



Office of Inspector General

Office
202.692.2900
[Website](#)
[OIG Reports](#)

Hotline
202.692.2915 | 800.233.5874
[Online Contact Form](#)
OIG@peacecorpsig.gov

To: Carol Spahn, Chief Executive Officer
Emily Haimowitz, Chief Compliance Officer

From: Joaquin Ferrao, Acting Inspector General *Joaquin Ferrao*

Date: June 29, 2022

Subject: Management Advisory Report: Peace Corps (b) (6), (b) (7)(C) Medical Case Review (IG-22-03-SR)

The purpose of this report is to bring to your attention needed improvements that the Office of Inspector General identified in the provision of medical care to Volunteers.

Our report makes five recommendations to improve the agency's actions regarding quality of care, clinical escalation, facility assessments, clinical documentation, and patient safety event reporting. The agency response to the report will be included in Appendix A.

Background

On (b) (6), (b) (7)(C), returned Peace Corps Volunteer (RPCV) (b) (6), (b) (7)(C), reported concerns to Peace Corps Office of Inspector General (OIG) regarding the quality of the medical care (b) (6), (b) (7)(C) received while serving in Peace Corps (b) (6), (b) (7)(C) from 2016-2018. In February 2021, OIG initiated a review of RPCV (b) (6), (b) (7)(C) medical care. This review was conducted as a collaboration between OIG's Evaluation and Investigation Units. This Management Advisory Report represents the evaluative portion of the review.

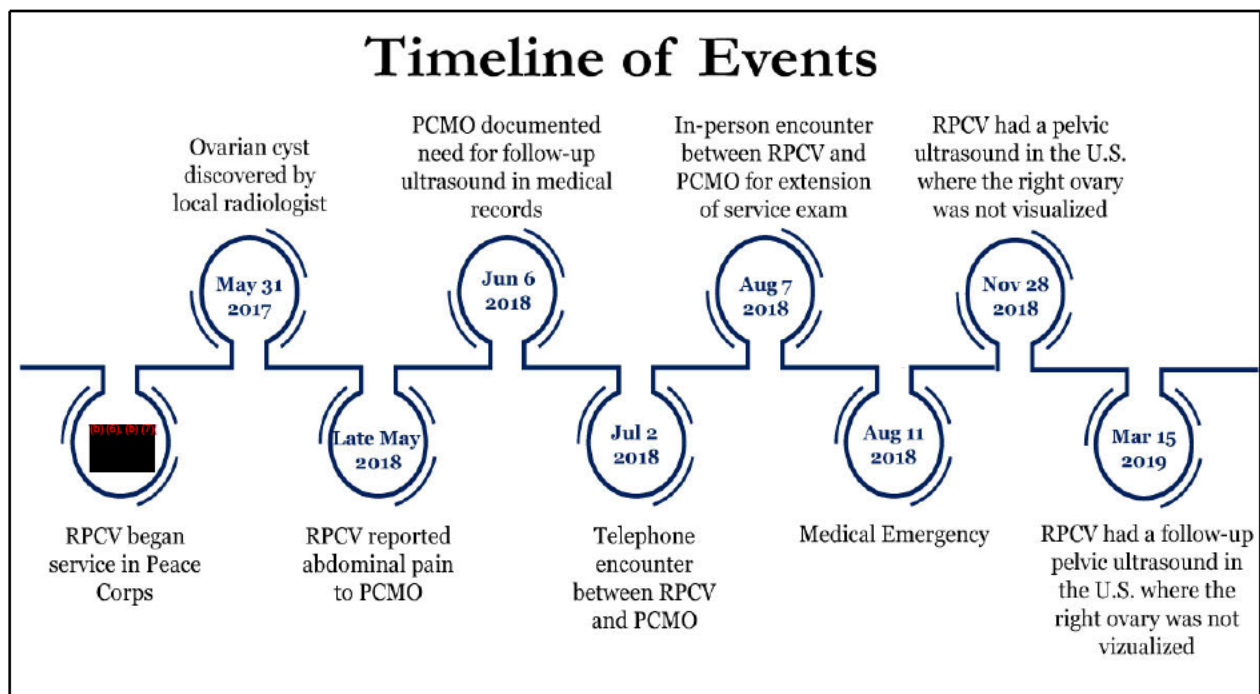
Timeline of Events

RPCV (b) (6), (b) (7)(C) started (b) (6), (b) (7)(C) service in (b) (6), (b) (7)(C) on (b) (6), (b) (7)(C). On May 31, 2017, (b) (6), (b) (7)(C) received an ultrasound during which the radiologist discovered a right ovarian cyst¹. RPCV (b) (6), (b) (7)(C) had a gynecological consult on June 1, 2017, and the local provider prescribed (b) (6), (b) (7)(C) medication but did not document recommending follow-up ultrasounds. According to RPCV (b) (6), (b) (7)(C), during the close of service ceremony in late May 2018, (b) (6), (b) (7)(C) reported sharp abdominal pain (7 out of 10) and nausea to the Peace Corps Medical Officer (PCMO). The Peace Corps' medical record contains a note that, during a phone call, RPCV (b) (6), (b) (7)(C) reported abdominal pain to the PCMO on June 6, 2018, and that a pelvic ultrasound was scheduled for June 16, 2018. According to RPCV (b) (6), (b) (7)(C) in late June 2018, (b) (6), (b) (7)(C) again reported acute abdominal pain (8 or 9 out of 10) to the PCMO and was reportedly told that (b) (6), (b) (7)(C) could see a specialist once (b) (6), (b) (7)(C) went to (b) (6), (b) (7)(C) for (b) (6), (b) (7)(C), which was scheduled for August 2018. According to the PCMO, RPCV (b) (6), (b) (7)(C) did not want to come back to the capital for the follow-up ultrasound because (b) (6), (b) (7)(C) pain level did not warrant the trip, though this was not reflected in RPCV (b) (6), (b) (7)(C) medical record. RPCV

