey, M. W. Reynolds, P. R. Hunt, J. R. Fonda, W. P. Milberg, J. L. Rudolph.

Acquisition and verification of data: J. R. Fonda.

Contributed to analysis and interpretation: J. R. Fonda, P. R. Hunt, R. E. McGlinchey.

Primary preparation of manuscript: J. R. Fonda.

Critical review and editing of manuscript: P. R. Hunt, R. E. McGlinchey, C. Yonan.

Contributed critical editing of manuscript: M. W. Reynolds, W. P. Milberg, J. L. Rudolph.

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Veterans
NEUROLOGY

Tampa VA Doctor Recognized for Contributions to Polytrauma Care

MOAA presents Dr. Steve Scott with its Distinguished Service Award

By Megan Moloney

On April 12, the Military Officers Association of America (MOAA) presented one of its highest annual awards to a Tampa VA physician for his leadership role in Veterans care.

Dr. Steven Scott is chief of Rehabilitation Medicine and director or the Polytrauma Center at the James A. Haley Veterans Hospital in Florida. MOAA presented Scott with its Distinguished Service Award, given to an organization or individual who has greatly aided people who served in the U.S. armed forces.

According to MOAA, Scott was recognized for "his leadership role in improving the lives of America's ill, injured and disabled Veterans and their families."

The Tampa Polytrauma Rehabilitation Center is one of five facilities in the country designed to provide intensive rehabilitative care to Veterans and Servicemembers with multiple injuries that result in physical, cognitive and/or psychological impairments and functional disability.

Between 2007 and 2014, when the Tampa VA opened its Polytrauma-Rehabilitation Center, more than 500,000 Veterans from Operation Enduring Freedom, Operation Iraqi Freedom, and Operation New Dawn entering the VA health care system were screened for possible TBI with more than 53,000 by the Tampa VA Hospital alone.

Scott has been with the Tampa VA since 1990, having directed both the spinal cord and traumatic brain injury (TBI) programs. A national leader in his field, he has provided his expertise to members of Congress on polytrauma care. He also credits the team at Tampa and throughout VA for the hard work they do to support wounded warriors.

"We welcome the opportunity to recognize the leadership and service of this year's awardees," said retired Air Force Lt. Gen. Dana Atkins, president and CEO of MOAA. "Each has shown a personal commitment to supporting this nation's defense and an enduring loyalty to advocate for those who serve and their families."

Tampa VA's Dr. Steven Scott, Under Secretary for Health Dr. David Shulkin and George Scott attended the MOAA Distinguished Service Award ceremony

At the awards ceremony, Scott acknowledged his parents, who were in attendance. His father, George, served in the South Pacific during World War II, while his mother's brother flew 31 missions as part of a B-17 crew. Scott shared three insights he realized during the course of his career serving Veterans with war-related injuries: 1) listen to Veterans; 2) be flexible and innovative; and 3) make connections.

MOAA's Distinguished Service Award has been presented annually since 1997.

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FIGHTING WAR
THEN FIGHTING PAIN

Growing up the youngest of 10 children, in a tough neighborhood, Ron knew the only way out was prison or the military. At age 17, he joined the Navy as a cook and eventually transferred to the Army. "I wound up in Vietnam," says Ron, "and served 5 consecutive tours of duty." After returning from Vietnam, Ron enjoyed a successful career in business.

Ron's exposure to Agent Orange in Vietnam caused medical issues. To make matters worse, the pain from existing lumbar radiculitis gradually took hold of his foot, leg, and lower back. "The pain was excruciating — a 15 on a scale of 1 to 10," recalls Ron. "It was like fire when it hit, and it took me to my knees. I could only sleep 2 to 3 hours a night even though I was taking enough pain pills to kill a horse."

Spinal Cord Simulation — An Option for Better Pain Relief

During a pain management class at the Birmingham Veterans Administration (VA) Medical Center, another veteran told Ron about spinal cord stimulation (SCS), also know as neurostimulation therapy. SCS is delivered with a small neurostimulator, similar to a pacemaker. The neurostimulator is implanted under the skin and disrupts the pain signals traveling between the spinal cord and the brain so you may feel pain relief.

Ron talked with his doctor at the VA medical center who suggested that Ron have a 1-week trial of SCS to experience the therapy before committing long term. Ron was ready for the possibility of pain relief. "When the stimulation was turned on, I felt immediate pain relief," describes Ron. "My pain went from 15 to a 7½. It was like being at a resort!"

Ron went on to receive long-term therapy. He reduced the number of pain pills he was taking from 7 a day to zero, and now speaks regularly in his community about SCS and the possibility of pain relief. Ron mentors other vets in five states and D.C. "I see too many young vets succumb to addiction, and hear of too many suicides," states Ron. "I want those guys to know there's hope beyond all the pain and all the drugs."

Risks of Spinal Cord Stimulation Therapy

"When I talk to groups about neurostimulation," explains Ron, "I tell them, 'Do your research. Neurostimulation isn't for everyone. I can tell you how I feel, but I can't guarantee how you'll feel. It's about managing pain, not totally getting rid of it.'"

Some patients do experience problems. The most frequently reported problems following neurostimulator implant surgery include infection, lead movement, pain at the implant site, loss of therapy effect, and therapy that did not meet the patient's expectations. Please see the Important Safety Information at the end of this story for more details. Remember to discuss the benefits and risks of this therapy and any treatment option with your doctor.

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Ron with his dog, Duke.

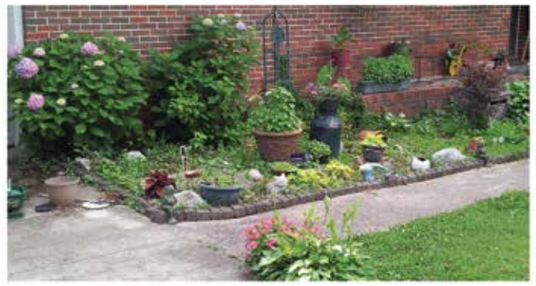
Safe Access to MRI Now and in the Future

One thing Ron really appreciates is that he can have safe* access to full-body MRI scans without having to get his neurostimulator removed. "Because of my days in combat, every time I go to the hospital they find something else wrong with me," chuckles Ron. "I have 2 to 3 MRIs a year." Medtronic spinal cord stimulation systems with SureScan® MRI Technology are the only systems of their kind to relieve pain *and* allow safe* access to an MRI scan on any part of the body.

"I'm not just smelling the roses, I'm growing the roses!"

With his pain in better control, Ron is in his yard every day. "My gladiator days are over. Now, to keep my mind and body active, I've taken up horticulture," says Ron. "I grow avocados and mangos, herbs, flowers, and vegetables. I'm not just smelling the roses, I'm growing the roses!"

*Under specific conditions. Neurostimulation systems require SureScan MRI implantable neurostimulator and SureScan MRI leads. Refer to approved labeling for full list of conditions.



With his pain in better control, Ron is able to work in his gardens.

MRI ANYWHERE ON THE BODY

Introducing Specify® SureScan® MRI Surgical leads — the latest addition to complete the Medtronic SureScan® MRI spinal cord stimulation (SCS) portfolio.

Medtronic delivers the first and only fully-implantable neurostimulator that allows safe* access to MRI — anywhere on the body.

For more information, visit *professional.medtronic.com/scs.*

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*Under specific conditions. Neurostimulation systems require SureScan MRI implantable neurostimulator and SureScan MRI leads. Refer to approved labeling for full list of conditions.

NEUROSTIMULATION SYSTEMS FOR PAIN THERAPY
Brief Summary: Product Technical Manuals and Programming Guides must be reviewed prior to use for detailed disclosure. Indication for Use: Chronic, intractable pain of the trunk and/or limbs-including unilateral or bilateral pain. **Contraindications:** Diathermy. **Warnings**: Defibrillation, diathermy, electrocautery, MRI, RF ablation, and therapeutic ultrasound can result in unexpected changes in stimulation, serious patient injury or death. Rupture/piercing of neurostimulator can result in severe burns. Electrical pulses from the neurostimulator may result in an inappropriate response of the cardiac device. **Precautions:** The safety and effectiveness of this therapy has not been established for: pediatric use, pregnancy, unborn fetus, or delivery. Follow programming guidelines and precautions in product manuals. Avoid activities that stress the implanted neurostimulation system. EMI, postural changes, and other activities may cause shocking/jolting. Patients using a rechargeable neurostimulator should check for skin irritation or redness near the neurostimulator during or after recharging. **Adverse Events:** Undesirable change in stimulation; hematoma, epidural hemorrhage, paralysis, seroma, CSF leakage, infection, erosion, allergic response, hardware malfunction or migration, pain at implant site, loss of pain relief, chest wall stimulation, and surgical risks. For full prescribing information, please call Medtronic at 1-800-328-0810 and/or consult Medtronic's website at www.medtronic.com. USA Rx Only Rev 0313

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Further, Together

Veterans
ONCOLOGY

Are You at Risk for Prostrate Cancer?

By Hans Petersen

Except for skin cancer, prostate cancer is the most common cancer in American men.

We asked VA's Dr. Anuradha Kunthur about the risk factors for prostate cancer. "African American ethnicity, family history of prostate cancer, a diet rich in animal fat, low vegetable intake, obesity and smoking are risk factors for prostate cancer."

And what can a Veteran do to protect against prostate cancer? "Smoking cessation, weight loss in obese patients, consuming a diet rich in cruciferous vegetables like cabbage, broccoli and limit your intake of animal fat."

Dr. Anuradha Kunthur treats Vietnam era Navy Veteran Harold Sadler. *Photo by Jeff Bowen, Central Arkansas Veterans Healthcare System*

Symptoms?

Dr. Kunthur points out that most of the patients with early stage prostate cancer will not have any symptoms. "Some patients may have frequent urination, urinary urgency, blood in the urine. Although these symptoms are commonly seen in patients with benign prostatic hypertrophy (an increase in the size of the prostate). Patients with bone metastasis may have bone pain."

Dr. Kunthur is also Assistant Professor in the Department of Hematology/Oncology at the University of Arkansas for Medical Science.

And what is the usual treatment for prostate cancer?

"Patients with prostate cancer are classified as low risk, intermediate risk and high risk categories.

"Patients with localized intermediate grade prostate cancer, with life expectancy of more than 10 years, are treated with radical prostatectomy with lymph node dissection or radiotherapy with external beam radiotherapy with androgen deprivation therapy and brachytherapy.

"High risk patients are treated with external beam radiation therapy with androgen deprivation therapy.

"Low risk patients with life expectancy of less than 10 years can be monitored closely and treated only if there is evidence of progressive disease. Low risk patients with life expectancy of more than 20 years can be either treated with radiation therapy, brachytherapy or radical prostatectomy.

Patients with metastatic disease are treated with androgen deprivation therapy.

Is there a test for prostate cancer?

Dr. Kunthur says, "Prostate cancer screening is controversial. Prostate specific antigen (PSA) is a protein produced by the prostate and is sensitive test for prostate cancer. Screening with PSA may reduce the chance of death from prostate cancer and the absolute benefit is small. "For most men, the potential benefits of screening are outweighed by the risks of the biopsy, over diagnosis and treatment. We recommend that Veterans first discuss with their doctor the pros and cons of prostate cancer screening. "Patients with high risk of prostate cancer, including African American men and men with family history of prostate cancer may benefit from prostate cancer screening." And when should a Veteran start screening for prostate cancer? "For average risk patients, PSA screening should be discussed at age 50 and age 40-45 for men with high risk factors."

Veterans who develop prostate cancer and were exposed to Agent Orange or other herbicides during military service do not have to prove a connection between their prostate cancer and service to be eligible to receive VA health care and disability compensation.

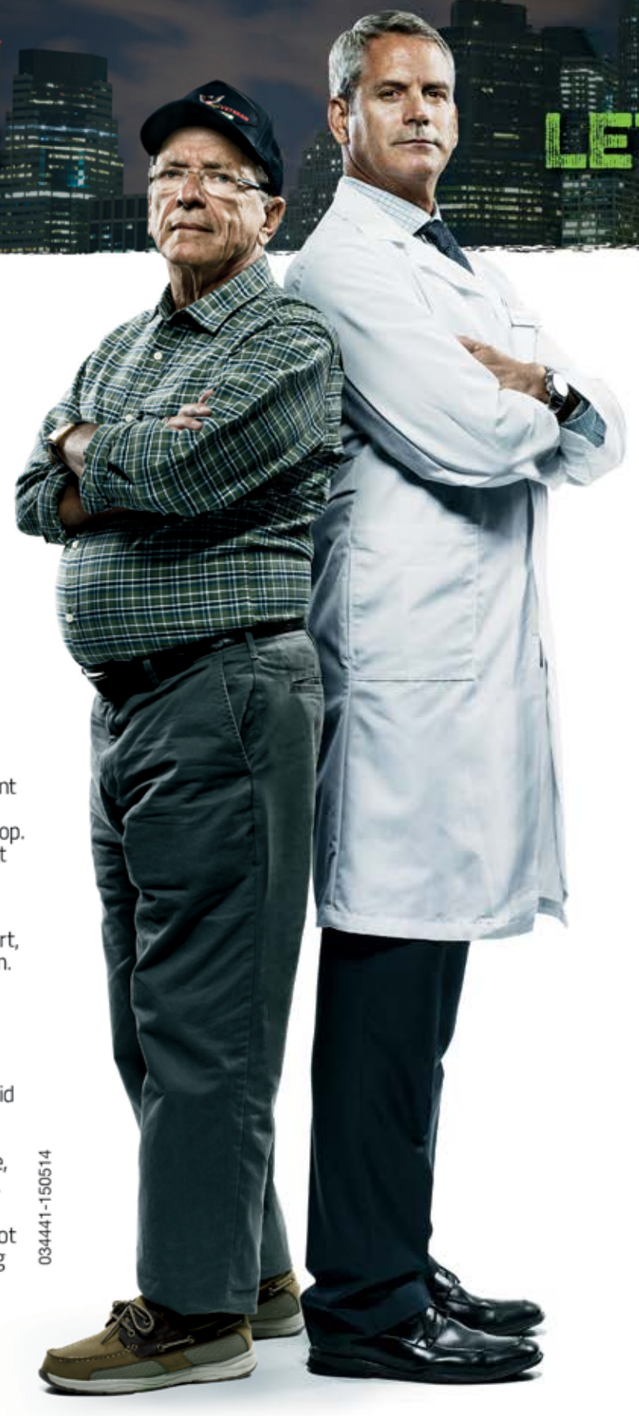
va.gov

VA Criteria for Use Updated September 2014. See www.pbm.va.gov for more information.

For men with mCRPC who have progressed on ADT

ZYTIGA® & PREDNISONE: LET'S DO THIS

(ABIRATERONE ACETATE)



In the final analysis of the pivotal phase 3 trial*...

ZYTIGA® + prednisone achieved a median OS of almost 3 years (34.7 months) after a median 4 years (49 months) of follow-up†

- **4.4 months improvement in median overall survival—34.7 months** with ZYTIGA® + prednisone vs **30.3 months** with placebo + prednisone (active compound)‡
  - **Co-primary end point**—median OS: hazard ratio (HR)=0.81; 95% CI: 0.70, 0.93; ***P*=0.0033**
- **Co-primary end point**—at the prespecified rPFS analysis, median not reached for ZYTIGA® + prednisone vs a median of 8.28 months for placebo + prednisone; HR=0.425; 95% CI: 0.347, 0.522; ***P*<0.0001**[§||]

49 MONTHS

REPRESENTS ONE OF THE LONGEST MEDIAN FOLLOW-UP PERIODS AMONG STUDIES OF PATIENTS WITH mCRPC[1]

IMPORTANT SAFETY INFORMATION

Hepatotoxicity—Monitor liver function and modify, withhold, or discontinue ZYTIGA® dosing as recommended (see Prescribing Information for more information). Measure serum transaminases [alanine aminotransferase (ALT) and aspartate aminotransferase (AST)] and bilirubin levels prior to starting treatment with ZYTIGA®, every two weeks for the first three months of treatment, and monthly thereafter. Promptly measure serum total bilirubin, AST, and ALT if clinical symptoms or signs suggestive of hepatotoxicity develop. Elevations of AST, ALT, or bilirubin from the patient's baseline should prompt more frequent monitoring. If at any time AST or ALT rise above five times the upper limit of normal (ULN) or the bilirubin rises above three times the ULN, interrupt ZYTIGA® treatment and closely monitor liver function.

