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To: Jody Olsen, Director
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From: Kathy A. Buller, Inspector General

Date: April 9, 2019

Subject: Management Advisory Report: Review of the Circumstances Surrounding the Death of a Volunteer in Peace Corps/Comoros (IG-19-04-SR)

Please find attached the Management Advisory Report: Review of the Circumstances Surrounding the Death of a Volunteer in Peace Corps/Comoros (IG-19-04-SR) for your review and response. This report makes seven recommendations. We request the agency's response to these recommendations by **Friday, May 24, 2019**. Once we receive the response, the report will be updated to include it in Appendix G.

Please provide us with an electronic copy of your signed cover memo and response. The response should provide your concurrence or non-concurrence with each recommendation. In addition, please use [TeamCentral](#) to document corrective action and upload documentation supporting any actions planned or implemented to address the recommendations.

cc: Michelle Brooks, Chief of Staff
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Management Advisory Report

Review of the Circumstances Surrounding the
Death of a Volunteer in Peace Corps/Comoros

IG-19-04-SR

April 2019

EXECUTIVE SUMMARY

This report provides the results of our review of the circumstances surrounding the death of Peace Corps Volunteer Bernice Heiderman (PCV Heiderman) on January 9, 2018, in Comoros. PCV Heiderman died from undiagnosed malaria, specifically cerebral malaria caused by the species *Plasmodium falciparum* (*P. falciparum*). This is the deadliest species of malaria when left untreated, and the dominant species in Comoros. Because of the risk of infection from malaria in Comoros, the Peace Corps requires all Volunteers to take antimalaria medication. The Peace Corps' medical technical guidelines for malaria diagnosis and treatment directs its medical officers to assume that all Volunteers serving in malaria endemic areas could become infected with malaria, and to always consider a diagnosis of malaria in any Volunteer with a fever. Rapid malaria tests and malaria treatment medication (Coartem) are provided to Peace Corps Volunteers and maintained in medical units in order to initiate treatment for malaria when necessary.

Our review found the Peace Corps medical officer (PCMO) in Comoros, PCMO Nizar Ahamada Said, did not consider a diagnosis of malaria at any point from January 2, 2018, until PCV Heiderman's death on the morning of January 9, 2018. Malaria test kits and treatment medication were available in Comoros to assist in diagnosing and treating PCV Heiderman throughout her illness, but were not used. Our review found that if PCV Heiderman had been diagnosed with malaria when her initial symptoms indicated a possible malaria infection (headache, nausea, diarrhea, lower abdominal pain, vomiting, dizziness, sweats, chills and a temperature of 37.9°C, or 100.2°F) and had she received timely treatment, she could have made a rapid, full recovery.

Our review also found that PCV Heiderman had not been adhering to her required malaria suppression medication regime for several months prior to her death from malaria. The Peace Corps medical unit in Comoros was unaware of this fact and assumed that PCV Heiderman was taking her antimalarial pills.

Our review identified several vulnerabilities associated with the Peace Corps' failure to provide an early diagnosis and prompt treatment for PCV Heiderman's malaria. The agency had staffed the medical unit in Comoros with one medical officer who had limited training in infectious diseases and limited clinical experience caring for non-immune travelers to Comoros, who are at greater risk of dying from untreated *P. falciparum* malaria. Unlike most Peace Corps overseas medical units which are staffed by at least two qualified medical officers, no other PCMO was available in Comoros to observe PCV Heiderman and discuss with PCMO Nizar possible diagnoses and causes of her illness.

In addition, PCMO Nizar had a clinical proclivity to associate a diagnosis of malaria with the presence of a high fever, based on his two years of experience treating patients at the local public hospital in Comoros. However, since PCMO Nizar detected only a mild fever in PCV

Heiderman, he never suspected malaria as a possible diagnosis. PCMO Nizar remained ‘anchored’ to his original diagnosis of a suspected headache disorder and a gastrointestinal disorder, and believed that his treatment for PCV Heiderman was effective, including up until the evening before her death. After reviewing PCMO Nizar’s consult note about PCV Heiderman on January 8, 2018, the Director of the Office of Medical Services, Dr. Colantino, called PCMO Nizar to discuss PCV Heiderman’s case and advised him to keep PCV Heiderman on IV fluid, monitor her vital signs and urine output, and to do lab work first thing in the morning of January 9. The recommended lab work included conducting a basic metabolic panel, including creatinine and electrolytes, and a complete blood count. Dr. Colantino did not ask Dr. Nizar if he had considered a diagnosis of malaria.

We found that the agency’s medical technical guidelines for the diagnosis and treatment of malaria were outdated and out of alignment in key respects with prevailing malaria diagnosis guidelines from the World Health Organization (WHO, 2015), which instructs doctors to suspect malaria in any sick patient with a mild fever of 37.5°C (99.5° F) and recommends using a rapid diagnostic test to confirm the presence of malaria parasites. The Peace Corps’ medical technical guidelines for malaria from 2006 were less clear than 2015 WHO Guidelines about the definition of “febrile” in terms of a temperature, and did not instruct medical officers to suspect and test for malaria using a rapid diagnostic test, although the agency does provide the tests to Volunteers and medical officers. PCMO Nizar in fact had rapid diagnostic test kits in the sick bay where PCV Heiderman died from undiagnosed, untreated *P. falciparum* malaria, but did not use any of them because he did not recognize PCV Heiderman’s symptoms as being consistent with a malaria infection.

PCMO Nizar, as well as other agency officials, expressed the viewpoint that it was more challenging to arrive at a diagnosis of malaria in PCV Heiderman because she did not have a high fever. We found that this viewpoint was inconsistent with clinical diagnosis guidelines that stress that patients with malaria typically present initially with non-specific symptoms, and that early diagnosis and prompt treatment for malaria, especially *P. falciparum* malaria in a non-immune patient, is key to patient survival.

While treating PCV Heiderman from January 2 through January 9, PCMO Nizar also did not follow the agency’s medical technical guidelines for clinical documentation. Specifically, PCMO Nizar did not record PCV Heiderman’s vital signs or document his clinical assessments of her condition for each of his encounters with her from January 2 through January 9. By not taking her vital signs, completing patient encounter forms, or documenting the basis for his assessment that PCV Heiderman’s condition was improving, Dr. Nizar made diagnostic and treatment decisions for PCV Heiderman based on insufficient clinical evidence. The lack of clinical data also made it challenging to review the provision of care for PCV Heiderman and difficult to create an accurate timeline of the circumstances surrounding her death.

PCMO Nizar did not follow the agency's clinical escalation policy related to medical emergencies or follow instructions he received from the Director of the Office of Medical Services on January 8, 2018. Specifically, on January 8, PCMO Nizar did not recognize that PCV Heiderman's vital signs had met the threshold for a medical emergency, and so did not initiate a clinical escalation properly. Had he recognized this, PCMO Nizar should have escalated the matter by placing a phone call to the Office of Health Services. Instead, PCMO Nizar submitted a written consult note through the agency's electronic medical records system with no specific request for guidance. When he was contacted late in the evening on January 8 by the Director of the Office of Medical Services about this consult note, PCMO Nizar maintained that PCV Heiderman was getting better and was not in crisis. PCMO Nizar then failed to follow the instructions he received on that call from the Director of OMS to call her back should PCV Heiderman's condition change in any way in the night of January 8. PCV Heiderman died in the early morning on January 9 before PCMO Nizar could perform the diagnostic tests that he had been instructed to do that morning.

Finally, we found that the agency's patient safety event review focused on the clinical decision-making of PCMO Nizar and that the agency had not yet assessed its systems or processes to identify ways to decrease the likelihood of another Volunteer death from undiagnosed malaria. OIG has four outstanding recommendations to the Peace Corps to improve its sentinel event review process in order to identify and address systemic or institutional vulnerabilities that contribute to serious adverse events.

This report also summarizes the investigative steps OIG took to respond to allegations that PCV Heiderman's death may have been a homicide.

This report makes 7 recommendations to the Peace Corps to address the vulnerabilities we identified and make it more likely that medical officers will provide timely diagnosis and prompt, effective treatment for malaria so that future Volunteer deaths from the disease can be prevented.

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BACKGROUND

Ms. Bernice Heiderman was a 24-year-old Peace Corps Volunteer in Comoros who died on the morning of January 9, 2018 in the capital of Moroni on the island of Grande Comore. PCV Heiderman had served as an English teacher at a middle school in Salimani-Itsandra, close to Moroni, since August 18, 2016. At the time of her death, PCV Heiderman had been under the care of the Peace Corps/Comoros medical officer, Dr. Nizar Ahamada Said, since January 2, 2018. From January 4 until her death on January 9, PCV Heiderman was staying in a hotel room that served as the post's sick bay¹ for sick or injured Volunteers on medical hold² status. The sick bay was close to the Peace Corps office and to PCMO Nizar's home. When she was put on medical hold, PCV Heiderman's symptoms included headache, dizziness, nausea, vomiting, diarrhea, dehydration, fatigue, lower abdominal pain, fever, sweats, and chills. PCMO Nizar provided treatment for PCV Heiderman's symptoms, but did not suspect or test PCV Heiderman for malaria or attempt to identify other potential infections.

¹ The Peace Corps did not use the local public hospital (El Marrouf hospital) in Moroni to provide routine or non-urgent medical care for Volunteers due to concerns about sub-standard conditions at the hospital, including the lack of a radiologist, infectious disease specialist, a pathologist, and other factors. Because the hospital had an intensive care unit, the agency had determined to only use it to stabilize a critically sick or injured Volunteer in preparation for an emergency medical evacuation to South Africa.

² Peace Corps *Technical Guideline 380 Medical Evacuation* provides that "A Volunteer may be placed on Medical Hold if an illness or injury precludes his/her return to site or country of service. This may occur while being evaluated at the post Health Unit, at COS or when out of the country on leave."

CAUSE OF DEATH

According to the May 2018 final autopsy report prepared by the Office of the Armed Forces Medical Examiner (AFME), PCV Heiderman died from malaria, specifically cerebral malaria caused by the species *P. falciparum*:

Findings confirm and support the clinical diagnosis of cerebral malaria with immunohistochemical evidence of Plasmodium falciparum in the brain, lungs, and liver.

The autopsy report lists the cause of death as “malaria”, and the manner of death as “natural”.

OIG HOMICIDE INVESTIGATION AND DEATH REVIEW

Following PCV Heiderman's death, the Peace Corps Office of Inspector General (OIG) undertook two activities to establish the facts and circumstances surrounding her death. In January 2018, before the cause of death had been established by the autopsy, OIG conducted an investigation in Comoros to determine if PCV Heiderman's death had been a homicide. This investigation was related to concerns that PCV Heiderman had expressed through text messages to her family and friends stating that she thought she was being poisoned. OIG investigators reviewed the text messages in question as well as collected and examined a variety of other evidence. OIG interviewed various witnesses and consulted with government pathologists from AFME and the Centers for Disease Control and Prevention's (CDC) Infectious Diseases Pathology Branch to ascertain the cause of death. A pathologist conducted an autopsy toxicology test that did not uncover the type of poison (Chloralose, a rodenticide) that had been initially considered as part of the homicide investigation, or other poisons.

After the May 2018 final autopsy report established malaria as the cause of PCV Heiderman's death, OIG undertook a review of the medical care she had received from the Peace Corps. The purpose of this review was to understand the circumstances surrounding PCV Heiderman's death and, in particular, why PCMO Nizar did not diagnose PCV Heiderman with malaria and treat her for it. Through the review, we developed a more complete understanding of the actions taken by PCMO Nizar to care for PCV Heiderman from January 2 through January 9, 2018, and of the actions that PCMO Nizar should have taken but did not.

OBJECTIVE, SCOPE AND METHODOLOGY OF OIG DEATH REVIEW

To help establish the facts and circumstances surrounding PCV Heiderman's death from malaria, OIG obtained and reviewed all the available medical records pertaining to PCV Heiderman's care. We obtained an independent medical expert opinion about the care PCV Heiderman received from the Peace Corps from January 2 until January 9, 2018 (See Appendix E). We also consulted with the Office of Healthcare Inspections within the Department of Veterans Affairs' Office of Inspector General for technical assistance that informed our assessment of the medical care received by PCV Heiderman.

The medical doctors who assisted us each reviewed available records of PCMO Nizar's encounters with PCV Heiderman, and pertinent medical technical guidelines that the Peace Corps expects its medical officers to follow when treating a Volunteer for malaria or when dealing with a medical emergency. In July 2018, OIG interviewed PCMO Nizar and the post's medical assistant, Ms. Anturia Mihidjai (MA Mihidjai) about the steps they took from January 2 to January 9 to provide medical care for PCV Heiderman. We also interviewed the Peace Corps' Director of the Office of Medical Services, Dr. Alison Colantino, regarding her communication with PCMO Nizar about PCV Heiderman's care. In September 2018, we received the agency's report (prepared by an external medical doctor) that reviewed the quality of care PCV Heiderman had received by PCMO Nizar. We also reviewed a report of the agency's assessments in July and August 2018 of the available medical facilities throughout Comoros. We conducted a complete evaluation of Peace Corps/Comoros operations in January 2019, which included gathering information about Volunteer awareness of the risks of malaria transmission and the agency's ability to meet Volunteer healthcare needs in the country. We interviewed other agency officials about the agency's ability to respond to medical emergencies in remote parts of the world with limited transportation options and sub-standard medical infrastructure, like Comoros. We also reviewed other medical and administrative records related to PCV Heiderman, as well as to the Peace Corps program in Comoros.

INFORMATION ABOUT COMOROS

The Union of the Comoros includes four main islands in the Mozambique Channel between the northwest coast of Madagascar and the east coast of Mozambique. Peace Corps Volunteers serve



on the islands of Grande Comore, Anjouan, and Moheli; the island of Mayotte remains under French administration. Comoros' population in 2015 was estimated at 788,000. Its human development index rank of 159 out of 188 countries places it in the lowest quartile of countries in human development. Comoros has limited health care infrastructure and chronic dysfunction, such as low attendance by doctors and nurses at health clinics, poor distribution of medical personnel throughout the country, and lack of funding for its healthcare system. The Peace Corps assessed the country's health facilities in July and August of 2018 (as part of the agency's response to the death of PCV

Heiderman) and concluded that there were "facilities, clinicians, and diagnostic centers able to provide basic medical care and acute stabilization" of Volunteers. This special site assessment report conveyed more than 30 recommendations to improve the Peace Corps/Comoros medical unit's functioning and its ability to refer Volunteers to local medical providers on each island.

INFORMATION ABOUT MALARIA IN COMOROS

The CDC provides information on the presence of endemic infectious diseases for each country. The CDC reports that malaria is present in all areas of Comoros, and that the primary species of malaria in the country is *P. falciparum*. The Peace Corps website provides information to anyone considering service in Comoros about the health risks Volunteers will face in the country, including malaria, and the agency stresses its requirement that all Volunteers in Comoros take antimalarial medication:

Malaria, HIV/AIDS, gastrointestinal infections, typhoid fever, and hepatitis are all common illnesses, most of which are entirely preventable with appropriate knowledge and interventions. Because malaria is endemic in Comoros, taking anti-malaria pills is required of all Volunteers.

According to the World Health Organization's (WHO) 2018 country brief on Comoros, there was a sharp decline in malaria cases in Comoros after 2013, from over 53,000 cases in 2013 to just 1,066 cases in 2016. However, in 2017 there was a significant increase in malaria cases to 3,230 including 3 deaths. The WHO also reports that the dominant species (100%) of malaria in Comoros is *Plasmodium falciparum*.

PEACE CORPS MALARIA PREVENTION PROGRAM

According to Peace Corps *Technical Guideline 840 (TG 840) on the Prevention of Malaria* (December 2014), which provides guidance to PCMOs on preventing malaria among Volunteers:

P. falciparum is the most dangerous species...and poses the greatest risk of death to non-immune persons and is the species most likely to develop resistance to anti-malarial drugs.

TG 840 sets the expectation that the agency's medical officers and Volunteers will act vigilantly to reduce Volunteers' risk of contracting malaria:

Malaria is a mosquito-borne parasitic disease endemic to many areas of the world served by Peace Corps Volunteers. It is a serious and sometimes fatal disease. As such, the Office of Medical Services (OMS) employs a comprehensive prevention program to prevent malaria in Volunteers. Medical officers and Volunteers are required to rigorously adhere to the components of the program.

TG 840 describes four main components of this comprehensive malaria prevention program: (1) providing Volunteers with screens and insect repellent to reduce their exposure to mosquito bites; (2) providing Volunteers with antimalarial medication; (3) educating PCMOs and Volunteers on malaria prevention measures; and (4) requiring that all Volunteers "rigorously adhere to malaria prevention measures." A Volunteer's failure or refusal to take required antimalarial medication constitutes grounds for administratively separating the Volunteer from service.

GUIDELINES FOR CLINICAL CONSIDERATION AND DIAGNOSIS OF MALARIA

The Peace Corps' 2006 medical technical guidelines for malaria diagnosis and treatment (TG 845), and guidelines from the World Health Organization (WHO) and the CDC all emphasize that the early symptoms of malaria are **nonspecific** and look like a minor illness. WHO Guidelines emphasize that an individual with malaria may initially appear to have a minor viral illness:

The first symptoms of malaria are nonspecific and similar to those of a minor systemic viral illness. They comprise headache, lassitude, fatigue, abdominal discomfort and muscle and joint aches, usually followed by fever, chills, perspiration, anorexia, vomiting and worsening malaise...

Peace Corps TG 845 alerts the agency's medical officers that a Volunteer with malaria may present with nonspecific respiratory or gastrointestinal disorder symptoms:

In practice, presenting symptoms are variable. The disease may present with nonspecific respiratory or gastrointestinal symptoms.

WHO 2015 Guidelines specify the circumstances in which a doctor should always suspect and test for the presence of malaria in a sick patient:

In malaria-endemic areas, malaria should be suspected in any patient presenting with a history³ of fever or temperature $\geq 37.5^{\circ}\text{C}$ and no other obvious cause...All cases of suspected malaria should have a parasitological test (microscopy or Rapid diagnostic test (RDT)) to confirm the diagnosis.

The CDC's 2013 malaria treatment guidelines for clinicians also stress that the symptoms of malaria are nonspecific and that doctors should consider a diagnosis of malaria in any sick patient with a fever and evaluate the patient "urgently":

Symptoms of malaria are generally non-specific and most commonly consist of fever, malaise, weakness, gastrointestinal complaints (nausea, vomiting, diarrhea), neurologic complaints (dizziness, confusion, disorientation, coma), headache, back pain, myalgia, chills, and/or cough. The diagnosis of malaria should also be considered in any person with fever of unknown origin regardless of travel history...Patients suspected of having malaria infection should be urgently evaluated.

