

# Office of Healthcare Inspections

Report No. 16-03705-60

# Healthcare Inspection Alleged Women's Health Care Issues Gulf Coast Veterans Health Care System Biloxi, Mississippi

**January 4, 2018** 

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# **Executive Summary**

The VA Office of Inspector General conducted a healthcare inspection in response to complaints received in 2016 regarding gynecology and women's health primary care services at the VA Gulf Coast Veterans Health Care System (system), Biloxi, MS. Specifically, the allegations were:

- A system gynecologist
  - Turned away patients by cancelling their consults for routine cancer screenings.
  - Did not order the correct test for a patient who was contemplating a hysterectomy.
  - Refused to perform two tubal ligations.
  - Refused to reorder medications for a patient.
  - o Failed to document gynecology procedures correctly.
  - Failed to use a colposcope to perform colposcopies.<sup>1</sup>
- A Women's Health Clinic physician assistant was not addressing a patient's medical care.
- System gynecologists live too far away to be on-call for surgical patients.

We did not substantiate that a gynecologist turned away patients by improperly cancelling or discontinuing consults made by the primary care providers. According to Veterans Health Administration (VHA) policy, the consult process is a two-way communication between providers. A feature of consult two-way communication in the electronic health record is that an automatic notification goes to the sender when the receiver takes certain actions. For example, when a receiver cancels the consult or completes the consult, the sender gets an electronic notification. While providers can elect to turn off/on some notifications, the electronic notification for cancelled or completed consults cannot be turned off. The gynecologist's process to cancel or discontinue the consults was performed as required by VHA and consistent with VHA cervical cancer screening guidance.

We did not substantiate that a system gynecologist, who was covering for a patient's regular gynecologist, failed to order a diagnostic procedure. The patient did not return to the covering gynecologist as planned for a complete examination, and the covering gynecologist did not have the opportunity to determine whether additional diagnostic procedures were needed. The patient subsequently visited her regular gynecologist and received treatment from a non-VA gynecologist.

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<sup>&</sup>lt;sup>1</sup> Colposcopy is a procedure utilizing a magnifying lens that allows the doctor to see and biopsy abnormal areas in the vulva, vagina, and cervix. <a href="https://www.acog.org/Search?Keyword=colposcopy">https://www.acog.org/Search?Keyword=colposcopy</a>. Accessed June 22, 2017.

We did not substantiate that a system gynecologist refused to provide tubal ligations for two patients. Both patients were counseled appropriately and had the procedure.

We substantiated that a system gynecologist did not reorder a medication for another gynecologist's patient. However, the medication was not emergent or new, and we determined that it was reasonable for the covering gynecologist to defer to the regular gynecologist on the matter of reordering long-term hormone therapy medication.

We did not substantiate a lack of procedure documentation by a gynecologist because the gynecologist's notes had the required information to describe and identify the patient's procedure, diagnosis and treatment. We did not substantiate that a gynecologist failed to use a colposcope during colposcopies. Documentation indicated that colposcopies were performed correctly as biopsies were taken and submitted for review.

We did not substantiate that a system physician assistant provided inadequate primary care, or that on-call practices for gynecology surgical patients were inadequate. Our review of the primary care patient's medical record showed that the system physician assistant provided appropriate care for specific medical problems. Our review of the system's on-call practices showed that the system had a process to cover surgical patients that met VHA expectations and requirements.

In the course of our inspection, we identified several other issues under the responsibilities of medical leadership:

- Primary care providers did not always follow VHA guidelines for cervical cancer screenings.
- Loop electrosurgical excision procedures were performed in the operating room with general anesthesia.
- Communication and collaboration was lacking between the gynecologists and other system providers and between providers and patients that may have caused patient care confusion, an unnecessary procedure, and limited pertinent discussions concerning safe and effective patient care.
- A care coordination agreement was outdated.
- One gynecologist's privileges were not in compliance with system required experience to perform surgical procedures.

In addition, while reviewing patient complaints, we found that the Patient Advocacy Program, under the responsibilities of system leadership, was not tracking complaints as required by VHA.

We recommended that the System Director:

- Ensure that System primary care providers receive education on VHA cervical cancer screening guidelines and that supervisors monitor compliance.
- Review and evaluate the routine use of general anesthesia for loop electrosurgical excision procedures conducted in the operating room and take action as appropriate.
- Utilize VHA resources to promote a culture that discourages behaviors that undermine safe patient care and effective communication and collaboration between providers and between providers and patients.
- Ensure that care coordination agreements between primary care and gynecology services meet system annual review requirements.
- Ensure that Patient Advocacy Program managers enter all complaints into the Patient Advocacy Tracking System database and track all reported complaints to resolution.
- Ensure that system gynecologists have current privileges that meet VHA and system policy requirements.

**Comments:** The Veterans Integrated Service Network and System Directors concurred with our recommendations and provided an acceptable action plan. (See Appendixes B and C, pages 23–27 for the Directors' comments.) Based on information provided, we consider Recommendation 2 closed. For the remaining open recommendations, we will follow up on the planned actions until they are completed.

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Healthcare Inspections

# **Purpose**

The VA Office of Inspector General (OIG) conducted a healthcare inspection to determine the merit of allegations made regarding gynecology (GYN)<sup>2</sup> and women's health primary care (PC)<sup>3</sup> services at the VA Gulf Coast Veterans Health Care System (system), Biloxi, MS.

# **Background**

The system comprises a medical center located in Biloxi, MS, and four community based outpatient clinics in Alabama, the Mississippi gulf coast, and the Florida panhandle. In fiscal year 2017, the system served over 68,000 patients, including more than 7,000 women veterans. It is part of Veterans Integrated Service Network 16.

#### **Cervical Cancer Screening**

Historically, cervical cancer was the leading cause of cancer death for women in the United States. However, in the past 40 years, the number of cases of cervical cancer and the number of deaths from cervical cancer have decreased significantly. This decline largely is the result of many women obtaining regular Papanicolaou (Pap) tests (also commonly referred to as Pap smears). Pap tests involve microscopic examination of cells from the cervix and vagina to detect pre-cancerous and cancerous lesions. In March 2012, the U.S Preventive Services Task Force published new cervical cancer screening guidelines, which Veterans Health Administration (VHA) adopted. For a summary of VHA guidelines, see the Table on the next page.

<sup>&</sup>lt;sup>2</sup> Gynecology is the study and treatment of female reproductive organ (including the breast) diseases by a specially trained provider.

<sup>&</sup>lt;sup>3</sup> Primary care, which is comprehensive care and is the first contact and continuing care for persons, includes health promotion, disease prevention, health maintenance, counseling, patient education, and diagnosis and treatment of acute and chronic illnesses. <a href="http://www.aafp.org/about/policies/all/primary-care.html">http://www.aafp.org/about/policies/all/primary-care.html</a>.

<sup>&</sup>lt;sup>4</sup> A Pap test is an exam where cells from the cervix and vagina are examined under a microscope. https://www.cdc.gov/cancer/cervical/basic\_info/screening.htm. Accessed June 17, 2017.

<sup>&</sup>lt;sup>5</sup> U.S. Preventive Services Task Force, <u>Cervical Cancer Screening</u>, March 2012. <u>https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/cervical-cancer-screening</u>. Accessed July 7, 2017.

<sup>&</sup>lt;sup>6</sup> VHA Patient Care Services Health Promotion and Disease Prevention, *Cervical Cancer Screening*, *Provider Fact* Sheet, June 2013.

<sup>&</sup>lt;sup>7</sup> VHA National Center for Health Promotion and Disease Prevention, http://vaww.prevention.va.gov/CPS/Screening for Cervical Cancer.asp. Accessed April 28, 2017.

**Table. VHA Cervical Cancer Screening Guidelines** 

Age Range	Recommended Cervical Cancer Screening
Younger than 21	No screening.
21–29	Pap test every 3 years for women who have a cervix. Do not conduct human papilloma virus testing in women younger than 30 unless such testing is indicated following an abnormal Pap test result.
30–65	Every 3 years; may lengthen the cancer screening interval to 5 years if requested and not high risk. <sup>9</sup>
Over 65	No screening if prior screening was adequate <sup>10</sup> or not otherwise at high risk for cervical cancer.

Source: VHA National Center for Health Promotion and Disease Prevention

#### **System Care for Women Veterans**

VHA Directive 1330.01, *Health Care Services for Women Veterans*, "establishes the minimum requirements to ensure that all eligible and enrolled women Veterans, irrespective of where they obtain care in VHA, have access to all medically necessary services." To meet those requirements, the system provides comprehensive PC and specialty services for women veterans.