Adverse Reactions—The most common adverse reactions (≥10%) are fatigue, joint swelling or discomfort, edema, hot flush, diarrhea, vomiting, cough, hypertension, dyspnea, urinary tract infection and contusion.

The most common laboratory abnormalities (>20%) are anemia, elevated alkaline phosphatase, hypertriglyceridemia, lymphopenia, hypercholesterolemia, hyperglycemia, elevated AST, hypophosphatemia, elevated ALT and hypokalemia.

Drug Interactions—Based on *in vitro* data, ZYTIGA® is a substrate of CYP3A4. In a drug interaction trial, co-administration of rifampin, a strong CYP3A4 inducer, decreased exposure of abiraterone by 55%. Avoid concomitant strong CYP3A4 inducers during ZYTIGA® treatment. If a strong CYP3A4 inducer must be co-administered, increase the ZYTIGA® dosing frequency only during the co-administration period [see Dosage and Administration (2.3)]. In a dedicated drug interaction trial, co-administration of ketoconazole, a strong inhibitor of CYP3A4, had no clinically meaningful effect on the pharmacokinetics of abiraterone.

ZYTIGA® is an inhibitor of the hepatic drug-metabolizing enzymes CYP2D6 and CYP2C8. Avoid co-administration with CYP2D6 substrates with a narrow therapeutic index. If alternative treatments cannot be used, exercise caution and consider a dose reduction of the CYP2D6 substrate drug. In a CYP2C8 drug interaction trial in healthy subjects, the AUC of pioglitazone, a CYP2C8 substrate, was increased by 46% when administered with a single dose of ZYTIGA®. Patients should be monitored closely for signs of toxicity related to a CYP2C8 substrate with a narrow therapeutic index if used concomitantly with ZYTIGA®.

Use in Specific Populations—Do not use ZYTIGA® in patients with baseline severe hepatic impairment (Child-Pugh Class C).

034441-150514

Prespecified secondary end point¶

ZYTIGA® + prednisone significantly delayed median time to opiate use for prostate cancer-related pain

Median time to opiate use	
ZYTIGA® + prednisone	Placebo + prednisone
NOT REACHED	23.7 MONTHS

Secondary end point—HR=0.686; 95% CI: 0.566, 0.833; ***P*=0.0001**

DELAY IN OPIATE USE WAS SUPPORTED BY A DELAY IN PATIENT-REPORTED PAIN PROGRESSION, FAVORING THE ZYTIGA® + PREDNISONE ARM

OS = overall survival; rPFS = radiographic progression-free survival.

***Study Design:** ZYTIGA®, in combination with prednisone, was evaluated in a phase 3, randomized, double-blind, placebo-controlled, multicenter trial in patients with mCRPC who had not received prior chemotherapy (N=1,088). Patients were using a luteinizing hormone-releasing hormone (LHRH) agonist or were previously treated with orchiectomy. In the ZYTIGA® arm, patients received ZYTIGA® 1,000 mg orally once daily + prednisone 5 mg orally twice daily. In the placebo arm, patients received placebo orally once daily + prednisone 5 mg orally twice daily. In this study, the co-primary efficacy end points were OS and rPFS. Select exclusion criteria included aspartate aminotransferase (AST) and/or alanine aminotransferase (ALT) ≥2.5X ULN, liver metastases, moderate or severe pain, opiate use for cancer pain, prior ketoconazole treatment for prostate cancer, a history of adrenal gland or pituitary disorders, and visceral organ metastases. Concurrent use of spironolactone was not allowed during the study period.

†At a prespecified final analysis for OS, 65% (354/546) of patients treated with ZYTIGA® + prednisone compared with 71% (387/542) of patients treated with placebo + prednisone had died.

‡Prednisone, as a single agent, is not approved for the treatment of prostate cancer.

§rPFS was assessed with the use of sequential imaging studies and was defined by bone scan identification of 2 or more new bone lesions with confirmation (Prostate Cancer Working Group 2 [PCWG2] criteria) and/or modified Response Evaluation Criteria In Solid Tumors (RECIST) criteria for progression of soft tissue lesions. Analysis of rPFS utilized centrally reviewed radiographic assessment of progression.

||At the prespecified rPFS analysis, 150 (28%) of patients treated with ZYTIGA® + prednisone and 251 (46%) of patients treated with placebo + prednisone had radiographic progression.

¶The secondary efficacy analysis presented here is as of the December 20, 2011, cutoff date.[1]

Reference: 1. Data on file. Janssen Biotech, Inc.

once-daily

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ZYTIGA® (abiraterone acetate) Tablets
Brief Summary of Prescribing Information.

INDICATIONS AND USAGE
ZYTIGA is a CYP17 inhibitor indicated in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer.

CONTRAINDICATIONS
Pregnancy: ZYTIGA can cause fetal harm when administered to a pregnant woman. ZYTIGA is not indicated for use in women. ZYTIGA is contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, apprise the patient of the potential hazard to the fetus and the potential risk for pregnancy loss *[see Use in Specific Populations]*.

WARNINGS AND PRECAUTIONS
Hypertension, Hypokalemia and Fluid Retention Due to Mineralocorticoid Excess: ZYTIGA may cause hypertension, hypokalemia, and fluid retention as a consequence of increased mineralocorticoid levels resulting from CYP17 inhibition *[see Clinical Pharmacology (12.1) in full Prescribing Information]*. In the two randomized clinical trials, grade 3 to 4 hypertension occurred in 2% of patients, grade 3 to 4 hypokalemia in 4% of patients, and grade 3 to 4 edema in 1% of patients treated with ZYTIGA *[see Adverse Reactions]*.

Co-administration of a corticosteroid suppresses adrenocorticotropic hormone (ACTH) drive, resulting in a reduction in the incidence and severity of these adverse reactions. Use caution when treating patients whose underlying medical conditions might be compromised by increases in blood pressure, hypokalemia or fluid retention, e.g., those with heart failure, recent myocardial infarction or ventricular arrhythmia. Use ZYTIGA with caution in patients with a history of cardiovascular disease. The safety of ZYTIGA in patients with left ventricular ejection fraction <50% or New York Heart Association (NYHA) Class III or IV heart failure (in Study 1) or NYHA Class II to IV heart failure (in Study 2) was not established because these patients were excluded from these randomized clinical trials *[see Clinical Studies (14) in full Prescribing Information]*. Monitor patients for hypertension, hypokalemia, and fluid retention at least once a month. Control hypertension and correct hypokalemia before and during treatment with ZYTIGA.

Adrenocortical Insufficiency: Adrenal insufficiency occurred in the two randomized clinical studies in 0.5% of patients taking ZYTIGA and in 0.2% of patients taking placebo. Adrenocortical insufficiency was reported in patients receiving ZYTIGA in combination with prednisone, following interruption of daily steroids and/or with concurrent infection or stress. Use caution and monitor for symptoms and signs of adrenocortical insufficiency, particularly if patients are withdrawn from prednisone, have prednisone dose reductions, or experience unusual stress. Symptoms and signs of adrenocortical insufficiency may be masked by adverse reactions associated with mineralocorticoid excess seen in patients treated with ZYTIGA. If clinically indicated, perform appropriate tests to confirm the diagnosis of adrenocortical insufficiency. Increased dosage of corticosteroids may be indicated before, during and after stressful situations *[see Warnings and Precautions]*.

Hepatotoxicity: In the two randomized clinical trials, grade 3 or 4 ALT or AST increases (at least 5X ULN) were reported in 4% of patients who received ZYTIGA, typically during the first 3 months after starting treatment. Patients whose baseline ALT or AST were elevated were more likely to experience liver test elevation than those beginning with normal values. Treatment discontinuation due to liver enzyme increases occurred in 1% of patients taking ZYTIGA. No deaths clearly related to ZYTIGA were reported due to hepatotoxicity events.

Measure serum transaminases (ALT and AST) and bilirubin levels prior to starting treatment with ZYTIGA, every two weeks for the first three months of treatment and monthly thereafter. In patients with baseline moderate hepatic impairment receiving a reduced ZYTIGA dose of 250 mg, measure ALT, AST, and bilirubin prior to the start of treatment, every week for the first month, every two weeks for the following two months of treatment and monthly thereafter. Promptly measure serum total bilirubin, AST, and ALT if clinical symptoms or signs suggestive of hepatotoxicity develop. Elevations of AST, ALT, or bilirubin from the patient's baseline should prompt more frequent monitoring. If at any time AST or ALT rise above five times the ULN, or the bilirubin rises above three times the ULN, interrupt ZYTIGA treatment and closely monitor liver function.

Re-treatment with ZYTIGA at a reduced dose level may take place only after return of liver function tests to the patient's baseline or to AST and ALT less than or equal to 2.5X ULN and total bilirubin less than or equal to 1.5X ULN *[see Dosage and Administration (2.2) in full Prescribing Information]*.

The safety of ZYTIGA re-treatment of patients who develop AST or ALT greater than or equal to 20X ULN and/or bilirubin greater than or equal to 10X ULN is unknown.

ADVERSE REACTIONS
The following are discussed in more detail in other sections of the labeling:
- Hypertension, Hypokalemia, and Fluid Retention due to Mineralocorticoid Excess *[see Warnings and Precautions]*.
- Adrenocortical Insufficiency *[see Warnings and Precautions]*.
- Hepatotoxicity *[see Warnings and Precautions]*.

Clinical Trial Experience: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

Two randomized placebo-controlled, multicenter clinical trials enrolled patients who had metastatic castration-resistant prostate cancer who were using a gonadotropin-releasing hormone (GnRH) agonist or were previously treated with orchiectomy. In both Study 1 and Study 2 ZYTIGA was administered at a dose of 1,000 mg daily in combination with prednisone 5 mg twice daily in the active treatment arms. Placebo plus prednisone 5 mg twice daily was given to control patients.

The most common adverse reactions (≥10%) reported in the two randomized clinical trials that occurred more commonly (>2%) in the abiraterone acetate arm were fatigue, joint swelling or discomfort, edema, hot flush, diarrhea, vomiting, cough, hypertension, dyspnea, urinary tract infection and contusion.

The most common laboratory abnormalities (>20%) reported in the two randomized clinical trials that occurred more commonly (≥2%) in the abiraterone acetate arm were anemia, elevated alkaline phosphatase, hypertriglyceridemia, lymphopenia, hypercholesterolemia, hyperglycemia, elevated AST, hypophosphatemia, elevated ALT and hypokalemia.

Study 1: Metastatic CRPC Following Chemotherapy: Study 1 enrolled 1195 patients with metastatic CRPC who had received prior docetaxel chemotherapy. Patients were not eligible if AST and/or ALT ≥2.5X ULN in the absence of liver metastases. Patients with liver metastases were excluded if AST and/or ALT >5X ULN.

Table 1 shows adverse reactions on the ZYTIGA arm in Study 1 that occurred with a ≥2% absolute increase in frequency compared to placebo or were events of special interest. The median duration of treatment with ZYTIGA was 8 months.

Table 1: Adverse Reactions due to ZYTIGA in Study 1

	ZYTIGA with Prednisone (N=791)		Placebo with Prednisone (N=394)	
System/Organ Class Adverse reaction	All Grades[1] %	Grade 3-4 %	All Grades %	Grade 3-4 %
Musculoskeletal and connective tissue disorders				
Joint swelling/discomfort[2]	29.5	4.2	23.4	4.1
Muscle discomfort[3]	26.2	3.0	23.1	2.3
General disorders				
Edema[4]	26.7	1.9	18.3	0.8
Vascular disorders				
Hot flush	19.0	0.3	16.8	0.3
Hypertension	8.5	1.3	6.9	0.3
Gastrointestinal disorders				
Diarrhea	17.6	0.6	13.5	1.3
Dyspepsia	6.1	0	3.3	0
Infections and infestations				
Urinary tract infection	11.5	2.1	7.1	0.5
Upper respiratory tract infection	5.4	0	2.5	0
Respiratory, thoracic and mediastinal disorders				
Cough	10.6	0	7.6	0
Renal and urinary disorders				
Urinary frequency	7.2	0.3	5.1	0.3
Nocturia	6.2	0	4.1	0
Injury, poisoning and procedural complications				
Fractures[5]	5.9	1.4	2.3	0
Cardiac disorders				
Arrhythmia[6]	7.2	1.1	4.6	1.0
Chest pain or chest discomfort[7]	3.8	0.5	2.8	0
Cardiac failure[8]	2.3	1.9	1.0	0.3

[1] Adverse events graded according to CTCAE version 3.0
[2] Includes terms Arthritis, Arthralgia, Joint swelling, and Joint stiffness
[3] Includes terms Muscle spasms, Musculoskeletal pain, Myalgia, Musculoskeletal discomfort, and Musculoskeletal stiffness
[4] Includes terms Edema, Edema peripheral, Pitting edema, and Generalized edema
[5] Includes all fractures with the exception of pathological fracture
[6] Includes terms Arrhythmia, Tachycardia, Atrial fibrillation, Supraventricular tachycardia, Atrial tachycardia, Ventricular tachycardia, Atrial flutter, Bradycardia, Atrioventricular block complete, Conduction disorder, and Bradyarrhythmia
[7] Includes terms Angina pectoris, Chest pain, and Angina unstable. Myocardial infarction or ischemia occurred more commonly in the placebo arm than in the ZYTIGA arm (1.3% vs. 1.1% respectively).
[8] Includes terms Cardiac failure, Cardiac failure congestive, Left ventricular dysfunction, Cardiogenic shock, Cardiomegaly, Cardiomyopathy, and Ejection fraction decreased

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Table 2 shows laboratory abnormalities of interest from Study 1. Grade 3-4 low serum phosphorus (7%) and low potassium (5%) occurred at a greater than or equal to 5% rate in the ZYTIGA arm.

Table 2: Laboratory Abnormalities of Interest in Study 1

	Abiraterone (N=791)		Placebo (N=394)	
Laboratory Abnormality	All Grades (%)	Grade 3-4 (%)	All Grades (%)	Grade 3-4 (%)
Hypertriglyceridemia	62.5	0.4	53.0	0
High AST	30.6	2.1	36.3	1.5
Hypokalemia	28.3	5.3	19.8	1.0
Hypophosphatemia	23.8	7.2	15.7	5.8
High ALT	11.1	1.4	10.4	0.8
High Total Bilirubin	6.6	0.1	4.6	0

Study 2: Metastatic CRPC Prior to Chemotherapy: Study 2 enrolled 1088 patients with metastatic CRPC who had not received prior cytotoxic chemotherapy. Patients were ineligible if AST and/or ALT ≥2.5X ULN and patients were excluded if they had liver metastases.

Table 3 shows adverse reactions on the ZYTIGA arm in Study 2 that occurred with a ≥2% absolute increase in frequency compared to placebo. The median duration of treatment with ZYTIGA was 13.8 months.

Table 3: Adverse Reactions in ≥5% of Patients on the ZYTIGA Arm in Study 2

	ZYTIGA with Prednisone (N=542)		Placebo with Prednisone (N=540)	
System/Organ Class Adverse reaction	All Grades[1] %	Grade 3-4 %	All Grades %	Grade 3-4 %
General disorders				
Fatigue	39.1	2.2	34.3	1.7
Edema[2]	25.1	0.4	20.7	1.1
Pyrexia	8.7	0.6	5.9	0.2
Musculoskeletal and connective tissue disorders				
Joint swelling/discomfort[3]	30.3	2.0	25.2	2.0
Groin pain	6.6	0.4	4.1	0.7
Gastrointestinal disorders				
Constipation	23.1	0.4	19.1	0.6
Diarrhea	21.6	0.9	17.8	0.9
Dyspepsia	11.1	0.0	5.0	0.2
Vascular disorders				
Hot flush	22.3	0.2	18.1	0.0
Hypertension	21.6	3.9	13.1	3.0
Respiratory, thoracic and mediastinal disorders				
Cough	17.3	0.0	13.5	0.2
Dyspnea	11.8	2.4	9.6	0.9
Psychiatric disorders				
Insomnia	13.5	0.2	11.3	0.0
Injury, poisoning and procedural complications				
Contusion	13.3	0.0	9.1	0.0
Falls	5.9	0.0	3.3	0.0
Infections and infestations				
Upper respiratory tract infection	12.7	0.0	8.0	0.0
Nasopharyngitis	10.7	0.0	8.1	0.0

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Table 3: Adverse Reactions in ≥5% of Patients on the ZYTIGA Arm in Study 2 (continued)

	ZYTIGA with Prednisone (N=542)		Placebo with Prednisone (N=540)	
System/Organ Class Adverse reaction	All Grades[1] %	Grade 3-4 %	All Grades %	Grade 3-4 %
Renal and urinary disorders				
Hematuria	10.3	1.3	5.6	0.6
Skin and subcutaneous tissue disorders				
Rash	8.1	0.0	3.7	0.0

[1] Adverse events graded according to CTCAE version 3.0
[2] Includes terms Edema peripheral, Pitting edema, and Generalized edema
[3] Includes terms Arthritis, Arthralgia, Joint swelling, and Joint stiffness

Table 4 shows laboratory abnormalities that occurred in greater than 15% of patients, and more frequently (>5%) in the ZYTIGA arm compared to placebo in Study 2. Grade 3-4 lymphopenia (9%), hyperglycemia (7%) and high alanine aminotransferase (6%) occurred at a greater than 5% rate in the ZYTIGA arm.