Peace Corps TG 845 instructs PCMOs caring for Volunteers in malaria areas to suspect that any Volunteer with a fever may have malaria:

³ "History" of fever in this context means that the patient reports having had a fever when describing his or her symptoms to a medical provider.

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...assume that all Volunteers are infected with the malaria parasite and that any Volunteer may develop the clinical signs and symptoms of malaria infection.... PCMOs should always consider the diagnosis of malaria in any febrile Volunteer who has been in a malarial area for more than one week...

TG 845, written in 2006 to follow CDC guidelines, does not define febrile, though it does mention that a patient's temperature may range from normal to 40.6° C, or 105° F. However, WHO Guidelines issued in 2015 clearly define the fever for the purpose of suspecting a diagnosis of malaria as a temperature of $\geq 37.5^{\circ}$ C. This difference and its significance will be discussed further later in the report. For a comparison of WHO and Peace Corps malaria guidelines, see Appendix B.

THE IMPORTANCE OF EARLY DIAGNOSIS AND PROMPT TREATMENT OF MALARIA

The World Health Organization's 2015 Guidelines for the Treatment of Malaria, 3rd edition, emphasizes as its first core principle that doctors must diagnose malaria early and treat it promptly to reduce the patient's risk of death from the disease:

Uncomplicated falciparum malaria can progress rapidly to severe forms of the disease, especially in people with no or low immunity, and *severe falciparum malaria is almost always fatal without treatment* [emphasis added]. Therefore, programmes should ensure access to early diagnosis and prompt, effective treatment within 24-48 hours of the onset of malaria symptoms.

WHO Guidelines state that early diagnosis and treatment is especially important for patients with no previous exposure to the disease (such as Peace Corps Volunteers) who are more at risk (as compared to residents of the country with prior exposure to malaria who may have partial immunity to the disease) of dying from untreated *P. falciparum* malaria:

Correct diagnosis in malaria-endemic areas is particularly important for the most vulnerable population groups, such as...*non-immune populations, in whom falciparum malaria can be rapidly fatal* [emphasis added].

According to the WHO, a patient whose malaria is diagnosed early and treated promptly with effective antimalarial medication is expected to make a rapid, full recovery. Conversely, a patient with undiagnosed *P. falciparum* malaria may develop severe malaria which, if left untreated, is usually fatal.

TIMELINE OF CARE OF PCV HEIDERMAN

Below is a description of the medical care the Peace Corps provided PCV Heiderman each day from January 2 through January 9, based on the available medical records of PCMO Nizar's encounters with PCV Heiderman; and on OIG's interviews of PCMO Nizar, MA Mihidjai, and Dr. Colantino. The Peace Corps medical technical guideline (TG 113) for clinical documentation standards states: "Vital Signs including blood pressure must be taken at every encounter."⁴ One of the challenges our review encountered in assessing the clinical care PCMO Nizar provided to PCV Heiderman was the general lack of sufficient clinical documentation of his encounters with her from January 2 through January 9, 2018.

The reader can also find a timeline constructed separately by an independent infectious disease specialist who reviewed the available medical records and who provided an opinion to inform this report. See Appendix E.

Tuesday, January 2, 2018

PCV Heiderman visited PCMO Nizar for the first encounter⁵ with the Peace Corps concerning her complaint of headache and dizziness. PCV Heiderman explained that she started feeling sick three days before (which would have been on December 30, 2017) and had vomited and lost her appetite. She said she had a runny nose and was congested. She did not report having had a fever, diarrhea, or abdominal pain. PCMO Nizar checked her vital signs during this visit. Her heart rate was 119 beats per minute, and her blood pressure was 100/60. She had a mild fever of 37.5°C (99.5°F).

PCMO Nizar's medical record of his encounter with PCV Heiderman on January 2 indicated his observations that her general appearance was weak and fatigued; her mental state was alert, oriented and logical; she had minor dehydration; and she was in a lot of pain (her pain level was noted as 8 out of 10). PCMO Nizar's diagnosis was a suspected headache disorder. He gave her medicine for nausea (Phenergan), antacid, acetaminophen for her headache, a decongestant (Phenylephrine), and told her to drink more water and rest. He noted his intention to follow-up soon with her.

⁴ According to TG 113, "The purpose of this guideline is to establish clinical documentation standards which assure accuracy, timeliness, and quality in the recording of clinical data and the provision of care. These standards assist in establishing criteria for review of clinical documentation, identification of provider educational needs, and support the performance evaluation process."

⁵ An encounter is the term Peace Corps uses to describe an interaction between a Volunteer and a Peace Corps medical officer regarding a health condition.

Wednesday, January 3, 2018

There was not an encounter between PCV Heiderman and PCMO Nizar, and no medical record for January 3.

Thursday, January 4, 2018

PCV Heiderman saw PCMO Nizar for the first time since January 2. According to our interview with PCMO Nizar we believe that PCV Heiderman called him on the morning of January 4 saying she was tired, and that he sent the Peace Corps driver and car to her house (a short distance from the Peace Corps office in Moroni) to bring her to the office so he could do a follow-up exam.

The medical record of PCMO Nizar's encounter with PCV Heiderman on January 4 indicates that she had a range of symptoms, including: diarrhea, lower abdominal pain, vomiting, nausea, dizziness, sweats, and chills. PCMO Nizar noted his observation that PCV Heiderman was fatigued and had moderate dehydration, as well as PCV Heiderman's vital signs which included a fever of 37.9°C, or 100.2°F. PCMO Nizar's diagnosis of PCV Heiderman on January 4 broadened his January 2 diagnosis of suspected headache disorder to include diarrhea and vomiting.

The medical record for January 4 notes that PCMO Nizar continued treating PCV Heiderman with the same medication for her headache, and that he put PCV Heiderman on an intravenous (IV) drip for hydration that included Phenergan to control her nausea and vomiting. According to our interview with MA Anturia Mihidjai, MA Mihidjai put the IV in PCV Heiderman on January 4. PCMO Nizar placed PCV Heiderman on a "medhold" status starting January 4 in a hotel near the Peace Corps office.

According to PCMO Nizar, PCV Heiderman required monitoring while on medhold at the hotel, so he stayed at the same hotel the night of January 4 in another room.

Friday, January 5, 2018

The medical record of his encounter with PCV Heiderman on January 5 contains PCMO Nizar's note that PCV Heiderman complained of a bad headache and dizziness, nausea and abdominal pain. He also noted that PCV Heiderman said she did not think she had a fever, her vomiting had improved, and she had no other complaints.

The medical record notes that her general appearance was fatigued and that her health history included diarrhea, vomiting, and a headache disorder. He described her mental status as "alert, oriented and logical," and noted minor abdominal tenderness. The medical record does not include PCMO Nizar's observations about PCV Heiderman's dehydration or indicate whether PCMO Nizar continued the IV drip for PCV Heiderman.

During our interview with PCMO Nizar he indicated that he stopped the IV drip on Friday after talking to PCV Heiderman, who, according to PCMO Nizar, was improving and told him “I’m doing much better.” PCMO Nizar said he left the IV catheter in her arm to make it easier to re-start the drip later if she needed it. As he had done the night before, PCMO Nizar stayed overnight in another room at the hotel on January 5.

PCMO Nizar did not take PCV Heiderman’s vital signs during his encounter with her on January 5.

Saturday, January 6, 2018

There is no medical record of PCMO Nizar’s encounter with PCV Heiderman on January 6.

In his interview, PCMO Nizar told us that he visited PCV Heiderman the morning of January 6 but did not check her vital signs. PCMO Nizar told us he thought PCV Heiderman’s condition was improving. He decided that he did not need to stay at the hotel any longer, but that PCV Heiderman should remain there over the weekend. If her condition continued to improve, PCMO Nizar planned to release her from medhold on Monday January 8.

Sunday, January 7, 2018

There is no medical record of PCMO Nizar’s encounter with PCV Heiderman on January 7.

According to PCMO Nizar, PCV Heiderman remained at the hotel and received at least one visit from a friend. PCMO Nizar said he visited PCV Heiderman Sunday morning. Though he was planning to release PCV Heiderman from the hotel sick bay on Monday morning, PCMO Nizar wanted PCV Heiderman to stay at the hotel Sunday: “it’s better for her to stay close to...me because I was staying just...five minutes away.” PCMO Nizar did not check PCV Heiderman’s vital signs on January 7.

It was unclear how many times PCMO Nizar visited PCV Heiderman on January 7. MA Mihidjai indicated that after PCMO Nizar left PCV Heiderman’s room, at some point during the night of January 7, the IV needle that was in PCV Heiderman’s arm to facilitate putting her back on an IV drip, must have come out.

Monday, January 8, 2018

There are several medical records from January 8 and reconstructing the timeline of events was challenging due to problems with the way the agency’s electronic medical records system fails to maintain accurate time zone information on the records. The following summary draws from several sources: medical records completed by PCMO Nizar of his encounters with PCV Heiderman; a separate note that PCMO Nizar entered into the agency’s medical records system; a subsequent note Dr. Colantino entered about her guidance to PCMO Nizar; our interviews with

PCMO Nizar, MA Mihidjai, and Dr. Colantino; and the medical doctors whom we consulted for our review.

Between approximately 8:00 am to 10:00 am

PCV Heiderman called PCMO Nizar early that morning to say that she was vomiting frequently. PCMO Nizar then called MA Mihidjai to meet him at the Peace Corps office at 7:30 am and accompany him to PCV Heiderman's hotel room. PCMO Nizar went to the Peace Corps office to tell the staff that he and MA Mihidjai had to go to the hotel to attend to PCV Heiderman. The medical record of PCMO Nizar's encounter with PCV Heiderman on Monday morning indicates that PCV Heiderman stated "I do still vomit a lot. My headache is fine now, no diarrhea and dizziness improved. No fever and no other concerns. I do feel my chest pain probably related to the vomit."

MA Mihidjai and PCMO Nizar told us that they saw that PCV Heiderman's IV needle was no longer in place when they visited her the morning of Monday January 8. To rehydrate PCV Heiderman, PCMO Nizar and MA Mihidjai attempted several times to place an IV but were unsuccessful. MA Mihidjai stated to us that it was "very hard" to find a vein for the IV needle due to PCV Heiderman's severe dehydration. PCMO Nizar noted PCV Heiderman's mental status as "alert, oriented, and logical thought" and that she had minor tenderness in the upper abdomen. Antiemetics⁶ and Cimetidine⁷ were prescribed.

After this morning encounter with PCV Heiderman, MA Mihidjai remained with PCV Heiderman until 10:00 am, then left PCV Heiderman to rest. PCMO Nizar told PCV Heiderman to try and drink to aid her rehydration, and that they would return after a few hours to try to place the IV again.

PCMO Nizar did not take PCV Heiderman's vital signs during his encounter with her on the morning of January 8.

Approximately 2:00 pm

According to MA Mihidjai, as well as to PCMO Nizar's medical record summarizing actions taken on January 8 before PCV Heiderman's death, PCMO Nizar and MA Mihidjai returned to PCV Heiderman's room at 2:00 pm in order to try again to place an IV. They were still unable to place the IV in PCV Heiderman.

PCMO Nizar did not create a Patient Encounter Form or record PCV Heiderman's vital signs during his encounter with her at 2:00 pm on January 8.

⁶ Antiemetics counteract vomiting.

⁷ Cimetidine is a H2 blocker usually prescribed for gastrointestinal conditions.

Approximately 4:30 pm to 5:00 pm

In the late afternoon of January 8 PCMO Nizar returned to PCV Heiderman's hotel room with his wife, a pediatric nurse, who succeeded in placing an IV in PCV Heiderman at 5pm. The IV contained Vogalene, an anti-nausea medication, and Cimetidine.

PCMO Nizar took PCV Heiderman's vital signs during this late afternoon encounter on January 8. PCV Heiderman's heart rate was 124 beats per minute and her blood pressure was 80/60 mmHg. Her temperature was 37.5°C (99.49°F). PCV Heiderman complained of nausea, vomiting, dizziness, fatigue, and a burning pain in her chest. PCMO Nizar described PCV Heiderman's mental state as "Agitated before the IV was placed but calm and could sleep after the IV is placed." PCMO Nizar noted that PCV Heiderman's skin showed signs of severe dehydration.

According to the medical record in which PCMO Nizar summarized his actions and PCV Heiderman's condition on January 8, and as PCMO Nizar said to us when interviewed July 18 in Comoros, PCV Heiderman's vomiting and nausea stopped after the IV was placed at 5:00 pm.

Between approximately 7:30 pm to 11:00 pm

PCMO Nizar returned to the office, and MA Mihidjai remained in the room with PCV Heiderman. PCMO Nizar submitted to the Office of Health Services a note through the agency's electronic medical record system called a "consult case message." According to PCMO Nizar, the reason he submitted this consult note the evening of January 8 was because he recognized that he did not understand what was happening to PCV Heiderman, and he wanted to inform the Office of Health Services about the case:

"...it's because for me it's...becoming strange. Like, I don't understand...the symptoms disappear for 48 hours...the symptoms that she [PCV Heiderman] has, disappearing for 48 hours. And then suddenly it's come...to other symptom. That's why [he submitted the consult note]. For me, it was something that make me [think]...something wrong is going on."

PCMO Nizar's consult note, which he labelled "Dehydration due to severe vomiting" summarized PCV Heiderman's condition as of 8:00 pm on January 8, but did not make a specific request for support:

PCV is medhold since January 4th for headache, dizziness, diarrhea and nausea...earlier January 8th we tried to place an IV again hard to find til 5pm, we were able to place a IV fluid. Vital were (P 123; T 37.5; BP 80/60 and So2 97). Vogalene was used and after 2h observation, no vomit, no diarrhea and PCV is sleeping now. The MA assistant is staying with PCV now til tomorrow.

PCMO Nizar then returned to PCV Heiderman's hotel room after 8:00 pm and observed that PCV Heiderman was not vomiting, had no dizziness or fever or other complaints.

According to PCMO Nizar's medical record of PCV Heiderman's condition the evening of January 8, PCV Heiderman had received 2.5 liters of IV fluid that evening. MA Mihidjai remained in the hotel room with PCV Heiderman and PCMO Nizar went home.

At 10:40 pm (2:40 pm EST) Dr. Alison Colantino, the Director of the Office of Medical Services for the Peace Corps, called PCMO Nizar after reviewing the consult note he had submitted a few hours earlier. Dr. Colantino explained to us that she called PCMO Nizar because she was concerned by PCV Heiderman's low blood pressure and dehydration as indicated in PCMO Nizar's consult note. Dr. Colantino discussed PCV Heiderman's case with PCMO Nizar and advised him to keep PCV Heiderman on IV fluid, monitor her vital signs and urine output, and to do lab work first thing in the morning of January 9. The recommended lab work included conducting a basic metabolic panel, including creatinine and electrolytes, and a complete blood count. Dr. Colantino did not ask PCMO Nizar if he had considered a diagnosis of malaria, or discuss testing PCV Heiderman for malaria.

At 10:45 pm on January 8, after speaking to Dr. Colantino, PCMO Nizar requested that MA Mihidjai, who PCMO Nizar had directed to stay with PCV Heiderman throughout the night, take the vitals of PCV Heiderman. MA Mihidjai reported to PCMO Nizar that PCV Heiderman's temperature was 37.5°C, her pulse was 110 beats per minute and her blood pressure was 100/60 mmHg.

At 10:50 pm Dr. Colantino called PCMO to get the update on PCV Heiderman's vital signs. Dr. Colantino informed us that she instructed PCMO Nizar on the phone to call either the agency's Regional Medical Officer in South Africa or herself if PCV Heiderman developed a fever, if her heartrate increased, if there were continued low blood pressure, or if there were other changes in her condition. According to Dr. Colantino, PCMO Nizar relayed to her on the phone that in his judgment PCV Heiderman was dehydrated, needed more fluids, but overall was doing better.

Tuesday January 9, 2018 from 1:00 am until time of death at approximately 6:00 am

Based on the medical record PCMO Nizar wrote following the death of PCV Heiderman, summarizing his actions on January 9:

At 1:00 am on January 9 MA Mihidjai called PCMO Nizar to report that PCV Heiderman had been sleeping but awoke and complained of stomach pain and hiccups. PCMO Nizar did not call Dr. Colantino or a Regional Medical Officer.

At 3:30 am PCMO Nizar instructed MA Mihidjai via a cellphone text message to administer cimetidine through PCV Heiderman's IV drip.

At 4:44 am MA Mihidjai texted PCMO Nizar that PCV Heiderman was in pain, had

heartburn, and felt hot, but was not sweating. PCMO Nizar did not call Dr. Colantino or a Regional Medical Officer.

At 5:18 am PCMO Nizar instructed MA Mihidjai via text message to take PCV Heiderman's vitals. PCV Heiderman's blood pressure was 100/60 mmHg; her pulse was 130 beats per minute, and no temperature was taken. MA Mihidjai informed OIG during our interview that there were no more single-use thermometers in the hotel room, and so she was unable to take PCV Heiderman's temperature at that moment.

At 5:20 am PCMO Nizar asked MA Mihidjai if PCV Heiderman was able to urinate.

At 5:28 am MA Mihidjai replied to PCMO Nizar that PCV Heiderman wanted to urinate but felt too nauseous to go to the bathroom so remained in bed.

In Washington, DC

At 9:33 pm in Washington DC on the evening of January 8, which was 5:33 am the morning of January 9 in Comoros, after her phone calls with PCMO Nizar, Dr. Colantino sent an email to Dr. Maxwell Mahari, a Regional Medical Officer for the Office of Health Services, based in Pretoria, South Africa. Dr. Colantino had not been updated by PCMO Nizar about PCV Heiderman's condition since speaking to PCMO Nizar by phone about 7 hours earlier. In her correspondence to Dr. Mahari, Dr. Colantino asked him to call Dr. Nizar about PCV Heiderman's condition and coach Dr. Nizar to pursue more aggressive care for PCV Heiderman if her condition had not improved. Dr. Colantino copied the agency's international health coordinator on her message to Dr. Mahari to signal the possible consideration of an emergency medevac of PCV Heiderman.

In Comoros

At about 5:40 am PCV Heiderman got out of bed with assistance from MA Mihidjai, sat on the toilet and collapsed while urinating. MA Mihidjai called PCMO Nizar to come to the hotel, stating that PCV Heiderman had collapsed in the bathroom. MA Mihidjai told PCMO Nizar that PCV Heiderman had a pulse.

At 5:51 am MA Mihidjai notified PCMO Nizar that she could no longer find PCV Heiderman's pulse and was starting cardiopulmonary resuscitation (CPR).

At 5:55 am PCMO Nizar arrived at the hotel room and continued efforts to resuscitate PCV Heiderman through CPR. PCMO Nizar continued CPR for approximately 4 more minutes.

PCV Heiderman died at approximately 6:00 am on January 9, 2018.

