

Posh Corps Podcast Ep. 15: Mefloquine

By Alan Toth

Transcript

- Narration: Malaria, it's an ancient disease spread by mosquitoes. It's likely been one of the most persistent causes of human death throughout history. According to the Centers for Disease Control Over 600,000 people dies of Malaria in 2012. Most Malarial endemic countries are developing nations. They are the places that American Peace Corps volunteers can be found living and working in rural communities.
- All Peace Corps volunteers who work in Malarial endemic countries are required to take anti-Malarial medications, but some Peach Corps volunteers think that the medication might be just as dangerous as Malaria itself. Sara Thompson is a returned Peace Corps volunteer who served in Burkina Faso from 2010 to 2012.
- Sara: I'd always really been interested in joining Peace Corps, but also I'd always been interested in development work. I'd always been interested in Africa and the conflict in Africa. I studied French actually, because I really wanted to go to French speaking Africa.
- Narration: Sara was placed in a tiny village in Eastern Burkina Faso, she worked with local women in a community garden.
- Sara: In Burkina Faso. Malaria is actually the number one cause of death and so the Peace Corps policy is, it's that it's mandated that Peace Corps volunteers take and anti-Malaria medication. The anti-Malarial medication that I took was Mefloquine.
- Narration: According to the Peace Corps Office of Medical Services, every volunteer in a malaria endemic country has an individual consultation with their Peace Corps Medical Officer, the Peace Corps staff members responsible for volunteer health care. The volunteer and the PCMO discuss the pros and cons of each medication and all possible risks and side effects, and decide on a medication together.
- Sara says that she was not offered an actual consultation about her malaria prophylaxis options.
- Sara: Peace Corps, pretty much, pre-determines which drug they're going to give you, and so they just hand you a bag with the anti-malarial prophylaxis and say, "this is what you're going to take.
- Narration: Sara says that when she arrived in Burkina Faso she was given several doses of Mefloquine, along with a waiver form, which listed the anti-malarial medications available to volunteers. The medications listed on the waiver were Mefloquine, Doxycycline, and Malarone.

Sara: So, like I said, I was just given Mefloquine and I didn't really question it. Everybody just says, "Oh you just get some bad dreams. It's not a big deal." But, even on the waiver, there's no indication that any of the side effects can be permanent.

Narration: Mefloquine which is sold under the brand name Lariam is an anti-Malarial drug developed by the Walter Reed Army Institute and Roche Pharmaceuticals. Use of Mefloquine for Malaria prevention or prophylaxis was actually tested on Peace Corps volunteers in 1989.

It was not a true double blind clinical trial. Peace Corps volunteers were trusted to take Mefloquine as directed. In fact, the side effects were so severe, that most volunteers secretly stopped taking it, but the effectiveness and the potential side effect of Mefloquine were determined based on this flawed study and the side effects of Mefloquine can be severe.

Sara: There were some days in which I would sleep excessively. You'd go to bed at 8 o'clock at night because the sun sets at 6, and so you go to bed at 8 and then you sleep to 6 or 8 in the morning so that's at least 10 hours. Then in the afternoon I would probably sleep another 4. So, it was just a lot of sleeping. I was light headed a lot of the time, also I would ... there were times where I would cry or I'd kind of over react to certain situations and even the Peace Corps Medical Officer wrote in my file that I wasn't adjusting to site very well and I actually thought I was. Little things like that you just justify everything because you're in a new country.

Narration: Mefloquine can cause side effects like headaches, nightmares, dizziness and anxiety, but it can also cause more serious side effects like depression, paranoia, hallucination and psychosis. These neurotoxic side effects are studied by Dr. Remington Nevin. Dr. Nevin is a consulting physician and epidemiologist. He worked at the Walter Reed Army Institute, and did his epidemiology studies at Johns Hopkins University. Dr. Nevin specializes in the evaluation of adverse reactions to antimalarial medications, particularly Mefloquine.