¹ RPCV (b) (6), (b) (7)(C) cyst was identified as being multiloculated with thick walls

(b) (6), (b) (7)(C) medical record documented a telephone encounter on July 2, 2018, where (b) (6), (b) (7)(C) reported six days of diarrhea which the PCMO presumed was infectious in origin. On August 7, 2018, (b) (6), (b) (7)(C) was evaluated by the PCMO as part of an extension of her Peace Corps service. The record of that visit reflected that (b) (6), (b) (7)(C) did not have abdominal pain or gynecologic issues.

On August 11, 2018, RPCV (b) (6), (b) (7)(C) experienced severe abdominal pain. (b) (6), (b) (7)(C) reported severe abdominal pain (9 out of 10) and vomiting to the PCMO. The PCMO escalated the case to the RMO on August 11, 2018. (b) (6), (b) (7)(C) was admitted to the local hospital on August 11, 2018 and local providers performed a CT scan and detected a large (11.6 cm) ovarian cyst. RPCV (b) (6), (b) (7)(C) was admitted to a second hospital later that day, where the local gynecologist diagnosed torsion of the ovary and performed surgery to remove the ovarian cyst. The surgical procedure note did not clearly document whether the right ovary was excised or left in place. Both the PCMO and RPCV (b) (6), (b) (7)(C) reported that RPCV (b) (6), (b) (7)(C) was told the right ovary had been saved.



Subsequently, RPCV (b) (6), (b) (7)(C) returned to the United States (U.S.) where (b) (6), (b) (7)(C) had a pelvic ultrasound on November 28, 2018, in which the right ovary was not visualized, and the provider reported that it may be “surgically absent.” On March 15, 2019, RPCV (b) (6), (b) (7)(C) received a follow-up pelvic ultrasound that did not visualize the right ovary. Our external medical consultant determined two possibilities existed for not visualizing the right ovary, either it was removed during the surgery or because of the ovarian torsion, the ovary necrosed or atrophied after the surgery. In RPCV (b) (6), (b) (7)(C) case, based on available medical records and the pathology report, our external medical consultant concluded the ovary was removed during the surgery.

What We Found

The PCMO who treated RPCV (b) (6), (b) (7)(C) did not follow the OHS standard of care

Office of Health Services (OHS) staff reported to OIG that PCMOs should follow the standard of care outlined in UpToDate, an online database which contains clinical guidelines that are based on a U.S. standard of care. UpToDate recommended,² for patients such as RPCV (b) (6), (b) (7)(C) monitoring ovarian cysts by conducting ultrasounds at three and nine months after diagnosis. UpToDate also recommended removing a large cyst laparoscopically as it posed a risk of torsion. RPCV (b) (6), (b) (7)(C) ovarian cyst was detected on May 31, 2017, but (b) (6), (b) (7)(C) did not receive follow-up ultrasounds to monitor the cyst at three and nine months after it was diagnosed. We found that this PCMO was not aware of the clinical guidelines in UpToDate, stating that, “The guidelines were to follow it up annually.” According to RPCV (b) (6), (b) (7)(C) medical record, on June 6, 2018, more than a year after the cyst was discovered, the PCMO recommended a follow-up ultrasound after RPCV (b) (6), (b) (7)(C) reported abdominal pain, but this ultrasound never took place.

Our external medical consultant reported that symptoms of ovarian torsion include mild to severe pelvic or abdominal pain and that some women experience intermittent, transient, episodes of abdominal pain days or months leading up to hospitalization for ovarian torsion. Furthermore, our external medical consultant stated, had the pelvic ultrasound recommended by the PCMO on June 6 [2018] been completed, it might have shown a large ovarian cyst, and elective surgery in (b) (6), (b) (7)(C) or another country could have been considered. On August 11, 2018, RPCV (b) (6), (b) (7)(C) cyst was measured at 11.6 cm. According to our external medical consultant, surgical removal may be considered for large (>10 cm), symptomatic ovarian cysts. We concluded that a follow-up ultrasound conducted according to the standard of care, outlined in UpToDate, may have detected a large ovarian cyst and steps could have been taken to remove it before RPCV (b) (6), (b) (7)(C) experienced a medical emergency in (b) (6), (b) (7)(C). Undergoing a surgical procedure in (b) (6), (b) (7)(C) posed elevated risks. In OHS’s (b) (6), (b) (7)(C) assessment, staff noted that the (b) (6), (b) (7)(C) in (b) (6), (b) (7)(C)³ “decimated the entire health care infrastructure of the country.”⁴

We recommend:

1. That OHS take steps to improve PCMOs’ review and awareness of UpToDate to improve quality of care when treating Volunteers.

