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

RICHARD ROE, ET AL., PLAINTIFFS, v. MARK T. ESPER, ET AL., DEFENDANTS.	CIVIL ACTION NO. 1:18-cv-01565
NICHOLAS HARRISON, ET AL., PLAINTIFFS, V. MARK T. ESPER, ET AL., DEFENDANTS.	CIVIL ACTION NO. 1:18-CV-00641

COMBINED REPLY IN SUPPORT OF PLAINTIFFS' MOTIONS FOR SUMMARY JUDGMENT AND OPPOSITION TO DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

I. INTRODUCTION

As 160 pages of briefing demonstrate, this case is ripe for summary judgment in Plaintiffs' favor. Defendants again argue that the Court is unable to review their decisions to refuse Sgt. Harrison a commission and to discharge Airmen Roe, Voe, and other similarly-situated Airmen solely because they have HIV. Defendants are again wrong that their actions evade judicial review. Defendants are bound by the U.S. Constitution and the Administrative Procedures Act (APA), which place limits on the authority and discretion they may exercise, as this Court has already ruled.

Defendants then attempt to justify their policies and decisions regarding deployment, retention, and commissioning of service members living with HIV based on a raft of factual information and opinion suggesting that HIV may present certain unquantifiable, but admittedly low, risks of adverse consequences. But a careful examination of undisputed facts shows that the Defendants demand zero risk when it comes to HIV. To mute facts that Defendants find unfavorable to their narrative, they contend that many of their own officers and witnesses are not authorized to speak on the issues upon which they testified. However, even without such testimony, Plaintiffs' experts' undisputed testimony and sources upon which they rely establishes the extremely low risks presented by all of the scenarios Defendants identify.

Defendants' concern that Plaintiffs seek to supplant military judgment about acceptable risk levels when it comes to HIV for that of their own (or that of the Court) is misplaced. Plaintiffs instead show that Defendants' restrictions on service people living with HIV are not rational or grounded in modern medical science. While nothing in life is entirely risk-free, the military accepts similar or higher levels of risk in deploying those who are not living with HIV and provides other deployed service members with the same or a higher level of support and medical care as service members living with HIV would need.

Because the undisputed facts demonstrate that Defendants' purported justifications for their restrictions on the service of people living with HIV are not rational, Plaintiffs are entitled to summary judgment and the relief they request. Moreover, the Air Force cannot justify its about-face regarding the discharge decisions for Airmen living with HIV. The undisputed facts show that the Air Force's re-interpretations of DoD instructions and its own regulations are contrary to the APA and should be reversed.

II. PLAINTIFFS' RESPONSES TO DEFENDANTS' STATEMENT OF UNDISPUTED FACTS

As an initial matter, all opinion testimony from Lt. Col. Jason Blaylock should be excluded under Federal Rule of Civil Procedure 37. Though Lt. Col. Blaylock was not disclosed as an expert witness, Defendants submitted a declaration on summary judgment in which he offers numerous opinions regarding HIV and the purported impacts of deploying service members with HIV. *See* Defs.' Ex. 36, Blaylock Decl.¶¶ 5-13, 17, 19-20, 23, 26-38. While several of Lt. Col. Blaylock's opinions are supported by nothing other than his thoughts and beliefs on the subject (*see, e.g.*, ¶ 37, regarding the risks during a mass casualty event), there are also several articles attached upon which Lt. Col. Blaylock has purportedly relied in forming some of these opinions.

Because Lt. Col. Blaylock was not disclosed as an expert, Plaintiffs were denied the opportunity to properly prepare for and depose him, to ask questions about the articles on which he purportedly relied in forming some opinions, and to otherwise probe the validity of those opinions. Defendants should not be permitted to offer on summary judgment an expert report in the guise of a declaration from a witness who was never disclosed as an expert.[1] *See Campbell v.*

[1] These are very different circumstances than presented by the testimony of Dr. Danaher, which Defendants moved this court to exclude. Plaintiffs rely not on a declaration but on the deposition

United States, 470 F. App'x 153, 156 (4th Cir. 2012) ("[T]he Federal Rules impose an 'automatic sanction' of exclusion of a party's expert witness for failure to adhere to the expert witness requirements set forth in Rule 26(a)[.]"). If this testimony is not excluded altogether, Plaintiffs request that the opinions offered be accorded little to no weight, particularly those that are *ipse dixit*.[2] *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.")

7. Though AMSWG must consider the five listed policy criteria to determine if a condition is disqualifying for service, AMSWG handled HIV differently. [redacted]

8. The third criteria makes clear that the accessions standards are designed to ensure the individual is "medically capable of satisfactorily completing required training and initial period of contracted service[,]" which is approximately 8 years, not an undefined "lifetime" of service. PSUF ¶ 35; Ex. 65, Ciminera Dep. 106:5-12; Defs.' Ex. 18, Ciminera Dep. 232:23-233:3.

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testimony of Dr. Danaher, a deposition at which opposing counsel had the opportunity to object and to ask questions of their own.

[2] Similarly, Lt. Col. Cron and Dr. Peel offer opinions in their declarations that they have not been qualified to present in this litigation. *See* Defs.' Ex. 26, Cron Decl. ¶ 30 ("The nature of expeditionary operations may present a meaningful risk of accidental HIV-transmission through blood-to-blood contact."); Defs.' Ex. 53, Peel Decl. ¶ 28 ("It is possible for HIV to develop resistance, over time, to an ART regimen—even in patients who take their medications consistently.") Those opinions are also *ipse dixit*. Perhaps recognizing this, Defendants have not cited to these paragraphs in these declarations. Nonetheless, to ensure a clean record, Plaintiffs request that they be struck, both because they violate FRCP 37 and because they are irrelevant.

9. This is an opinion, not a fact, that stands at the heart of this case. Based on undisputed facts, Plaintiffs demonstrate throughout their opening brief why this opinion is wrong.

13. This statement is irrelevant because service members with HIV who meet certain health thresholds should not require a waiver to deploy.

17. For 30 years, the Air Force retained Airmen living with HIV despite the categorical bar to their deployment. PSUF ¶¶ 16, 49.

20. The Air Force's application of the world-wide deployability criteria is selective. If the Air Force were applying the deployment criteria as written, it would involuntarily separate all Airmen with HIV and, in fact, all Airmen who require a waiver to deploy. *See* Ex. 12, DoDI 1332.18, Encl. 1, App. 2 at 31; PSUF ¶ 44 ("Whether the Service member is deployable individually or as part of a unit, with or without prior notification, to any vessel or location specified by the Military Department.").

21. The testimony regarding the contents of status of forces agreements is from individuals who have never seen them. Ex. 66, Shell Dep. 254:10-16, 269:1-19; Ex. 40, Cron Decl. ¶ 32; Defs.' Ex. 21, Cron Dep. 197:11-198:8.

22. Defendants have cited no country's laws that prohibit someone living with HIV to be placed there as a part of a foreign military.

23. The testimony cited regarding the contents of status of forces agreements lacks foundation, as it is from an individual who has never seen them. In fact, after receiving "feedback from another governmental agency" that health care facilities in some host nations may refuse to treat HIV-positive patients, the CENTCOM waiver authority decided not to confirm the report because "confirming it would require individual review of the Status of Forces agreements in place between a given nation and the United States." Ex. 40, Cron Decl. ¶ 32. In

addition, speculation regarding potential discrimination by a foreign actor does not justify government-sponsored discrimination against U.S. citizens.

26. The cited criterion actually contemplates worldwide deployability (to "any vessel or location") without a waiver ("with or without prior notification"). Ex. 8, DoDI 1332.18 App. 2 Encl. 3 § 4(a) at 28. Even if this criteria regarding worldwide deployability is in fact narrowed to consider only CENTCOM or other contingency deployments, its application to all Airmen living with HIV would result in their involuntary separation.

28. In 2018, the Air Force did not "determine" but decided, over the objections of its own infectious disease specialists, that its 30-year practice of returning Airmen with HIV to service in line with AFI 44-178 conflicted with language in DoDI 6485.01 that was revised slightly in 2013. PSUF ¶¶ 16, 49, 79.

29. To the extent that this statement claims the SAFPC first learned at this 2017 meeting that CENTCOM was unlikely to grant waivers for HIV, it is not supported by the declaration cited. CENTCOM has never granted a waiver for HIV. PSUF ¶ 54. Further, the CENTCOM waiver authority delegated authority to the services (in this case, the Air Force) to determine medical waivers for deployment to CENTCOM for members of that Service. *See* Ex. 74, Cron Dep. 24:8-26:6, 37:21-39:2.

34. The only "other potentially negative information" regarding Harrison's suitability for appointment was a perception that Harrison had not disclosed acquisition of a sexually transmissible infection (STI) to Army medical personnel. Harrison shared this information with the doctor directly (as evidenced by the Army's knowledge of the STI). PSSUF ¶ 105. While this alleged non-disclosure is irrelevant to the matter before this Court, it is clear Defendants are attempting to set up a basis to deny Sgt. Harrison a commission on other grounds. Any alleged

violation of "safe sex orders," which are also outdated and unsupported by current science, would be an impermissible basis on which to deny Sgt. Harrison's application for a commission.

35. The Army DCS G-1 chose not to endorse the request and not to route it to the DoD for it to consider relieving the Army from the minimum requirements of DoDI 6485.01.

36. *See* Plaintiffs' response to Defendants' Fact No. 37. No age waiver should be necessary, because a person between 18 and 64 years of age is eligible for appointment as an officer in the National Guard. *See* 32 U.S.C. § 313(b).

37. Those who pre-selected Harrison for the open position in the DC National Guard (who were unaware of his HIV status) viewed obtaining a commission for Harrison as a mere formality; in fact, they informed Harrison's commanding officer, Captain Jeremiah Harvey, that he likely would commission as a captain based on his extensive experience in the Army. Defs.' Ex. 28, Harrison Dep. 182:3-184:21.

38. The unit Harrison "wished to join" was not overstrength at the time of his application; in fact, he had been pre-selected for an open billet. Defs.' Ex. 28, Harrison Dep. 182:3-184:21.

40. Plaintiffs dispute this statement to the extent it attempts to turn Roe's and Voe's HIV-positive status into more than one basis for their discharge decisions. The other factors identified are relevant only in conjunction with HIV status, making it the sole basis for these decisions.

43. Harrison, Roe, and Voe have all experienced intentional discrimination (*i.e.*, disparate treatment) based on their HIV status in the form of policies that prevent them from deploying and/or commissioning. PSUF ¶¶ 34-46. Roe and Voe's processing through the DES is similarly tainted by disparate treatment based on HIV status. PSUF ¶¶ 10-12, 14-16. Plaintiffs understood the questions to be asking about interpersonal acts of discrimination.

44. People living with HIV are able to maintain a suppressed viral load with approximately 85% adherence to their medications. PSUF ¶ 62; Ex. 67, Hardy Dep. 78:11-79:1, 83:13-83:22, 117:12-118:5, 233:18-243:1, 257:5-257:25, 260:18-260:21.