At the time of our site visit in July 2016, PC for women veterans was provided by two full-time PC providers (not gynecologists) in the Women's Health Clinic, located in the medical center in Biloxi, as well as other designated PC providers in clinics outside of the Biloxi area. Examples of PC services included care for acute and chronic illnesses and gender-specific PC, such as breast and cervical cancer screening.

Specialty GYN care was provided at the system by two full-time board certified gynecologists. One gynecologist generally worked at two community based outpatient clinics and the other worked at the medical center. Examples of specialty GYN services

<sup>&</sup>lt;sup>8</sup> Human Papillae Virus (HPV) is the name of a group of related viruses that may cause cancer in the cervix and other areas of the body. https://www.acog.org/Search?Keyword=HPV, Accessed June 22, 2017.

<sup>&</sup>lt;sup>9</sup> High risk women includes those with HIV positive tests, transplants, immunocompromised status, treatment for cervical cancer, and a history of significant abnormal Pap test results. http://vaww.prevention.va.gov/CPS/Screening for Cervical Cancer.asp, Accessed July 7, 2017.

Adequate prior screening for those >65 years of age means: the last 3 Pap tests (done once every 3 years) were negative or two consecutive negative cytology and HPV test results within 10 years before cessation of screening, with the most recent test occurring within 5 years, and not otherwise at high risk for cervical cancer. <a href="http://vaww.prevention.va.gov/CPS/Screening for Cervical Cancer.asp">http://vaww.prevention.va.gov/CPS/Screening for Cervical Cancer.asp</a>. Accessed July 7, 2017.

<sup>&</sup>lt;sup>11</sup>VHA Handbook 1330.01, *Health Care Services for Women Veterans*, May 2, 2010. This Handbook was in effect during the time of the events discussed in this report. It was rescinded and replaced by VHA Directive 1330.01, *Health Care Services for Women Veterans*, February 15, 2017 that contains the same or similar language regarding medically necessary services for women veterans.

<sup>&</sup>lt;sup>12</sup> A physician who has special training in diagnosing and treating diseases of the female organs. https://www.cancer.gov/publications/dictionaries/cancer-terms?cdrid=46378. Accessed July 27, 2017.

included diagnostic procedures for women with abnormal Pap test findings and surgical procedures, including tubal ligations.<sup>13</sup>

#### **Coordination of Services for Additional/Specialty Services**

VHA uses specific methods to communicate requests for additional and specialty services, including specialty GYN services. Two such methods are consults and the use of a service agreement or care coordination agreement.<sup>14,15</sup>

#### Consults

According to VHA policy, a consult is a request by a provider for an opinion, advice, or expertise regarding evaluation or management of a specific patient problem. The consult process allows two-way communication, on behalf of the patient, between the provider requesting the consult (sender) and another health care provider (receiver) who is responding to the consult. A feature of two-way communication occurring with consults is an automatic notification to the sender when the receiver takes certain actions. For example, when a receiver cancels the consult or completes the consult, the sender gets an electronic notification. While providers can elect to turn off/on some notifications, the electronic notification for cancelled or completed consults cannot be turned off. 18

#### Care Coordination Agreement

According to VHA policy, a care coordination agreement defines work flow rules between two or more services within or between facilities. The agreement is a written document that is developed based on discussion and consensus between/among the involved services and facilities. The document is signed by service chiefs from the involved services. VHA policy recommends that services review the agreement annually.<sup>19</sup>

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<sup>&</sup>lt;sup>13</sup> Tubal ligation, also known as tubal sterilization, is a permanent method of birth control for women. Fallopian tubes are removed or cut and tied. It is the most popular form of birth control worldwide. <a href="http://www.mayoclinic.org/tests-procedures/tubal-ligation/basics/definition/prc-20020231">http://www.mayoclinic.org/tests-procedures/tubal-ligation/basics/definition/prc-20020231</a>. Accessed November 20, 2017.

<sup>&</sup>lt;sup>14</sup> VHA Directive 2008-056, VHA Consult Policy, September, 16, 2008. This Directive was in effect at the time of the events discussed in this report. It was rescinded and replaced in August 2016 by VHA Directive 1232(1), Consult Processes and Procedures, August 24, 2016, amended September 23, 2016. The 2008 Directive used the term service agreement while the 2016 Directive used the term care coordination agreement. For this report, we use the term care coordination when referring to the agreement between services within the context of consults.

<sup>&</sup>lt;sup>15</sup> VHA Memorandum, Under Secretary for Health, *Consult Business Rule Implementation*, (Consult Business Rules) May 23, 2013.

<sup>&</sup>lt;sup>16</sup> VHA Directive 2008-056, VHA Directive 1232 (1).

<sup>&</sup>lt;sup>17</sup> VHA Memorandum, Under Secretary for Health, *Consult Business Rule Implementation*, (Consult Business Rules) May 23, 2013.

<sup>&</sup>lt;sup>18</sup> VHA Office of Information and Technology Product Development, *Consult/Request Tracking User Manual Version 3.0*, February 2016.

<sup>&</sup>lt;sup>19</sup> VHA Directive 2008-056; VHA Directive 1232(1); VHA Memorandum, Under Secretary for Health, *Consult Business Rule Implementation*, (Consult Business Rules) May 23, 2013.

#### **Prior Reports**

In June 2017, OIG published *Review of VHA Care and Privacy Standards for Women Veterans* (Report No. 15-03303-206, June 19, 2017). In the analysis of VHA's provision of gender-specific care to women veterans, we found that 1,236 of 2,294 women's health providers (53.9 percent) had women veteran populations of less than 10 percent of their total patient panel. We noted that VHA had appropriately identified providers with a low women patient panel as those who would need additional opportunities to maintain their practice skills; however, we could not verify that the provided documentation satisfied the proficiency requirements for all of these providers. We recommended that the Acting Under Secretary for Health ensure that requirements for women's health provider designation are routinely reviewed and strengthened, when appropriate. The Acting Under Secretary for Health concurred with our recommendation and provided acceptable action plans. We are continuing to follow up on the status of those corrective actions.

See Appendix A for other relevant OIG reports published in the past 5 years.

#### **Allegations**

OIG received the following allegations from a letter received in mid-May 2016 and from interviews with the complainant in July 2016:

- A system gynecologist:
  - Turned away patients by cancelling their consults for routine cancer screenings.
  - Did not order the correct test for a patient who was contemplating a hysterectomy.
  - Refused to perform two tubal ligations.
  - o Refused to reorder medications for a patient.
  - o Failed to document gynecology procedures correctly.
  - o Failed to use a colposcope to perform colposcopies. 20
- A Women's Health Clinic physician assistant was not addressing a patient's medical care.
- System gynecologists live too far away to be on-call for surgical patients.

<sup>&</sup>lt;sup>20</sup> Colposcopy is a procedure utilizing a magnifying lens that allows the doctor to see and biopsy abnormal areas in the vulva, vagina, and cervix. <a href="https://www.acog.org/Search?Keyword=colposcopy">https://www.acog.org/Search?Keyword=colposcopy</a>. Accessed June 22, 2017.

# **Scope and Methodology**

We initiated our inspection in June 2016. We interviewed the complainant and conducted an onsite visit on July 18–20, 2016. We interviewed the Acting Women Veterans Health Program Manager, the Medical Director of Women Veterans Health, GYN physicians, Women's Health providers, a registered nurse, the Chief of Surgery, the Patient Advocate, and the Chief of Medical Administration Services.

We reviewed care coordination agreements between PC and GYN; VHA policies and procedures; and the American College of Obstetrics and Gynecology (ACOG), American Society for Colposcopy and Cervical Pathology, United States Preventive Health Services, and American Cancer Society practice guidelines. We assessed whether the system's Patient Advocate Program had addressed specific issues related to gynecologic complaints, and we reviewed meeting minutes and Peer Review Committee procedures.

The complainant provided the names of 12 patients who the complainant felt had received inadequate care and 10 additional names of patients whose GYN consults were cancelled or discontinued. A program supervisor provided another patient name for us to review for inadequate GYN care. We reviewed each patient's electronic health record (EHR) for the issue presented by the complainant as well as overall GYN care and documentation in the EHRs of the 13 patients who allegedly received inadequate care. We conferred with a GYN consultant regarding the gynecological care of 10 of the 13 patients.