² For premenopausal patients with low-risk masses as published in Up-To-Date Management of an adnexal mass from Jan 13, 2020.

³ The (b) (6), (b) (7)(C) in (b) (6), (b) (7)(C) occurred between (b) (6), (b) (7)(C) and (b) (6), (b) (7)(C).

⁴ The poor state of (b) (6), (b) (7)(C) healthcare infrastructure has been documented by numerous international organizations including the United Nations and World Health Organization.

The PCMO did not escalate RPCV (b) (6), (b) (7)(C) case in accordance with Peace Corps medical technical guidelines

The Peace Corps' Clinical Escalation Policy (TG 212) requires PCMOs to consult with the Regional Medical Officer for any condition likely to require emergency surgery or hospitalization. According to UpToDate,⁵ patients with ovarian cysts are at risk for torsion of the ovary or fallopian tube, which requires urgent surgical intervention. We found that the PCMO who treated RPCV (b) (6), (b) (7)(C) should have escalated RPCV (b) (6), (b) (7)(C) condition earlier to the RMO. The PCMO escalated the case to OHS on the day of the surgery, but not when RPCV (b) (6), (b) (7)(C) reported pain two months before the medical emergency occurred. The OHS staff we interviewed reported that RPCV (b) (6), (b) (7)(C) case should have been escalated when (b) (6), (b) (7)(C) reported pain, because it could have indicated an ovarian torsion. We determined that the PCMO was not fully aware of Peace Corps' escalation policy, telling OIG that even though RPCV (b) (6), (b) (7)(C) reported pain it was not to a point that (b) (6), (b) (7)(C) thought it required escalation. Had the PCMO consulted with the RMO, the need to conduct a follow-up ultrasound might have been emphasized. As we explained in the previous finding, had the standard of care been followed, a follow-up ultrasound after RPCV (b) (6), (b) (7)(C) reported pain might have shown a large ovarian cyst, and removal in (b) (6), (b) (7)(C) or another country could have been considered.

We recommend:

- 2. That OHS improve implementation of and PCMOs' awareness of the clinical escalation policy.**

RPCV (b) (6), (b) (7)(C) had surgery in a facility that had not been assessed according to the policy because OHS's oversight of the post was ineffective

According to TG 204, the PCMO will visit and assess all hospitals, clinics and private doctors that have been selected to provide care to Volunteers a minimum of once every three years. We found the PCMOs in Peace Corps/ (b) (6), (b) (7)(C) never visited or assessed the facility where RPCV (b) (6), (b) (7)(C) had surgery on August 11, 2018 prior to (b) (6), (b) (7)(C) surgery. We determined that OHS's oversight of medical resource assessments in Peace Corps/ (b) (6), (b) (7)(C) was ineffective because their process did not result in corrective action. OHS conducted an in-country assessment of the health unit in (b) (6), (b) (7)(C) in (b) (6), (b) (7)(C) and found that local medical resources were in the process of being reassessed. However, three years later in (b) (6), (b) (7)(C) when OHS conducted another in-country assessment, staff had still not completed their assessments of local medical resources according to the policy. Given the requirement to assess facilities once every three years, the facility where (b) (6), (b) (7)(C) had emergency surgery in 2018 should have been assessed at least once between OHS's 2016 and 2019 assessments. Consequently, Peace Corps staff subjected RPCV (b) (6), (b) (7)(C) to

⁵ Management of an adnexal mass, 1/13/2020.

unnecessary risk because they had not predetermined where (b) (6), (b) (7)(C) could go for surgery while (b) (6), (b) (7)(C) was experiencing a medical emergency.

We recommend:

- 3. That OHS develop a process to ensure recommendations from their health unit assessments are addressed.**

The PCMO did not follow agency guidelines when documenting RPCV (b) (6), (b) (7)(C) case

Peace Corps' medical technical guideline on clinical documentation (TG 113) stated that all routine patient encounters must address unresolved problems from previous visits. The PCMO recorded RPCV (b) (6), (b) (7)(C) need for a follow-up ultrasound during a phone consult on June 6, 2018, but the ultrasound was not conducted. The PCMO had two subsequent encounters with RPCV (b) (6), (b) (7)(C) but RPCV (b) (6), (b) (7)(C) medical record does not include any documentation from those encounters that confirms the PCMO raised the need for a follow-up ultrasound to RPCV (b) (6), (b) (7)(C) or explains why the follow-up ultrasound was not completed.

According to TG 113, the PCMO Support Unit periodically reviewed a sample of charts from new PCMOs and scored them for completeness. The guideline stated that scores below 90 percent do not meet the standard. At the time, the guideline stated that a PCMO may be placed on remediation for scoring below the standard, but this was not required. We reviewed the chart review scores for the new PCMO who treated RPCV (b) (6), (b) (7)(C) who was hired in (b) (6), (b) (7)(C), and found that only one of the chart review scores met the standard in the first half of 2018. We determined that Peace Corps' policy did not provide sufficient controls for new PCMOs who did not meet Peace Corps' clinical documentation standards.