Table 4: Laboratory Abnormalities in >15% of Patients in the ZYTIGA Arm of Study 2

	Abiraterone (N=542)		Placebo (N=540)	
Laboratory Abnormality	Grade 1-4 %	Grade 3-4 %	Grade 1-4 %	Grade 3-4 %
Hematology				
Lymphopenia	38.2	8.7	31.7	7.4
Chemistry				
Hyperglycemia[1]	56.6	6.5	50.9	5.2
High ALT	41.9	6.1	29.1	0.7
High AST	37.3	3.1	28.7	1.1
Hypernatremia	32.8	0.4	25.0	0.2
Hypokalemia	17.2	2.8	10.2	1.7

[1]Based on non-fasting blood draws

Cardiovascular Adverse Reactions: In the combined data for studies 1 and 2, cardiac failure occurred more commonly in patients treated with ZYTIGA compared to patients on the placebo arm (2.1% versus 0.7%). Grade 3-4 cardiac failure occurred in 1.6% of patients taking ZYTIGA and led to 5 treatment discontinuations and 2 deaths. Grade 3-4 cardiac failure occurred in 0.2% of patients taking placebo. There were no treatment discontinuations and one death due to cardiac failure in the placebo group.

In Study 1 and 2, the majority of arrhythmias were grade 1 or 2. There was one death associated with arrhythmia and one patient with sudden death in the ZYTIGA arms and no deaths in the placebo arms. There were 7 (0.5%) deaths due to cardiorespiratory arrest in the ZYTIGA arms and 3 (0.3%) deaths in the placebo arms. Myocardial ischemia or myocardial infarction led to death in 3 patients in the placebo arms and 2 deaths in the ZYTIGA arms.

Post Marketing Experience
The following additional adverse reactions have been identified during post approval use of ZYTIGA. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Respiratory, Thoracic and Mediastinal Disorders: non-infectious pneumonitis.

Musculoskeletal and Connective Tissue Disorders: myopathy, including rhabdomyolysis.

DRUG INTERACTIONS
Drugs that Inhibit or Induce CYP3A4 Enzymes: Based on *in vitro* data, ZYTIGA is a substrate of CYP3A4.

In a dedicated drug interaction trial, co-administration of rifampin, a strong CYP3A4 inducer, decreased exposure of abiraterone by 55%. Avoid concomitant strong CYP3A4 inducers during ZYTIGA treatment. If a strong CYP3A4 inducer must be co-administered, increase the ZYTIGA dosing frequency *[see Dosage and Administration (2.3)* and *Clinical Pharmacology (12.3) in full Prescribing Information]*.

In a dedicated drug interaction trial, co-administration of ketoconazole, a strong inhibitor of CYP3A4, had no clinically meaningful effect on the pharmacokinetics of abiraterone *[see Clinical Pharmacology (12.3) in full Prescribing Information]*.

Veterans
ONCOLOGY

Fort Hood Soldier's Spirit an Inspiration to All

By Ms. Gloria Montgomery

As Sgt. 1st Class Shonta Tucker assists her Warrior Transition Brigade (WTB) Soldier settle into position, she issues a challenge to him: "OK, Specialist Schallberg, three sets of crunches, 20 each."

The counting begins with a slight pause between each repetition.

"Nineteen, 20, stop," the soft-spoken, 40-year-old Fort Hood WTB platoon sergeant tells him.

But the 46-year-old Army specialist's spirit and stubborn determination continues and he adds five to the count.

"Well, OK," a surprised Tucker says, keenly aware of his strengths and weaknesses, along with the potential dangers in exceeding his limit.

"Oh, I'm fine," he says, confident that five extra crunches aren't going to shock his system into overdrive and cause a seizure, joking with his platoon sergeant that the extra effort is for that "beach body."

Two years ago, a physically fit Spc. Mark Schallberg had that beach body and was running marathons side-by-side with Army Soldiers young enough to be his son or daughter. But in February 2013, a week after running a 13.5-mile half marathon, he suffered a grand mal seizure.

No warnings, no headaches. Nothing.

"Just a fluke," he says.

'Tumor diagnosis stops time'

Then, on March 1, 2013, a month after the seizure, everything related to time instantly stopped when he received the devastating news: He had a malignant brain tumor.

Sgt. 1st Class Shonta Tucker spends numerous after-duty hours on the Internet researching new exercises to help keep her Soldier, Spc. Mark Schallberg, upbeat and excited about working out. Diagnosed with brain cancer in 2013, Schallberg was bedridden and confined to a wheelchair before physical therapy helped him regain the ability to walk. *Photo Credit: Ms. Gloria Montgomery*

"That's the day I quit doing the math," says Schallberg after learning doctors originally thought it was a glioblastoma, a common type of malignant tumor that spreads quickly. "I just thought death since most people die quickly after being diagnosed with a glio."

Schallberg's tumor, located primarily in the right parietal lobe, was a huge mass one quarter the size of his brain. A biopsy revealed good news: It wasn't a glioblastoma, but instead, a stage two astrocytoma tumor that originates from star-shaped cells that make up the brain's supportive tissue. Radiation to shrink the mass and chemotherapy to kill the cells followed. Most of all, it bought him time. Today, his cancer is in remission with brain swelling controlled with steroid treatments.

"It really is a miracle," says the former marketing executive from Chicago who enlisted in June 2010 at the age of 40 because he wanted to pursue a career in the emerging field of fiber optics and thought the Army would be a good fit.

The Soldier, who was assigned to the 324th Network Support Company, 1st Cavalry Division when he learned he had brain cancer, also enlisted because

Photo Credit: Ms. Gloria Montgomery

he was sure he would deploy at some time.

But the cancer got to him first.

"I feel real shorted and guilty that I never had the chance to deploy," he says, admitting he is sometimes more upset about that than the cancer.

In late 2013, bedridden in a nursing home, Schallberg became a WTB Soldier in Transition where his only mission is healing. It is here, he says, where he met his angels: his WTB care team, whom Schallberg credits with helping him and his Family, get through one crisis after another.

'WTB a spiritual place'

"There's a spirit and closeness here," he says, grateful to the individualized care that the WTB provides to its wounded, ill and injured Soldiers in their healing, recovery and transitioning. "From the top to the bottom, everyone has backed me 100 percent in what I need."

Special to that individualized care is Sergeant 1st Class Tucker who studied sports medicine at the College of Charleston, South Carolina, and now uses that "college knowledge" to design simple workout routines to improve his range of motion and improve his mobility.

"I've seen him go from being bedridden to wheelchair to rocker," she says, adding that she believes that just getting his mobility back has given her Soldier hope. "It's also given me hope because I've witnessed his progress, and it inspires me to keep on helping him so he moves forward and not goes backward."

Besides Tucker, Schallberg praises his WTB nurse case manger, Robin Donald, for being a "miracle worker" for hooking him up with an Austin inpatient rehab hospital where physical therapists worked tirelessly with him to help him regain his mobility and strength.

"It just blows my mind, really, how many people have helped me," he says.

'Every move has purpose'

Today, Schallberg's every movement has a measured purpose, which requires intense concentration.

"I have to practice 'heal to toe' and keep my left foot straight," he says joking that if he didn't, he would be walking into walls since the tumor on the right side of his brain has robbed him of the ability to control movement and actions of his left arm and leg.

Though the tumor is stable for now, Schallberg refuses to let the unknown ruin his life, adding that he is constantly reminding his two sons, ages 8 and 12, that life is about living to the fullest.

"When they tell me 'dad, you might die,' I tell them that at least I'm smiling because it doesn't matter. Everyone is going to die at some point," he says, reminding them that no one has control of what might happen next. "You just live day by day, stay positive and don't get bogged down by all the garbage in the world."

And that attitude is exactly what inspires his platoon sergeant to pour over the Internet after hours to research what she can do to improve his life.

"It's his smile," she says. "He's just so upbeat about his illness that it just makes me want to dig deeper. If I can enlighten one Soldier to make them feel good about themselves, I feel good about myself as well. It makes me proud to be a Soldier."

For Schallberg, one thing is for certain: He's going to keep on living like there's no tomorrow.

"This is the only life you have," he says, "so you can either be a jerk when you wake up every morning or you can be positive and make a difference in other people's lives."

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Veterans
OPTHALMOLOGY

VA Palo Alto Health Care System Raises Awareness for Glaucoma in January

January is National Glaucoma Awareness Month, which is the best time to remind all Veterans to take preventative measures to maintain good eye health. Glaucoma is the second leading cause of blindness in the world.

As one of the leading causes of blindness, glaucoma affects more than three million people in America and more than 280,000 Veterans. It is also known as the "sneaky thief of sight" because a person may not be aware that they have glaucoma and have lost a significant amount of vision irreversibly before they are diagnosed and treated.

Everyone should have their eyes screened regularly, especially if at high risk for glaucoma. High risks include a family history of glaucoma, being African-American, and aging.

Regular Eye Screening is Important

Dr. Patricia Ferrell, an ophthalmologist who specializes in glaucoma treatment at the VA Palo Alto Health Care System, recommends everyone to have your eyes screened regularly, especially if you are at high risk for glaucoma. High risks include a family history of glaucoma, being African-American, and aging.

"Having your eyes dilated is an important part of your eye exam, which can help to detect glaucoma early," says Dr. Ferrell.

While more common among older adults, glaucoma can occur at any age for various genetics or disease-related reasons or from trauma.

Early diagnosis and good follow-up in those who have glaucoma or are suspected of having glaucoma are key ways to maintaining vision and preventing permanent loss of vision from glaucoma.

How Does VAPAHCS Contribute to Glaucoma Awareness and Treatment?

VAPAHCS offers glaucoma treatment along with general and other specialized care within Optometry and Ophthalmology services.

> As one of the leading causes of blindness, glaucoma affects more than three million people in America and more than 280,000 Veterans.

According to Dr. Ferrell, the VAPAHCS services are able to provide full care for the various types of glaucoma.

This can be difficult for patients dependent on the private sector to obtain due to costs. However, at VAPAHCS, treatment options are available to the Veteran without worrying if the patient can afford them.

This is usually true for many VAPAHCS services because issues of dealing with insurance companies or copays are either minimal or non-existent for most Veterans.

va.gov

Veterans
ORTHOPEDICS

Focus on Falls Prevention

By Joe Murphy, APR, NCPs Public Affairs Officer

Falls are a major concern at health care facilities nationwide, which is why Chanedra Mells, MPH, has focused her patient safety fellowship on fall prevention at the James A. Haley Veterans' Hospital, Tampa, Fla.

"After studying literature related to a Breakthrough Series on fall and injury prevention, I learned that fall prevention in hospice and palliative care was identified as an area of significant concern," she said. "In light of this, I decided to survey the current status of our efforts in these areas."

She learned that previous fiscal years' fall rates at the facility hospice and palliative care unit were higher than other VISN 8 hospice and palliative care units.

"It turns out that traditional evidence-based fall prevention interventions are not as effective when used with hospice and palliative care patients," Mells said. "Fall prevention strategies need to be modified for these patients."

Conventional fall reduction methods, such as adding strengthening exercises and reducing medications, were not being used because they often did not align with providing comfort and maintaining the best possible quality of life for patients, which are traditional hospice goals.

"Our facility's fall prevention policy is focused on the use of screening and fall risk assessments," she noted, "which we use to select the most appropriate evidence-based interventions."

Current facility fall prevention interventions include:

NCPS Patient Safety Fellow Chanedra Mells, MPH

- Bed or chair alarms
- Frequent monitoring
- Close observation
- Low beds
- Personal items kept within close reach
- One-to-one **

"Although the nursing staff selects interventions based on a patient's fall risk screening and assessment, falls still occur in the unit because a patient's physical and mental status sometimes changes from day-to-day, increasing their fall risk," said Mells.

Though she has not yet completed her efforts, she has begun to focus on efforts that could reduce the fall rate.

"Firstly, try to identify the root cause of why patients are falling," Mells said. "Is there a pattern that can be found among patients who fall? Is it restlessness? Need to sit up? Go to bathroom?"

She also recommends reviewing current literature to determine the effectiveness of fall prevention equipment, such as bed alarms.

"We can't prevent all falls," Mells said. "Many of our Veterans want to be independent and may get up without asking for help, which can lead to a fall."

"Therefore our goal at the VA has continued to be injury prevention. So if someone does fall in our care, we want to prevent them from being injured," she concluded. "I'm glad that my fellowship is focused on contributing to this effort."

** When nurses and/or nurse assistants sit with a patient around the clock; used for patients with a very high risk of falling.

Learn More

- NCPS offers wide range of fall prevention strategies in the Falls Toolkit
- The Joint Commission Sentinel Event Statistics. Event Type by Year 2002-2014.
- Boyle, D. (2012). Falls in Older Adults with Cancer: A Call to Action Cancer Network.
- Kline, N. E., Davis, M.E., & Thom, B. Fall Risk Assessment and Prevention Cancer Network.
- Capezuti, E. et al (2008) Bed-Exit Alarm Effectiveness. Archives of Gerontology and Geriatrics.
- Currie, L. (2008). Fall and injury prevention. An evidence based handbook for nurses. AHRQ.
- Gray, J. (2007). Protecting Hospice Patients: A New Look at Falls Prevention. American Journal of Hospice and Palliative Medicine.
- Goodridge, D., & Marr, H. (2002). Factors Associated with falls in an inpatient palliative care unit: an exploratory study. International Journal of Palliative Nursing.

patientsafety.va.gov

Veterans
PHARMACY

VA Mail-Order Pharmacy Receives Highest Score in Mail Order Segment of J.D. Power Study

For the fifth consecutive year, VA's Consolidated Mail Outpatient Pharmacy scored the highest in overall satisfaction in the J.D. Power National Pharmacy Study, Mail-Order segment.

The study, conducted annually, measures satisfaction among consumers who filled a mail-order prescription within the last 90 days.

"VA's first-class pharmacy services are an important component of the exceptional health care available to our Veterans," said Dr. Carolyn Clancy, Interim Under Secretary for Health. "We are proud to learn from our Veterans through this study that VA is delivering on that commitment."

Customer satisfaction with Mail-Order Pharmacy is measured across four key factors: cost competitiveness, prescription delivery, prescription ordering, and customer service.

VA also led the mail-order pharmacy industry nationwide in 2010, 2011, 2012 and 2013. VA participates in this annual survey as a way to compare itself against industry leaders and to ensure VA health care meets the highest standards.

With nearly 9 million Veterans enrolled, VA operates the largest integrated health care delivery system in the United States, with a mission to honor America's Veterans by providing exceptional health care that improves their health and well-being. VA provides a broad range of primary care, specialized care, and related medical and case management services.

va.gov

Sec. Bob McDonald visits the pharmacy in the Charlotte Community Based Outpatient Clinic.

Veterans
PHYSICAL THERAPY

Occupational Therapists in Home-Based Primary Care

By Hans Petersen

Here's another positive way teams of VA health care professionals are taking care of a special group of Veterans. And VA's occupational therapists are key members of those teams. It's Home Based Primary Care (HBPC) which is a VA health care program provided to Veterans in their home, Veterans who have complex health care needs for whom routine clinic-based care is not effective. The HBPC team at the Durham VA Medical Center in North Carolina is comprised of physician, physician assistant/nurse practitioner, social worker, occupational/physical therapy team, pharmacist, dietitian, psychologist and access to chaplain services.