We did not review the system breast health program (as this was not part of the complaint), consults for the Choice program, and GYN service panel size. We limited our site visit to the Biloxi Women's Health Clinic and Surgical Center in Biloxi, where the majority of patient encounters and the complaints were focused.

Five policies cited in this report were expired.

- 1. VHA Handbook 1003.1, Key Elements of VHA's Veteran Customer Service Program, August 6, 2003 (expired 2008).
- 2. VHA Handbook 1003.4, *Patient Advocacy Program*, September 2, 2005 (expired September 30, 2010).
- VHA Directive 2010-018, Facility Infrastructure Requirements to Perform Standard, Intermediate, or Complex Surgical Procedures, May 6, 2010 (expired May 31, 2015).
- 4. VHA Directive 2010-025, *Peer Review for Quality Management*, June 3, 2010 (expired June 30, 2015).
- 5. VHA Handbook 1101.04, *Medical Officer of the Day*, August 30, 2010 (expired August 2015).

We considered these policies to be in effect, as they had not been superseded by more recent policy or guidance. In a June 29, 2016 memorandum to supplement policy provided by VHA Directive 6330(1),<sup>21</sup> the VA Under Secretary for Health (USH) mandated the "...continued use of and adherence to VHA policy documents beyond their recertification date until the policy is rescinded, recertified, or superseded by a more recent policy or guidance."<sup>22</sup> The USH also tasked the Principal Deputy Under Secretary for Health and Deputy Under Secretaries for Health with ensuring "...the timely rescission or recertification of policy documents over which their program offices have primary responsibility."<sup>23</sup>

We **substantiate** allegations when the facts and findings support that the alleged events or actions took place. We **do not substantiate** allegations when the facts show the allegations are unfounded. We **cannot substantiate** allegations when there is no conclusive evidence to either sustain or refute the allegation.

We conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

<sup>&</sup>lt;sup>21</sup> VHA Directive 6330(1), *Controlled National Policy/Directives Management System*, June 24, 2016, amended January 11, 2017.

<sup>&</sup>lt;sup>22</sup> VA Under Secretary for Health Memorandum. Validity of VHA Policy Document, June 29, 2016.

<sup>&</sup>lt;sup>23</sup> Ibid.

# **Inspection Results**

#### Issue 1: GYN Quality of Care Issues

#### **Cancelled Consults**

We did not substantiate that a gynecologist "turned away" patients by either cancelling or discontinuing consults from a PC provider. GYN and PC services had a care coordination agreement; however, instructions specific as to when to make a consult referral and pre-work items were not inclusive of all situations. In addition, the "annual" agreement that we reviewed during our 2016 site visit was dated July 9, 2014.

VHA policy that was in effect at the time of the events discussed in this report stated: "specialty [GYN] clinics may not be utilized for routine breast and cervical cancer screening" (CCS) and that CCS will be performed by the patient's PC provider in accordance with VHA guidelines.<sup>24</sup> According to VHA and the 2014 care coordination agreement between GYN and PC, a gynecologist may perform a routine CCS instead of a PC provider if the patient requests a gynecologist and accommodations are made.<sup>25</sup>

VHA requires specific processes to be followed when either cancelling or discontinuing consults. A receiving provider cancels a consult from the sending provider when pre-work is needed before the consult can proceed or the consulting service is no longer available. Generally, a receiving provider discontinues a consult when the consult is received by the wrong or inappropriate service, such as a gynecologist receiving a request to provide routine CCS without a specific request by the patient for a gynecologist. Because this type of consult is a two-way communication process with an alert notification feature, the sending provider is alerted when the receiving provider initiates an action such as canceling or discontinuing the consult. The alert ensures that sending providers are aware of the consult status and can provide appropriate care to the patients.

Of the 10 patients alleged by the complainant to have canceled consults, we determined that two patients' consults were canceled because of the need for additional testing, while eight patients' consults were discontinued because the consult was for routine CCS which should have been provided by the PCP. For the two patients whose 2016

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<sup>&</sup>lt;sup>24</sup> VHA Handbook 1330.01, *Health Care Services for Women Veterans*, May 21, 2010. This Handbook was in effect at the time of the events discussed in this report. It was rescinded and replaced by VHA Directive 1330.01, *Health Care Services for Women Veterans in February 15*, 2017, which contains the following language regarding CCS in specialty GYN clinics: "Specialty gynecology clinics may not be utilized solely for routine breast and cervical cancer screening."

<sup>&</sup>lt;sup>25</sup> Ibid.

<sup>&</sup>lt;sup>26</sup> VHA Memorandum, Under Secretary for Health, *Consult Business Rule Implementation*, (Consult Business Rules) May 23, 2013. VHA Directive 2008-056 and VHA Directive 1232(1) contain the same or similar language regarding canceling and/or discontinuing a consult.

<sup>&</sup>lt;sup>28</sup> VHA Office of Information and Technology Product Development, *Consult/Request Tracking User Manual Version 3.0*, February 2016.

GYN consults were cancelled by the gynecologist because of the need for additional testing, we found that the receiving provider (gynecologist) listed specific instructions for pre-work (additional to the ones listed in the 2014 care coordination agreement) in the cancelled consults. As required by VHA policy, the requested pre-work would need to be completed before the consult could proceed. Pre-work may include additional tests or procedures needed before the gynecologist can suggest a diagnosis and treatment.<sup>29,30</sup> The PC provider would have been notified about the consult cancellations and responsible for addressing the required pre-work with the patients.<sup>31</sup>

For the eight patients whose 2016 GYN consults were discontinued by the gynecologist because the consult request was for routine CCS (reason clearly stated in discontinuation of consult), we determined that there was no additional information in the EHR suggesting that the patient requested a gynecologist. The receiving provider (gynecologist) acted appropriately by discontinuing the consults based on the information in the consult, and this was in accordance with VHA requirements. The patients were not "turned away" because the sending PC provider would have received electronic notifications and provided or arranged for these patients to have routine CCSs.<sup>32</sup>

#### Failure to Order a Diagnostic Procedure

We did not substantiate that a system gynecologist failed to order a required diagnostic procedure.

VHA guidance indicates that, besides procedure algorithms, providers may order diagnostic procedures based on clinical judgment. The patient at issue was seen by a gynecologist who was covering for the patient's regular gynecologist. The patient did not return for a scheduled appointment and did not receive a full exam by the covering gynecologist. Thus, the covering gynecologist did not have the opportunity to fully determine what additional procedures may have been needed or to apply clinical judgment to order diagnostic procedures. The patient subsequently received treatment from both her regular gynecologist and a gynecologist outside of the VHA system.

Once gynecological test results are established, VHA uses the risk and assessment guidelines from the American Society for Colposcopy and Cervical Pathology to determine the next step to be taken for diagnosis and treatment options.<sup>33</sup> These guidelines and algorithms were established to assist decision-making and are not meant

<sup>&</sup>lt;sup>29</sup> VHA Memorandum, Under Secretary for Health, Consult Business Rule Implementation, (Consult Business Rules) May 23, 2013. VHA Directive 2008-056; VHA Directive 1232(1).

<sup>&</sup>lt;sup>30</sup> GCVHCS Memorandum NO 136-06-15, Consultations, July 10, 2015 (Updated GCVHCS Memorandum NO 136-06-16, Internal Consult Management, November 14, 2016).

<sup>&</sup>lt;sup>31</sup> VHA Memorandum, Under Secretary for Health, Consult Business Rule Implementation, (Consult Business Rules) May 23, 2013.

<sup>&</sup>lt;sup>32</sup> Ibid.

<sup>&</sup>lt;sup>33</sup> VHA National Center for Health Promotion and Disease Prevention. http://vaww.prevention.va.gov/CPS/Screening for Cervical Cancer.asp. Accessed April 28, 2017.

to replace clinical judgment by the individual provider.<sup>34</sup> To assess specific test results for CCS, the diagnostic algorithms address two types of atypical<sup>35</sup> glandular<sup>36</sup> cervical cells: endometrial<sup>37</sup> and endocervical.<sup>38</sup>

During a scheduled 2016 visit with her regular gynecologist, a post-menopausal patient (over 35) complained of vaginal bleeding for approximately one week. The patient's CCS showed atypical cells, which were favored to be endocervical.