If Peace Corps policy had included sufficient clinical oversight for new PCMOs who did not meet the agency's clinical documentation standards, RPCV (b) (6), (b) (7)(C) ultrasound might not have been missed. As noted above, had the pelvic ultrasound recommended by the PCMO on June 6, 2018 been completed, it might have shown a large ovarian cyst, and removal in (b) (6), (b) (7)(C) or another country could have been considered before RPCV (b) (6), (b) (7)(C) experienced a medical emergency.

We recommend:

- 4. That OHS update the clinical documentation review guidelines to increase controls on new PCMOs who do not meet clinical documentation standards.**

OHS did not identify and report deficiencies in care that the PCMO provided to RPCV

(b) (6), (b) (7)(C)

The Peace Corps' medical technical guideline 167 describes the process for reporting and investigating a patient safety event, which is an event that could have or did result in harm to a patient, including a deviation from the standard of care. The guideline states that the staff member who identifies an event is responsible for reporting the event to OHS's quality improvement unit. We established in a previous finding, that the PCMO deviated from the standard of care in RPCV (b) (6), (b) (7)(C) case by not conducting follow-up ultrasounds to monitor the cyst; however, this was not reported as a patient safety event even though OHS reviewed (b) (6), (b) (7)(C) case on multiple occasions.

We determined that RPCV (b) (6), (b) (7)(C) case was not reported as a patient safety event because Peace Corps' patient safety event reporting process was ineffectively implemented. This is not the first time that OIG identified issues surrounding Peace Corps' patient safety policy. In 2016, OIG found that Peace Corps' patient safety policy was not effectively implemented.⁶ The Peace Corps reported two patient safety events pertaining to RPCV (b) (6), (b) (7)(C) surgery; however, both related to local providers as opposed to the care that the Peace Corps provided to RPCV (b) (6), (b) (7)(C). Although OHS reviewed RPCV (b) (6), (b) (7)(C) case on numerous occasions following (b) (6), (b) (7)(C) surgery, they failed to identify a clear patient safety event when the PCMO did not follow-up on the ultrasounds that RPCV (b) (6), (b) (7)(C) required, according to the standard of care. If Peace Corps staff were appropriately focused on proactively identifying and reporting patient safety events, the PCMO's deviation from the standard of care should have been reported and addressed. By not identifying the patient safety event, the quality improvement unit was not able to make recommendations for improvement that might prevent similar issues from occurring in the future.

We recommend:

5. That OHS improve identification and reporting of patient safety events.

Conclusion

OIG's review of the medical care provided to RPCV (b) (6), (b) (7)(C) highlighted several systemic issues in Peace Corps' implementation of their policies which ultimately contributed in RPCV (b) (6), (b) (7)(C) not receiving the follow up medical care that (b) (6), (b) (7)(C) needed. Follow up medical care was particularly important in a country such as (b) (6), (b) (7)(C). The lack of high-quality medical services in (b) (6), (b) (7)(C) posed a risk to Volunteer health in the event of a medical emergency, such as the one

⁶ [Follow-Up Evaluation of Issues Identified in the 2010 Peace Corps/Morocco Assessment of Medical Care pg. 14 \(patient safety was formerly called sentinel events\).](#)

RPCV (b) (6), (b) (7)(C) experienced. Our review includes five findings and recommendations which if implemented, should improve future provision of medical care to Volunteers.

cc: Victor Sloan, Associate Director, Office of Health Services
James Golden, Deputy Director, Office of Health Services
Sam Stebbins, Medical Director, Office of Health Services
Donna Richmond, Chief Quality Improvement Officer, Office of Health Services
Dave Noble, Chief of Staff
Kristin Wells, General Counsel
(b) (6), (b) (7)(C), Expert Advisor to the Chief Compliance Officer

Appendix A: Agency Response to the Management Advisory Report



MEMORANDUM

To: Joaquin Ferrao, Acting Inspector General

Through: Emily Haimowitz, Chief Compliance Officer

EMILY
HAIMOWITZ

Signature

From: Carol Spahn, Chief Executive Officer

Spahn, Carol

Signature

Date: May 6, 2022

CC: Dave Noble, Chief of Staff
Carl Sosebee, Senior Advisor to the Director
Kristin Wells, General Counsel
Victor Sloan, Associate Director, Office of Health Services
James Golden, Deputy Associate Director, Office of Medical Services
Samuel Stebbins, Director of Medical Services, Office of Health Services
Donna Richmond, Chief, Quality Improvement & Education Training, Office of Health Services
(b) (6), (b) (7)(C), International Health Coordinator, Office of Health Services
(b) (6), (b) (7)(C), International Health Coordinator, Office of Health Services
(b) (6), (b) (7)(C), Associate General Counsel, Office of the General Counsel
(b) (6), (b) (7)(C), Intermittent Expert, Office of the General Counsel
(b) (6), (b) (7)(C), Advisor to the Chief Compliance Officer

Subject: Agency Response to the Management Advisory Report on the Peace Corps (b) (6), (b) (7)(C)
Medical Case Review (IG-22-03-SR)

Thank you for the Management Advisory Report, "Peace Corps (b) (6), (b) (7)(C) Medical Case Review IG-22-03-SR" hereinafter "MAR." The Office of Inspector General's (OIG) MAR raises important issues for our attention and we appreciate the opportunity to respond. Our response outlines several areas of improvements we plan to make to enhance processes moving forward, in addition to areas where we've made progress since this incident in 2017 and 2018. The Peace Corps deeply regrets the Volunteer's medical experience and the potential long-term impacts.