Dr. Nevin: We know that Mefloquine is a neurotoxic, it's somewhat like lead and mercury in that a small amount, in some people, can cause a psychiatric effects that can last long after the drug has been stopped and neurological effects that can be permanent. These are not uncommonly disabling and interfere with the patients ability to work and enjoy a high kind of quality of life.

Narration: Near the end of her service Sara Thompson experienced some of the more severe neurotoxic side effects of Mefloquine.

Sara: What had happened was that I had gotten so dizzy to the point that I was vomiting. The room just would not stop spinning. I couldn't lie down, I couldn't sit up, I couldn't really walk straight in a straight line and I was just super worried. I called the PCMO and I said, "Look, I don't think I hit my head, but this is really starting to freak me out,"

Sara: He said, "Oh yeah, you'll be fine. " Because I was going into the capitol in a few days anyway because I was doing close of service evaluation. He said, "Just come in and we'll look at you then." I said, "Okay." It was... I will never forget that night, it was the worst night.

Interviewer: How long did that last?

Sara: For probably, I would say, 3 to 6 hours.

Interviewer: When you did go in, to COS, what did the PCMO tell you or did they determine anything?

Sara: They just said it was an ear infection. That ear infections usually cause dizziness and so they gave me some anti-nausea pills.

Narration: Sara ended her service in 2012 and returned to the United States but her neurological issues continued.

Sara: Then when I finally got back to my parents house in Omaha, Nebraska in December. I'll never forget it, I'd get up in the middle of the night to go to the restroom or something and I would just fall over as though I had been drinking and I was drunk and I hadn't had anything that day. The sense of equilibrium was so great I couldn't go to the restroom in the middle of the night without falling down. There was that, there were a lot of headaches, headaches or migraines very, very frequently.

Narration: After service, returned volunteer health care is covered through a program called the Federal Employees Compensation Act or FECA which is administered by the Department of Labor. Sara filed a FECA claim which allowed her to visit a general practitioner, but the GP wasn't able to diagnosis her problem. Sara was told that she would need to see a specialist. She went to a neurologist who told her that she had an inner ear problem.

Sara: For some reason I just felt like that wasn't it. I mean my symptoms were a little more nuanced than that. I felt like there were some other things with my body that just weren't right. I talked to a RPCV, actually, and I said, "Look I'm having these really weird symptoms, I have no idea what's going on." She said, "Well did you take Mefloquine? I said, "Yeah." She goes, "It might related to that." She actually pointed me in the direction of Dr. Remington Nevin.

Narration: Sara consulted with Dr. Remington Nevin. He reviewed her Peace Corps medical file and discussed her continuing symptoms. Dr. Nevin concluded that Sara was likely suffering from the continuing side effects of Mefloquine.

Sara: When I got Dr. Nevin's evaluation it was just really hard, because like I said, I thought that the Mefloquine toxicity, to me after my preliminary research, it was just related to the dizziness. I didn't think that I had been affected too much beyond

that and in Dr. Nevin's medical evaluation, he could point to specific instances in which the PCMO wrote, "Well she cries a lot, she's not adjusting to her site very well. She seems to freak out." I can't remember the exact jargon but the fact that it seems I was cognitively effected even before I was physically effected, was pretty telling.

Narration: In 2013 the Food and Drug Administration issued a Black Box Warning, it's strongest possible warning, regarding the neurologic and psychiatric side effects of Mefloquine use. The FDA was responding to a series of Mefloquine studies which were performed over the previous 10 years. These studies found that the incidents of adverse side effects to Mefloquine use was much higher than previously thought the warning indicated that, " Neurologic side effects can occur at time during drug use and can last for months to years after the drug is stopped, or can be permanent." After the Black Box Warning was issued, the US Army ordered their commanders and medical personnel to stop prescribing Mefloquine to special forces and elite combat units.