The patient's regular gynecologist was on leave when the results were published by the pathology lab. The covering gynecologist spoke with the patient about the test results approximately 2 weeks later, at which time the patient requested to be seen by the covering gynecologist. An appointment was made. However, at the appointment, which occurred within a week's time, the patient refused to have a pelvic exam as she The covering gynecologist ordered a pelvic exam for the next appointment in 1–2 weeks with a plan for a hysteroscopy dilation and curettage.<sup>39</sup>

The patient did not return to see the covering gynecologist but, 7 days later, went to see her regular gynecologist who performed a pelvic exam and recommended a colposcopy as the next step to evaluate the cervical abnormalities. After the regular gynecologist performed the colposcopy, the patient was referred to a GYN oncologist outside the VA medical system. Approximately, one month later, the non-VA oncologist did further tests and found atypical endometrial cells. A few months later, the outside GYN oncologist performed a hysterectomy with removal of the ovaries/fallopian tubes.

In the context of the suggested guidelines<sup>40</sup> and the patient's initial test results, a colposcopy procedure would be indicated to rule out cervical cancer before any surgery, such as the hysteroscopic dilation and curettage, was performed. However, the patient did not return to the covering gynecologist for a complete pelvic exam, and, though initial test results were indicative of endocervical cells, without a complete exam, we are uncertain whether the covering gynecologist would have ordered a colposcopy. In

http://vaww.prevention.va.gov/CPS/Screening\_for\_Cervical\_Cancer.asp. Accessed April 28, 2017.

https://www.cancer.gov/types/cervical/pap-hpv-testing-fact-sheet. Accessed June 21, 2017.

<sup>&</sup>lt;sup>34</sup> VHA National Center for Health Promotion and Disease Prevention.

<sup>35</sup> Atypical cells are cells that do not appear normal and the doctor is uncertain about what the cell changes are. https://www.cancer.gov/types/cervical/pap-hpv-testing-fact-sheet. Accessed June 21, 2017. Glandular cervical cells are cells that come from the glands in the walls of the cervix.

https://www.cancer.gov/publications/dictionaries/cancer-terms?cdrid=659607. Accessed June 21, 2017.

Endometrial cells are located in the endometrium (lining of the uterus).

<sup>&</sup>lt;sup>38</sup> Endocervical cells are located in the cervix, <a href="https://www.cancer.gov/types/cervical/pap-hpv-testing-fact-sheet">https://www.cancer.gov/types/cervical/pap-hpv-testing-fact-sheet</a>. Accessed June 21, 2017.

<sup>&</sup>lt;sup>39</sup> In these procedures, the cervix is dilated and the uterine lining is visualized and scraped to evaluate abnormal uterine bleeding and rule out malignancy (biopsy) in post-menopausal women. https://innovativegyn.com/procedures/hysteroscopy/. Accessed July 2017.

<sup>&</sup>lt;sup>40</sup> The American Society for Colposcopy and Cervical pathology GYN algorithm workup guidelines suggest two possible testing paths for women with CCS results that show atypical endometrial or endocervical cells. When atypical endometrial cells are detected, further testing from endometrial and endocervical samplings are suggested. For all other atypical cell results, the algorithm suggests a colposcopy (with endocervical/endometrial sampling if the patient is older than 35 or is at risk for endometrial cancer).

addition, the algorithms are guidance and are not a replacement for clinical judgment by the gynecologist in determining next steps for diagnosis and treatment.<sup>41</sup>

#### Refusal to Perform Tubal Ligations

We did not substantiate that a system gynecologist refused to provide tubal ligations for two patients.

Providers must discuss a treatment's risks and benefits before performing or ordering a treatment or surgery. Therefore, when patients request a tubal ligation, a gynecologist will first discuss the risks and benefits of the procedure. 42,43,44

We reviewed the EHR records of two patients who requested tubal ligations in 2016.<sup>45</sup> The first patient requested a tubal ligation during a visit with a gynecologist who was covering for her regular gynecologist. The covering gynecologist referred the patient back to her regular gynecologist for further discussion. This patient returned to her regular gynecologist, discussed the desire for a tubal ligation, and had a tubal ligation.

According to the EHR review, the second patient discussed a tubal ligation with the gynecologist (who was her regular gynecologist) and the gynecologist performed the procedure the next month.

#### Reordering Medication

We substantiated that a system gynecologist refused to reorder a hormone therapy medication for another gynecologist's patient. However, the medication was a non-emergent one, the gynecologist who was covering for the patient's regular gynecologist had ordered the medication once already, and the patient's regular gynecologist was due back close in time to the second request for the medication. We found it was reasonable for the covering gynecologist to defer to the regular gynecologist on the matter of reordering a long-term hormone therapy medication.

Medical centers are required to have physician coverage for emergency and inpatient acute care services, including diagnosis and treatment (which includes medications);<sup>46,47</sup> however, coverage for non-emergent situations varies and may

<sup>&</sup>lt;sup>41</sup> American Society for Colposcopy and Cervical Pathology, ASCCP Algorithms, August 2014.

<sup>&</sup>lt;sup>42</sup> Informed Consent for elective and emergency surgery, questionnaire study, BJOG, Andrea Akkad et al,

October 2004. http://onlinelibrary.wiley.com/doi/10.1111/j.1471-0528.2004.00240.x/pdf. Accessed June 26, 2017.

<sup>&</sup>lt;sup>43</sup> Obtaining Informed Consent From Patients, Kristina M Cordasco, March 2013, <a href="https://www.ncbi.nlm.nih.gov/books/NBK133402/">https://www.ncbi.nlm.nih.gov/books/NBK133402/</a>. Accessed June 22, 2017.

<sup>&</sup>lt;sup>44</sup> VHA Handbook 1004.01, *Informed Consent for Clinical Treatments and Procedures*, August 14, 2009, revised May 22, 2017.

<sup>&</sup>lt;sup>45</sup> Tubal Ligations are a type of permanent birth control, where the fallopian tubes are cut or blocked (surgically) to permanently prevent pregnancy. <a href="http://www.mayoclinic.org/tests-procedures/tubal-ligation/basics/definition/prc-20020231">http://www.mayoclinic.org/tests-procedures/tubal-ligation/basics/definition/prc-20020231</a>. Accessed June 22, 2017.

<sup>&</sup>lt;sup>46</sup> VHA Directive 1101.05(2), *Emergency Medicine*, September 2, 2016, amended March 7, 2017.

<sup>&</sup>lt;sup>47</sup> VHA Handbook 1101.04, *Medical Officer of the Day*, August 30, 2010.

depend on the covering provider's access to the patient's record and comfort with the non-emergent issue.

The patient at issue had a prescription for ongoing long-term hormonal therapy<sup>48</sup> from her regular gynecologist. The covering gynecologist counseled the patient about using the smallest dose of her hormone over the shortest amount of time and about titrating her off the medication (long-term hormone replacement therapy and risks).<sup>49</sup> In addition, the covering gynecologist agreed to refill the medication for a 4-month time frame with instructions that the patient should contact her regular gynecologist for additional refills. The covering gynecologist declined to refill the prescription shortly before the end of the 4-month time frame and instructed the patient to discuss the continuation of hormonal therapy with her regular gynecologist, who refilled her prescription at the end of the 4-month time frame.

#### **Lack of Procedure Documentation**

We did not substantiate that a gynecologist failed to document GYN procedures correctly.

VHA requires documentation of all patient care activities in the patient's EHR. The entries by VHA staff should be timely, accurate, concise, and complete; however, entries should also be clinically relevant statements concerning the patient.<sup>50</sup>

We reviewed 24 GYN consults and the progress/surgical notes from 9 patient EHRs (time frame for fiscal year 2016). The notes were written by the gynecologist at issue and included procedures such as pelvic exams, intra-uterine device placements, and CCS. Our review found the overall documentation to be timely and sufficiently accurate to recognize the procedure being performed as well as the diagnosis and treatment of the patients.

#### Colposcopy Procedures Performed Incorrectly

We did not substantiate that a system gynecologist failed to use a colposcope to perform colposcopies on two patients.

We conducted interviews with key VHA subject matter experts and reviewed ACOG definitions and facts about the procedure. Colposcopies are typically performed using a magnifying device to better visualize the cervix, vulva, and vagina. The most common

<sup>&</sup>lt;sup>48</sup> The patient had been on this therapy since 2013. Long-term hormonal treatment is the ongoing use of female hormones to replace the ones the body no longer makes after menopause. Replacement is for menopausal symptoms such as hot flashes, and vaginal issues such as dryness, itching and burning. Risks include heart disease, stroke, blood clots, and breast cancer. Since treatment may pose more health risks than benefits in some instances, patients should discuss risks and benefits in their circumstances with their physician. <a href="http://www.mayoclinic.org/diseases-conditions/menopause/in-depth/hormone-therapy/art-20046372">http://www.mayoclinic.org/diseases-conditions/menopause/in-depth/hormone-therapy/art-20046372</a>. Accessed June 29, 2017.