There are a number of issues and conclusions in the MAR that deserve specific attention. Before responding to the specific recommendations in the MAR, the agency wishes to address (1) clinical standards of care for ovarian cysts, (2) clinical documentation concerns, and (3) actions taken by the Office of Health Services (OHS) to enhance its oversight and operations.

I. Clinical Standards of Care for Ovarian Cysts

The MAR states on page 3 the following:

Office of Health Services (OHS) staff reported to OIG that PCMOs should follow the standard of care outlined in UpToDate, an online database which contains clinical guidelines that are based on a U.S. standard of care. UpToDate recommended, for patients such as RPCV (b) (6), (b) (7)(C) monitoring ovarian cysts by conducting ultrasounds at three and nine months after diagnosis.

UpToDate is a repository of articles, clinical guidelines, research, and expert opinions, and describes itself as an evidence-based clinical decision support tool. It is accurate that UpToDate identifies undisputed standards when such undisputed standards exist. However, UpToDate more generally pulls together relevant information that allows clinicians to better apply evidence to the unique situations of their patients. OHS also uses evidence and information available from other sources such as the Centers for Disease Control and Prevention and professional medical associations in determining appropriate care for Volunteers. Peace Corps Medical Officers (PCMO) are licensed and credentialed professionals who are expected to exercise independent decision making based on a combination of their clinical expertise, professional judgment, and the evidence available from a variety of sources.

The MAR concludes definitively that conducting ultrasounds for ovarian cysts at three and nine months after diagnosis is a universally agreed upon standard of care. The determination is based on an expert opinion from UpToDate published 32 months after the Volunteer's ovarian cyst was identified. However, there is no agreed upon *single standard of care* for monitoring ovarian cysts. A recent expert opinion in UpToDate titled *Approach to the patient with an adnexal mass*, dated February 22, 2022 notes that:

Surveillance typically includes one or more pelvic ultrasounds and/or measurement of serum tumor markers; however, there is no consensus regarding the best approach and various surveillance frequencies have been described. [Emphasis supplied.]

Additionally, both the American College of Obstetricians and Gynecologists and the Society of Radiologists in Ultrasound indicate that the ideal interval for ultrasound follow-up of ovarian cysts is undefined. The Agency believes that the American College of Obstetricians and Gynecologists is one of the most authoritative sources for care related to ovarian cysts.

The Agency references the American College of Obstetricians and Gynecologists, Practice Bulletin, (Number 174, November 2016) titled, *Evaluation and Management of Adnexal Masses*. The purpose of this Practice Bulletin is described as follows:

Adnexal masses (ie, masses of the ovary, fallopian tube, or surrounding tissues) commonly are encountered by obstetrician–gynecologists and often present diagnostic and management dilemmas. Most adnexal masses are detected incidentally on physical examination or at the time of pelvic imaging. Less commonly, a mass may present with symptoms of acute or intermittent pain. Management decisions often are influenced by the age and family history of the patient. Although most adnexal masses are benign, the main goal of the diagnostic evaluation is to exclude malignancy.

In the Practice Bulletin, it states:

*Repeat ultrasound imaging is recommended whenever the diagnosis is uncertain and when cancer remains within the differential diagnoses. **The ideal interval and duration for ultrasound follow-up has yet to be defined.** However, in one study, masses that were monitored and eventually diagnosed as malignancies all demonstrated growth by 7 months. **Some experts recommend limiting observation of stable masses without solid components to 1 year, and stable masses with solid components to 2 years.** [Emphasis supplied.]*

The Agency also references the Society of Radiologists in Ultrasound consensus statement from 2010 titled, *Management of Asymptomatic Ovarian and Other Adnexal Cysts Imaged at US*. That document generally documents the lack of definitive timeframes for follow-up imaging of ovarian cysts, and the need to tailor follow-up ultrasounds to a patient's specific presentation. The consensus statement indicates that an annual ultrasound is a reasonable course of action. According to the consensus statement, it would also have been reasonable for the PCMO, who first incidentally-identified the ovarian cyst, to have considered a follow-up ultrasound at 6 to 12 weeks after identification.

The OIG's external, independent medical expert also identified both the American College of Obstetricians and Gynecologists Practice Bulletin and the Society of Radiologists in Ultrasound consensus statement as the relevant standards of care for this case. The OIG's expert did not identify a standard of care which supports the Peace Corps OIG's definitive conclusion that conducting ultrasounds at three and nine months after diagnosis is the standard of care.

In the rationale for Recommendation 1, the PCMOs' actions are not being assessed against the most authoritative standards of care for ovarian cysts. UpToDate and other sources acknowledge several times in their reviews on adnexal masses and ovarian cysts, the lack of consensus among experts regarding an ideal interval for surveillance imaging. When the PCMOs' actions are compared with the standards established by the American College of Obstetricians and Gynecologists Practice Bulletin and the Society of Radiologists in Ultrasound consensus statement, the Peace Corps medical records show that the PCMO's actions in June 2018 were generally consistent with the standards. The medical records, contained within PCMEDICS, show that on June 6, 2018, slightly more than 12 months after initial identification, the PCMO recommended and planned to schedule an ultrasound for June 16th. At that time, the Volunteer reported that "pain is no longer there and it is neither impairing (b) (6), (b) (7)(C) function." OIG interviews with participants in this case also indicate that the ultrasound did not occur on June 16th, based on a joint decision between the Volunteer and the PCMO in connection with the Volunteer's desire to come to the capital city at a later date for programming activities.