In addition the army ordered it's medical workers to begin assessing that some rank and file soldiers accused of malingering or diagnosed with PTSD may in fact be suffering from Mefloquine neurotoxicity. One might have expected the Peace Corps Headquarters to do the same and re-evaluate their own use of the drug, but that didn't happen. On the same day that the Black Box Warning was issued, a Senior Medical Officer at Peace Corps Headquarters sent an email to colleagues at the CDC. The Message asked one simple question, "Do you think we can still get away with using Mefloquine?"

This email sent my Dr, Barry Simon at Peace Corps was obtained by a Freedom of Information request filed by Dr. Remington Nevin. The documents released by Peace Corps contained a full correspondence between Peace Corps and the CDC. Officials at the CDC responded to Dr. Simon but they didn't directly answer Dr. Simon's question. They simply stated that CDC recommendations regarding Mefloquine use had not changed. The next day, Dr. Thomas Wilkinson, another Senior Medical Officer at Peace Corps, contacted the CDC as well. He wrote, "We're getting killed with the volunteer response to the new FDA boxed warning for Mefloquine."

Wilkinson asked his colleagues at the CDC to look over a document that he had drafted to calm the volunteers. The document that Wilkinson had drafted was titled, "The Positive Deviant, forget what others are saying and decide for yourselves." Wilkinson wrote about the dangers of malaria. He wrote that malaria is transmitted by mosquitoes and that these mosquitoes are particularly attracted to the traces of alcohol in the sweat of Peace Corps volunteers. He wrote extensively about the anti-malarial medications available to volunteers. He described Mefloquine as, "The weird uncle of the family." Wilkinson acknowledged the FDA Black Box warning, but he claimed that the FDA was influenced by media rumors which have no basis in science. Wilkinson described the other anti-Malarial drugs, Chloroquine, Doxycycline and Malarone in the same anecdotal terms.

Malarone, is the newer anti-malarial drug which was listed but not described in the medication waiver that Sara Thompson received from Peace Corps.

Wilkinson described it as "Princess Malarone" He wrote, "Princess Malarone slurps down cash like it was fruit punch at a tea party. It costs about \$10 to buy Doxy for you for a 6 month supply, but that same 6 months will cost us between \$700 and \$1,200 to get Malarone." Wilkinson asked readers to consider Peace Corps' limited budget and whether or not they liked the idea of asking Peace Corps to spend so much money enriching the pharmaceutical industry by providing Malarone to volunteers.

Here's Dr. Nevin.

Dr. Nevin: In reading some of the correspondence that took place internally at Peace Corps days after the black box warning. One really does see an attempt to second guess, trivialize, even mock the FDA's decision. Evidence of neurotoxicity even if not proven, needs to be taken very seriously. Because of the extraordinary consequences so for the Peace Corps to seemingly demand irrefutable proof of the drug's neurotoxicity before committing to a safer policy, strikes me as being profoundly irresponsible.

Narration: Dr. Nevin felt so strongly about the issue that he sent a letter to Peace Corps Director Carrie Hessler-Radelet, urging her to reconsider her agency's Mefloquine policy. Dr. Nevin reports that he never received a response.

Dr. Nevin: It could be that Peace Corps felt that to acknowledge the drug's dangers would place them in a position of them having to account for possible harm to it's volunteers over many prior decades, and that was an acknowledgement they did not feel comfortable taking.

Sara: I would love, love love, to see a medical practitioner and try to get more information and try to see, well what our options for treatment, then what should I be doing as somebody who suffers from Mefloquine toxicity? Because not Dr. Nevin can't recommend treatment or any thing because he's not a practitioner, but unfortunately I'm not independently wealthy. I can't keep seeing specialists. Like I said, I spent about \$2,500 seeing that one specialist and I've not been reimbursed any of that by the Department of Labor.

I talked to the Peace Corps Post Service Unit and I told the contact there, "Look, I'm experiencing these symptoms and I really think could be related to Mefloquine toxicity and they said, how would I get a more comprehensive diagnosis on my FECA claim, because I was really worried and I'm still very worried. What happens if these symptoms either get worse or if I have to deal with cognitive issues that have become so debilitating to me that I can't even work, but I don't have any of this information reflected on my FECA Claim. The Post Service Unit specifically chastised me and said that Mefloquine toxicity is very controversial issue and it's not really

accepted within the medical community and I probably wouldn't have a very good case to make with FECA. That was, I think that was the beginning of the end for me in dealing with Peace Corps and the Post-Service Medical Unit.