<sup>49</sup> Menopausal Hormone Therapy, US Department of Health and Human Services, NIH, 2005.

<sup>&</sup>lt;sup>49</sup> Menopausal Hormone Therapy, US Department of Health and Human Services, NIH, 2005. https://www.nhlbi.nih.gov/files/docs/pht\_facts.pdf. Accessed June 22, 2017.

<sup>&</sup>lt;sup>50</sup> VHA Handbook 1907.01, Health Information Management and Health Records, March 19, 2015.

magnifying device is called a colposcope. <sup>51,52</sup> In some instances, usually in geographic areas where the colposcope and/or associated equipment are not readily available, the provider may examine the cervix, vulva, and vagina using a solution to enhance visualization, rather than a colposcope. Examination done with the solution rather than a colposcope would not be called a colposcopy. <sup>53</sup>

VHA requires that patient's EHR documentation include clinically relevant statements concerning the patient. In that context, VHA does not require that all specific procedure-related tasks, such as listing all of the equipment used in a procedure (specimen container, tube of lubricant, eight inch swab, and colposcope), be documented in the patient's EHR.<sup>54</sup>

We reviewed the EHRs of the two patients at issue who underwent colposcopy procedures. We found that the gynecologist documented that a colposcopy had been performed, biopsies were obtained, and the biopsies were sent to the laboratory for analysis. The gynecologist did not document a list of the specific equipment (such as the colposcope) used during the procedure; however, the gynecologist told us that to identify issues that may need to be addressed, the colposcopy procedure involved the use of a colposcope.

#### Issue 2: Alleged Failure of a Physician Assistant To Provide Adequate Care

We did not substantiate that a system physician assistant (PA) provided inadequate PC to a patient with medical issues, including hypertension.

We reviewed the specific patient's EHR for calendar year 2016. The PA addressed the patient's medical issues, specifically anemia, hypertension, and edema. The PA adjusted the patient's medication, ordered laboratory tests, and recommended diet and other lifestyle changes. The patient's condition improved with these changes, and the PA continued to monitor and instruct the patient on medications, diet, and lifestyle.

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<sup>&</sup>lt;sup>51</sup> A colposcope is a magnifying instrument designed to facilitate visual inspection of the vagina and cervix. https://www.merriam-webster.com/dictionary/colposcope. Accessed July 7, 2017.

<sup>&</sup>lt;sup>52</sup> Solutions applied to the vaginal/cervix area may also be used to visualize the cervix, vulva and vagina with or without the aid of a magnifying device. In some circumstances, providers may solely use visualization when a colposcope is not available: however, this process is generally performed in geographic areas where equipment like the colposcope is unobtainable. Sanad, Ahmad, MD, Ibrahim, Emad, MD, Gomaa, Wafaey, MD, Evaluation of Cervical Biopsies Guided by Visual Inspection with Acetic Acid, Journal of Lower Genital Tract Disease, January 2014.

http://journals.lww.com/jlgtd/Citation/2014/01000/Evaluation of Cervical Biopsies Guided by Visual.4.aspx. Accessed February 8, 2017.

<sup>&</sup>lt;sup>53</sup> Sanad, Ahmad, MD, Ibrahim, Emad, MD, Gomaa, Wafaey, MD, Evaluation of Cervical Biopsies Guided by Visual Inspection with Acetic Acid, Journal of Lower Genital Tract Disease, January 2014, <a href="http://journals.lww.com/jlgtd/Citation/2014/01000/Evaluation of Cervical Biopsies Guided by Visual.4.aspx">http://journals.lww.com/jlgtd/Citation/2014/01000/Evaluation of Cervical Biopsies Guided by Visual.4.aspx</a>. Accessed February 8, 2017.

<sup>&</sup>lt;sup>54</sup> VHA Handbook 1907.01, *Health Information Management and Health Records*, March 19, 2015.

#### Issue 3: Alleged Lack of Adequate On-Call Care for GYN Surgery Patients

We did not substantiate that patients who received GYN surgery at the system are at risk because the gynecologist performing surgery lived too far away to oversee patients' post-operative care.

VHA medical centers that have inpatient surgical programs must maintain an infrastructure to safeguard patients when surgery is performed.<sup>55</sup>

If surgery is performed at a VA medical center, such as the system, VHA requires post-operative care to be overseen by post-anesthesia care unit (PACU) staff or intensive care unit staff if a PACU is not available during off-hours. VHA medical center leadership must also ensure that post-operative licensed independent medical providers and surgical providers are available in-house or on-call 24 hours a day and 7 days per week to handle post-operative issues. Surgical on-call staff must be available in person within 60 minutes, and medical on-call staff must be available within 15 minutes by telephone or 60 minutes in person. While some specialty care services such as cardiology have on-call requirements for post-operative patients, GYN does not. In addition, medical center surgical infrastructure must provide a means to safely and timely transfer a patient who requires treatment or therapy (including surgery and post-operative treatments) that the medical center is unable to provide. Transfers must be to another medical center with the capacity to provide those needed services.

According to system policies, a surgical patient receives post-operative care in a PACU. The system surgeon writes orders for PACU patients but, at a minimum, one anesthesiologist must be immediately available for PACU patients until they are admitted to another system unit or discharged. The PACU availability coincides with the elective surgery schedule. If a surgery occurs outside of the PACU hours, patients will remain in the operating room or be transferred to the intensive care unit for PACU care. The Chief of Surgery and Chief of Anesthesiology ensure that all surgical and anesthesia providers have the clinical expertise to provide care, and the Chief Nurse for Acute Care ensures that nursing staff have the clinical expertise needed for each unit. If the patient needs care not provided at the system, a provider may transfer the patient to another facility. The transferring provider must certify, in a clinical determination, that the medical benefits for the patient from another facility outweigh the risks of the transfer. Documentation of the clinical determination must include the reason the patient is being transferred and, if the condition is acute, the transfer should occur within 2 hours.

<sup>&</sup>lt;sup>55</sup> VHA Directive 2010-018, *Facility Infrastructure Requirements to Perform Standard, Intermediate, or Complex Surgical Procedures*, May 6, 2010. This Handbook expired May 31, 2015, and has not yet been updated.

<sup>&</sup>lt;sup>56</sup> Ibid.

<sup>&</sup>lt;sup>57</sup> Ibid.

<sup>&</sup>lt;sup>58</sup> Ibid.

<sup>&</sup>lt;sup>59</sup> GCVHCS Memorandum NO. 112-05-15, Post anesthesia Care Unit, April 22, 2015.

<sup>&</sup>lt;sup>60</sup> GCVHCS Memorandum NO 06-02-15, Inter-Facility (VA and Non-VA) Transfer Policy, July 7, 2015.

The Chief of Surgery told us that in-house system surgical staff are available to attend to surgical emergencies 24 hours a day/7 days a week and, in the event a GYN emergency cannot be resolved at the system, the patient would be transferred to Keesler Air Force Base, which is nearby and has a GYN department. The surgical gynecologist confirmed the process described by the Chief of Surgery and added that GYN surgery is elective and only performed on Tuesdays because of the lack of surgical post-operative patient beds. The surgical gynecologist is not required to be on-call but is available to the in-house surgical staff by telephone if questions arise about GYN surgical patients.

We determined that the system process of coverage meets VHA expectations to safeguard patients after surgery and does not require that the gynecologist be on-call when GYN surgery is performed.

#### **Issue 4: Other Findings**

We identified additional issues concerning annual cervical cancer screening; the use of the operating room setting and general anesthesia<sup>61</sup> for a GYN procedure that could have been performed in a clinic setting; poor communication and collaboration between GYN and other system staff and patients; an outdated care coordination agreement; Patient Advocacy Program issues; and a GYN provider's privileges that were not clearly defined.

#### VHA Cervical Cancer Screening Guidelines

While reviewing patient records for cancelled or discontinued consults, we noted that system PC providers did not consistently follow VHA cervical cancer screening guidelines.

