EXHIBIT 26

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

NICHOLAS HARRISON, *et al.*, Plaintiffs, v. MARK ESPER, Secretary of Defense, *et al.*, Defendants.	No. 1:18-cv-641 (LMB/IDD)

RICHARD ROE, *et al.*, Plaintiffs, v. MARK ESPER, Secretary of Defense, *et al.*, Defendants.	No. 1:18-cv-1565 (LMB/IDD)

DECLARATION OF LIEUTENANT COLONEL KEVIN CRON

I, Lieutenant Colonel Kevin Cron, do hereby state and declare as follows:

1. I am currently assigned to the US Army Medical Directorate - Armed Forces Research Institute of Medical Sciences (USAMD-AFRIMS), and serve as the Health Security Cooperation Officer to the Joint United States Military Advisory Group – Thailand (JUSMAGTHAI). Before serving in that position, I served as the Preventive Medicine Officer and primary waiver action officer for U.S. Central Command ("Central Command" or "CENTCOM").

2. This declaration pertains to my time at CENTCOM, where I was assigned from June 22, 2015 to July 5, 2019. During that time, I acted on behalf of the CENTCOM Surgeon to develop and interpret CENTCOM medical readiness standards and advised commanders and units on deployment issues and issued or confirmed determinations for over 16,000 medical waiver

applications, including applicants from all branches of the U.S. Armed Forces, as well as a variety of governmental, non-governmental, and contracting agencies. I also was responsible for assessing wartime medical and environmental threats, integrating threat analyses into operational and strategic plans, and developing programs to minimize medically-related threats to CENTCOM personnel, forces, and missions.

3. In the exercise of my duties, I have been made aware of this lawsuit by counsel from the Department of Defense ("DoD") Office of General Counsel.

4. I submit this declaration in support of Defendants' Motion for Summary Judgment. I base this declaration on my personal knowledge and on information made available to me in the performance of my duties. Unless otherwise noted, the opinions in this declaration are my own and relate to the duties assigned to me in the CENTCOM Surgeon's office, and are based upon policies and procedures in effect during my time in the CENTCOM Surgeon's office. This declaration supplements and is in addition to the declaration I previously submitted in support of Defendants' Response to Plaintiffs' Motion for a Preliminary Injunction filed on January 25, 2019.

The Role of CENTCOM

5. CENTCOM is one of six geographic Combatant Commands, with an area of responsibility (AOR) covering 20 nations in the Middle East, Central Asia, and South Asia, and the strategic waterways that surround them. It serves as a joint headquarters, and has component headquarters representing the Army, Navy, Air Force, and Marine Corps, as well as a joint special operations component.

6. Combatant Commands perform different roles than the various military Services, i.e., the Army, Air Force, Navy, and Marine Corps. In terms of readiness, a primary role of the Services is to act as a "force provider," meaning that the Services are responsible for recruiting, organizing, training, and equipping their associated forces for potential use anywhere in the world. By contrast, the geographic Combatant Commands plan, oversee, and coordinate military operations and

activities exclusively within their AOR, which are in turn executed through their Service components. The focus on specific areas, operations, and missions required specific standards to ensure that the medical conditions of deploying personnel did not represent an unacceptable level of risk.

Medical Standards for Deployment in Central Command

7. Deployment to the CENTCOM area of responsibility is governed by a variety of regulations. For determining medical suitability for deployment, one of the primary regulations is Department of Defense Instruction ("DODI") 6490.07 (Deployment-Limiting Medical Conditions for Service Members and DoD Civilian Employees). This document served as a basis for developing additional CENTCOM-specific policies.

8. DODI 6490.07 puts forth baseline guidance on medical deployability for the Department of Defense. Enclosure 3 states, "[i]n general, individuals with the conditions in paragraphs a. through h. of this enclosure, based upon a medical assessment as described in Enclosure 2 and Reference (l), shall not deploy unless a waiver is granted." Subsequent paragraphs then list conditions which should be considered to be disqualifying unless a specific exception is made. Among these is paragraph (e)(2): "[a] diagnosis of human immunodeficiency (HIV) antibody positive with the presence of progressive clinical illness or immunological deficiency. The cognizant Combatant Command surgeon shall be consulted in all instances of HIV seropositivity before medical clearance for deployment." Enclosure 2, paragraph 3 outlines the requirement to seek a waiver for any potentially-disqualifying condition, while Enclosure 4 additionally specifies that Combatant Commanders shall "[s]erve as the final approval authority for exceptions to the medical standards (waivers) made pursuant to the procedures in this Instruction". These sections serve as the basis for MOD 13, the Central Command-specific regulation described further below.

9. Enclosure 3 of DODI 6490.07 provides a list of medical conditions that usually preclude deployment, but Enclosure 3 explicitly states that the list is "not intended to be all-

inclusive." Each Combatant Command, including CENTCOM, is permitted to establish their own medical readiness standards, which may be more stringent or elaborate than those in DODI 6490.07, or those of the individual Services, as they are best positioned to determine the appropriate tolerance and nature of medical risk within their associated AORs, in light of their specific missions, operational environments, health threats, and other Command-specific factors.

10. Combatant Commands' medical standards have to consider not only typical military work environments and common occupational hazards for their area of responsibility, but also variations in conditions that could occur due to changing conditions or unexpected events. The impact of a given medical condition, and the risk it represents to the individual, the fighting force, and to mission objectives can change substantially based upon operational factors which may change rapidly. Command-specific medical policies reflect the Combatant Commander's tolerance (informed by their Command Surgeon) for this medical risk, based on a number of military considerations presented by the nature of the Combatant Command's area of responsibility. Up-to-date information is needed to properly characterize that risk, as well as to evaluate how well it might be mitigated, and, finally, to determine if the potential benefits of the deployment merit assuming whatever risk remains. Although the Services' opinions are sought and considered, the final policy is ultimately the Combatant Commander's prerogative.

11. Differences in the conditions, missions, capabilities, and risks between the Combatant Commands have resulted in differences in policy. For example, planning in CENTCOM involves consideration of active, substantial, and long-term combat operations that rely almost entirely on expeditionary medical facilities,[1] with associated logistical and security challenges. AFRICOM, with an area of responsibility encompassing most of the African continent, had more strict medical policies than CENTCOM even though its combat operations tended to be of a smaller

[1] Expeditionary medical facilities generally have limited medical resources, including a limited blood supply and limited pharmaceutical capabilities.

scale. That is because the huge geographic distances in their area of responsibility would present extraordinary difficulties in transporting medical supplies or would impact medical evacuations. These differences, and many others, are considered by the Command Surgeon, as the Commander's senior medical expert, of each Combatant Command when determining the medical readiness standards appropriate for their AOR.

12. CENTCOM's medical readiness standard that was applicable during the time Plaintiffs were being processed through the Disability Evaluation System is known as MOD THIRTEEN TO USCENTCOM INDIVIDUAL PROTECTION AND INDIVIDUAL-UNIT DEPLOYMENT POLICY ("MOD 13"), issued in March 2017. "MOD" is short for "modification," and represents an updating or revision of a previously-issued order. Each MOD is numbered sequentially, and reflects updates and changes in standards and policy, along with clarifications, made to address feedback from the Services or deployed forces and based on the evolution of the operations in the AOR. The original order for MOD 13 was issued in 2001, though the title has been retained largely for purposes of name recognition. The MOD is issued as a stand-alone order from the Commander, and generally replaces its predecessor entirely, with retained elements incorporated into the updated version.[2]

13. In addition to providing medical standards, the MODs also incorporate a summary of DoD policies for medical topics such as health assessments and some immunizations. They also consolidate recommendations concerning topics such as force health protection measures and elective immunizations. These requirements and standards cannot be waived by CENTCOM, as they did not originate under CENTCOM authority (for instance, anthrax immunization is required for the CENTCOM AOR by DoD policy, so a DoD-level waiver would be required to waive it).

[2] Before I left CENTCOM, I provided a complete draft of MOD 14 to my successor. With some minor changes, MOD 14 was published in October 2019. MOD 15, published in April, 2020, is the current CENTCOM policy. The policies relating to HIV in MOD 14 and MOD 15 are unchanged from MOD 13.

Similarly, if Service policy (i.e. a Department of the Army regulation) prohibited a Service member from deploying, they would not be able to deploy without a Service waiver, even if CENTCOM had no objection, with the converse also being true (i.e. the Service cannot waive a Combatant Command policy).

The MOD Update Process

14. CENTCOM revises its medical standards through its practices, and by issuing new MODs. This may occur for several reasons. For example, the DoD medical policies upon which the MOD is based may change, or changes in medical technology and understanding may indicate that an update is warranted. Updates may also stem from feedback received during the waiver process, as the various Services will sometimes ask questions about diagnoses that are not included, propose alternate medical standards to be applied, or identify inconsistencies and other opportunities for improvement. In addition, CENTCOM medical staff monitors and receives reports on the types of diagnoses that result in evacuation from the AOR, as well as the challenges confronting the healthcare providers and Command Surgeons serving in the deployed environment. Additionally, CENTCOM reviews its own waiver process and outcomes to identify conditions that were often approved or disapproved in order to determine whether new conditions should be added or removed from the list of conditions that generally preclude deployment. When CENTCOM determines that policies or conditions have sufficiently changed, or when it has received sufficient feedback indicating a change is warranted, CENTCOM will update the MOD.

Deployment Waivers in General

15. When an individual has a disqualifying medical condition, they may request that they be granted a waiver to be allowed to deploy to CENTCOM. Only the CENTCOM Surgeon or his or her representative may approve the waiver and allow the deployment. When a waiver request is submitted, it should confirm that the commanding officer of the person for whom the waiver is sought is aware of and approves the waiver request. CENTCOM encourages waiver requests to be

sent by medical professionals, as they tend to include appropriate supporting information that facilitates the processing of waivers; however, CENTCOM will consider waivers submitted by individuals. As the waivers are time, place, and duty-specific, they are provided only for a specific deployment (i.e. quick reaction forces, global response forces, and other groups which might deploy somewhere in the AOR within the next year are not provided rolling waivers or blanket waivers).

16. The decision to grant a deployment waiver is a risk calculation that accounts for the applicant's condition, occupation, and time/location of deployment. Thus, to determine whether a waiver is advisable, CENTCOM needs to know approximately when and where a Service member is expected to be located within theater, as well as the job they will be expected to perform. CENTCOM considers not only the patient's current condition and stability, but also how they will be impacted by reasonably anticipated contingencies, such as loss, theft, or destruction of medication, if their condition requires regular clinical monitoring, how their condition will impact the evaluation of routine medical issues, what secondary effects their treatment may have, and how their condition will influence, and be influenced by, operational activities within active combat zones, and if the medical providers in the AOR are trained to provide adequate care for that condition. It is necessarily a complex process.

17. For a waiver to be granted, the need to have the specific Service member or civilian in theater must be great enough to validate taking on this additional risk. Optimally, the risk of deploying them needs to be less than the risk of not deploying them, or conversely, the benefit of deploying them should exceed the benefit of not doing so. CENTCOM may grant a waiver for any waiverable medical condition in cases of extraordinary need for a unique skill to support a particular mission or operation. On the other hand, if the capability provided by a Service member is not essential, or can be provided by an alternate Service member without the risk presented by the condition, it makes less sense to expose the individual, force, and mission to that additional risk. Some medical conditions are common enough to justify paying the resource cost for mitigating

measures (for example, providing eyeglasses for mild vision impairment or deploying physical therapists to offer in-theater recovery options for minor injuries) but the aggregate benefit would still need to meet or exceed the risk, in addition to justifying the cost.

18. CENTCOM generally refuses to consider waiver applications that are submitted more than six weeks in advance of a deployment, as conditions of the patient, theater, and/or deployment may change.

19. When granted, waivers were valid for fifteen months or until a deployment was completed, whichever occurred first. If a waiver was initially denied, it could be resubmitted with updated information, or an appeal made as described in MOD 13. By this process, determinations made by a Service component would be appealed to one of the CENTCOM waiver action officers. If that decision was appealed, the Command Surgeon would be directly consulted (or re-consulted if they were involved in the original decision). Appeals of that decision would in turn be presented by the Command Surgeon to the Chief of Staff, who would seek guidance from the Commander if needed. The decision of the Chief of Staff was final, though we would consider a new waiver if the condition substantially changed or resolved (i.e., a successfully treated cancer, or successful discontinuation of a disqualifying medication with adequate control of the underlying medical condition). Though much less common, appeals of approved waivers could also be made in the same fashion, which would sometimes occur when a potential employer felt that the risk of the applicant's condition had not been properly portrayed or considered.

20. Enclosure 3 of DODI 6490.07 generally prohibits the deployment of Service members with "known blood-borne diseases that may be transmitted to others in a deployed environment." Active diseases such as Zika virus or West Nile virus infection may also fall into this category. An individual with those conditions would not be granted a waiver to deploy to CENTCOM at least until the conditions had resolved.

CENTCOM Deployment Limitations Regarding HIV

21. MOD 13 contains CENTCOM-specific guidance relating to HIV.[3] Paragraph 15.G.1 states: "the cognizant Combatant Command surgeon shall be directly consulted in all instances of HIV seropositivity before medical clearance for deployment." Tab A, Paragraph 7.C.2 states that "[c]onfirmed HIV infection is disqualifying for deployment." Paragraph 15.C of MOD 13 also notes that "[d]eployed health service support infrastructure is designed and prioritized to provide acute and emergency support to the expeditionary mission. All personnel (uniformed service members, government civilian employees, volunteers, DoD contract employees) traveling to the CENTCOM AOR must be medically, dentally and psychologically fit." This is an important caveat that is considered in every waiver decision. MOD 13 also makes clear that "the final authority of who may deploy to the CENTCOM AOR rests with the CENTCOM Surgeon and/or the Service Component Surgeon's waiver authority, not the individual's medical evaluating entity or deploying platform."

22. In addition, if an individual was discovered to be HIV-positive after he or she had been deployed, that individual would have been promptly removed from theater.

Considerations Made in Adopting HIV Deployment Limitations

23. The HIV-related policies in MOD 13 were largely retained from MOD 11 and 12, and originated in earlier versions of the policy. MOD 10, published in September, 2008, listed HIV as disqualifying with a note that no waivers would be granted, though as a Commander's policy, an exception could theoretically have been made by the Commander.

24. During the policy review process that culminated in MOD 13, there was broad consensus across stakeholders that HIV was incompatible with service in a combat zone. This was true even though the review process presumed that the HIV-positive individual had a well-

[3] To prevent duplication, key military policies discussed in this document are attached as exhibits to Defendants' Motion for Summary Judgment.

controlled viral load at an undetectable level from an accepted test, and that the individual was on an effective and tolerated antiretroviral therapy (ART) regimen prior to deployment. Nonetheless, it was determined to maintain a general prohibition on deployments of HIV-positive individuals for several reasons.

25. The CENTCOM area of responsibility presents many challenges. The AOR covers 20 countries and more than 4 million square miles. Operations in the AOR are expeditionary in nature, and health service support plans are designed to meet the reasonably anticipated needs of a pre-screened warfighting population without complex medical needs. Conditions requiring highly specialized medical personnel, treatments, or medications cannot be reliably supported.

26. There is currently no cure for HIV, and individuals must maintain rigid compliance with their individualized medication regimens. If treatment is discontinued, disrupted, or altered, the virus may re-emerge, with a significant chance of becoming resistant to the original regimen. There are many ways medication could be lost, stolen, or destroyed in the deployed environment. Moreover, replacing these medications in a timely manner may not be possible, given the logistical constraints in theater as well as environmental, operational, geopolitical, and other factors that could hinder timely medical re-supply. CENTCOM would routinely deny waivers for any medical condition that is similarly dependent upon medications which could not be readily and easily replaced.

27. In addition, the nature of deployed operations can be disruptive to set schedules – operations often occur during nighttime hours, and local events may require irregular or unplanned work extensions or activities which interfere with proper medication compliance. Again, waivers were generally denied for other conditions that required rigid adherence to the medications, with the classic example being insulin dependent diabetes.

28. Expeditionary medical facilities are established and staffed to provide limited health care for deployed forces. They are designed with the understanding that they will largely care for the

acute and emerging healthcare issues of a pre-screened deployed force, with a particular emphasis on care of trauma, psychiatric, and orthopedic patients. This paradigm assumes that those with significant, inadequately managed chronic medical issues, or those which require specialized evaluation or monitoring not readily and reliably available, will not deploy. Laboratory support is limited, with a presumption that complex patients will be stabilized and evacuated to a higher level of care. Likewise, pharmacies have limited stock, and resupply is frequently delayed by a variety of operational, administrative, and environmental factors.

29. Current HIV anti-retroviral therapy (ART) regimens, while improved, may still have side effects that can develop over time, and healthcare providers in theater may be unfamiliar with these medications. Additionally, deployed healthcare providers treating a known HIV-positive patient for even routine complaints must consider that the virus may have reactivated, and confirm that it has not, even if the patient professes rigid compliance. This will require testing and clinical resources.

30. The nature of expeditionary operations may present a meaningful risk of accidental HIV-transmission through blood-to-blood contact. For example, in trauma scenarios, a patient may be incapacitated in the field, with treating medics moving quickly and working with limited protective equipment and poor lighting on wounds which may feature embedded shrapnel or bone fragments.

31. Fresh whole blood is a preferred resuscitation fluid for battlefield trauma, and CENTCOM operations plan for a "walking blood bank" capability in the event that an unforeseen event, such as a mass casualty, depletes an isolated unit's blood supply. Though every effort is made to screen blood donors, the extreme situations which would indicate activation of the walking blood bank may require donations from unscreened donors. While a known HIV-positive individual would not be asked to donate blood to the walking blood bank blood, there is a possibility that they would

not understand their ability to infect others through transfusion, even if their viral count is undetectable.

32. MOD 13 and DoD policy requires that CENTCOM consider host nation laws regarding deployment of individuals with infectious diseases such as HIV. Many of the nations within the CENTCOM AOR have legal prohibitions against entering their countries with HIV, and it was felt that disregarding these laws may be a source of additional disruption to our relations with these countries. We had received feedback from another governmental agency that some Host Nation healthcare providers in our AOR may refuse to treat HIV-positive patients, and would be legally obligated to report them to government authorities if we needed to use a Host Nation healthcare capability, possibly resulting in delay of care, deportation, or expulsion. The CENTCOM staff felt this report was credible, but confirming it would require individual review of the Status of Forces agreements in place between a given nation and the United States. However, CENTCOM had already concluded, for the independent medical reasons discussed above, that deployment of an HIV-positive Service member would require a waiver, that the details of the proposed deployment would be required to establish what local laws or Status of Force agreements were applicable, and then it would be the responsibility of the entity requesting a waiver to justify that the deployment of an HIV-positive Service member would outweigh the possible risks. As a practical matter, it was not necessary to further analyze issues relating to specific foreign policies with respect to any individual waiver because waivers would be independently denied for medical reasons.

Deployment Waivers for HIV

33. While serving as the waiver authority for CENTCOM, I reviewed waiver requests from HIV-positive service members for planned deployments. I conducted a thorough risk assessment for each waiver request and, consulting with the CENTCOM Surgeon and Component Surgeons, we determined in each case that the risks of deploying an HIV-positive Service member

were too great to justify waiver approval. I never granted a waiver for a confirmed HIV diagnosis during my time at CENTCOM, and to the best of my knowledge, CENTCOM never has.[4]

34. It is theoretically possible that a waiver for an HIV-positive Service member could be granted. Deployment decisions in CENTCOM are ultimately the CENTCOM Commander's prerogative. The Combatant Commander generally follows the Command Surgeon's recommendations, but could override the Surgeon's recommendations and authorize a deployment if required by the particular needs of the mission. During my four years at CENTCOM, I can recall this happening only a single time, and not for HIV. That individual was critically involved in key aspects of a mission, had irreplaceable skills, and needed to be physically present within the area of responsibility. In order for a waiver to be granted for an individual with HIV to deploy, the HIV-positive individual likely would similarly need to possess unique or irreplaceable skills in order to offset the military and medical risks posed by the infection.

35. It is my understanding that the plaintiffs were relatively junior Airmen in fairly common career fields without specialized skills. In my assessment, individuals such as these would not realistically meet the standard described above to justify granting a waiver, and I therefore believe it would be highly unlikely that they would be granted a waiver from CENTCOM.

* * *

In accordance with 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct. Executed this 2nd day of June 2020.

[4] One individual who initially tested positive for HIV was allowed to deploy after it was determined that the initial test was falsely positive, and he did not actually have the disease.

LTC KEVIN CRON, M.D., M.P.H.

Health Security Cooperation Officer

Armed Forces Research Institute of Medical Sciences

Bangkok, Thailand

U.S. Army

EXHIBIT 27

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

NICHOLAS HARRISON and OUTSERVE-SLDN, INC.,	Plaintiffs,	
vs.		No. 1:18-cv-00641 LMB-IDD
JAMES N. MATTIS, In His Official Capacity As Secretary of Defense; MARK ESPER, In His Official Capacity As the Secretary of the Army; and the UNITED STATES DEPARTMENT OF DEFENSE,	Defendants.	
RICHARD ROE, VICTOR VOE, and and OUTSERVE-SLDN, INC.,	Plaintiffs,	
vs.		No. 1:18-cv-01565
JAMES N. MATTIS, In His Official Capacity As Secretary of Defense; HEATHER A. WILSON, In Her Official Capacity as Secretary of the AIR FORCE; and the UNITED STATES DEPARTMENT OF DEFENSE,	Defendants.	

VIDEOTAPED 30(b)(6) DEPOSITION OF THE DEPARTMENT OF DEFENSE GIVEN BY DONALD SHELL

DATE: Friday, March 8, 2019
TIME: 9:41 a.m.
LOCATION: Winston & Strawn
1700 K Street, N.W.
Washington, D.C.

REPORTED BY: Denise M. Brunet, RPR
Reporter/Notary

Veritext Legal Solutions
1250 Eye Street, N.W., Suite 350
Washington, D.C. 20005

A P P E A R A N C E S

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(Appearances continued on the next page.)

APPEARANCES (continued):

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ALSO PRESENT: Solomon Francis, Videographer

C O N T E N T S

(Exhibits continued on the next page.)

(*Exhibits attached to the transcript.)

THE WITNESS: Yes.
BY MR. SCHOETTES:
Q All right. We're going to mark the next exhibit, Exhibit 4.
(Shell Deposition Exhibit Number 4 was marked for identification.)
BY MR. SCHOETTES:
Q Do you recognize this document?
A Yes.
Q And what is this document?
A Department of Defense personnel policies regarding members of the Armed Forces infected with human immunodeficiency virus: Report to the Committees on the Armed Services of the Senate and House of Representatives, August 2018.
Q Did you personally assist in the creation of this document?
A Yes.
Q Which office was tasked with putting this report together?
A The Office of the Assistant Secretary of Defense for Health Affairs.
Q Who from within that office was responsible for putting the -- this 2018 report together?

MR. NORWAY: Objection. Form.
You may answer.
THE WITNESS: I was.
BY MR. SCHOETTES:
Q Did Tom McCaffrey have any role in putting this report together?
MR. NORWAY: You may answer.
THE WITNESS: It would be dependent on the dates that the report was published and when Mr. McCaffrey began his tenure as the Acting Assistant Secretary of Defense. So I would imagine, since the report was made final in August of 2018, Mr. McCaffrey was in that role at that time.
BY MR. SCHOETTES:
Q So if he was in the role in April of 2018, would this have been -- this report have been his responsibility?
MR. NORWAY: Objection. Form. Objection. Foundation.
You may answer.
THE WITNESS: Yes.
BY MR. SCHOETTES:
Q And were you his point of contact for putting this report together?

A Through the Deputy Assistant Secretary of Defense for Health Service Policy and Oversight, yes.

Q What did you do as the person responsible for pulling this report together?

MR. NORWAY: Scott, are you asking -- are you asking for what he -- what duties he performed? I guess I'm confused by your question -- your use of "you" there in your question.

MR. SCHOETTES: I'm sorry. Yes, I'm asking what role Dr. Shell played in putting this report together for Congress.

MR. NORWAY: Objection.

You can answer.

THE WITNESS: As it states in the data collection section -- in the last sentence it says, "Service-level information was obtained from each of the military departments at the request of the Office of the Assistant Secretary of Defense for Health Affairs. So my role was to prepare the documentation to request the information from the services, to then receive the information from the services, and then to compile that information into the report and then to draft the report and

about taking two bottles of 90 tablets on any deployment anywhere?

MR. NORWAY: Objection. Foundation. Objection. Form. Objection. Outside of scope.