45. Nearly all—99.8%—of active duty service members studied had achieved viral suppression, indicating they had properly adhered to their medication. PSUF ¶¶ 59, 65; *see also* Defs.' Ex. 36, Blaylock Decl. ¶ 23 (citing a newer study with comparable results). Though, as Lt. Col. Murray notes, a newly-diagnosed individual may not respond to the *first* medication regimen offered, there is almost always a simple regimen that will produce durable viral suppression if taken as prescribed. PSUF ¶ 61; Ex. 43, Hendrix Rep. ¶¶ 52, 61.

46. Viral load testing after treatment interruption would not be necessary if the service member's medications were lost, destroyed or ran out before resupply, because such testing is not necessary if the healthcare provider is relatively certain the medication was not taken intermittently before it was stopped altogether. PSUF ¶ 63; Ex. 67, Hardy Dep. at 128:23-130:19; Ex. 20, Hardy Rep. ¶18. The standards call for viral load testing to ensure the regimen is still effective because self-report on adherence is of questionable reliability in the general population.

47. The precise timing of viral rebound is not relevant to this litigation, because viral rebound has no significant effects on the health of the individual or the risk of transmission through the types of exposures at issue here. PSUF ¶¶ 63, 85-87.

48. True but misleading. As discussed above, intermittent adherence to an ART regimen may lead to resistance to one or more of the medications in that regimen. If it ever occurs, the development of viral resistance after a complete halt to medications is extremely rare. Ex. 67, Hardy Dep. 128:23-130:19; Ex. 20, Hardy Rep. ¶ 18.

49. The precise level of adherence is uncertain, but studies show that approximately 85% adherence is sufficient. PSUF ¶ 62; Ex. 67, Hardy Dep. 83:13-83:22, 117:12-118:5. Newer ART regimens are generally more forgiving in terms of minimum adherence required. Ex. 20, Hardy Rep. ¶ 19. Missing roughly one dose per week is the same as missing between 4-5 doses a month or 13-14 doses every three months. Ex. 67, Hardy Dep. 257:5-257:25.

50. Plaintiffs do not dispute that deployment conditions are highly variable. However, the opinions presented regarding the purported effect of deployment on HIV medication adherence are *ipse dixit*. Studies show that those who establish a pattern of adherence to their HIV medications generally maintain that adherence. Ex. 45, Hendrix Rbtl. Rep. ¶ 9. If anything, highly disciplined individuals, like service members, would be expected to maintain better adherence than members of the general public. Defs.' Ex. 36, Blaylock Decl. ¶23.

51. Resupply of medication after it is lost or destroyed would occur through a mail-order pharmacy and is not expected to be "readily available from military medical supplies." Ex. 35. Blaylock Dep. 99:7-99:22. As discussed above (PRDSF ¶ 46), viral load testing upon resumption of treatment is not necessary if treatment interruption has not been intermittent.

52. The type of side effects and comorbidities to which Defendants are referring are generally asymptomatic and develop over a long period of time; they are not ones that suddenly appear or produce symptoms during the span of a deployment. Ex. 43, Hendrix Rep. ¶ 65, Ex. 45, Hendrix Rbtl. Rep. ¶ 3; Ex. 20, Hardy Rep. ¶ 10.

53. All medications have some side effects. With respect to HIV medications prescribed today, most patients report minimal to no side effects. Ex. 20, Hardy Rep. ¶¶ 10, 20. Those who report more severe and lasting side effects are switched to different medications during the initial phase of treatment. Ex. 45, Hendrix Rbtl. Rep. ¶ 3.

54. There is no scientific support for these statements. Mild dehydration, lack of sleep, and lack of "regular" meals are not known to aggravate any side effects produced by HIV or HIV medications. Ex. 43, Hendrix Rep. ¶ 64; Ex. 24, Wiesen Dep. 92:13-21. A person with HIV needs to remain approximately 85% adherent to their medications to avoid viral rebound, but disruptions to the medications do not "aggravate" side effects. PSUF ¶ 62; PRDSF ¶ 49.

55. Plaintiffs do not dispute that there is some evidence of a slightly higher prevalence of these chronic conditions (*i.e.*, comorbidities) among people living with HIV than in the general population. Ex. 20, Hardy Rep. ¶ 20. However, it is not clear whether there is a correlative or causal relationship between them, and these conditions develop slowly over a long period of time and therefore are seen primarily in those aging with HIV. Ex. 20, Hardy Rep. ¶ 20; Defs.' Ex. 33, Hardy Dep. 157:11-159:14. They are not conditions that are likely to develop to the point of affecting a service member's ability to perform their duties even during very long term service and almost certainly would not do so during a period of initial service.

56. Symptomatic neurocognitive impairment is relatively rare among people with HIV in the current treatment era and tends to occur in those who have been living with HIV for many years. PSUF ¶¶ 80-82; Ex. 20, Hardy Rep. ¶ 28; Ex. 68, Hendrix Dep.[3] 263:22-269:9.

57. Plaintiffs agree that neurocognitive impairment in people living with HIV is not well-documented or understood. *See* Ex. 20, Hardy Rep. ¶ 28. Defendants' own study and others demonstrate that those who are diagnosed and placed on treatment in a timely matter have no greater incidence of neurocognitive impairment than those who do not have HIV. *Id.*; Ex. 2,

[3] The parties inadvertently referenced different versions of Dr. Hendrix's deposition transcript. The testimony is identical, but the number of lines of text per page differs. The Court should review the deposition exhibits each party submitted to ensure the pincites in that party's brief tie the correct testimony.

2018 Report at 20. Defendants also admit that the slightly higher prevalence of mild neurocognitive impairments among people with HIV in the civilian population may be due to substance abuse or depression. Defs.' Ex, 36, Blaylock Decl. ¶ 11. By definition, asymptomatic neurocognitive impairment will have no noticeable effect on the service member's ability to perform their duties. Ex. 43, Hendrix Rep. ¶ 65.

58. Testing should not be necessary, except for the rare instance of the most serious form of HIV-associated neurocognitive impairment. Ex. 43, Hendrix Rep. ¶ 65.

60. Because Defendants did not include cost of treatment in response to interrogatories seeking the reasons underlying the challenged policies, PSUF ¶ 29; Ex. 23, Harrison Defs.' Objs. and Resps. to Pls.' First Set of Interrog. to Defs.' Nos. 1- 23, Interrog. 17 and 18, this testimony and the arguments based upon it should be excluded under FRCP 37. Furthermore, the DoD is already paying for ART for the 1800 service members with HIV currently serving. Refusing to deploy them does not change the costs of their treatment. PSUF ¶ 57.

61. HIV can be transmitted via the exposures described, but this statement does not describe the per-act risks for each of these exposures.

62. By carefully phrasing this statement, Defendants make it seem like Dr. Hendrix has undermined his own opinion regarding the effects of a suppressed viral load on "non-sexual" transmission risks. But all non-sexual transmission risks cannot be lumped together in this way. Dr. Hendrix's opinions are focused on the types of exposures that could occur in a deployed setting, which do not include breastfeeding. Plaintiffs' expert has merely stated the irrefutable principle that a very small amount of virus in the body fluid serving as a potential route of transmission greatly reduces the level of risk from the baseline risk for that type of exposure. PSUF ¶ 85; Ex. 43, Hendrix Rep. ¶¶ 48, 50, 76. Because there are no documented cases of

transmission through wound-to-wound contact in the military or civilian contexts, risk of transmission via this route is theoretical at baseline and is further reduced by an undetectable viral load. PSUF ¶ 85; Ex. 3, Cron Dep. 199:23-200:1; Ex. 66, Shell 30(b)(6) Dep. 64:4-14.

64. A person can have a detectable viral load and still be incapable of transmitting HIV. Current testing technologies detect HIV with as low as 20 copies/ml. Studies have demonstrated that people with viral loads of less than 400 copies/ml are incapable of transmitting HIV sexually. Ex. 68, Hendrix Dep. 125:12-127:4, 132:7-133:17.

67. While Defendants assert it is "possible" that a donation "might" be provided by a service member experiencing viral rebound, because of the "possibility" of unreported non-adherence, this is a very remote possibility. Before transmission could occur, this would also need to be one of the instances in which the "walking blood bank" was activating donors who were not prescreened and the results of the HIV testing were not available prior to use of the blood. Ex. 43, Hendrix Rep. ¶ 68-69; Ex. 45, Hendrix Rbtl. Rep. ¶ 11. Defendants' witnesses' opinions that service members may succumb to peer pressure to donate are *ipse dixit*.

68. The risk of HIV transmission through blood donation with an undetectable viral load is not known, but it may still present a non-negligible risk. Ex. 45, Hendrix Rbtl. Rep. ¶ 11. Plaintiffs agree that HIV-positive people with an undetectable viral load should not donate blood.

71. There are various factors that could make a person ineligible to donate blood, and the ability to donate blood is not a qualification for deployment. PSUF 98.

72. These witnesses have not been qualified as experts to provide opinion testimony on this subject. Furthermore, the "difficult choices" described in the quoted testimony involve disobeying a direct order not to donate blood, and Defendants are asking the Court to determine that it is reasonable to conclude such orders will not be followed.

73. *See* response to Def. Fact No. 72. Furthermore, Col. Murray assumes service members will not follow direct orders, and that such orders and the HIV counseling statement are insufficient. His opinion is *ipse dixit* and insufficient to create a genuine dispute of fact. It also does not consider the service member's desire to protect other service members from HIV.

74. *See* Plaintiffs' responses to Def. Fact Nos. 72 & 73.

75. The witnesses had no first-hand knowledge of the events, as such it is inadmissible hearsay. Ex. 69, Lute Dep. 110:13-111:9; Defs.' Ex. 35, Blaylock Dep. 109:10-110:11. Even if considered, it is irrelevant because the blood was donated in a civilian setting where it was known it would be tested for HIV prior to its use. *Id*.

78. As an initial matter, though "potential communicability" is mentioned in the 2014 and 2018 Reports to Congress (which serve as Defendants' complete reasons for the policies at issue) transmission in the context of providing medical care is mentioned only in the context of one service member providing "buddy-aid" to another. The risk of HIV transmission to combat surgeons and physician assistants is not among the justifications offered in the Reports. *See* PSUF ¶ 29; Ex. 2, 2018 Report at 9. For this reason, Plaintiffs ask the Court to exclude evidence on this subject and the arguments based on it under FRCP 37. Furthermore, the types of procedures performed by various types of caregivers are very different. *See* Defs.' Ex. 53, Peel Decl. ¶¶ 59-61. While all extremely low, the risks in these various contexts are not the same. *See* PSSUF ¶¶ 106, 107 (describing the category of procedures that are exposure-prone).