SUMMARY OF MEDICAL EXPERT OPINION REGARDING CARE OF PCV HEIDERMAN

The full text of the report by an independent medical expert who reviewed the medical records related to PCMO Nizar's care for PCV Heiderman from January 2 to January 9 can be found in Appendix E to this report.

Excerpts from opinion of medical expert consulted for OIG review

Throughout her course this woman had signs and symptoms that are well characterized as indicators of malaria. These included chills, sweats, headaches, nausea and vomiting. While not specific for malaria, such abnormalities should trigger its consideration as a possible cause of illness. It is expected that a physician tasked with caring for patients previously living in the US and now visiting a malaria endemic region be aware of this. Diagnosis and initiation of treatment for malaria at an earlier stage would likely have proven lifesaving.

US travelers to malaria endemic regions are at particular risk for severe complications. Unlike the local population, travelers from non-malaria endemic countries (such as the US) typically lack immunity to the infection. Infections in people such as this volunteer can quickly progress with potentially devastating consequences. Malaria in US travelers to the Comoros is a medical emergency and should be treated accordingly. Delay in diagnosis and treatment can lead to severe complications including death. It is expected that a clinician caring for US travelers to a malaria endemic region be aware of the differences in immunity and potential outcomes of malaria between the local population and such travelers. Failure to consider the potential devastating complication of malaria in this US traveler to The Comoros was a major contributor to her death.

An additional important point of this case is the failure to proactively attempt to identify a potentially treatable underlying infection for her symptoms. While her infection was ultimately proven to be malaria, a patient with similar presentation could have had other potentially treatable infections that require specific therapies. These include typhoid fever, bacterial sepsis and meningitis.

In summary this case represented multiple failures that conspired to lead to the death of this woman. These included a failure to consider the diagnosis of malaria in a timely fashion, failure to obtain laboratory testing that would have assisted in establishing the correct diagnosis, failure to initiate prompt treatment for malaria and failure to recognize the limitation of what is medically feasible in the Comoros. Hence a mechanism for transfer to a locale with more advanced medical facilities was not activated in a timely fashion. An additional area of concern is lack of a process for systematically evaluating a patient whose symptoms should raise the alarm for a range of treatable infections.

In short, PCV Heiderman's recorded symptoms from January 2 through the 9 were consistent with malaria and should have led PCMO Nizar to consider and test for malaria.

Although as noted below there is a lack of clinical documentation in this case, the medical records that do exist show that PCV Heiderman's symptoms were "well characterized as indicators of malaria." Specifically, on January 4 PCV Heiderman's symptoms should have led PCMO Nizar to consider and test for the disease. Had he recognized the need to do so, it is more likely than not that he could have confirmed the presence of malaria in PCV Heiderman and initiated prompt treatment with Coartem. The 2015 WHO Guidelines indicate that patients who are diagnosed in the early stage of malaria and receive timely therapy are expected to make a rapid, full recovery.

The next section of this report provides our assessment of the reasons why PCMO Nizar did not suspect that PCV Heiderman's symptoms were consistent with malaria. We also offer our analysis of the systemic or institutional vulnerabilities we identified that the Peace Corps should address in order to mitigate the risk that similar clinical errors by other medical officers will lead to similar results for other sick Volunteers in malaria-endemic areas.

OIG ASSESSMENT OF PCV HEIDERMAN'S CARE AND RELATED VULNERABILITIES

As our timeline of events indicates, at no point from January 2 until her death on January 9 did PCMO Nizar consider that PCV Heiderman may have had malaria or another life-threatening illness. Rapid malaria test kits to detect the presence of the malaria parasite and medication (Coartem) to treat malaria were available throughout the time PCV Heiderman was on medical hold but they were not used because PCMO Nizar failed to consider malaria as a possible cause of PCV Heiderman's illness. As already noted, the agency's medical technical guidelines for the diagnosis and treatment of malaria (TG845) instructs medical officers caring for Volunteers to assume that Volunteers in malaria-endemic areas have been infected with malaria and to always consider a diagnosis of malaria in any febrile Volunteer. TG 845 also cautions medical officers that the initial symptoms of malaria are variable, nonspecific and appear similar to a respiratory or gastrointestinal illness.

During OIG's interview with PCMO Nizar he said "I didn't think of it" when answering our questions about whether he ever suspected a diagnosis of malaria. Below we present our understanding of the factors that explain why PCMO Nizar did not consider that PCV Heiderman's symptoms may have been caused by malaria.

PCMO Nizar, acting by himself, was convinced that PCV Heiderman had a gastrointestinal disorder and was responding to his treatment.

PCMO Nizar thought that PCV Heiderman had a gastrointestinal disorder and did not reconsider this diagnosis because he observed that PCV Heiderman's symptoms had improved as a result of the medication he gave her to stop her vomiting and nausea. PCMO Nizar acknowledged that this caused him to fail to consider other possible causes of PCV Heiderman's illness:

"I went straight to the...symptom that I had for somebody with...her vomiting...I went to gastro[interitis]. Because you will see like, most of the procedure that I did were focused on only that...So that's where I mi- why probably I missed the - thinking of ..."

When asked to explain why he did not consider the possibility that PCV Heiderman may have had malaria, PCMO Nizar said that he observed PCV Heiderman's symptoms improve in response to the medication he was using to treat her vomiting and nausea:

"After giving the Vogalene and her symptom disappear....That's...keeping me in the wrong...direction."

PCMO Nizar believed that PCV Heiderman's symptoms were due to a gastrointestinal disorder, and that she was responding positively to the treatment he had been providing her. However, in the late afternoon of January 8 PCMO Nizar began to suspect that something else was wrong

with PCV Heiderman. That evening he submitted the consult note to the Office of Health Services.

Our review identified that PCMO Nizar's conviction that PCV Heiderman had a headache and gastrointestinal disorder exposed a vulnerability related to the manner in which the Peace Corps had staffed the medical unit in Comoros. Specifically, PCMO Nizar had limited experience as a clinician treating non-immune visitors to Comoros and had no qualified colleague on site with whom he could discuss patient care. Further, no other medical officer was available to directly observe PCV Heiderman in this case.

PCMO Nizar said that in hindsight it would have been very helpful to have another Peace Corps medical officer on site to observe PCV Heiderman and consider alternatives to his diagnosis of gastroenteritis. Had another doctor been with him, PCMO Nizar said, he could have discussed PCV Heiderman's case and become 'unanchored' to his incorrect diagnosis:

"I think...it's possible. It's possible. Uh, because one man thinking, it's never be the same...as two-man thinking."

The fact that PCV Heiderman was not improving should have been evident by her worsening state of dehydration--she progressed from mild dehydration on January 2 to moderate dehydration on January 4 to severe dehydration by January 8. PCV Heiderman had a persistent high heart rate and other unstable vital signs, including low systolic blood pressure on January 8, which PCMO Nizar observed before reassuring Dr. Colantino by phone that he believed PCV Heiderman was doing better.

Based on our discussion with PCMO Nizar, our review of the medical records (despite their being incomplete) and our discussions with other Office of Health Service doctors about this case, we concluded that the presence of another qualified medical officer in Comoros would have increased the likelihood that other possible causes of PCV Heiderman's symptoms would have been considered and a timely diagnosis of malaria could have been made.

Among 62 countries, Peace Corps/Comoros was one of just five where the Peace Corps had a sole medical officer. Other posts have at least two medical officers. Office of Health Service doctors and other medical staff expressed discomfort about having only one PCMO in a vulnerable environment like Comoros. Comoros has limited medical resources, few doctors, no suitable hospitals the Peace Corps is willing to use, and is difficult to access in an emergency due to its remoteness and the infrequency of flights to and from the country. OHS officials we interviewed expressed the viewpoint that the agency should have at least two qualified medical officials at every Peace Corps post, no matter how small, and consider this the cost of doing business anywhere. The agency's report (*Comoros Special Site Assessment*) in July and August 2018 assessing the healthcare facilities in Comoros includes a recommendation that the Peace Corps/Comoros be staffed with an additional medical officer:

Peace Corps Comoros must be staffed with two full-time PCMOs credentialed for independent practice (Nurse Practitioner, Medical Doctor or equivalent) and one Medical Assistant (ideal) or Medical Secretary to assist in the administrative aspects of the Peace Corps health unit management.

A March 2019 article in the Journal of the American Medical Association (JAMA) summarized results from a study that found that a collaborative or team-based approach to patient diagnosis achieved a significantly higher degree of diagnostic accuracy compared to a model of diagnosis characterized by a single medical practitioner assessing a patient and arriving at a diagnosis on his or her own⁸. There is arguably a stronger case to be made in isolated environments such as Comoros where acceptable medical facilities and access to other qualified medical professionals are limited.

We recommend:

- 1. That the Director deploy at least two qualified medical officers to Comoros and assess the need to have a minimum of two qualified medical officers at posts with an active Volunteer population, prioritizing in the short term those posts with just one medical officer and additional vulnerabilities or factors (e.g. a medical officer with limited clinical experience, a remote archipelago with inadequate local medical facilities) that complicate the agency's ability to meet Volunteers health care needs.**

PCMO Nizar had limited training and experience diagnosing malaria in non-immune patients with the early nonspecific symptoms of malaria.

Our review also found that PCMO Nizar did not suspect malaria in PCV Heiderman because his experience and training did not prepare him well enough to recognize the early signs and symptoms of malaria in a non-immune patient. PCMO Nizar's clinical experience with malaria had been mostly limited to observing or treating partially immune patients at the local public hospital in Comoros during two years of practice prior to being hired by the Peace Corps in 2015. PCMO Nizar had limited training in tropical medicine from his years of medical schooling in China. Reflecting on this training, PCMO Nizar recalled only one non-immune patient coming to the hospital with malaria—a Chinese individual who had returned from a trip to Africa. PCMO Nizar did not have other exposure in medical school to malaria or tropical medicine.

PMCO Nizar's relevant clinical experience after medical school came in Comoros from 2013 to 2015. During this time he diagnosed and treated malaria at the local public hospital in Moroni

⁸ "Comparative Accuracy of Diagnosis by Collective Intelligence of Multiple Physicians vs Individual Physicians." Barnett, Michael, MD, MS; Boddupalli, Dhruv, MD, MBA; Nundy, Shantanu, MD, MBA; Bates, David W., MD, MSc. JAMA Network Open. March 1, 2019.

where most patients had contracted malaria multiple times. At that hospital PCMO Nizar estimated he saw, over a two-year period, on average seven Comorian patients with malaria per week, or approximately 700 patients in total. PCMO Nizar said that most local patients would come to the hospital late, when their malaria had already progressed to an advanced stage, some in a coma and near death. Therefore, PCMO Nizar did not have experience or medical training that would have helped him diagnose a non-immune sick patient with the sort of non-specific initial symptoms of uncomplicated malaria that PCV Heiderman exhibited on January 2 and January 4.

Our review found that while the Peace Corps had determined that PCMO Nizar was sufficiently qualified to be hired as its medical officer for Comoros, he had minimal training in infectious disease or tropical medicine. PCMO Nizar's medical experience in Comoros treating partially-immune patients may have compromised his ability to diagnose the non-immune American patients he was hired to treat.

The malaria prevention training that the Peace Corps provided PCMO Nizar during the continuing medical education sessions he attended in 2016 and 2017 focused on updates to the agency's medical technical guidelines related to its malaria prevention program, TG 840. The Peace Corps continuing medical education sessions did not address malaria diagnosis and treatment (TG 845), or when and how to suspect a diagnosis of malaria in a non-immune patient with non-specific symptoms. PCMO Nizar did not have relevant training or experience in this area and would have benefitted from continuing medical education training that focused on diagnosing malaria, especially in a non-immune sick patient with non-specific symptoms.

We reviewed documents pertaining to PCMO Nizar's qualifications and the agency's efforts to provide guidance and feedback to him, as a newly hired medical officer, on the quality of his clinical documentation (chart review). We also reviewed documents related to the Office of Health Services efforts to mentor PCMO Nizar during his first months of work as a new medical officer (mentor report). It was not possible to ascertain from documents provided to PCMO Nizar during this chart review process or from his mentor's reports if the Peace Corps Office of Health Services had assessed PCMO Nizar's ability to suspect malaria in a sick Volunteer at an early stage. The agency's template for assessing the clinical skills of new doctors (the "PCMO mentoring checklist") did not specify an assessment of a clinician's knowledge of TG 845, the proper threshold for suspecting malaria, or of the clinician's management of sick patients with non-specific symptoms.

We recommend:

- 2. That the associate director for the office of health services establish during hiring, chart review, mentoring, continuing medical education events or other clinical oversight and support processes, improved training for medical officers on diagnosing and treating sick patients in malaria areas that incorporates critical diagnostic considerations found in WHO Guidelines, including the importance of early consideration of a malaria diagnosis based on initial non-specific symptoms, particularly for non-immune patients such as Peace Corps Volunteers.**

PCMO Nizar and Dr. Colantino did not follow the agency's medical technical guidelines to always consider a diagnosis of malaria in a febrile Volunteer.

Peace Corps TG 845 instructs PCMOs caring for Volunteers in malaria areas to suspect that any Volunteer with a fever may have malaria:

...assume that all Volunteers are infected with the malaria parasite and that any Volunteer may develop the clinical signs and symptoms of malaria infection.... PCMOs should always consider the diagnosis of malaria in any febrile Volunteer who has been in a malarial area for more than one week...

TG 845 also states that a Volunteer with malaria may have a temperature that ranges from normal to very high. However, as seen in the timeline above, neither PCMO Nizar nor Dr. Colantino considered a diagnosis of malaria. The specific symptom that PCMO Nizar understood to be a cardinal sign of malaria was a high fever, based on his experience and his understanding of medical guidance:

"Well, for me...having the volunteer for four days without any high fever, for me it was...not the indicator that would show me."

"...when we read the literature, you would say okay, high fever, chills."

PCMO Nizar was not the only medical professional who reviewed PCV Heiderman's medical records from January 2 to 9 and expressed that PCV Heiderman's fever was not consistent with their understanding of malaria. When we asked Dr. Colantino if PCMO Nizar should have suspected that PCV Heiderman may have had malaria, Dr. Colantino also asserted that she had reviewed PCV Heiderman's vital signs in the agency's electronic medical records system and maintained that she didn't have a fever:

"You have to keep in mind though the definition of fevers. When you say that there were some fevers, the definition of fever...a clinical definition of fever is...and it depends where you go—but 100.3°F or

higher...when you go through what's documented...she doesn't meet the clinical definition of fever.”

In addition, the September 2018 report prepared by an external medical doctor consulted by the Peace Corps to review PCV Heiderman's care also observed that the lack of a “high fever” in PCV Heiderman had made it more difficult for PCMO Nizar to suspect malaria:

Falciparum malaria was a more challenging diagnosis in this case, which represented an atypical presentation in this nonimmune PCV...She did not have the more typical symptoms of high fevers, rigors and severe malaise which would be usual in a non-immune individual.

The WHO Guidelines from 2015 for malaria diagnosis instruct clinicians to base a suspicion of malaria in a sick patient on a fever of 37.5°C (99.5°F); and do not use the words ‘high fever’ in its diagnostic guidance. Peace Corps medical technical guidelines for malaria diagnosis are from 2006 and do not define the temperature threshold for suspicion of malaria. When we asked PCMO Nizar if he was familiar with TG 845, he said that he was. He noted that “febrile” as written in TG 845 was not helpful. PCMO Nizar expressed that instead, TG 845 should more clearly state that PCMOs treating Volunteers in malaria areas should always keep malaria in their differential diagnosis in order to rule out malaria as a matter of routine for all sick patients.

On January 4, PCV Heiderman's symptoms included a fever of 37.9°C (100.2°F) along with a range of other symptoms and met the threshold identified in WHO's guidelines for suspecting and testing for malaria.

In contrast to the WHO's 2015 guidelines, TG 845 does not include a defined fever threshold but instead uses the term “febrile:

assume that all Volunteers are infected with the malaria parasite and that any Volunteer may develop the clinical signs and symptoms of malaria infection.... PCMOs should always consider the diagnosis of malaria in any febrile Volunteer who has been in a malarial area for more than one week...

By not defining ‘febrile’, TG 845 allows for ambiguity regarding when to suspect malaria, and leaves it to the discretion of its medical officers to interpret what ‘febrile’ means based on their training and experience. PCMO Nizar told us that he did not consider malaria in PCV Heiderman because she did not have a “high” fever. Dr. Colantino also stated that PCV Heiderman's recorded temperature had not met the clinical definition of a fever.

TG 845 contains language regarding the typical presentation of malaria that has the potential to reinforce a medical officer's proclivity to delay consideration of a diagnosis of malaria until the patient develops a high fever instead of suspecting malaria at an earlier stage of disease progression. Specifically, although TG 845 states that an individual with malaria may have a temperature that ranges from normal to very high (105°F, 40.5°C), it also notes:

Most Volunteers will have a temperature of 102°F [38.9°C] or higher at some time in their illness.

The degree of fever included as guidance in TG 845 is 2.5°F higher than the 99.5°F defined in the 2015 WHO Guidelines.

In our interview with him, PCMO Nizar did not express an understanding of the urgency of an early diagnosis and treatment for malaria in a non-immune patient, or what the early symptoms of malaria can look like. The World Health Organization's (WHO) 2015 *Guidelines for the Treatment of Malaria* (3rd edition)—provide that when a non-immune person in a malaria endemic area (such as Peace Corps Volunteers in Comoros or other places where malaria is endemic) contracts malaria, the disease can progress very rapidly from non-specific symptoms to severe malaria, and if left untreated, severe malaria is almost always fatal. Compared to 2015 WHO Guidelines, the Peace Corps TG 845 does not convey the same sense of urgency or provide useful guidance to medical officers on this topic.

OIG also notes its concern related to the agency's maintenance of two discrete medical technical guidelines for malaria, one focused on prevention (TG 840) and another on diagnosis and treatment (TG 845). By maintaining its own medical technical guidelines for malaria prevention and for malaria diagnosis the agency elevates the risk that its guidelines will become outdated, out of alignment with one another, or that one will be out of alignment with prevailing authoritative guidance on malaria, as has happened. Our review identified that the agency's malaria diagnosis guidelines were out of date and that a review and revision of the Peace Corps' TG 845 to include updated resources is warranted. In Appendix B we compare TG 845 to the 2015 WHO Guidelines and highlight some areas that should be considered for update⁹.

To improve the likelihood that other medical officers--especially recently hired doctors from malaria endemic areas whose experience is based on treating patients with partial immunity--will suspect malaria at an early stage, we recommend:

We recommend:

- 3. That the associate director for the office of health services update the agency's medical technical guidelines for the diagnosis and treatment of malaria, and specify in them when the agency expects medical officers to suspect malaria, consistent with the most recent WHO Malaria Guidelines.**

⁹ TG 845 has not been updated since 2006 and does not reflect current agency practice. For example, TG 845 states that rapid diagnostic tests to confirm malaria diagnosis are not available for widespread clinical use. However, Peace Corps does use RDTs widely, and in this case was available to both PCMO Nizar and the Volunteer. While not a factor in this case because the PCMO did not suspect malaria, this outdated guidance could cause confusion.