You may answer.

THE WITNESS: I can't make a blanket statement about what a service member will or will not be able to carry with them that's required to maintain their health and well-being in a vague deployment question. Each deployment situation is different and requires something different of each service member in that environment. So there is no one blanket answer to agree with.

BY MR. SCHOETTES:

Q Are people allowed to deploy with dyslipidemia?

MR. NORWAY: Objection. Outside of scope.

You can answer if you know.

THE WITNESS: Anyone with a chronic disease of hyperlipidemia [sic], given they undergo the medical waiver, might be allowed to deploy. Where they might be allowed to deploy, when and if they might be allowed to deploy is decided through the waiver and the evaluation

process.
BY MR. SCHOETTES:
Q You think dyslipidemia requires a waiver to deploy?
MR. NORWAY: Objection. Foundation. Objection. Outside of scope.
You can answer if you know.
THE WITNESS: Each service -- there are -- there's a policy requiring the evaluation of medical conditions that can potentially limit deployment. And so there are a list of medications, there are a list of -- excuse me. There's a list of conditions or categories of conditions. And each service will decide, based on that departmental policy, where the service member with each particular chronic disease falls.
So someone with dyslipidemia may or may not require medication. And so it is possible for a person with dyslipidemia who does not meet any of the criteria or conditions or concern to be able to deploy. But once again, it's a hypothetical and would require a specific response based on the experience of the services and their medical commanders.
BY MR. SCHOETTES:

neurological deficits in those with HIV infection.

A It is referencing in the general population, which I'm not sure whether it's applicable to service members operating high-speed and dangerous equipment, but it says in a Danish population, that severe neurological deficits approach that of the uninfected population.

MR. SCHOETTES: I have nothing further.

MR. NORWAY: I have no cross.

MR. SCHOETTES: None?

MR. NORWAY: None. So we're going to read and sign.

MR. SCHOETTES: Okay.

MR. NORWAY: And, Scott, I am going to speak to my client and I will get back to you about some of the testimony on SOFA agreements.

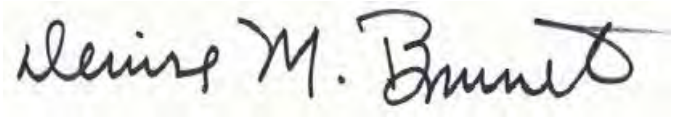
MR. SCHOETTES: Okay. Sounds good. Thank you, Dr. Shell.

THE VIDEOGRAPHER: The time is the 6:33 p.m. This concludes today's testimony given by Dr. Donald Shell. We are now off the record.

(Whereupon, at 6:33 p.m., the deposition of DONALD SHELL was concluded.)

CERTIFICATE OF NOTARY PUBLIC

I, Denise M. Brunet, the officer before whom the foregoing deposition was taken, do hereby certify that the witness whose testimony appears in the foregoing deposition was sworn by me; that the testimony of said witness was taken by me stenographically and thereafter reduced to print by means of computer-assisted transcription by me to the best of my ability; that I am neither counsel for, related to, nor employed by any of the parties to this litigation and have no interest, financial or otherwise, in the outcome of this matter.



Denise M. Brunet
Notary Public in and for
The District of Columbia

My commission expires:
December 14, 2022

Veritext Legal Solutions
1100 Superior Ave
Suite 1820
Cleveland, Ohio 44114
Phone: 216-523-1313

March 15, 2019

To: Mr. Norway

Case Name: Roe, Richard, Et Al. v. Shanahan, Patrick M., Et Al.

Veritext Reference Number: 3235712

Witness: Donald Shell , 30(b)(6) Deposition Date: 3/8/2019

Dear Sir/Madam:

Enclosed please find a deposition transcript. Please have the witness review the transcript and note any changes or corrections on the included errata sheet, indicating the page, line number, change, and the reason for the change. Have the witness' signature notarized and forward the completed page(s) back to us at the Production address shown above, or email to production-midwest@veritext.com.

If the errata is not returned within thirty days of your receipt of this letter, the reading and signing will be deemed waived.

Sincerely,
Production Department

NO NOTARY REQUIRED IN CA

DEPOSITION REVIEW
CERTIFICATION OF WITNESS

ASSIGNMENT REFERENCE NO: 3235712
CASE NAME: Roe, Richard, Et Al. v. Shanahan, Patrick M., Et Al.
DATE OF DEPOSITION: 3/8/2019
WITNESS' NAME: Donald Shell , 30(b)(6)
In accordance with the Rules of Civil Procedure, I have read the entire transcript of my testimony or it has been read to me.
I have made no changes to the testimony as transcribed by the court reporter.

_____ _____
Date Donald Shell , 30(b)(6)
Sworn to and subscribed before me, a Notary Public in and for the State and County, the referenced witness did personally appear and acknowledge that:

They have read the transcript;
They signed the foregoing Sworn Statement; and
Their execution of this Statement is of their free act and deed.

I have affixed my name and official seal

this _____ day of_____, 20____.

_____
Notary Public
_____
Commission Expiration Date

DEPOSITION REVIEW
CERTIFICATION OF WITNESS

ASSIGNMENT REFERENCE NO: 3235712
CASE NAME: Roe, Richard, Et Al. v. Shanahan, Patrick M., Et Al.
DATE OF DEPOSITION: 3/8/2019
WITNESS' NAME: Donald Shell , 30(b)(6)

In accordance with the Rules of Civil Procedure, I have read the entire transcript of my testimony or it has been read to me.

I have listed my changes on the attached Errata Sheet, listing page and line numbers as well as the reason(s) for the change(s).

I request that these changes be entered as part of the record of my testimony.

I have executed the Errata Sheet, as well as this Certificate, and request and authorize that both be appended to the transcript of my testimony and be incorporated herein.

April 12, 2019 _____
Date Donald Shell , 30(b)(6)

Sworn to and subscribed before me, a Notary Public in and for the State and County, the referenced witness did personally appear and acknowledge that:

They have read the transcript;
They have listed all of their corrections in the appended Errata Sheet;
They signed the foregoing Sworn Statement; and
Their execution of this Statement is of their free act and deed.

I have affixed my name and official seal this 12 day of April, 2019.

Mulugeta Tadesse
Notary Public

11/08/2022
Commission Expiration Date

MULUGETA TADESSE NOTARY PUBLIC PRINCE GEORGE'S COUNTY, MD

Mulugeta Tadesse
NOTARY PUBLIC
Prince George's County
State of Maryland
My Commission Expires
11/08/2022

ERRATA SHEET

VERITEXT LEGAL SOLUTIONS MIDWEST

ASSIGNMENT NO: 3/8/2019

PAGE/LINE(S) /	CHANGE	/REASON
9/19	Personnel and Readiness Correction	
125/11	...we're looking an an "N" of one or a number...	
129/17	supporting that for other than sexual transmission	/Correction

April 12, 2019

Date

Donald Shell , 30(b)(6)

SUBSCRIBED AND SWORN TO BEFORE ME THIS 12

DAY OF April , 2019 .

Mulugeta Tadesse

Notary Public

MULUGETA TADESSE NOTARY PUBLIC PRINCE GEORGE'S COUNTY, MD

Mulugeta Tadesse
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Table X: HIV Restrictions in Foreign Nations

The table below provides an overview of the various restrictions involved with attempting to gain residency or a work visa as an HIV positive individual in a foreign country. The Middle East, North Africa, and Eastern European regions have the most restrictions for HIV positive individuals. The majority of the information was collected from hivtravel.org, which cites as it's resources an aggregation of information from the United States Department of State, German Embassies, UNAIDS, and Foreign Affairs and International Trade Canada. The information was validated against additional research, including information from the US State Department. In instances where policy was undefined or in flux, or contradictory reports were identified, the country was marked as "Unclear," and an explanation was provided in the notes.

Restrictions were categorized into:

(1) Not Allowed - HIV positive individuals are not allowed permanent residency in these countries
(2) Unclear - Restrictions in these countries are difficult to define due to loosely defined policy or contradictory reports
(3) Special Consideration - HIV positive individuals undergo unique evaluation before being admitted
(4) Evaluation - A medical evaluation of the HIV positive individual is conducted before admittance
(5) No Restrictions - There are no restrictions for HIV positive individuals

Country	Restriction	Notes/Overview	Combatant Command
Afghanistan	No Restriction		Central Command
Albania	No Restriction		European Command
Algeria	No Restriction		Africa Command
Andorra	No Restriction		European Command
Angola	Unclear	It is reported that a medical check-up requirement for work visa applicants ("Visto de Trabalho"), authorised under Law 2/07 and Presidential Decree 108. According to the International Organisation of Migration (IOM), the check-up does not require HIV testing. However, the Embassy of Angola in Serbia web site indicates the contrary.	Africa Command
Antigua and Barbuda	No Restriction		Southern Command
Argentina	No Restriction		Southern Command
Armenia	Special Consideration	Antiretroviral medications can be imported for personal use and for the duration of the planned stay (up to six weeks). A medical certificate including the diagnosis in Russian or Armenian language has to be presented at customs. No information on residency.	European Command

Aruba	Not Allowed	The Government of Aruba, albeit part of the Kingdom of the Netherlands, does not provide a working permit to people living with HIV. And for living in Aruba, one needs a working and residency permit. Even marital status would not change this.	Southern Command
Australia	Evaluation	HIV testing for permanent visa applicants remains in force. People living with HIV are treated similarly to other people with chronic health conditions and disabilities during the country's immigration health assessment process. Applications for visas from people living with HIV will be assessed against criteria applying to anyone with a chronic health condition. Applicants for visas to visit or migrate to Australia are required to meet certain health requirements. These help ensure that: -Risks to public health in the Australian community are minimized -Public expenditure on health and community services is contained -Australian residents have access to health and other community services in short supply.	Indo-Pacific Command
Austria	No Restriction		European Command
Azerbaidjan	Not Allowed	People applying for an electronic visa through the official electronic visa portal are required to confirm they are HIV-negative and free from hepatitis B and C. Without this confirmation, applicants are not able to receive a visa.	European Command
Bahamas	No Restriction		Northern Command
Bahrain	Not Allowed	All foreigners declared HIV positive risk immediate deportation; deportation may be applied to all "communicable diseases." Although an individual is not required to declare HIV status upon arrival, the government revokes visas of non-Bahrainis who are HIV positive. [Note: Information should be verified with the Embassy of the Kingdom of Bahrain before travelling]	Central Command

Bangladesh	Unclear	There are no specific entry regulations for people with HIV/AIDS in Bangladesh (information provided by the Embassy's Attorney of confidence). Neither a medical certificate nor an HIV test result is requested. This also applies to long-term residents. It is possible however, that foreigners with HIV/AIDS are deported if the competent authorities find out about their condition.	Indo-Pacific Command
Barbados	No Restriction		Southern Command
Belarus	Special Consideration	The U.S. Department of State is unaware of any HIV/AIDS entry restrictions for visitors to Belarus on a 30-day visit. Long-term residents (those spending more than 90 days a year in Belarus) or students must obtain an HIV/AIDS test in Belarus and submit the results to the Department of Citizenship and Migration when applying for an extension of stay or residency. We recommend that you verify this information with the Embassy of Belarus before you travel.	European Command
Belgium	Special Consideration	A health certificate stating absence of a transmittable disease that would present a danger for public health is required from non-EU residency permit applicants. A residency permit can be granted regardless of HIV infection. The following conditions can be grounds for denying such a permit: -Illnesses that require the patient to be under quarantine (as defined by WHO guidelines from May 25, 1951). -Active tuberculosis -Syphilis -Transmittable infectious conditions or contagious parasitic diseases	European Command
Belize	No Restriction		Southern Command

Benin	Special Consideration	An HIV test is required when applying for a long-term residence permit. In case of a positive test result, law does not forbid the grant of a long-term residence permit. The permit is granted at the discretion of the officer dealing with the application. There are no specific residence regulations regarding people with HIV/AIDS. The Embassy can't judge how the problem is handled in practice. Nothing has been heard about controls, deportations or expulsions. It is possible that residence permits won't be extended in the case of a positive test result.	Africa Command
Bermuda	Unclear	The U.S. Department of State is unaware of any HIV/AIDS entry restrictions for visitors to or foreign residents of Bermuda. However, visitors with visible indicators of any communicable disease can be refused entry into Bermuda.	Northern Command
Bhutan	Unclear	Some HIV/AIDS entry restrictions exist for visitors to and foreign residents of Bhutan. For stays longer than two weeks, applicants must present the results of an HIV/AIDS test completed within the six months prior to their visit. The test can also be administered by Bhutanese officials upon arrival.	Indo-Pacific Command
Bolivia	No Restriction		Southern Command
Bosnia Herzegovina	No Restriction (except for one province)	The Republika Srpska (province of Bosnia Herzegovina) has a law on population protection from infectious diseases. The law requires that foreigners with long-term residency status (i.e., staying for more than three months) have to perform regular medical examinations. Related testing includes HIV, syphilis and hepatitis B and C. At application, test results should be no older than three months.	European Command
Botswana	No Restriction		Africa Command
Brazil	No Restriction		Southern Command

Brunei	Not Allowed	People who wish to work or study in Brunei need a work and residence permit. On application for these permits, people must undergo a health examination in their country of origin and again within two weeks of entering Brunei. This health check includes HIV testing. No medical certificate has to be presented when entering the country. Local authorities will deport HIV-positive foreigners to their native country. A person's residence permit will be cancelled if HIV is detected.	Indo-Pacific Command
Bulgaria	No Restriction		European Command
Burkina Faso	No Restriction		Africa Command
Burundi	No Restriction		Africa Command
Cabo Verde	No Restriction		Africa Command
Cambodia	No Restriction		Indo-Pacific Command
Cameroon	No Restriction		Africa Command
Canada	Special Consideration	Under the Immigration and Refugee Protection Act ("IRPA"), foreign nationals are inadmissible as permanent immigrants to Canada if their health condition might reasonably be expected to cause an "excessive demand" on health or social services, or if their application to immigrate includes a family member in this situation. Due to the high cost of antiretroviral medications, people living with HIV are generally deemed medically inadmissible if they apply to immigrate to Canada. Today's proposed changes include increasing the cost threshold for defining what constitutes "excessive demand," to three times the current level of $6,655 per year. This increase to the cost threshold may mean that many people living with HIV will no longer be found medically inadmissible and excluded from immigration to Canada.	Northern Command
Cayman Islands	Unclear	Although there are no specific HIV/AIDS entry restrictions for visitors to the Cayman Islands, people living with HIV/AIDS can be denied permission to land if a Health Officer certifies that their entry to the Islands would be dangerous to the community. This is according to Section 82 (c) of the Cayman Immigration Law (2007 Revision).	Southern Command
Central African Republic	No Restriction		Africa Command

Chad	No Restriction		Africa Command
Chile	No Restriction		Southern Command
China	Unclear	In case of a long-term professional stay in China (longer than six months): Check the situation carefully. Until recently, a negative HIV status was mandatory for foreigners staying in China on long-term permits. Tests have also been performed in China and without consent of those concerned. A positive HIV test result led to immediate deportation, job loss and unemployment.	Indo-Pacific Command
Colombia	No Restriction		Southern Command
Comores	No Restriction		Africa Command
Congo (Brazzaville)	No Restriction		Africa Command
Congo (Kinshasa)	No Restriction		Africa Command
Costa Rica	No Restriction		Southern Command
Cote D'Ivoire	No Restriction		Africa Command
Croatia	No Restriction		European Command
Cuba	Not Allowed	There are no restrictions for people with HIV/AIDS for short-term stays of up to three months (tourist visa). An HIV test is mandatory for longer stays. An HIV test result must be presented upon application for a long-term visa. There are no controls at the border. The extension of a residency permit requires a negative HIV test result. There is no information about the consequences for a person entering the country who is detected to be HIV positive. Antiretroviral medication for personal use can be carried along.	Southern Command
Cyprus	Not Allowed	Foreigners (non-EU citizens only) applying for a residence permit in order to work or to study must undergo a medical examination by the Health Ministry in order to exclude an infection with HIV, hepatitis B/C or syphilis. The authorities will not grant a residence permit in the case of a positive test result. For all other foreigners (EU citizens, tourists, employees of international companies, UN staff), there are no mandatory medical examinations.	European Command
Czech Republic	No Restriction		European Command
Denmark	No Restriction		European Command
Dijibouti	No Restriction		Africa Command

Dominican Republic	Not Allowed	Medical checks are mandatory for people applying for work or residence permits. Residency is restricted for people with infectious diseases. A positive HIV test will result in denial of a residence permit. The same happens if a person refuses to get tested.	Southern Command
Ecuador	Not Allowed	For people applying for student permits, work permits and voluntary, missionary or religious visas, a doctor's certificate and an HIV test is required. Applicants must be free of communicable diseases.	Southern Command
Egypt	Not Allowed	An HIV test has to be performed at the Health Ministry's central laboratory for all people who apply for a residence or work permit (students, foreign employees, immigrants). Tests performed abroad are not recognized. Foreigners diagnosed with HIV while in the country are expelled. The regulations are based on a Ministerial Decree.	Central Command
El Salvador	No Restriction		Southern Command
Equatorial Guinea	Unclear	You may have to present an HIV test certificate, and HIV-positive status could lead to refusal of entry or deportation. The U.S. Department of State is unaware of any HIV/AIDS entry restrictions for visitors to or foreign residents of Equatorial Guinea. However, the Government of Equatorial Guinea is starting to require medical documentation, including the determination of the HIV status of third country nationals who are renewing or obtaining residency in Equatorial Guinea.	Africa Command
Eritrea	Unclear	Some HIV/AIDS entry restrictions exist for visitors to and foreign residents of Eritrea. Please verify this information with the Embassy of Eritrea before you travel.	Africa Command
Estonia	No Restriction		European Command
Ethiopia	No Restriction		Africa Command
Fiji	No Restriction		Indo-Pacific Command
Finland	No Restriction		European Command
France	No Restriction		European Command
Gabon	No Restriction		Africa Command
Gambia	No Restriction		Africa Command
Georgia	No Restriction		European Command
Germany	No Restriction		European Command

Ghana	No Restriction		Africa Command
Greece	No Restriction		European Command
Grenada	No Restriction		Southern Command
Guatemala	No Restriction		Southern Command
Guinea	No Restriction		Africa Command
Guinea Bissao	Unclear	The visa application form may include questions relating to infectious diseases. There is no information on whether foreigners with a known HIV infection are subject to specific residence regulations or whether there are regulations regarding the control, deportation or expulsion of those concerned.	Africa Command
Guyana	No Restriction		Southern Command
Haiti	No Restriction		Southern Command
Honduras	Evaluation	Work permit applicants must provide a medical certificate that has been issued within the six months prior to the application, indicating that the applicant does not suffer from any infectious or contagious disease. This medical certificate must be issued by a doctor in Honduras.	Southern Command
Hong Kong	No Restriction		Indo-Pacific Command
Hungary	Special Consideration	There are no laws or regulations that would formally ban people living with HIV from applying for, and receiving, long-term or permanent residency. The only requirement is that a person living with HIV has a valid social security/health insurance account with the state insurance fund. This can be done even without formal employment as long as the person pays a certain fee to the insurance fund each month. No HIV test is required for a person who seeks residency in Hungary. However, they must undergo treatment in order not to be expelled. If the person refuses to be treated for his/her HIV, then they may be expelled from the country.	European Command
Iceland	No Restriction		European Command
India	No Restriction		Indo-Pacific Command
Indonesia	No Restriction	The Indonesian Government screens incoming passengers in response to reported outbreaks of pandemic illnesses.	Indo-Pacific Command

Iran	Not Allowed	Foreigners applying for a work and residence permit, or who wish to stay for more than three months, must present a health certificate with a negative HIV test result. Exceptions are holders of diplomatic, service or special passports, and tourists and businessmen staying for less than three months.	Central Command
Iraq	Not Allowed	All foreigners are required to be tested for HIV at a state laboratory within 10 days of entry into Iraq. All stays beyond 10 days require an HIV test. Diplomats are excluded from these regulations.	Central Command
Ireland	No Restriction		European Command
Israel	Not Allowed	Work permit applicants are required to present a medical certificate of medical examinations and blood tests performed in clinics or hospitals recognized by the Israeli diplomatic post in the country of application. The certificate must cover, inter alia, results of tests for tuberculosis, hepatitis and HIV.	European Command
Italy	No Restriction		European Command
Jamaica	No Restriction		Southern Command
Japan	No Restriction		Indo-Pacific Command
Jordan	Not Allowed	You must undergo medical exams to obtain a residency permit. This includes mandatory testing for tuberculosis, HIV and hepatitis C. A positive HIV test leads to deportation.	Central Command
Kazakhstan	Not Allowed	Visitors applying for a work or residency permit, which is required for US citizens who wish to spend more than six months in Kazakhstan, must submit negative HIV test results with their application to the Migration Police in the city where they intend to work or reside. The results must be less than three months old.	Central Command
Kenya	Not Allowed		Africa Command
Kiribati	Unclear	No information provided.	Indo-Pacific Command
Korea (North)	Not Allowed	If a person's HIV-positive status becomes known, he/she is sent back to his/her country of origin. The reason given for this is the lack of experience with HIV/AIDS and the lack of treatment options.	Indo-Pacific Command
Korea (South)	No Restriction		Indo-Pacific Command

Kosovo	No Restriction		European Command
Kuwait	Not Allowed	If an HIV infection or HIV-related illness becomes known, the residence permit is withdrawn. The affected person has to leave Kuwait, or else is deported. Health checks at the border are not yet in effect, but the implementation of these is currently being discussed by Kuwaiti officials.	Central Command
Krygyzstan	Unclear	Some HIV/AIDS restrictions exist for visitors and residents in the Kyrgyz Republic. An HIV test is required to apply for a work visa. It is recommended to contact the Embassy fo the Kyrgyz Republic before you travel.	Central Command
Laos	No Restriction		Indo-Pacific Command
Latvia	No Restriction		European Command
Lebanon	Not Allowed	In accordance with Lebanese labour laws, all new migrants are required to submit negative HIV and STD lab test results along with their application for a work permit. Migrant workers testing HIV positive are deported and, in accordance with the law, repatriation costs are borne by the recruitment agency. As of 2007, however, in such cases, foreigners are given access to ARV treatment prior to deportation.	Central Command
Lesotho	No Restriction		Africa Command
Liberia	No Restriction		Africa Command
Libya	No Restriction	Some HIV/AIDS entry restrictions exist for visitors to and foreign residents of Libya. Please verify this information with the Libyan Embassy before traveling.	Africa Command
Lichtenstein	No Restriction		European Command
Lithuania	No Restriction	HIV/AIDS are not a condition considered to be a threat to public health in Lithuania. HIV positive people are advised not to indicate that they have a public health threatening disease while filling in applications for residency in order to circumvent possible problems.	European Command
Luxembourg	No Restriction		European Command
Macedonia	No Restriction		European Command
Madagascar	No Restriction		Africa Command
Malawi	No Restriction		Africa Command

Malaysia	Not Allowed	A full medical check-up (HIV, hepatitis, diagnostic reference levels, drug abuse and pregnancy) is required within one month of arrival and on a yearly basis. Special provisions for migrant workers (domestic staff and low skill workers) stipulate denial of permission to enter, or expulsion, if the HIV test result is positive.	Indo-Pacific Command
Maldives	No Restriction		Indo-Pacific Command
Mali	No Restriction		Africa Command
Malta	No Restriction		European Command
Marshall Islands	Not Allowed	Some HIV entry restrictions exist for visitors to and foreign residents of the Marshall Islands. HIV testing is required for temporary visitors staying more than 30 days and applicants for residence and work permits.	Indo-Pacific Command
Mauritania	No Restriction		Africa Command
Mauritius	Not Allowed	Migrant workers have to submit results of their HIV test for employment. No employment in case the test result is positive.	Africa Command
Mexico	No Restriction		Northern Command
Micronesia	No Restriction	The U.S. Department of State is unaware of any HIV/AIDS entry restrictions for visitors to or foreign residents of the Federated States of Micronesia. No restrictions for Pohnei State. Status of other States in Micronesia is unknown (each State has its own border control policies and regulations).	Indo-Pacific Command
Moldova	No Restriction		European Command
Monaco	No Restriction		European Command
Mongolia	No Restriction		Indo-Pacific Command
Montenegro	No Restriction		European Command
Montserrat	Unclear	Some HIV/AIDS entry restrictions may exist. Please contact the British Embassy before you travel.	Southern Command
Morocco	No Restriction		Africa Command
Mozambique	No Restriction		Africa Command
Myanmar (Burma)	No Restriction		Indo-Pacific Command
Namibia	No Restriction		Africa Command