79. Plaintiffs do not dispute that the incidence of exposure may increase in providing combat medical care, but disagree that the risk of transmission from a particular type of exposure is increased based on the setting. A needle-stick is a needle-stick, regardless of where it occurs. Risk of transmission from an HIV-positive caregiver to a patient is not among the justifications

Defendants offered for the challenged policies. However, the Society of Healthcare Epidemiologists of America issued guidelines in 2010 stating that health care workers living with HIV could perform most procedures regardless of their viral load and could perform "exposure-prone, invasive procedures" as long as they maintained a viral load of less than 500 copies/ml. PSSUF ¶¶ 106, 107. The reverse would be true as well: that a patient with an undetectable/suppressed viral load does not present a significant risk to their caregiver.

80. Though the first statement may be true for medics and those providing buddy-aid, Defendants provide no support for the existence of open wounds and abrasions for surgeons and physicians' assistants. There has never been a documented transmission of HIV through wound-to-wound contact, in the military or civilian context. PSUF ¶ 85; Ex. 24, Murray Decl. ¶¶ 51; Ex. 68, Hendrix Dep. 92:14-93:18; Ex. 3, Cron Dep. 199:23-200:1; Ex. 66, Shell 30(b)(6) Dep. 64:4-14. Whatever the volume of blood from an injury, only the amount of blood that is able to find its way to the bloodstream of the HIV-negative person is relevant.

82. The reduced use of universal precautions, such as sterile gloves, and less than rigorous infection control procedures raise the level of risk of all types of infections. HIV actually is less infectious than other viruses and is much less of a threat than bacterial infections in such settings. *See* Defs.' Ex. 22, Murray Dep, 139:7-17; Ex. 68, Hendrix Dep. 314:10-316:21. This is another example of the stricter standard that is applied to HIV than other risks.

83. Because service members with HIV make up less than .1% of the members of the military (and less than .4% of the general population of the U.S.), the chances a combat surgeon will be exposed—even if needlestick and similar injuries are much more common in combat medical care—is extremely low. Ex. 43, Hendrix Rep. ¶ 69. Removal from the field for viral load testing (and initiation of treatment) would only be required if the surgeon subsequently

seroconverted, which could be evaluated in the field using a simple HIV antibody test. Defs.' Ex. 46, Taylor Dep. 130:10-131:21.

84. Defendants again point to something that "may" happen but make no attempt to quantify the risk. However often it "may" happen, the risk of transmission from a patient with an undetectable viral load is "thought to be very low" and, in any event, is less than .23%, even in the absence of PEP. PSUF ¶ 86; Defs.' Ex. 54, 2018 PEP Guidelines at 10-11.

87. Lt. Cron himself admits that the military deploys many people who require daily medication ("it's hard to find somebody who doesn't take medication for something"), which is all that a service member with HIV needs to remain healthy. PSUF ¶ 61; Ex. 43, Hendrix Rep. ¶¶ 52-53; Ex. 3, Cron Dep. 111:14-16; Ex. 67, Hardy Dep. 82:17-83:4.

89. Under global health standards of care, transportation of a service member for HIV-related monitoring care should not be necessary on a deployment as long as 15 months. PSUF ¶¶ 67, 68; Ex. 45, Hendrix Rbtl. Rep. ¶ 5.

92. As Defendants discuss in DSUF 92, they will always need to maintain supply lines to forward troops, even in future conflicts. Regarding transportation of service members over long distances, see Plaintiffs' response to DSUF 89.

93. An HIV diagnosis should have no impact on the type of medical services that are provided in the field. Ex. 43, Hendrix Rep. ¶¶ 59-60.

94. Viral load testing is not required on deployments as long as 15 months. *See* PRDSF 89. Viral rebound will occur only if the service member stops taking their medications. Ex. 20, Hardy Rep. ¶ 18; Defs.' Ex. 36, Blaylock Decl. ¶ 30-31. After a servicemember is on a stable regimen, they should not experience symptomatic side effects. Ex. 43, Hendrix Rep. ¶ 64.

96. These are the optimal standards of care for patients in the U.S. PSUF ¶ 96. The World Health Organization recommends monitoring every 12 months after achieving viral suppression. PSUF ¶ 67. With 99.8% viral suppression, members of the military do not need viral load monitoring as frequently as less-disciplined members of the general population. PSUF ¶ 59, 65.

97. This is an opinion, not a statement of fact. Under global health standards of care, HIV-related monitoring care should not be necessary on a deployment as long as 15 months. PSUF ¶ 67. Furthermore, if it was needed, the undisputed facts demonstrate that monitoring care could be made available and would not be resource intensive. PSUF ¶¶ 70, 73-76.

98. Viral load testing is not required on deployments as long as 15 months. *See* PRDSF 89. The cited testimony does not establish that blood samples must be "tested within days to produce reliable results." It is true that the blood sample must be processed and placed into a cold chain for transportation. PSUF ¶ 72. Viral load tests are not positive/negative, and the results are never "dangerous" (as a false negative HIV test might be).

100. Under global health standards of care, HIV-related monitoring care should not be necessary on a deployment as long as 15 months. PSUF ¶ 67; PRDSF 89.

101. PEP guidelines for occupational exposures of health care workers are very cautious and aim to further minimize even the very lowest of risks. PSUF ¶ 87. They are also designed for a well-resourced medical facility in the U.S., where ease of access to PEP makes even a very small incremental benefit worthwhile.

102. Given that service members with HIV make up less than .1% of the military, and that a healthcare exposure requires an injured service member with HIV and a deep penetrating wound to the surgeon, the need for PEP will remain very low. Ex. 43, Hendrix Rep. ¶ 69.

103. An "exposure" to a large quantity of blood refers to the amount of blood finding its way through a portal and into the provider's body. Also, the PEP Guidelines are referring to a deep injury to the provider, not to the patient. Defs.' Ex. 54, 2018 PEP Guidelines at 10.

104. The "2018 PEP Guidelines" were actually published in 2013, and the relevant sections have not been updated. Ex. 4, 2013 PEP Guidelines at 875 (US00004427). They do not mention viral load testing as part of follow-up. Defs.' Ex. 54 ("PEP Guidelines"), at passim. They also do not contemplate "treatment," but rather monitoring for potential side effects or drug interactions. The testing to which they refer is a regular HIV antibody test and routine blood work, not viral load testing. Defs.' Ex. 54, PEP Guidelines at 26-28. Col. Murray's assertions regarding removing the exposed member from the theater seem to be based on a misunderstanding regarding the type of follow-up testing suggested by the Guidelines.

III. PLAINTIFFS' SUPPLEMENTAL STATEMENT OF FACTS IN OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

105. [redacted]

106. In 1991, the Centers for Disease Control and Prevention (CDC) issued guidelines for preventing the transmission of HIV from HIV-positive health care workers to their patients during exposure-prone invasive procedures. *See* Ex. 71, CDC, Recommendations for Preventing Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Patients During Exposure-Prone Invasive Procedures (retired), 40 MMWR 1-9 (July 12, 1991)

https://www.cdc.gov/mmwr/preview/mmwrhtml/00014845.htm. In those guidelines, the CDC described exposure-prone invasive procedures as surgical procedures involving the "digital palpation of a needle tip in a body cavity or the simultaneous presence of the [health care worker's] fingers and a needle or other sharp instrument or object in a poorly visualized or highly confined anatomic site." *Id*. These guidelines have since been retired.

107. The CDC retired its 1991 guidelines (and has not issued new ones) after the Society for Healthcare Epidemiologists of America (SHEA) issued guidelines on the same subject in 2010. *See* Ex. 72, SHEA Guideline for Management of Healthcare Workers Who Are Infected with Hepatitis B Virus, Hepatitis C Virus, and/or Human Immunodeficiency, 31 Infection Control and Hospital Epidemiology 203-230 (March 2010), https://www.shea-online.org/images/guidelines/BBPathogen_GL.pdf. In its guidelines, SHEA "recommends that an HIV-infected provider who has a viral burden of less than $5x10^2$ GE/mL [500c/ml] not be excluded from any aspect of patient care, including the performance of Category III procedures." *Id*. at 204. Category III procedures defined as those "for which there is definite risk of bloodborne virus transmission or that have been classified previously as 'exposure-prone'[,]" and that includes trauma surgery. *Id*. at 206, Table 2.

IV. REPLIES TO DEFENDANTS' RESPONSES TO PLAINTIFFS' STATEMENT OF UNDISPUTED FACTS

To conserve space, Plaintiffs reply below only to Defendants' responses to Plaintiffs' undisputed facts that warrant a reply; the lack of a reply regarding a particular fact indicates that Plaintiffs are standing on their original statement of fact without further comment. Also, citations back to the same statement of undisputed fact are not included.

8. **Dispute not material**. Those who pre-selected Harrison for the open position in the DC National Guard (not knowing he was HIV-positive) viewed obtaining a commission as a

mere formality; in fact, he was told he would commission as a captain based on his extensive experience in the Army. Ex. 73, Harrison Dep. 184:8-186:21.

25. **Dispute not material**. Over time, the increasing sensitivity of viral load tests has lowered the number below which the virus is considered "undetectable." *See* Defs.' Ex. 53, Peel Decl. ¶ 25; Ex. 68, Hendrix Dep. 133:18-135:5; *see also* PRDSF ¶ 64.

26. **No dispute.** Plaintiffs were not referring only to medications introduced in the last few years. PSUF ¶ 62.

28. **Dispute not material**. Whether people living with HIV in general are marginalized or lacking in political power are addressed in the suspect classification inquiry, not whether the plaintiffs in this case are. *Roe* ECF 268 at 41.

42. **No dispute**. HIV is the only condition requiring the approval of the Combatant Command *surgeon*, and the only condition for which this requirement is specified in the listing (*see* Ex. 29 DoDI 6490.07 Encl. 3, at 11, § e(2)).

44. **No dispute**. Defendants are quoting a different section of the regulation.

47. **No dispute**. Defendants *submitted* the declaration from Lt. Col. Lute in which she makes the statement they now try to disclaim. Ex. 34, Lute Decl. ¶ 4. She merely answered questions about the same statement at her deposition. Ex. 35, Lute Dep. 193:17-196:1.

50. **Dispute not material**. Defendants have admitted elsewhere that a deployment waiver for a service member with HIV would be highly unlikely. Ex. 40, Cron Decl. ¶ 11, Ex. 74, Cron Dep. 24:24-26:6; Ex. 3, Cron Dep. 41:11-15.

56. **No dispute/dispute not material**. Lt. Col. Cron indicated that 15 months was the longest deployment to CENTCOM and did not testify that the "ultimate length of a contingency deployment . . . can exceed 15 months." Ex. 3, Cron Dep. 192:16-24.

59. **No dispute**. [redacted]

61. **No dispute.** Plaintiffs did not state that all people who need daily medication are permitted to join the military; rather, Plaintiffs provided specific examples of those who are. The rest of the assertions are supported by written policies that were accurately quoted.