- 4. That the associate director for the office of health services, taking into consideration prevailing malaria diagnosis and treatment guidelines, develop guidance for the treatment of sick patients (or make modifications to TG 113) that addresses when Peace Corps medical officers should consider and document in their assessment a suspected diagnosis of malaria as a matter of routine.**

PCMO Nizar did not follow the agency's clinical documentation standards and made diagnostic and treatment decisions without sufficient clinical data.

The agency's clinical documentation standards, TG 113 (Appendix C), are in place in to "...assure accuracy, timeliness, and quality in the recording of clinical data and the provision of care. These standards assist in establishing criteria for review of clinical documentation, identification of provider educational needs, and support the performance evaluation process."

As noted in the timeline above, PCMO Nizar had several encounters with PCV Heiderman from January 2 until January 9 which were poorly documented, and which failed to comply with the documentation standards. This lack of documentation included failure to take vital signs for some of his encounters with PCV Heiderman on January 5, 6, 7 and 8, and a failure to document some encounters.

As already noted PCMO Nizar did not consider malaria or other possible causes of PCV Heiderman's symptoms, so his 'Assessment' on each of the Patient Encounter Forms simply notes his observations of her symptoms (headache, nausea, vomiting, diarrhea) rather than an attempt to assess the underlying cause of her symptoms. PCMO Nizar did not undertake a more systematic differential diagnosis to rule out the range of possible causes of PCV Heiderman's symptoms which would have logically included malaria given her symptoms and the presence of malaria throughout Comoros. The lack of documentation in this case reflected the medical officer's failure to make clinical care decisions for PCV Heiderman based on sufficient clinical observations, including of PCV Heiderman's vital signs, and on sufficient assessments of potential underlying causes of her observed symptoms. The poor clinical documentation created gaps in the understanding of PCV Heiderman's condition while under the medical officer's care.

We recommend:

- 5. That the associate director for the office of health services specify in technical guidance such as TG 113 the degree of documentation required to reflect the medical officer's assessment of possible underlying causes of the patient's symptoms.**

PCMO Nizar did not follow the agency's clinical escalation policy or respond to Dr. Colantino's instructions on January 8 regarding communicating PCV Heiderman's condition.

In addition to the main clinical error of failing to consider malaria as a possible cause of PCV Heiderman's illness, PCMO Nizar did not properly inform the Office of Health Services about PCV Heiderman's condition.

The agency's clinical escalation policy (TG 212) requires Peace Corps Medical Officers to notify the Office of Health Services (OHS) or their regional medical officer (RMO) if a Volunteer "is experiencing a significant illness or has sustained a significant injury" as soon as possible. TG 212 (see Appendix D) lists the types of situations in which the PCMO must notify either OHS or his or her RMO. Among the serious health situations listed in TG 212 were four that applied to PCV Heiderman's condition, namely:

- Any condition likely to require emergency surgery or hospitalization.
- Any condition accompanied by unstable vital signs, including significant tachycardia (>130 bpm) or bradycardia (< 45 bpm), symptomatic cardiac dysrhythmias, hypotension (< 90 mmHg systolic), hypertension (>200mmHg systolic), tachypnea (>26 breaths/min), hypoxia (< 92% at sea level), or temperature greater than 39.5°C.
- Any condition likely to require transfer to a higher-level facility in-country or an emergency medical evacuation.
- When clinical presentation of uncertain etiology may represent a serious underlying condition, e.g., chest pain, syncope, shortness of breath, altered mental state.

PCV Heiderman required an IV drip on January 8 which was very difficult for MA Mihidjai and PCMO Nizar to place due to her degree of dehydration. Had an acceptable hospital been available in Comoros, it is likely that PCMO Nizar would have taken PCV Heiderman to it the morning or afternoon of January 8 when efforts to get PCV Heiderman on an IV drip were unsuccessful. The policy does not explicitly address situations such as Comoros where hospitalization or transfers to high level facilities are generally not approved or available.

Also, on January 8, PCV Heiderman's hypotensive systolic blood pressure reading in the afternoon (80 mmHg systolic) met the threshold for a clinical escalation.

PCMO Nizar was provided, and said that he was familiar with, the agency's clinical escalation policy. However, when asked about it, he expressed an erroneous understanding of the policy. PCMO Nizar told OIG he thought that he was supposed to place a phone call to the office of health services during the weekend, and that during other normal business hours he could submit a consult note through the agency's medical records system. He said he thought that whether or

not to follow the escalation policy by placing a phone call was a case by case consideration. This was incorrect.

PCV Heiderman's vital signs and condition had met the threshold on January 8 for the clinical escalation policy, and PCMO Nizar should have immediately called the Office of Health Services or the Regional Medical Officer in Pretoria. However, OIG assesses that PCMO Nizar did not recognize PCV Heiderman's condition to be an emergency, and therefore did not follow the clinical escalation policy as designed. Instead, as described above in the timeline of care, PCMO Nizar entered a note into the agency's electronic medical records system. His note did not convey a sense of urgency or a request for assistance. Dr. Colantino read and responded to PCMO Nizar's consult note about two hours later only because she happened to be reviewing all the consult notes on Monday afternoon, January 8, to prepare in advance for a standing triage meeting the next morning, January 9. Had Dr. Colantino not been preparing in advance for the Tuesday morning meeting, PCMO Nizar's consult note about PCV Heiderman would not have been read by an Office of Health Services official until after PCV Heiderman's death. Dr. Colantino, as noted in the timeline above, directed PCMO Nizar on January 8 to call her or the RMO should PCV Heiderman's condition change during the night of January 8, and PCMO Nizar also failed to do that.

We recommend:

- 6. That the associate director for the office of health services examine the threshold for clinical escalation and adjust or clarify the threshold as appropriate to take into account that the agency's ability to respond to a medical emergency may be complicated by factors such as the lack of suitable local medical facilities, the lack of flights to the country, or other complexities.**

Peace Corps/Comoros Took a Passive and Ineffective Approach to Implementing a Main Component of the Agency's Malaria Prevention Program

We identified vulnerabilities in the approach Peace Corps/Comoros took to implementing the agency's malaria prevention program. Three of the four components of Peace Corps malaria prevention program were completed. Specifically, the Peace Corps provided PCV Heiderman with a bed net, training about malaria and how to reduce her exposure to the risk of contracting the disease, information about the agency's malaria prevention policy and program, and a box of treatment pills (Coartem) to treat the disease if directed by her Peace Corps medical officer. PCV Heiderman, like all Volunteers serving in malaria endemic areas, signed a form acknowledging her understanding of the agency's requirement that she take her antimalarial medication, and she completed a personal health plan in which she noted her intention to adhere to her malaria

prophylaxis. The Peace Corps also provided training to PCMO Nizar in 2016 and 2017 on malaria prevention measures, including updates to the agency's malaria prevention program (TG 840) regarding the different malaria chemoprophylaxis options for Volunteers.

With respect to one key component of the agency's malaria prevention program--providing Volunteers with antimalarial medication--TG 840 sets the expectation that the agency's medical officers will provide malaria medication to Volunteers. The manner by which posts provide the medication to Volunteers varies, and posts have discretion to manage the distribution of the medication. The agency promotes as a best practice--but does not require--that its medical officers track each Volunteer's medication regime(s) to know when the Volunteer will need a prescription re-fill, including antimalarial medication.

In Comoros, the post's health unit distributed malaria medication depending on Volunteers' requests for additional medication. The post would send periodic reminders to all Volunteers about the importance of taking their antimalarial medication, and expected Volunteers to request more medicine when they needed it. Volunteers who lived close to the medical office, like PCV Heiderman, would visit the office to pick up their antimalarial medication. Volunteers would then sign the medication log book at the office with their signature and ID number. However, health unit staff did not consult the medication log book to identify Volunteers who had fallen out of compliance with their malaria chemoprophylaxis adherence, nor did they maintain a separate tracking system to anticipate when each Volunteer would require more medicine.

The post's medication log book showed that PCV Heiderman only obtained 120 Doxycycline pills between August 2016 and January 2018: she obtained 60 pills of Doxycycline on August 3, 2016 which would have lasted her until October 2, 2016; she obtained 60 more pills on January 27, 2017. After January 27, 2017 post's medication log book had no record of additional Doxycycline being dispensed to PCV Heiderman. If PCV Heiderman had taken all of those pills (we do not know if she did or did not take the 120 pills the Peace Corps provided her) she would have experienced two major gaps in her malaria suppression medication during her service in Comoros: a gap of approximately 4 months between October 2016 and January 2017, and a longer gap of approximately 9 months from late March 2017 until her death from malaria in early January 2018.

PCMO Nizar thought that PCV Heiderman had been taking her Doxycycline when he treated her in January 2018 and was not aware that it had been almost a year since PCV Heiderman last obtained Doxycycline from the health unit. According to PCMO Nizar, PCV Heiderman asked him during one of his initial encounters (January 2 or 4) if she should be taking her Doxycycline along with the other medicine he was using to treat her symptoms. He indicated to us that he had told PCV Heiderman to keep taking her Doxycycline and assumed her question meant that she had been taking it. The doctor acknowledged that he did not verify with her that she had the pills

and did not see her take them. He said that in hindsight this assumption on his part may have contributed to his failure to consider malaria as a possible cause of her illness.

Had the medical staff in Comoros established a process in 2016 or 2017 to track the provision of malaria medication to Volunteers, staff may have become aware that PCV Heiderman had not obtained sufficient antimalarial medication. Staff could have used that information to counsel PCV Heiderman (as well as other Volunteers) about the importance of rigorously adhering to the antimalarial medication schedule and could have provided her with the medication she needed, or administratively separated her if she expressed an unwillingness to take antimalarial medication. Had that process been in place before January 2018, it is possible that PCMO Nizar would have known that PCV Heiderman's malaria protection had been compromised, and thus been more likely to suspect malaria as a cause of her illness.

Based on evaluation fieldwork in Comoros in January 2019 we became aware that PC/Comoros had taken, since PCV Heiderman's death, a more active approach to tracking Volunteer requests for refills of their antimalarial medication and to communicating with Volunteers about their prophylaxis schedules. We also became aware that some Volunteers did not believe malaria remained a risk in Comoros and were not taking their antimalarial medication.

For this reason, we concluded that the medical unit in Comoros should take a more active approach to monitoring Volunteers' malaria suppression medication schedules and administratively separating Volunteers who do not consistently adhere to the requirement to take antimalarial drugs.

We recommend:

- 7. That the Peace Corps medical officer(s) in Comoros institute a process to track and provide Volunteers with malaria chemoprophylaxis on a schedule that makes it possible for Volunteers to rigorously adhere to their antimalarial medication requirement, and administratively separate Volunteers who fail to adhere to their malaria prophylaxis schedules.**

PEACE CORPS PATIENT SAFETY EVENT REVIEW

The Peace Corps patient safety event policy (TG 167) requires the agency to undertake a root cause analysis of the systemic factors that contributed to serious negative health outcomes including Volunteer deaths. The Peace Corps consulted an external medical doctor to review PCV Heiderman's care and provide a summary report (see Appendix F). This September 2018 report was provided to OIG as the agency's root cause analysis report regarding the death of PCV Heiderman. The report focused on PCMO Nizar's clinical decisions and observed that PCMO Nizar had failed to "...consider a possible underlying etiology for her persistent severe symptoms. PCMO [Nizar] needed to have performed basic labs when she had persistent symptoms..." The reviewer also noted that since the medical infrastructure in Comoros was poorly equipped to handle a patient with a severe illness, PCV Heiderman should have been medically evacuated when it was clear that she was severely dehydrated and the IV access was "tenuous." The review further noted that PCMO Nizar had failed to follow the clinical escalation policy in a timely manner.

However the reviewer's report includes a timeline with several errors, and draws some conclusions that are inconsistent with the results of OIG's review. For example, its timeline for Sunday January 7 includes information for Monday, January 8. This timeline error was likely due to how the agency's electronic medical records system failed to maintain accurate original timestamp information on Patient Encounter Forms that had been created in one time zone (Comoros) and then reviewed in another time zone (Washington, DC). The reviewer's report incorrectly states that PCMO Nizar notified a Regional Medical Officer on January 8, but that notification did not occur. And the reviewer's report concludes that:

Falciparum malaria was a more challenging diagnosis in this case, which represented an atypical presentation in this nonimmune PCV. It was more difficult to make a diagnosis of malaria in country [sic] where transmission was widely considered to have been interrupted...She did not have the more typical symptoms of high fevers, rigors and severe malaise which would be usual in a non-immune individual.

As demonstrated above, PCV Heiderman's range of symptoms were in fact consistent with well-established indicators of malaria, including chills, abdominal pain, sweats, headaches, nausea and vomiting, and fever. Also, PCMO Nizar understood that malaria remained a risk to Volunteers in Comoros. It is correct that PCV Heiderman's fever was not "high"; however, it is also true that each time her vitals were taken she had a fever that met the clinical threshold for suspecting malaria as defined by the 2015 WHO Guidelines. The WHO Guidelines do not state that a high fever is a typical symptom of a patient with malaria. The fact that PCMO Nizar had a clinical proclivity to consider a diagnosis of malaria only when treating a patient with a high fever was one of the main vulnerabilities that led to the failure to properly diagnose PCV Heiderman.

The reviewer's report also concludes that:

The primary significant errors in medical decision-making made by the PCMO included the failure to obtain any laboratory investigations when the PCV had persistent and severe illness and the failure to adequately monitor PCV's volume status. In particular performing a CBC may have lead [sic] to consideration of malaria and a basic metabolic panel would have led to consideration of more serious electrolyte imbalances. The PCMO also did not follow the chain of notification in a timely manner.

As provided above, our review identified that the main clinical error PCMO Nizar committed was a failure to consider malaria in PCV Heiderman based on her initial symptoms. Our review determined that PCV Heiderman's chance of surviving malaria would have been significantly enhanced provided PCMO Nizar had undertaken an earlier diagnosis based on her non-specific symptoms.

Although the agency's root cause analysis report did identify failures of the PCMO to investigate the causes of PCV Heiderman's illness and to follow the agency's clinical escalation policy, it did not assess the agency's systems or processes to identify potential improvements that would decrease the likelihood of a similar negative health outcome (i.e. a Volunteer death from undiagnosed malaria). For that reason, we concluded that the agency has not yet adhered to its policy on patient safety events (sentinel events). The OIG has several recommendations to the Peace Corps regarding its sentinel event review process, four of which remain open¹⁰:

6. That the associate director of the Office of Health Services implement a screening process for root cause analyses that considers severity and frequency of negative health outcomes.
7. That the associate director of the Office of Health Services ensure staffing is sufficient to adequately implement a more effective sentinel event reporting system and that staff involved in root cause analyses have not had direct involvement in the case.
8. That the associate director of the Office of Health Services perform all root cause analyses in a manner that includes key components (system focus, cause/effect, action plan and measures).
9. That the associate director of the Office of Health Services improve staff understanding of best practices for selecting sentinel events for review and for carrying out root cause analyses.

The recently enacted Sam Farr and Nick Castle Peace Corps Reform Act of 2018 mandates that the Director implement the aforementioned recommendations¹¹. Because OIG has these open recommendations we are not making another recommendation, however we urge the agency to undertake a robust root cause analysis to identify potential vulnerabilities in its systems and processes related to malaria protection and early diagnosis.

¹⁰ Final Program Evaluation Report: OIG Follow-Up Evaluation of Issues Identified in the 2010 Peace Corps/Morocco Assessment of Medical Care [IG-16-01-E]. March 2016 (recommendations 6,7,8 and 9)

¹¹ The law establishes timeframes for the Peace Corps to report to Congress on its progress in implementing the recommendations.

CONCLUSION

Our review identified numerous instances where PCMO Nizar departed from the standard of care as well as vulnerabilities associated with PCMO Nizar's inability to effectively manage PCV Heiderman's illness. These vulnerabilities were related to the doctor's training and experience, as well as the support and guidance the Peace Corps made available to him, and together they help explain why the doctor did not suspect that PCV Heiderman had malaria.

The doctor worked by himself, without the support of another medical officer at Peace Corps/Comoros with whom he could discuss PCV Heiderman's condition and treatment. PCMO Nizar did not escalate the case to the Regional Medical Officer in South Africa or to OHS as required by policy. Had another medical officer been on site to observe PCV Heiderman and discuss her care with PCMO Nizar, such consult would have increased the likelihood that PCV Heiderman's blood would have been tested for malaria and that effective treatment could have been initiated.

Further, the agency's clinical oversight processes did not appear to include sufficient opportunity for medical professionals in the Office of Health Services to identify and address observable risks related to PCMO Nizar's approach to diagnosing patients presenting with non-specific symptoms consistent with possible malaria.

TG 845 was 12 years old and poorly aligned with more current, authoritative guidance on malaria diagnosis and treatment, specifically the 2015 guidelines from the World Health Organization. WHO guidelines on malaria diagnosis and treatment include specific instructions to doctors about when to suspect and test for malaria based on a sick patient's initial, non-specific symptoms. WHO guidelines direct doctors to always suspect and test for malaria in any sick patient with a history of fever of at least 37.5°C (99.5°F) and no other known causes. This specific guidance for when to suspect and test for malaria is lacking in TG 845. PCMO Nizar did not suspect PCV Heiderman had malaria because she did not have the high fever that he associated with malaria. In her consultation with him on January 8, Dr. Colantino did not ask PCMO Nizar if he had considered a diagnosis of malaria. Dr. Colantino stated that PCV Heiderman's temperature had not met the clinical definition of a fever. The highest temperature PCMO Nizar recorded for PCV Heiderman between January 2 and January 9 was 37.9°C, or 100.2°F on January 4. Her other recorded symptoms on that day included: diarrhea, abdominal pain, vomiting, nausea, dizziness, and sweats and chills, all of which were consistent with possible malaria and should have led the doctor to test her blood for malaria.

At critical times, PCMO Nizar failed to document and check for vitals. The lack of clinical documentation in this case reflected the medical officer's failure to make clinical care decisions for PCV Heiderman based on sufficient observations, including of PCV Heiderman's vital signs, and on sufficient assessments of the potential underlying causes of her observed symptoms. The

poor clinical documentation created gaps in the understanding of PCV Heiderman's condition while under the medical officer's care. Not only did this hamper our review, but it made it more difficult to perform effective clinical oversight.