April is Occupational Therapy Month, an opportunity to learn more about this important profession that helps Veterans across the lifespan do the things they want to do and live life to its fullest. Occupational therapists focus on "doing," using occupations and meaningful life activities to help individuals maximize their potential. Today, comprehensive primary care requires a coordinated team-based approach that promotes shared decision-making, sustained relationships with patients and families, and quality improvement activities. In contrast to services reimbursed by other funding mechanisms such as Medicare, HBPC provides comprehensive care of the patient often for the remainder of their life. HBPC targets frail, chronically ill Veterans who require interdisciplinary health care teams, continuity, coordination of care, and the integration of diverse services to cover their complex medical, social, rehabilitative, and behavioral care needs.

Jim Mathues, OT, coordinated a Home Depot Grant project to improve accessibility in the home of this Veteran who had been limited to living in his basement due to environmental barriers but now can enjoy his upstairs patio with door widening and ramp installation.

To manage the complex health problems of chronically or terminally ill patients, HBPC is provided directly by an interdisciplinary team.

This team promotes collaboration and coordination among all team members. The HBPC team members work interdependently in assessing, planning, problem solving, and decision-making to meet the complex needs of Veterans.

The Role of Occupational Therapy

\The use of Occupational Therapy within the Home Based Primary Care at the Durham VA Medical Center is a non-traditional approach for the use of OT services with a proactive focus on prevention, education and wellness. This contrasts from traditional home therapy services which have a short-term, rehabilitative or restorative focus.

Occupational Therapists contribute to the team by performing the initial and ongoing assessments of the Veteran's functional status in the home environment. This allows them to monitor and support clients as they go through the natural aging process and into the end-of-life.

Occupational Therapists also evaluate the Veteran's home for safety and structural modifications needed to make the home environment safe and accessible, including adaptive equipment needs.

Occupational Therapists maximize function and safety in the home environment supporting Veterans' goal to remain in their home during the aging process.

Important Interventions

Other important interventions include helping with lifestyle modification to minimize the impacts of chronic conditions such as chronic obstructive pulmonary disease, diabetes and dementia. They also focus on safety and falls prevention within the home environment.

There are numerous other unseen tasks involving a lot of important details such as educating the Veteran and their families about access to VA or community resources including grants to assist with modifying their home and automobile for accessibility, home repair resources and community transportation options.

As the largest health care system in the nation, VA is the single largest employer of occupational therapists, whose primary goal is to help Veterans optimize their functional performance in areas that are meaningful to their lives.

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Veterans
PHYSICAL THERAPY

Veterans Health Administration: Occupational Therapy Works

By Karen Duddy, Occupational Therapy Supervisor-VA Long Beach Healthcare System

When we are healthy, it is easier to accomplish what we set out to do, such as going to work, traveling, meeting up with friends, and taking care of our personal needs. Having chronic health conditions makes it more difficult to manage needs due to fatigue and illness. Often people with these conditions end up giving up on socializing and other enjoyable activities. This is problematic because giving up activities results in poorer health, and quality of life.

Occupational therapy has joined with primary care to help Veterans improve their health and well-being by being able to do what they need and want to do in their everyday lives. Occupational therapy can assist Veterans in continuing to take care of their health needs while still doing the activities they enjoy, simply by adapting or doing things differently. Occupational therapy helps Veterans prevent health declines by managing their daily health needs and showing them how to continue to participate in activities that are important to them.

"Occupation" refers to everything that people do during the course of everyday. We work with people throughout their lives to maintain their current level of activities (prevention) or restore function after an injury or illness (rehabilitation). The focus of our work with primary care is to help Veterans who are at risk for declines in health to stay active and take care of their everyday needs.

Improving the Quality of Life

Taking care of ourselves and being able to do what we enjoy keeps us healthier and improves the quality of our lives. Occupational therapy does this by helping Veterans discover solutions to their identified issues.

Occupational therapy also helps Veterans in their homes after being in the hospital by making sure they can take care of themselves, get groceries, cook meals, take care of their pets, and manage their VA appointments. During a primary care visit, the provider can have an occupational therapist join the visit and problem-solve together when there are concerns about the Veteran's self-care or safety.

Occupational therapy helps people figure out what is important to them and discover their interests and capabilities. This includes helping Veterans develop plans and take steps to reach their goals. Some Veterans want to organize their lives and take care of personal business, while others want to get back into a more healthy routine. Some Veterans want to feel useful again and give back to their community or fellow Veterans. Then together we explore volunteer opportunities.

Helping Veterans Do What is Important to Them

Occupational therapy and primary care are about health promotion and disease prevention by enabling Veterans do what is important to them, regardless of their limitations, throughout their lives.

The intent is to enable the Veteran to engage in his or her usual occupations, because occupation influences health. If you want to change the human being, you have to change the human doing.

Karen Duddy is supervisor of the occupational therapy department at VA Long Beach. She is currently pursuing a doctor of occupational therapy degree from Boston University.

Duddy developed an "Everyday Matters" workshop, a 6-week health promotion program for patients at risk for lifestyle-related declines in health and function resulting from chronic conditions.

Emphasis of the "Everyday Matters" program is on clarifying the health, wellness and performance goals of the individual, and identifying and resolving barriers to everyday activities. Veterans begin to understand ways they can adapt so they can fully participate in those things that are most meaningful to them. Seeing oneself as a resource or expert in their own lives helps the Veteran to self-advocate and participate in care decisions with their provider.

VA Long Beach occupational therapists Thomas Tousignant and Dorene Doi participate in primary care visits directly with providers, perform evaluations of how Veterans function in their homes, complete telehealth and in-person visits, and participate in inter-professional group education through the primary care program.

Tousignant and Doi participated in the design of the program and successfully implemented the workshop to a pilot group. They are currently in the process of submitting a proposal for outcomes research with Dr. Anthony Vo, Chief of Primary Care, as principal investigator. The goal is to obtain outcomes and disseminate the "Everyday Matters" program throughout VA and continue developing innovative ways occupational therapy and primary care can partner to optimize function and quality of life for various at-risk Veteran populations.

va.gov

Veterans
PHYSICAL THERAPY

Mindfulness in Motion: Tai Chi Helps Veterans Heal

By Meredith A. H. Thomas, Lead Public Affairs Specialist

"Inhale now pause and exhale. Try to become aware of your body as you're doing this."

Air Force Veteran and Ralph H. Johnson VA Medical Center volunteer Lester Pittman sits straight-backed in a chair, feet planted firmly on the ground and palms face up in his lap, as he guides a group of Veteran patients through a relaxing breathing routine. The exercises are part of a mindfulness class offered free of charge to Veterans, which incorporates gentle yoga moves, mindful breathing and Tai Chi, a form of martial arts.

"The important thing to remember is just to breathe," Pittman says. "This simple act is central to all mindfulness exercises and it can make all the difference. Focused breathing is one of the core building blocks of health along with movement and healthful eating."

Pittman instructs fellow Veterans to incorporate gentle, controlled stretches into their routine over time so they can slowly improve their flexibility, mobility and wellness. The class begins with a series of shoulder, neck and knee rolls that help loosen up stiff joints and are especially helpful for aging bodies. Though Pittman is quick to explain that the classes are geared toward all mobility levels and everyone is invited to participate.

"Tai Chi practitioners will often say that they are 'playing' at Tai Chi," he said. "The movements are often much like dancing. There's a sort of looseness to it and it's something everyone can do. You just work at continually improving the fluidity of the movements and, in doing that, you improve your range of motion and can often ease minor aches and pains."

Tai chi is a centuries-old, related mind and body practice. It involves certain postures and gentle movements with mental focus, breathing, and relaxation. The movements can be adapted or practiced while walking, standing, or sitting.

According to the National Institutes of Health (NIH) Center for Complementary and Integrative Health, practicing tai chi may improve balance and stability in older people and those with Parkinson's, reduce pain from knee osteoarthritis, help people cope with fibromyalgia and back pain, and promote quality of life and mood in people with heart failure and cancer.

Purple Heart recipient Army Veteran Major Anthony Smith volunteers at the Memphis VA, teaching Tai Chi to Veterans.

The classes began in early April and are held every Monday from 2:30 p.m. to 3:30 p.m. at the Goose Creek VA Outpatient Clinic collocated with Naval Health Clinic Charleston at the Naval Weapons Station.

The group is open to Veterans currently enrolled in VA health care, their family members and other significant parties who wish to attend with the Veteran. Participants must have proper identification, either a military ID or a base badge, to gain access to the Navy base. Day passes will not be issued for attendance to these group sessions.

For additional information, please call 843-577-5011, press 1, then 3145.

va.gov

Veterans
PULMONOLOGY

The Interventional Pulomology Service at the Michael E. DeBakey VA Medical Center Helps Veterans Breathe Easier

Using advanced, minimally invasive techniques, the Pulmonary Department at the Michael E. DeBakey VA Medical Center (MEDVAMC) offers a new Interventional Pulmonology Service to treat Veterans with respiratory problems.

Interventional pulmonology is a relatively new field within pulmonary medicine that focuses on the use of advanced diagnostic and therapeutic techniques to manage patients with lung cancer and any other diseases that cause airway obstructions. With the new Interventional Pulmonology Service, the Pulmonary Department is ready to handle a wide variety of breathing issues.

"Our bronchoscopy suite is fully equipped now. The Interventional Pulmonology Service that we assembled provides the highest level of care possible within this new field," said Interventional Pulmonologist Roberto Casal, MD, Bronchoscopy Laboratory director. "We have developed a great team of dedicated respiratory therapists, nurses, anesthesiologists, pathologists, and pulmonologists. The combination of advanced procedures we perform are not available at any other VA in the country."

The Interventional Pulmonology Service offers different techniques to unblock windpipes obstructed by a tumor and improve breathing. Some of these techniques include argon plasma coagulation which is the application of heat produced by an electric current to destroy tumor tissue or stop bleeding; cryotherapy, the destruction of airway tumors by freezing the tissue; and microdebrider bronchoscopy where a rotating blade cuts a tumor and removes it simultaneously. After tumors are removed, stents (artificial pipes) are sometimes placed to maintain an airway.

Advanced diagnostic procedures such as Electromagnetic Navigation and Endobronchial Ultrasound (EBUS) are also performed on a daily basis. The former is sort of a "GPS" system that allows doctors to navigate through airways and biopsy small lung nodules. It has a very low risk of complications and a high level of accuracy.

The EBUS technique uses a special bronchoscope with an ultrasound transducer at the tip that lets doctors see and take samples of objects like lymph nodes and tumors near the windpipe. This is a very safe procedure that has increased the yield of these biopsies to more than 90 percent. It is routinely done before surgery for patients with lung cancer, avoiding a more invasive surgical procedure called mediastinoscopy.

A combination of advanced techniques was recently used to treat Clara Traylor. While sedated, a rigid bronchoscope was inserted through Traylor's throat and into her trachea, and a large benign tumor that blocked 90 percent of her main windpipe was easily removed. This non-surgical procedure was life-changing for this patient.

"When I was first referred to Dr. Casal, I could barely breathe. He recommended the rigid bronchoscopy procedure," said Traylor. "I first saw him the beginning of the week, the procedure took place in the middle of the week, and by the end of the week, I was home breathing like normal again."

When I was first referred to Dr. Casal, I could barely breathe. He recommended the rigid bronchoscopy procedure," said Clara Traylor with Interventional Pulmonologist Roberto Casal, MD, Bronchoscopy Laboratory director. "I first saw him the beginning of the week, the procedure took place in the middle of the week, and by the end of the week, I was home breathing like normal again."
Photo by Quentin Melson, Public Affairs Specialist (TCF Intern)

Also an assistant professor of Medicine at Baylor College of Medicine, Casal's main clinical interests are interventional pulmonology focusing on new and minimally invasive technologies for diagnosis, staging, and management of lung cancer; bronchoscopic management of benign central airway obstruction; management of hemoptysis and both benign and malignant pleural diseases.

Casal has advanced training in flexible and rigid bronchoscopy, bronchoscopic electrocautery, LASER bronchoscopy, cryotherapy, balloon bronchoplasty,endobronchialstentplacement, endobronchial valve placement, endobronchial brachytherapy, photodynamic therapy, auto-fluorescence bronchoscopy, endobronchial ultrasound,

continued on page 174

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electromagnetic navigation bronchoscopy, and pleuroscopy.

With specializing training in interventional pulmonology from MD Anderson Cancer Center, he brought a wealth of knowledge and expertise to the MEDVAMC Pulmonary Department.

"I spent an entire year in fellowship training at MD Anderson for interventional pulmonology, performing more than 800 procedures" said Casal. "When I arrived at the Houston VA, I began to assemble the equipment and tools for an Interventional Pulmonary Service. Dr. Carabello, our Medical Care Line executive, and Dr. Kalavar, our chief of staff, were especially helpful once they saw the improved quality of life benefits for our Veterans."

Using the modern techniques of interventional pulmonology, Casal has been able to assist patients who would otherwise be hospital-bound in their last days.

"Without this treatment, many patients with airway blockages would have to stay in the hospital because they would be unable to breathe without high oxygen supplements, and even morphine assistance to relieve their feeling of suffocation," said Casal. "With the therapeutic treatments the Interventional Pulmonology Service offers, we are able to non-surgically remove blockages in the windpipe and return patients to their homes to be with loved ones."

"Beyond a doubt, our Interventional Pulmonology Service improves the quality of life for our patients," said Blase A. Carabello, MD, Medical Care Line executive at the MEDVAMC and the W. A. "Tex" and Deborah Moncrief, Jr. Chair at Baylor College of Medicine. "We are proud the Michael E. DeBakey VA Medical Center has some of the best doctors and nurses in the country and offers the latest, minimally invasive alternatives for our Veterans."

houston.va.gov

VA Pulmonologist Wins Prestigious Award

An Interventional Pulmonologist at the Michael E. DeBakey VA Medical Center (MEDVAMC) in Houston has been named the winner of a prestigious American Association for Bronchology and Interventional Pulmonology (AABIP) award. Dr. Roberto Casal, Director of the MEDVAMC's Bronchoscopy Lab and Director of the Interventional Pulmonary Program at Baylor College of Medicine, will receive the 2015 George McLennan Memorial Award for Advances in Interventional Pulmonology at a conference next month. This prestigious award is presented to individuals for their contributions to the field of interventional pulmonology and who are judged by their peers to have a high likelihood of continued success.

Dr. Roberto Casal, Director of the MEDVAMC's Bronchoscopy Lab and Director of the Interventional Pulmonary Program at Baylor College of Medicine will received the 2015 George McLennan Memorial Award for Advances in Interventional Pulmonology.

"Dr. Casal is a dedicated, respected clinician and a well-known leader in the field of interventional pulmonology, both nationally and internationally," said Dr. Bykem Bozkurt, Chief of Medicine at the MEDVAMC. "He has been published in numerous journals and serves in leadership positions for the AABIP and the World Association for Bronchology and Interventional Pulmonology. The MEDVAMC and our patients are fortunate to have a clinician of his caliber at our Medical Center."

Casal has been at the MEDVAMC since 2009. He was instrumental in establishing the Interventional Pulmonology Service at the Medical Center and effectively run the facility's busy Bronchology Lab. In addition to being recognized by his peers for excellent patient care, Casal is a leading researcher in his field. He has presented at numerous national and international conferences and been published in numerous medical journals including the American Journal of Respiratory and Critical Care Medicine and CHEST. He was also actively involved in the writing of the first clinical guidelines for the use of endobronchial ultrasound, a minimally invasive bronchoscopic technique utilized to diagnose and stage patients with lung cancer.

According to Casal, he considers it an honor to care for the men and women who have served in the U.S. military. "I am privileged to be able to apply the latest medical principles and practices here at the VA," he said. "The most rewarding part of my job is making a difference in the lives of our Veteran patients."