63. **No dispute**. Nothing to which Lt. Col. Blaylock testifies is inconsistent with the statement made in Dr. Hendrix's rebuttal report: resistance to ART is "less likely" to develop from treatment interruption than from intermittent cessation (as Lt. Col. Blaylock testifies, Ex. 25, Blaylock Dep. 203:18 -204:13); in fact, it is unlikely to develop from treatment interruption (as Dr. Hendrix testifies, Ex. 45 Hendrix Rbtl. Rep. ¶ 8). Similarly, there is support for the proposition that symptoms may not appear for years (Ex. 45, Hendrix Rbtl. Rep. ¶ 7) and nothing Defendants' witnesses say contradicts this. Furthermore, the length of time to viral rebound after treatment interruption is not relevant.

64. **No dispute**. Plaintiffs did not state that all patients with asthma or thyroid conditions are permitted to deploy, and Plaintiffs are analogizing to these conditions regarding a need for medication or assistive device and the potential effects on a person's ability to perform their duties in the event of the loss or destruction of the medication or assistive device. PSUF ¶ 61.

65. **No dispute**. Nothing in Defendants' response contradicts Plaintiffs' statement that for all people living with HIV, the primary purpose of monitoring follow-up (*i.e.*, after achieving viral suppression) is to ensure continued adherence to an ART regimen.

67. **No dispute**. Plaintiffs' statement remains undisputed, because it is not attempting to describe the standard of care currently employed by the military. PSUF ¶ 67.

68. **No dispute**. Defendants provide an opinion, but do not dispute any facts asserted.

70. **No dispute/dispute not material**. Plaintiffs' statement does not discuss the level of training of deployed medical professionals. PSUF ¶ 71. Also, service members with HIV should not customarily need follow-up monitoring care on deployments up to 15 months. PSUF ¶ 67.

72. **No dispute/dispute not material**. The deposition testimony is accurately quoted. Defendants cannot create a disputed issue of fact by submitting a declaration that attempts to contradict deposition testimony. Even Dr. Peel's new declaration does not say that shipping blood samples may be impossible; in fact, it describes the process by which they could be shipped from a Role 2 medical facility. Defs.' Ex. 53, Peel Decl. ¶¶ 58, 62, 66.

73. **No dispute/dispute not material**. Dr. Peel's deposition testimony is accurately quoted. Defendants cannot create a disputed issue of fact by submitting a declaration that attempts to contradict that deposition testimony.

74. **No dispute/dispute not material**. Dr. Peel's deposition testimony is accurately quoted. Defendants cannot create a disputed issue of fact by submitting a declaration that attempts to contradict her deposition testimony.

75. **No dispute**. Col. Wiesen is the DoD's designee regarding the reasons underlying Defendants' contention that a person living with HIV is not fit or capable of performing their duties in the military, which includes application of the "excessive time lost" criterion in DoDI 6130.03. Ex. 75, Wiesen Dep. 28:6-20.

76. **No dispute**. If HIV monitoring care is necessary on a particularly long deployment, it is not an emergent or time-sensitive need. Like R&R, it could be arranged based on the needs of the military, location of the deployment, the risk of transportation, and as circumstances allow.

86. **No dispute**. [redacted]

[redacted] *see also* Defs.' Ex. 51, Murray Decl. ¶ 51. [redacted]

87. **No dispute**. Defendants do not actually dispute Plaintiffs' experts' characterization of the risks related to occupational exposures for health care workers. PSUF ¶ 87. Plaintiffs cited evidence supporting the extremely low risk and further reduction, to near zero, caused by an undetectable viral load. PSUF ¶ 87. Plaintiffs did not say the risk was eliminated entirely. PSUF ¶ 87. The frequency of occupational exposures does not change the per-exposure risk of transmission.

95. **No dispute**. Plaintiffs agree that this statement does not describe donors who are used if pre-screened donors are not available. But see PSUF 98.

96. **No dispute**. Defendants do not dispute this statement of fact; they merely argue regarding its implications.

98. **No dispute/dispute not material**. In the testimony cited in DSUF ¶ 71, Defendants admit that the inability to donate blood does not make one non-worldwide deployable, but state it may disqualify a member from some missions as part of a small team operating in a remote location. Defs.' Ex. 21, Cron Dep. 108:6-19. If Defendants refrain from assigning others who cannot donate blood to those particular missions, it seems they could refrain from assigning service members with HIV to those missions.

99. **No dispute**. Service members can get tattoos after being screened or while deployed,

and as Defendants' expert acknowledges, people have sex while deployed. DSUF ¶ 64.

100. **No dispute**. The walking blood bank collects and transfuses fresh whole blood. DSUF ¶ 65; *see also* Ex. 40, Cron Decl. ¶ 37.

V. LEGAL BASES FOR PLAINTIFFS' CLAIMS

Defendants' argument that the deployment policies are committed to agency discretion by law is essentially a reboot of their argument for deference to the military, which has been acknowledged and rejected as a basis for ruling in Defendants' favor on these claims by both this Court and the Fourth Circuit. *Roe v. Shanahan*, 359 F. Supp. 3d 382 (E.D. Va. 2019); *Roe v. Dep't of Def.*, 947 F.3d 207 (4th Cir. 2020). This rebooted deference argument is framed this time as whether the APA's waiver of sovereign immunity encompasses the claims at issue in these cases. *Roe* ECF 284, *Harrison* ECF 272, Mem. in Supp. of Defs.' Cross-Mot. for Summ. J. and in Opp'n to Pls.' Mot. for Summ. J. ("Defs.' Br.") at 42. The scope of the APA's sovereign immunity waiver turns on whether there are "judicially manageable standards . . . for judging how and when an agency should exercise its discretion." *Speed Mining, Inc. v. Fed. Mine Safety & Health Review Comm'n*, 528 F.3d 310, 317 (4th Cir. 2008) (quoting *Heckler v. Chaney*, 470 U.S. 821, 830 (1985); *Serv. Women's Action Network v. Mattis*, 320 F. Supp. 3d 1082, 1096-97 (N.D. Cal. 2018) (courts are "uniquely qualified" to perform" a legal analysis of military regulations (quoting *Dibble v. Fenimore*, 339 F.3d 120, 127 (2d Cir. 2003)). Applying essentially the same standard in the context of justiciability and deference, this Court has already determined that these cases are justiciable and that there are manageable standards by which the actions of Defendants may be evaluated under the APA and the Constitution. *Roe*, 359 F. Supp. at 406. The Fourth Circuit agrees. *Roe*, 947 F.3d at 219. Federal courts may accord appropriate deference to the military and nonetheless take action to address legal harms in the type of exceptional circumstances presented by these cases. *Roe*, 359 F. Supp. at 405-06.

Furthermore, Defendants' argument that the APA may not be applied to the substance of the policies underlying the decisions to discharge Roe and Voe—as differentiated from the "procedures" used—finds no support in the law. Establishing policy or rules is considered agency action and is subject to arbitrary and capricious review under the APA. *See, e.g., Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 46 (1983) (holding that the Dept. of Transportation's decision to rescind seatbelt requirements was arbitrary and capricious because, *inter alia*, "the agency was too quick to dismiss the safety benefits of automatic seatbelts"); *Sierra Club v. Dep't of the Interior*, 899 F.3d 260, 293-94 (4th Cir. 2018) (rejecting blanket conclusions as arbitrary and capricious where agency failed to explain likely inconsistencies between facts in the record and the agency's mission). Among the factors considered are whether the agency has "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs contrary to the evidence before the agency, or [offers an explanation that] is so implausible that it could not be ascribed to a difference of opinion or the product of agency expertise." *State Farm*, 463 U.S. at 43. The policies underlying the discharge decisions of Roe and Voe are undoubtedly subject to APA review. *See Roe*, 359 F. Supp. 3d at 411-12; *Roe*, 947 F.3d at 219-20.

To be crystal clear, Plaintiffs' equal protection claims place all people living with HIV on one side of the equal protection equation and all people who do not have HIV on the other side, because that is the line that Defendants draw in their policies. *Harrison*, ECF 1, Compl. for Declaratory and Injunctive Relief ("Harrison Compl.") at ¶¶ 27-34; *Roe* ECF 1, Compl. for Declaratory and Injunctive Relief, ("Roe Compl.") at ¶¶ 34-39, 92-100. Plaintiffs are challenging the categorical bars to their accession and deployment. *Id.* ¶¶ 92-100; Harrison Compl. ¶¶ 71-78. It is true that Plaintiffs demonstrate the irrationality of those categorical bars by pointing out that

all service members with an undetectable viral load for six months and a normal CD4 count—which by Defendants' own admission is the vast majority of active duty service members living with HIV (PSUF ¶¶ 59, 65)—should be able to deploy. PSUF ¶ 49. But in doing so, Plaintiffs are not redefining the group being discriminated against (as Defendants claim in their opposition brief, *Roe* ECF 276 at 1 n.1) or the contours of their equal protection claims.

Defendants argue that Plaintiffs are unable to demonstrate intentional discrimination, but this is patently false and misapplies equal protection doctrine. Defendants' policies explicitly target service members with HIV for adverse treatment, subjecting Harrison, Roe, and Voe to intentional *de jure* discrimination. *See Morrison v. Garraghty*, 239 F.3d 648, 657 (4th Cir. 2001) (noting the prison policy at issue drew a "rather explicit" distinction based on race, which was sufficient on its own to establish intentional discrimination); PSUF ¶ 34 (DoD instruction categorically barring enlistment and commissioning of service members with HIV); PSUF ¶ 40 (DoD instruction resulting in categorical bar to deployment of service members with HIV). As people who met all other eligibility requirements and were trained by the military to serve as members of the Armed Forces, Harrison, Roe, and Voe are similarly situated to service members not living with HIV in all relevant respects. The validity of the classification at issue—and, therefore, the relevance of HIV status while deployed—are not considered at this point in the equal protection analysis, but are instead analyzed through review of Defendants' justifications for its disparate treatment of this group (*see* Argument *infra*). *See City of Cleburne v. Cleburne Living Ctr., Inc.*, 473 U.S. 432, 448-50 (1985). Defendants turn equal protection analysis on its head to argue otherwise.

Although a showing of animus is not necessary for Plaintiffs to prevail, an inference of animus is warranted here. The U.S. Supreme Court has noted that a lack of rational basis for

disparate treatment is sufficient to demonstrate animus for purposes of equal protection. *See Romer v. Evans,* 517 U.S. 620, 632 (1996); *Cleburne*, 473 U.S. at 450. And ignorance regarding the extremely low (or non-existent) risk of HIV transmission in these contexts and deep-seated beliefs about the limitations and deficiencies of service members with HIV *that will not succumb to science or reason* are the definition of bigotry.