II. Clinical Documentation Concerns

The medical documentation in this case should have been more thorough, both by Peace Corps clinicians and non-Peace Corps clinicians treating the Volunteer. In the Agency's internal review of this case, a documentation issue not raised in the MAR was identified that the Peace Corps found to be the cause of the limited monitoring of the Volunteer's cyst. When the Volunteer's cyst was first identified, incidentally as the result of an ultrasound for a medically

unrelated issue in May 2017, it was not recorded in the Volunteer's problem list. Rather the incidental finding was recorded in the electronic medical record (i.e. PCMEDICS) in the ultrasound report associated with the unrelated medical problem.

Problem lists inside of PCMEDICS facilitate Volunteer care by providing a comprehensive and accessible list of patient problems in one place. The problem list is a list of illnesses, injuries, and other factors that affect the health of a Volunteer, including any resolution of the issue. The problem list provides a concise summary that can be reviewed to aid a PCMO in focusing their care and follow-up on outstanding issues.

Had the ovarian cyst been on the problem list, the information would have been more salient to the PCMOs in the diagnostic process. Actively considering an ovarian cyst in the diagnostic process may have led to an alternate treatment path for the Volunteer's care prior to the need for emergency surgery.

III. Actions Taken to Enhance Oversight and Operations

This case occurred in 2017-2018. Since that time, OHS has undertaken a number of actions to enhance the quality of healthcare provided to Volunteers that are relevant to this case. First, with regard to the Peace Corps' clinical escalation policy, the Peace Corps provided PCMOs with a webinar training in August 2021 on the clinical escalation policy. In February 2022, OHS updated and redrafted the policy to better clarify when PCMOs should immediately notify and consult with OHS Headquarters, Regional Medical Officers, and notify Country Directors regarding Peace Corps Volunteers who have serious health conditions.

Second, with regard to clinical documentation review, OHS updated its policies and procedures in January 2022 to enhance the accuracy, timeliness, and quality of clinical documentation, as well as adherence to the Peace Corps clinical documentation standards. The new policies and procedures establish criteria for the review of clinical documentation standards, care offered and provided, and the recording of clinical data. The Peace Corps also provided PCMOs with a webinar training in January 2022 explaining the new policies. OHS anticipates that the new policies and procedures will support the clinical decision making process, implementation of medical management plans, continuity of care, and facilitate risk management strategies.

Third, with regard to patient safety events, OHS has contracted with two, independent patient safety organizations (PSOs) certified by the U.S. Department of Health and Human Service's Agency for Healthcare Research and Quality. PSOs are organizations with expertise in conducting and analyzing patient safety activities in order to provide feedback aimed at promoting learning and preventing future patient safety events. The Peace Corps believes that using an independent PSO with expertise in patient safety will allow the Peace Corps to improve the patient safety event review process and provide better support of Volunteer health and safety.

Recommendation 1

That the Office of Health Services take steps to improve Peace Corps Medical Officers' review and awareness of UpToDate to improve quality of care when treating Volunteers.

Concur**Response:**

OHS concurs that PCMOs should be aware of and use all Peace Corps-provided decision support tools to assist in delivering the best possible care to Volunteers. OHS no longer utilizes UpToDate. The Agency's most recent procurement for an evidence-based clinical decision support tool awarded the contract to EBSCO DynaMed + Micromedex. OHS will hold an additional mandatory PCMO training webinar to enhance awareness of decision support tools to improve Volunteer care, including EBSCO DynaMed + Micromedex.

Documents to be Submitted:

- Presentation to PCMOs February 2, 2022
- PCMO training webinar on EBSCO DynaMed + Micromedex
- Presentation from additional PCMO training webinar on decision support tools

Status and Timeline for Completion: September 2022

Recommendation 2

That the Office of Health Services improve implementation of and Peace Corps Medical Officers' awareness of the clinical escalation policy.

Concur

Response: OHS concurs that PCMOs should be aware of and follow the clinical escalation policy. OHS held a training session in August 2021. Updated policies were rolled out in February 2022 and OHS will hold a mandatory PCMO training webinar to enhance awareness of the revised clinical escalation policy. Additionally, OHS will ensure that the clinical escalation policy is reviewed in detail with new PCMOs as part of the PCMO mentoring process.

Documents to be Submitted:

- Presentation from PCMO training webinar on the clinical escalation policy
- TG 187, Attachment B, Mentoring Checklist

Status and Timeline for Completion: September 2022

Recommendation 3

That the Office of Health Services develop a process to ensure recommendations from their health unit assessments are addressed.

Concur

Response: In 2021, the Peace Corps approved funding for the Office of the Chief Information Officer and OHS to procure Quality Improvement database software to enhance managing, tracking, disseminating, and archiving information received from site assessment recommendations. The Statement of Work has been developed and is currently in the final stages of the procurement process. Once the software is implemented, OHS will be better able to manage recommendations, including decisions to close recommendations. The Office of the Chief Compliance Officer will provide independent monitoring, oversight, and reporting to ensure the intent of the recommendations are fully addressed within an agreeable timeframe.