Casal is the youngest recipient of this prestigious award.

houston.va.gov

Veterans
RHEUMATOLOGY

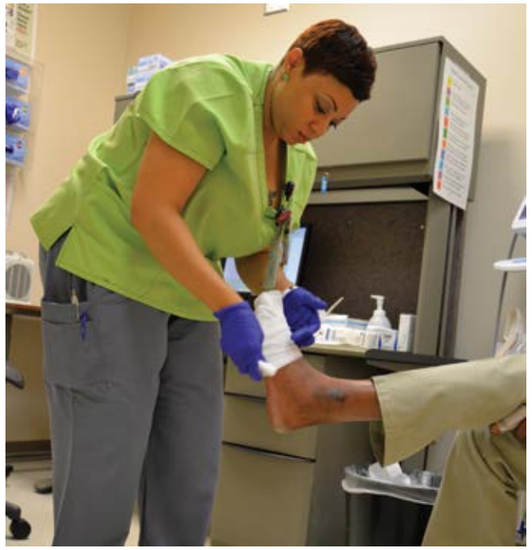
STRIDE-GO Study

STo Rytelling to Improve DiseasE Outcomes in Gout: The STRIDE-GO Study

By Jasvinder A. Singh, MD, MPH

BACKGROUND/RATIONALE:

Poor disease self-management in chronic diseases is a problem and is associated with poorer health outcomes and higher health care resource utilization. Compared to Caucasians, African-Americans have even poorer disease self-management worse outcomes in most chronic diseases. Patients often do not perceive disease severity and susceptibility to disease complications since severe symptoms of chronic conditions such as such as gout, chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF) etc. are usually intermittent. Our objective is to develop a patient-centered, culturally relevant narrative intervention, or "storytelling", based on the Health Belief Model (HBM) for behavior change, using narrative communication theory as methodological framework for intervention delivery. We aim to improve disease self-management among African-American Veterans, using gout as our "test case". storytelling in the patient's own voices has the power to directly and more effectively address patients' intrapersonal and structural barriers to optimal disease management and reinforce the benefits associated with chronic disease self-management. While shown to be successful in hypertension, an asymptomatic chronic disease, no evidence of its efficacy exists for chronic symptomatic diseases, such as COPD, CHF, gout etc.



Alexis Carson, MSN, RN, rewraps a Veteran's foot after examination.

OBJECTIVE(S):

Our long-term objective is to improve health outcomes in Veterans and reduce health disparities. The objective of the proposed study, the first step in this direction, is to develop a novel storytelling intervention in Veterans' own voices to improve disease self-management and outcomes in African-American Veterans with gout, the most common type of inflammatory arthritis in Veterans, associated with significant pain and suffering, utilization and cost.

METHODS:

To achieve these objectives, we will perform in-depth interviews in 36 African-American veterans with gout at Birmingham and Philadelphia VA using HBM probes to identify barriers and facilitators to optimal gout self-management. We will create an intervention video by inviting storytelling stars from our qualitative work, chosen due to their eloquence and persuasive of their stories, videotaping the stories, rating stories on constructs of HBM theory, and testing feasibility in focus groups in African-American veterans with gout at Birmingham and Philadelphia VA, iteratively refining and finalizing the storytelling intervention alongside a control intervention. We will develop a storytelling manual to be made available to other investigators and present HSR&D Cyber seminars for knowledge dissemination.

IMPACT:

This study serves the VA's mission of improving the health of veterans and by focusing on understudied minorities with poorer disease outcomes, addresses a priority area of health disparities. The results of this study will lead to a low cost patient-centered intervention for African American Veterans with gout to improve patient outcomes, that we propose to test in a future randomized trial. Gout will serve as a "use case" for chronic disease self-management. If successful, the storytelling intervention can be adapted to other chronic diseases such as COPD, CHF etc.

hsrd.research.va.gov

Veterans
RHEUMATOLOGY

Research Shows Veterans More Likely to Have Arthritis

By Kimberly Woodruff, Staff Writer

In a recent study conducted by the Centers for Disease Control, arthritis is among the most common chronic conditions affecting veterans. The study found that arthritis is more prevalent among veterans than non-veterans.

According to research, about one in three veterans, or 34.7 percent, across all 50 states have arthritis. The CDC study showed that it was slightly more common for men than women, and higher in middle-aged (45-64 years) compared to younger (18-44 year olds) people.

The results found that traumatic and overuse injuries are common among active duty military, and those injuries put the member at risk for developing osteoarthritis, the most common form of arthritis.

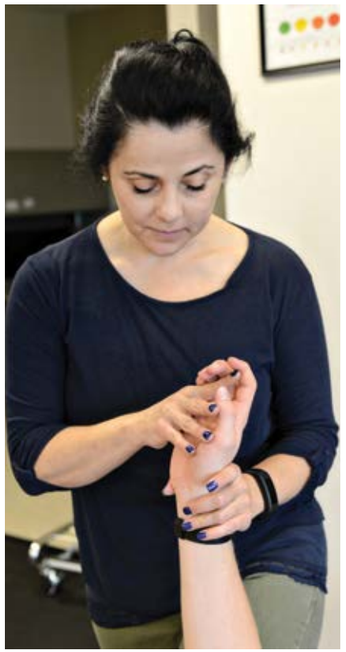
Former 72nd Mission Support Group commander, retired Col. Dean Jackson, can relate. He suffers with arthritis.

"It's no wonder. Military members go to the field carrying heavy packs and running around," said Mr. Jackson. "I've broken bones and suffered stress fractures and was told by the doctors I would most likely have degenerative disks and arthritis — and I do."

Mr. Jackson remains very active and spends time working with older veterans, who tell him frequently they are in pain and can't move.

"I want everyone at Tinker to know about the help and opportunities available to them," said Mr. Jackson.

Capt. Alexander Ford, Physical Therapy element leader with the 72nd Medical Group, said there are many jobs in the armed forces that are at higher risk for developing arthritis.



Kelley Jaques, a physical therapist with the 72nd Medical Operations Squadron, helps a patient with range of motion stretches to help with arthritis.
Air Force photo by Kelly White/Released

"Security Forces have to wear all the heavy armor and others like the maintainers who have to climb around in small spaces, up and down ladders, have more demands on their bodies, it is just the nature of the job," said Capt. Ford. "Also, those on jump status, jumping out of planes, it puts a lot of stress on the joints."

The CDC and the Mayo Clinic both agree that obese people are more likely to develop arthritis due to carrying excess pounds, which causes stress on their joints. Other factors include previous injuries, age and family history.

The physical therapy clinic on Tinker sees mostly active duty members between the ages of 25-35, so Captain Ford isn't seeing as many cases of arthritis as he would if he saw older patients.

However, Captain Ford said he can see the potential for development of arthritis later in life.

"Movement to maintain flexibility and strength can help to prevent the onset of osteoarthritis," said Captain Ford. "The best exercises are lower impact such as cycling, swimming and walking."

He added that exercise can help maintain a healthy weight, thus adding less pressure on the joints.

According to Captain Ford, there are medications to help alleviate pain and it is best for a person to consult their doctor for the options.

Ice and heat can also help with swelling and dealing with pain.

Getting help is the best thing for improving function in the joints, reducing depression and pain.

The Civilian Health and Promotion Service offer classes for those suffering with arthritis.

af.mil

IN APPROPRIATE PATIENTS WITH MODERATELY TO SEVERELY ACTIVE RA

IT'S TIME FOR SIMPONI ARIA® (GOLIMUMAB)

IMPROVEMENT IN SIGNS AND SYMPTOMS

PRIMARY ENDPOINT: At Week 14, 59% of patients receiving SIMPONI ARIA® + MTX (231/395) achieved ACR20 response vs 25% of patients receiving placebo + MTX (49/197); *P*<0.001.[1,2*]

RAPID RESPONSE AT WEEK 2[1,2*]:

33% OF PATIENTS RECEIVING SIMPONI ARIA® + MTX (131/395) ACHIEVED ACR20 RESPONSE

vs

12% OF PATIENTS RECEIVING PLACEBO + MTX (23/197) (*P*<0.001)

*GO-FURTHER™ was a global, multicenter, randomized, double-blind, placebo-controlled study in 592 adult patients who had moderately to severely active RA despite a stable dose of MTX (15-25 mg/week) for ≥3 months and who had not been previously treated with an anti-TNF agent. Moderately to severely active RA was defined as ≥6 swollen joints (out of 66 total) and ≥6 tender joints (out of 68 total), RF-positive and/or anti-CCP antibody–positive, and CRP ≥1.0 mg/dL. Patients were randomized to receive SIMPONI ARIA® 2 mg/kg + MTX (n=395) or placebo + MTX (n=197) as a 30-minute IV infusion at Weeks 0 and 4, and then q8 weeks through Week 100. At Week 16, patients in the placebo + MTX group with <10% improvement from baseline in both swollen joint count and tender joint count began receiving SIMPONI ARIA® 2 mg/kg beginning with an induction regimen at Weeks 16 and 20, followed by maintenance infusions q8 weeks in a blinded manner. At Week 24, all patients remaining in the placebo + MTX group began receiving SIMPONI ARIA® 2 mg/kg beginning with an induction regimen at Weeks 24 and 28, followed by maintenance infusions q8 weeks in a blinded manner. All patients continued to receive MTX. The primary endpoint was the percentage of patients achieving an ACR20 response at Week 14.

SELECTED IMPORTANT SAFETY INFORMATION

Serious and sometimes fatal side effects have been reported with SIMPONI ARIA® (golimumab), including infections due to tuberculosis, invasive fungal infections (eg, histoplasmosis), bacterial, viral, or other opportunistic pathogens. Prior to initiating SIMPONI ARIA® and periodically during therapy, evaluate patients for active tuberculosis and test for latent infection. Lymphoma, including a rare and fatal cancer called hepatosplenic T-cell lymphoma, and other malignancies can occur in adults and children, and can be fatal. Other serious risks include melanoma and Merkel cell carcinoma, heart failure, demyelinating disorders, lupus-like syndrome, hypersensitivity reactions, and hepatitis B reactivation. Prior to initiating SIMPONI ARIA®, test patients for hepatitis B viral infection. Please see related and other Important Safety Information inside.

FIRST-LINE BIOLOGIC ACCESS NATIONWIDE†

AVAILABLE FOR

100%

OF **MEDICARE PART B** PATIENTS[3]

AVAILABLE FOR

>75%

OF **COMMERCIALLY INSURED** PATIENTS[3‡]

ELIGIBLE **COMMERCIALLY INSURED** PATIENTS PAY JUST

$5 per infusion[§]

†First-line biologic: Brand-name drug that does not require trial on another biologic product prior to utilization.
‡Based on an analysis of major insurers that includes approximately 90% of commercially insured patients.
§The SimponiOne® rebate expires after $20,000 maximum annual benefit or 12 months from first eligible date of service, whichever comes first. Program is not available to individuals enrolled in federal or state subsidized healthcare programs that cover prescription drugs, including Medicare, such as the Medicare Part D prescription drug benefit, Medicaid, TRICARE®, or any other federal or state healthcare plan, including pharmaceutical assistance programs.

References: 1. SIMPONI ARIA® (golimumab) [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **2.** Weinblatt ME, Bingham CO III, Mendelsohn AM, et al. Intravenous golimumab is effective in patients with active rheumatoid arthritis despite methotrexate therapy with responses as early as week 2: results of the phase 3, randomised, multicentre, double-blind, placebo-controlled GO-FURTHER trial. *Ann Rheum Dis*. 2013;72:381-389. **3.** Data on file. Janssen Biotech, Inc.

Simponi ARIA® golimumab for infusion

IMPORTANT SAFETY INFORMATION

SERIOUS INFECTIONS

Patients treated with SIMPONI ARIA® (golimumab) are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. Discontinue SIMPONI ARIA® if a patient develops a serious infection.

Reported infections with TNF blockers, of which SIMPONI ARIA® is a member, include:

- **Active tuberculosis (TB), including reactivation of latent TB. Patients frequently presented with disseminated or extrapulmonary disease. Test patients for latent TB before SIMPONI ARIA® use and during therapy. Initiate treatment for latent infection prior to SIMPONI ARIA® use.**
- **Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Consider empiric anti-fungal therapy in patients at risk for invasive fungal infections who develop severe systemic illness.**
- **Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria.**

Consider the risks and benefits of treatment with SIMPONI ARIA® prior to initiating therapy in patients with chronic or recurrent infection. Do not start SIMPONI ARIA® in patients with clinically important active infections, including localized infections. Closely monitor patients for the development of signs and symptoms of infection during and after treatment with SIMPONI ARIA®, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy, who are on treatment for latent TB, or who were previously treated for TB infection.

Risk of infection may be higher in patients greater than 65 years of age, patients with co-morbid conditions and/or patients taking concomitant immunosuppressant therapy. Other serious infections observed in patients treated with SIMPONI ARIA® included sepsis, pneumonia, cellulitis, and abscess.

MALIGNANCIES

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which SIMPONI ARIA® is a member. Approximately half the cases were lymphomas, including Hodgkin's and non-Hodgkin's lymphoma. The other cases represented a variety of malignancies, including rare malignancies usually associated with immunosuppression and malignancies not usually observed in children or adolescents. Malignancies occurred after a median of 30 months after the first dose of therapy. Most of the patients were receiving concomitant immunosuppressants.

In the controlled portions of clinical trials of TNF blockers including the subcutaneous formulation of golimumab, more cases of lymphoma have been observed among patients receiving anti-TNF treatment compared with patients in the control groups. In clinical trials, the incidence of malignancies other than lymphoma and non-melanoma skin cancer per 100 patient-years of follow-up was 0.56 (95% CI: 0.01, 3.11) in the SIMPONI ARIA® group compared with an incidence of 0 (95% CI: 0.00, 3.79) in the placebo group. Cases of acute and chronic leukemia have been reported with TNF-blocker use, including SIMPONI ARIA®. The risks and benefits of TNF-blocker therapy should be considered prior to initiating therapy in patients with a known malignancy or who develop a malignancy.

Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers. These cases have had a very aggressive disease course and have been fatal. Nearly all reported cases have occurred in patients with Crohn's disease or ulcerative colitis, and the majority were in adolescent and young adult males. Almost all of these patients had received treatment with azathioprine or 6-mercaptopurine concomitantly with a TNF blocker at or prior to diagnosis. A risk for the development for HSTCL in patients treated with TNF blockers cannot be excluded.

Melanoma has been reported in patients treated with TNF-blocking agents, including SIMPONI ARIA®. Merkel cell carcinoma has been reported in patients treated with TNF-blocking agents. Periodic skin examination is recommended for all patients, particularly those with risk factors for skin cancer.

HEPATITIS B REACTIVATION

The use of TNF blockers, of which SIMPONI ARIA® is a member, has been associated with reactivation of hepatitis B virus (HBV) in patients who are chronic hepatitis B carriers. In some instances, HBV reactivation occurring in conjunction with TNF-blocker therapy has been fatal. The majority of these reports have occurred in patients who received concomitant immunosuppressants.

HEPATITIS B REACTIVATION (CONTINUED)

All patients should be tested for HBV infection before initiating TNF-blocker therapy. For patients who test positive for hepatitis B surface antigen, consult a physician with expertise in the treatment of hepatitis B before initiating TNF-blocker therapy. Exercise caution when prescribing SIMPONI ARIA® for patients identified as carriers of HBV and closely monitor for active HBV infection during and following termination of therapy with SIMPONI ARIA®. Discontinue SIMPONI ARIA® in patients who develop HBV reactivation, and initiate antiviral therapy with appropriate supportive treatment. Exercise caution when considering resumption of SIMPONI ARIA®, and monitor patients closely.

HEART FAILURE

Cases of worsening congestive heart failure (CHF) and new-onset CHF have been reported with TNF blockers, including SIMPONI ARIA®. Some cases had a fatal outcome. Exercise caution in CHF patients receiving SIMPONI ARIA® and monitor them closely during therapy. Discontinue SIMPONI ARIA® if new or worsening symptoms of heart failure appear.

DEMYELINATING DISORDERS

Use of TNF blockers, of which SIMPONI ARIA® is a member, has been associated with rare cases of new-onset or exacerbation of demyelinating disorders, including multiple sclerosis (MS) and Guillain-Barré syndrome. Cases of central demyelination, MS, optic neuritis, and peripheral demyelinating polyneuropathy have rarely been reported in patients treated with the subcutaneous formulation of golimumab. Exercise caution in considering the use of SIMPONI ARIA® in patients with these disorders. Consider discontinuation if these disorders develop.

AUTOIMMUNITY

Treatment with TNF blockers, including SIMPONI ARIA®, may result in the formation of antinuclear antibodies. Rarely, treatment with TNF blockers may result in a lupus-like syndrome. Discontinue treatment if symptoms of a lupus-like syndrome develop.