VI. ARGUMENT

As in Plaintiffs' opening brief, the argument is set forth in two parts. The first part responds to Defendants' arguments about the categorical bar to the contingency deployment of service members living with HIV, and the second part responds to Defendants' arguments regarding the Air Force's decisions to discharge Roe, Voe, and other service members with HIV.[4]

Two matters, however, are worth addressing at the outset. First, Defendants ground many of their arguments on the fact that HIV is a contagious disease. Technically true, but ultimately a diversion. There is no dispute that the vast majority of service members with HIV are managing the condition in a way that makes it no longer contagious except in the most rare and extreme circumstances. PSUF ¶¶ 59, 65. This indisputable truth—the details of which are further elucidated below—defeats many of Defendants' arguments, including that the accessions standards require that the candidate be "free of contagious diseases *that may endanger the health or safety of other members*." PSUF ¶ 35; Ex. 1, DoDI 6130.03 (emphasis added). Service

[4] Defendants' argument that MMAA lacks standing should again be rejected. Plaintiffs supported MMAA's standing with verified interrogatory responses, sworn depositions, and documentary evidence in response to Defendants' motion to dismiss. The Court considered this evidence barely three months ago and concluded that MMAA had standing. *Roe* ECF 261; *Harrison* ECF 250. Nothing has changed since then. Although standing is subject to review at all stages of litigation, that principle does not defeat law-of-the-case doctrine. *See Baron Fin. Corp. v. Natanzon*, 509 F. Supp. 2d 501, 519-20 (D. Md. 2007).

members with an undetectable viral load do not have a disease that has any likelihood of endangering the health or safety of other members. Second, as a corollary to the first point, it is completely circular to argue that the accessions standards should survive because a person living with HIV is unable to deploy world-wide. The argument stacks one policy on top of another that is already foundationless. The undisputed facts about the deployability of service members with HIV also resolve the challenge to the accessions policy in Plaintiffs' favor.

A. Categorical Policies and Practices Based on a Requirement of Zero Risk Are Not Rational.

As Plaintiffs predicted, Defendants' arguments on accessions and deployment rise and fall on one premise: that it is rational to base a categorical policy and practice on the need or desire for quantifiably *no* risk. Placing the bar that high, though, sets the policies up for failure: a standard that strict is unachievable, and thus irrational. Furthermore, Defendants' evidence of risk—their attempt to show that the unachievable standard is not met—is nothing but hypothesis and theory. Since mere speculation and conjecture are insufficient to defeat (or achieve) summary judgment, Defendants' efforts fail.

1. Speculative risks to the health of deployed service members with HIV fail to create a triable issue.

Though protecting the health of deployed service members is doubtless a legitimate goal, the means of achieving it cannot be irrational. Defendants do not require that the risk to the health of other deployed service members—including service members with other chronic medical conditions—be zero or even near-zero before deploying them. PSUF ¶ 88. It is not rational to impose such a standard upon service members living with HIV. *Roe*, 947 F.3d at 228. Contrary to Defendants' contention, Plaintiffs' argument regarding deployment does not depend on every single service member with HIV maintaining an undetectable viral load or on no chance of adverse consequences while deployed. Rather, Plaintiffs argue that it is not rational for

Defendants to think—without any evidence in support—that a significant number of service members will suddenly stop taking their HIV medication while deployed, or for Defendants to cite non-existent or exceedingly rare consequences of HIV and its treatment as a basis for refusing to deploy all service members living with HIV.

To be clear, the only thing a person with HIV who has already achieved viral suppression needs is to take their medication as prescribed to maintain that viral suppression—and therefore their health. PSUF ¶ 65. Adherence to those medications is required, but it is undisputed that approximately 85% adherence (over the course of a month) is sufficient. PSUF ¶ 62. The Defendants want to characterize that as "strict adherence," but it actually allows for over four missed doses a month. And service members with HIV have an amazing record of success in maintaining viral suppression. PSUF ¶¶ 59, 65. Defendants' attempt to undermine their own data showing that 99.8% of active duty service members diagnosed from 2012–2016 achieved viral suppression falls flat, because excluding an entire class of people based on that 0.2% (who could legitimately be excluded from deployment) is by definition irrational.

Furthermore, Plaintiffs do not dispute that people who stop taking their medication altogether will experience viral rebound; instead, Plaintiffs demonstrate that viral rebound has no consequences in the short term or effect on the service member's deployment. Regardless of the length of time before viral rebound occurs (again Defendants quibble over details that are not material), it is easily reversed and does not lead to viral resistance. PSUF ¶ 63. Viral resistance occurs when only one or two effective medications remain in the person's blood stream, allowing the virus to mutate around them. PSUF ¶ 63. When all three (or four) medications are present *or not present at all*, the virus is not able to mutate around any of them, and it is not possible for people with HIV on a single tablet regimen (STR)—most people today—to take

only one or two of their medications. Ex. 43, Hendrix Rep. ¶ 53. While theoretically possible, viral resistance when all medications are stopped at one time would be exceedingly rare. PSUF ¶ 63. Defendants present no information to credibly dispute any of this.[5]

Therefore, even if the loss or destruction of a service member's HIV medications occurs—and again, Defendants assume this will occur with some frequency without any support for that assumption—it should have little to no effect on the health of the member or their deployment. PSUF ¶¶ 63, 64. And when the service member obtains a resupply of their medication, they will go back on them. PSUF ¶¶ 60-63. As Navy veteran, former military judge, and current Fourth Circuit Judge Wynn noted at oral argument, the military has to be able to resupply its troops wherever they are—and that would remain true for future conflicts. *See* Oral Argument at 13:48-15:05, *Roe v. Dep't of Def.*, Appeal No. 19-1410, https://www.ca4.uscourts.gov/OAarchive/mp3/19-1410-20190918.mp3. It simply cannot have troops in the field without food, water, munitions, and other supplies. *Id.* While the circumstances of future conflicts may make it harder to resupply a particular unit and it may take longer to do so than it does in a "mature theater" (DSUF ¶ 92), the military will eventually be able to get the service member their medications or their deployment will end. In the meantime, viral rebound will have had no significant impact on anyone. PSUF ¶ 63.

As Plaintiffs' memorandum in support makes clear, postponing HIV monitoring during a 15-month deployment would not be a significant deviation from the global standard of HIV care,

[5] Furthermore, even a service member with a non-suppressed viral load does not present a significant risk of transmission. PSUF ¶¶ 85, 86, 87. Defendants do not dispute that there has ***never been*** a documented transmission of HIV as the result of wound-to-wound contact or catastrophic injury exposure, whether on a battlefield or in the civilian context. Given the lack of a documented case, there is only a theoretical risk of transmission even if the service member has a non-suppressed viral load. *Id.* A suppressed viral load provides the proverbial "icing on the cake," by reducing that extremely low (theoretical) risk even lower or to zero. *Id.*

which recommends such monitoring evaluation every 12 months. PSUF ¶¶ 67, 68. Contrary to Defendants' assertion, monitoring is not necessary to remain stable. PSUF ¶ 68. As stated above, the *only* thing that is required to remain virally suppressed and healthy is daily medication. PSUF ¶¶ 26, 62, 65. Plaintiffs would liken HIV monitoring care to regularly scheduled dental cleanings, but significantly delaying a teeth cleaning has more consequences—even if one flosses and brushes everyday—than does a delayed HIV check-up if one has been taking their medications. And once again, Defendants speculate about a future conflict in which deployments will last longer than 15 months in highly hostile environments. DSUF ¶ 14. Should that come to pass, Defendants are more than capable of transporting a service member once during a deployment to obtain any care deemed necessary, as described in Plaintiffs' opening brief. PSUF ¶¶ 75, 76. Defendants know they cannot leave personnel in a very hostile environment for years at a time—they are simply grasping at straws with these arguments about future conflicts.

Defendants are also grasping at straws regarding side effects. [redacted] If a person experiences any significant, non-transient side effects when they initiate treatment, they are switched to medications with minimal to no side effects for them. Ex. 43, Hendrix Rep. ¶ 58. Any side effects of HIV itself or HIV-related comorbidities, like low-grade inflammation, take years if not decades to result in health problems. PSUF ¶ 66. Though Defendants claim any such long term side effects or comorbidities impact the analysis of who is accepted into the military, the accessions standards explicitly acknowledge that they are designed to ensure the person can complete the term of initial service—which is usually eight years, not a decade or longer. PSUF ¶ 35; PRDSF ¶ 8.

Finally, Defendants' purported concerns about neurocognitive impairments are not well-

founded in the scientific literature and are belied by their own study. PSUF ¶¶ 80, 81, 82; DSUF ¶ 57. If symptomatic impairments exist in service members with HIV, they are not clinically significant and, as Defendants admit, tend to develop over the long term—in other words, among those who are aging with HIV. PSUF ¶ 80. They should not exist in people with HIV during an initial term of service, the period on which the accessions standards are focused. PRDSF ¶ 8; Ex. 43, Hendrix Rep. ¶ 65; Ex. 20, Hardy Rep. ¶ 28. The rare case of a more significant neurocognitive impairment could be handled under the standards applying to neurological conditions. PSUF ¶ 81. It is not rational to maintain a categorical exclusion on accessions or deployment based on speculation about a condition that *may* affect some percentage of people with HIV many years down the road.[6]

2. The risk of transmission to others in a deployed environment does not provide a rational basis for refusing to deploy service members with HIV

Likewise, speculative and unquantified risks about the possibility of HIV transmission in a deployed environment does not create a triable issue. Defendants do not dispute that the risk of HIV transmission in a deployed environment is extremely low; instead, they argue only that Plaintiffs cannot prove that the risk is zero, doubling down on their contention that any non-zero risk is sufficient to justify their blanket policies prohibiting the deployment or accession of people living with HIV. They are wrong.

[6] Contrary to Defendants' assertion, Plaintiffs never suggested that people living with HIV "have no interest" in maintaining their privacy and confidentiality regarding their HIV. Plaintiffs merely said that the same "need to know" standard could be applied in a deployed environment, and that it was nonsensical to deny service members the ability to serve and deploy—and perpetuate stigma and discrimination—based on Defendants' inability to prevent stigma and discrimination based on HIV status. *Roe* ECF 270 at 50-51.

a. The extremely remote risk of transmission through the blood supply does not justify the refusal to deploy service members with HIV.

As with the other purported justifications for the categorical bar to deployment, Defendants posit a non-zero risk of transmission through blood donation, without any meaningful attempt to demonstrate a degree of risk sufficient to uphold the challenged policies.

As this Court has stated, and the Fourth Circuit has endorsed, the purported concern about blood donation from a service member with HIV "fades from view after a servicemember has been diagnosed with HIV and thus knows that he cannot give blood, especially if he has been subject to disruptions in his antiretroviral treatment." *Roe*, 359 F. Supp. 3d at 415. Defendants go to great lengths to attempt to convince the Court that service members with HIV will abandon all military discipline and moral obligations to the safety and well-being of their injured comrades if they feel peer pressure in circumstances that trigger use of the "walking blood bank." DSUF ¶¶ 67, 70. But there is no support for the *ipse dixit* opinions provided by Defendants' witnesses on this subject. PRDSF ¶ 67. The only shred of (inadmissible) information to support Defendants' speculation is a hearsay story about a service member who allegedly donated blood in the civilian context after a night out drinking with his buddies. DSUF ¶ 75. This is not evidence; it's conjecture, insufficient to create a triable issue.