Narration: Sara decided in order to get the money to see a specialist, she would sue Peace Corps.

Sara: I did a lot of research to see if I could sue Peace Corps. I talked to a few attorneys and everybody said, "No of course you can't sue Peace Corps." The more people kept telling me I could not do it, the more I grew determined to do it.

Narration: Sara couldn't get a lawyer to take her case so she wrote the suit herself. One major part of her complaint was with the way Peace Corps prescribes Mefloquine. Proper use of Mefloquine requires users to take one pill per week. The CDC recommends that users should start taking Mefloquine at least 2 weeks prior to arrival in a Malarial endemic area. This regimen allow the levels of Mefloquine in the body to be gradually built up. For many years Peace Corps did not prescribe mefloquine to volunteers in this fashion.

Instead Peace Corps volunteers were given a *loading dose* of Mefloquine. Which means that they were instructed to take one Mefloquine pill every day for three days. This loading dose floods the body with the drug, forcing Mefloquine to reach effective levels. A loading dose is associated with higher incidence of adverse side effects.

Dr. Nevin: Yeah, loading doses are not recommend. It can take a few days for the effects of a single tablet to fully manifest and be brought to the attention of the user. It's critical to use Mefloquine in a more safe manner to be aware of how you are responding to each individual dose, and if you do experience any psychiatric or neurological effect that you think may be attributable to the drug, to immediately stop the drug and take no more tablets. Because that could be an indication of a personal susceptibility of what could be permanent neurotoxicity.

Narration: Sara believes that Peace Corps prescribed a loading dose of Mefloquine to volunteers in their country of service to avoid litigation. An exemption in Federal Tort Law prevents suits against the government which arise on foreign soil, so Peace Corps can't be held responsible for prescribing Mefloquine to volunteers overseas. Sara's suit against the Peace Corps was rejected by the court for this very reason.

Sara: I do blame Peace Corps absolutely but I want to make the distinction, because I know a lot of return Peace Corps volunteers say, "well if you're gong to go overseas to a developing country. You have to expect that something is going to happen or you're going to get sick. You will be affected for the rest of your life." My response to that is: I do, I have a Staph infection in the form of boils, I don't blame Peace Corps for that, that's something very common in West Africa from what I saw, but I do blame a government agency for distributing a drug contrary to CDC and FDA recommendations. The 3 pills that you take right upon arrival in country, that's not

all recommend by the FDA. In fact the FDA recommends against that practice.

Narration: Peace Corps continues to prescribe Mefloquine to volunteers in Malarial endemic areas, but they have slightly changed their policy regarding loading doses. In a 2014 Malaria prevention guide produced by the Peace Corps Office of Medical Services, Peace Corps Medical Officers are not encouraged to provide loading doses of Mefloquine to volunteers. The guide also states that if a volunteer does elect to take Mefloquine, then the Peace Corps Medical Officer must provide the FDA guidelines regarding Mefloquine use to the volunteers.

Despite the fact that the FDA produced new guidelines for Mefloquine in 2013. The Malaria prevention guide still directs Peace Corps Medical Officers to provide volunteers with the 2003 FDA Mefloquine guidelines. The 2003 guidelines do not contain the strong warning about potential long term side effects.

Sara: Every volunteer has the right to know what situation they're going to be going into, be it a Malaria place or a place where you're more likely to be sexually assaulted or a place you're more likely to be in a high crime area. Every volunteer has the right to this information and the fact that they specifically withhold this information is criminal.

Narration: A Peace Corps spokesperson sent the following statement regarding this story. " Malaria is a dangerous and potentially deadly illness. The agency works closely with the Centers for Disease Control to ensure that all policies on Malaria suppressant medications are up to date and based on the best medical information available."