Nauru	No Restriction	The Ministry of Health of Nauru is currently considering whether to put restrictions in place. Please inquire directly with Republic of Nauru Permanent Mission to the United Nations in New York.	Indo-Pacific Command
Nepal	No Restriction		Indo-Pacific Command
Netherlands	No Restriction	Residence regulations for people with HIV/AIDS: Foreigners are requested to have sufficient financial resources, a health insurance and a passport. These conditions don't apply in the case of an emergency (For example if the person in question would quickly die without treatment). This policy is compatible with Article 3 of the European Human Rights Convention.	European Command
New Zealand	Special Consideration	While HIV-positive people may not, prima facie, meet the definition of "acceptable standard of health", waivers of this requirement will be available for family members of New Zealand citizens and residents, and for refugees if they fulfil the criteria set by Immigration New Zealand. Applicants of temporary visas are not in general eligible for a medical waiver unless they fulfil some specific criteria. 20 HIV-positive people per year are accepted as quota refugees.	Indo-Pacific Command
Nicaragua	Special Consideration	According to the immigration authorities, extended residency will only exceptionally be granted to HIV-positive people. For example, it will be granted to people who participate in the rehabilitation programme for drug users offered by organizations established in Nicaragua (such as Patriarca).	Southern Command
Niger	No Restriction		Africa Command
Nigeria	Unclear	Some HIV/AIDS entry restrictions exist for visitors to and foreign residents of Nigeria. Nigerian authorities have the discretion to deny entry to foreigners who are "undesirable for medical reasons" and may require HIV tests for foreigners marrying Nigerian citizens. Please verify this information with the Embassy of Nigeria before you travel.	Africa Command

Norway	No Restriction	Foreigners with a known HIV infection are not subject to specific residence regulations. Persons who stay in Norway for longer than 3 months are offered a tuberculosis test and an HIV test, in order to arrange for any necessary treatment as quickly as possible.	European Command
Oman	Not Allowed	All long-term visa applications (employment, residence, etc.) require a medical exam, including an HIV test. Persons testing HIV positive are expelled.	Central Command
Pakistan	No Restriction		Central Command
Panama	No Restriction	The authorities still require a "certificate of good health" from people intending to stay in Panama for more than three months. This certificate can be issued to a person living with HIV.	Southern Command
Papua New Guinea	Not Allowed	The Government of Papua New Guinea imposes HIV/AIDS entry restrictions for visitors and foreign residents. If you request residency or intend to remain long term in Papua New Guinea, you are required to have an HIV test performed at a US medical facility.	Indo-Pacific Command
Paraguay	Special Consideration	Anyone applying for permanent residency in Paraguay is required to undergo HIV testing at the regional medical laboratory. No residence permit is granted if the HIV test result is positive, except when the patient can pay for his own treatment.	Southern Command
Peru	No Restriction		Southern Command
Philippines	No Restriction		Indo-Pacific Command
Poland	Special Consideration	HIV-testing is mandatory for longer stays (beyond 3 months), independent of purpose of stay. All pregnant women suspected to be infected and also children born from women suspected if being infected have to undergo testing. There are no controls at the border, and no certificates have to be presented. There are no regulations about the control or deportation of people with HIV.	European Command
Portugal	No Restriction		European Command

Qatar	Not Allowed	An HIV test is required for everybody intending to stay for more than one month. There is no HIV testing on entry. Those testing HIV positive will be denied work visas and will be deported (exception: residents who contract HIV during residence).	Central Command
Romania	No Restriction		European Command
Russia	Not Allowed	A negative HIV test result is required for long-term stays (more than three months), for students and for foreign employees. Foreign residents found to be HIV positive are expelled.	European Command
Rwanda	No Restriction		Africa Command
Samoa	Evaluation	An HIV test is required for residency or work permit applicants. Visitors indicating they have tested HIV positive will be subject to questioning by a health professional upon entry.	Indo-Pacific Command
San Marino	No Restriction		European Command
Sao Tome and Prinicipe	Unclear	No information provided.	Africa Command
Saudi Arabia	Not Allowed	A negative HIV test result is required for residence and work permit applicants. Deportations of people diagnosed with HIV have been reported.	Central Command
Senegal	No Restriction		Africa Command
Serbia	No Restriction		European Command
Seychelles	Unclear	To work on the Seychelles, a work permit is required. A full medical examination is required and all tests are compulsory, including HIV. Discrimination has been known to occur with HIV positive individuals.	Africa Command
Sierra Leone	No Restriction		Africa Command
Singapore	Not Allowed	An HIV test is mandatory for stays beyond 90 days. Foreign workers applying for an employment pass are required to undergo a medical screening for HIV and a positive test will result in the rejection of a foreign worker's application.	Indo-Pacific Command
Slovakia	No Restriction		European Command
Slovenia	No Restriction		European Command

Solomon Islands	Not Allowed	Some HIV/AIDS entry restrictions exist for visitors to and foreign residents of the Solomon Islands. According to the Solomon Islands Immigration Act, an immigration officer can bar you from entering the country or deport you if you refuse to submit to an examination by a government medical officer after being required to do so. Border officers may require a medical certificate. An HIV test is required for stays over 90 days. Deportation is possible.	Central Command
Somalia	No Restriction		Africa Command
South Africa	No Restriction		Africa Command
South Sudan	No Restriction		Africa Command
Spain	No Restriction		European Command
Sri Lanka	Evaluation	The U.S. Department of State is unaware of any HIV/AIDS entry restrictions for visitors to or foreign residents of Sri Lanka; however, Sri Lankan law does allow immigration officials to refer visitors and foreign residents to a physician for examination if a public health risk is suspected. In practice this is a rare occurrence, but travelers should be aware that Sri Lankan law allows for the denial of entry to any foreigner who, upon referral from an immigration officer, is certified by a physician as posing a public health risk. Travelers who refuse a medical examination under these circumstances may be refused entry. Please verify this information with the Embassy of Sri Lanka before traveling.	Indo-Pacific Command
St. Kitts and Nevis	Unclear	Some HIV/AIDS entry restrictions may exist. Please contact the Embassy of Saint Kitts and Nevis before you travel.	Southern Command
St. Lucia	No Restriction		Southern Command
St. Vincent and Grenadines	Unclear	Some HIV entry restrictions may exist. Please contact the Embassy of Saint Vincent and the Grenadines before you travel. HIV-positive foreigners have no access to treatment and services.	Southern Command
Sudan	Not Allowed	Some HIV entry restrictions exist for visitors and foreign residents of Sudan. Sudanese law requires a negative HIV test result in order to obtain a work or residence visa.	Africa Command

Suriname	Special Consideration	On May 5, 2008, the Republic of Suriname adopted a new law establishing entry restrictions targeting people with HIV from certain countries and regions. Citizens from countries in Africa, Asia and Eastern Europe, who require a visa to enter Suriname, must present evidence of health and travel insurance plus a health certificate stating the absence of leprosies, sexually transmitted diseases, hepatitis B, HIV and tuberculosis. The Foreign Ministry has sent a note in this regard to its missions abroad. Most likely, short-term visitors will not face any problems when entering the country. There are no border controls. Working migrants do not need to present a negative HIV test result when applying for a work permit. However, it may be possible that employers demand such a test. There is no law forbidding that.	Southern Command
Swaziland	No Restriction		Africa Command
Sweden	Unclear	There are no specific entry or residence regulations for people with HIV/AIDS. Neither a medical certificate nor an HIV test result is required when entering the country. Foreigners with a known HIV infection are not subject to specific residence regulations. There are no regulations regarding the control, deportation or expulsion of those concerned. In case of doubt, the health authorities may force a foreign national to undergo an HIV test.	European Command
Switzerland	No Restriction		European Command

Syria	Not Allowed	No HIV test is required for a short-term tourist visa. Tourist visas (multiple entry visas) are granted for up to six months. Foreigners applying for residency in order to work or to study in Syria have to undergo HIV testing. This also applies to a person married to a Syrian national and intending to take residence in the country. Diplomats are exempt. It is very likely that foreigners diagnosed with HIV will be expelled.	Central Command
Tadjikistan	No Restriction		Central Command
Taiwan	No Restriction		Indo-Pacific Command
Tanzania	No Restriction		Africa Command
Thailand	Evaluation	Users of this site reported that teacher recruitment agencies require health checks including HIV tests. The HIV test is not essential for obtaining a work permit from the authorities.	Indo-Pacific Command
Timor Leste	No Restriction		Indo-Pacific Command
Togo	No Restriction		Africa Command
Tonga	Evaluation	An HIV test is required for stays of more than 90 days. It is unclear	Indo-Pacific Command
Trinidad and Tobago	No Restriction		Southern Command
Tunisia	Not Allowed	There are no specific regulations concerning short-term stays in Tunisia. However, the granting of work and residency permits can be subject to health checks, and their granting may be denied in the presence of HIV. The regulations target foreign employees and immigrants.	Africa Command
Turkey	No Restriction		European Command
Turkmenistan	Unclear	The U.S. Department of State is unaware of any HIV/AIDS entry restrictions for visitors to or foreign residents of Turkmenistan. A positive HIV test result may lead to deportation.	Central Command
Turks and Caicos Islands	Unclear	Residence and work permit applicants are required to submit a local medical certificate with their application. Please contact the Turks and Caicos embassy before traveling.	Northern Command
Tuvalu	Unclear	No information provided.	Indo-Pacific Command
Uganda	No Restriction		Africa Command

Ukraine	No Restriction		European Command
United Arab Emirates	Not Allowed	In principle, people with HIV/AIDS are not allowed to enter or stay in the United Arab Emirates. Health exams, including an HIV test, are performed when applying for a residency permit. A later detected HIV-infection may lead to deportation.	Central Command
United Kingdom and Gibraltar	No Restriction		European Command
United States of America	No Restriction		Northern Command
Uruguay	No Restriction		Southern Command
Uzbekistan	No Restriction		Central Command
Vanuatu	No Restriction		Northern Command
Vatican, Holy See	Unclear	There are no proper entry regulations for the Vatican, as inner state affairs are delegated to the authorities of Italy.	European Command
Venezuela	Special Consideration	The presentation of an HIV test result is not required when entering Venezuela. There are no specific entry or residence regulations for people with HIV/AIDS. Art. 32 of the law on foreigners (Ley de Extranjeros) partially prohibits the entry of people who have a disease. It is possible that this measure could be applied to people with HIV. However, no such case is known.	Southern Command
Vietnam	No Restriction		Indo-Pacific Command
Virgin Islands	Evaluation	A medical test is required for work and residence permits. Excerpt from "Immigration Medical requirements", effective from January 1, 2018: ... persons are no longer mandated to have medical certificates upon entry to the territory but can opt to have their medicals done locally in order to be deemed free of infectious diseases such as tuberculosis, yellow fever, malaria, plague, viral haemorrhagic fever and West Nile virus. Although HIV is not specifically listed and mentioned, the physician is also asked to report sexually transmitted diseases on the medical form.	Northern Command

Yemen	Not Allowed	Independent of purpose and duration of stay, people with known HIV infections are not allowed to enter Yemen. Tourists staying less than 3 months are not controlled, whether on entry nor during their stay. Residence or work permit applicants need to undergo HIV-testing in order to receive their permits. The regulations target students, foreign employees, refugees and immigrants.	Central Command
Zambia	No Restriction		Africa Command
Zimbabwe	No Restriction		Africa Command

Special Consideration Restriction

Country	Restriction	Notes/Overview	Combatant Command
Armenia	Special Consideration	Antiretroviral medications can be imported for personal use and for the duration of the planned stay (up to six weeks). A medical certificate including the diagnosis in Russian or Armenian language has to be presented at customs. No information on residency.	European Command
Belarus	Special Consideration	The U.S. Department of State is unaware of any HIV/AIDS entry restrictions for visitors to Belarus on a 30-day visit. Long-term residents (those spending more than 90 days a year in Belarus) or students must obtain an HIV/AIDS test in Belarus and submit the results to the Department of Citizenship and Migration when applying for an extension of stay or residency. We recommend that you verify this information with the Embassy of Belarus before you travel.	European Command
Belgium	Special Consideration	A health certificate stating absence of a transmittable disease that would present a danger for public health is required from non-EU residency permit applicants. A residency permit can be granted regardless of HIV infection. The following conditions can be grounds for denying such a permit: -Illnesses that require the patient to be under quarantine (as defined by WHO guidelines from May 25, 1951). -Active tuberculosis -Syphilis -Transmittable infectious conditions or contagious parasitic diseases	European Command

Benin	Special Consideration	An HIV test is required when applying for a long-term residence permit. In case of a positive test result, law does not forbid the grant of a long-term residence permit. The permit is granted at the discretion of the officer dealing with the application. There are no specific residence regulations regarding people with HIV/AIDS. The Embassy can't judge how the problem is handled in practice. Nothing has been heard about controls, deportations or expulsions. It is possible that residence permits won't be extended in the case of a positive test result.	Africa Command
Canada	Special Consideration	Under the Immigration and Refugee Protection Act ("IRPA"), foreign nationals are inadmissible as permanent immigrants to Canada if their health condition might reasonably be expected to cause an "excessive demand" on health or social services, or if their application to immigrate includes a family member in this situation. Due to the high cost of antiretroviral medications, people living with HIV are generally deemed medically inadmissible if they apply to immigrate to Canada. Today's proposed changes include increasing the cost threshold for defining what constitutes "excessive demand," to three times the current level of $6,655 per year. This increase to the cost threshold may mean that many people living with HIV will no longer be found medically inadmissible and excluded from immigration to Canada.	Northern Command
Hungary	Special Consideration	There are no laws or regulations that would formally ban people living with HIV from applying for, and receiving, long-term or permanent residency. The only requirement is that a person living with HIV has a valid social security/health insurance account with the state insurance fund. This can be done even without formal employment as long as the person pays a certain fee to the insurance fund each month. No HIV test is required for a person who seeks residency in Hungary. However, they must undergo treatment in order not to be expelled. If the person refuses to be treated for his/her HIV, then they may be expelled from the country.	European Command

New Zealand	Special Consideration	While HIV-positive people may not, prima facie, meet the definition of "acceptable standard of health", waivers of this requirement will be available for family members of New Zealand citizens and residents, and for refugees if they fulfil the criteria set by Immigration New Zealand. Applicants of temporary visas are not in general eligible for a medical waiver unless they fulfil some specific criteria. 20 HIV-positive people per year are accepted as quota refugees.	Indo-Pacific Command
Nicaragua	Special Consideration	According to the immigration authorities, extended residency will only exceptionally be granted to HIV-positive people. For example, it will be granted to people who participate in the rehabilitation programme for drug users offered by organizations established in Nicaragua (such as Patriarca).	Southern Command
Paraguay	Special Consideration	Anyone applying for permanent residency in Paraguay is required to undergo HIV testing at the regional medical laboratory. No residence permit is granted if the HIV test result is positive, except when the patient can pay for his own treatment.	Southern Command
Poland	Special Consideration	HIV-testing is mandatory for longer stays (beyond 3 months), independent of purpose of stay. All pregnant women suspected to be infected and also children born from women suspected if being infected have to undergo testing. There are no controls at the border, and no certificates have to be presented. There are no regulations about the control or deportation of people with HIV.	European Command

Suriname	Special Consideration	On May 5, 2008, the Republic of Suriname adopted a new law establishing entry restrictions targeting people with HIV from certain countries and regions. Citizens from countries in Africa, Asia and Eastern Europe, who require a visa to enter Suriname, must present evidence of health and travel insurance plus a health certificate stating the absence of leprosies, sexually transmitted diseases, hepatitis B, HIV and tuberculosis. The Foreign Ministry has sent a note in this regard to its missions abroad. Most likely, short-term visitors will not face any problems when entering the country. There are no border controls. Working migrants do not need to present a negative HIV test result when applying for a work permit. However, it may be possible that employers demand such a test. There is no law forbidding that.	Southern Command
Venezuela	Special Consideration	The presentation of an HIV test result is not required when entering Venezuela. There are no specific entry or residence regulations for people with HIV/AIDS. Art. 32 of the law on foreigners (Ley de Extranjeros) partially prohibits the entry of people who have a disease. It is possible that this measure could be applied to people with HIV. However, no such case is known.	Southern Command

Restrictions are Unclear

Country	Restriction	Notes/Overview	Combatant Command
Angola	Unclear	It is reported that a medical check-up requirement for work visa applicants ("Visto de Trabalho"), authorised under Law 2/07 and Presidential Decree 108. According to the International Organisation of Migration (IOM), the check-up does not require HIV testing. However, the Embassy of Angola in Serbia web site indicates the contrary.	Africa Command
Bangladesh	Unclear	There are no specific entry regulations for people with HIV/AIDS in Bangladesh (information provided by the Embassy's Attorney of confidence). Neither a medical certificate nor an HIV test result is requested. This also applies to long-term residents. It is possible however, that foreigners with HIV/AIDS are deported if the competent authorities find out about their condition.	Indo-Pacific Command
Bermuda	Unclear	The U.S. Department of State is unaware of any HIV/AIDS entry restrictions for visitors to or foreign residents of Bermuda. However, visitors with visible indicators of any communicable disease can be refused entry into Bermuda.	Northern Command
Bhutan	Unclear	Some HIV/AIDS entry restrictions exist for visitors to and foreign residents of Bhutan. For stays longer than two weeks, applicants must present the results of an HIV/AIDS test completed within the six months prior to their visit. The test can also be administered by Bhutanese officials upon arrival.	Indo-Pacific Command
Cayman Islands	Unclear	Although there are no specific HIV/AIDS entry restrictions for visitors to the Cayman Islands, people living with HIV/AIDS can be denied permission to land if a Health Officer certifies that their entry to the Islands would be dangerous to the community. This is according to Section 82 (c) of the Cayman Immigration Law (2007 Revision).	Southern Command

China	Unclear	In case of a long-term professional stay in China (longer than six months): Check the situation carefully. Until recently, a negative HIV status was mandatory for foreigners staying in China on long-term permits. Tests have also been performed in China and without consent of those concerned. A positive HIV test result led to immediate deportation, job loss and unemployment.	Indo-Pacific Command
Equatorial Guinea	Unclear	You may have to present an HIV test certificate, and HIV-positive status could lead to refusal of entry or deportation. The U.S. Department of State is unaware of any HIV/AIDS entry restrictions for visitors to or foreign residents of Equatorial Guinea. However, the Government of Equatorial Guinea is starting to require medical documentation, including the determination of the HIV status of third country nationals who are renewing or obtaining residency in Equatorial Guinea.	Africa Command
Eritrea	Unclear	Some HIV/AIDS entry restrictions exist for visitors to and foreign residents of Eritrea. Please verify this information with the Embassy of Eritrea before you travel.	Africa Command
Guinea Bissao	Unclear	The visa application form may include questions relating to infectious diseases. There is no information on whether foreigners with a known HIV infection are subject to specific residence regulations or whether there are regulations regarding the control, deportation or expulsion of those concerned.	Africa Command
Kiribati	Unclear	No information provided.	Indo-Pacific Command
Krygyzstan	Unclear	Some HIV/AIDS restrictions exist for visitors and residents in the Kyrgyz Republic. An HIV test is required to apply for a work visa. It is recommended to contact the Embassy fo the Kyrgyz Republic before you travel.	Central Command
Montserrat	Unclear	Some HIV/AIDS entry restrictions may exist. Please contact the British Embassy before you travel.	Southern Command

Nigeria	Unclear	Some HIV/AIDS entry restrictions exist for visitors to and foreign residents of Nigeria. Nigerian authorities have the discretion to deny entry to foreigners who are "undesirable for medical reasons" and may require HIV tests for foreigners marrying Nigerian citizens. Please verify this information with the Embassy of Nigeria before you travel.	Africa Command
Sao Tome and Prinicipe	Unclear	No information provided.	Africa Command
Seychelles	Unclear	To work on the Seychelles, a work permit is required. A full medical examination is required and all tests are compulsory, including HIV. Discrimination has been known to occur with HIV positive individuals.	Africa Command
St. Kitts and Nevis	Unclear	Some HIV/AIDS entry restrictions may exist. Please contact the Embassy of Saint Kitts and Nevis before you travel.	Southern Command
St. Vincent and Grenadines	Unclear	Some HIV entry restrictions may exist. Please contact the Embassy of Saint Vincent and the Grenadines before you travel. HIV-positive foreigners have no access to treatment and services.	Southern Command
Sweden	Unclear	There are no specific entry or residence regulations for people with HIV/AIDS. Neither a medical certificate nor an HIV test result is required when entering the country. Foreigners with a known HIV infection are not subject to specific residence regulations. There are no regulations regarding the control, deportation or expulsion of those concerned. In case of doubt, the health authorities may force a foreign national to undergo an HIV test.	European Command
Turkmenistan	Unclear	The U.S. Department of State is unaware of any HIV/AIDS entry restrictions for visitors to or foreign residents of Turkmenistan. A positive HIV test result may lead to deportation.	Central Command
Turks and Caicos Islands	Unclear	Residence and work permit applicants are required to submit a local medical certificate with their application. Please contact the Turks and Caicos embassy before traveling.	Northern Command
Tuvalu	Unclear	No information provided.	Indo-Pacific Command
Vatican, Holy See	Unclear	There are no proper entry regulations for the Vatican, as inner state affairs are delegated to the authorities of Italy.	European Command

Evaluation Required

Country	Restriction	Notes/Overview	Combatant Command
Australia	Evaluation	with HIV are treated similarly to other people with chronic health conditions and disabilities during the country's immigration health assessment process. Applications for visas from people living with HIV will be assessed against criteria applying to anyone with a chronic health condition. Applicants for visas to visit or migrate to Australia are required to meet certain health requirements. These help ensure that: -Risks to public health in the Australian community are minimized -Public expenditure on health and community services is contained -Australian residents have access to health and other community services in short supply.	Indo-Pacific Command
Honduras	Evaluation	Work permit applicants must provide a medical certificate that has been issued within the six months prior to the application, indicating that the applicant does not suffer from any infectious or contagious disease. This medical certificate must be issued by a doctor in Honduras.	Southern Command
Samoa	Evaluation	An HIV test is required for residency or work permit applicants. Visitors indicating they have tested HIV positive will be subject to questioning by a health professional upon entry.	Indo-Pacific Command

Sri Lanka	Evaluation	The U.S. Department of State is unaware of any HIV/AIDS entry restrictions for visitors to or foreign residents of Sri Lanka; however, Sri Lankan law does allow immigration officials to refer visitors and foreign residents to a physician for examination if a public health risk is suspected. In practice this is a rare occurrence, but travelers should be aware that Sri Lankan law allows for the denial of entry to any foreigner who, upon referral from an immigration officer, is certified by a physician as posing a public health risk. Travelers who refuse a medical examination under these circumstances may be refused entry. Please verify this information with the Embassy of Sri Lanka before traveling.	Indo-Pacific Command
Thailand	Evaluation	Users of this site reported that teacher recruitment agencies require health checks including HIV tests. The HIV test is not essential for obtaining a work permit from the authorities.	Indo-Pacific Command
Tonga	Evaluation	An HIV test is required for stays of more than 90 days. It is unclear	Indo-Pacific Command
Virgin Islands	Evaluation	A medical test is required for work and residence permits. Excerpt from "Immigration Medical requirements", effective from January 1, 2018: ... persons are no longer mandated to have medical certificates upon entry to the territory but can opt to have their medicals done locally in order to be deemed free of infectious diseases such as tuberculosis, yellow fever, malaria, plague, viral haemorrhagic fever and West Nile virus. Although HIV is not specifically listed and mentioned, the physician is also asked to report sexually transmitted diseases on the medical form.	Northern Command

No Restriction

Country	Restriction	Notes/Overview	Combatant Command
Afghanistan	No Restriction		Central Command
Albania	No Restriction		European Command
Algeria	No Restriction		Africa Command
Andorra	No Restriction		European Command
Antigua and Barbuda	No Restriction		Southern Command
Argentina	No Restriction		Southern Command
Austria	No Restriction		European Command
Bahamas	No Restriction		Northern Command
Barbados	No Restriction		Southern Command
Belize	No Restriction		Southern Command
Bolivia	No Restriction		Southern Command
Bosnia Herzegovina	No Restriction (except for one province)	The Republika Srpska (province of Bosnia Herzegovina) has a law on population protection from infectious diseases. The law requires that foreigners with long-term residency status (i.e., staying for more than three months) have to perform regular medical examinations. Related testing includes HIV, syphilis and hepatitis B and C. At application, test results should be no older than three months.	European Command
Botswana	No Restriction		Africa Command
Brazil	No Restriction		Southern Command
Bulgaria	No Restriction		European Command
Burkina Faso	No Restriction		Africa Command
Burundi	No Restriction		Africa Command
Cabo Verde	No Restriction		Africa Command
Cambodia	No Restriction		Indo-Pacific Command
Cameroon	No Restriction		Africa Command
Central African Republic	No Restriction		Africa Command
Chad	No Restriction		Africa Command