VHA guidelines<sup>62</sup> for CCS are based on the March 2012 U.S. Preventive Services Task Force recommendations.<sup>63,64</sup> The frequency of conducting CCS changed from performing yearly Pap screenings to every three years for women age 21–65. Women ages 30–65 can lengthen the screening interval screening to every 5 years (if Pap smears are done in combination with HPV testing). The guidelines recommend

<sup>&</sup>lt;sup>61</sup> General anesthesia patients are unconscious and have no awareness or sensations. Types of available anesthetic drugs include gases or vapors inhaled through a breathing mask or tube and those introduced through a vein. <a href="https://www.asahq.org/whensecondscount/patients%20home/preparing%20for%20surgery/effects%20of%20anesthesia">https://www.asahq.org/whensecondscount/patients%20home/preparing%20for%20surgery/effects%20of%20anesthesia</a>. Accessed April 28, 2017.

<sup>&</sup>lt;sup>62</sup> VHA National Center for Health Promotion and Disease Prevention. http://vaww.prevention.va.gov/CPS/Screening\_for\_Cervical\_Cancer.asp. Accessed April 28, 2017.

<sup>&</sup>lt;sup>63</sup> VHA Patient Care Services Health Promotion and Disease Prevention, *Cervical Cancer Screening*, *Provider Fact* Sheet, June 2013.

<sup>&</sup>lt;sup>64</sup> U.S. Preventive Services Task Force, <u>Screening for Cervical Cancer</u>, March 2012. <a href="https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/cervical-cancer-screening.">https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/cervical-cancer-screening.</a>
Accessed July 7, 2017.

stopping CCS in women at the age of 65 or if the woman has had a hysterectomy or has a life expectancy of less than 10 years.<sup>65</sup>

The reasoning for some of the CCS changes is that cervical cancer does not suddenly develop or progress quickly, so frequent testing is not really needed unless a pre-existing problem exists. In addition, frequent screening may lead to unnecessary GYN procedures that could result in patient discomfort and pregnancy complications.<sup>66</sup>

In seven of eight routine CCS consults, PC providers did not follow the VHA guidelines described in the paragraph above. These patients (who qualified for Pap screenings every 3 years) had undergone a CCS within the previous 3 years, and routine CCSs (screenings not related to abnormal results) were being requested before the 3-year time period had lapsed. We did not find discussion in the EHR regarding a need for annual screening. GYN notes for these patients frequently referenced annual exams and annual Pap screenings. In addition, a system women's health provider confirmed that many system PC providers did not follow VHA CCS guidelines.

#### Loop Electrosurgical Excision Procedures<sup>67</sup> Performed Under General Anesthesia

During our EHR review, we identified that one of the gynecologists had performed a loop electrosurgical excision procedure (LEEP) in the operating room, under general anesthesia. According to system providers, all LEEPs were performed in the system operating room under general anesthesia rather than in an ambulatory setting.

ACOG guidance indicates that gynecologists generally perform LEEPs<sup>68</sup> in a GYN office using local anesthesia. The procedure should only take a few minutes and the risk or possible complication in the first few weeks after the LEEP is heavy bleeding. The VHA Acting Director of Reproductive Health Women's Health Service, Office of Patient Care Services, and the Chair of the National Surgical Advisory Board Committee for GYN informed us that LEEPs are generally done in the ambulatory setting. System medical leadership was unaware that LEEPs were being performed in the system operating rooms and that patients were receiving general anesthesia for these procedures.

<sup>&</sup>lt;sup>65</sup> VHA National Center for Health Promotion and Disease Prevention, http://vaww.prevention.va.gov/CPS/Screening for Cervical Cancer.asp. Accessed April 28, 2017.

<sup>&</sup>lt;sup>66</sup> Xandre, Pamela, Reducing Unnecessary Pap Smears in a Community Clinic: Is the US Still Over-screening for Cervical Cancer? Clinical Nursing Studies: June 2015, Vol 3, No. 4: 53–59.

<sup>&</sup>lt;sup>67</sup> Loop electrosurgical excision procedure is a procedure in which an electrical current passes through a wire loop and is utilized to remove abnormal tissue from the cervix. The procedure is generally performed in an outpatient setting under local anesthesia. <a href="http://www.acog.org/Patients/FAQs/Loop-Electrosurgical-Excision-Procedure-LEEP">http://www.acog.org/Patients/FAQs/Loop-Electrosurgical-Excision-Procedure-LEEP</a>. Accessed June 22, 2017.

<sup>&</sup>lt;sup>68</sup> ACOG Loop Electrosurgical Excision Procedure, <a href="http://www.acog.org/Patients/FAQs/Loop-Electrosurgical-Excision-Procedure-LEEP">http://www.acog.org/Patients/FAQs/Loop-Electrosurgical-Excision-Procedure-LEEP</a>. Medscape, <a href="http://emedicine.medscape.com/article/1998067-overview">http://emedicine.medscape.com/article/1998067-overview</a>. Accessed May 5, 2017.

<sup>&</sup>lt;sup>69</sup>Local anesthesia is the numbing of a part of your body that is undergoing minor surgery or a procedure. Side effects are minimal and usually related to how much anesthesia is injected. American Society of Anesthesiologists, <a href="https://www.asahq.org/whensecondscount/patients%20home/preparing%20for%20surgery/effects%20of%20anesthesia">https://www.asahq.org/whensecondscount/patients%20home/preparing%20for%20surgery/effects%20of%20anesthesia</a>. Accessed May 5, 2017.

When a patient receives general anesthesia for surgery, the patient risks more side effects and recovery issues than when a local anesthesia is used. Side effects for local anesthesia are minimal and usually related to local site reactions or infections, or to how much anesthesia or numbing agent is injected. Side effects and risks for general anesthesia include confusion, hypothermia, nausea, vomiting, delirium, and cognitive dysfunction with a risk of long-term memory loss. Patients also take a longer time to recover or wake up from the sedation that occurs with general anesthesia.<sup>70</sup>

To validate that the system was using general anesthesia for these patients, the system Chief of Surgery reviewed the EHRs of seven patients who underwent LEEPs from July 2015 through August 2016. All of these patients underwent the procedure in the operating room under general anesthesia. The Chief of Surgery informed us he would be reviewing the process.

#### Collaboration/Communication

We identified a lack of communication and collaboration between the two system gynecologists, which resulted in divergent treatment plans and duplicative invasive testing. In addition, we found other examples of ineffective/discourteous communication between the Women's Health Program providers and a system gynecologist as well as communication issues between patients and the same gynecologist.

Effective communication is necessary for the delivery of high quality, safe patient care. To enhance provider/patient communication, The Joint Commission has requirements addressing provider behaviors and provider communication as it relates to establishing and maintaining professional relationships with patients, families, and other members of the health care teams. Provider communication should include sensitivity to diversity and a responsible attitude towards patients and others in the medical profession. VHA guidance recommends a workplace culture that includes civility, respect, and engagement. This workplace process encourages civil and respectful interactions and communication that address problem behaviors and conflicts by direct discussion and collaboration/cooperation. The expected outcome of effective, civil, and respectful

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American Society of Anesthesiologist: Effects of Anesthesia.
 <a href="https://www.asahq.org/whensecondscount/patients%20home/preparing%20for%20surgery/effects%20of%20anesthesia">https://www.asahq.org/whensecondscount/patients%20home/preparing%20for%20surgery/effects%20of%20anesthesia</a>.
 Accessed June 22, 2017.
 The Joint Commission Leadership LD 03.01.01, January 1, 2009. The Joint Commission standards were in effect

<sup>&</sup>lt;sup>71</sup> The Joint Commission Leadership LD 03.01.01, January 1, 2009. The Joint Commission standards were in effect at the time of the events in this report. The leadership standards were updated in July 1, 2017; LD 03.01.01 remained the same; however LD03.04.01 was added and stated that effective communication is an essential tool to prevent a compromise of patient safety and quality of care; the Medical Staff standards changed to include interpersonal communication and professionalism when granting, revising, or revoking privileges (MS 7.01.03), and effective communication (PC.02.01.21) was added to directly address effective provider-patient communication as necessary for safe patient care.