USE WITH OTHER DRUGS

The concomitant use of a TNF blocker and abatacept or anakinra was associated with a higher risk of serious infections, therefore the use of SIMPONI ARIA® in combination with these products is not recommended. Care should be taken when switching from one biologic to another since overlapping biological activity may further increase the risk of infection. A higher rate of serious infections has also been observed in RA patients treated with rituximab who received subsequent treatment with a TNF blocker. The concomitant use of SIMPONI ARIA® with biologics approved to treat RA is not recommended because of the possibility of an increased risk of infection.

HEMATOLOGIC CYTOPENIAS

There have been reports of pancytopenia, leukopenia, neutropenia, and thrombocytopenia in patients receiving SIMPONI ARIA® in clinical trials. Additionally, aplastic anemia has been reported in patients receiving TNF blockers. Exercise caution when using SIMPONI ARIA® in patients who have or had significant cytopenias.

VACCINATIONS/THERAPEUTIC INFECTIOUS AGENTS

People receiving SIMPONI ARIA® can receive vaccinations, except for live vaccines. Use of live vaccines could result in clinical infections, including disseminated infections. Administration of live vaccines to infants exposed to SIMPONI ARIA® *in utero* is not recommended for 6 months following the mother's last SIMPONI ARIA® infusion during pregnancy due to an increased risk of infection. It is recommended that therapeutic infectious agents not be given concurrently with SIMPONI ARIA® due to the possibility of clinical infections, including disseminated infections.

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HYPERSENSITIVITY REACTIONS

Serious systemic hypersensitivity reactions (including anaphylaxis) have been reported following administration of the subcutaneous formulation of golimumab and SIMPONI ARIA®, some occurring after the first dose. Hypersensitivity reactions including hives, pruritus, dyspnea, and nausea, were reported in association with infusions of SIMPONI ARIA®. If an anaphylactic or other serious allergic reaction occurs, discontinue SIMPONI ARIA® immediately and institute appropriate therapy.

ADVERSE REACTIONS

The most serious adverse reactions were serious infections and malignancies.

Upper respiratory tract infection was the most common adverse reaction reported in the Phase 3 trial through Week 24, occurring in 6.5% of patients treated with SIMPONI ARIA® as compared with 7.6% of patients in the control group. The rate of infusions associated with an infusion reaction was reported in 1.1% of SIMPONI ARIA® infusions compared with 0.2% of infusions in the control group.

Please see brief summary of full Prescribing Information for SIMPONI ARIA® on the following pages.

Simponi ARIA® golimumab for infusion

janssen Immunology
PHARMACEUTICAL COMPANIES OF Johnson & Johnson

 04/16 046137-160122

Brief Summary of Prescribing Information for SIMPONI ARIA® (golimumab)

SIMPONI ARIA® (golimumab) injection, for intravenous use

See package insert for full Prescribing Information.

WARNING: SERIOUS INFECTIONS AND MALIGNANCY

SERIOUS INFECTIONS

Patients treated with SIMPONI ARIA are at increased risk for developing serious infections that may lead to hospitalization or death *[see Warnings and Precautions]*. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Discontinue SIMPONI ARIA if a patient develops a serious infection.

Reported infections with TNF blockers, of which SIMPONI ARIA is a member, include:

- **Active tuberculosis, including reactivation of latent tuberculosis. Patients with tuberculosis have frequently presented with disseminated or extrapulmonary disease. Test patients for latent tuberculosis before SIMPONI ARIA use and during therapy. Initiate treatment for latent tuberculosis prior to SIMPONI ARIA use.**
- **Invasive fungal infections including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Consider empiric antifungal therapy in patients at risk for invasive fungal infections who develop severe systemic illness.**
- **Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria.**

Consider the risks and benefits of treatment with SIMPONI ARIA prior to initiating therapy in patients with chronic or recurrent infection.

Monitor patients closely for the development of signs and symptoms of infection during and after treatment with SIMPONI ARIA, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy *[see Warnings and Precautions]*.

MALIGNANCY

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF-blockers, of which SIMPONI ARIA is a member *[see Warnings and Precautions]*.

INDICATIONS AND USAGE: Rheumatoid Arthritis SIMPONI ARIA, in combination with methotrexate (MTX), is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis. **CONTRAINDICATIONS:** None. **WARNINGS AND PRECAUTIONS: Serious Infections** Patients treated with SIMPONI ARIA are at increased risk for developing serious infections involving various organ systems and sites that may lead to hospitalization or death. Opportunistic infections due to bacterial, mycobacterial, invasive fungal, viral, or parasitic organisms including aspergillosis, blastomycosis, candidiasis, coccidioidomycosis, histoplasmosis, legionellosis, listeriosis, pneumocystosis, and tuberculosis have been reported with TNF-blockers. Patients have frequently presented with disseminated rather than localized disease. The concomitant use of a TNF-blocker and abatacept or anakinra was associated with a higher risk of serious infections; therefore, the concomitant use of SIMPONI ARIA and these biologic products is not recommended *[see Warnings and Precautions and Drug Interactions]*. Treatment with SIMPONI ARIA should not be initiated in patients with an active infection, including clinically important localized infections. Patients greater than 65 years of age, patients with co-morbid conditions and/or patients taking concomitant immunosuppressants such as corticosteroids or methotrexate may be at greater risk of infection. Consider the risks and benefits of treatment prior to initiating SIMPONI ARIA in patients: • with chronic or recurrent infection; • who have been exposed to tuberculosis; • with a history of an opportunistic infection; • who have resided or traveled in areas of endemic tuberculosis or endemic mycoses, such as histoplasmosis, coccidioidomycosis, or blastomycosis; or • with underlying conditions that may predispose them to infection. Monitoring Closely monitor patients for the development of signs and symptoms of infection during and after treatment with SIMPONI ARIA. Discontinue SIMPONI ARIA if a patient develops a serious infection, an opportunistic infection, or sepsis. For patients who develop a new infection during treatment with SIMPONI ARIA, perform a prompt and complete diagnostic workup appropriate for an immunocompromised patient and initiate appropriate antimicrobial therapy and closely monitor them. Tuberculosis Cases of reactivation of tuberculosis or new tuberculosis infections have been observed in patients receiving TNF-blockers, including patients who have previously received treatment for latent or active tuberculosis. Evaluate patients for tuberculosis risk factors and test for latent infection prior to initiating SIMPONI ARIA and periodically during therapy. Treatment of latent tuberculosis infection prior to therapy with TNF-blockers has been shown to reduce the risk of tuberculosis reactivation during therapy. Prior to initiating SIMPONI ARIA, assess if treatment for latent tuberculosis is

needed; An induration of 5 mm or greater is a positive tuberculin skin test, even for patients previously vaccinated with Bacille Calmette-Guerin (BCG). Consider anti-tuberculosis therapy prior to initiation of SIMPONI ARIA in patients with a past history of latent or active tuberculosis in whom an adequate course of treatment cannot be confirmed, and for patients with a negative test for latent tuberculosis but having risk factors for tuberculosis infection. Consultation with a physician with expertise in the treatment of tuberculosis is recommended to aid in the decision whether initiating anti-tuberculosis therapy is appropriate for an individual patient. Cases of active tuberculosis have occurred in patients treated with the subcutaneous formulation of golimumab during and after treatment for latent tuberculosis. Monitor patients for the development of signs and symptoms of tuberculosis including patients who tested negative for latent tuberculosis infection prior to initiating therapy, patients who are on treatment for latent tuberculosis, or patients who were previously treated for tuberculosis infection. Consider tuberculosis in the differential diagnosis in patients who develop a new infection during SIMPONI ARIA treatment, especially in patients who have previously or recently traveled to countries with a high prevalence of tuberculosis, or who have had close contact with a person with active tuberculosis. Invasive Fungal Infections If patients develop a serious systemic illness and they reside or travel in regions where mycoses are endemic, consider invasive fungal infection in the differential diagnosis. Consider appropriate empiric antifungal therapy and take into account both the risk for severe fungal infection and the risks of antifungal therapy while a diagnostic workup is being performed. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. To aid in the management of such patients, consider consultation with a physician with expertise in the diagnosis and treatment of invasive fungal infections. Hepatitis B Virus Reactivation The use of TNF-blockers, of which SIMPONI ARIA is a member, has been associated with reactivation of hepatitis B virus (HBV) in patients who are chronic hepatitis B carriers (i.e., surface antigen positive). In some instances, HBV reactivation occurring in conjunction with TNF-blocker therapy has been fatal. The majority of these reports have occurred in patients who received concomitant immuno-suppressants. All patients should be tested for HBV infection before initiating TNF-blocker therapy. For patients who test positive for hepatitis B surface antigen, consultation with a physician with expertise in the treatment of hepatitis B is recommended before initiating TNF-blocker therapy. The risks and benefits of treatment should be considered prior to prescribing TNF-blockers, including SIMPONI ARIA, to patients who are carriers of HBV. Adequate data are not available on whether antiviral therapy can reduce the risk of HBV reactivation in HBV carriers who are treated with TNF-blockers. Patients who are carriers of HBV and require treatment with TNF-blockers should be closely monitored for clinical and laboratory signs of active HBV infection throughout therapy and for several months following termination of therapy. In patients who develop HBV reactivation, TNF-blockers should be stopped and antiviral therapy with appropriate supportive treatment should be initiated. The safety of resuming TNF-blockers after HBV reactivation has been controlled is not known. Therefore, prescribers should exercise caution when considering resumption of TNF-blockers in this situation and monitor patients closely. **Malignancies** Malignancies in Pediatric Patients Malignancies, some fatal, have been reported among children, adolescents, and young adults who received treatment with TNF-blocking agents (initiation of therapy ≤ 18 years of age), of which SIMPONI ARIA is a member. Approximately half the cases were lymphomas, including Hodgkin's and non-Hodgkin's lymphoma. The other cases represented a variety of malignancies, including rare malignancies that are usually associated with immuno-suppression, and malignancies that are not usually observed in children and adolescents. The malignancies occurred after a median of 30 months (range 1 to 84 months) after the first dose of TNF-blocker therapy. Most of the patients were receiving concomitant immunosuppressants. These cases were reported postmarketing and are derived from a variety of sources, including registries and spontaneous postmarketing reports. Use of SIMPONI ARIA in patients under 18 years of age has not been established. Malignancies in Adult Patients The risks and benefits of TNF-blocker treatment including SIMPONI ARIA should be considered prior to initiating therapy in patients with a known malignancy other than a successfully treated non-melanoma skin cancer (NMSC) or when considering continuing a TNF-blocker in patients who develop a malignancy. In the controlled portions of clinical trials of TNF-blockers including the subcutaneous formulation of golimumab more cases of lymphoma have been observed among patients receiving anti-TNF treatment compared with patients in the control groups. Patients with RA and other chronic inflammatory diseases, particularly patients with highly active disease and/or chronic exposure to immunosuppressant therapies, may be at higher risk (up to several fold) than the general population for the development of lymphoma, even in the absence of TNF-blocking therapy. Cases of acute and chronic leukemia have been reported with TNF-blocker use, including SIMPONI ARIA, in rheumatoid arthritis and other indications. Even in the absence of TNF-blocker therapy, patients with rheumatoid arthritis may be at a higher risk (approximately 2-fold) than the general population for the development of leukemia. Rare postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL) have been reported in patients treated with TNF-blocking agents. This rare type of T-cell

lymphoma has a very aggressive disease course and is usually fatal. Nearly all of the reported TNF-blocker associated cases have occurred in patients with Crohn's disease or ulcerative colitis. The majority were in adolescent and young adult males. Almost all these patients had received treatment with azathioprine (AZA) or 6-mercaptopurine (6–MP) concomitantly with a TNF-blocker at or prior to diagnosis. A risk for the development for hepatosplenic T-cell lymphoma in patients treated with TNF-blockers cannot be excluded. Melanoma has been reported in patients treated with TNF-blocking agents, including SIMPONI ARIA. Merkel cell carcinoma has been reported in patients treated with TNF-blocking agents. Periodic skin examination is recommended for all patients, particularly those with risk factors for skin cancer. In controlled trials of other TNF-blockers in patients at higher risk for malignancies (e.g., patients with chronic obstructive pulmonary disease [COPD], patients with Wegener's granulomatosis treated with concomitant cyclophosphamide) a greater portion of malignancies occurred in the TNF-blocker group compared to the controlled group. In an exploratory clinical trial evaluating the use of the subcutaneous formulation of golimumab in patients with severe persistent asthma, more patients treated with golimumab reported malignancies compared with control patients. The significance of this finding is unknown. During the controlled portion of the Phase 3 trial in RA for SIMPONI ARIA, the incidence of malignancies other than lymphoma and NMSC per 100-patient-years of follow-up was 0.56 (95% CI: 0.01, 3.11) in the SIMPONI ARIA group compared with an incidence of 0 (95% CI: 0.00, 3.79) in the placebo group. **Congestive Heart Failure** Cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF-blockers, including SIMPONI ARIA. Some cases had a fatal outcome. In several exploratory trials of other TNF-blockers in the treatment of CHF, there were greater proportions of TNF-blocker treated patients who had CHF exacerbations requiring hospitalization or increased mortality. SIMPONI ARIA has not been studied in patients with a history of CHF and SIMPONI ARIA should be used with caution in patients with CHF. If a decision is made to administer SIMPONI ARIA to RA patients with CHF, these patients should be closely monitored during therapy, and SIMPONI ARIA should be discontinued if new or worsening symptoms of CHF appear. **Demyelinating Disorders** Use of TNF-blockers, of which SIMPONI ARIA is a member, has been associated with rare cases of new onset or exacerbation of central nervous system (CNS) demyelinating disorders, including multiple sclerosis (MS) and peripheral demyelinating disorders, including Guillain-Barré syndrome. Cases of central demyelination, MS, optic neuritis, and peripheral demyelinating polyneuropathy have rarely been reported in patients treated with the subcutaneous formulation of golimumab. Prescribers should exercise caution in considering the use of TNF-blockers, including SIMPONI ARIA, in patients with central or peripheral nervous system demyelinating disorders. Discontinuation of SIMPONI ARIA should be considered if these disorders develop. **Autoimmunity** Treatment with TNF blockers, including SIMPONI ARIA, may result in the formation of antinuclear antibodies (ANA). Rarely, treatment with TNF blockers, may result in the development of a lupus-like syndrome *[see Adverse Reactions]*. If a patient develops symptoms suggestive of a lupus-like syndrome following treatment with SIMPONI ARIA, treatment should be discontinued. **Use with Abatacept** In controlled trials, the concurrent administration of another TNF-blocker and abatacept was associated with a greater proportion of serious infections than the use of a TNF-blocker alone; and the combination therapy, compared to the use of a TNF-blocker alone, has not demonstrated improved clinical benefit in the treatment of RA. Therefore, the combination of TNF-blockers, including SIMPONI ARIA, and abatacept is not recommended *[see Drug Interactions]*. **Use with Anakinra** Concurrent administration of anakinra (an interleukin-1 antagonist) and another TNF-blocker was associated with a greater portion of serious infections and neutropenia and no additional benefits compared with the TNF-blocker alone. Therefore, the combination of anakinra with TNF-blockers, including SIMPONI ARIA, is not recommended *[see Drug Interactions]*. **Switching Between Biological Disease Modifying Antirheumatic Drugs (DMARDs)** Care should be taken when switching from one biologic product to another biologic product since overlapping biological activity may further increase the risk of infection. **Hematologic Cytopenias** There have been postmarketing reports of pancytopenia, leukopenia, neutropenia, aplastic anemia, and thrombocytopenia in patients receiving TNF-blockers. In clinical studies, cases of pancytopenia, leukopenia, neutropenia, and thrombocytopenia have also occurred in SIMPONI ARIA-treated patients. Caution should be exercised when using TNF-blockers, including SIMPONI ARIA, in patients who have or have had significant cytopenias. **Vaccinations/Therapeutic Infectious Agents** Live Vaccines Patients treated with SIMPONI ARIA may receive vaccinations, except for live vaccines. In patients receiving anti-TNF therapy, limited data are available on the response to live vaccination, or on the secondary transmission of infection by live vaccines. Use of live vaccines could result in clinical infections, including disseminated infections. Therapeutic Infectious Agents Other uses of therapeutic infectious agents such as live attenuated bacteria (e.g., BCG bladder instillation for the treatment of cancer) could result in clinical infections, including disseminated infections. It is recommended that therapeutic infectious agents not be given concurrently