The other measures employed to protect the blood supply created through the walking blood bank—pre-selection and screening of donors, secondary use of those who have donated in the previous six months, third line use of other potential donors, rapid testing for pathogens when available—are all extra precautions on top of the clear mandate to service members with HIV that they are not to donate blood. PSUF ¶¶ 93, 94, 95. Not only would a member with HIV need to choose to donate blood despite the counseling received and in violation of a direct order, but all of these other circumstances would need to coalesce into a "perfect storm" before an actual

transmission could occur—including overcoming the reduced chances of HIV transmission from a person with an undetectable viral load *and* the mitigating effects of post-exposure prophylaxis, if it was administered after donor blood test results came back positive. Harrison ECF 257, Mem. in Supp. of Pls.' Mot. for Summ. J.; *Roe* ECF 270, Mem. in Supp. of Pls.' Mot. for Summ. J. ("Pls.' Opening Br.") at 55-56. The chances of this are beyond remote.

Defendants also mischaracterize Plaintiffs' arguments in an effort to set up "straw men" to knock down. When Plaintiffs state/argue that there are others who are not eligible to donate blood per FDA guidelines or whose blood type cannot be transfused to most other people, Plaintiffs are responding to the purported requirement—which Defendants created from whole cloth—that every deployed service member must be eligible to donate blood, as well as to the proposition that service members in small units increase the risks to the unit if their blood cannot be transfused to other unit members. PSUF ¶ 98. Despite Defendants' apparent argument to the contrary, performing a pre-deployment HIV test does not eliminate the bases for the FDA deferrals, because those deferrals are based on a number of blood-borne pathogens, including some for which service members are not tested prior to deployment. PSUF ¶ 98. With respect to the latter, it is no answer that the plasma of service members with AB+ blood could still be utilized, because donations are transfused as fresh whole blood through the walking blood bank, not as blood components. DSUF ¶ 65. Because the military does not organize its units by blood type, which would be necessary if the ability to donate blood to all others in the unit was a requirement, Defendants' arguments on this topic do not hold water.[7]

[7] Like most of Defendants' purported justifications for the categorical bar to the deployment of people living with HIV, host nation requirements appear to be a reflexive holdover from a bygone era—a purported justification about which no one in the military appears to have any solid information. PRDSF ¶¶ 21-23. Defendants have offered nothing but speculation and supposition about how host nation requirements actually operate to prevent service members

b. The risk of acquiring HIV while performing surgery is vanishingly low.

Though "potential communicability" is mentioned in the 2014 and 2018 Reports to Congress—which serve as Defendants' response to interrogatories seeking the complete reasons for the policies at issue—transmission risk in providing medical care is mentioned only in the context of one service member providing "buddy-aid" to another. PSUF ¶ 30. The risk of HIV transmission to combat surgeons and physician assistants is not among the justifications offered. PRDSF ¶ 78. These arguments should be set aside by the Court under FRCP 37. Nonetheless, Plaintiffs address them below.

Though Defendants attempt to blur the lines regarding which medical personnel would actually be at risk if providing care to service members with HIV, the only personnel placed at any risk would be personnel who experienced a needle-stick or who were performing "exposure-prone, invasive procedures," which are surgical procedures involving the "digitainterl palpation of a needle tip in a body cavity or the simultaneous presence of the [health care worker's] fingers and a needle or other sharp instrument or object in a poorly visualized or highly confined anatomic site." PSSUF ¶¶ 106, 107. In other words, procedures involving a sharp object and the health care workers' finger(s) inside a patient's body. *Id.* Notably, the current standards under which health care workers living with HIV are permitted to practice allow them to perform *all* procedures except exposure-prone, invasive procedures regardless of their viral load, and to perform exposure-prone, invasive procedures as long as they maintain a viral load below 500. PSSUF 107. There are *no* standards by which a medical professional ethically could refuse to

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with HIV from deploying. *Id.* None of the defense witnesses had seen a pertinent status of forces agreement that might apply to deployed service members on a contingency deployment. *Id.* The Court should not countenance such a rickety assertion to allow other countries to deny the constitutional rights of the men and women who serve our country.

perform surgery on a patient living with HIV, regardless of the patient's viral load.

Plaintiffs are not claiming there is absolutely no risk of HIV transmission if a medical professional cuts himself while working in a highly-confined anatomical site or is stuck with a hollow-bore needle *and* the patient has a non-suppressed viral load. PSUF ¶ 87. And Plaintiffs acknowledge that it cannot be definitively established that there is zero risk of transmission even if that service member patient is virally suppressed (which is why public health guidelines still recommend post-exposure prophylaxis be used by civilian medical personnel working in the U.S. in the event of even such a very low-risk exposure). PSUF ¶ 87. Rather, Plaintiffs show that exposures like these will be rare and that if they occur, the risk of transmission is still extremely low. PRDSF ¶¶ 83, 84; PSUF ¶ 84. Because transmission requires both an exposure and transmission as a result of that exposure, that makes the risk of an actual transmission in these circumstances extremely, extremely low—and that is *before* taking into account the mitigation of post-exposure prophylaxis. PSUF ¶ 87. Mere conjecture of this extremely rare occurrence is not enough to justify a categorical ban applying to all service members with HIV.

c. The risk of other types of battlefield transmission is virtually non-existent.

There is no dispute that the risk of transmission through other types of battlefield exposures is infinitesimal—and quite possibly zero. As discussed above, these risks are exceedingly low even before taking into account the effects of a suppressed viral load. PSUF ¶ 90. And Plaintiffs' experts provide unchallenged opinions extrapolating the information regarding the reduction in sexual transmission risk created by an undetectable viral load to these other situations. PSUF ¶ 89. Defendants know there will never be direct evidence of the precise effect of an undetectable viral load on the risk of transmission via wound-to-wound contact, both because the baseline risk is too low to measure (there have been no documented cases) and there

could never be an ethical controlled study, as there was with respect to the risks of sexual transmission. This is yet another example of Defendants irrationally demanding that Plaintiffs demonstrate zero risk when there is no dispute that the risk is virtually non-existent. PSUF ¶ 85.

Because Plaintiffs do not claim that the risk from being near an HIV-positive service member experiencing a catastrophic injury is zero, Defendants' argument that there is a non-zero risk does not create a triable issue. Rather, Plaintiffs establish an extremely low risk based on studies done on victims of suicide bombings in the civilian context. PSUF ¶ 86. Critically, Defendants do not dispute those facts. PRPSUF ¶ 86. Nor do they dispute that the quantum of blood on a bone shard traveling away from the victim of a catastrophic injury, which could potentially penetrate a bystander, is less than the amount of blood from a needle-stick exposure (PSUF ¶ 86), and the Fourth Circuit has ruled the extremely low risk of transmission from needle stick is *not* sufficient to justify Defendants' categorical exclusions. *Roe*, 947 F.3d at 227-28.

Because they are so extremely low, the risks discussed above do not require mitigation. While Plaintiffs discuss post-exposure prophylaxis (PEP) as a method of mitigating or eliminating any residual risk that may exist as a result of such exposures, such mitigation measures should never be necessary. PSUF ¶ 87. Plaintiffs are merely pointing out that PEP could be used, when available, as an added precaution.

The Court should also reject outright Defendants' eleventh-hour attempt to invoke the risk of sexual transmission or the cost of treatment for service members with HIV as a justification for their deployment or accessions policy. As noted above, in response to two interrogatories asking Defendants to "explain in detail each of the reasons underlying DoD's policies that prohibit HIV-positive persons" from enlisting, commissioning or deploying, Defendants responded that the DoD had "set forth it's (*sic*) complete reasoning underlying the

policies" in the 2014 and 2018 reports to Congress. PSUF ¶ 29. Neither the risk of sexual transmission nor the cost of treatment is mentioned in these reports as justifications for the deployment or accessions policies.[8] *See* Ex. 2, 2018 Report, *passim*; Defs.' Ex. 13, 2014 Report, *passim*. Under FCRP 37, Defendants should not be permitted to raise them now.

B. Plaintiffs Roe, Voe, and MMAA Also Prevail on Their APA Claims, Because the Air Force's Decisions to Separate Roe and Voe Were Arbitrary and Capricious and Otherwise Contrary to Law.

The above conclusion as to the deployment and accessions policies dooms Defendants' retention practice as well. Beyond that, Defendants have failed to raise a triable issue that the retention decisions and practice are not both contrary to law and arbitrary and capricious.

1. The Air Force's decisions to separate Airmen living with HIV are contrary to the Air Force's own regulations.

Air Force Instruction 44-178 is unequivocal: "HIV seropositivity alone is not grounds for medical separation or retirement for ADAF members." PSUF ¶ 49 (AFI 44-178, § 2.4.1). The AFI so provides in two places: section 2.4.1, under the discussion of clinical evaluation in the HIV program, and Attachment 9, which discusses retention and separation. AFI 44-178 is consistent with the DoDI it implements: DoDI 6485.01 likewise provides for treatment of Service members with HIV infection but adds that a "Service member with laboratory evidence of HIV infection determined to be fit for duty will be allowed to serve in a manner that ensures access to appropriate medical care." PSUF ¶ 39. The DoD reported to Congress in 2018 that

[8] The cost of medical care is also not a legitimate basis for discrimination. *See Mem. Hosp. v. Maricopa Cty.*, 415 U.S. 250, 263 (1974) (holding that government may not "protect the public fisc by drawing an invidious distinction between classes"); *see also Plyler v. Doe*, 457 U.S. 202, 226-27 (1982) (rejecting state's purported interest in the "preservation of the [its] limited resources for the education of its lawful residents"). Furthermore, Defendants are already providing medications and care to 1800+ service members living with HIV. PSUF ¶ 57. Refusing to deploy them does not change that.

"DoD and Service policies restrict involuntary separation of a Service member solely due to being HIV positive" (PSUF ¶ 29; Ex. 2, 2018 Report at 2), only months before the Air Force attempted to discharge Roe and Voe. Both this Court and the Fourth Circuit recognized the unequivocal nature of the prohibition on discharges in their opinions relating to the preliminary injunction. *See Roe*, 359 F. Supp. 3d at 417; *Roe*, 947 F.3d at 214-15.

Using circular reasoning, the Air Force argues, as it has in the past, that Roe and Voe were not discharged because of HIV seropositivity "alone" but because they were expected to deploy "relatively frequently" to Central Command's area of responsibility and they were unlikely to be able to deploy to CENTCOM because of their HIV status. Defs.' Br. at 77. The only bar to Roe's and Voe's deployment was Defendants' own regulations, which restrict deployability based on HIV status "alone." Thus, they are being discharged because of HIV "alone." Although Defendants argue that the bar is a medical limitation, rather than an administrative one, the undisputed evidence is to the contrary: as set forth above at pages 25-35, there is no medical reason that Roe and Voe cannot deploy to CENTCOM or elsewhere.