Documents to be Submitted:

- Quality Improvement Database Software documentation
- Standard Operating Procedure on Site Assessment Recommendations

Status and Timeline for Completion: December 2022

Recommendation 4

That the Office of Health Services update the clinical documentation review guidelines to increase controls on new Peace Corps Medical Officers who do not meet clinical documentation standards.

Concur

Response: New PCMOs receive regular check-ins and support in accordance with an established protocol by a PCMO mentor. OHS agrees that clinical documentation and clinical care will be improved by further clarifying clinical documentation review guidelines, particularly surrounding accurate and complete documentation of issues in the problem list. OHS will add the review of the problem list to the current chart review tool and provide feedback as needed.

Documents Submitted:

- Revised chart review scoring tool, TG 113 attachment A-PCMO Scoring Tool

Status and Timeline for Completion: September 2022

Recommendation 5

That the Office of Health Services improve identification and reporting of patient safety events.

Concur

Response: OHS does not agree that the definitive standard of care presented in the MAR indicates a missed patient safety event or was applicable to the PCMO's monitoring and care in this case. However, it is clear that a documentation failure at the initial diagnostic stage coupled with undocumented reasoning related to the Volunteer's ultimate follow up ultrasound may have contributed to the need to have emergency surgery in country. OHS will incorporate this case study into its ongoing and continuous efforts to identify and report on patient safety events.

Documents to be Submitted:

- Patient Safety Events - TG 167 Updates slide set presentation
- Revised TG 167 "Patient Safety Events"
- CME Agenda for PCMOs
- CME Presentation
- OHS Staff Education Materials

Status and Timeline for Completion: September 2022

Appendix B: OIG Comments

Management concurred with all 5 recommendations. Five recommendations remain open. In its response, management described actions it is taking or intends to take to address the issues that prompted each of our recommendations. We wish to note that in closing recommendations, we are not certifying that the agency has taken these actions or that we have reviewed their effect. Certifying compliance and verifying effectiveness are management's responsibilities. However, when we feel it is warranted, we may conduct a follow-up review to confirm that action has been taken and to evaluate the impact.

OIG will review and consider closing recommendations 1, 2, 3, and 4 when the documentation reflected in the agency's response to the preliminary report is received. For recommendation 5, additional documentation is required, as explained below. This recommendation will remain open pending confirmation from the chief compliance officer that the documentation reflected in our analysis below is received. Additionally, OIG has provided comments to address and clarify several issues conveyed in the agency's response.

Clinical Standards of Care for Ovarian Cysts

In responding to our report, the agency stated, "The MAR concludes definitively that conducting ultrasounds for ovarian cysts at three and nine months after diagnosis is a universally agreed upon standard of care." (p.2). In our report, we do not state nor conclude that conducting ultrasounds for ovarian cysts at three and nine months after diagnosis is a universally agreed upon standard of care. We acknowledge that UpToDate is not the only source of clinical guidance; however, we used UpToDate as criteria because Office of Health Services (OHS) staff informed us that they used it as their standard of care and provided it to all Peace Corps medical officers (PCMOs).

The agency also stated in its response, "The determination is based on an expert opinion from UpToDate published 32 months after the Volunteer's ovarian cyst was identified. However, there is no agreed upon single standard of care for monitoring ovarian cysts." (p.2). We agree that there is no single standard that provides the ideal interval for follow-up ultrasounds. However, both UpToDate and the Society of Radiologists in Ultrasound consensus statement from 2010, which the agency referenced in its response, recommended short-term serial monitoring, i.e., repeated imaging after diagnosis, for patients such as RPCV (b) (6), (b) (7)(C). As noted, OIG made its finding and recommendation based on UpToDate because it was identified by OHS staff as their standard of care and UpToDate was provided to all PCMOs. However, our external medical consultants identified guidance citing an even shorter interval, 6-12 weeks, for repeat imaging as being appropriate in this case.

Referring to the Society of Radiologists in Ultrasound consensus statement from 2010, the agency further noted "...the lack of definitive timeframes for follow-up imaging of ovarian cysts, and the need to tailor follow-up ultrasounds to a patient's specific presentation. The consensus statement indicates that an annual ultrasound is a reasonable course of action." The OIG agrees that it is reasonable to tailor follow-up imaging to the patient's specific presentation. It is therefore important to emphasize that RPCV (b) (6), (b) (7)(C) was found to have a multiloculated cyst with thick walls. In contrast, the reference to "annual ultrasound" cited by the agency applies to

simple cysts defined in the consensus statement as “round or oval... with smooth, thin walls... and no solid components or septations...”¹

Another response provided by the agency read, “In the Practice Bulletin, it states: ‘...Some experts recommend limiting observation of stable masses without solid components to 1 year, and stable masses with solid components to 2 years.’” (p.3). The statement in the Practice Bulletin is a reference to an article² that concerns stable masses. The article goes on to state that evidence supports the use of initial short-term serial monitoring, and notes that the goal of monitoring the mass is to observe for worrisome growth or increasing complexity as an indicator of malignancy. RPCV (b) (6), (b) (7)(C) did not have short-term serial monitoring to establish that the mass was stable or to observe for worrisome growth. Further, the reference to “limiting observation” to one year or in some cases two years is provided in the context of prolonged or lifelong monitoring, which the authors suggest cause potential harms that outweigh benefits. Our report does not address prolonged monitoring of the cyst. Rather, our report documents that no short-term serial monitoring was performed for RPCV (b) (6), (b) (7)(C).