PCMO Nizar also erroneously thought that PCV Heiderman had been adhering to her antimalarial medication. This false presumption, combined with the way PCV Heiderman's symptoms did not conform to his experience treating Comorian patients, also contributed to the doctor's failure to suspect malaria. PCV Heiderman had asked the doctor while under his care from January 2 if she should take her malaria pills along with the medication he was providing her for her nausea, headache and other symptoms. As a result of this communication the doctor assumed that PCV Heiderman was taking her daily antimalarial pills. In fact, as the post's medication log book indicated, PCV Heiderman had not obtained the malaria suppression medication she required for almost a year before her fatal illness, and had likely experienced more than one gap of several months in her malaria suppression medication since October of 2016. The doctor was unaware of these lapses in PCV Heiderman's malaria suppression medication. The post took a passive approach to the distribution and tracking of required malaria chemoprophylaxis, trusting that Volunteers would request and obtain refills for the medication. The doctor did not know PCV Heiderman had not obtained the quantity of doxycycline she required for protection from malaria.

Our report makes seven recommendations to the Peace Corps to address these vulnerabilities.

LIST OF RECOMMENDATIONS

1. That the Director deploy at least two qualified medical officers to Comoros and assess the need to have a minimum of two qualified medical officer at posts with an active Volunteer population, prioritizing in the short term those posts with just one medical officer and additional vulnerabilities or factors (e.g. a medical officer with limited clinical experience, a remote archipelago with inadequate local medical facilities) that complicate the agency's ability to meet Volunteers health care needs.
2. That the associate director for the office of health services establish during hiring, chart review, mentoring, continuing medical education events or other clinical oversight and support processes, improved training for medical officers on diagnosing and treating sick patients in malaria areas that incorporates critical diagnostic considerations found in WHO Guidelines, including the importance of early consideration of a malaria diagnosis based on initial non-specific symptoms, particularly for non-immune patients such as Peace Corps Volunteers.
3. That the associate director for the office of health services update the agency's medical technical guidelines for the prevention and treatment of malaria, and specify in them when the agency expects medical officers to suspect malaria, consistent with the most recent WHO Malaria Guidelines.
4. That the associate director for the office of health services, taking into consideration prevailing malaria diagnosis and treatment guidelines, develop guidance for the treatment of sick patients (or make modifications to TG 113) that addresses when Peace Corps medical officers should consider and document in their assessment a suspected diagnosis of malaria as a matter of routine.
5. That the associate director for the office of health services specify in technical guidance such as TG 113 the degree of documentation required to reflect the medical officer's assessment of possible underlying causes of the patient's symptoms.
6. That the associate director for the office of health services examine the threshold for clinical escalation and adjust or clarify the threshold as appropriate to take into account that the agency's ability to respond to a medical emergency may be complicated by factors such as the lack of suitable local medical facilities, the lack of flights to the country, or other complexities.
7. That the Peace Corps medical officer(s) in Comoros institute a process to track and provide Volunteers with malaria chemoprophylaxis on a schedule that makes it possible for Volunteers to rigorously adhere to their antimalarial medication requirement, and administratively separate Volunteers who fail to adhere to their malaria prophylaxis schedules.

APPENDIX A: QUALIFICATIONS AND TRAINING OF PEACE CORPS/COMOROS MEDICAL UNIT STAFF

Qualifications and Training of Peace Corps Medical Officer, PCMO Nizar.

PCMO Nizar completed his medical education at China's Shanghai Jiao Tong University. He received a Bachelor of Medicine, Bachelor of Surgery (MBBS) degree in 2010 (a five-year program), followed by a Master of Surgery degree in June, 2013. After completing his degree in surgery, PCMO Nizar returned to Comoros and worked at hospitals there for approximately two years from September 2013 until being selected by the Peace Corps in the fall of 2015 to be its Peace Corps medical officer for Volunteers in Comoros. In July 2015 the Peace Corps determined that PCMO Nizar had met its eligibility requirements for core privileges, which allowed PCMO Nizar to treat conditions that fall within the typical scope of a Doctor of Medicine or a Doctor or Osteopathy.

Peace Corps policy requires that to be eligible for core privileges, applicants for PCMO positions should have Doctor of Medicine degrees, or an equivalent degree from a foreign medical school, and a valid clinical license to practice medicine. According to OHS officials we spoke to, PCMO Nizar's medical degrees (an MBBS degree and a Master of Surgery degree) qualified him for the PMCO position, and the Peace Corps employs other medical officers with medical training and experience similar to PCMO Nizar's.

Qualifications and Training of Peace Corps Medical Assistant, Anturia Mihidjai

Ms. Mihidjai holds a bachelor's degree in nursing and had experience as a nurse, dental and pharmaceutical technician prior to being selected in February 2015 to be the medical assistant for Peace Corps/Comoros. Ms. Mihidjai was required to work under the direct clinical supervision of PCMO Nizar. The Peace Corps had not granted her clinical privileges that would have allowed her to provide independent medical treatment for any conditions. Her scope of work included providing administrative support for the operation of the health unit, such as maintaining an inventory of medical supplies, corresponding with pharmacists and laboratories, sterilizing equipment, accompanying Volunteers to medical appointments, and other support functions.

OIG determined that Ms. Mihidjai consistently acted under the direct supervision of PCMO Nizar from January 2 through January 9, and did not make her own independent clinical care decisions at any point during PCV Heiderman's illness.

APPENDIX B: COMPARISON OF THE WORLD HEALTH ORGANIZATION AND PEACE CORPS MALARIA GUIDELINES

Area of Comparison	WHO Guidelines (2015)	Peace Corps TG 845 (2006) and TG 840 (2014)
Do Guidelines Reflect Current Standards of Care?	Yes. 3 rd edition of WHO Guidelines, published in 2015, is the most recent and cited by medical doctors we consulted as setting standards of care internationally.	<p>No. TG 845 was last updated in November of 2006 and based its recommendations on guidance from the CDC.</p> <p>TG 845 is 12 years old and does not contain current information about rapid diagnostic tests (see below).</p> <p>TG 845 also does not sufficiently emphasize several points about malaria we noted in WHO Guidelines, specifically: the risk of death from <i>P. falciparum</i> malaria is under-stated on p.1 and on p.8 of TG 845 (see below comparison of how guidelines discuss fatality rate).</p> <p>TG845 does not define ‘febrile’ on p.2 so fails to provide useful guidance to PCMOs on when to suspect (and hence to test for) malaria. By contrast WHO Guidelines recommend suspecting malaria if a fever is at or above 37.5° Celsius.</p> <p>TG845 provides information about the sort of temperature (102°F, 38.9°C) that “most Volunteers will have” that could cause PCMOs to disregard lower level fevers as being irrelevant to a consideration of malaria, as PCMO Nizar did.</p>
What do guidelines say about using Rapid Diagnostic Tests (RDTs)?	<p><i>Since 2012 the WHO has recommended that RDTs should be selected in accordance with the following criteria, based on the results of the assessments of the WHO Malaria RDT Product Testing programme...For detection of P. falciparum in all transmission settings...</i></p> <p><i>The tests have many potential advantages, including: rapid provision of results and extension of diagnostic services to the lowest-level health facilities and communities...</i></p>	TG 845 states: <i>This test, a rapid and simply accomplished dipstick antigen capture assay, appears promising for field diagnosis; however, it is currently not available for widespread clinical use.</i>

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<p>What do guidelines say about the fatality rate of malaria, and the importance of early diagnosis and treatment?</p>	<p>...severe <i>falciparum</i> malaria is <u>almost always fatal</u> without treatment. Therefore, programmes should ensure access to early diagnosis and prompt, effective treatment within 24-48 h of the onset of malaria symptoms.</p>	<p>TG 845 states: <i>Infection with the species P. falciparum can be life threatening...In the absence of medical treatment, parasitemia of more than 5% is often fatal.</i></p> <p>TG 845 under “Treatment of Uncomplicated Malaria” on page 7 lists a key principle of malaria management: “Recognize early infection due to <i>P. falciparum</i>.”</p> <p><i>It is imperative that PCMOs maintain a high index of suspicion and a willingness to presumptively treat Volunteers in malaria endemic areas who exhibit signs and symptoms of malaria infection. Medical Officers should not delay treatment for an ill Volunteer with presumed malaria. Delaying treatment worsens the prognosis and may result in significant disease complications and treatment complications secondary to the use of potentially toxic intravenous drugs. The mortality rate for P. falciparum malaria, if not adequately and promptly treated, can be as high as 25%.</i></p>
<p>What do the guidelines say about how malaria affects a non-immune person?</p>	<p><i>Travelers who acquire malaria are often non-immune people living in cities in endemic countries with little or no transmission or are visitors from non-endemic countries travelling to areas with malaria transmission. Both are at higher risk for severe malaria.</i></p> <p><i>Correct diagnosis in malaria-endemic areas is particularly important for the most vulnerable population groups, such as young children and non-immune populations, in whom falciparum malaria can be rapidly fatal.</i></p>	<p>TG 845 offers no direct guidance for PCMOs on this topic. It states:</p> <p><i>Signs and symptoms also depend on the malaria species, the Volunteer’s degree of immunity, and whether the Volunteer has regularly taken chemoprophylaxis.</i></p> <p>TG 840 on malaria prevention states:</p> <p><i>P. falciparum malaria is the most dangerous species among the five. It poses the greatest risk of death to non-immune persons.</i></p>
<p>What do the guidelines say are the signs and symptoms of malaria, and how it progresses?</p>	<p><i>The first symptoms of malaria are nonspecific and similar to those of a minor systemic viral illness. They comprise headache, lassitude, fatigue, abdominal discomfort and muscle and joint aches, usually followed by fever, chills, perspiration, anorexia, vomiting and worsening malaise....At this early stage of disease progression...a rapid, full recovery is expected, provided prompt, effective antimalarial treatment is given. If ineffective or poor-quality medicines are given or if treatment is delayed, particularly in P. falciparum malaria, the parasite burden often continues to increase and the patient may develop</i></p>	<p>TG 845 states: <i>Malaria classically presents with nonspecific and irregular fever, chills, headache, and malaise...Often there is a...phase...that is similar to a non-specific viral illness. Initial symptoms may progress over 1-2 days to include any of the following:</i></p> <p><i>Malaise, myalgia, backache</i></p> <p><i>Mild or severe headache, dizziness, fatigue</i></p> <p><i>Anorexia, nausea, vomiting, diarrhea</i></p> <p><i>Slight fever with chills</i></p>

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	<p><i>potentially lethal severe malaria. Disease progression to severe malaria may take days but can occur within a few hours.</i></p>	<p><i>Dry cough, shortness of breath</i></p> <p><i>In practice, presenting symptoms are variable. The disease may present with nonspecific respiratory or gastrointestinal symptoms.</i></p> <p><i>A cyclical or periodic fever pattern may or may not be present.</i></p> <p><i>Most physical signs are nonspecific. The Volunteer may seem only slightly ill...there may be sweating, anxiety, and distress.</i></p> <p><i>Temperature may range from normal to 105°F (40.6°C).</i></p> <p><i>Most Volunteers will have a temperature of 102°F [38.9°C] or higher at some time in their illness.</i></p>
<p>When do guidelines say doctors should suspect and test for malaria in a sick patient in a malaria endemic area?</p>	<p><i>The signs and symptoms of malaria are non-specific. Malaria is suspected clinically primarily on the basis of fever or a history of fever. There is no combination of signs or symptoms that reliably distinguishes malaria from other causes of fever; diagnosis based only on clinical features has very low specificity and results in overtreatment. Other possible causes of fever and whether alternative or additional treatment is required must always be carefully considered. The focus of malaria diagnosis should be to identify patients who truly have malaria, to guide rational use of antimalarial medicines.</i></p> <p><i>In malaria-endemic areas, malaria should be suspected in any patient presenting with a history of fever or temperature $\geq 37.5^{\circ}\text{C}$ and no other obvious cause.</i></p> <p><i>All cases of suspected malaria should have a parasitological test (microscopy or Rapid diagnostic test (RDT)) to confirm the diagnosis. Both microscopy and RDTs should be supported by a quality assurance programme.</i></p>	<p>TG 845 states: <i>PCMOs should assume that all Volunteers are infected with the malaria parasite and that any Volunteer may develop the clinical signs and symptoms of malaria infection.... PCMOs should always consider the diagnosis of malaria in any febrile Volunteer who has been in a malarial area for more than one week...</i></p> <p>TG 845 does not define “febrile” for purposes of establishing a temperature threshold for the clinical suspicion of malaria.</p>

APPENDIX C: PEACE CORPS CLINICAL DOCUMENTATION STANDARDS



Peace Corps Technical Guideline 113 Clinical Documentation Standards

1. PURPOSE

The purpose of this guideline is to establish clinical documentation standards which assure accuracy, timeliness, and quality in the recording of clinical data and the provision of care. These standards assist in establishing criteria for review of clinical documentation, identification of provider educational needs, and support the performance evaluation process.

2. BACKGROUND

Clinical documentation ensures that a complete, accurate, clear, consistent, and secure record of health care is created. It substantiates decisions and management plans; supports continuity of care; facilitates proactive and reactive risk management strategies, and provides useful information for quality improvement and data gathering for research purposes. Medical records are viewed as foundations of professional healthcare which makes crucial the evaluation processes.

3. PROCESS

PCMEDICS is the Peace Corps electronic medical record. Most of the necessary documentation forms/tools are located within PCMEDICS. The forms assist the provider to meet documentation standards and provide a standardized template to facilitate the clinical management of the patient.

To ensure standard documentation practices and support appropriate care, the following standards are implemented:

A. ROUTINE ENCOUNTER DOCUMENTATION TOOLS

- 1) **Summary Page** is the screen or "page" that opens when a Volunteer's name is selected and his/her PCMEDICS record is opened. The page contains numerous informational data fields. The PCMO is required to review medications, allergies, and active medical problems with each Volunteer during every encounter and document updates to the corresponding fields as necessary.
- 2) **New Encounter Form** is located in PCMEDICS in the Encounter History dropdown box in the Volunteer name banner. This form is used to document the Consultation/Brief Description/Reason for Visit, Visit Category, Record Sensitivity, Facility, Date of Service, and Issues (Injuries/Medical/Allergies). Completing/Saving this form is required in order to open the PEF and document an encounter.
- 3) **Vital Signs Form** is located in the Clinical Tab. Vital Signs including blood pressure must be taken at every encounter.
 - a. LMP must be documented for all female Volunteers in the appropriate field.
 - b. If the PCMO is not seeing the Volunteer face to face, temperature



**Peace Corps
Technical Guideline 113
Clinical Documentation Standards**

should be taken by the Volunteer, conveyed to the PCMO and documented by the PCMO.

- 4) **Patient Encounter Form (PEF)** is the primary documentation form for the majority of patient encounters. It is located in PCMEDICS under the Clinical Tab. The PEF is used to document the following Visit Categories: Office Visit, Telephone Consult, E-mail/Text/Portal Communication, Supply Refill, Immunization Only, Lab/Diagnostics Only, Local Consultant Visit, Training Event Consultation, Mental Consultation (HQ), Hospitalization, Medical Accompaniment, Health Unit Observation, Initial Clinical Intake Interview, Interim Health Evaluation, 72 Hour COS Checkout. The PEF should also be used for Sexual Assault Follow-Up visits in conjunction with the Sexual Assault Follow Up form. The PEF should not be used to document other Sexual Assault Visit Categories.

B. SEXUAL ASSAULT DOCUMENTATION TOOLS

In addition to the Summary Page, New Encounter Form, and Vital Signs Form specialized forms are used to document Sexual Assault Encounters. These forms are located under the Sensitive Tab in PCMEDICS.

- 1) **Volunteer Reporting Preference Statement (VRPS)**, also known as the Volunteer Preference Statement (VPS) is located in MS 243 "Procedures for Responding to Sexual Assault", Annex II. A prior version is also located within PCMEDICS, however, because Volunteers are not always available to sign the document at the time it is explained to them, complete the paper form of the document, obtain Volunteer signature, and then scan the document into the SA Folder in PCMEDICS. This form must be completed for all Volunteers who are Sexually Assaulted.
- 2) **Sexual Assault Clinical Exam Authorization** is found in PCMEDICS, however, at this time, use the paper form located in TG540, Attachment C, obtain the Volunteer signature, and then scan the document into the SA Folder in PCMEDICS. This form must be filled out for all Volunteers who require or desire a physical exam.
- 3) **Female and Male Sexual Assault Exam Forms** are found in PCMEDICS under the Sensitive Tab. This form must be used to document the Initial Evaluation for ALL Sexually Assaulted Volunteers. It may also be used if the Initial Evaluation is split between two separate encounters. Some Volunteers may want to have the physical exam done during one visit and the history taken during a second encounter. Use one form for the first encounter and open a second form for the second encounter, annotating on the form in the VS Notes box that it is a continuation of the Initial Evaluation. Ensure all unused blanks are filled out or populated with N/A if not applicable.
 - a. Tabs A-F must be completed to the fullest extent possible as appropriate for the history of the assault.
 - b. Sections E and F must be completed on all Volunteers who have been Sexually Assaulted.
 - c. The Summary Note at the end of Section I must be completed on all Initial Evaluation encounters.
 - d. If the Volunteer chooses a Restricted Report, the Assessment in the Summary Note is not selected via SNOMED but is



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documented.

e. If the Volunteer chooses a Standard Report the Assessment in the Summary Note is selected via SNOMED and is therefore automatically placed on the Problem List located on the Summary Page.

- 4) **Sexual Assault Standing Orders and Treatment Plan and Sexual Assault Discharge Instructions Forms** are located within PCMEDICS under the Sensitive Tab. Both of these forms are completed during the Initial Evaluation. Orders are automatically populated onto the Discharge Instructions. Ensure all unused blanks are filled out or populated with N/A if not applicable. The Volunteer must sign the Discharge Instructions and is to be given a copy of the form so that he/she can reference it for information and the follow-up appointment schedule. The signed Discharge Instruction form is then scanned into the SA Folder in PCMEDICS.
- 5) **Sexual Assault Follow-Up Form** is located at the Sensitive Tab in PCMEDICS. This form is used at every Sexual Assault Follow-Up appointment or telephone call. The form is a Mental Health Evaluation and STD/ASD Screening, identical to Section E and F of the Sexual Assault Exam Form. In addition to using the Sexual Assault Follow-Up Form for follow-up appointments or contacts, the PCMO must also open a PEF and use it to complete the encounter including other pertinent history elements, a physical exam as necessary, and required elements of assessment, medications, labs, and patient education.