In their brief, Defendants assert that "CENTCOM's deployment policy is not a categorical ban." Defs.' Br. at 74. But as the Fourth Circuit noted, Defendants have taken inconsistent positions on this issue. *Roe*, 947 F.3d at 221. In the 2018 Report to Congress, the DoD described the bar as categorical, reporting that "current Service policies do not permit HIV-infected Service members to deploy to combat theaters of operation or in support of other contingency operations." *Id*. Even accepting Defendants' current position that MOD 13 (or the current MOD 15) is not written as a categorical bar, it is clear that that is how the policy is implemented. Indeed, just three sentences later, Defendants admit that "[t]o date, no service member with HIV has possessed [the] rare characteristics [of highly specialized skills to

complete a mission with an extraordinary need] required for a waiver." Defs.' Br. at 74. This admission is particularly telling in light of Lt. Col. Cron's testimony that between 2015 and 2019, over 30,000 persons applied for a medical waiver to deploy to CENTCOM. PSUF ¶ 54.

Further, the Air Force justified its decision to discharge Roe and Voe on the basis of a categorical bar. Roe and Voe had not been asked to deploy to CENTCOM. They had not sought a waiver and been refused. There had been no determination that they could not operate in the austere conditions of a proposed location, or that the proposed location had host nation requirements that restricted their entry. Instead, the Air Force predicted that if they were asked to deploy, they would not be allowed to. Based on this prediction, it decided to discharge them.

The Defendants posit that Plaintiffs are seeking a hypothetical waiver process pursuant to which military officials would review waiver requests from Airmen with HIV as part of the DES process. Defs.' Br. at 75-76. But Plaintiffs are not seeking a "hypothetical waiver process," especially one with a preordained result, given the testimony of Martha Soper and Lt. Col. Cron that waivers for persons with HIV are never granted. What they are seeking is for Defendants to stop using deployability to do indirectly what DoD and Air Force regulations prohibit them from doing directly: discharge Roe, Voe, and other Airmen based on their HIV status.

2. The Air Force's decisions to separate Roe and Voe were arbitrary and capricious.

Second, the inconsistent votes on Voe's retention clearly demonstrate the arbitrary and capricious nature of the Air Force's action. In the five months between the two votes, the AFPB took no new or additional evidence about Voe. Neither his job nor his medical condition changed. Nor had the pertinent regulations changed in any way. Indeed, the discussion supporting the two opposing conclusions is identical: Voe was "asymptomatic" with "a viral load of zero" and thus "meets [the] criteria for retention according to the 11 Oct 2017 ... [m]emo

stat[ing] that 'Asymptomatic HIV alone is not unfitting for continued service.'" PSUF ¶ 16. Defendants argue the inconsistency should be disregarded because the initial decision had not been sent to Voe. Ms. Soper tellingly admits that "there is no regulatory guidance which definitively states when an SAFPC decision is final … ." Defs.' Ex. 25, Soper Decl. ¶ 41. She continues: "The SAFPC has, on several occasions, revisited decisions upon receipt of new information about cases, and then reconsidered decisions in light of the new facts." *Id.* This may be true; but here, there was no new information or new facts, only a contrary result.

Further, contrary to Defendants' argument, Defs.' Br. at 78, there was no "material change" in Air Force policy between the two votes. Defendants concede that before 2017, the Air Force generally returned asymptomatic HIV positive airmen to duty without entering the DES. Defs.' Br. at 78; Ex. 25, Soper Decl. ¶ 27. Nothing in the pertinent DoDIs or AFIs changed in 2017 or 2018. Rather, the Air Force employed a new interpretation of existing regulations (DoDI 6485.01 was last reissued years earlier, in 2013) to allow the Air Force to do what no other Service branch was doing and what the Air Force had not done in the past: refer Airmen living with HIV—even those who are asymptomatic and are on the path to or have achieved viral suppression—into the DES. Once in the DES, the Air Force relied on deployability restrictions to do what the DoD told Congress in 2014 and 2018 it would not do and was not doing (and indeed, what the Defendants in *Harrison* told this Court would not happen at the preliminary injunction hearing): discharge service members living with HIV.

3. The Air Force's decisions to separate Airmen living with HIV based on a "prediction" that they cannot deploy are contrary to policies that require an individualized assessment of fitness for duty.

Finally, by deciding to separate Roe and Voe based on a prediction they would not be allowed to deploy to CENTCOM, the Air Force acted arbitrarily by denying Plaintiffs the required individualized assessment of their fitness for continued service. As noted by the Fourth

Circuit, DoD regulations require individualized determinations based on objective evidence to determine a service member's fitness for duty or separation under the DES. They require "objective evidence in the record, as distinguished from personal opinion, speculation, or conjecture, to determine a Service member is unfit because of disability." *Roe*, 947 F.3d at 222.

Defendants contend that the Fourth Circuit based its decision on an "incomplete" understanding of the policies at issue, particularly the CENTCOM deployment and waiver policy. Defs.' Br. at 73. In fact, the record at the preliminary injunction stage contained not only the policies themselves, but declarations from Lt. Col. Cron, the waiver action officer, and Ms. Soper, which detailed the waiver process and made clear Roe and Voe were "highly unlikely" to receive a waiver if they requested one, and the administrative records for Roe and Voe.

Despite the submission of additional declarations, the problem for Defendants at this stage of the proceedings is the same as the problem at the preliminary injunction stage: that despite efforts to convince this Court that CENTCOM's deployment policy is not a categorical bar and that deployment waivers (and discharge decisions) are made on an individualized basis, they assert that they nevertheless can predict that a waiver would never be granted for a service member living with HIV, so that the service member can be separated through the DES process without a question about deployment having ever arisen.

By predicting HIV-positive service members would be denied a waiver and in using this predictive assessment to discharge these Service members, the Air Force violated DoD regulations, failed to consider the criteria for discharge, and explained its decision in a manner contrary to the evidence before it. See *Roe*, 947 F.3d at 224.

VII. CONCLUSION

For the foregoing reasons, Plaintiffs' motions for summary judgment should be granted.

Dated: July 2, 2020

Respectfully submitted,

/s/ John W. H. Harding

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**pro hac vice*

CERTIFICATE OF SERVICE

I certify that, on the 2nd day of July, 2020, I caused this document to be filed electronically through the Court's CM/ECF system, which automatically sent a notice of electronic filing to all counsel of record.

Dated: July 2, 2020

Respectfully submitted,

/s/ *John W. H. Harding*

John W. H. Harding

EXHIBIT 64

AMSWG Meeting (Audio Recording)
(Aug. 5, 2015) (US00012348_0001)

UNDER SEAL

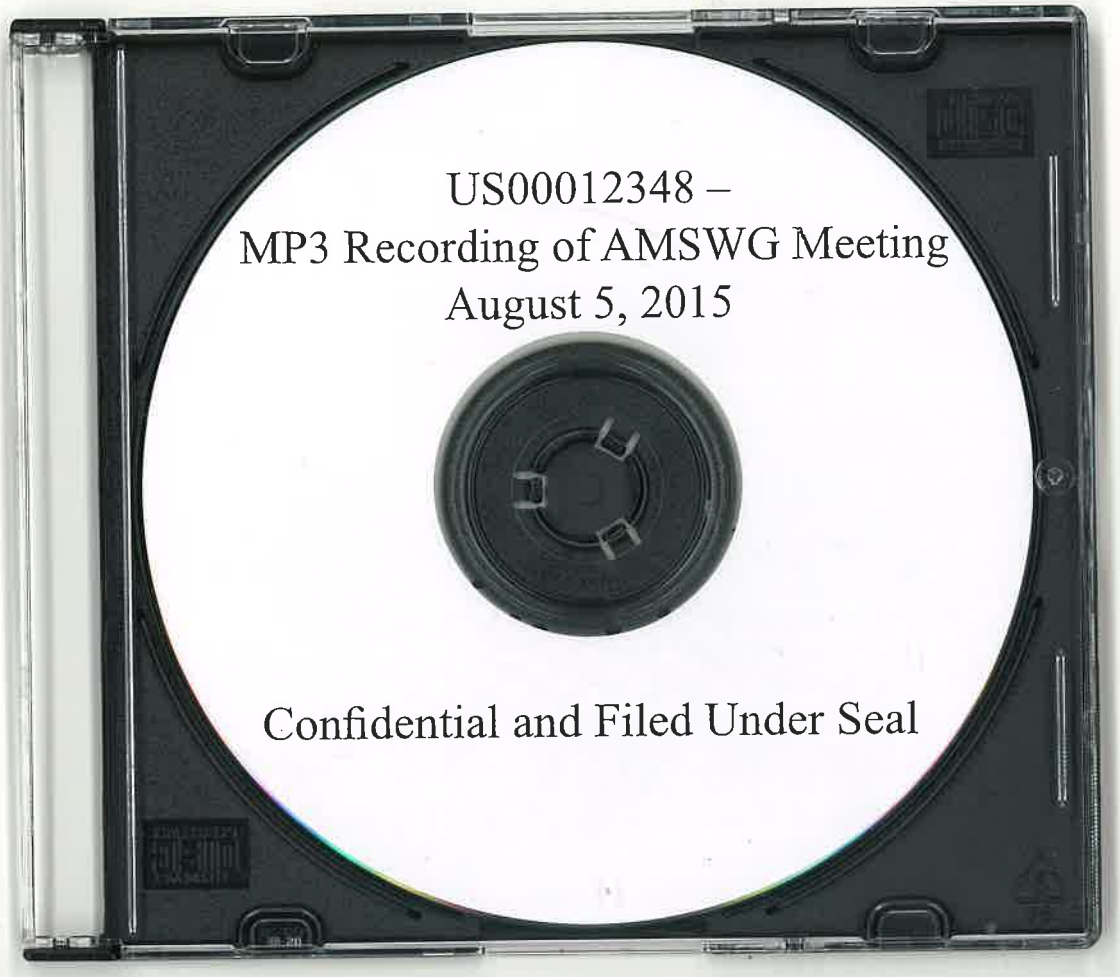
US00012348 –
MP3 Recording of AMSWG Meeting
August 5, 2015
Confidential and Filed Under Seal

EXHIBIT 65

Excerpts from the March 5, 2019 30(b)(6) Deposition of Department of Defense Given By Paul Ciminera

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

- - - - - - - - - - - - - - - - - - - x
NICHOLAS HARRISON and OUTSERVE-SLDN, INC., : Plaintiffs, : vs. : No. 1:18-cv-00641 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. :
- - - - - - - - - - - - - - - - - - - x
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. :
- - - - - - - - - - - - - - - - - - - x

VIDEOTAPED 30(b)(6) DEPOSITION OF DEPARTMENT OF DEFENSE GIVEN BY PAUL CIMINERA

DATE: Tuesday, March 5, 2019
TIME: 9:05 a.m.
LOCATION: Winston & Strawn
1700 K Street, N.W.
Washington, D.C.

MS. BERMAN: Objection. Mischaracterizes testimony.

You can answer.