Chile	No Restriction		Southern Command
Colombia	No Restriction		Southern Command
Comores	No Restriction		Africa Command
Congo (Brazzaville)	No Restriction		Africa Command
Congo (Kinshasa)	No Restriction		Africa Command
Costa Rica	No Restriction		Southern Command
Cote D'Ivoire	No Restriction		Africa Command
Croatia	No Restriction		European Command
Czech Republic	No Restriction		European Command
Denmark	No Restriction		European Command
Dijibouti	No Restriction		Africa Command
El Salvador	No Restriction		Southern Command
Estonia	No Restriction		European Command
Ethiopia	No Restriction		Africa Command
Fiji	No Restriction		Indo-Pacific Command
Finland	No Restriction		European Command
France	No Restriction		European Command
Gabon	No Restriction		Africa Command
Gambia	No Restriction		Africa Command
Georgia	No Restriction		European Command
Germany	No Restriction		European Command
Ghana	No Restriction		Africa Command
Greece	No Restriction		European Command
Grenada	No Restriction		Southern Command
Guatemala	No Restriction		Southern Command
Guinea	No Restriction		Africa Command
Guyana	No Restriction		Southern Command
Haiti	No Restriction		Southern Command
Hong Kong	No Restriction		Indo-Pacific Command
Iceland	No Restriction		European Command
India	No Restriction		Indo-Pacific Command

Indonesia	No Restriction	The Indonesian Government screens incoming passengers in response to reported outbreaks of pandemic illnesses.	Indo-Pacific Command
Ireland	No Restriction		European Command
Italy	No Restriction		European Command
Jamaica	No Restriction		Southern Command
Japan	No Restriction		Indo-Pacific Command
Korea (South)	No Restriction		Indo-Pacific Command
Kosovo	No Restriction		European Command
Laos	No Restriction		Indo-Pacific Command
Latvia	No Restriction		European Command
Lesotho	No Restriction		Africa Command
Liberia	No Restriction		Africa Command
Libya	No Restriction	Some HIV/AIDS entry restrictions exist for visitors to and foreign residents of Libya. Please verify this information with the Libyan Embassy before traveling.	Africa Command
Lichtenstein	No Restriction		European Command
Lithuania	No Restriction	HIV/AIDS are not a condition considered to be a threat to public health in Lithuania. HIV positive people are advised not to indicate that they have a public health threatening disease while filling in applications for residency in order to circumvent possible problems.	European Command
Luxembourg	No Restriction		European Command
Macedonia	No Restriction		European Command
Madagascar	No Restriction		Africa Command
Malawi	No Restriction		Africa Command
Maldives	No Restriction		Indo-Pacific Command
Mali	No Restriction		Africa Command
Malta	No Restriction		European Command
Mauritania	No Restriction		Africa Command
Mexico	No Restriction		Northern Command

Micronesia	No Restriction	The U.S. Department of State is unaware of any HIV/AIDS entry restrictions for visitors to or foreign residents of the Federated States of Micronesia. No restrictions for Pohnei State. Status of other States in Micronesia is unknown (each State has its own border control policies and regulations).	Indo-Pacific Command
Moldova	No Restriction		European Command
Monaco	No Restriction		European Command
Mongolia	No Restriction		Indo-Pacific Command
Montenegro	No Restriction		European Command
Morocco	No Restriction		Africa Command
Mozambique	No Restriction		Africa Command
Myanmar (Burma)	No Restriction		Indo-Pacific Command
Namibia	No Restriction		Africa Command
Nauru	No Restriction	The Ministry of Health of Nauru is currently considering whether to put restrictions in place. Please inquire directly with Republic of Nauru Permanent Mission to the United Nations in New York.	Indo-Pacific Command
Nepal	No Restriction		Indo-Pacific Command
Netherlands	No Restriction	Residence regulations for people with HIV/AIDS: Foreigners are requested to have sufficient financial resources, a health insurance and a passport. These conditions don't apply in the case of an emergency (For example if the person in question would quickly die without treatment). This policy is compatible with Article 3 of the European Human Rights Convention.	European Command
Niger	No Restriction		Africa Command
Norway	No Restriction	Foreigners with a known HIV infection are not subject to specific residence regulations. Persons who stay in Norway for longer than 3 months are offered a tuberculosis test and an HIV test, in order to arrange for any necessary treatment as quickly as possible.	European Command
Pakistan	No Restriction		Central Command

Panama	No Restriction	The authorities still require a "certificate of good health" from people intending to stay in Panama for more than three months. This certificate can be issued to a person living with HIV.	Southern Command
Peru	No Restriction		Southern Command
Philippines	No Restriction		Indo-Pacific Command
Portugal	No Restriction		European Command
Romania	No Restriction		European Command
Rwanda	No Restriction		Africa Command
San Marino	No Restriction		European Command
Senegal	No Restriction		Africa Command
Serbia	No Restriction		European Command
Sierra Leone	No Restriction		Africa Command
Slovakia	No Restriction		European Command
Slovenia	No Restriction		European Command
Somalia	No Restriction		Africa Command
South Africa	No Restriction		Africa Command
South Sudan	No Restriction		Africa Command
Spain	No Restriction		European Command
St. Lucia	No Restriction		Southern Command
Swaziland	No Restriction		Africa Command
Switzerland	No Restriction		European Command
Tadjikistan	No Restriction		Central Command
Taiwan	No Restriction		Indo-Pacific Command
Tanzania	No Restriction		Africa Command
Timor Leste	No Restriction		Indo-Pacific Command
Togo	No Restriction		Africa Command
Trinidad and Tobago	No Restriction		Southern Command
Turkey	No Restriction		European Command
Uganda	No Restriction		Africa Command
Ukraine	No Restriction		European Command

United Kingdom and Gibraltar	No Restriction		European Command
United States of America	No Restriction		Northern Command
Uruguay	No Restriction		Southern Command
Uzbekistan	No Restriction		Central Command
Vanuatu	No Restriction		Northern Command
Vietnam	No Restriction		Indo-Pacific Command
Zambia	No Restriction		Africa Command
Zimbabwe	No Restriction		Africa Command

HIV Positive Individuals Not Allowed

Country	Restriction	Notes/Overview	Combatant Command
Aruba	Not Allowed	The Government of Aruba, albeit part of the Kingdom of the Netherlands, does not provide a working permit to people living with HIV. And for living in Aruba, one needs a working and residency permit. Even marital status would not change this.	Southern Command
Azerbaidjan	Not Allowed	People applying for an electronic visa through the official electronic visa portal are required to confirm they are HIV-negative and free from hepatitis B and C. Without this confirmation, applicants are not able to receive a visa.	European Command
Bahrain	Not Allowed	All foreigners declared HIV positive risk immediate deportation; deportation may be applied to all "communicable diseases." Although an individual is not required to declare HIV status upon arrival, the government revokes visas of non-Bahrainis who are HIV positive. [Note: Information should be verified with the Embassy of the Kingdom of Bahrain before travelling]	Central Command
Brunei	Not Allowed	People who wish to work or study in Brunei need a work and residence permit. On application for these permits, people must undergo a health examination in their country of origin and again within two weeks of entering Brunei. This health check includes HIV testing. No medical certificate has to be presented when entering the country. Local authorities will deport HIV-positive foreigners to their native country. A person's residence permit will be cancelled if HIV is detected.	Indo-Pacific Command

Cuba	Not Allowed	There are no restrictions for people with HIV/AIDS for short-term stays of up to three months (tourist visa). An HIV test is mandatory for longer stays. An HIV test result must be presented upon application for a long-term visa. There are no controls at the border. The extension of a residency permit requires a negative HIV test result. There is no information about the consequences for a person entering the country who is detected to be HIV positive. Antiretroviral medication for personal use can be carried along.	Southern Command
Cyprus	Not Allowed	Foreigners (non-EU citizens only) applying for a residence permit in order to work or to study must undergo a medical examination by the Health Ministry in order to exclude an infection with HIV, hepatitis B/C or syphilis. The authorities will not grant a residence permit in the case of a positive test result. For all other foreigners (EU citizens, tourists, employees of international companies, UN staff), there are no mandatory medical examinations.	European Command
Dominican Republic	Not Allowed	Medical checks are mandatory for people applying for work or residence permits. Residency is restricted for people with infectious diseases. A positive HIV test will result in denial of a residence permit. The same happens if a person refuses to get tested.	Southern Command
Ecuador	Not Allowed	For people applying for student permits, work permits and voluntary, missionary or religious visas, a doctor's certificate and an HIV test is required. Applicants must be free of communicable diseases.	Southern Command
Egypt	Not Allowed	An HIV test has to be performed at the Health Ministry's central laboratory for all people who apply for a residence or work permit (students, foreign employees, immigrants). Tests performed abroad are not recognized. Foreigners diagnosed with HIV while in the country are expelled. The regulations are based on a Ministerial Decree.	Central Command

Iran	Not Allowed	Foreigners applying for a work and residence permit, or who wish to stay for more than three months, must present a health certificate with a negative HIV test result. Exceptions are holders of diplomatic, service or special passports, and tourists and businessmen staying for less than three months.	Central Command
Iraq	Not Allowed	All foreigners are required to be tested for HIV at a state laboratory within 10 days of entry into Iraq. All stays beyond 10 days require an HIV test. Diplomats are excluded from these regulations.	Central Command
Israel	Not Allowed	Work permit applicants are required to present a medical certificate of medical examinations and blood tests performed in clinics or hospitals recognized by the Israeli diplomatic post in the country of application. The certificate must cover, inter alia, results of tests for tuberculosis, hepatitis and HIV.	European Command
Jordan	Not Allowed	You must undergo medical exams to obtain a residency permit. This includes mandatory testing for tuberculosis, HIV and hepatitis C. A positive HIV test leads to deportation.	Central Command
Kazakhstan	Not Allowed	Visitors applying for a work or residency permit, which is required for US citizens who wish to spend more than six months in Kazakhstan, must submit negative HIV test results with their application to the Migration Police in the city where they intend to work or reside. The results must be less than three months old.	Central Command
Kenya	Not Allowed		Africa Command
Korea (North)	Not Allowed	If a person's HIV-positive status becomes known, he/she is sent back to his/her country of origin. The reason given for this is the lack of experience with HIV/AIDS and the lack of treatment options.	Indo-Pacific Command
Kuwait	Not Allowed	If an HIV infection or HIV-related illness becomes known, the residence permit is withdrawn. The affected person has to leave Kuwait, or else is deported. Health checks at the border are not yet in effect, but the implementation of these is currently being discussed by Kuwaiti officials.	Central Command

Lebanon	Not Allowed	In accordance with Lebanese labour laws, all new migrants are required to submit negative HIV and STD lab test results along with their application for a work permit. Migrant workers testing HIV positive are deported and, in accordance with the law, repatriation costs are borne by the recruitment agency. As of 2007, however, in such cases, foreigners are given access to ARV treatment prior to deportation.	Central Command
Malaysia	Not Allowed	A full medical check-up (HIV, hepatitis, diagnostic reference levels, drug abuse and pregnancy) is required within one month of arrival and on a yearly basis. Special provisions for migrant workers (domestic staff and low skill workers) stipulate denial of permission to enter, or expulsion, if the HIV test result is positive.	Indo-Pacific Command
Marshall Islands	Not Allowed	Some HIV entry restrictions exist for visitors to and foreign residents of the Marshall Islands. HIV testing is required for temporary visitors staying more than 30 days and applicants for residence and work permits.	Indo-Pacific Command
Mauritius	Not Allowed	Migrant workers have to submit results of their HIV test for employment. No employment in case the test result is positive.	Africa Command
Oman	Not Allowed	All long-term visa applications (employment, residence, etc.) require a medical exam, including an HIV test. Persons testing HIV positive are expelled.	Central Command
Papua New Guinea	Not Allowed	The Government of Papua New Guinea imposes HIV/AIDS entry restrictions for visitors and foreign residents. If you request residency or intend to remain long term in Papua New Guinea, you are required to have an HIV test performed at a US medical facility.	Indo-Pacific Command
Qatar	Not Allowed	An HIV test is required for everybody intending to stay for more than one month. There is no HIV testing on entry. Those testing HIV positive will be denied work visas and will be deported (exception: residents who contract HIV during residence).	Central Command
Russia	Not Allowed	A negative HIV test result is required for long-term stays (more than three months), for students and for foreign employees. Foreign residents found to be HIV positive are expelled.	European Command

Saudi Arabia	Not Allowed	A negative HIV test result is required for residence and work permit applicants. Deportations of people diagnosed with HIV have been reported.	Central Command
Singapore	Not Allowed	An HIV test is mandatory for stays beyond 90 days. Foreign workers applying for an employment pass are required to undergo a medical screening for HIV and a positive test will result in the rejection of a foreign worker's application.	Indo-Pacific Command
Solomon Islands	Not Allowed	Some HIV/AIDS entry restrictions exist for visitors to and foreign residents of the Solomon Islands. According to the Solomon Islands Immigration Act, an immigration officer can bar you from entering the country or deport you if you refuse to submit to an examination by a government medical officer after being required to do so. Border officers may require a medical certificate. An HIV test is required for stays over 90 days. Deportation is possible.	Central Command
Sudan	Not Allowed	Some HIV entry restrictions exist for visitors and foreign residents of Sudan. Sudanese law requires a negative HIV test result in order to obtain a work or residence visa.	Africa Command
Syria	Not Allowed	No HIV test is required for a short-term tourist visa. Tourist visas (multiple entry visas) are granted for up to six months. Foreigners applying for residency in order to work or to study in Syria have to undergo HIV testing. This also applies to a person married to a Syrian national and intending to take residence in the country. Diplomats are exempt. It is very likely that foreigners diagnosed with HIV will be expelled.	Central Command
Tunisia	Not Allowed	There are no specific regulations concerning short-term stays in Tunisia. However, the granting of work and residency permits can be subject to health checks, and their granting may be denied in the presence of HIV. The regulations target foreign employees and immigrants.	Africa Command

United Arab Emirates	Not Allowed	In principle, people with HIV/AIDS are not allowed to enter or stay in the United Arab Emirates. Health exams, including an HIV test, are performed when applying for a residency permit. A later detected HIV-infection may lead to deportation.	Central Command
Yemen	Not Allowed	Independent of purpose and duration of stay, people with known HIV infections are not allowed to enter Yemen. Tourists staying less than 3 months are not controlled, whether on entry nor during their stay. Residence or work permit applicants need to undergo HIV-testing in order to receive their permits. The regulations target students, foreign employees, refugees and immigrants.	Central Command

HIV Country Restrictions, Summary of Findings

Request 1: Identify country entry and exit requirements for Service members deployed to a Foreign Nation (e.g., VISA requirements)

BLUF: The regulations for Service members entering and exiting a country to perform their duty are often determined by Status of Forces Agreements (SOFAs), which typically require Service members to provide a military ID and military orders upon entry and exit.

Summary of findings:

Status of Force Agreements establish the framework for US military personnel to operate in a foreign country, which include the foreign jurisdiction and applicable legislation toward US personnel.[1] These agreements often determine the requirements needed for Service members to enter or exit the country, and typically include a military ID and military orders.

A detailed review of each SOFA is required to determine similarities and differences of agreements; however, preliminary review of four separate agreements (between the US and Japan, South Korea, Iraq, and Afghanistan) indicate that each agreement: require Service members and dependents to enter and exit the country through designated facilities; and require Service members to present a military ID and orders for entrance and exit. The Korean SOFA contains an additional provision, which requires dependents to have a Korean VISA. Furthermore, the preliminary review suggests that military personnel and dependents must obtain a passport if they wish to travel for personal matters (e.g., tourism); consequently, this would require Service members to meet host nation requirements for civilian entry.

Request 2: Review of international policy for Military and/or US government personnel to perform professional duties in a host nation if the individual presents with HIV positive status

BLUF: Individual or multilateral treaties or agreements specifically addressing requirements associated with communicable diseases or HIV status were unable to be identified. Similarly, SOFAs, which establish the framework for US military personnel to operate in a host nation, do not appear to have specific requirements regarding HIV status. However, a SOFA typically states that U.S. personnel must obey host nation law, which would include restrictions on residency and employment.

Summary of findings:

International and host nation policy that specifically address requirements associated with military or government personnel and HIV status were unable to be identified. Current policy for US Defense personnel includes the requirement for safeguards in order to enter a foreign country and perform professional duties.[2] These requirements are typically implemented through Status of Force Agreements (SOFAs)[2], which are multilateral or bilateral agreements that establish the framework for U.S military personnel to operate in a foreign country, and provides the manner by which host nation laws are applied toward U.S personnel, often including their dependents (with some limitations).

1. USAF Academy Legal Office, *Status of Forces Agreement*, 1.
2. International Security Advisory Board, *Report on Status of Forces Agreements*, (2015), 1.

Currently, the US has a SOFA with over 100 nations[3], which includes SOFAs that are classified.[4] A detailed review of each SOFA is required to determine similarities and differences of agreements; however, preliminary review of four separate agreements (between US and Japan, South Korea, Iraq, and Afghanistan) illustrate that U.S. personnel are required to obey the laws of the host country. Although no specific requirements regarding communicable disease, including HIV, were identified, it can be inferred that host nation laws associated with HIV status would be applicable to US military and government personnel.

Research performed on international treaties and agreements revealed ambiguity regarding the interaction of US military personnel in an environment without an established SOFA. Although Treaties in Force (TIF) provide information on HIV and AIDS, the scope of a TIF is associated with international development and HIV education, and do not appear to establish requirements for US military personnel.[5]

Request 5: Identify reported cases of a US Service member being expelled from a country or host nation due to HIV status.

BLUF: No publicly available information was identified regarding the deportation of a Service member by a country due to a change in HIV positive status.

Summary of findings:

Restrictions and policies associated with host nations regarding HIV positive status is country-specific. A review of publically available information revealed that these policies and regulations vary greatly between countries; however, no information was identified that indicate an Active Duty Service Member (ADSM) was deported due to a change in HIV status.

To enable military readiness, DoD policies are developed to address deployability, which includes the ability of a Service member to enter or remain in a host nation. Consequently, policy associated with the ability of an ADSM to deploy should reflect host nation requirements.

3. International Security Advisory Board, *Report on Status of Forces Agreements*, (2015), 1.
4. International Security Advisory Board, *Report on Status of Forces Agreements*, (2015), 58.
5. United States Department of State, *Treaties in Force A List of Treaties and Other International Agreements of the United States in Force on January 1, 2018*, (2018).

FILED UNDER SEAL
EXHIBIT 28

FILED UNDER SEAL
EXHIBIT 29

FILED UNDER SEAL
EXHIBIT 30

FILED UNDER SEAL
EXHIBIT 31

EXHIBIT 32

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

- - - - - - - - - - - - - - - - - -x
NICHOLAS HARRISON, et al., :
Plaintiffs, :
vs. : Case No.
PATRICK M. SHANAHAN, et al., : 1:18-cv-641-LMB-IDD
Defendants. :
- - - - - - - - - - - - - - - - - -x
RICHARD ROE, et al., :
Plaintiffs, :
vs. : Case No.
PATRICK M. SHANAHAN, et al., : 1:18-cv-1565-LMB-IDD
Defendants. :
- - - - - - - - - - - - - - - - - -x

Washington, D.C.
Friday, May 10, 2019

Deposition of CRAIG WALTER HENDRIX, M.D., a witness herein, called for examination by counsel for the Defendants in the above-entitled matter, pursuant

to notice, the witness being duly sworn by KAREN YOUNG, a Notary Public in and for the District of Columbia, taken at the offices of Winston & Strawn LLP, 1700 K Street, Northwest, Washington, D.C., at 9:04 a.m. on Friday, May 10, 2019, and the proceedings being taken down by stenotype and transcribed by KAREN YOUNG.

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C O N T E N T S

THE WITNESS:

E X H I B I T S

E X H I B I T S (continued)

- - -

Q. So at basic training --
A. At basic training.
Q. And is it because they're all housed together?
A. That's part of it.
Q. And what are the other parts besides --
A. I think that's it.
Q. That's it? Okay. Besides that grant, do you have any background in treating or consulting for basic or initial entry training for the military?
A. No, we -- I had -- there were interactions with the -- so Lackland -- Wilford Hall was on Lackland Air Force Base. That's the Air Force's -- I think it may be their only primary entry training facility for enlisted personnel, and we had occasional work over there with the trainees. I think it was more of an educational nature. Some was research related to vaccines I think primarily, but I only remember going over -- even going to that side of the base two or three times, and some of it was actually for a research study for personnel.
Q. Okay. Have you participated as an

investigator on any studies related to HIV like drug resistance?

A. So I've participated in lots of studies where drug resistance was an outcome of the study that was being measured. I'd have to say it was -- it would be rare that it would have been a primary outcome. The issue is that every time we're doing a study of treatment --

Q. Uh-huh.

A. -- or a study for prevention, resistance is an issue.

Q. Okay.

A. So it's -- it's inherent in almost all the studies I've done, especially those over a longer period of time.

Q. And what do you mean, that it's an outcome?

A. So if -- if -- in the treatment setting, if someone is on -- if it's a study of treatment or just in routine care, if someone is -- is on antiretroviral drugs, there is a concern that if they poorly adhere to the medication regimen, which is most often that one pill once a day, if they're

inadherent to that and they miss a certain amount of doses and their drug concentrations fall, the concentrations may fall to a level that suppresses wild type, the natural, the most commonly -- the hardiest virus that's there that's the most easily transmitted and most commonly transmitted, but suppression of that allows the spontaneous mutations that occur to occasionally be a mutation that's resistant to the drugs they're on, but the mutation makes the new -- this novel mutation on rare occasion not susceptible to those medications at the low concentration, and then it starts to overgrow, and it's sort of a stuttering pattern where it gradually -- so that's always the theoretical concern, and that's the best explanation for why we get these resistance events that occur, especially when folks -- well, two things. When we only had one drug, which is -- we had two drugs when I was doing this on active duty, and then we just started to have three drugs, but when there was only one drug, the chance of resistance is much higher. It's like there's a mutation that occurs every time the virus replicates.

Occasionally that mutation is a resistant mutation.

If there's two drugs on board, that ten to the minus four chance becomes ten to the minus eight, then it's much less likely, but it will occur eventually. And then with three drugs, it's ten to the minus 12, and that just doesn't happen. It's so rare, it just doesn't happen that there is a resistance mutation to all three drugs that occurs spontaneously in that setting. So that's why resistance with the current therapy -- this has been true for a while -- is such an exceedingly rare event, and you know, I think most providers haven't seen it in their -- in their patients that are highly adherent to the drug.

Q. Given a large enough population, you would expect to see resistance.

A. So I don't think that's -- well, if -- well, I would have to sort through the numbers to think of what that -- if you think about what that ten to the minus 12th means in terms of the likelihood of that occurring, the spontaneous resistance to all the drugs they're on, there is a

population size that could be so large that there could be a resistance event. So it's not impossible, but it's -- I would say it's vanishingly small --

Q. Okay.

A. -- in the highly adherent patient.

Q. Have you been an investigator for any study that wasn't -- that involved the interruption of antiretroviral therapy?

A. No. May I clarify?

Q. Sure.

A. I've been an investigator in studies that -- the initial study of most HIV drugs is to give monotherapy for a brief period of time and then it stops, and then they go back to a provider and then they start whatever their chronic regimen is going to be. It's very hard to find people for this because everybody pretty much is started as soon as they're diagnosed. So I have stopped, but it's not what you're describing I think as like a structured treatment interruption or something kind of like that. I have not studied that.

Q. Those are -- those are different things.

A. They're different things. One is just -- one is -- for two reasons. Well, the important reason is that what I'm describing is someone has a -- whatever their set point viral load is, it goes -- if the drug works, it goes down a log or two, ten fold or a hundred fold, and then when the -- when the drug stops, whether they're suppressed or not, because some are not after just ten days of dosing, they come back at some rate, not often as fast as they go down, but they come back.

But there's a very different situation in a structured treatment interruption where people are usually virally suppressed, they have no measurable load, and then the drug is stopped, and there's no -- there's no pressure to stop replication, and it is allowed to resume at some rate based on -- there's probably quite a number of factors. I don't study this, but it's a function of their immune system, and it may have something to do with the prior viral load, but if they're fully suppressed, this takes time.