with SIMPONI ARIA. **Hypersensitivity Reactions** In postmarketing experience, serious systemic hypersensitivity reactions (including anaphylaxis) have been reported following administration of the subcutaneous and intravenous formulations of golimumab including SIMPONI ARIA. Hypersensitivity reactions including hives, pruritus, dyspnea, and nausea, were reported during infusion and generally within an hour after infusion. Some of these reactions occurred after the first administration of golimumab. If an anaphylactic or other serious allergic reaction occurs, administration of SIMPONI ARIA should be discontinued immediately and appropriate therapy instituted. **ADVERSE REACTIONS:** The most serious adverse reactions were: • Serious Infections *[see Warnings and Precautions]* • Malignancies *[see Warnings and Precautions]* **Clinical Trials Experience** Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice. The safety data described below are based on one, randomized, double-blind, controlled Phase 3 trial in patients with RA receiving SIMPONI ARIA by intravenous infusion (Trial 1). The protocol included provisions for patients taking placebo to receive treatment with SIMPONI ARIA at Week 16 or Week 24 either by patient response (based on uncontrolled disease activity) or by design, so that adverse events cannot always be unambiguously attributed to a given treatment. Comparisons between placebo and SIMPONI ARIA were based on the first 24 weeks of exposure. Trial 1 included 197 control-treated patients and 463 SIMPONI ARIA-treated patients (which includes control-treated patients who switched to SIMPONI ARIA at Week 16). The proportion of patients who discontinued treatment due to adverse reactions in the controlled phase of Trial 1 through Week 24 was 3.5% for SIMPONI ARIA-treated patients and 0.5% for placebo-treated patients. Upper respiratory tract infection was the most common adverse reaction reported in the trial through Week 24 occurring in 6.5% of SIMPONI ARIA-treated patients as compared with 7.6% of control-treated patients, respectively. Infections Serious infections observed in SIMPONI ARIA-treated patients included sepsis, pneumonia, cellulitis, abscess, opportunistic infections, tuberculosis (TB), and invasive fungal infections. Cases of TB included pulmonary and extrapulmonary TB. The majority of the TB cases occurred in countries with a high incidence rate of TB *[see Warnings and Precautions]*. In the controlled phase of Trial 1 through Week 24, infections were observed in 27% of SIMPONI ARIA-treated patients compared with 24% of control-treated patients, and serious infections were observed in 0.9% of SIMPONI ARIA-treated patients and 0.0% of control-treated patients. Through Week 24, the incidence of serious infections per 100 patient-years of follow-up was 2.2 (95% CI 0.61, 5.71) for the SIMPONI ARIA group, and 0 (0.00, 3.79) for the placebo group. In the controlled and uncontrolled portions of Trial 1, 958 total patient-years of follow-up with a median follow-up of approximately 92 weeks, the incidence per 100 patient-years of all serious infections was 4.07 (95% CI: 2.90, 5.57) in patients receiving SIMPONI ARIA *[see Warnings and Precautions]*. In the controlled and uncontrolled portions of Trial 1, in SIMPONI ARIA-treated patients, the incidence of active TB per 100 patient-years was 0.31 (95% CI: 0.06; 0.92) and the incidence of other opportunistic infections per 100 patient-years was 0.42 (95% CI: 0.11, 1.07). Malignancies One case of malignancy other than lymphoma and NMSC with SIMPONI ARIA was reported through Week 24 during the controlled phase of Trial 1. In the controlled and uncontrolled portions through approximately 92 weeks, the incidence of malignancies per 100 patient-years, other than lymphoma and NMSC, in SIMPONI ARIA-treated patients was 0.31 (95% CI: 0.06, 0.92) and the incidence of NMSC was 0.1 (95% CI: 0.00, 0.58). Liver Enzyme Elevations There have been reports of severe hepatic reactions including acute liver failure in patients receiving TNF-blockers. In the controlled phase of Trial 1, through Week 24, ALT elevations ≥ 5 x ULN occurred in 0.8% of SIMPONI ARIA-treated patients and 0% of control-treated patients and ALT elevations ≥ 3 x ULN occurred in 2.3% of SIMPONI ARIA-treated patients and 2.5% of control-treated patients. Since many of the patients in the Phase 3 trial were also taking medications that cause liver enzyme elevations (e.g., nonsteroidal anti-inflammatory drugs [NSAIDs], MTX, or isoniazid prophylaxis), the relationship between SIMPONI ARIA and liver enzyme elevation is not clear. Autoimmune Disorders and Autoantibodies At Week 20 in Trial 1, 17% of SIMPONI ARIA-treated patients and 13% of control patients were newly antinuclear antibody (ANA)-positive (at titers of 1:160 or greater). Of these patients, one SIMPONI ARIA-treated patient and no control-treated patients had newly positive anti-dsDNA antibodies *[see Warnings and Precautions]*. Administration Reactions In the controlled phase of Trial 1 through Week 24, 1.1% of SIMPONI ARIA infusions were associated with an infusion reaction compared with 0.2% of infusions in the control group. The most common infusion reaction in SIMPONI ARIA treated patients was rash. No serious infusion reactions were reported. Immunogenicity Antibodies to SIMPONI ARIA were detected in 13 (3%) golimumab-treated patients following IV administration of SIMPONI ARIA in combination with MTX through Week 24 of Trial 1. All patients who were positive for antibodies to golimumab had neutralizing antibodies based on an *in vitro* cell-based assay. The small number of patients positive for antibodies to SIMPONI ARIA limits the ability to draw definitive conclusions regarding the relationship between antibodies to golimumab and clinical efficacy or safety measures. The data

Veterans
RHEUMATOLOGY

Water Aerobics Offers Fitness Alternative for Older Community

By Capt. Cody Butler and Senior Airman Jessica StCyr, 78th Medical Operations Squadron

Today there are more than 40 million adults in the United States ages 65 and older, but just one in four exercise regularly.

Common concerns of achy joints, cardiovascular problems, fear of falling, being too out of shape or not being able to keep up with the younger crowd in the gym reduce many individuals to only walking to stay active.

While there's nothing wrong with walking, let's face it, Georgia heat can be brutal. Besides, you can only walk laps around the mall or WalMart so many times before you're asked to leave.

> Water aerobics is not only a fun way to exercise and stay cool, but it's also known to be used as therapy for individuals with medical conditions like Multiple Sclerosis or Rheumatoid arthritis.

A group of seniors participates in a water aerobics class at the Robins Fitness Center, April 27, 2016. According to the Centers For Disease Control, water-based exercise can help people with chronic diseases like arthritis. It improves use of affected joints without worsening symptoms. *U.S. Air Force photo by Tommie Horton*

Instead, one can beat the heat and still exercise regularly by visiting a local pool.

According to the Aquatic Exercise Association, exercising in water puts less stress on problematic bone and joint areas and provides cardiovascular support by increasing the heart rate and influencing blood flow.

Water also provides natural resistance that helps build strength while improving balance and flexibility.

Water aerobics is not only a fun way to exercise and stay cool, but it's also known to be used as therapy for individuals with medical conditions like Multiple Sclerosis or Rheumatoid arthritis.

Although some local facilities have water aerobics classes, here are four easy ways to make a splash and build strength on your own:

Aqua walking/jogging — walk or jog from one side of the pool to the other in a shallow body of water.

Water Jacks — similar to jumping jacks; begin in an upright position in waist deep water and jump once to bring your legs out and once more to bring them back together. Raise your arms above your head or up to the surface of the water.

Flutter Kicks — Holding on to the edge of the pool, lay flat on your stomach and make your back as straight as possible. Alternate kicking your feet for 15-30 seconds. To make it more challenging, increase the speed of the kicks.

Use your imagination. For example, for legs, try performing slow and controlled high knees or balancing on one leg. For arms, try circles in the water. Be sure to check with your primary care physician before attempting new exercises, and always remember to stretch before and after exercising.

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Veterans
WOMEN'S HEALTH

VA Selects New Director of the Center for Women Veterans

The Department of Veterans Affairs announced the appointment of a new director of the Center for Women Veterans.

Kayla M. Williams assumed duties this week as Director, serving as primary advisor to the Secretary on Department policies, programs and legislation that affect women Veterans.

"Kayla embodies everything it means to be a true advocate for women Veterans and I am proud to welcome her to VA in this leadership role," said Secretary of Veterans Affairs Robert A. McDonald.

"This is an important time for VA as we prepare for the growing number of women we expect to take advantage of the VA services they have earned. I know Kayla will be tremendously helpful in improving services for female Veterans now and in future."

Kayla M. Williams

Williams is a member of the Army Education Advisory Committee, a former member of the VA Advisory Committee on Women Veterans, a 2013 White House Woman Veteran Champion of Change, and a 2015 Lincoln Award recipient.

She worked eight years at the RAND Corporation conducting research on servicemember and Veteran health needs and benefits, international security, and intelligence policy.

Williams graduated cum laude with a BA in English Literature from Bowling Green State University and earned an MA in International Affairs with a focus on the Middle East from American University.

She is author of two books. Love My Rifle More Than You: Young and Female in the U.S. Army, is a memoir about her deployment to Iraq. Her second book is, Plenty of Time When We Get Home: Love and Recovery in the Aftermath of War, about her family's journey from trauma to healing.

> "This is an important time for VA as we prepare for the growing number of women we expect to take advantage of the VA services they have earned. I know Kayla will be tremendously helpful in improving services for female Veterans now and in future."

Williams is coming from Pittsburgh, PA with her husband, a combat-wounded veteran, and their two children.

The Center for Women Veterans was established by Congress in November 1994 by Public Law (P.L.) 103-446 and monitors and coordinates VA's administration of health care and benefits services and programs for women Veterans.

The Center serves as an advocate for a cultural transformation in recognizing the service and contributions of women Veterans and women in the military.

va.gov

New Members Appointed to VA Advisory Committee on Women Veterans

Five new members were recently appointed to the Department of Veterans Affairs (VA) Advisory Committee on Women Veterans (Committee), an expert panel that advises VA's Secretary on issues and programs impacting women Veterans. Established in 1983, the Committee makes recommendations to the Secretary for policy and legislative changes.

"The Committee's guidance is instrumental in shaping VA policy for women Veterans, and providing insight on their diverse needs," said Secretary of Veterans Affairs Robert A. McDonald. "VA anticipates the important contributions and fresh perspectives the newest members will offer to this invaluable Committee."

Elisa Basnight, Esq., Director of the VA Center for Women Veterans

New Members VA Advisory Committee on Women Veterans

Kailyn Bobb, Plumas Lake, CA. A U.S. Air Force Veteran; currently pursuing a doctoral degree in clinical psychology from California School of Professional Psychology, Alliant International University.

Keith Howard-Streicher, Alexandria, VA. A Veteran of the U.S. Army; currently serves as Assistant Director, Veterans Affairs and Rehabilitation Division, at The American Legion.

Edna Boyd Jones, Norcross, GA. A retired U.S. Army Colonel, with service in the Gulf War and Operation Iraqi Freedom; currently serves as the Assistant Professor of Nursing at Albany State University.

Leslie N. Smith, King George, VA. A retired U.S. Army Captain; currently serves as co-founder and spokesperson for Fatigues to Fabulous, a non-profit women Veterans organization.

Janet M. West, Jacksonville, FL. An active duty U.S. Navy Lieutenant Commander, with service in Operation Enduring Freedom and Iraqi Freedom; currently serves as senior medical officer at Jacksonville Naval Air Station Branch Health Clinic.

Mary Westmoreland (Retired U.S. Army Colonel), who has diligently served on the Committee since 2012, was appointed as the Committee's new chair. Committee members Sara McVicker (U.S. Navy Veteran) Washington, DC, and Tia Christopher (U.S. Navy Veteran), Dallas, TX were reappointed for an additional term.

va.gov

From left to right: Ireatha L. Wardsworth, RN, MSN, Maternity Care Coordinator; Rola El-Serag, MD, Medical Director of Women's Health Program; and Carmen I. Rivera, RN, BSN, Breast Care Coordinator.

Veterans
WOMEN'S HEALTH

More Healthcare Options for Women Veterans

VA has enhanced provision of care to women Veterans by focusing on the goal of developing Designated Women's Health Providers (DWHP) at every site where women access VA. VA has trained over 2,000 providers in women's health and is in the process of training additional providers to ensure that every woman Veteran has the opportunity to receive her primary care from a DWHP.

VA now operates a Women Veterans Call Center (WVCC), created to contact women Veterans and let them know about the services they may be eligible for. From April 2013 to April 2014 the WVCC received over 9,600 incoming calls and made over 93,000 outbound calls.

She's your guide to VA.

The Women Veterans Call Center is staffed by knowledgeable VA employees who provide information about benefits, eligibility and services specifically for women Veterans. All the representatives at the Women Veterans Call Center are women, and many are Veterans themselves that can relate to women Veterans, their families and friends.

The Call Center staff is trained to answer questions and provide personalized information about claims, education, and health care, as well as information about VA cemeteries and survivors' benefits. If there is an urgent matter, the Women Veterans Call Center can connect women Veterans with the National Call Center for Homeless Veterans or the Veterans Crisis Line.

In addition to linking women Veterans to information, the Women Veterans Call Center makes direct referrals to Women Veteran Program Managers (WVPM) located at every VA Medical Center. The Women Veteran Program Manager helps the woman Veteran coordinate services.

Over 58,000 women Veterans served. VA has found that women Veterans underutilize VA care, largely due to a lack of knowledge about VA benefits and available services and their eligibility for them.

In response, the Call Center contacts women Veterans to let them know about the services they may be eligible for. From April 2013 to March 2015 the Call Center has successfully contacted over 183,000 women Veterans.

The WVCC receives, on average, 50 calls per day and makes, on average, 800 calls per day.

In addition to receiving calls, WVCC reaches out to women Veterans to let them know about the services they may be eligible for, and they help connect them to benefits they deserve.

va.gov

Veterans
WOMEN'S HEALTH

A Healthy Pregnancy Begins with a Healthy You

by Hans Petersen, VA Staff Writer

If you are a woman Veteran thinking about starting or expanding your family VA provides full maternity care coverage, as well as the first 7 days of newborn care. Services are usually provided by a pregnancy care provider and hospital in your community and coordinated by your VA Maternity Care Coordinator.

Jenny Fisher, an Army Veteran who served in Iraq and is dealing with PTSD, looked for help with her pregnancy at the VA Medical Center in New York City. She delivered her lovely daughter, Simone, with the help and support of VA Women's Health.

VA supports you deciding when motherhood is right for you. Whether you want to start or grow your family or choose a birth control method to prevent pregnancy, VA has a full range of services to support your reproductive goals.

Jenny Fisher thinks it's a good idea. "I was 100% satisfied with my care at the VA. They were great."

A planned pregnancy is a healthier pregnancy. It's always better to talk with your health care provider about being healthy and preparing for pregnancy (preconception care) whether you want to become pregnant soon or maybe sometime in the future. Visit our Women's Health website where you will find a healthy checklist, a reproductive life plan and other resources to help you manage your pregnancy goals.

Navy Veteran Ashley Chadwell bounces three-year-old Liam on her knee and says, "I am glad I went to the VA. Doctor Zephyrin was great. I would definitely recommend that women Veterans thinking about a family visit to their VA hospital and see how they can help."

Ashley needed to have her medications carefully monitored by her VA doctors during her pregnancy. "Everything went really well."

We know that some women Veterans may need help getting pregnant. We offer infertility services including counseling, infertility assessment and some infertility treatment. We are here to guide you through the process and provide emotional support.

As Dr. Laurie Zephyrin points out, "There are very exciting innovations going on in the VA around maternity care." She is VA's National Director for Reproductive Health.

April Andrews, former Army Medic, delivered her baby recently and her care was covered through VA maternity care benefits at the Salt Lake City VA Medical Center.

VA is marking National Women's Health Week by promoting a Women and Maternity Care campaign nationwide to raise awareness of VA's maternity benefits among VHA providers, staff and women Veterans. In addition to maternity and newborn benefits, VA offers a full range of reproductive health services including preconception care, birth control (contraception care), and care for women entering the menopausal transition.

April Andrews, former Army Medic, delivered a cute little bundle of joy through the prenatal and postpartum care program at the Salt Lake City VA Medical Center. VA maternity benefits also covered her delivery and newborn care. After years in the Army and a tour in Iraq, April says she is comforted by visiting the women's clinic and being around other female Veterans.

"I love my VA. When I go to the Women's Clinic I feel like I am going to my girlfriend's house. I feel like they truly care about me."

Dr. Zephyrin adds, "VA covers a wide range of maternity benefits. Many of our women Veterans receive this care through community health care providers. We want to make sure women Veterans are receiving the highest quality maternity care."