<sup>&</sup>lt;sup>72</sup> The Joint Commission Sentinel Event Alert Issue 40, July 9, 2008: Behaviors that undermine a culture of safety, <a href="https://www.jointcommission.org/assets/1/18/SEA">https://www.jointcommission.org/assets/1/18/SEA</a> 40.PDF. Accessed June 21, 2017.

communication is safe patient care and effective teamwork between providers caring for patients and between providers and their patients.<sup>73</sup>

During our review of patient EHRs, we found two instances of poor communication and collaboration between the two system gynecologists. In one instance, a patient went to a covering gynecologist, and although she was supposed to return to the covering gynecologist, she went to see her regular gynecologist (who had been away). The patient did not return to the covering gynecologist; however, the regular gynecologist did not communicate to the covering gynecologist that he/she had resumed the patient's care. The gynecologists had different plans for the patient, but the patient's EHR did not contain documentation that the gynecologists had discussed the plans. The covering gynecologist discovered that the patient was not returning when he/she received notification that the planned visit with the covering gynecologist was cancelled. Before the visit was canceled, the patient had two different plans, which could have caused confusion about the patient's care and which provider was directing the patient's care.

During the second instance, the patient oscillated between the gynecologists (which was known to both gynecologists as one was covering for the other), and, because one of the gynecologists did not trust the other's initial testing techniques and results, a colposcopy was repeated. Results from both tests were negative; the EHR does not contain documentation that the gynecologists discussed the tests or the initial procedure.

Both instances demonstrated a lack of communication and collaboration between the two GYN providers, which may have caused both confusion and ineffective communication about the patient's care and an unnecessary procedure.

According to a women's health program provider, one gynecologist was "unprofessional" and "rude," and program providers would take measures to avoid the gynecologist. We reviewed a summary of patient complaints pertaining to this GYN provider. Complaints detailed a spectrum of behavior that included rude demeanor, hanging up on a patient, not treating patients with dignity and respect, accepting a personal call during patient care, and insensitivity. These actions by the GYN provider limited patient care discussions between providers as well as with patients, and may have prevented pertinent communication concerning the safe and effective care of patients.

#### Care Coordination Agreement

We determined that the PC/GYN care coordination agreement was outdated. We found that the agreement stated it would be reviewed annually and revised/renewed as necessary. The GYN supervisor also stated that the agreement should be reviewed annually and as necessary. While onsite, we requested the most recent care

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<sup>&</sup>lt;sup>73</sup> VA National Center for Organization Development, *Civility, Respect, and Engagement in the Workplace*, <a href="https://www.va.gov/ncod/crew.asp">https://www.va.gov/ncod/crew.asp</a>. Accessed September 22, 2017.

coordination agreement, and the system provided us with the agreement from 2014. When we requested the agreement again in March 2017, the system provided the 2014 version and a draft 2016 agreement.

#### Patient Advocacy Program

When reviewing patient complaints, we identified that the Patient Advocacy Program managers did not fully utilize the Patient Advocate Tracking System (PATS); specifically, not all complaints were entered into PATS. In addition, we found that not all complaints were tracked to resolution.<sup>74</sup>

VHA requires each VA medical center and/or system to have a Patient Advocacy Program to ensure that patient complaints are resolved in a proactive and timely manner. The VHA also requires full utilization of its web-based PATS to track patient complaints. VHA's goal is to have all complaints entered into PATS, which will provide both VHA medical centers/systems and national leaders with a comprehensive understanding of patient issues and concerns. Service chiefs utilize PATS data to determine quality improvement efforts necessary to improve patient satisfaction. The program of the patient issues and concerns.

According to the Patient Advocacy Program Manager, not all patient complaints were entered into PATS. Complaints that were sent from service level advocates to system level advocates are entered; however patient complaints without service level advocates were not entered. The Patient Advocacy Program Manager also told us that entered complaints did not always include all of the required data, such as resolution. We reviewed PATS complaints from June 2015 through June 2016 and identified six complaints related to women's health and GYN care; four (67 percent) had no documented resolution.

Because the Patient Advocacy Program Manager's regular work duties include oversight of the Patient Advocacy, Patient Centered Care, and Transformational Care Programs, and collateral duties, including responding to congressional inquiries, the manager's time to oversee the Patient Advocacy Program management activities has been limited. Without effective and timely processes to ensure PATS captures all information, including follow-up and resolution, data will not be reflective of trends that may indicate system issues.

#### **GYN Provider Privileges**

We found that a system gynecologist's privileges were not granted in accordance with VHA policy and medical staff bylaws.

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<sup>&</sup>lt;sup>74</sup> VHA Handbook 1003.1, *Key Elements of VHA's Veteran Customer Service Program*, August 6, 2003. This Handbook expired August 31, 2008, and has not yet been updated.

<sup>&</sup>lt;sup>75</sup> VHA Handbook 1003.4, *Patient Advocacy Program*, September 2, 2005. This Handbook expired September 30, 2010 and has not yet been updated.
<sup>76</sup> Ibid.

VHA requires all providers, who are permitted by law to practice medical care and procedures independently, to seek credentialing and privileges at the medical center where they are employed or are providing services. The term "credentialing" refers to the systematic process of screening and evaluating qualifications and other credentials, including, but not limited to: licensure, required education, relevant training and experience, and current competence and health status. Privileging for clinical purposes is defined as the process that allows the provider to provide/perform specific medical or other patient care services within the scope of the individual's license, based on the individual's clinical competence as determined by peer references, professional experience, health status, education, training, and licensure.<sup>77</sup>

According to Section 3.01 of the system Bylaws and Rules of the Medical Staff, qualifications for membership and privileging include current competence that is consistent with the assignment and privileges of the provider.<sup>78</sup> The privileging form includes a requirement that a gynecologist requesting privileges must demonstrate that he/she has provided treatment, such as surgical procedures, in the past 24 months.

We reviewed a gynecologist's request and approval for privileges that had been signed by the gynecologist and system medical leadership, including the gynecologist's supervisor, specifying that the gynecologist had privileges without modification to provide surgical care <sup>79</sup> to patients to correct or treat various conditions, illnesses, and injuries of the female reproductive system. Conversely, we were informed by the Chief of Surgery that, in practice, the gynecologist's privileges were limited because he/she had not performed major surgery for several years.

The Chief of Surgery also informed us that he reviewed the surgery schedule in advance to ensure that the gynecologist at issue was not scheduled to perform major surgery. We did not find evidence that the gynecologist performed major surgery during our review period. However, VHA policy requires that physician privileges accurately reflect the services and procedures that the physician currently has the competence to provide/perform at a facility.

# **Conclusions**

We did not substantiate that a gynecologist turned away patients by cancelling or discontinuing consults made by the PC providers. According to VHA policy, the consult process is a two-way communication between providers, so when a consult is cancelled or discontinued, the provider sending the consult receives an alert notifying him/her of the consult status so the provider can follow up with the patient. The gynecologist's process to cancel or discontinue the consults was performed as required by VHA and was consistent with VHA CCS guidance.

<sup>&</sup>lt;sup>77</sup> VHA Handbook 1100.19, Credentialing and Privileging, October 15, 2012.

<sup>&</sup>lt;sup>78</sup> GCVHCS Bylaws and Rules of the Medical Staff of the GCVHCS, 2015.

<sup>&</sup>lt;sup>79</sup> This is not the surgical gynecologist described in Issue 3.

We did not substantiate that a system gynecologist failed to order a required diagnostic procedure. The patient did not return to the gynecologist for her complete examination, and the gynecologist did not have the opportunity to determine whether additional diagnostic procedures were needed, in accordance with VHA guidance and/or clinical judgment of the issues. The patient visited her regular gynecologist and eventually received treatment from a non-VA gynecologist.

We did not substantiate that a system gynecologist refused to provide tubal ligations for two patients. Both patients were counseled appropriately and had the procedure.

We substantiated that a system gynecologist did not reorder a medication for another gynecologist's patient. However, the medication was not emergent, and we found it was reasonable for the covering gynecologist to defer to the regular gynecologist on the matter of reordering long-term hormone therapy medication.

We did not substantiate a lack of documentation by a gynecologist after a procedure because the gynecologist's notes had the required information to describe and identify the patient's procedure, diagnosis, and treatment. In addition, we did not substantiate that a gynecologist failed to use a colposcope during colposcopies. Documentation indicated that colposcopies were performed correctly as biopsies were taken and submitted for review.

We did not substantiate that a system physician assistant provided inadequate PC, or that on-call practices for gynecology surgical patients were inadequate. Our review of the PC patient's medical record showed that the system physician assistant provided adequate care. Our review of the system's on-call practices showed that the system had a process to cover surgical patients that met VHA expectations and requirements.