Q. So those structured treatment studies have

A. -- in terms of viral load and risk of transmission. In addition, the vertical transmission gives you similar loads because with the data, there's a nice French study that looks at -- looks at this where you have -- where mom and baby don't get anything, mom gets nothing, baby gets something to prevent, mom has interventions at different times during her pregnancy, and all the risks are different. And so that's useful information to understand the difference between transmission at birth and transmission in utero. And the other is the sexual. I said it also -- you have similar kinds with viral load and transmission risk, but all this data together is very useful to understand what the risks are, what the impact of viral load and volume and transmission risk, how they combine.

Q. I understand, but I'm really only asking --

A. Okay.

Q. -- about what studies you've looked at and whether or not they involved individuals taking antiretroviral therapies.

MR. SCHOETTES: Objection, asked and

answered, but you can -- you can answer again.

A. I think I answered that. The CDC studies in the Parul paper for the most part are not antiretrovirals. The French study with vertical transmission is with and without --

Q. Okay.

A. -- and -- and durations, and the sexual transmission studies, and there are many of those, look at with and without, and looking at viral load and risk of transmission based on viral load that -- and the viral load can only be low -- in those -- you only have a range there because we're now in an antiretroviral era.

Q. Okay. What about the occupational exposure studies?

A. So the best --

MR. SCHOETTES: Objection, vague. If you want to put a finer point on what you're asking about those studies, but you can answer if you know what he's asking.

BY MR. NORWAY:

Q. Did you -- and I can reask the question.

Did you base your opinion on occupational exposure studies that involved patients or individuals who are taking antiretroviral medications?

A. My understanding is the Parul study that CDC uses does not involve antiretroviral medications. That was relatively early when there was not much penetration or effectiveness of -- if there were antiretroviral drugs, it was one, it was at most two. There was not -- you did not see viral suppression.

Q. I see, so you're basing the -- are you using the Parul study -- Parul study for both the risk of injection drug use and occupational exposure?

A. No, that didn't -- I don't think the Parul -- I'm trying to remember. No, it is -- it is on -- I'm sorry, there's two things. There's the Cardo study that is -- that looks at the occupational risk. The Parul study is a review that, to my recollection, must include the Cardo study of occupational risk, but the Parul is a much broader study. It's not -- you know, it's a -- it's a review. It's not a single study.

Q. Okay.

at the very end.

A. So thank you, yes, so the -- I see the first author is Flynn, and based on this title and the publication, I am aware of this study. Not the study results, because I actually -- I'm on an IRB that reviews this study periodically because there's Hopkins investigators. This is mostly in Africa --

Q. Okay.

A. -- if it's the IMPAACT PROMISE study, sound familiar, but it was not a French study.

Q. And this study is reporting that there were two instances of mothers with undetectable viral loads that transmitted the virus to their infants, correct?

A. That's -- yes, it refers to those two on the second page.

Q. Yeah.

A. I see those.

Q. Is this the first instance that you are aware of where there's a reported case of transmission -- vertical transmission of HIV where the mother was taking antiretroviral therapy?

A. Yes, other than the study that I mentioned where the focus of that study was not on breast feeding, as it is here, so I don't know the breast feeding risk data --

Q. Uh-huh.

A. -- much, so thank you.

Q. So the other -- let's take a step back.

A. But may I -- may I --

Q. Go ahead.

A. So just to clarify, because the one thing I was trying to find here, which I'm not -- I'm probably moving too fast, is that the diagnosis of the infection -- it's essential to know that -- to confirm this, they need to know that these infants had no HIV DNA anywhere in the body subject to the limits of detection at the time of birth to identify that it was in fact a postpartum infection, and that's hard to do. That's what I was looking for, but I don't -- I don't see it, but I've read this quickly.

Q. So let -- let me break that down. In the case of vertical transmission, mother to child, there

are multiple ways in which the infant can become infected, correct?

A. Yes.

Q. One of the ways it would be, it would be infected while it was in the womb.

A. Yes.

Q. A second way would be it would be infected during the process of giving birth.

A. Yes.

Q. And the third way is that the infant could become infected by breast feeding.

A. Yes.

Q. Okay. The study that you were referring to -- does it identify mothers who are on antiretroviral therapy who transmit HIV to their infant before birth?

A. No, it -- I'm sorry, it -- now as I remember, it excludes breast feeding from the population.

Q. Okay.

A. So it only includes the first two of the categories you mentioned, in utero and peripartum.

Q. Peripartum?
A. But not postpartum in the one I was describing.
Q. Okay, so did -- did that study document transmission of HIV vertically in utero when the mother was taking antiretroviral therapy?
A. It showed no transmissions in 2,600 live births in the women that were consistently on antiretroviral therapy prior to and throughout and had a suppressed viral load.
Q. Okay, so that would be both -- I'm sorry, can you -- can you tell me again what were the first two modes of transmission?
A. Oh, it would be in utero --
Q. In utero.
A. -- and peripartum.
Q. Okay, so the study that you're referring to show that there was no transmissions in utero or peripartum, correct?
A. Yes.
Q. Okay, and you haven't -- you haven't reviewed the IMPAACT PROMISE research, correct?

A. No, sir.

Q. Okay, you can set that aside. So in paragraph 49 of your report, we're going back to Exhibit 4, about halfway through, you talk about the most intimate forms of contact, correct?

MR. SCHOETTES: I'm sorry, what paragraph did you say again?

MR. NORWAY: Forty-nine.

MR. SCHOETTES: Thanks.

THE WITNESS: Yes, I say that.

BY MR. NORWAY:

Q. Are you referring to sexual --

A. I'm referring to sex.

Q. Okay.

A. I don't know why I was shy in that instance.

Q. Okay. What research do you base your opinion on that an individual with -- living with HIV who has a suppressed or undetectable viral load is incapable of transmitting HIV?

A. So there's a series of studies beginning probably first with Quinn et al., who's a colleague

at Hopkins and actually a commissioned corps officer, who published the first looking at the relationship between viral load and transmission and saw that below 400, there were -- I think there were essentially no transmissions.

There were a series of other studies looking -- randomizing and prospectively treating, that would be HPTN 052. Mike Cohen was the first author for that study. I'm an investigator on that, and there were no linked transmissions, and by linked, I mean that it was a -- it was a serodiscordant couple study in which there were no linked, no genetically linked, so the infections that occurred occurred not from the virally suppressed partner, but from other sex partners that were presumably but unknown, whether they were on or not on antiretroviral drugs.

And then there's a series of other -- so that's a heterosexual contact. A series of other studies looking, some in the same setting, some in -- there's -- then there are studies looking at men that have sex with men. There's some other heterosexual

and there's some other MSM studies. Sorry, MSM, all in caps for men that have sex with men, all of which show no transmission when there's undetectable viral load.

But the undetectable is defined a little bit different in each one, but in general, it's -- in Quinn it was less than 400. I think it was less than 200 in Cohen. I think it was 200 or 50 in some of the others. There was a very recent one in the Lancet HIV. Rodger with a D was the first author. So I think they've looked at most of the populations, and this is the basis for the U equals U in terms of full suppression, undetected equals --

Q. Okay.

A. -- uninfected.

Q. Yeah, let me just -- let me ask, so -- so the -- the research that you're referring to form the scientific basis for the U versus U recommendations, correct?

A. Yes.

Q. I'm going to hand you a document that I'll ask the court reporter to mark as Exhibit Number 10.

MR. SCHOETTES: Again, just for the clarity of your transcript, you said U versus U.

MR. NORWAY: Oh, I'm sorry. U equals U. Thank you for clarifying, Scott. Correct that on the transcript. Nine? It's 9.

(Hendrix Exhibit No. 9 was marked for identification.)

BY MR. NORWAY:

Q. And I'll give you a moment to take a look at this, Dr. Hendrix. Just let me know when you've finished.

A. Okay.

Q. Do you recognize any of the authors of this?

A. I know Bob, Karl and Tony, yes, sir.

Q. And are they all well known HIV researchers?

A. Well, no, actually. So Tony Fauci is the director of the National Institute of Allergy, Infectious Diseases, and he is a well known HIV researcher. Karl Dieffenbach and Bob Eisinger are

not researchers. I don't know the early careers, but for the two decades that I've known both of them, they're staff guys. They're -- they're in the extramural program that manages grants. I know them each in different roles. Karl's the one that signs off on almost all of my grants, but they're not researchers per se. They're very smart people.

Q. But Dr. Fauci is.

A. Dr. Fauci is, yeah. I'm just -- they're not -- they're not all researchers. Fauci is on the ground doing research in addition to running NIAID at the NIH. The other two work for him.

Q. Okay. Does this -- does this opinion piece from the Journal of the American Medical Association summarize the research that you were referring to earlier?

A. Yes, the key papers are here.

Q. Okay, and I'm going to actually direct you to the box that's on page 2 because it's easier to do that. So -- and in this article, the authors say that in order for antiretroviral therapy to provide maximum benefit, taking medications as prescribed is

essential, correct?

A. That's what it says.

Q. Okay. Do you agree with that?

A. Yes.

Q. Does the validity of the U versus U concept depend on achieving and maintaining an undetectable viral load?

A. Yes.

Q. Yes, and is taking antiretroviral medications as prescribed essential for maintaining -- achieving and maintaining an undetectable viral load?

A. Largely. The only -- the only qualifier is that taking it as prescribed may not mean perfection because there is also evidence that suppression is complete even if there's a small degree of nonadherence, but adherence needs to be good.

Q. Okay. What do you mean by a small degree of nonadherence?

A. So it would -- specifically it would be an occasional missed dose at a frequency of, say, you know, one -- one a week roughly, like 85 percent --

if 85 percent adherence is maintained in a consistent way, which is on average, it's like missing a dose a week, I don't think there's evidence that there would -- I think there is evidence that there would not be a loss of full suppression. There's other patterns of nonadherence that may not have that impact.

Q. Let's talk about the other patterns of nonadherence. So what -- your answer to my last question involved essentially one missed dose a week, correct? Is -- is as prescribed -- let me -- let me see if I can frame the question. If there is a pattern of nonadherence of two missed doses a week back to back, does that reduce or -- the validity of the U versus U concept?

A. So I think 85 sticks in my head, so two would be -- you know, one minus 28 is more than that. I would be concerned at that level for treatment and full suppression.

Q. Okay. So you would also be concerned if --

A. Right.

Q. -- if they missed three --

A. In terms of full suppression at some point

in time.

Q. Okay, at some point in time.

A. At some point in time, yes.

Q. And if they take a dose, then is your concern lessened?

MR. SCHOETTES: Objection, vague.

BY MR. NORWAY:

Q. Let me -- let me -- so after -- after the individual has missed two doses in a row, if they took a third dose, would your concern be less? Never mind. It's a bad question. It's a bad question. So in the -- in the -- in the context of U versus U, in your opinion, you become concerned once an individual misses two doses in a row?

MR. SCHOETTES: Objection, mischaracterizes prior testimony and vague. You may answer.

A. So I'll just repeat what I said before. I'm comfortable with data -- I can't think of the author and the journal, but I'm comfortable with data that adherence can be 85 percent -- I think that's in general. I added an opinion, not -- based on principles and other data, but not a study that was

done in a way to see if there was a -- a week holiday, for example, but there is no increased risk because the viral load is not going to be changing much in that week. That's not a good thing. I don't want it to continue, but that's also -- if I'm off for a week, I'm exceeding this 15 percent tolerance.

Q. Okay.

A. That makes -- it's very complicated. I'm -- I'm happy to say 85 percent is going to be really good at maintaining full viral suppression.

Q. Yeah, and what I'm -- what I'm asking is in your opinion, how long after a person stops taking their medication do you become concerned that they may transmit HIV.

MR. SCHOETTES: You can answer that.

A. So -- so the two important things there would be at what point -- the critical thing is at what -- how much later are they not suppressed, so how long's it take for them to get from fully suppressed, which is below whatever number, depending on the test, to something that's going to be over, say, 400, you know, 200, 400 based on the Quinn

papers. Some of these other papers here, they use different numbers, and that period of time I think is -- I think the range on average is four to ten or 12 weeks.

So until that point in time, I would have a -- I wouldn't be so worried that there's an issue because they would maintain -- it takes the virus a while to ramp up to some level. If it's not detectable until four to eight weeks -- four to 12 weeks later, then I would think not until they get to that category would they be transmissible.

Q. Okay.

A. Would they be infectious with -- through a sexual transmission.

Q. Yes, so that's -- that's actually what I was -- where I was going. So the -- so is it your opinion that an individual who stops taking their antiretroviral therapy would not become infectious until after their virus rebounds above the suppressed level?

A. Yes, but -- it is, but in a way, it's -- yes.

Q. Okay.
A. That's fair.
Q. And how many virus particles -- or what's the viral load that you would consider suppressed?
MR. SCHOETTES: Objection, vague. You can answer.
A. So the number -- the number used to define that in most of these studies I think was 200. I only qualify that to say that in fact, their level may be well below that. We don't know. It's a -- there's no way to know what's under the -- I mean, it's how much is below the sea in an iceberg, but the numbers are when it goes below that, there aren't transmissions.
Q. So when you -- when you talk about viral suppression in your opinions, are you talking about individuals who have viral loads less than 200?
A. Generally. They're -- they're all included, but yes -- most of the data is 200, so most of the time I'm talking about 200.
Q. And if you're talking about some -- someone who has undetectable viral load, what are you

referring to?

A. Well, it depends on the specific study and -- and -- and the actual practice in the clinic, you know, whether -- whether they're using a test that is 200 or 50 or 40 or 20.

Q. And did different studies use different levels based on the technology that was used at the time?

A. So there's some evolution -- there's some evolution just based on timing of Quinn and the Swiss -- I can't remember the number from the Swiss paper, but the Quinn was 400, and I know that was done in the '90s. There were much -- there were more recent -- the 052 was more recent. I was involved in that, and that was -- I think that was 200. The 50 things, they get -- they get more expensive, but they also get easier and more portable in ways too, but -- so again, it varies -- it varies with the study.

MR. NORWAY: I'll hand the court reporter a document for her to mark as Exhibit 10. Here you go, Scott.

(Hendrix Exhibit No. 10

was marked for identification.)

THE WITNESS: Okay.

BY MR. NORWAY:

Q. Have you read this article before?

A. No.

Q. Okay, and does this article talk about or address the plasma viral rebound following the cessation of antiretroviral therapy?

A. Yes.

Q. And they -- they actually monitor patients who have stopped taking their medications, correct?

A. Yes.

Q. Is it a fair characterization of the study that they found that 78 or 79 percent of the patients had viral loads greater than 400 copies per mill four weeks after stopping treatment?

A. Yes.

Q. And the difference in those numbers is simply when they began antiretroviral therapy.

A. Yes.

Q. Okay. Okay, we can set this aside. Do you

-- do you want to add anything?

A. No, I was just looking for what the -- what the -- what the median time is for -- for that, but that's fine, this is helpful. Thanks.

Q. Oh, okay. I do not know if the median time is --

A. Yeah.

Q. -- in here, but if you -- if you want, your counsel can ask you questions afterwards. So I want to go back to U versus U.

A. Equals.

Q. I'm sorry, U equals U, and please do continue to correct me. That is --

MR. SCHOETTES: It's very lawyerly.

MR. NORWAY: Yes.

MR. SCHOETTES: Not to be U versus U.

BY MR. NORWAY:

Q. U versus U, I think that is -- that is my -- my hang-up, because you never -- so in -- in the context of U versus U, is there a risk of transmitting HIV during the first six months after a person begins antiretroviral therapy?

MR. SCHOETTES: You just did it again.

BY MR. NORWAY:

Q. Let me ask again. In the context of U equals U, is there a risk of sexually transmitting HIV during the first six months of antiretroviral therapy?

A. May I refer --

Q. I would -- the U versus U.

A. Thank you.

Q. And that is the document marked as Exhibit Number 9.

A. Oh, it's right here.

Q. And if you would like --

A. Yes, so my understanding is there is a -- there is a period -- so I'm sorry, can you repeat the question? It's -- the question was the timing of the viral suppression. What was the --

Q. No, so I'll --

MR. SCHOETTES: Let him repeat --

BY MR. NORWAY:

Q. -- repeat the question. In the context of U versus U, is there a risk of sexually transmitting

HIV during the first six months of antiretroviral therapy?

A. Yes.

Q. Does the U versus U concept --

A. Equals.

Q. Thank you. Does the U equals U concept also require viral load testing in accordance with the guidelines published by the Health and Human Services, HHS?

A. Yes.

Q. And -- okay, you have the right page. So the guidelines require testing at the time antiretroviral therapy begins, correct?

A. Yes.

Q. And they then require viral load testing every two to eight weeks after initiation, and then -- correct?

A. My understanding is that the more routine was to test a month after and then every three to four months for a while until you have full suppression, and then less frequently.

Q. Correct, and that is -- oh, I'm sorry. And

what you just described is actually described as number 3 in the Fauci piece, correct? And you're looking on the second page, first column, last paragraph.

A. Yes, I see both of those. Your numbers and my numbers are at different stages. Thank you.

Q. Yeah, and then the next set of testing under the guideline once the viral load is suppressed is to repeat testing every three to four months, correct?

A. For a period.

Q. Correct. Then for individuals who are then adherent to treatment consistently for a period of two years, the guidelines then change the period of testing, correct?

A. Yes.

Q. And what -- and what do the guidelines recommend for a period of testing for an individual who is adherent to treatment with consistently suppressed viral load?

A. So the Department of Health and Human Services in -- that's referred to in Exhibit 9 says

six months. I think the World Health Organization and Aidsmap in similar situation may recommend 12 months.

Q. What is Aidsmap?

A. Aidsmap is where Exhibit 8 was published. This is not -- it's not in this paper, but it's just the source, but the Aidsmap also makes recommendations for treatment.

Q. Is it an organization connected with the government of Britain?

A. I don't know for sure. I associate it with Britain, but I don't -- I don't know the answer to that.

Q. Okay, no worries. We can move on. And following what we were just reading in Exhibit 9, this article notes that when antiretroviral treatment is stopped, viral rebound usually occurs within two to three weeks, correct?

MR. SCHOETTES: Where are we?

A. This is --

Q. This is page --

MR. SCHOETTES: Thank you.

MR. NORWAY: 452.

MR. SCHOETTES: Got it.

BY MR. NORWAY:

Q. Second column.

A. So that's what it says, the only -- I'm only parsing this to say there's viral rebound and then rebound to the detectable.

Q. Correct.

A. And the recommendations were based on the detectable, but it's -- the difference is weeks between this recommendation and the data you just showed me from the early -- from Exhibit 10 --

Q. Uh-huh.

A. -- which had a median that was north of four weeks, but it's --

Q. So this is saying viral rebound, okay, and do you -- are you -- are you saying there's a difference in the way this article is using viral rebound and what you use as viral rebound?

MR. SCHOETTES: Objection to the extent it mischaracterizes prior testimony, but you can answer.

A. So what I'm -- what I'm trying to -- what

I'm looking for now to answer your question specifically is that theoretically, there may be a change in the viral load. One might call that rebound, although it's not yet detectable. I don't know what to do with that because we have established data about suppression below a certain level, we'll say 200 for the sake of argument. We understand there's a --

Q. Uh-huh.

A. -- variability around that across studies. Exhibit 10 refers to and I refer to a Li paper. That's where the -- the time to rebound I think as they define is between four and 12 weeks. So these numbers are varying, the methods are different, and I'm not sure how you could measure -- it's certainly not -- we know it's not a hundred percent at two weeks. I'm not sure what percentage might even be above detectable. I don't have the data on that, but that's an important factor.

Q. So what I want to understand is when -- when you talk about viral rebound in your opinion, are you referring rebound to pre -- rebound to levels

of virus load that a patient would have had before taking antiretroviral therapy?

A. No, I would be -- I would be concerned if it's at a level of detection because level of detection is associated with transmission risk.

Q. Okay.

A. Not needing to go any higher.

Q. And the level of detection is 200?

A. On average in papers.

Q. Okay. And so do I understand it correctly that when -- when this paper talks about levels that would have been associated with risks -- increased risk of HIV transmission, right, it is talking about viral rebound to detectable levels, and -- and -- and -- I'm sorry, I'm looking at article number 9, or Exhibit 9.

MR. SCHOETTES: Objection to the extent that the document speaks for itself. If you want to give him a chance to review the entire document to figure out how they're defining viral rebound, we can take the time to do that.

BY MR. NORWAY:

was done about HIV transmission through breast feeding, correct?

A. I have to read it because this is clearly not the paper I was referring to.

Q. Okay.

A. So I would have to read through this. This is just from last summer, and I was looking at a published paper I think from 2015 or something.

Q. Okay.

MR. SCHOETTES: Take your time, read through it.

A. Yeah, so let me read through the -- okay, I may have to come back to it to answer a question related to it. This -- I'm not familiar with this study, so --

Q. Okay.

A. This is all I have.

Q. So my -- my first question was actually that, have you seen the Flynn studies before?

A. This Flynn --

Q. I'm sorry, I was -- I will refer to this study as the Flynn study. It is identified on page 2

Q. And I'm -- I'm looking at Exhibit 9. You can set Exhibit 10 to the side.

MR. SCHOETTES: You don't need this, yeah. Oh, you want to look at something else?

A. I wanted to look at 10 to -- to help answer his question. The only way to give this number is to do a study in folks that are -- have been persistently suppressed, stop therapy and measure it at two weeks and at three weeks to know what the number is. I have not seen a paper that does that.

Q. Okay.

A. That's why I'm resistant to -- to answer directly the truth of their statement. I thought that the Hamlyn paper, Exhibit 10, might be helpful.

Q. Uh-huh.

A. They don't look until four weeks.

Q. Yeah, I was going -- I was going to just say that the first data point on this paper is four weeks, and at four weeks, nearly 80 percent of this population had detectable viral load, correct?

A. That's correct, and in the Lee paper, it was not so much, as I recall.

Q. What do you mean, not so much?

A. Well, they gave a range for the time to above -- I think it was 200 in the Li paper, and the range wouldn't be four -- there would be some at four because otherwise they wouldn't say that, but the others are also taking place over the rest of this period. I don't know the distribution, the population density over that time interval.

Q. Uh-huh.

A. But --

Q. Okay, perfect. Thank you. And is that what you wanted to discuss about Exhibit Number 10?

A. Yes.

Q. So do you disagree with the statement in Exhibit Number 9 that viral rebound usually occurs within two to three weeks?

A. I don't have any evidence to agree or refute it.

Q. Okay, and -- and this article states, and this is once again in the box to help you look at it, that stopping therapy negates the validity of assuming that U equals U, correct?

A. Yes, yes.

Q. Let's move on to your expert report. So I'd like to talk about paragraph 51, and I'm on page 20 of your expert report.

A. Okay.

Q. Am I correct that in paragraph 51, you disclose an opinion that anyone who is exposed to the blood containing HIV should be provided post-exposure prophylactics?

MR. SCHOETTES: Objection to the extent it mischaracterizes the report. You may answer.

A. I don't know if I have an opinion about that. I do believe that the -- the level of exposure as far as -- falls below established transmission risks. The CDC is very conservative in their recommendations, but I don't have a formed opinion on whether or not the statement about the PEP was a point that that is a way to additionally reduce the risk, however small it might be.

Q. Okay, so this is a -- well, so does paragraph number 51 in your report disclose your opinion that the military can further reduce the risk

treatment facility where there will be a formulary at some point back in the line to provide it. Now, whether he goes far enough to get to the supply or it gets to one point and the supply moves forward one step in the system, like if he goes from 1 to 2, and the drug's at 3 and it's got to go to stage 2, I think it's possible.

Q. Okay, so you're assuming that the exposed soldier is being evacuated, correct?

A. He'll be -- I do think that the soldier -- the nature of the wounds I'm describing is going to -- will be moved as soon as possible, whenever possible, back to a higher level of care than the -- the medic with the group.

Q. Okay. What about the soldiers who are exposed to the blood who were not injured by -- in that way with a deep penetrating wound?

A. So I think that's a harder call. The CDC's recommendation with occupational exposures are graded, and it would be -- I think one could come up with a -- a rational policy with that as a starting point to make those decisions. As I said, I'm not

making the recommendation. I think it's -- I would recommend that they look at this as a way to further reduce the risk because the risk does currently exist because there's HIV infected soldiers in the field. So I think they should look at it, independent of our primary issue, should look at that, and those are some of the issues, but you could make a graded response, as the CDC has a graded recommendation based on the type and extent of the exposure, of the occupational exposure. If you have --

Q. Is that -- is it -- is it your understanding that the occupational exposure guidelines -- oh, yes, never mind. Okay, I got it. So in your answer regarding -- regarding PEP, you are basically saying -- I'm trying to understand that there is -- you're recommending a analysis of the risk to determine how far forward to position PEP medications, right?