C. CLINICAL DOCUMENTATION STANDARDS—ROUTINE ENCOUNTERS

All Routine Patient Encounters must include the following elements:

- 1) A problem list is in use, completed appropriately and current
- 2) Medications are reconciled/updated
- 3) Allergies, including reactions (Document NKA or list Allergy and reaction)
- 4) Chief complaint is identified
- 5) (S) Encounter contains problem-focused medical history (HPI)
- 6) (S) Volunteer safety is documented
- 7) (O) Complete vital signs for each visit (including LMP)
Note: Phone consult must have temperature and/or assess fever
- 8) (O) Problem focused physical exam
- 9) (A) Assessments are consistent with findings
- 10) (P) Plans of action/treatment are consistent with assessment; see following:
 - 9A. Appropriate consultation with OHS/RMO/In- Country Consultants
 - 9B. Diagnostic and Lab testing is appropriate to assessment
 - 9C. Patient Education documented
 - 9D. Medications are appropriate to assessment and prescribed correctly
 - 9E. Patient follow-up documented and appropriate
- 11) Unresolved problems from previous visits are addressed
- 12) Three patient identifiers on each scanned page (name, DOB, gender or SSN/ID)
- 13) Consultant reports and/or diagnostic testing results are reviewed, translated, initialed, dated and scanned into PCMEDICS



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- 14) Continuity and coordination of care between PCMO and consultants
- 15) Care is medically appropriate
- 16) Provider signature and date within 72 hours

D. CLINICAL DOCUMENTATION STANDARDS—SEXUAL ASSAULT

ALL Sexual Assault, Aggravated Sexual Assault, and Rape patient encounters must include the following elements:

- 1) The problem list is complete and updated appropriately per Volunteer Preference Statement
- 2) Medications are reconciled/updated
- 3) Allergies, including reactions (Document NKA or list Allergy and reaction)
- 4) Sexual Assault Encounter Form (SAEF) is used for documentation of the encounter & signed by PCMO
- 5) (S) Sexual Assault history (HPI) is completed (SAEF, Section C, boxes 1-3 and others completed as indicated)
- 6) (S) PCV safety is documented
- 7) (O) Vital Signs obtained and LMP documented (SAEF Section B, box 1)
- 8) (O) Mental Health Status is documented (Sections E & F completed)
- 9) (O) Problem focused physical exam documented (Sections G-I as appropriate)
- 10) (A) Assessments are consistent with findings (Section L Summary note)
- 11) (P) Sexual Assault Standing Orders & Treatment Plan are initiated (button @ top right of form) & signed by PCMO
 - 10A. Appropriate consultation and follow-up with OHS/RMO/In-Country Consultants
 - 10B. Diagnostic and Lab testing is appropriate for the assessment (Standing Orders)
 - 10C. Sexual Assault Discharge Information /Instructions are implemented, signed by Volunteer & PCMO and scanned into PCMEDICS
 - 10D. Medications are appropriate for the assessment and prescribed correctly (Standing Orders)
- 12) Three patient identifiers on each scanned page (name, DOB, gender or SSN/ID)
- 13) Consultant reports & test results are reviewed, translated, initialed, dated and scanned into PCMEDICS
- 14) Volunteer Preference Statement is signed by Volunteer & PCMO and scanned into PCMEDICS
- 15) Sexual Assault Clinical Exam Authorization is completed and signed by Volunteer & PCMO and scanned into PCMEDICS
- 16) Care is medically appropriate
- 17) Sexual Assault Forensic Exam (SAFE) if performed is documented on medical forms in Sexual Assault Kit (SAK) per TG 542

E. DOCUMENTATION REVIEW

- 1) Routine Encounters
 - a. During each quarter of the fiscal year, the Quality Improvement Unit will review the PCMEDICS documentation of 10 Volunteer encounters completed by each PCMO.
 - b. Quality Improvement Nurses will select encounters for review from



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-
- the PCMO list of completed encounters during the specified scheduled review quarter.
 - c. Selected encounters will represent and reflect clinical management. Encounters documenting medication pick-up, COS physical forms, IST or mid-service evaluations or immunization updates will not be selected for review.
 - d. If available within the review period, at least one encounter documenting each the following types of illness will be reviewed:
 - Gastrointestinal**
 - Respiratory**
 - Mental Health**
 - Sexual Assault**
 - e. Chart reviews are an important element in PCMO annual performance review and scores will be utilized in this process.
- 2) Aggravated Sexual Assault and Rape Encounters
- a. SNOMED Codes are not used to document the Assessment/Diagnosis on Restricted Report Sexual Assaults; therefore, for **all Aggravated Assault and Rape encounters** PCMOs must send the Volunteer's name and DOB to the **Quality Improvement Unit via SFTP e-mail with the subject line: "SA (country) for Review"**.
 - b. The Quality Improvement SARRRP Nurse will review the encounter(s) as they are reported by the PCMO.

F. SCORING STANDARD

95-100%: Excellent (**E**)

90-94%: Meets Standards (**MS**)

Less than 90% does not meet standards: Needs Improvement (**NI**)

G. SCORING GUIDELINES AND INTERVENTIONS

- 1) Charts will be reviewed by clinicians who are knowledgeable in Peace Corps documentation standards and current clinical practice standards.
- 2) PCMOs will receive appropriate and timely feedback.
- 3) PCMOs who consistently score 95% and above for a period of one year (four submissions) will be assigned a two times per year submission schedule (this rule does not pertain to Aggravated Sexual Assault and/or Rape Charts).
- 4) All Aggravated Assault and Rape charts must be reviewed. PCMOs will notify Quality Improvement Unit via SFTP e-mail message when Aggravated Sexual Assault and/or Rape charts are ready for review.
- 5) If at any time the PCMO review scores fall below 90%, OHS reserves the right to place PCMO on remediation
- 6) Reviewer must notify OHS Clinical Director when a PCMO is placed on remediation.



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H. MONITORING, EVALUATION, AND REPORTING

- 1) The Quality Improvement Unit will present QI quarterly and annual reports to the Quality Council regarding the status of clinical oversight/chart reviews and interventions; these reports will include a separate section on the results of the aggravated sexual assault and rape cases.
- 2) The Quality Improvement Unit will submit the results of the clinical oversight/chart reviews and interventions regarding aggravated sexual assault and rape cases to the Sexual Assault Risk Reduction and Response Program (SARRRP) on a quarterly and annual schedule.

APPENDIX D: PEACE CORPS CLINICAL ESCALATION POLICY



Peace Corps
Technical Guideline 212

CLINICAL ESCALATION POLICY

1. PURPOSE

The purpose of this policy is to provide guidance regarding Peace Corps Medical Officer (PCMO) reporting of hospitalizations, critical injuries and illnesses to the Office of Health Services (OHS).

2. BACKGROUND

It is the responsibility of PCMOs to report by phone, the status of Peace Corps Volunteers (PCV) or Peace Corps Trainees (PCT) to the Office of Health Services when a significant illness, injury, or hospitalization occurs.

3. ESCALATION PROCESS

The PCMO should notify OHS/RMO if a PCV/T is experiencing a significant illness or has sustained a significant injury as soon as possible. Notification should never delay care in a life threatening situation. Situations in which OHS/RMO *must* be notified include, but are not limited to:

- Life threatening or potentially life threatening conditions.
- Any condition likely to require emergency surgery or hospitalization.
- Any condition accompanied by unstable vital signs, including significant tachycardia (>130 bpm) or bradycardia (<45 bpm), symptomatic cardiac dysrhythmias, hypotension (<90 mmHg systolic), hypertension (>200 mmHg systolic), tachypnea (>26 breaths/min), hypoxia ($<92\%$ at sea level), or temperature greater than 39.5°C .
- Any condition likely to require transfer to a higher level facility in-country or an emergency medical evacuation.
- Trainee or Volunteer with an acute psychiatric problem who is a threat to the PCV/T or others.
- Any Volunteer involved in a motor vehicle accident, motorcycle accident or pedestrian accident involving a motorized vehicle.
- Prior to any surgical procedure requiring anesthesia.
- Prior to any blood or blood product transfusion.
- Loss of consciousness.
- When clinical presentation of uncertain etiology may represent a serious underlying condition, e.g., chest pain, syncope, shortness of breath, altered mental state.
- When a condition or diagnosis carries a possible prognosis of long term disability or morbidity, e.g., traumatic injury with possible loss of function.
- When a condition may lead to significant cosmetic deformity, e.g., large facial lacerations, facial leishmaniasis.
- When a condition or diagnosis is associated with a significant radiographic abnormality.
- After a physical or sexual assault where there is significant trauma or psychological issues.

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When reporting to OHS/RMO, the PCMO should have as much of the following information available as possible:

- Recent and past medical history
- Mechanism of traumatic injury and status of anyone else involved in the trauma
- Working diagnosis
- Vital signs and any available laboratory or imaging studies
- Initial plan of care
- Location of PCV including the capabilities of the healthcare facilities
- Safety of PCV
- Potential need to move PCV and plan of action should this become necessary
- PCMO follow-up plan
- Determine if permission given to speak to family members

APPENDIX E: EXPERT OPINION OF DR. SHMUEL SHOHAM



I have been asked to comment on the events leading up to the death of a volunteer who had been working in The Comoros as part of a Peace Corps assignment. In this letter I will address her clinical presentation, medical management and ultimate death due to severe malaria. I will specifically address the following points:

- How unusual was the patient's presentation of malaria in this case?
- How should a doctor with clinical experience diagnosing malaria have responded to these symptoms?

Medical qualifications

I am an Associate Professor of Medicine at Johns Hopkins University School of Medicine. I am certified by the American Board of Internal Medicine in the subspecialty of Infectious Diseases and am licensed to practice medicine in the State of Maryland and the District of Columbia. I have over 17 years of experience in management of patients with invasive infections including illnesses such as malaria. I am the author or co-author of over 100 original articles, book chapters and topic reviews. I serve as a reviewer and expert consultant to multiple journals, professional societies and government agencies in the US and abroad and am a member of professional guideline committees for the American Society of Transplantation (AST), the European Organization for Research and Treatment of Cancer/Invasive Fungal Infections Cooperative Group and Infectious Diseases Mycoses Study Group (EORTC/MSG) and the National Comprehensive Cancer Network (NCCN). In 2015 the Washington, DC Chapter of the American College of Physicians honored my commitment to excellence in medical care and service to the College with their highest award, the John F. Maher Memorial Laureate Award. In 2017, I completed specialized training in reducing patient harm and graduated from the Armstrong Institute Patient Safety and Quality Improvement Leadership Academy, Johns Hopkins Medicine.

Facts of the case:

At the time of her death on January 9, 2018 the volunteer was a 24-year-old woman who was in overall good health. Over an approximately 10 day period she progressed from being asymptomatic to succumbing to severe malaria, which by then had involved multiple organs including her brain. The timeline of her clinical presentation and course are as follows:

- January 2: She reported a 3-day history of headaches with dizziness when getting out of bed. She reported to adhering with the prescribed anti-malaria treatment (doxycycline). At that time she had nasal congestion and physical exam findings of temperature 99.49F, heart rate of 119/min and blood pressure of 100/60. She was diagnosed with a new headache disorder



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and given symptomatic treatment with promethazine, an antacid, acetaminophen, and phenylephrine.

- January 4: She reported no improvement in her original symptoms. She also had additional symptoms of diarrhea, vomiting, sweats, chills and lower abdominal pain at that time. Examination showed temperature of 100.2F, heart rate of 100/min and blood pressure of 100/60. She was treated with IV fluids and promethazine.
- January 5: She reported ongoing headache described and associated dizziness. While the diarrhea and nausea were reported as improving, her exam showed lower abdominal tenderness. The vital signs were not checked. She was treated symptomatically with acetaminophen with codeine.
- January 8-9: She was noted to vomiting and reported chest pain. The diarrhea and dizziness had improved on that day. Her examination showed temperature of 99.4F, heart rate of 124/min and blood pressure 80/60. She was treated symptomatically with acetaminophen, cimetidine, promethazine and metopimazine. Treatment with IV fluids was given, but this was not consistently successful due to poor venous access. She ultimately received 2.5 liters of isotonic IV fluids with transient improvement in hemodynamic status. Early in AM of January 9 she developed hemodynamic instability with more tachycardia (heart rate 130/min), felt hot and collapsed. Shortly after that she died of severe malaria with multiorgan involvement.
- Autopsy showed *Plasmodium falciparum* in lung, liver brain as confirmed by immunohistochemical studies. Plasmodium species antigen was present in post-mortem blood.

Analysis

This volunteer died of severe malaria. She was at risk for acquiring this infection and for developing severe disease once infected. Had she received timely therapy it is more likely than not that her death would have been prevented.

1. As a traveler to the Comoros she was at risk for this infection. The United States Centers for Disease Control and Prevention (CDC) identifies all areas of the Comoros as having malaria (primarily due to *Plasmodium falciparum*). Longer durations of stay in a malaria-endemic area, as in this case, may also increase the chance of infection. Doxycycline, which she reported to be taking, is a recommended method of prevention. However, no chemoprophylactic regimen is completely effective, and failure of prophylaxis for malaria is a well-known phenomenon. A clinician knowledgeable in malaria is expected to recognize that infection can be acquired and can progress despite a patient's report of taking doxycycline.
2. Throughout her course this woman had signs and symptoms that are well characterized as indicators of malaria. These included chills, sweats, headaches, nausea and vomiting. While not specific for malaria, such abnormalities should trigger its consideration as a possible cause of illness. It is expected that a physician tasked with caring for patients previously

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living in the US and now visiting a malaria endemic region be aware of this. Diagnosis and initiation of treatment for malaria at an earlier stage would likely have proven lifesaving.

3. US travelers to malaria endemic regions are at particular risk for severe complications. Unlike the local population, travelers from non-malaria endemic countries (such as the US) typically lack immunity to the infection. Infections in people such as this volunteer can quickly progress with potentially devastating consequences. Malaria in US travelers to the Comoros is a medical emergency and should be treated accordingly. Delay in diagnosis and treatment can lead to severe complications including death. It is expected that a clinician caring for US travelers to a malaria endemic region be aware of the differences in immunity and potential outcomes of malaria between the local population and such travelers. Failure to consider the potential devastating complication of malaria in this US traveler to The Comoros was a major contributor to her death.
4. An additional important point of this case is the failure to proactively attempt to identify a potentially treatable underlying infection for her symptoms. While her infection was ultimately proven to be malaria, a patient with similar presentation could have had other potentially treatable infections that require specific therapies. These include typhoid fever, bacterial sepsis and meningitis.

In summary this case represented multiple failures that conspired to lead to the death of this woman. These included a failure to consider the diagnosis of malaria in a timely fashion, failure to obtain laboratory testing that would have assisted in establishing the correct diagnosis, failure to initiate prompt treatment for malaria and failure to recognize the limitation of what is medically feasible in the Comoros. Hence a mechanism for transfer to a locale with more advanced medical facilities was not activated in a timely fashion. An additional area of concern is lack of a process for systematically evaluating a patient whose symptoms should raise the alarm for a range of treatable infections.

Respectfully submitted, July 4, 2018



Shmuel Shoham, MD

Associate Professor of Medicine
Johns Hopkins University School of Medicine
Baltimore, MD 21205

APPENDIX F: PATIENT SAFETY EVENT REVIEW--LETTER FROM DR. PRINCY KUMAR



Princy N. Kumar, MD
*Professor of Medicine and Microbiology
Division Chief*

Department of Medicine
Division of Infectious Diseases
and Travel Medicine

Thomas M. Wilkinson, M.D.
Medical Officer and Clinical Supervisor
Chief, Health Informatics Unit
Office of Health Services, United States Peace Corps
1111 20th St NW, Room 5136
Washington, DC 20526

September 5, 2018

Dear Dr. Wilkinson,

Please find below my review regarding Ms. Bernice Heiderman's death following a brief illness during her Peace Corps service in Comoros.

Sincerely,

A handwritten signature in dark ink, appearing to read "Princy N. Kumar".

Princy N. Kumar, MD, FIDSA, MACP
Professor of Medicine and Microbiology
Chief, Division of Infectious Diseases and Travel Medicine
Senior Associate Dean of Students
Georgetown University School of Medicine
[Redacted]

[Redacted]



Princy N. Kumar, MD
Professor of Medicine and Microbiology
Division Chief

Department of Medicine
Division of Infectious Diseases
and Travel Medicine

Summary of BH

BH was a 24 year old female PCV in Comoros who presented for care on January 2nd 2018 with a 3 day history of non-specific symptoms consisting of headache, dizziness, vomiting, and coryza without self-reported fever. Her exam revealed a temperature of 37.5 and a pulse of 119, blood pressure 110/60. She appeared fatigued and weak but alert and oriented.

On January 3rd 2018 (day 4 of illness), she reported acute diarrhea, worsening non-bloody emesis, worsening orthostatic dizziness, intermittent hand numbness, sweats and chills with a borderline temperature of 37.9 (while taking Tylenol 650 mg TID). Her vital signs were stable (BP 100/60, HR 100). She was noted to have moderate dehydration and mild upper abdominal pain. She received IV fluids, antiemetics, and ongoing Tylenol.

On January 4th 2018 (day 5 of illness) she had persistent headache, orthostatic dizziness and stomach pain, but her vomiting and diarrhea had both improved and only mild abdominal pain on palpation. She had no self-reported fever, but vitals were not assessed at that visit as she was assessed at the hotel. She received Tylenol with codeine and ongoing supportive care.

Not assessed by health care provider January 5th or 6th (Friday and Saturday). Reports of other PCV's visiting

On January 7th 2018 (day 8 of illness) she again reported significant vomiting, but resolution of headache and improvement in dizziness, and chest pain that she attributed to vomiting. She was noted to have minor tenderness to the upper abdomen. She had no self-reported fever, but vitals were not assessed at that visit as she was assessed at the hotel. She was reassessed the same day as vomiting had

become persistent, noted to be agitated, hypotensive 80/60, tachycardic p 124, T 37.5 with difficulty placing an intravenous, but ultimately received 2.5-3L of IV fluid along with supportive care. She was admitted to the hotel overnight with a diagnosis of severe dehydration, with the medical assistant sleeping next door.

January 8th 2018 (day 9 illness) ongoing emesis with multiple failed attempts at IV placement (ultimately successful at 5 pm), although after IV fluids she appeared to improve without vomiting or dizziness, and vitals had stabilized (afebrile, T-37.5, heart rate 110, BP 100/60). PCMO spoke with CD. OMS/HQ are consulted. Following the request for consultation Dr. Colantino calls PCMO directly and is told that she is doing better, though IV is tenuous. Dr Colantino recommends repeating vital signs and to obtain a basic metabolic panel and a complete blood count. She then emails RMO (Mahari) that she is worried and requests that PCMO is coached on more aggressive care if she does not improve

January 9th 2018 (day 10 illness) from 1-4 am she described non-specific symptoms including stomach pain, hiccoughs, heart burn. Blood pressure was stable but tachycardia to 130. She went to the toilet to urinate with MA assistance, and collapsed while urinating, and was pulseless. CPR was performed unsuccessfully.

Autopsy Report:

The autopsy report conclusively confirms the diagnosis of malaria, based on the combined findings of P. falciparum antigen (Binax Now) present in blood, and immunohistochemical evidence of plasmodium falciparum in brain, lung, and liver, and splenomegaly. There was noted to be abundant intravascular and intraerythrocytic malarial parasites and intrahepatic malarial pigment. The findings were confirmed by the Center for Disease Control and Prevention, infectious disease pathology branch.