VA knows that some women Veterans want to prevent pregnancy until they are ready to start a family. That's why we offer a wide-variety of birth control options. Talk to your VA health

care provider to choose the best birth control method for your lifestyle.

When choosing a birth control method consider: your future pregnancy plans, your relationship or partner status and your general medical health. Make sure you tell your provider about all of your health issues and medicines.

VA also offers emergency contraception options to reduce your risk for an unplanned pregnancy if you have unprotected sex or your regular birth control fails.

Dr. Zephyrin concludes, "When women Veterans come to VA, they may be surprised to see the range of services that we provide. We are undergoing a transformation in Women's Health Services including reproductive health services nationally."

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Infertility in Iraq and Afghanistan Veterans

According to a study of Veterans who served in Operation Enduring Freedom (OEF) and Operation Iraqi Freedom (OIF), or elsewhere during the same time period, 15.8% of women and 13.8% of men reported that they had experienced infertility. Infertility is defined as trying with a partner to get pregnant for more than 12 months.

Infertility among the general population in the U.S. ranges from 8% to 20%, depending on the definition used. Infertility can be defined in many different ways, so it is difficult to make direct comparisons between the Veteran population and the non-Veteran population. The causes of infertility were similar between the Veterans participating in the study and that of couples in the U.S. undergoing fertility treatment. Causes included problems with ovulation or issues with sperm or testes.

Infertility treatment

Women Veterans were more likely to seek care for infertility than male Veterans. Approximately 40% of men and women Veterans with a history of infertility reported that they or their partner sought infertility treatment.

Findings from the New Generation Study

The findings are from the National Health Study for a New Generation of U.S. Veterans, a long-term study on the health of 30,000 OEF/OIF Veterans and 30,000 Veterans from the same era who were not deployed. Read the abstract on self-reported infertility.

Health concerns?

Talk to your health care provider or local VA Environmental Health Coordinator if you are concerned about infertility.

VA offers a variety of health care benefits to eligible Veterans, including infertility evaluations and some treatment.

Not enrolled in the VA health care system? Find out if you qualify. OEF/OIF/OND Veterans are eligible for VA health care for five years after leaving the military.

There are other ways to qualify too, including by having a service-connected disability.

Sources

- Stephen EH, Chandra A. Declining estimates of infertility in the United States: 1982-2002. Fertil Steril. 2006; 86: 516-523.
- Zinaman MJ, Clegg ED, Brown CC, O'Connor J, Selevan SG. Estimates of human fertility and pregnancy loss. Fertil Steril 1996; 65:503-509.
- Assisted Reproductive Technology (ART) Report 2010. Available at http://www.cdc.gov/art/ART2010/PDFs/ART_2010_National_Summary_Report.pdf Accessed July 22, 2015.

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AFM 2016

DIRECTORY OF ADVERTISERS

FLUAD (Influenza Vaccine, Adjuvanted)
Suspension for Intramuscular Injection
2015-2016 Formula
Initial U.S. Approval: 2015

BRIEF SUMMARY:
See package insert for full prescribing information.

1 INDICATIONS AND USAGE

FLUAD is an inactivated influenza vaccine indicated for active immunization against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. FLUAD is approved for use in persons 65 years of age and older. Approval is based on the immune response elicited by FLUAD. Data demonstrating a decrease in influenza disease after vaccination with FLUAD are not available. *[see Clinical Studies (14)]*

4 CONTRAINDICATIONS

Do not administer FLUAD to anyone with a history of severe allergic reaction (e.g. anaphylaxis) to any component of the vaccine, including egg protein *[see Description (11)]*, or to a previous influenza vaccine.

5 WARNINGS AND PRECAUTIONS

5.1 Guillain-Barré Syndrome

If Guillain-Barré syndrome (GBS) has occurred within 6 weeks of receipt of prior influenza vaccine, the decision to give FLUAD should be based on careful consideration of the potential benefits and risks. The 1976 swine influenza vaccine was associated with an elevated risk of GBS. Evidence for a causal relationship of GBS with other influenza vaccines is inconclusive; if an excess risk exists, it is probably slightly more than 1 additional case per 1 million persons vaccinated. *[see References (1)]*

5.2 Preventing and Managing Allergic Reactions

Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.

5.3 Latex

The tip caps of the prefilled syringes contain natural rubber latex which may cause allergic reactions in latex sensitive individuals. *[see Description (11)]*

5.4 Altered Immunocompetence

The immune response to FLUAD in immunocompromised persons, including individuals receiving immunosuppressive therapy, may be lower than in immunocompetent individuals. *[see Concurrent Use With Immunosuppressive Therapies (7.2)]*

5.5 Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines including FLUAD. Ensure procedures are in place to avoid injury from falling associated with syncope.

5.6 Limitations of Vaccine Effectiveness

Vaccination with FLUAD may not protect all vaccine recipients against influenza disease.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, the adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine and may not reflect rates observed in clinical practice.

Solicited adverse reactions were assessed in a multicenter, observer-blind, randomized controlled study (Study 1) conducted in the United States, Colombia, Panama and the Philippines. The safety analysis set included 3545 FLUAD recipients and 3537 AGRIFLU (Influenza Vaccine) recipients. The enrolled subject population in Study 1 was 65 to 97 years of age (mean 72 years) and 64% were female. Within each treatment group, 53% were Asian, 28% were Caucasian, 18% were Hispanic, 1% were Black, and fewer than 1% each were Native American/ Alaskan, Pacific Islander/Hawaiian, or Other.

Solicited local (injection site) and systemic adverse reactions were collected from subjects in Study 1 who completed a symptom diary card for seven days following vaccination. The reported frequencies of solicited local and systemic adverse events from Study 1 are presented in Table 1.

Table 1. Percentages of Subjects ≥ 65 Years of Age With Solicited Local and Systemic Adverse Reactions in Days 1-7 After Administration of FLUAD or AGRIFLU (a U.S. Licensed Comparator) NCT01162122

Study 1			
		FLUAD (N[a]=3418-3496) Percentage	AGRIFLU (N[a]=3420-3488) Percentage
Local			
Injection site Pain	Any	25.0	12.2
	Moderate[b]	3.9	1.9
	Severe[c]	0.3	0.2
Tenderness	Any	21.1	11.2
	Moderate	3.0	1.0
	Severe	0.1	0.2
Erythema	Any	1.2	0.5
	25 to ≤ 50 mm	1.1	0.5
	51 to ≤ 100 mm	0.2	<0.1
	> 100 mm	0.0	0.0
Induration	Any	1.3	0.5
	25 to ≤ 50 mm	1.0	0.5
	51 to ≤ 100 mm	0.3	0.0
	> 100 mm	0.0	0.0

(cont)

Local *(cont from previous page)*			
Swelling	Any	1.2	0.4
	25 to ⩽ 50 mm	1.0	0.4
	51 to ⩽ 100 mm	0.2	<0.1
	> 100 mm	<0.1	0.0
Systemic			
Myalgia	Any	14.7	9.7
	Moderate	2.6	1.8
	Severe	0.3	0.7
Fatigue	Any	13.3	10.4
	Moderate	3.1	2.4
	Severe	0.4	0.6
	PLT[d]	0.0	<0.1
Headache	Any	13.2	11.2
	Moderate	3.0	2.6
	Severe	0.4	0.6
	PLT	0.0	<0.1
Arthralgia	Any	8.5	7.8
	Moderate	1.6	1.6
	Severe	0.2	0.6
Chills	Any	6.7	4.7
	Moderate	1.5	1.2
	Severe	0.3	0.3
	PLT	<0.1	0.0
Diarrhea	Any	4.8	4.5
	Moderate	1.3	0.9
	Severe	0.3	0.2
	PLT	<0.1	<0.1
Fever	Any	3.6	3.4
	⩾ 38.0°C to ⩽ 38.4°C	1.8	1.7
	⩾ 38.5°C to ⩽ 38.9°C	1.3	1.3
	39.0°C to ⩽ 40.0°C	0.4	0.4
	⩾ 40.0°C	0.1	0.0
Nausea	Any	2.9	2.8
	Moderate	0.4	0.6
	Severe	0.1	0.1
	PLT	<0.1	0.0
Vomiting	Any	1.4	1.7
	Moderate	0.4	0.5
	Severe	<0.1	0.1
	PLT	<0.1	0.0

[a] N = number of subjects with safety data.

[b] Moderate: pain, tenderness, myalgia, fatigue, headache, arthralgia, chills, nausea, vomiting defined as "some limitation in normal daily activity", diarrhea defined as "4 to 5 stools a day".

[c] Severe: pain, tenderness, myalgia, fatigue, headache, arthralgia, chills, nausea, vomiting defined as "unable to perform normal daily activity", diarrhea defined as "6 or more watery stools a day".

[d] Potentially life threatening (PLT) reaction defined as requiring emergency room visit or hospitalization.

Unsolicited Adverse Events (AEs): The clinical safety of FLUAD was assessed in fifteen (15) randomized, controlled studies. The total safety population in these trials included 10,952 adults 65 years of age and older, comprising 5,754 who received FLUAD and 5,198 who received other US licensed influenza vaccines. The percentage of subjects with an unsolicited AE within 30 days following vaccination was similar between vaccine groups (16.9% FLUAD vs. 18.0% active comparator).

Serious Adverse Events (SAEs) and Deaths: In Study 1, in which subjects were followed for SAEs and deaths for one year following vaccination (N=3,545 FLUAD, N=3,537 AGRIFLU), the percentages of subjects with an SAE were similar between vaccine groups (7% FLUAD vs. 7% AGRIFLU). Four SAEs (1 FLUAD and 3 AGRIFLU) were assessed as related to study vaccination over one year of observation and 2 of these occurred (1 FLUAD and 1 AGRIFLU) within 21 days following study vaccination. There were 98 deaths (n=52 FLUAD, n=46 AGRIFLU) over one year of which none occurred within the first 21 days following vaccination.

In 14 additional randomized, controlled studies, SAEs were collected over a 3 to 4-week period in 4 studies, over a 8-week period in 1 study, and over a 6-month period in 9 studies (N= 2,209 FLUAD, N=1,661 US licensed influenza vaccines). The percentages of subjects with an SAE within 30 days (1.1% FLUAD vs. 1.8% AGRIFLU) or within 6 months (4.3% FLUAD vs. 5.9% AGRIFLU) were similar between vaccine groups. The percentages of deaths within 30 days (0.3% FLUAD vs. 0.6% active comparator) or within 6 months (1.0% FLUAD vs. 1.5% active comparator) were also similar.

Adverse Events of Special Interest (AESIs): Rates of new onset neuroinflammatory and immune mediated diseases were assessed in a *post hoc* analysis of the 15 randomized controlled studies over the time periods specified above for SAEs. The percentage of subjects with an AESI at any time after vaccination was similar between vaccine groups (0.9% FLUAD vs. 0.9% active comparator). There were no notable imbalances for specific AESIs.

Safety of Annual Revaccination: In 5 of the randomized, controlled trials, subjects were followed for SAEs and deaths for 6 months following revaccination (N=492 FLUAD, N=330 US licensed and non-US licensed influenza vaccines). After the second annual vaccination, the percentages of subjects with an SAE were similar between vaccine groups (6.1% FLUAD vs. 5.5% comparator influenza vaccines); 23 deaths (n=17 FLUAD, n=6 comparator influenza vaccines) were reported. Causes of death included cardiovascular events, malignancy, trauma, gastrointestinal disorders, and respiratory failure. Clinical characteristics of the deaths, including the variable causes, timing since vaccination, and underlying medical conditions, do not provide evidence for a causal relationship with FLUAD.

6.2 Postmarketing Experience

The following adverse events have been spontaneously reported during post-approval use of FLUAD in Europe and other regions since 1997.

Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to the vaccine.

Blood and lymphatic system disorders:
Thrombocytopenia (some cases were severe with platelet counts less than 5,000 per mm^3), lymphadenopathy

General disorders and administration site conditions:
Extensive swelling of injected limb lasting more than one week, injection site cellulitis-like reactions (some cases of swelling, pain, and redness extending more than 10 cm and lasting more than 1 week)

Immune system disorders:
Allergic reactions including anaphylactic shock, anaphylaxis and angioedema

Musculoskeletal and connective tissue disorders:
Muscular weakness

Nervous system disorders:
Encephalomyelitis, Guillain-Barré Syndrome, convulsions, neuritis, neuralgia, paraesthesia, syncope, presyncope

Skin and subcutaneous tissue disorders:
Generalized skin reactions including erythema multiforme, urticaria pruritus or non-specific rash

Vascular disorders:
Vasculitis with transient renal involvement

7 DRUG INTERACTIONS

7.1 Concomitant Use With Other Vaccines

There are no data to assess the concomitant administration of FLUAD with other vaccines. If FLUAD is to be given at the same time as other injectable vaccine(s), the vaccine(s) should be administered at different injection sites.

Do not mix FLUAD with any other vaccine in the same syringe.

7.2 Concurrent Use With Immunosuppressive Therapies

Immunosuppressive or corticosteroid therapies may reduce the immune response to FLUAD.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category B: A reproductive and developmental toxicity study has been performed in rabbits with a dose level that was approximately 15 times the human dose based on body weight. The study revealed no evidence of impaired female fertility or harm to the fetus due to FLUAD. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this vaccine should be used during pregnancy only if clearly needed.

In a reproductive and developmental toxicity study, the effect of FLUAD on embryo-fetal and post-natal development was evaluated in pregnant rabbits. Animals were administered FLUAD by intramuscular injection twice prior to gestation, during the period of organogenesis (gestation day 7) and later in pregnancy (gestation day 20), 0.5 mL (45 mcg)/rabbit/occasion (approximately 15-fold excess relative to the adult human dose based on body weight). No adverse effects on mating, female fertility, pregnancy, embryo-fetal development, or post-natal development were observed. There were no vaccine-related fetal malformations or other evidence of teratogenesis.

8.4 Pediatric Use

The safety and effectiveness of FLUAD in the pediatric population has not been established.

8.5 Geriatric Use

Safety and immunogenicity of FLUAD have been evaluated in adults 65 years of age and older. *[See Adverse Reactions (6.1) and Clinical Studies (14)]*

Manufactured by: Novartis Vaccines and Diagnostics Limited.

An affiliate of: Novartis Vaccines and Diagnostics, Inc., 350 Massachusetts Avenue, Cambridge, MA USA 02139
1-855-358-8966

Introducing FLUAD™, a next-generation flu shot for the 65+ generation. Because people 65 and older can have weakened immune systems, they could benefit from a flu vaccine created especially for their generation.[1,2] FLUAD was shown in clinical trials to provide a strong immune response and have an acceptable safety profile.[2] Today, the 65+ generation is less concerned about being hip and more concerned about being healthy. FLUAD was designed specifically to help them stay that way.[2] Right on!

Get in the groove, choose FLUAD for your patients 65+.

FLUAD™
influenza vaccine, adjuvanted

Power to the people 65+

To learn more, visit **www.fluad.com**.

IMPORTANT SAFETY INFORMATION[2]

INDICATIONS

FLUAD is an inactivated influenza vaccine indicated for active immunization against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. FLUAD is approved for use in persons 65 years of age and older.

CONTRAINDICATIONS

Severe allergic reaction to any component of the vaccine, including egg protein, or after a previous dose of any influenza vaccine.

WARNINGS AND PRECAUTIONS

- If Guillain-Barré Syndrome (GBS) has occurred within six weeks of previous influenza vaccination, the decision to give FLUAD should be based on careful consideration of the potential benefits and risks.
- The tip caps of the prefilled syringes contain natural rubber latex which may cause allergic reactions in latex sensitive individuals.

ADVERSE REACTIONS

- The most common (≥10%) local (injection site) adverse reactions observed in clinical studies were injection site pain (25%) and tenderness (21%).
- The most common (≥10%) systemic adverse reactions observed in clinical studies were myalgia (15%), headache (13%) and fatigue (13%).

Please see Brief Summary of Prescribing Information for FLUAD adjacent to this ad.

References: 1. What you should know and do this flu season if you are 65 years and older. Centers for Disease Control and Prevention website. http://www.cdc.gov/flu/about/disease/65over.htm. Updated 2015. Accessed November 11, 2015. **2.** FLUAD [package insert]. Cambridge, MA: Novartis Vaccines and Diagnostics, Inc.; 2015.

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