A. I think -- I think that's an important question for the -- for the medics and logistical teams to decide, how -- how far forward they need to put it. I don't know how far forward it is

currently. I just know that it is at some level available.

Q. Do you know how many doses are available at that level?

A. I don't know the answer to that.

Q. And you don't -- do you have an opinion regarding how those forward supplied units would replenish their supply of PEP medications in combat?

A. I assume, based on all the medical facilities I've been part of, they would resupply in the same way they resupply every other medication. When they're -- once they hit a certain number in their inventory, they put in an order for that drug to be replenished, which is what they would do for all the other medications they have, for routine stuff and -- and more acute -- more acute illnesses, injuries that occur.

Q. Are you assuming that the units who would be carrying the post-exposure medications would be -- would have the capacity to carry additional medications?

MR. SCHOETTES: Objection to the extent it

mischaracterizes prior testimony. You can answer.

A. So -- so I said before that I don't know at what -- so I know it's being deployed. These drugs are on the formulary in the field. There's an amazingly extensive formulary that CENTCOM, which is what I've looked at, has in the field. What I said I don't know -- I know that -- I'm sure this is not something a medic's going to carry in his bag. That would be a bad idea. He's got far more likely -- he has need for things that have far more likely need than this. How much further back, I don't know.

Q. So you don't have an opinion of whether a combat support hospital would have room to carry additional medications.

A. I don't know what a combat support hospital's capacity is for any additional medications, and I'm sure everything they have is very well reasoned.

Q. Okay. Are you assuming that whatever level has the -- the PEP medications have personnel that are adequately trained to properly identify and provide the medications to exposed soldiers?

fully suppressed, and you know, after folks have been on for a while, usually the -- it's like a one percent switch per year, and this is after they're chronically suppressed, but one percent switch per year. So I think -- I think the frequency of that occurrence, which is a minor increase depending on what the combination is, it's a minor increase over this risk, over this burden of carrying the pills, which is what your question was.

Q. Is this a person in that situation, a person who has to take additional medications or different medications than a single-tablet regimen in the same capable of being deployed?

MR. SCHOETTES: Objection.

BY MR. NORWAY:

Q. In your opinion.

MR. SCHOETTES: Objection, vague. You can answer.

A. Yes.

Q. Okay. In your opinion, is there an increased -- never mind. Do you know -- have you seen any information regarding the types of regimens

that soldiers or service members are currently taking in the military?

A. I have no primary experience with that, no, other than I think I -- I know I've looked at that. I mean, I remember that I've looked at that for one of the -- one of the plaintiffs, Harrison, and there was insufficient detail to my recollection for the other two to know what the regimens were, but I'll just say but that's just a slice.

Q. And if I recall correctly, Sergeant Harrison was taking Biktarvy, correct?

A. That's my recollection.

Q. And so you don't know what percentage of active duty service members are being prescribed single-tablet regimens currently?

A. I don't know the answer, no. I don't know that I've ever seen that anywhere.

Q. What is the average yearly cost of a one or two day pill regimen?

MR. SCHOETTES: Objection, vague. You can answer.

A. I don't know what it would cost the

military. These regimens are anywhere -- my estimates from -- and it's not that they're not known. It's just that I don't have it in my head. I would say, you know, between 15 and 25 thousand dollars a year, and -- which is more than PreP. Even PreP is 10 to 12 thousand a year, but those are -- those are different costs than the Veterans Administration pays, for example. I can't tell you how much less. I don't remember that, but it's less, but there are -- the military has advantages that civilians don't have.

Q. Did you review the slide presentation that was attached to Colonel Murray's deposition?

A. I did look at that.

Q. And do you recall seeing a slide in which he noted that the cost of HIV medications is approximately $25,000 per year?

A. I don't recall specifically, but the range I just gave includes that, and I'm sure that's -- I accept that that's accurate.

Q. My math is very much off.

MR. SCHOETTES: Wait for a question.

A. Okay.

Q. Assuming the average cost of HIV medications is approximately $25,000 per year and the number of active duty service members living with HIV is 1,800, and you can use a calculator if you want. What would be the annual cost to the military of HIV medications alone? So it's $25,000 per year, 1,800.

MR. SCHOETTES: Objection, outside the scope, but you can answer.

A. I'm not -- I'm not going to do the math. If you want me to do the math, I'll do the math if we want to take time to do that.

Q. It's about 45 million?

A. I -- I will trust you. It's shy of 50, yes. I'm rounding, yes.

Q. Okay. So in paragraph 53, moving on from the first part that we're saying -- or that we've already discussed, in the sentence that begins with "Furthermore" --

A. Okay.

Q. You refer to two medical conditions, dyslipidemia? Did I say that correctly?

A. That's fine, dyslipidemia.
Q. Dyslipidemia, and hypothyroidism, correct?
A. Correct.
Q. Is dyslipidemia a contagious disease?
A. No.
Q. What is it?
A. It is abnormal lipids, fats, in the blood, dyslipidemia, and it's -- it's what puts -- among other things, what put people at risk of cardiovascular disease, high cholesterol among them.
Q. Are you aware of the guidelines for -- that provide recommendations for treating dyslipidemia?
A. I don't do that, so I would not be very familiar. There's -- I know a little bit about it, so --
Q. Okay. Do you know how many guidelines there are?
A. No, I don't know how many guidelines there are. Those are written by cardiologists. They're used routinely by regular general internists and primary practice docs.
Q. Do you know what the recommended first-line

Q. Let me ask it another way. Are there any older single-drug -- or single-tablet combinations that are not prescribed today commonly?

A. Yeah, so -- so the first -- so Atripla, which is efavirenz, tenofovir, disoproxil fumarate and emtricitabine, was the most potent and effective and long -- long-lasting in terms of years in the market as the single drug one pill once a day. I mean, I think it was probably the first one pill once a day. I may be wrong, but -- and it was true for many, many years until some of these other drugs, especially these integrase transfer inhibitors came along. It had issues. It was the drug that was -- if I remember correctly, when I said 30 percent, it was a drug that was dominant in the period when that 30 -- predominant, dominant. Predominant's a better word.

Q. So Atripla had significant number or significant adverse effects, correct?

A. Yes.

Q. Okay, and is it -- is Atripla commonly prescribed today?

A. I think much less so. It's not on the Army's primary list.

Q. So in paragraph 5, in your last sentence, you refer to a person who has already achieved viral suppression on a particular antiretroviral therapy regimen changing to another regimen based on side effects, correct?

A. Yes.

Q. And can you quantify what you mean by rare in this sentence?

A. Yes.

MR. SCHOETTES: Objection to the extent that it does not fully correctly characterize the statement in the report, but you can answer.

A. So I refer to this study, and I could -- I could point to it. It is on the list of the references I provided that looked at the -- the risk of -- it looked at the rate of changing a regimen based on adverse events, which was at a certain percentage. I think it was probably in the teens early, but then as the years follow, there's an 18 percent reduction on average until a plateau of one

percent. So in this case, when I say more rare, I'm saying year over year, there's a -- a decreasing rate, and at a steady state, it's one percent, and I would consider that rare.

Q. And I wanted to just explore what you -- what you mean by that. First, is that study the same study that you indicated a moment ago reflected a 30 percent discontinuation rate?

MR. SCHOETTES: Objection. No, no, I'll let it go. Go ahead.

A. So there's two studies.

Q. Okay.

A. There's two studies, so it is different, and -- yeah, I'll leave it at that.

Q. When was the study that you're referring to in the last sentence, or that -- that is used to --

A. So I do think this one, given the duration of time that they followed up to see the steady state, was more recent than the other one that was -- the other one that started at 30 and went down to five with older meds -- older medications, and then this study was I think with newer medications,

because it actually started at a lower rate. The total rate of changes from the inception -- from the first regimen was broken down into changes based on side effects and changes based on resistance that could occur, because I know there's two curves that are moving in parallel but at different rates. So the side effect curve I think is in the teens to start, and that's why I think it's more recent, but I don't remember exactly the year.

Q. And is that -- is -- is it that -- or do I understand the -- what you're saying correctly, and if I don't, please correct me. Are you saying that that study showed -- or that study reported that 17 percent of the people who were on those regimens had a change in the first year?

A. Yes, that's my recollection. It's -- I think it's in the -- for adverse -- the newer -- the more recent study that follows over a longer period of time, it starts around 17 percent. I think there's a -- and then there's the 18 percent relative change for a few years, and then it's that one percent.

Q. And then -- and it sort of levels off?
A. Then it's at one percent, and the one percent is attributed to side effect changes.
Q. Okay, and then there was a second curve in that study that essentially did the same analysis for resistance.
A. I think that's right. I know there's two curves. I think it's resistance and I think it's probably only resistance. There's not three curves. There's two curves. It should be resistance. That's sort of what's left over, but I'm pretty sure that's the case.
Q. What was the percentage for resistance?
A. I don't remember, but it was -- early on, it was higher, and what I don't remember is sort of how far back it started, because the -- what's happening during -- given the duration of the study is the drugs that are able to be switched to are also changing, which is part of the reason that you're able to stay low, but I just don't remember what those numbers were.
Q. Do you remember any authors on that paper?

A. If I can look --

Q. Sure.

A. I can --

Q. Well, why don't you -- when we take a break, why don't you take a look. And is that paper the basis of your opinion that patients rarely stop taking single-tablet regimens because of adverse effects?

A. Not only. There's also the -- you know, being in meetings and conferences and -- local meetings that your providers talk about how they care for patients and discussions of this that just sort of occur before and after conferences and national and international conferences, and it's generally true in medical practice that the side effects occur early. You find -- you find another drug if they're not tolerable, you switch to it and you stick with it, and changes aren't very common after that.

Q. Okay.

A. This is -- this is not unique to -- to HIV, and actually, you find good medicines with low side effects with easier adherence over time, and then you

stick with it. Adherence improves, efficacy improves and you stick with that.

Q. And different HIV medications can cause different side effects, correct?

A. Yes.

Q. And people taking some HIV medicine may have different side effects from -- let me rephrase that. So people taking the same HIV medication can have different side effects from the same medication, correct?

A. Yes.

Q. Can -- can some adverse effects from HIV medications appear months and years after the medication's started?

A. So I would say yes, but it is uncommon, given the data I referred to.

Q. And what effects -- what adverse effects would you expect to I guess show themselves months and years after a patient has been on that medication?

A. So in my -- this is a general experience that would include only a number of the HIV drugs,

but the what I call annoyance symptoms that are commonly associated with almost every drug that's licensed because these things happen often in people's lives. They make a connection in the context of a clinical study and it's forever attributed to the drug. Those sorts of things probably do occur in some frequency, but that changes quickly. They get used to the drug, they find out it's not really related to the drug and they persist because they're getting some benefits, whether it's manifest benefits or just in their head that they know it's good for them.

But those are sorted out early. There are other things, and I would -- the one that I would put in the category would be renal dysfunction that may occur at some level over time sporadically, but it's also reversible -- it's identifiable, it's treatable. Doesn't need to be treated. It's identifiable. Switching the medications is the treatment, is the -- is the proper thing to do, and then change to a drug that has a lower risk for that, and if someone already has a risk for that at the start, you

wouldn't put them on the drug to start with in the first place.

Q. Is -- is liver function also possible -- or liver --

A. So I think less so. The liver -- so in my experience and from the data I know, a couple things have happened, that the old drugs, the old nucleosides and other classes of drugs, older drugs, non -- non-nucs, non-nucleoside analogs, reverse transcriptase inhibitors, NNRTI, and the protease inhibitors to some degree had some associated liver side effects, but the integrase inhibitors don't, and there's really not a compelling reason even to check for this.

The newer nucleosides that are used, the NRTIs, tenofovir, either form, and emtricitabine are not associated with liver side effects. There is -- there's an odd regulatory thing where there's a black box warning for those, but there's not good data that there's any association between anything related to liver like lactic acidosis and -- and those two drugs.

The lactic acidosis was related to other drugs that nobody uses anymore as far as -- some people may use them. They're available I think, but they're uncommonly used. They're not on any of the lists -- they're on the list, but they're not on any of the recommended regimens we looked at.

Q. Okay. Do your -- okay, what are the -- what are the adverse effects that are associated with integrase -- or integrase inhibitors?

A. Well, I would have to look because they are so rare. There's not a renal -- so the categories we went through before, there's -- there aren't -- there's not a renal toxicity, there's not a liver, there's not a hematologic toxicity. There's no dyslipidemia that I know of. So those are kind of the big ones that could -- you know, would be a reason to change and might be -- might persist, and I don't remember what the acute things might be. I imagine they are also fatigue, nausea. Usually bowels are disrupted. Everybody -- there's some percentage of that both in placebo and drug that occurs, but I can't be more precise than that. I

just don't -- I just don't know specifically, but their value in these fixed-dose regimens is that they like -- the TAF in particular and the emtricitabine have such a terrific side effect profile that they're -- they're really a nice match, they're a nice pharmacokinetic match. They're formulated, and it's a nice one pill once a day regimen. I don't think there's much reason to worry about much of this stuff.

Q. What are the adverse effects that are associated with TAF?

A. So -- so TAF -- the only reason -- I should say it this way. The two big things for TAF is that it does not have the only two important side effects that TDF had, the first of which -- the most important of which that's best documented and clinically important is the renal dysfunction, which there's a little glomerial, but it's mostly tubular disease, and the other is that there's a bone density change. The difficulty with that is the experience is those changes have an impact over decades, and it's not clear what to do with the data, and I think

most of the practitioners kind of throw up their hands like what do we do with this, and the changes are small. The --

Q. Can I -- can I interrupt you? Sorry.

A. Sorry.

Q. So those two adverse effects that you just described, are they associated with TDF?

A. Yes, they're associated with TDF, and they are far less -- I can't say they're zero, but they are far less and I think relatively insignificant with TAF, and as one example of that, the recommendation for -- I mentioned before that you wouldn't put someone on a drug if they already had a risk factor.

So if you already have renal failure, some -- some degree of renal dysfunction, you wouldn't go on the drug. You can have a much lower level of renal function and still go on TAF. I mean, it's that much different in terms of how you can use it. You can use it in more people. The chance of getting renal dysfunction if you're normal is much lower. So it's a really really nice advantage because you can

use it in a larger -- a larger proportion of patients.

Q. And what was the third --

A. Emtricitabine.

Q. Tricitabine?

A. Em -- FTC. That's the easiest, FTC.

Q. And what are the adverse effects associated with FTC?

A. So I really have to search to figure out what they are. You know, it's a nucleoside class and it's sort of painted with a broad brush that the black box -- it's included in the black box warning as a drug in the class, but I can't -- it's -- I think side effects with that are so uncommon, it doesn't have any of the list of things we talked about. So there may be some nuisance symptomatic things that are not associated with long-term organ dysfunction that go away.

Q. Okay.

A. So -- so these things go away, as they typically do with these drugs.

Q. If a patient were required to switch from

individualized to those kinds of variables to sort it out.

Q. And why would a patient not have other options?

A. If they -- the word I used before was burned through. If they have gone through all possible combinations of these 30 or so drugs that are licensed that could be used.

Q. Because of resistance?

A. Well, for multiple reasons, because of resistance and because of side effects, because there might be some -- you know, if they're -- if they're very sensitive to TDF causing renal toxicity, then, you know, then I'll put them on TAF. TAF, the only reason TAF -- I don't think it would work is if another part of their problem was side effects, if there were side effects related that affected adherence that led to resistance, then I wouldn't go from TDF to TAF because they'll have resistance to the same organisms, so I'd have to -- I have to address both of those things whenever I make a switch.

Q. So sometimes when -- when a virus becomes resistant to one medication, it can become also resistant to other medications?

A. It's possible.

Q. Is that like a class-wide resistance?

A. Sometimes there's class-wide -- there are class-wide resistances and there are drug-specific resistances, and it all depends. There are very useful -- and there's so much details with this that the docs don't keep it in their heads. The virologists know this stuff, but the virologists put together the tables and the docs will -- they'll get a result, and the results typically will tell you, you know, sort of what's -- what's it sensitive to.

So they'll give you the -- the dosing, the treatment recommendations based on the result of the -- of the genetic test for the virus. So that's kind of built into the test, which is true for lots of tests. So you don't need to be a virologist to interpret the data. You could -- you could -- you actually could look it up yourself here, and I would be comfortable looking at the table to decide what it

is.

And -- and some of the advantages of the recent drugs is there are not as many of the class effects. Even before the integrase inhibitors, there's other drugs that didn't have class resistance problems, because it's a huge problem, to -- to have one of those, because you lose many drugs instead of just the single one you're on.

Q. Okay, that was going to be my next question, are -- so if there's -- if a patient develops a resistance to an entire class, then you can't prescribe the medications in that class.

A. In that class.

Q. Okay. Is there -- are there reports of class resistance to integrase inhibitors yet?

A. So I'm not as familiar with the -- if there's a single mutation that's a class killer, and I -- and I also should direct, if I may before, there -- I'm not sure there are -- given all the drugs in each of the five, six, seven classes that there are -- I lose track. There are lots of classes that are options, and within them, there are cross-resistance

Q. How about this. Can you summarize for me the opinion that you're providing in the last three sentences of this paragraph 59?

MR. SCHOETTES: Will you give him time to read the entire paragraph?

MR. NORWAY: Well, he's already read it.

MR. SCHOETTES: Okay.

THE WITNESS: Last three, so one, two --

BY MR. NORWAY:

Q. Last three sentences.

A. Last three sentences. Sentences or lines?

Q. Sentences.

A. Okay. Yeah, so -- so what I'm getting at is if the soldier is virally suppressed, they're immunologically normal, and the CD4 cells, unless there's some intercurrent second -- and the CD4 cells were normal because these were all checked on the way to full suppression, so -- and I think what I said, there may be a recommendation, so I'll yield that, but the fact is the CD4 cells, if they went back to normal, the viral suppression is complete, and one lags the other, if there's intercurrent infection or

illness, the differential diagnosis is all the usual things that a normal person has.

Therefore -- and getting a CD4 count would be to rule out those very rare instances of other acquired immune deficiencies. I can't even tell you what's on the list, it's so rare. There are some natural immune deficiencies, but AIDS is so named because it sort of takes the place as the one acquired one, or the most important of the acquired ones. With a viral suppression and previously normal CD4 cells, it's not going to be an opportunist infection. You're wasting your time, and therefore, the differential is the same as it is in primary care.

Q. Okay, and so this portion of your opinion is based on the assumption that the HIV virus is suppressed, and suppression is continued.

A. And I would -- so I would -- you were trying to say something?

MR. SCHOETTES: No, go ahead.

A. So -- so that's the -- that's the first part, but the other part of it, like we referred to

before, is that even after -- even after viral suppression for whatever reason, if there's a discontinuation of the medication or there's resistance that develops, we're now on a glide path that has a median of about eight years until we get to opportunistic infection territory, and then we worry about unusual things that need different work-ups, and we have to pay attention to CD4 cells.

Somewhere during that time, someone is going to do -- you know, there will be a viral load, there will be -- that will be positive. There will then be an evaluation of a CD4, which could by that time, maybe not, but could by that time be declining, and then you're going -- you'll start to worry and you'll worry about the regimen they're on.

But there's not a risk that the fever that they have or the headache or the diarrhea is related to an opportunistic infection, or that a cancer is secondary to HIV. Those will not be occurring until eight years -- eight years plus on average. You're not even susceptible on average until eight years later.

Q. Those are AIDS-defining illnesses that you're talking --

A. Those are AIDS -- I've made a short list of AIDS-defining illnesses.

Q. So let's -- let's focus on your opinions regarding the CD4 counts. Is it -- is it essentially your opinion that it's really not necessary to take a CD4 count of a service member who's living with HIV who has a record of viral suppression and a normal CD4 count?

MR. SCHOETTES: Objection, confusing. You can answer.

A. Yes, if they've been established as normal, and normal is no viral load or undetectable. That's the normal value, and normal CD4 is greater than 500, if that has been established with some temporal record, and we talked about the two years seems reasonable for those, I don't know what I would do with this -- I don't know why I would order it, a CD4 count, in the -- in the absence of a viral load that would tell me I have some reason to order a CD4 count.

suppressant drugs that would change CD4 cells among others that would be -- you know, cause a lymphopenia, and the CD4 cells would be among those, yes.

Q. Corticosteroids -- are they one class of drugs that would do that?

A. So I'm not aware that corticosteroids would cause a reduction directly. In fact, acutely corticosteroids cause an increase in white blood cells generally because they change the way that the cells are trafficked. Cells are usually rolling along vessels, and since corticosteroids release the cells from the walls of vessels and they go in the bloodstream, so that the numbers at least go up, but I don't know about CD4 cells in particular.

Q. Okay.

A. In fact, my guess is the direction's the other way. I don't know that they're known to decrease them or necessarily decrease their function, but corticosteroids have other impacts on the -- on the immune system.

Q. Okay. So they modulate the immune system.

A. Yes.

Q. Yes. I want to ask you, in paragraph 65, and in paragraph 65, you discuss neurocognitive impairments and what you understand Dr. Hardy is addressing, correct?

A. Yes.

Q. Are you offering an opinion on -- or regarding the likelihood that an individual living with HIV may develop a neurocognitive impairment?

A. I'm agreeing that it can occur.

Q. Okay. So you refer to Dr. Hardy's opinion in this statement, correct?

A. Yes.

Q. Okay. Is your opinion different than the opinion that Dr. Hardy presented on this topic?

MR. SCHOETTES: Objection, vague, unclear whether you're referring specifically to Dr. Hardy's report, which was at the time of this report, or if you're also referring to opinions offered during his deposition.

BY MR. NORWAY:

Q. Well, you've read both, correct, sir?

obviously knowable, but I -- I'm not very confident. I think I assumed it was on board ship.

Q. Okay.

A. I'm well aware the Navy has lots of people that are in fixed locations involved in Southwest Asia.

Q. To your knowledge, does the Navy assign its sailors living with HIV to overseas location that are -- that are only -- let me start this. To your knowledge, is the Navy's policy to assign its HIV positive sailors to overseas locations that are supported by significant medical facilities?

A. I don't know the detail.

Q. Okay. To your knowledge, does the Navy policies require sailors who are living with HIV to be assigned to ships that are staffed with medical officers?

A. So I don't know.

MR. NORWAY: Why don't we take a break.

(Recessed at 4:27 p.m.)

(Reconvened at 4:47 p.m.)

BY MR. NORWAY:

Q. So Dr. Hendrix, if -- is there a risk of transmission of HIV if an individual who has a suppressed viral load donates blood and that blood is transfused into an individual who does not have HIV?

A. I think there is a theoretical risk that's vanishingly small.

Q. So there is a risk.

A. There is a vanishingly small risk.

Q. Is the answer to my question yes?

A. Yes.

Q. What is your understanding of what the military calls the walking blood bank?

A. That there will be circumstances, the frequency actually is about ten percent actually based on their published data, that there will not be a unit of blood, whole blood, which is typically what's done now, which is more useful, a unit of whole blood available for transfusion for whatever the need is in a forward position so that the Army has SOPs for a minimal level of testing to qualify blood on the spot from a donor that's in the unit, and that could be broad depending on what the unit

actually is, but it could just be the squad where someone will donate.

What -- what I'm not sure about is -- I mean, I don't know all the SOPs. I know that it does not have the same level of safety of risk reduction that the Red Cross and -- you know, that you would have CONUS or at a -- at a medical center where you had all the appropriate testing for -- you know, for -- for transmissible agents, presumably the blood tags and other things. The ABO incompatibility will still be sorted out, but -- so it's just not the full panel so there's some increased risk, but it makes it immediately available for transfusion -- for donation and then transfusion to the -- to the soldier that needs it.

Q. It's blood that's donated in theater and then quickly used thereafter.

A. In theater, yes.

Q. And as you stated, there's an increased risk of transfusion-transmitted infections with the use of the walking blood bank, correct?

A. Yes.

A. So there's -- there's several. One is the preexisting -- it's an assumption. The preexisting risk factor for what is applicable in the majority of persons at least in the Air Force that I've spoken to of HIV infection risk being men having sex with men, that they cannot donate, so they come into the military with that knowledge. When they're HIV infected, they speak with the public health officer and physician and their commander. The first two talk about HIV -- they go over the risk -- the risk of transmission, both sexual and to first responders and health care providers. Then the commander gives them the so-called, quote, safe sex order, which prohibits them from doing certain things and requires them from -- requires them to notify health care providers -- used to require first responder.