Assessment:

Medical decision making and clinical performance:

- Received attentive daily in person assessment, but there was no consistency in performing vital signs or appropriately assessing fluid balance/response to resuscitation
- Up until January 7th 2018 her clinical symptoms were not severe and were generally non-specific, and appeared to improve and might have been reasonably mistaken for any number of bacterial or viral syndromes, and she was showing signs of intermittent clinical improvement with supportive care. However on January 7th she showed signs of significant volume depletion and had persistent vomiting for over 1 week. At minimum a basic CBC, CMP and electrolytes should have been performed with close clinical monitoring of fluid balance (not done), and PCMO fails to perform any work-up or consider a possible underlying etiology for her persistent severe symptoms
- PCMO needed to have performed basic labs when she had persistent symptoms, particularly when they became severe.

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- Infrastructure in Comoros not equipped to handle any patient with severe illness (ICU modern equipment, but from description non-functional), hence she needed to be medically evacuated when it becomes clear that she is significantly volume depleted and that IV access is tenuous.
- It appears that the PCMO did not follow the chain of notification in a timely manner. The RMO was notified only on January 8th 2018, 9 days into the illness and Peace Corps headquarters also received notification only on January 8th, 2018.
- Once Peace Corps headquarters was notified they took immediate action with Dr Allison Colantino placing a phone call directly to the PCMO and providing recommendations. Dr Colantino also then follows up by sending an email to RMO, Maxwell Mahari so that recommendations could be instituted in a more timely manner, given time difference. However by the time Peace Corp has been notified, it is essentially too late.

Conclusion:

The autopsy report is conclusive for cerebral malaria. Falciparum malaria was a more challenging diagnosis in this case, which represented an atypical presentation in this nonimmune PCV. It was more difficult to make diagnosis of malaria in country where transmission was widely considered to have been interrupted. The PCV also presented with GI-predominate symptoms, and a fluctuating course which seemed to improve at times, both of which are less common. She did not have the more typical symptoms of high fevers, rigors and severe malaise which would be usual in a non-immune individual, and in most case series of imported malaria over 95% of non-immune travelers have fever. However she did have low grade temperatures of 37.5-37.9, and malaria is a diagnosis that should be considered in any ill PCV within a potentially malaria-endemic zone whether or not fever is present. The primary significant errors in medical decision-making made by the PCMO included the failure to obtain any laboratory investigations when the PCV had persistent and severe illness and the failure to adequately monitor the PCV's volume status. In particular performing a CBC may have lead to consideration of malaria and a basic metabolic panel would have led to consideration of more serious electrolyte imbalances. The PCMO also did not follow the chain of notification in a timely manner.

Respectfully submitted,



Princy N. Kumar, MD, FIDSA, MACP
Professor of Medicine and Microbiology
Chief, Division of Infectious Diseases and Travel Medicine

WHO report – Comoros in 2015 ~1500 presumed and confirmed cases of malaria, only 1 death from malaria in 2015.

<http://www.who.int/malaria/publications/world-malaria-report-2016/WMR-2016-annexes.pdf>

APPENDIX G: AGENCY RESPONSE TO THE REPORT



MEMORANDUM

To: Kathy Buller, Inspector General

From: Jody K. Olsen, Director
Anne Hughes, Chief Compliance Officer

Date: May 24, 2019

CC: Michelle K. Brooks, Chief of Staff
Carl Sosebee, Senior Advisor to the Director
Robert Shanks, General Counsel
Shawn Bardwell, Associate Director, Office of Safety and Security
Karen Becker, Associate Director, Office of Health Services
Patrick Young, Associate Director, Office of Global Operations
Johnathan Miller, Regional Director, Africa Region
Tim Hartman, Chief of Operations, Africa Region
Randa Wilkinson, Country Director, Comoros

Subject: Agency Response to the Management Advisory Report: Review of the Circumstances Surrounding the Death of a Volunteer in Peace Corps/Comoros (IG-19-04-SR)

Thank you for the opportunity to respond to the Management Advisory Report: *Review of the Circumstances Surrounding the Death of a Volunteer in Peace Corps/Comoros* (MAR). The Peace Corps continues to mourn the tragic loss of Peace Corps Volunteer Bernice Heiderman (PCV Heiderman). The agency has undertaken a rigorous internal review of this case and is implementing numerous changes in response to this event.

The agency responds below to the specific recommendations outlined in the MAR. However, there are a number of statements and conclusions in the MAR that should be addressed. In the following three sections, the agency addresses three areas of the MAR: PCV Heiderman's non-adherence to Peace Corps' malaria prevention program, clinically relevant errors in the interpretation of the medical information, and the implication that Peace Corps headquarters staff

were not sufficiently proactive in addressing PCV Heiderman's case and did not follow the agency's Technical Guideline.

I. PCV Heiderman did not adhere to malaria prevention steps and prophylaxis requirements, or fully disclose her prophylaxis non-compliance, which affected the diagnosis.

The MAR states:

...the Peace Corps provided PCV Heiderman with a bed net, training about malaria and how to reduce her exposure to the risk of contracting the disease, information about the agency's malaria prevention policy and program, and a box of treatment pills (Coartem) to treat the disease if directed by her Peace Corps medical Officer. PCV Heiderman, like all Volunteers serving in malaria endemic areas, signed a form acknowledging her understanding of the agency's requirement that she take her antimalarial medication, and she completed a personal health plan in which she noted her intention to adhere to her malaria prophylaxis.¹²

PCV Heiderman did not properly use the prevention strategies available to her as required by Peace Corps policy. As the MAR points out, "TG 840 sets the expectation that the agency's medical officers *and Volunteers* will act vigilantly to reduce Volunteers' risk of contracting malaria"¹³ (emphasis added). The agency's TG 845 *Diagnosis and Treatment of Malaria* states, "Volunteers should not stop any chemoprophylactic regimen without consulting the Peace Corps Medical Officer (PCMO). Improper self-discontinuation of prophylaxis places a Volunteer at risk for malaria."

The MAR states that PCV Heiderman had not been adhering to her required malaria suppression medication for several months prior to falling ill at the end of December 2017 and did not notify the PCMO of this fact. Instead, as stated in the MAR, "PCV Heiderman asked him during one of his initial encounters (January 2 or 4) if she should be taking her Doxycycline along with the other medicine he was using to treat her symptoms. He...told PCV Heiderman to keep taking her Doxycycline and assumed her question meant that she had been taking it."¹⁴ The Patient Encounter Forms (PEF) document Doxycycline on PCV Heiderman's active medication list, reflecting the PCMO's belief that his patient had been taking her antimalarial medications. This inaccurate assumption about malaria chemoprophylaxis, the atypical presentation of the disease, and the PCMO's incomplete documentation made diagnosis of malaria far more difficult than the MAR concludes.

¹² Management Advisory Report: Review of the Circumstances Surrounding the Death of a Volunteer in Peace Corps/Comoros (IG-19-04-SR) (MAR) at 29.

¹³ MAR at 7.

¹⁴ MAR at 30.

PCV Heiderman’s decision not to disclose her non-adherence with malaria prevention medication to the PCMO conveyed a very different risk profile, which contributed to the PCMO’s assessment of potential diagnoses.

II. The MAR contains clinically relevant errors in the interpretation of the medical information and the complexity of the case.

a. The MAR relies on WHO recommendations to the exclusion of other authorities, including the Centers for Disease Control and Prevention and the Peace Corps’ guidelines, and does not consider the challenges in medical diagnosis and decision-making.

The MAR refers to the 2015 WHO ‘Guidelines for the Treatment of Malaria’¹⁵ (WHO Guidelines) and relies upon them for establishing clinical standards in the care of malaria to the exclusion of all other authorities including the Centers for Disease Control and Prevention (CDC) and the Peace Corps’ Technical Guidelines (TGs) effective at the time of this case.

The Peace Corps has historically aligned its malaria policy, specifically TG 845 *Diagnosis and Treatment of Malaria*, with recommendations from the CDC, a primary, authoritative external resource for the Peace Corps. Subsequent to PCV Heiderman’s death, the 2018 Farr-Castle Peace Corps Reform Act requires Peace Corps to follow CDC guidance¹⁶. The PCMO and the Director of Medical Services’ actions should be evaluated against the Technical Guidelines that medical staff were expected to use. It is not reasonable to expect Peace Corps clinicians to have used external, retrospectively identified guidelines in their clinical determinations in January 2018. The evaluation should have included a more detailed discussion of the medical literature, including the discrepancies and areas where guidance and guidelines vary in their descriptions of patients’ symptoms (e.g., a description of temperature ranges) to better assess clinical decision-making in this case.

b. The MAR contends that PCV Heiderman had a fever, concluding that the PCMO and the Director of Medical Services should have made a definitive diagnosis of malaria.

Throughout the MAR, the words “temperature” and “fever” are used interchangeably.¹⁷ In medical literature they are distinct and should not be used interchangeably.¹⁸ This conflation of

¹⁵

https://apps.who.int/iris/bitstream/handle/10665/162441/9789241549127_eng.pdf;jsessionid=93AC020106E14B98FE8A51E3ECD8CD37?sequence=1

¹⁶ 22 U.S.C. §2504(f), a(e)

¹⁷ MAR at i; ii; 1; 9; 11; 12; 24; 25; 32; 34; 38.

¹⁸ The word “temperature” refers to an objective data point – a quantifiable number. The word “fever” is a qualitative term used to classify temperature ranges and add clinical significance to a range of quantitative temperature recordings. For accuracy of an impartial assessment of a medical case, it is imperative that any reviewer

terms results in the conclusory statements that PCV Heiderman had a fever. However, there is no uniform description or criterion of “fever” in malaria related medical literature. PCV Heiderman’s recorded temperatures did not rise to the level of a fever according to many clinical definitions of fever, including definitions from CDC¹⁹ and the Infectious Disease Society of America²⁰.

The OIG’s medical expert appropriately uses the word temperature in his timeline. He does not define the temperature as fevers or say that PCV Heiderman had fevers, in patterns either typical or atypical to malaria. The MAR quotes its medical expert’s conclusion by adding the term ‘fever’, however, this is not what the OIG’s medical expert stated.

The Director of Medical Services explained to the OIG staff in an interview that PCV Heiderman’s temperature did not meet the threshold for a fever, based on the documentation maintained in the medical record by the PCMO.²¹ The agency’s TG 845 states that when diagnosing malaria a Volunteer’s temperature, “may range from normal to 105°F (40.6°C). Most Volunteers will have a temperature of 102°F or higher at some time in their illness.” The Peace Corps’ expert, Dr. Princy Kumar, Chief of the Division of Infectious Diseases and Travel Medicine at Georgetown University, and an expert in malaria, reported that “(Heiderman) did not have the more typical symptoms of high fevers, rigors and severe malaise which would be usual in a non-immune individual.”²²

c. The MAR oversimplifies diagnostic decision-making and does not consider, discuss, or analyze the complexities that would have been expected with a dynamic, 10-day course of illness.

The MAR oversimplifies the complexities of the case, because by the time OIG and the expert consultants were writing the MAR they were fully aware that malaria was the ultimate cause of death. The oversimplification occurs when the MAR applies early symptoms of malaria as typical throughout the clinical course of the disease and does not consider what severe malaria at a late stage presentation would typically look like. A patient within 7.5 hours of death from malaria, as was the case when the Director of Medical Services first reviewed the PCMO consult note in the agency’s electronic medical record system, would not typically be described as improving (see Section III). A person with cerebral malaria, as PCV Heiderman was later found

understand the medical differences in these terms and also recognize that there is no uniform agreement in the medical literature of the precise range of quantified temperatures that should be classified as a clinical fever.

¹⁹ <https://www.cdc.gov/quarantine/maritime/definitions-signs-symptoms-conditions-ill-travelers.html>

²⁰ <https://www.idsociety.org/globalassets/idsa/practice-guidelines/2008-newfever-in-critically-ill.pdf>

²¹ MAR at 24-25.

²² MAR at 55.

to have had, is usually obtunded, stuporous, or comatose.²³ They are typically ICU-level patients and they appear critically ill.²⁴

Given that PCV Heiderman first reported symptoms on December 30, the information that the patient was feeling better would be atypical for a non-immune individual sick with malaria for at least 10 days. By omitting this important contextual information, the MAR does not consider or include all material facts that informed the clinical decision-making at the time of the evolving case.

d. The MAR failed to correct erroneous factual information and inaccurately questioned the accuracy of the agency expert's report.

An error in the MAR lists PCV Heiderman's hypotensive systolic blood pressure reading on the afternoon of January 8 as 60 mmHG systolic. The medical record documents her blood pressure reading as 80 mmHg systolic. This is a medically significant difference and would be readily noted by a medical professional. A blood pressure of 60 mmHG systolic would constitute shock, and would present with pale cold extremities and altered mental status.

The MAR also states that the report submitted by the Peace Corps' external consultant, Dr. Princy Kumar, Chief of the Division of Infectious Diseases and Travel Medicine at Georgetown University, included a timeline with several errors. The version attached as Appendix F to the MAR does not contain the errors reported by the OIG. The Peace Corps notified OIG of this matter prior to publication.

III. The MAR conveys an inaccurate impression that Peace Corps headquarters staff were not proactive in addressing the Volunteer's case and that the Director of Medical Services did not follow the agency's medical technical guidelines.

Typically, the agency is provided with an exposure draft of a MAR and given an informal opportunity to correct any inaccuracies in the draft or clarify issues that may have been overlooked. This case was unusual in that two exposure drafts of the MAR were issued. The second exposure draft contained six additions, which were not present in the first exposure draft, regarding the actions of the Washington, D.C. based Director of Medical Services. It is understood that the text was added to the second exposure draft after the first exposure draft was

²³ *Obtundation* is a state similar to lethargy in which the patient has a lessened interest in the environment, slowed responses to stimulation, and tends to sleep more than normal with drowsiness in between sleep states. *Stupor* means that only vigorous and repeated stimuli will arouse the individual, and when left undisturbed, the patient will immediately lapse back to the unresponsive state. *Coma* is a state of unarousable unresponsiveness. <https://www.ncbi.nlm.nih.gov/books/NBK380/>.

²⁴ Storm J, Craig AG Pathogenesis of cerebral malaria—inflammation and cytoadherence *Front Cell Infect Microbiol.* 2014 Jul 29;4:100

shared and discussed with PCV Heiderman's family, but without the addition of any new factual information supporting the additional changes.

Consistent with the agency's TG 370 *Field Consultation and Communication*, the Office of Medical Services provides consultation to overseas medical personnel. As part of a first consult, the Director of Medical Services is expected to review the available information and recommend a plan of management. When the Director of Medical Services was reviewing notes in the medical record system, she saw the recorded blood pressure of 80/60, and recognized that this was low and met the criteria per TG 212 *Clinical Escalation* for the PCMO to contact headquarters. The Director of Medical Services immediately called the PCMO directly. The PCMO provided an update on vital signs over the phone. PCV Heiderman's blood pressure had improved to 100/60, which is considered near the low range of normal for women and a value near her known baseline during service.

Further, at the time of the Director of Medical Services' call to the PCMO, the Patient Encounter Form (PEF) did not document a fever and included documentation that PCV Heiderman herself said she did not feel feverish. Likewise, PCV Heiderman's recorded temperature that day was 37.5°C (99.5°F), which is not typically considered a fever according to the Peace Corps' malaria diagnosis guideline, TG 845 (see Section II. b.). During the call with the PCMO, who had firsthand, in-person knowledge of PCV Heiderman's situation, he indicated: PCV Heiderman was getting better; that he felt that the situation was under control; that antibiotics were not necessary; and that he did not believe hospitalization was necessary.

The revisions to the second exposure draft reference the fact that the Director of Medical Services did not discuss a possible malaria diagnosis with the PCMO. The clear implication is that failure to do so was improper. The agency maintains that the Director of Medical Services responded reasonably and thoroughly given the information she was provided at the time she worked to determine a cause and treatment for PCV Heiderman's symptoms. She immediately recommended additional tests and worked to ensure that resources were in place to activate a medical evacuation, if necessary.

The MAR implies that someone in the Director of Medical Services' position would arrive at a precise final diagnosis in less than an hour based on the incomplete information provided. The PCMO's anchoring on the diagnosis of gastrointestinal illness, the inclusion of Doxycycline anti-malarial medication on all PEF notes, the incomplete documentation and nonspecific clinical findings, the patient's and physician's assurances that she was feeling better, and the atypical temperature in a non-immune individual would not lead to an immediate diagnosis of malaria. The Director of Medical Service's actions were appropriate and reasonable given the context, circumstances, and timing.

The death of Bernice Heiderman in Comoros was a tragic event. It is important that the agency learns from this tragedy to better ensure that a case like this is not repeated.

Recommendation 1

That the Director deploy at least two qualified medical officers to Comoros and assess the need to have a minimum of two qualified medical officers at posts with an active Volunteer population, prioritizing in the short term those posts with just one medical officer and additional vulnerabilities or factors (e.g. a medical officer with limited clinical experience, a remote archipelago with inadequate local medical facilities) that complicate the agency's ability to meet Volunteers health care needs.

Concur

Response: The Office of Health Services (OHS) and the Office of Global Operations will recruit and add another PCMO in Comoros. The agency is currently assessing the need to have a minimum of two qualified medical officers at all other single PCMO posts.

Documents to be Submitted:

- *RMO Report*
- *Site assessment reports for single PCMO posts*
- *TG 204, Attachment J-Assessment of Air Ambulance Services*

Status and Timeline for Completion:

September 2019

Recommendation 2

That the associate director for the office of health services establish during hiring, chart review, mentoring, continuing medical education events or other clinical oversight and support processes, improved training for medical officers on diagnosing and treating sick patients in malaria areas that incorporates critical diagnostic considerations found in WHO Guidelines, including the importance of early consideration of a malaria diagnosis based on initial non-specific symptoms, particularly for non-immune patients such as Peace Corps Volunteers.

Partially Concur

Response: The Office of Medical Services (OMS) bases its recommendations for the prevention, diagnosis and treatment of malaria on the most recent guidance from the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO), current literature, expert consensus opinion, and evidence-based guidelines where they exist. The agency partially concurs with this recommendation because it does not solely rely on WHO Malaria Guidelines.

All PCMO candidates are asked an interview question, "What infectious and/or tropical diseases do you have experience treating?" as part of the hiring process. OHS' epidemiology unit has established improved training as referenced, including circulating to all posts a reminder email and review of malaria symptoms, testing, management and follow-up with links to current

review articles and resources on the epidemiology SharePoint site. In March 2019 a “Malaria Toolkit” was released on SharePoint with resources for post administration, PCMOs, and Volunteers, this was announced in the March OHS newsletter.