The agency further stated, “The medical records, contained within PCMEDICS, show that on June 6, 2018, slightly more than 12 months after initial identification, the PCMO recommended and planned to schedule an ultrasound for June 16th. At that time, the Volunteer reported that ‘pain is no longer there and it is neither impairing (b) (6), (b) (7)(C) function.’ ” (p.3). OIG’s external medical consultant reported, “it is possible that the abdominal pain experienced by RPCV (b) (6), (b) (7)(C) in June of 2018 was due to intermittent torsion of the ovarian cyst.” Also, according to the American College of Obstetricians and Gynecologists Practice Bulletin 178, “Symptoms of unilateral, intermittent, and then acutely worsening pelvic pain may indicate an ovarian torsion.” Both sources describe ovarian torsion as intermittent. That RPCV (b) (6), (b) (7)(C) pain was not present at a certain point is consistent with this description.

The agency also responded that, “OIG interviews with participants in this case also indicate that the ultrasound did not occur on June 16th, based on a joint decision between the Volunteer and the PCMO in connection with the Volunteer’s desire to come to the capital city at a later date for programming activities.” (p.3). The PCMO reported that RPCV (b) (6), (b) (7)(C) decided not to come into the capital for the ultrasound. However, RPCV (b) (6), (b) (7)(C) stated that the PCMO said (b) (6), (b) (7)(C) could see a specialist about the pain in August when (b) (6), (b) (7)(C) went to (b) (6), (b) (7)(C). We did not find sufficient evidence to conclude that RPCV (b) (6), (b) (7)(C) was told (b) (6), (b) (7)(C) needed a follow-up ultrasound or that it was a joint decision between the Volunteer and the PCMO to delay the ultrasound.

¹ Deborah Levine, Douglas L. Brown, Rochelle F. Andreotti, Beryl Benacerraf, Carol B. Benson, Wendy R. Brewster, Beverly Coleman, Paul DePriest, Peter M. Doubilet, Steven R. Goldstein, Ulrike M. Hamper, Jonathan L. Hecht, Mindy Horrow, Hye-Chun Hur, Mary Marnach, Maitray D. Patel, Lawrence D. Platt, Elizabeth Puscheck, Rebecca Smith-Bindman, *Management of asymptomatic ovarian and other adnexal cysts imaged at US: Society of Radiologists in Ultrasound Consensus Conference Statement Radiology*, Sep. 2010, Volume 256: Number 3, pp. 943-54.

² Elizabeth Suh-Burgmann, Walter Kinney, *Potential harms outweigh benefits of indefinite monitoring of stable adnexal masses*, *American Journal of Obstetrics and Gynecology*, Dec. 2015, Volume 213, Issue 6, pp. 816.e1; 816-818.

Clinical Documentation Concerns

Additionally, the agency said in its response, “In the Agency’s internal review of this case, a documentation issue not raised in the MAR was identified that the Peace Corps found to be the cause of the limited monitoring of the Volunteer’s cyst... Had the ovarian cyst been on the problem list, the information would have been more salient to the PCMOs in the diagnostic process.” Although we did not reference the problem list in our report, it factored into our finding that the PCMO failed to meet the agency’s documentation standards, which resulted in critical information missing from RPCV (b) (6), (b) (7)(C) medical record. Technical Guideline 113 covers clinical documentation standards. The problem list is an element of the documentation standards, but the guideline requires PCMOs to follow-up on all active medical problems at every encounter regardless of whether they are on the problem list. The PCMO knew that RPCV (b) (6), (b) (7)(C) had a cyst that required an ultrasound yet failed to document it on the problem list or to document any follow-up to this problem in subsequent patient encounters. Our recommendation to improve the review of clinical documentation should be applied to all relevant documentation practices.

Recommendation 5: That the Office of Health Services improve identification and reporting of patient safety events.

Agency Response:

Concur

Response: OHS does not agree that the definitive standard of care presented in the MAR indicates a missed patient safety event or was applicable to the PCMO’s monitoring and care in this case. However, it is clear that a documentation failure at the initial diagnostic stage coupled with undocumented reasoning related to the Volunteer’s ultimate follow up ultrasound may have contributed to the need to have emergency surgery in country. OHS will incorporate this case study into its ongoing and continuous efforts to identify and report on patient safety events.

Documents to be Submitted:

- Patient Safety Events - TG 167 Updates slide set presentation
- Revised TG 167 “Patient Safety Events”
- CME Agenda for PCMOs
- CME Presentation
- OHS Staff Education Materials

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OIG Analysis: The agency stated in its response that using an independent PSO with expertise in patient safety will allow the Peace Corps to improve the patient safety event review process and provide better support of Volunteer health and safety. OIG requests the agency provide documentation that describes the roles and responsibilities of independent PSOs regarding the identification and reporting of patient safety events.