I didn't see that in the most recent examples, and to notify sex partners, and to use condoms, among other things, but -- and also, they are told not to donate blood. That then is repeated every time there's a new commander to effect a new order, and every time they are evaluated at their

periodic I think on average annual evaluation at the -- at the military center to which they're referred where there's centralized evaluations of these soldiers.

So in the period of time that one would be identified infected and then achieve the point of viral suppression, one would expect there would be one, two, three occasions and probably at least two interviews on those three occasions reinforcing that they must not donate blood.

Q. Okay. Did you review the deposition testimony of Lieutenant Colonel Lute?

A. I did, but that was months ago, and you can -- I did.

Q. Okay.

A. I did. I just don't remember much.

Q. Do you recall that she testified that she personally knew of a soldier who donated blood even though he was aware that he was HIV positive?

A. So that's believable, but I would imagine that'd be quite rare.

Q. Okay, and she testified that the incident

instance, especially when it may have, even though vanishingly small, may put another at some risk. And they -- it's an order. If they disobey the order, they could go to jail.

Q. Would you agree that military personnel are predominantly young and governed more by peer pressure than by established social norms?

MR. SCHOETTES: Objection, calls for speculation, outside the scope, vague. You can answer.

A. I have no -- I have no -- I have no primary experience in a social setting with the population. I would have had a fair bit of exposures one on one in care setting or casualty in -- you know, in a unit when I was a 22-year-old that was not really allowed to -- "fraternize" is the word they use, which even meant, you know, you don't go out for drinks with a sergeant who's your own age, and that would only be one on one, but it wouldn't have been in groups, and we would -- we probably would not have been perceived unfortunately as peers. So I've never been a peer to the population you're describing except in my own

experience, if you want me to reflect on that.

Q. Well, I'm asking you if the military personnel are predominantly young, and if they are governed more by peer pressure than by established social norms.

MR. SCHOETTES: Objection. Same objections as before.

A. So the first part is a fact. The second part I don't know. Same as the previous answer. I mean, I don't know.

Q. Okay. Are service members specifically trained at risk-taking?

MR. SCHOETTES: Objection, vague.

A. So I -- I would phrase it differently. I would say that soldiers -- you know, almost like the Marines. Marines are trained to run torward the fire, not away from it. As it turns out, that is not a natural response, but it is a trained response that is part of their service in the military.

Q. Is that -- is what you described risk-taking?

A. And they are asked to -- they are act --

But again, if -- you know, the viral load reduction is substantial when there's viral suppression. It's hard -- it's hard to characterize whether this risk is more like an injection drug use exposure or more like an occupational exposure with a sharp. It's probably somewhere in between, but -- but that's conjecture based on the facts that I've had that are not exactly in line with what you're -- what you're -- your scenario.

Q. Moving to the health care worker who is exposed to the blood of an HIV positive person, can you characterize the level of exposure in a blood splash situation?

MR. NORWAY: Objection, form.

A. So in the -- in the CDC's list of the -- excuse me, in the Cardo study, and I think consistent with subsequent studies that I do not know as well, there is a -- there is a risk of transmission of the splash to a mucus membrane. So there are two things. You can splash to a mucus membrane, you can splash to an open bleeding wound. If you splash to a mucus membrane, that is far lower risk. I can't quantitate

that for you by recall right now, but that is a much lower risk than a hollow bore needle or a penetrating bloody instrument.

If there is contact on a -- on a bleeding wound on the -- on the uninfected at-risk person, there would have to be mixing, and then the blood would have to get into the blood supply. I mean, presumably it might stay in the wound for an extended period and might somehow gain access to CD4 cells there, but the risks are based on blood to blood in a vessel. In fact, the description in the paper is in two vessels, that it's penetrating sufficient not just to be in tissue, but to penetrate vessels.

So those are the -- those are the modifiers of the risk as best I understand them and from that Cardo -- original Cardo study.

Q. In the context of U equals U -- well, first of all, the U equals U premise is regarding transmission risks in what context?

A. Only in the --

MR. NORWAY: Objection form.

A. Sorry. Sexual transmission.

Q. And when you say over a year, do you mean it took place over a year --

A. During -- during --

Q. Let me finish, or it was more than a year?

MR. NORWAY: Objection, form.

A. I think it took place over a year.

Q. When side effects related to --

A. Can I -- I'm sorry, may I --

Q. Yes.

A. -- clarify my answer to that? So I think -- there's been lots of numbers, and I'm trying to keep these all together. I think what that was were those were the discontinuations from the primary regimen that were occurring in a certain period of time. I think the majority of those occurred in the -- majority of the 30 percent occurred in the first year.

In the later epoch of time where there -- and -- and additionally, the drugs changed, which was part of the study. It was five percent in that early period of time. That's why I introduced the other one that looked over a longer period of time within

an individual, which provided more granular and relevant data, that there was -- there was a continual decline. It was highest in the first year, continued to decline and went down to one percent.

Q. Okay. Earlier, we talked about the side effects that were not symptom based but were effects on organs and body systems that may take place over a longer period of time. Can you describe what the acute effects of such drug side effects are on organs and bodily systems?

MR. NORWAY: Objection, form.

A. So the -- the two of those that -- the hepatic changes do not occur with the drugs that are currently used. Were we still using those drugs to a certain degree, the hepatic effects are not -- there aren't acute symptoms. The -- so that's not so relevant, and the point of those kinds of things is that laboratory tests are what identify the side effect.

Eventually there will be symptoms if -- if it all progresses, but that takes time. It's not like you take the drug for a couple of additional

days and next week your liver fails. These are indolent processes that take a long period of time and are cumulative, cumulative toxicities over time as these -- creatinine indicates a renal failure. Liver transaminase is the case of renal failure. Liver transaminase is the case of liver failure or liver toxicity if it occurs, but they're -- they're long-term processes.

Q. When you say a long-term process, can you give me an idea of how long you are talking about?

A. Many months.

MR. NORWAY: Objection, form.

A. Many months. It -- there -- because they're -- you know, they're -- they're cumulative, so it's -- the doses are chosen so that these risks are very low, and they are -- it's not even a concern -- neither of those are concern for the integrase inhibitors. They're a very low concern for the TAF, and it's not a concern for FTC. So the three most commonly prescribed drugs, those things that are indolent in some -- with some older drugs are not concerns with these most recent -- not significant

just says ART, and I don't see dates, dates, dates. Oh, enrollment was stopped on 11 January 2006. There are no integrase inhibitors in this study. This would be -- Atripla would be the most commonly used regimen. There may be some residual protease inhibitors and there may be some other non-nucleosides. That's just sort of an epidemiologic historic reflection based on the practice at the time.

Q. Is Atripla a regimen that is recommended by the DHHS guidelines?

MR. NORWAY: Objection, form. Thank you for waiting.

THE WITNESS: No.

MR. SCHOETTES: I'm done.

FURTHER EXAMINATION BY COUNSEL FOR THE DEFENDANTS

BY MR. NORWAY:

Q. I'd just like to follow up on that a little bit. You'd mentioned today that there are no longer -- or there haven't been any recent cessation of treatment studies, correct?

A. I'm sorry, there's no -- they're no longer

done. That's -- that's done. That's a closed book.

Q. Do you know if there are any cessation studies for -- or that -- that included integrase?

A. I don't think there were. I would have to look, but I do not think so. That's easily determined, but I think not because the integrase inhibitors are much more -- are much more recent, having been -- there's one, raltegravir, but raltegravir has I think only recently moved to kind of the top of the list, as it was in the top four here, so I think not.

MR. NORWAY: Okay. I think I'm done.

(Whereupon, at 7:28 p.m., the taking of the instant deposition ceased.)

UNITED STATES OF AMERICA)

ss:

DISTRICT OF COLUMBIA)

I, KAREN YOUNG, a Notary Public within and for the District of Columbia, do hereby certify that the witness whose deposition is hereinbefore set forth was duly sworn and that the within transcript is a true record of the testimony given by such witness.

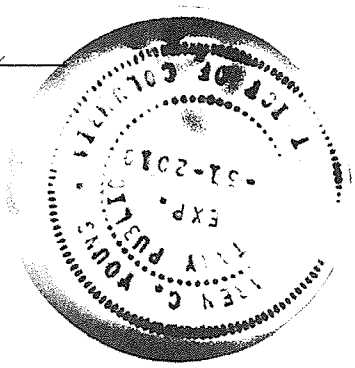
I further certify that I am not related to any of the parties to this action by blood or marriage and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 22nd day of May, 2019.

Karen Young

My Commission Expires:

July 31, 2019



Notice Date: 05/22/2019

Deposition Date: 05/10/2019

Deponent: Craig Walter Hendrix, M.D.

Case Name: Harrison, et al. v. Shanahan

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I hereby certify that I have read and examined the foregoing transcript, and the same is a true and accurate record of the testimony given by me. Any additions or corrections that I feel are necessary, I will attach on a separate sheet of paper to the original transcript.

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I hereby certify that the individual representing himself/herself to be the above-named individual, appeared before me this _____ day of _____, 20__, and executed the above certificate in my presence.

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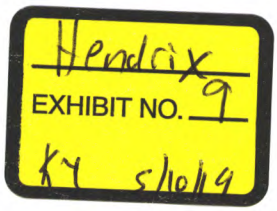

VIEWPOINT

HIV Viral Load and Transmissibility of HIV Infection

Undetectable Equals Untransmittable

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In 2016, the Prevention Access Campaign, a health equity initiative with the goal of ending the HIV/AIDS pandemic as well as HIV-related stigma, launched the Undetectable = Untransmittable (U = U) initiative.[1] U = U signifies that individuals with HIV who receive antiretroviral therapy (ART) and have achieved and maintained an undetectable viral load cannot sexually transmit the virus to others. This concept, based on strong scientific evidence, has broad implications for treatment of HIV infection from a scientific and public health standpoint, for the self-esteem of individuals by reducing the stigma associated with HIV,[2] and for certain legal aspects of HIV criminalization.[3] In this Viewpoint, we examine the underlying science-based evidence supporting this important concept and the behavioral, social, and legal implications associated with the acceptance of the U = U concept.

A major breakthrough in HIV/AIDS therapeutics came in 1996 with the advent of 3-drug combinations of antiretrovirals, including the newly developed protease inhibitors. These therapeutic regimens resulted in substantial decreases in viral load in a high percentage of patients, usually below the level of detection in plasma and sustained for extended periods.[2] Although not appreciated at the time, the accomplishment of a sustained, undetectable viral load was likely the definitive point when the U = U concept became a reality. Proof of that concept would await further clinical trials and cohort studies. Based on a review of scientific data, a statement from Switzerland in 2008 indicated that individuals with HIV who did not have any other sexually transmitted infection, and achieved and maintained an undetectable viral load for at least 6 months, did not transmit HIV sexually.[4] This was the first declaration of the U = U concept, but it was not universally embraced because it lacked the rigor of randomized clinical trials.

In 2011, the HIV Prevention Trials Network (HPTN) study 052 compared the effect of early with delayed initiation of ART in the partner with HIV among 1763 HIV-discordant couples, of whom 98% were heterosexual. The finding of a 96.4% reduction in HIV transmission in the early-ART group, vs those in the delayed group, provided the first evidence of treatment as prevention in a randomized clinical trial.[5] At that point, the study could not address the durability of the finding or provide a precise correlation of the lack of transmissibility with an undetectable viral load. Importantly, after 5 additional years of follow-up, the durable, protective effect of early ART to maintain viral suppression and prevent HIV transmission was validated. There were no linked transmissions when viral load was durably suppressed by ART.[6]

Subsequent studies confirmed and extended these findings. The PARTNER 1 study determined the risk of HIV transmission via condomless sexual intercourse in 1166 HIV-discordant couples in which the partner with HIV was receiving ART and had achieved and maintained viral suppression (HIV-1 RNA viral load <200 copies/mL). After approximately 58 000 condomless sexual acts, there were no linked HIV transmissions.[3] Since a minority of the HIV-discordant couples in PARTNER 1 were men who have sex with men (MSM), there was insufficient statistical power to determine the effect of an undetectable viral load on the transmission risk for receptive anal sex. In this regard, the Opposites Attract study evaluated transmissions involving 343 HIV-discordant MSM couples in Australia, Brazil, and Thailand. After 16 800 acts of condomless anal intercourse there were no linked HIV transmissions during 588.4 couple-years of follow-up during which time the partner with HIV had an undetectable viral load (<200 copies/mL).[3]

Building on these studies, the PARTNER 2 study conclusively demonstrated that there were no cases of HIV transmission between HIV-discordant MSM partners despite approximately 77 000 condomless sexual acts if the partner with HIV had achieved viral suppression and the uninfected partner was not receiving preexposure prophylaxis or postexposure prophylaxis.[7]

The validity of the U = U concept depends on achieving and maintaining an undetectable viral load in an individual with HIV. Because of the promise of U = U, achieving and maintaining an undetectable viral load becomes an aspirational goal and offers hope for persons with HIV. The principles involved in achieving and maintaining an undetectable viral load are related to (1) taking ART as prescribed and the importance of adherence; (2) time to viral suppression; (3) viral load testing recommendations; and (4) the risk of stopping ART (**Box**).

Taking ART as prescribed is essential for achieving and maintaining an undetectable viral load. The Centers for Disease Control and Prevention (CDC) reported that of the individuals with HIV in the United States in HIV clinical care in 2015, approximately 20% had not achieved viral suppression (<200 HIV-1 RNA copies/mL) at their last test. CDC also noted that 40% of the individuals in HIV clinical care that same year did not maintain viral suppression for more than 12 months.[8] Lack of adherence with ART is associated with many factors, including the lack of accessibility of quality health care. The stability of health care provided by programs such as the Ryan White HIV/AIDS Program shows that high rates of viral suppression are possible in the context of quality care delivery.

Box. Principles to Achieve and Maintain an Undetectable Viral Load

- In order for antiretroviral therapy (ART) to provide maximum benefit, taking medication as prescribed is essential.
- Achieving an undetectable viral load can take up to 6 months of ART. Once achieved, continued adherence is required.
- According to guidelines from the Department of Health and Human Services, viral load testing should be performed every 3-4 months after the plasma HIV-1 RNA level reaches undetectable (<200 copies/mL). If viral suppression and stable immunologic status are maintained for >2 years, the viral load testing can be extended to every 6 months thereafter.
- Stopping therapy negates the validity of assuming that U = U.

The guidance that viral suppression measured at 6 months after starting therapy is required for U = U has several origins. First, Partners PrEP trial, a prospective cohort study conducted among 4747 heterosexual HIV-discordant couples in Kenya and Uganda, was designed to determine the risk of HIV transmission prior to and following achieving viral suppression (<80 HIV-1 RNA copies/mL). HIV incidence prior to initiation of ART was 2.08 per 100 person-years, 1.79 for 0 to 6 months after initiation of ART, and 0.00 with more than 6 months of ART, indicating that residual HIV transmission risk persists during the first 6 months of ART, during which time there is incomplete suppression of HIV in blood and genital compartments.[9] Second, a case of a linked transmission in Partners PrEP occurred when the treated partner had been taking ART for fewer than 4 months and prior to complete viral suppression.[3] These findings support the requirement for 6 months of ART to achieve virologic suppression.

The recommended schedule for viral load testing for individuals with HIV in the United States, according to the Panel on Antiretroviral Guidelines for Adults and Adolescents,[2] includes testing (1) at entry into care; (2) on initiation of ART or at the time of treatment regimen modification; (3) 2 to 8 weeks after ART initiation or modification and repeated every 4 to 8 weeks until the HIV-1 RNA viral load is suppressed to less than 200 HIV-1 RNA copies/mL; and (4) repeated every 3 to 4 months. For individuals who are adherent to treatment with consistently suppressed viral load and stable immunologic status for more than 2 years, the guidelines panel[2] recommends that monitoring can be extended to 6-month intervals.

Stopping ART represents a significant challenge to successful implementation of U = U. When ART is stopped, viral rebound usually occurs within 2 to 3 weeks. The SPARTAC and SMART clinical trials used stopping ART to determine if the same degree of protection from progression to AIDS could be achieved by ART dosed for defined intervals or continuously delivered. In both studies, stopping ART resulted in viral rebound to levels that would have been associated with increased risk of HIV transmission.[10] A systematic review of 12 recent clinical studies concluded that there is negligible risk (0.00 transmissions/100 person-years, 95% CI, 0.00-0.28) of HIV sexual transmission among HIV-discordant partners when the partner with HIV adheres to ART and maintains a suppressed viral load (<200 HIV-1 RNA copies/mL) measured routinely every 4 to 6 months.[3] To enhance the overall success of the U = U concept, it is important to implement programs that help patients remain in care and address the challenges in their lives that result in their stopping therapy.

In summary, even though the clinical data underpinning the concept of U = U have been accumulating for well over a decade, it is only recently that an overwhelming body of evidence has emerged to provide the firm basis to now accept this concept as scientifically sound. This has important implications in several areas. The U = U concept provides incentives for individuals with HIV to seek, initiate, and adhere to ART. In addition, it adds incentives to efforts to control and ultimately end the HIV/AIDS pandemic because treatment as prevention is a critical tool in preventing the spread of HIV infection.[2] The U = U concept also bridges the best of biomedical science with current concepts in behavioral and social science by removing the sense of fear and guilt that a person may be harming someone else, as well as the feeling of self-imposed and external stigma that many people with HIV experience. Finally, this concept has legal implications related to the criminalization of certain persons with HIV whereby criminal law is used to penalize alleged, perceived, or potential HIV exposure of one person to another.

ARTICLE INFORMATION

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Conflict of Interest Disclosures: None reported.

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PLOS ONE

Plasma HIV Viral Rebound following Protocol-Indicated Cessation of ART Commenced in Primary and Chronic HIV Infection

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Abstract

Objectives: The magnitude of HIV viral rebound following ART cessation has consequences for clinical outcome and onward transmission. We compared plasma viral load (pVL) rebound after stopping ART initiated in primary (PHI) and chronic HIV infection (CHI).

Design: Two populations with protocol-indicated ART cessation from SPARTAC (PHI, n = 182) and SMART (CHI, n = 1450) trials.

Methods: Time for pVL to reach pre-ART levels after stopping ART was assessed in PHI using survival analysis. Differences in pVL between PHI and CHI populations 4 weeks after stopping ART were examined using linear and logistic regression. Differences in pVL slopes up to 48 weeks were examined using linear mixed models and viral burden was estimated through a time-averaged area-under-pVL curve. CHI participants were categorised by nadir CD4 at ART stop.

Results: Of 171 PHI participants, 71 (41.5%) rebounded to pre-ART pVL levels, at a median of 50 (95% CI 48–51) weeks after stopping ART. Four weeks after stopping treatment, although the proportion with pVL≥400 copies/ml was similar (78% PHI versus 79% CHI), levels were 0.45 (95% CI 0.26–0.64) $\log_{10}$ copies/ml lower for PHI versus CHI, and remained lower up to 48 weeks. Lower CD4 nadir in CHI was associated with higher pVL after ART stop. Rebound for CHI participants with CD4 nadir >500 cells/mm^3 was comparable to that experienced by PHI participants.

Conclusions: Stopping ART initiated in PHI and CHI was associated with viral rebound to levels conferring increased transmission risk, although the level of rebound was significantly lower and sustained in PHI compared to CHI.

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Introduction

Long-term use of antiretroviral therapy (ART) in HIV-positive persons may be challenged by the need for high-level adherence, development of drug resistance, toxicities, and cost. Treatment strategies conferring durable virological control, whilst minimising ART exposure are highly desirable. With this goal in mind, strategic interruption of ART was the focus of several studies [1–3].

However, interruption of ART is no longer a recommended strategy [2] and the level of HIV plasma viral load (pVL) following ART stop has been shown to reach levels comparable to pre-treatment values [2–4], increasing onward transmission risk [5]. Inaccessible reservoirs of latently-infected resting memory CD4 T-cells are hypothesised to be the major source contributing to viraemia rebound after stopping ART [6,7].

Recent research has shown the dramatic effect of ART to prevent onward viral transmission [8], and mathematical models predict that it may potentially be possible to eliminate HIV infection at a population level with universal treatment coverage for all HIV-positive individuals, irrespective of CD4 count [9]. However, although not recommended, consideration of the

potential impact of individuals choosing to stop ART could be considerable, and data are needed on subsequent viral rebound to better inform future transmission models. Furthermore, final results from SPARTAC suggested that ART initiated in primary HIV infection (PHI) was associated with a change in pVL set-point out to 60 weeks after stopping therapy [10] whilst the SMART trial reported that interruption of ART in chronic infection (CHI) was associated with an increased risk of all-cause mortality

The level of viral rebound following interruption of ART commenced in at different stages of HIV infection is, therefore, highly relevant from both a clinical and public health perspective and warrants further investigation.

We, therefore, wanted to compare the pVL changes observed after cessation of ART initiated in chronic HIV infection with those in PHI by comparing viral rebound between individuals enrolled in two protocol-indicated ART interruption studies; SPARTAC and SMART.

Methods

Ethics statement

The SPARTAC trial was approved by the following authorities: Medicines and Healthcare products Regulatory Agency (UK), Ministry of Health (Brazil), Irish Medicines Board (Ireland), Medicines Control Council (South Africa), and the Uganda National Council for Science and Technology (Uganda). It was also approved by the following ethics committees in the participating countries: Central London Research Ethics Committee (UK), Hospital Universitário Clementino Fraga Filho Ethics in Research Committee (Brazil), Clinical Research and Ethics Committee of Hospital Clinic in the province of Barcelona (Spain), The Adelaide and Meath Hospital Research Ethics Committee (Ireland), University of Witwatersrand Human Research Ethics Committee, University of Kwazulu-Natal Research Ethics Committee and University of Cape Town Research Ethics Committee (South Africa), Uganda Virus Research Institute Science and ethics committee (Uganda), The Prince Charles Hospital Human Research Ethics Committee and St Vincent's Hospital Human Research Ethics Committee (Australia), and the National Institute for Infectious Diseases Lazzaro Spallanzani, Institute Hospital and the Medical Research Ethics Committee, and the ethical committee Of the Central Foundation of San Raffaele, MonteTabor (Italy). The INSIGHT SMART trial was approved by the University of Minnesota institutional review board. All participants signed a written informed consent.

Study populations

Viral dynamics following treatment interruption were compared using data from SPARTAC and SMART participants. SPARTAC is an international RCT comparing no therapy, 12-week ART, or 48-week ART initiated within a maximum of 6 months from the last documented HIV negative test date. The primary outcome measure was time to confirmed CD4 cell count <350 cells/mm^3, or the initiation of long-term therapy. PHI was identified according to the trial protocol. The trial recently reported a significant difference in time to the primary endpoint for the 48-week, but not the 12-week, ART arm compared to no therapy, although not significantly longer than the time already spent on therapy [10]. SMART is an international RCT which compared a CD4-guided strategy of planned treatment interruptions versus continuous ART in chronically HIV-infected individuals. Eligible participants with CD4>350 cells/mm^3 were randomised to either a Drug Conservation (DC) or Viral Suppression (VS) arm. Enrolment was stopped on 11th January 2006 and participants in the DC arm were recommended to re-initiate ART as interim results clearly indicated superiority of the VS arm [2].

Individuals were included in this analysis if they underwent protocol-indicated ART cessation, i.e. on ART at time of randomisation to the DC arm in SMART (hereafter, the chronically-infected population) or randomised to one of the two treatment arms in SPARTAC (hereafter, the PHI population), and had a CD4 cell count and pVL available at the time of ART stop. Subsequent pVL measurements were scheduled at 4, 12, 24, 36, 48 and 4, 8, 16, 32, 40, 48 weeks after ART stop in SPARTAC and SMART respectively. pVLs were determined locally; for included participants, 40, 59, <1 and $<1\%$ from SPARTAC and 20, 74, 4 and 2% from SMART were measured using bDNA, PCR, NASBA and other assays, respectively.