Malaria educational sessions were conducted during 2018 Continuing Medical Education (CME) cycle and will be during the 2019 CMEs. Malaria policy lectures were conducted during all OSTs in February 2018, October 2018 and February 2019. Both TG 840 *Prevention of Malaria* and TG 845 *Malaria Diagnosis and Treatment* are in the final process of external review.

Documents to be Submitted:

- Email to all posts about WHO temperature cutoff and need to test for Malaria in any illness in endemic countries
- TG 840 and 845 (See response #3)
- 2018 sample CME lecture on Malaria best practices
- 2019 sample OST lecture on Malaria policy
- 2018 sample CME agenda including lecture schedule
- 2019 planning documents for CME agenda
- OHS March Newsletter announcing malaria toolkit resource

Status and Timeline for Completion:

August/September 2019 (CME cycle)

Recommendation 3

That the associate director for the office of health services update the agency’s medical technical guidelines for the prevention and treatment of malaria, and specify in them when the agency expects medical officers to suspect malaria, consistent with the most recent WHO Malaria Guidelines.

Partially Concur

Response: As noted in Recommendation 2, OMS bases its recommendations for the prevention, diagnosis and treatment of malaria on the most recent guidance from the CDC and WHO, current literature, expert consensus opinion, and evidence-based guidelines where they exist. The agency partially concurs with this recommendation because it does not solely rely on WHO Malaria Guidelines.

TGs 840 *Prevention of Malaria* and 845 *Malaria Diagnosis and Treatment* have both been updated and urge all PCMOs and Volunteers and Trainees working and living in malaria endemic areas to test for malaria when ill, whether with classic signs or non-specific illness. These updated TGs are with the CDC for peer review. The Domestic Malaria Chief in the CDC's Division of Malaria and Parasitic Diseases is our first peer reviewer has completed the review. After this review is complete, the agency will have a State Department Infectious Disease expert

review as well as outside experts in the neuropsychiatric side effects of antimalarial medication. These TGs and attachments are set to be complete prior to the PCMO CME this summer.

Documents to be Submitted:

- Updated TG 840 *Prevention of Malaria and relevant attachments*
- Updated TG 845 *Malaria Diagnosis and Treatment and relevant attachments*

Status and Timeline for Completion:

August 2019

Recommendation 4

That the associate director for the office of health services, taking into consideration prevailing malaria diagnosis and treatment guidelines, develop guidance for the treatment of sick patients (or make modifications to TG 113) that addresses when Peace Corps medical officers should consider and document in their assessment a suspected diagnosis of malaria as a matter of routine.

Concur

Response: TG 845 *Malaria Diagnosis and Treatment* has been updated to incorporate guidance on malaria evaluation and diagnosis.

In addition, there is extensive information in TG 845 on differential diagnosis, signs and symptoms, fever periodicity, laboratory diagnosis, and treatment. OHS also requires a consultation entered into PCMEDICS for all cases of presumed and confirmed malaria.

The escalation policy, TG 212 *Clinical Escalation Policy*, has been updated and circulated. It provides guidance regarding Peace Corps Medical Officer (PCMO) reporting of hospitalizations, critical injuries and illness to OHS.

TG 113 *Clinical Documentation Review* will be updated to incorporate documentation standards for presumed and confirmed malaria cases and documentation requirements.

Documents to be Submitted:

- *TG 845 Malaria Diagnosis and Treatment*
- *TG 212 Clinical Escalation Policy*
- *TG 113 Clinical Documentation Review*

Status and Timeline for Completion:

August 2019

Recommendation 5

That the associate director for the office of health services specify in technical guidance such as TG 113 the degree of documentation required to reflect the medical officer's assessment of possible underlying causes of the patient's symptoms.

Concur

Response: The updated TG 845 *Diagnosis and Treatment of Malaria* will contain guidance on malaria evaluation and diagnosis. PCMOs are instructed to suspect malaria until proven otherwise. There is also a section on writing required OHS consults for all cases of presumed and confirmed malaria cases.

In addition, TG 113 *Clinical Documentation Review* will be updated to integrate the requirements outlined in TG 845 and strengthen the requirements for clinical documentation.

Documents to be Submitted:

- *TG 845 Diagnosis and Treatment of Malaria*
- *TG 113 Clinical Documentation Review*

Status and Timeline for Completion:

August 2019

Recommendation 6

That the associate director for the office of health services examine the threshold for clinical escalation and adjust or clarify the threshold as appropriate to take into account that the agency's ability to respond to a medical emergency may be complicated by factors such as the lack of suitable local medical facilities, the lack of flights to the country, or other complexities.

Concur

Response: The Associate Director of OHS has examined the threshold for clinical escalation, and a revised clinical escalation policy, *TG 212 Clinical Escalation Policy*, has been completed and circulated to PCMOs and OHS staff. It will provide guidance regarding the PCMO reporting of hospitalizations, critical injuries and illnesses to OHS.

Documents to be Submitted:

- *TG 212 Clinical Escalation Policy*

Status and Timeline for Completion:

May 2019

Recommendation 7

That the Peace Corps Medical Officer(s) in Comoros institute a process to track and provide Volunteers with malaria chemoprophylaxis on a schedule that makes it possible for Volunteers to rigorously adhere to their antimalarial medication requirement, and administratively separate Volunteers who fail to adhere to their malaria prophylaxis schedules.

Concur

Response: The Comoros PCMO instituted a process to track malaria prophylaxis distribution for each PCV beginning in January 2019. The tracking is being done by the PCMO with assistance by the Medical Assistant (MA) for follow-up.

In addition, the PCV Comoros Health Manual is being updated with more detailed information about malaria and malaria prevention. The final update will be completed by June 1, 2019.

Concurrently, the PCMO will discuss compliance during site visits and use the document TG 204 to record her/his findings. Program staff will also include a conversation about health and taking malaria prophylaxis during their more frequent site visits. If Volunteers are found to be non-compliant with taking their malaria prophylaxis, staff will inform the PCMO, and the PCMO will inform the Country Director. Peace Corps Manual Section 262 *Peace Corps Medical Services Program* provides that “V/Ts who refuse to take required immunizations/vaccinations and medical prophylaxes will be administratively separated, as set out in MS 284 Early Termination of Service.” If the Country Director determines that a V/T is refusing to take malaria prophylaxis, s/he will begin the administrative separation process as described in MS 284.

During Pre-Service Training (PST) all the Peace Corps Trainees (PCTs) received a session on malaria presented by a Peace Corps Medical Officer. This session provides background information on malaria, including transmission, symptoms, prevention and treatment. It stresses the importance of taking malaria prophylaxis and contacting the PCMO if malaria is suspected. It also outlines the potential consequences of not taking the prescribed prophylaxis. In addition, the Peace Corps/Department of State video KNOW Malaria was viewed by the PCTs. All Volunteers at Post have received a two-day Malaria Training by Health the APCD from PC Senegal. The training covers aspects of malaria infection and prevention, as well as activities useful in schools and at the community level.

Documents to be Submitted:

- *Tracking of Malaria Prophylaxis for current and future Volunteers*
- *Updated chapter on malaria for the PCV Comoros Health Manual*
- *TG 204, Attachment A PCMO Site Visit Checklist*
- *TG 204, Attachment B Non-PCMO Site Visit Checklist*
- *Updated PCV Comoros Handbook 2019-2020 (pages 64 and 113)*
- *PST Malaria Training Session Outline*
- *PST Malaria PowerPoint presentation*

Status and Timeline for Completion:

June 2019

APPENDIX H: OIG COMMENTS

OIG Comments Concerning the Agency's Responses to the Review's Recommendations

Management concurred with recommendations 1,4,5,6 and 7, and partially concurred with recommendations 2 and 3. 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 1,3,4,5,6 and 7 when the documentation reflected in the agency's response to the preliminary report is received. For recommendation 2 additional documentation is required. This recommendation remains open pending confirmation from the chief compliance officer that the documentation reflected in our analysis below is received.

OIG commends the agency for its responses to the MAR's recommendations, which are generally thorough and responsive. The actions the agency has undertaken thus far appear well crafted to address the vulnerabilities identified in the MAR.

However, after providing our analysis of the agency's response to the MAR's recommendations, we address some of the statements the agency made in its response to other information in the MAR (see below).

Recommendation 2

That the associate director for the office of health services establish during hiring, chart review, mentoring, continuing medical education events or other clinical oversight and support processes, improved training for medical officers on diagnosing and treating sick patients in malaria areas that incorporates critical diagnostic considerations found in WHO Guidelines, including the importance of early consideration of a malaria diagnosis based on initial non-specific symptoms, particularly for non-immune patients such as Peace Corps Volunteers.

Partially Concur

Response: The Office of Medical Services (OMS) bases its recommendations for the prevention, diagnosis and treatment of malaria on the most recent guidance from the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO), current literature, expert consensus opinion, and evidence-based guidelines where they exist. The agency partially concurs with this recommendation because it does not solely rely on WHO Malaria Guidelines.

All PCMO candidates are asked an interview question, “What infectious and/or tropical diseases do you have experience treating?” as part of the hiring process. OHS’ epidemiology unit has established improved training as referenced, including circulating to all posts a reminder email and review of malaria symptoms, testing, management and follow-up with links to current review articles and resources on the epidemiology SharePoint site. In March 2019 a “Malaria Toolkit” was released on SharePoint with resources for post administration, PCMOs, and Volunteers, this was announced in the March OHS newsletter.

Malaria educational sessions were conducted during 2018 Continuing Medical Education (CME) cycle and will be during the 2019 CMEs. Malaria policy lectures were conducted during all OSTs in February 2018, October 2018 and February 2019. Both TG 840 *Prevention of Malaria* and TG 845 *Malaria Diagnosis and Treatment* are in the final process of external review.

Documents to be Submitted:

- Email to all posts about WHO temperature cutoff and need to test for Malaria in any illness in endemic countries
- TG 840 and 845 (See response #3)
- 2018 Sample CME lecture on Malaria best practices
- 2019 Sample OST lecture on Malaria policy
- 2018 sample CME agenda including lecture schedule
- 2019 planning documents for CME agenda
- OHS March Newsletter announcing malaria toolkit resource

Status and Timeline for Completion:

August/September 2019 (CME cycle)

OIG Analysis: In addition to the documents listed above, OIG requests that the agency provide documentation of its actions to establish improved guidance or training on malaria diagnosis for medical officers during *mentoring* and *chart review* processes. Please refer to the paragraph in the report that precedes recommendation 2; the paragraph presents the results of our review of agency processes to provide guidance and feedback to new medical officers, including through chart reviews and mentoring, on their clinical documentation and management of sick patients.

OIG notes that the agency has partially concurred with the recommendation on the basis that it does not rely solely on WHO Guidelines. OIG understands that the agency does not rely solely on WHO Guidelines. The recommendation does not contain language that requires the agency to rely solely on WHO Guidelines.

OIG will review the documents to be submitted for evidence that the agency has incorporated in them information about the importance of an early consideration of a

malaria diagnosis based on initial non-specific symptoms, particularly for non-immune patients.

OIG Comments Concerning Other Statements in the Agency's Response to the Review

The agency's response to the MAR includes some statements that we address below.

I. PCV Heiderman did not adhere to malaria prevention steps and prophylaxis requirements, or fully disclose her prophylaxis non-compliance, which affected the diagnosis.

On the second page of the agency's response, the agency correctly states that "The Patient Encounter Forms (PEF) document Doxycycline on PCV Heiderman's active medication list..." The agency then asserts that the Doxycycline noted on these PEFs reflected PCMO Nizar's "belief" that PCV Heiderman had been taking her antimalarial medication. Based on our interview of PCMO Nizar, and as noted on page 30 of the MAR, he did not verify during his encounters with PCV Heiderman that she had been taking her doxycycline every day. Doxycycline was noted next to 'Current Medications' on the PEFs because the agency's electronic medical record system *automatically populated* PCV Heiderman's PEF with this information by pulling it from the previous PEF that PCMO Nizar had created for PCV Heiderman. Its presence on the PEF was therefore not reliable evidence of PCMO Nizar's belief that PCV Heiderman was taking this medication.

The agency's response further states on the second page that the presentation of malaria in this case was "atypical" without support for this characterization. The MAR presents extensive evidence that PCV Heiderman's recorded signs and symptoms were well characterized as indicators of malaria, especially the early signs and symptoms documented in the PEFs for January 2, 4, and 5. The medical technical guidelines we reviewed, including TG845, and information about malaria signs and symptoms from the CDC and the World Health Organization described the range of signs and symptoms noted on the PEFs for PCV Heiderman. This is significant because one of the principle vulnerabilities the MAR documented was that PCMO Nizar did not consider a diagnosis of malaria in PCV Heiderman because he did not recognize her non-specific symptoms as being consistent with a possible malaria infection. As noted in the MAR, PCMO Nizar had a clinical proclivity to consider a diagnosis of malaria based on the specific symptom of a high fever.

More importantly, as noted in the MAR, the agency's malaria technical guidelines instruct medical officers to assume that Volunteers serving in malaria areas have become infected with malaria and may develop the signs and symptoms of a malaria infection. The agency's medical guidelines require PCMOs to consider a diagnosis of malaria in any Volunteer regardless of the extent to which Volunteers may disclose or fail to disclose their adherence to their required malaria prophylaxis schedule. PCMO Nizar understood this requirement yet did not consider a

diagnosis of malaria because he did not observe the specific symptom of a *high* fever in PCV Heiderman that he believed signaled a malaria infection.

There is not a reasonable basis for the agency to state that the diagnosis of malaria in this case was more difficult to make as a result of PCV Heiderman's undisclosed non-adherence to malaria medication, or because her symptoms were atypical.

II. The MAR contains clinically relevant errors in the interpretation of the medical information and the complexity of the case.

The agency's response indicates its perception that OIG relies on World Health Organization guidelines "to the exclusion of other authorities." However, our MAR made broad use of Peace Corps medical technical guidelines and referenced other authorities including the CDC and WHO Guidelines. The MAR's recommendations were not written to preclude Peace Corps from referring to or incorporating malaria diagnostic guidance from other authoritative sources.

The MAR included 2 recommendations that Peace Corps incorporate diagnostic guidelines and considerations found in the WHO's 2015 malaria guidelines because: 1) Peace Corps medical technical guideline 845 was out of date and 2) the incorporation and consideration of these more recent and authoritative WHO guidelines would have made it more likely that PCMO Nizar would have tested PCV Heiderman for a possible malaria infection. The PEFs for each of the documented encounters PCMO Nizar had with PCV Heiderman included the signs and symptoms that the WHO Guidelines indicate should prompt a suspicion of malaria. This was less clear when we compared the PEFs to the more ambiguous ("febrile") and outdated malaria diagnostic guidance found in TG 845. The 2015 WHO Guidelines appeared specifically written to provide unambiguous guidance to clinicians designed to increase the likelihood of identifying a malaria infection before it progresses to serious or complicated malaria, especially in developing countries where the risk of malaria infection is high, and the availability of advanced medical care is limited.

On the third page of the agency's response to the MAR, the agency says that "Subsequent to PCV Heiderman's death, the 2018 Farr-Castle Peace Corps Reform Act requires Peace Corps to follow CDC guidance." While under 22 U.S.C. §2504(f) the Peace Corps is required to follow Centers of Disease Control and Prevention guidance "regarding the prescription of medications" to volunteers, the act does not require or suggest that the Peace Corps limit its medical technical guidance for malaria diagnosis and treatment to the CDC, or prevent the agency from considering and incorporating diagnostic guidance found in other authoritative sources such as the WHO Guidelines.

On the third page of the agency's response, the agency incorrectly states that our MAR presents a conclusion that PCMO Nizar and the Director of the Office of Medical Services "should have made a definitive diagnosis of malaria." This overstates what the MAR says. As noted in the MAR, TG 845 directs medical officers to "always consider the diagnosis of malaria in any

febrile Volunteer who has been in a malaria area for more than one week.” The MAR states that the PCMO and the Director of OMS did not consider a diagnosis of malaria. The MAR provides an assessment of why malaria was not considered in order to identify the underlying vulnerabilities the agency should address to reduce the risk that other medical officers would fail to consider a diagnosis of malaria when treating a patient with similar symptoms.

On the fifth page of the agency’s response, it states that the MAR includes a systolic blood pressure reading on the afternoon of January 8 as 60 mmHg systolic. The timeline in the MAR on page 15 correctly states the blood pressure as 80/60 mmHg on the afternoon of January 8. However, the agency is correct that the MAR includes on page 28 the wrong hypotensive systolic blood pressure number “(60 mmHg systolic)”, which should read “(80 mmHg systolic).” In our analysis we utilized the reading to discuss the threshold for clinical escalation. The reading of 80 mmHg systolic was below the agency’s threshold for a clinical escalation. The error did not impact our finding and conclusion, but OIG will make the necessary correction on page 28 of the report.

On the fifth page of the agency’s response, it states that the appended report by the external consultant does not contain the errors the MAR reported. The agency provided OIG with two versions of the consultant’s report. Both reports contained timeline errors. As the MAR states, the information in the consultant’s report related to January 7th includes information for January 8th, not January 7th.

III. The MAR conveys an inaccurate impression that Peace Corps headquarters staff were not proactive in addressing the Volunteer’s case and that the Director of Medical Services did not follow the agency’s medical technical guidelines.

The agency notes that without any new factual information supporting additional changes, OIG added text to the report after the first exposure draft was shared with the agency and PCV Heiderman’s family. Our final report does include edits we made during our final review of the report, based in part on input we received from the agency and PCV Heiderman’s family. This final review was part of our quality assurance process. As a part of that process both the Agency and the personal representative for PCV Heiderman were provided exposure drafts of this report in order to identify any perceived errors or inaccuracies in it.²⁵ We then made edits to the MAR that we determined were reasonable, important, and supportable based on the evidence we had collected.

With respect to the particular finding that PCMO Nizar and Dr. Colantino had not followed relevant medical diagnostic guidelines for malaria, OIG updated the finding to more clearly present criteria that was in the exposure draft but had not been directly cited in the finding

²⁵ OIG notes that the personal representative for PCV Heiderman was provided an exposure draft because the family served as an important source of information to understand the facts and circumstances surrounding her death.

statement: that neither physician had followed the agency's guidelines in TG 845 to "always consider" a diagnosis of malaria. The finding statement in the final MAR references the physicians' non-adherence to TG 845 in order to focus the rest of the finding on the underlying reasons why the agency's guidelines were not followed in this case.

OIG disagrees that the MAR conveys inaccurate impressions. The MAR accurately describes the actions of Dr. Colantino on January 8th, specifically as of 2:40 pm EST when she called PCMO Nizar after having reviewed the consult note he had entered a few hours earlier. The MAR summarizes Dr. Colantino's discussions with PCMO Nizar and other actions she took. The MAR includes a finding that PCMO Nizar did not follow the agency's clinical escalation properly or the instructions he had received from Dr. Colantino by phone on January 8th.

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