We identified several other issues:

- PC providers did not always follow VHA guidelines for CCS;
- LEEPs were performed in the operating room with general anesthesia;
- Communication and collaboration was lacking between gynecologists and other system providers and between providers and patients;
- A care coordination agreement was outdated;
- The Patient Advocacy Program was not tracking complaints as required by VHA;
   and
- One gynecologist's privileges were not in compliance with system-required experience to perform surgical procedures.

We made six recommendations.

# Recommendations

- 1. We recommended that the System Director ensure that system primary care providers receive education on Veterans Health Administration cervical cancer screening guidelines and that supervisors monitor compliance.
- 2. We recommended that the System Director review and evaluate the routine use of general anesthesia for loop electrosurgical excision procedures conducted in the operating room and take action as appropriate.
- 3. We recommended that the System Director utilize Veterans Health Administration resources to promote a culture that discourages behaviors that undermine safe patient care and effective communication and collaboration between providers and between providers and patients.
- 4. We recommended that the System Director ensure that care coordination agreements between primary care and gynecology services meet system annual review requirements.
- 5. We recommended that the System Director ensure that Patient Advocacy Program managers enter all complaints into the Patient Advocacy Tracking System database and track all reported complaints to resolution.
- 6. We recommended that the System Director ensure that system gynecologists have current privileges that meet Veterans Health Administration and system policy requirements.

## **Prior OIG Reports**

## System Reports

VA's Federal Information Security Modernization Act Audit for Fiscal Year 2015

3/15/2016 | 15-01957-100

Combined Assessment Program Review of the Gulf Coast Veterans Health Care System, Biloxi, Mississippi

1/20/2015 | 14-04214-70

Review of Community Based Outpatient Clinics and Other Outpatient Clinics of Gulf Coast Veterans Health Care System, Biloxi, Mississippi 1/12/2015 | 14-04380-79

Healthcare Inspection – Community Living Center Patient Care, Gulf Coast Veterans Health Care System, Biloxi, Mississippi 5/28/2014 | 14-01119-168

**Audit of the Community Nursing Home Program** 3/29/2013 | 11-00331-160

Healthcare Inspection – Alleged Quality of Care and Problems with Services, VA Gulf Coast Veterans Health Care System, Biloxi, Mississippi 3/19/2013 | 12-02612-141

### **Topic Related Reports**

**Review of VHA Care and Privacy Standards for Women Veterans** 6/19/2017 | 15-03303-206

OIG reports are available on our web site at www.va.gov/oig.

# **VISN Director Comments**

# **Department of Veterans Affairs**

# **Memorandum**

- Date: October 27, 2017
- From: Director, South Central VA Health Care Network (10N16)
- Healthcare Inspection— Alleged Women's Health Care Issues, Gulf Coast Veterans Health Care System, Biloxi, Mississippi
- Director, Bedford Office of Healthcare Inspections (54BN)
  Director, Management Review Service (VHA 10E1D MRS Action)
  - 1. The South Central VA Health Care Network (VISN 16) has reviewed and concurs with the responses submitted by the Gulf Coast Veterans Health Care System, Biloxi, MS, regarding the Alleged Women's Health Care Issues Draft Report.

Skye McDougail, PhD

Director, South Central VA Health Care Network (10N16)

(original signed by Shannon C. Novotny, MPA, FACHE)

# **System Director Comments**

# Department of Veterans Affairs

# **Memorandum**

- Date: October 24, 2017
- From: Interim Director, Gulf Coast Veterans Health Care System (520/00)
- Healthcare Inspection—Alleged Women's Health Care Issues, Gulf Coast Veterans Health Care System, Biloxi, Mississippi
- Director, South Central VA Health Care Network (10N16)
  - 1. Gulf Coast Veterans Health Care System has reviewed and concurs with this Health Inspection report.
  - We recognize the opportunities for improvements in our practice and corrective actions have been implemented to address the recommendations

M. Christopher Saslo, DNS, ARNP-BC, FAANP

Interim Director, Gulf Coast Veterans Health Care System

# **Comments to OIG's Report**

The following Director's comments are submitted in response to the recommendations in the OIG report:

#### **OIG Recommendations**

**Recommendation 1.** We recommended that the System Director ensure that System primary care providers receive education on Veterans Health Administration cervical cancer screening guidelines and that supervisors monitor compliance.

#### Concur

Target date for completion: January 31, 2018

System response: The Director will ensure that identified health care providers in Primary Care, Gynecology and Women's Health at Gulf Coast Veterans Health Care System receive education on Veterans Health Administration cervical cancer screening guidelines. To ensure compliance, random audits of training records and/or training attendance rosters will be conducted to ensure the education has been completed. The threshold for compliance will be 90% or greater of targeted staff will complete the required education.

**Recommendation 2.** We recommended that the System Director review and evaluate the routine use of general anesthesia for loop electrosurgical excision procedures conducted in the operating room and take action as appropriate.

#### Concur

Target date for completion: November 2, 2017

System response: In June 2017, the Chief of Surgical Service conducted an evaluation and determined loop electrosurgical procedures could be safely performed outside the operating room in an outpatient setting. As such, he provided direction to both the staff gynecologist of the change, and followed that direction with a memorandum. Since that time there have been no loop electrosurgical excisions performed in the operating room.

**Recommendation 3.** We recommended that the System Director utilize Veterans Health Administration resources to promote a culture that discourages behaviors that undermine safe patient care and effective communication and collaboration between providers and between providers and patients.

#### Concur

Target date for completion: January 31, 2018

System response: Leadership at Gulf Coast Veterans Health Care System recognizes the value of open communication and collegiality in the workplace. On July 18, 2017, the Chief of Surgery met with one of the staff gynecologist to discuss conduct and provided advisement on the need to work collaboratively with peers and reinforced that continued disruptive behavior would not be tolerated. In addition, the Director supports continuous staff training in the area of 'Just Culture' and on the principles of 'Stop The Line'. Currently, such training is being offered in a variety of different settings to include New Employee Orientation, and Annual Review. To further promote and demonstrate a commitment to safe patient care and effective communication/collaboration amongst staff, a new station memorandum on 'Just Culture' is being developed by Patient Safety. As an adjunct, the Director will also dedicate a segment of his facility wide video blog to discussing positive culture, patient safety and workplace collegiality.

**Recommendation 4.** We recommended that the System Director ensure that care coordination agreements between primary care and gynecology services meet System annual review requirements.

#### Concur

Target date for completion: December 31, 2017

System response: The Director and the Chief of Staff will ensure that the care coordination agreements between Primary Care and Gynecology are reviewed annually (no later than November 30<sup>th</sup> each fiscal year) by Primary Care Leadership and Surgery Service to determine that they meet all necessary requirements. The approved agreement will be submitted to the Executive Committee of the Medical Staff thereafter as a matter of record.

**Recommendation 5.** We recommended that the System Director ensure that Patient Advocacy program managers enter all complaints into the Patient Advocacy Tracking System database and track all reported complaints to resolution.

#### Concur

Target date for completion: December 31, 2017

System response: The Director will ensure that all patient complaints are entered into the Patient Advocacy Tracking System database and tracked to resolution. This will include complaints from Services with a Service-level advocate as well as those who do not have a Service-level advocate. Routine reporting on the status of all complaints (e.g., open/unresolved, pending resolution, closed/resolved) will be made to facility leadership by Community & Public Affairs (Patient Advocate's Office) starting in November 2017 as a means of tracking compliance.

**Recommendation 6.** We recommended that the System Director ensure that System gynecologists have current privileges that meet Veterans Health Administration and System policy requirements.

#### Concur

Target date for completion: January 31, 2018

System response: The Director will ensure that system gynecologists have current privileges that meet Veterans Health Administration and system policy requirements. A review and updating of gynecological privileges has been initiated by the Chief of Surgery Service, the Chief of Staff's Office and the Professional Credentials Office. The new privileges are more detailed and better outline the clinical practice, as well as the site of practice, for gynecological providers. Once the new privileges are finalized and approved, current gynecological providers will be transitioned to the new set.

#### Appendix D

# **OIG Contact and Staff Acknowledgments**

Contact	For more information about this report, please contact the OIG at (202) 461-4720.
Inspection Team	Nancy Barsamian, RN, MPH, Team Leader Elaine Kahigian, RN, JD, Project Leader Robin Moyer, MD Clarissa Reynolds, CNHA, MBA Debra Zamora, RN, DNP
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Appendix E

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#### **VA Distribution**

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