Statistical methods

We examined the time following ART stop for pVL to reach pre-ART levels in the PHI population, using survival methods. We then compared pVL levels at 4 weeks after stopping ART in the PHI participants, and up to 48 weeks afterwards, with those in chronically-infected individuals. Using linear and ordered logistic regression, respectively, we examined differences in absolute levels and in the proportions with pVL<400, 400–3499, 3500–9999, 10,000–49,999 or $\geq 50{,}000$ copies/ml at 4 weeks after ART stop [5]. Using linear mixed models, we examined differences in pVL levels and slopes over 4–48 weeks after ART stop, and estimated predicted pVLs at 4 and 36 weeks after ART stop for representative PHI and chronically-infected participants (male infected through sex with men, aged 40 years and with CD4 600 cells/mm^3 at ART stop). We estimated the complete viral burden, through a time-averaged area–under-pVL curve, over the whole period after stopping ART. We then categorised the chronically-infected participants according to their nadir CD4 count at ART stop in order to assess whether any differences over 48 weeks between the populations could be explained solely by nadir CD4.

Follow-up began from the date of first stopping all drugs in the ART regimen and was censored at the last pVL measurement, the 48 week visit, when ART was re-initiated, or 11th January 2006 for SMART participants, whichever was earliest.

We restricted analyses to participants who had suppressed pVL to <400 copies/ml at the time of ART stop, as this was the limit of the least sensitive assay used across both trials. pVL data were $\log_{10}$-transformed and values <400 copies/ml were treated as $=400$ copies/ml for all participants to avoid confounding by trial, as a greater proportion of pVLs were measured using this detection limit in the PHI compared to chronically-infected participants (13 versus 6% <400 copies/ml and 9 vs. 16%, respectively, <50 copies/ml). CD4 and pVL at ART stop were defined by those closest to ART stop (up to 24 and 12 weeks before, respectively, and no more than 2 weeks after). Subsequent pVLs were defined by those closest to the scheduled visits (allowing a $+/-2$ week window around the week 4 and 6 visits and a $+/-4$ week window around subsequent visits). Pre-ART pVLs in PHI participants were estimated as the mean of all available pVLs before ART initiation (9%, 85%, 5%, 1% participants had 1, 2, 3 and 4 pre-ART pVLs available, respectively). We also restricted analyses to include sexually-infected individuals only as few were from other risk groups in the PHI population.

Models were adjusted for the effect of sex/risk group (sex between men (MSM), heterosexual men or heterosexual women), age and CD4 at ART stop. No adjustments were made for time on ART, as this is confounded by duration of infection and, therefore, by trial, nor for ART class (also confounded by trial). Using only

data from the chronic population, however, we investigated the possible effect of ART class on viral rebound. We also investigated whether there were differences in the effects of participant characteristics at ART stop for PHI compared to chronically-infected participants, and CD4 nadir up to ART stop, where appropriate, using interactions.

As SMART participants were enrolled into the trial with prevalent HIV infection, duration of HIV infection and time since first initiation of ART may not have been known and so reported values should be regarded as best estimates. In particular, the duration of infection is based on first known HIV positive result, therefore, the intervals are likely to be underestimates.

Results

Description of the population

Of the 243 SPARTAC participants randomised to one of the two treatment arms, 16 were excluded because they did not initiate ART (n = 5), did not stop ART (n = 6), were on ART for <15 days (n = 4) or did not have a pVL at ART stop (n = 1). Of the 2290 SMART participants on ART at the time of randomisation to the DC arm, 256 were excluded because they did not stop ART (n = 42, 25 of whom were randomised in the month prior to 11th January 2006), stopped ART after 11th January 2006 (n = 20), did not have a pVL at ART stop (n = 1) or did not have any subsequent pVLs after stopping ART (n = 193, 153 of whom only stopped in the month prior to 11th January 2006). Additional exclusions were as follows: 43 SPARTAC and 384 SMART participants with pVL≥400 copies/ml at ART stop, 125 SMART participants with reported risk group IDU, and 2 SPARTAC and 75 SMART participants with other/unknown route of HIV transmission. Therefore, 182 PHI and 1450 chronically-infected participants were included in our analyses.

Participant demographics, ART exposure and CD4 at time of treatment discontinuation are shown in Table 1. Compared to those chronically-infected, PHI participants were younger (median 34 versus 44 years), more likely to be female (33% versus 24%), had considerably less ART exposure (6% versus 44% ever exposed to ≥3 drug classes) and were more likely to be on a protease inhibitor regimen at the time of ART stop (94% versus 36%). At ART stop, median CD4 was slightly higher among PHI compared to chronically-infected participants (707 versus 646 cells/mm^3). Among chronically-infected participants, 76% had nadir CD4<350 cells/mm^3. Five-hundred and fifty-nine (39%) chronically-infected participants were censored on 11th January 2006 due to discontinuation of the SMART DC arm. A further 17 (9%) PHI and 463 (32%) chronically-infected participants were censored before their 48 week visit due to ART re-initiation. The median (IQR) follow-up was 48 (45, 49) and 27 (12, 43) weeks for the PHI and chronically-infected participants, respectively, and the median (IQR) number of RNA measurements included per individual was 6 (5, 6) and 4 (3, 6), respectively.

Time to pVL reaching pre-ART levels in PHI participants

Among the PHI participants, the median (IQR) pre-ART pVL was 4.5 (3.9, 5.1) $\log_{10}$ copies/ml. Eleven participants had pre-ART pVL<400 copies/ml and were, therefore, omitted from the analyses of estimating time to reaching pre-ART pVL. Nine participants, who had higher median pre-ART pVL (5.5 $\log_{10}$ copies/ml), were censored before reaching pre-ART levels due to ART re-initiation (one at 5 weeks and the remainder ≥25 weeks after ART stop). A total of 71 (42% of 171) participants were observed to rebound to pre-ART pVL levels, at a median of 50 (95% CI 48, 51) weeks. A quarter of participants had rebounded to pre-ART levels by 15 (95% CI 12, 26) weeks.

pVL rebound after ART stop by PHI versus chronically-infected participants

At 4 weeks after ART stop, the proportions with pVL<400 copies/ml were similar in the two groups (Table 2), but median pVL levels were significantly lower among PHI compared to chronically-infected participants (unadjusted median 3.7 versus 4.4 $\log_{10}$ copies/ml, respectively; adjusted pVL 0.45 (95% CI 0.26, 0.64) $\log_{10}$ copies/ml lower, p<0.001; Table 3). Higher CD4 cell count at ART stop was weakly associated with lower week 4 pVL, and persons infected through heterosexual contact had lower week 4 pVL compared to MSM, but with no evidence that this effect differed between the PHI and chronically-infected groups (p = 0.4). There was no association between age at ART stop and week 4 pVL (p = 0.6).

Considering only the chronically-infected participants, pVL was significantly higher at 4 weeks after ART stop for those on PI-based or triple NRTI regimens, compared to those on NNRTI-based regimens (0.69 [0.56,0.81] and 0.58 [0.38,0.79] $\log_{10}$ copies/ml, respectively). There was no evidence of a difference for other highly-active or suboptimal regimens, compared to NNRTI-based regimens (0.36 [−0.01,0.74] and 0.17 [−0.07,0.42] $\log_{10}$ copies/ml, respectively.

Over 48 weeks after ART stop, median pVL remained lower in individuals with PHI compared to chronically-infected participants (Figure 1a), with evidence to suggest that chronically-infected participants rebounded more rapidly than PHI participants (i.e. had steeper slope; adjusted p<0.0001; Figure 1b). Predicted pVLs for representative participants are given in Figure 1b.

The median (IQR) viral burden was 1.12 (0.56, 1.69) and 1.55 (1.03, 1.99) $\log_{10}$ copies/ml amongst PHI and chronically-infected participants, respectively. After adjustment, viral burden was, on average, 0.28 (95% CI 0.17, 0.39) $\log_{10}$ copies/ml lower for PHI versus chronically-infected participants (p<0.001).

The associations between longer-term pVL rebound and sex/risk group, CD4 cell count and age at ART stop were qualitatively similar as those for the week 4 pVL rebound (results not shown).

pVL rebound after ART stop, categorising the chronically-infected participants by nadir CD4 count

Over 4–48 weeks after ART stop, pVL remained significantly higher in chronically-infected participants with nadir CD4<500 cells/mm^3, compared to PHI participants. Lower CD4 nadir was associated with faster rebound (Figures 2a and 2b). For every 8 weeks the pVL in PHI participants increased, on average, by 0.17 (95% CI 0.14, 0.20) $\log_{10}$ copies/ml compared to 0.15 (0.01, 0.29), 0.33 (0.21, 0.44), 0.46 (0.36, 0.57) and 0.71 (0.60, 0.81) $\log_{10}$ copies/ml in chronically-infected participants with nadir CD4≥500, 350–499, 200–349, and <200 cells/mm^3, respectively. Predicted pVL levels for representative participants are given in Figure 2b.

We observed a similar relationship for viral burden: chronically-infected participants with a lower nadir CD4 had higher viral burden, compared with PHI participants (0.39 [95% CI 0.27, 0.51], 0.29 [0.18, 0.41] and 0.20 [0.06, 0.33] $\log_{10}$ copies/ml higher viral burden for nadir CD4<200, 200–349 and 350–499 cells/mm^3 respectively), but there was no difference in viral burden between chronically-infected participants with CD4 nadir ≥500 cells/mm^3 and PHI participants (0.04 [−0.12 to 0.20] $\log_{10}$ copies/ml).

Table 1. Participant characteristics at ART stop.

	CHRONIC HIV INFECTION (SMART) N = 1450	PHI (SPARTAC) N = 182
Sex, female (n, %)	350 (24%)	60 (33%)
Age, years (median, IQR)	44 (38, 51)	34 (28, 42)
HIV exposure (n, %)		
Sex between men	890 (61%)	114 (63%)
Sex between men & women (male)	222 (15%)	8 (4%)
Sex between men & women (female)	338 (23%)	60 (33%)
Time since first diagnosed HIV positive, months (median, IQR)	96 (60, 144)	6 (4, 13)
Number of ART drugs, ever (median, IQR)	5 (4, 7)	3 (3, 3)
Number of ART classes, ever (n, %)		
1	48 (3%)	0 (0%)
2	763 (53%)	171 (94%)
≥3	639 (44%)	11 (6%)
Estimated time on therapy, months (median, IQR)	72 (48, 96)	3 (3, 11)
ART type at stop (n, %)		
NNRTI based	674 (46%)	8 (4%)
PI based	521 (36%)	171 (94%)
3 NRTI	132 (9%)	2 (1%)
3 class	84 (6%)	0 (0%)
NRTI sparing	3 (<1%)	0 (0%)
Suboptimal ART	36 (2%)	1 (1%)
Nadir CD4 count up to ART stop, cells/mm^3 (median, IQR; below: n, %)	230 (132, 340)	-
<200	592 (41%)	-
200–349	515 (36%)	-
350–499	226 (16%)	-
≥500	117 (8%)	-
CD4 count at ART stop, cells/mm^3* (median, IQR; below: median, IQR by nadir CD4)	646 (495, 848)	707 (586, 919)
nadir CD4<200 cells/mm^3	568 (456, 724)	-
nadir CD4 200–349 cells/mm^3	618 (494, 784)	-
nadir CD4 350–499 cells/mm^3	806 (646, 993)	-
nadir CD4≥500 cells/mm^3	948 (784, 1176)	-

*Closest up to 24 weeks before ART stop. NB: 2 chronically-infected participants had CD4 count <350 cells/mm^3 at ART stop (contrary to SMART inclusion criteria), but both were measured on the day of ART stop and both participants had previous CD4 count >350 cells/mm^3 within the previous 6 weeks.

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The effects of sex/risk group and age at ART stop were similar to those for week 4 pVL rebound (results not shown). However, we found evidence of an interaction between nadir CD4 and CD4 cell count at stop ($p = 0.04$ and 0.0006 in the linear mixed model for pVL up to 48 weeks and the linear regression for viral burden, respectively). CD4 count 100 cells/mm^3 higher at ART stop was associated with a higher viral burden of 0.05 (95% CI 0.03, 0.08) and 0.02 (−0.002, 0.05) $\log_{10}$ copies/ml for chronically-infected participants with nadir CD4<200 and 200–349 cells/mm^3, respectively. Among chronically-infected participants with nadir CD4 350–499 or ≥500 cells/mm^3, there was no evidence of such an association (viral burden 0.002 [−0.03, 0.04] and −0.01 [−0.05, 0.03] $\log_{10}$ copies/ml higher per 100 cells/mm^3 higher CD4 at ART stop, respectively). Among PHI participants, there was evidence to suggest that higher CD4 at ART stop was associated with lower viral burden (0.04 [95% CI 0.003, 0.08] $\log_{10}$ copies/ml lower per 100 cells/mm^3 higher CD4 at ART stop). The effect on viral burden of PHI versus chronic infection/nadir CD4 remained robust with or without adjustment for CD4 count at ART stop.

Discussion

This is the first study to compare HIV pVL dynamics between PHI and chronically-infected individuals undergoing a protocol-indicated ART interruption. We observed that pVL rebound after stopping ART initiated in PHI was lower than that observed in chronic infection, at 4 weeks after treatment interruption, and this

Table 2. pVL levels at 4 weeks after ART stop by PHI versus chronically-infected participants.

pVL, copies/ml	Chronic HIV infection (SMART) N = 1327*	PHI (SPARTAC) N = 156*
<400	284 (21%)	35 (22%)
400–3499	161 (12%)	34 (22%)
3500–9999	110 (8%)	36 (23%)
10,000–49,999	235 (18%)	25 (16%)
≥50,000	537 (40%)	26 (17%)

Values are n (%). pVL = plasma viral load.
Adjusted p-value from ordered logistic regression <0.001.
*Of participants with a week 4 pVL available.
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difference was sustained over 48 weeks of follow-up. In addition, the overall viral burden, as estimated by the area under the pVL by time curve, was significantly lower in PHI compared to chronically-infected participants.

Our findings support those from a smaller study which observed significantly shorter time to viral rebound following treatment interruption in participants who initiated treatment in PHI compared to chronic infection [11]. However, they did not consider the stage of infection prior to commencing therapy. We found that, as anticipated, when participants with chronic infection were stratified by nadir CD4 at time of stopping ART, lower nadir CD4 was associated with higher pVL after stopping therapy. Compared to PHI, viral rebound was higher in chronically-infected participants with nadir CD4<500 cells/mm^3, but similar to levels experienced by those with nadir CD4≥500 cells/mm^3. Interestingly, in chronically-infected participants with CD4 nadir <200 cells/mm^3, higher CD4 count at ART stop was associated with subsequent higher viral burden. Thus, it could be hypothesised that the degree of viral rebound may be related to the degree of immune reconstitution occurring during ART, or to the number of CD4 target cells available for viral infection at ART stop [12].

The observed difference in virological impact of stopping ART in PHI versus chronic infection may reflect differences in viral reservoir size although no data were available from either trial on HIV reservoir size and we were, therefore, unable to directly examine this. A study of ART initiated during PHI found that 36

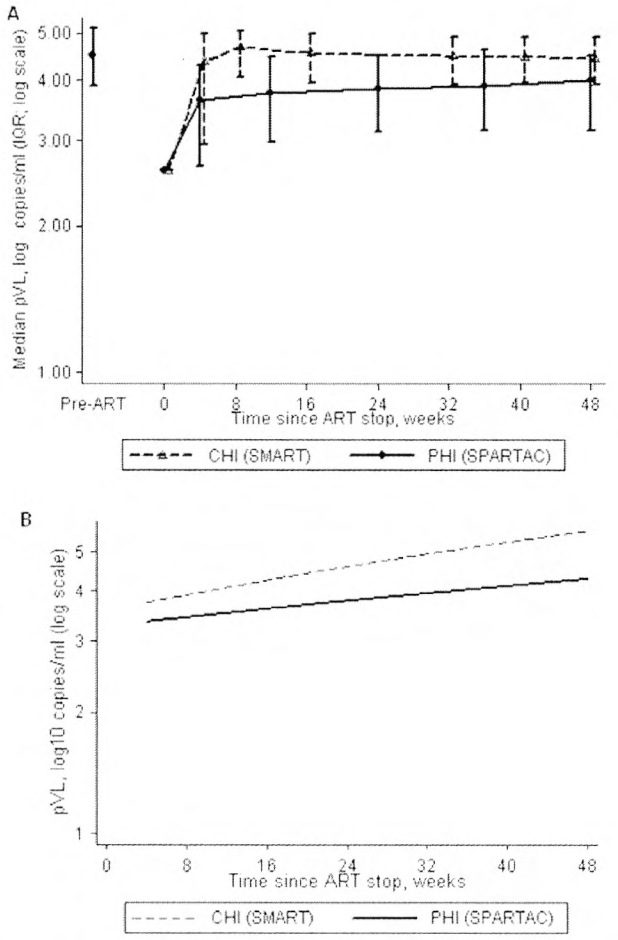

Figure 1. pVL after ART stop in primary (PHI) and chronic HIV infection (CHI). a. median (IQR) pVL up to 48 weeks after ART stop. b. predicted pVL over 4–48 weeks after ART stop, based on a representative participant (male infected through sex with men, aged 40 years and with CD4 count 600 cells/mm^3 at ART stop; values in brackets are the 95% CI). CI = confidence intervals, IQR = interquartile range, pLV = plasma viral load.
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Table 3. Factors associated with pVL level (log_{10} copies/ml) at 4 weeks after ART stop (from adjusted linear regression model*).

	Coefficient (95% CI)	P
PHI, versus chronically-infected	−0.45 (−0.64, −0.26)	<0.001
Age at ART stop, per 10 years	0.01 (−0.04, 0.07)	0.6
Sex/risk group, vs men infected through sex with men		<0.001
Male, infected through sex with women	−0.14 (−0.30, 0.03)	
Female, infected through sex with men	−0.33 (−0.47, −0.20)	
CD4 count at ART stop, per 100 cells/mm^3	−0.02 (−0.04, 0.002)	0.08
Constant**	4.26 (4.18, 4.34)	-

CI = confidence interval. pVL = plasma viral load. Coefficients are interpreted as the value of log_{10} copies/ml lower pVL for a negative sign, and higher for a positive sign.
*Adjusted for factors in the table.
**Mean week 4 pVL for a chronically-infected male infected through sex with men, aged 40 years and with CD4 600 cells/mm^3 at ART stop.
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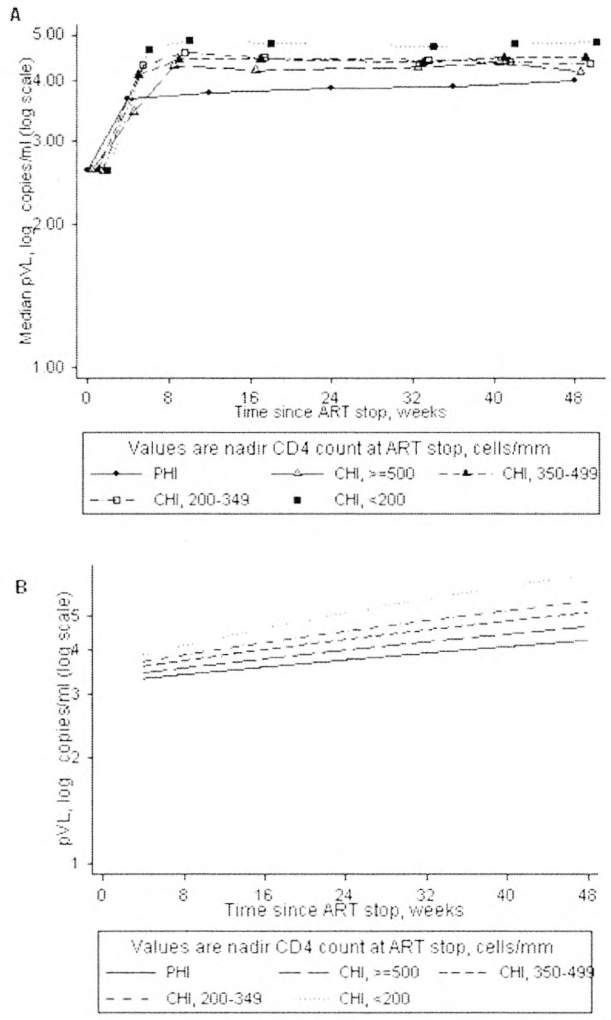

Figure 2. pVL after ART stop in primary (PHI) and chronic HIV infection (CHI), with CHI participants categorised by nadir CD4 count. a. median (IQR) pVL up to 48 weeks after ART stop. b. predicted pVL over 4–48 weeks after ART stop, based on a representative participant (male infected through sex between men, aged 40 years and CD4 count 600 cells/mm^3 at ART stop; values in brackets are the 95% CI). CI = confidence intervals, IQR = interquartile range, pLV = plasma viral load.
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weeks of therapy reduced proviral HIV-1 DNA to levels comparable to those seen in long-term non-progressors whilst, although levels were also reduced in chronic infection, they remained significantly higher than in PHI and long-term non-progressors [13]. This was supported by others reporting evidence for decay of the reservoir in patients who initiated ART early in infection [14] and a significant reduction in its size in those initiating ART early, compared to chronic, infection [15]. However, others quantifying the viral reservoir in treated PHI participants reported that, although a reduction in reservoir size is observed after even short-course ART initiated in PHI, complete abolition of viral replication is not achieved and viral reservoir may be re-expanded even after short-term rebound of viraemia [16].

As the majority of studies examining short-course ART in PHI are observational in nature, the reason for starting or stopping therapy may be related to prognosis. In our analysis, the protocol-indicated ART cessation in both trial populations minimises the effect of this potential source of bias, although this study has some limitations. It was not possible to adjust for ART duration, which was longer for the chronically-infected compared to PHI participants, or for ART class. It is also possible that some SMART participants may have initiated ART in primary infection, although this information is not captured. Our analyses, restricted to the chronically-infected participants only, however, indicated that those previously on NNRTI-based regimens had lower week 4 pVL rebound compared to those on other regimens. Since a greater proportion of chronically-infected, compared to PHI participants, were previously on NNRTI-based regimens, adjustment for ART class would have only served to augment the differences reported here between the groups. Longitudinal analysis of both populations is also subject to bias due to informative censoring, in particular due to exclusion of data for individuals who re-initiated ART. However, since a higher proportion of chronically-infected compared to PHI participants reinitiated therapy (32% versus 9% before week 48), the results presented here are likely to be an underestimate of the difference between the two populations. Although pVL assays varied according to location, it is unlikely, given the pVL ranges in these analyses, that use of different commercial pVL assays would significantly affect the results.

In both trials, pVL was not measured until 4 weeks following treatment interruption. Although PHI participants were not observed to rebound to pre-ART pVL levels until a median of 50 weeks, the pVL levels may have been greater before week 4. Earlier and more frequent testing would give a better indication of immediate viral dynamics following ART cessation. The move in the HIV prevention field to explore a universal "test and treat" strategy [9,17–18] is currently receiving much scientific and advocacy interest. Although mathematical models are encouraging, the effectiveness of such an approach will depend on sustained adherence to therapy. Transmission risk has been shown to be higher in those with pVL>1500 copies/ml [5,19]. The data presented in our analysis show that, irrespective of disease stage and nadir CD4 count, the level of rebound viraemia on stopping ART in the vast majority of individuals reaches a level above which transmission can occur. Targeting individuals with ART during PHI could have a marked impact on HIV transmission [20], but it is crucial that strategies investigating the use of ART as transmission prevention examine the consequences of ART discontinuation and viral rebound on onward transmission. In addition to the impact of pVL on transmission, the sexual behaviour of those individuals critically impacts their transmission risk at a population level [21]. In the SMART trial, individuals did not reduce high-risk sexual behaviour despite treatment interruption and detectable pVL [22]. This was not investigated in SPARTAC. However, in a recent study looking at onward HIV transmission amongst 47 individuals treated in PHI who stopped ART, there were at least five new primary infection events originating from these persons within 16–61 weeks after stopping early ART [23].

This analysis provides estimates for the viral rebound following cessation of ART initiated in PHI or chronic infection, and may inform mathematical models evaluating the potential population effect of universal treatment on HIV incidence for individuals stopping ART. The demonstrated differences in viral load dynamics following ART cessation between PHI and chronic infection indicate that the consequences of treatment interruption may differ, potentially reflecting differences in immunological status, HIV activation and reservoir size. This analysis supports

the necessity for sustained virological suppression to limit onward transmission risk if a "test and treat" approach is to deliver a sustained population level effect on HIV incidence.

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We thank the participants of the SPARTAC and SMART trials

SPARTAC Trial Investigators

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Conceived and designed the experiments: EH SF AB KP FE. Performed the experiments: EH FE. Analyzed the data: FE KP AB. Contributed reagents/materials/analysis tools: DC GT MS CP JO JW SF. Wrote the paper: EH FE. Contributed to subsequent drafts and approved the final version: KP SF JO DC MS JW MM CP AB GT.

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