BY MR. SCHOETTES:

Q Let me rephrase that. You put a time limitation when you are looking at when separation may result due to medical unfitness as a result of a particular condition?

A It's not an absolute cut off at eight years, but I tend to weigh risks that would occur within the initial period of service, which is typically eight years, more than risks that would occur beyond eight years.

Q And then when you're looking at those risks, is it a -- what kind of -- what level of risk would you consider disqualifying based on this criteria? Would it have to be something that is more likely than not? Would it have to be something that is going to occur more than 5 percent of the time? Is there some basis upon which the level of risk is evaluated?

MS. BERMAN: Objection. Vague. Calls for speculation.

You can answer.

THE WITNESS: In general, we look at the

EXHIBIT 66

Excerpts from the March 8, 2019 30(b)(6) Deposition of the Department of Defense Given by Donald Shell

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.

THE WITNESS: I don't know the exact number for the risk.
BY MR. SCHOETTES:
Q Has there ever been a documented case of transmission via wound-to-wound contact?
MR. NORWAY: Objection. Outside of scope.
You may answer.
THE WITNESS: I can't say exactly.
BY MR. SCHOETTES:
Q Has there ever been a documented case of HIV transmission on the battlefield?
MR. NORWAY: You may answer.
THE WITNESS: Not that I'm aware of.
BY MR. SCHOETTES:
Q What is pre-exposure prophylaxis in the context of HIV?
MR. NORWAY: Objection. Outside of scope.
You may answer if you know.
THE WITNESS: Pre-exposure prophylaxis is treating someone who is HIV-negative with Truvada, with the use of a medication to diminish the likelihood that they would contract HIV from their interaction or exposure to someone who is

countries that discuss the operations and activities of U.S. military forces while in those other countries?

A I believe that there are certain documents in existence.

Q Do you know what those agreements are called?

MR. NORWAY: Objection. Vague.

You can answer.

THE WITNESS: I believe they may be called SOFAs or -- but I don't have access to those specific documents that are used by the department.

THE REPORTER: SOFAs?

THE WITNESS: S-O-F-As, status of force agreements, I believe, but I'm...

BY MR. SCHOETTES:

Q Sir, you're here to testify about this topic today, but you don't have access to the status of force agreements that are at issue?

MR. NORWAY: He's here to testify more broadly about country restrictions. Objection to the extent it mischaracterizes the reason why -- or the topic for which we're representing him for.

You may go ahead and answer.

THE WITNESS: I said that I am not responsible for SOFA agreements, nor have access to departmental SOFA agreements, that my looking into host nation requirements led me into this -- attempting to understand better what those host nation requirements are, but I don't have visibility or access to all of the status of force agreements between the department of the United States and all the countries around the world.

BY MR. SCHOETTES:

Q Did you look at or review the -- did you review the status of forces agreements that were provided to plaintiffs in this case?

MR. NORWAY: Objection. Form.

You may respond.

THE WITNESS: I looked at some, yes.

BY MR. SCHOETTES:

Q You reviewed the provisions of the status of forces agreements?

A The documents that were provided addressing host nations. If status of forces agreement were publicly facing and made available and included in the inquiry that I made on my own about looking at host nation requirements, then the documents I provided are documents that I've

EXHIBIT 67

Excerpts from the May 7, 2019 Deposition of
William David Hardy, M.D.

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.
Tuesday, May 7, 2019

Deposition of WILLIAM DAVID HARDY, 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

lifestyle changes they have incorporated into their life to remember to take that pill every day, because that's the learning curve that's so important.

And to tell you the truth, the physician does very little of that these days. The persons who actually do that are medical cases managers, nurses, adherence counselors, people who actually work in the field who might be positive themselves who offer their own experience to this new patient and says here, here's what I do.

So doctors prescribe, doctors check and watch viral loads, but a lot of the more socio -- what do I call it? Behavioral work is actually now done in large part by people who work in concert with the prescriber to help the person learn to take the medications, because we learned early on that just having the patient come in and hear from the doctor and walk out the door is never enough, is never enough, because this not a ten-day or 14-day course of antibiotics, which would probably work if -- even if they got half of it in their body. This is a situation where we expect the adherence, number one, to be good. At least 85 percent is what we're looking for, and long term. So we're really trying to do -- instill a long-term behavioral change in

these people who become HIV positive.

Q. Also in this paragraph, you talk about consistent adherence leads to a CD4 T cell count rebound. Does the -- the CD4 cell count of every person taking this therapy rebound?

A. Good question. I would say in my experience, yes. I've not had a patient -- other than the ones that die from opportunistic infections because they got treated too late, that one percent, I've had -- I've been amazingly surprised that patients who even come in to start seeing me who have initially five T cells, as long as they -- in concert with them taking the medication and bringing their viral load down consistently undetectable, that their T cells even starting that low will build. It takes -- it may take a longer period of time, but they will build even starting as low as five T cells, and clinical trials have shown the same thing. It takes longer if you're starting lower, but it will actually occur. What is key here is getting the virus and keeping the virus undetectable.

Q. And by a longer period of time, what do you mean by that?

A. The period of time that T cells -- it depends on where a T cell count is starting. Our

Q. So what's this shortly after time frame that goes from 200 to less than 50 or --

A. Oh, probably two weeks.

Q. And what's the basis for your opinion that it takes a couple weeks?

A. Part of it is clinical trials that have looked at time to get to this -- to this level, and then some clinical trials would follow people as commonly as every -- even every week to see how their viral load is going down. So we would know that if it was 200 here at week ten, that by the time we checked it again at week 12, it was gone from less -- had gone from, say, 195 copies of virus down to less than 20. So it's usually a very short period of time because that -- that fall from 95 -- 195 down to less than 20 could be even as short as one week.

Q. Does it continuously stay undetectable after that?

A. As long as a person continues to take their medication on a daily basis, yes.

Q. And I've noticed that you've qualified some of these statements with "almost" or "usually." Are these statements true for all patients continuously adhering to their medication?

A. As best we can tell, yes, as best we can

tell, yeah. Currently what we're seeing is that long-term detectability is really depending upon several issues, but it's very simply the fact the patient who has committed to take the pill every day. Access to the pill is another important part of this because even though the patient wants to take the pill every day and can take the pill every day, if the patient doesn't have access to the pill, that's a problem. So it's really, you know, the issue of a patient being and remaining adherent to taking the pill every day, number one. Number two, having access to that pill.

Q. Can you define what you mean by consistent adherence?

A. Daily. Daily, but I'll say at least 85 percent. What studies have shown is that even with -- with our integrase inhibitors, we know that if even 85 percent adherence is reached, taking 85 percent of the pills over, say, a three-month period, that -- that undetectability will be preserved, and that's kind of what I would call consistent, at least 85 percent.

Q. Okay. I think in the -- yeah, in paragraph 17, if you want to turn to paragraph 17 --

A. Uh-huh.

So I learned by watching what was happening that there are -- this is a subset of my patients that I know can be seen on a once-a-year basis because their lives are so stable, and I say lives because there's a lot of stuff in their life that is just going very smoothly. They have figured it out, is what I would call, they have figured it out, how to take their medications, and the monitoring part of it is something that is only a reassurance that they're doing okay, after two years of knowing that they're doing okay.

There was once this concept many years ago that somehow our antiretroviral medications were just going to fail for no good reason, and we now know that that just doesn't happen. Resistance does not develop to patient -- viral resistance to medications does not develop out of the blue. The drugs just don't stop working all of a sudden even though they're being taken, and we've had lots of clinical trial data that has proven that to us.

So as long as the pill is getting into the person on a regular basis, at least 85 percent of the time, we can assure the fact that that viral load's going to stay undetectable and that T cell count's going to stay stable, and those are I think lessons

that we've learned a lot from clinical trials that have monitored patients extremely closely for even as long as ten years, and we've learned that lesson, that we don't really need to see patients -- we don't need to monitor patients for HIV that closely.

What happens in reality is that sometimes we see patients more often not for HIV, but for other reasons, but the good thing about this annual sort of thing is that, you know, it starts -- it has now fallen in line with medical care for men over 40 -- over 45, and to see a physician once a year for a physical examination, and for HIV positive women, they are still recommending to get a Pap smear every year, and more often if they have certain types of HPV found in the cervix, but that monitoring for that reason, not for the HIV reasons specifically, actually now falls in line with annual monitoring.

So it actually kind of makes more sense. It puts them into the same kind of monitoring pattern that they were -- would have been in just because of their age already.

Q. What ratio of the patients you monitor approximately are on six-month monitoring cycles versus a year?

A. It depends on your patient population. The

virologic test back in our routine sort of turn-around time after blood's drawn, sent, processed and results are coming back. At that point when labs are being reviewed, blip is detected, patient is called, and it depends on how fast the patient can come in and get that blood sample drawn. It's usually about ten days -- ten to 14 days from the -- when the first sample is drawn.

Q. What is cross-resistance?

A. Cross-resistance means that resistance to one medication within the same class causes resistance to other medications within the same class.

Q. And how frequently does that occur?

A. Depends upon the class. One of our classes called the NNRTI class, NNRTI, all in caps, class, cross-resistance is very common. In other classes, such at the protease inhibitor class, cross-resistance, number one -- or resistance, number one, is very rare, and cross-resistance hardly ever occurs. So it really depends upon the class of the medications.

Q. In this same paragraph, paragraph 18, towards the bottom of the paragraph, you state, "I would not expect a patient to develop viral

resistance to a medication after abruptly stopping or discontinuing medications."

A. Right.

Q. What do you mean by abruptly stopping or discontinuing the medication?

A. Well, we have clinical trial data with two of our most commonly and -- and recommended integrase inhibitor regimens, and also with pretty much all of our boosted protease inhibitor regimens, that even when a patient for some reason stops the medication, loses access, goes to jail or prison and the medications for one reason or another are stopped abruptly, that when that virus rebounds, it is not resistant to the medications the patient was on. Abruptly stopping is -- is sometimes the best thing to do because pharmacokinetically, all the medications leave the body at the same rate, and that's great.

If a patient takes the medications intermittently, that can be a more troublesome sort of situation because the virus is being sort of sprinkled with a little bit of medication on an intermittent basis, and that's a good way that resistance causes, and that's why usually stopping the medication abruptly is what we tell patients to

do.

If, for example, they find themselves in a situation where they are about to run out of medication and they have, say, for example, five pills left, and they think well, I'm going to make these last for ten days. I'll take one today, none tomorrow, one the next day. We say don't do that. Take it every day as -- as directed, and then when you run out, you run out.

A -- a clean stop is the best way to stop HIV medications, because in that way, what happens is is the levels of the medication drop quickly, and we know that that is not associated with viral resistance for some reason. It's been done many times and studied many times. So we tell patients if you run out or you find yourself near the end of your bottle, just run out and then come in and tell -- start again because that's the way we train people to avoid resistance.

Q. You mentioned when you first started talking that the clinical studies involved a couple of classes of drugs. Trying to remember which ones.

A. Integrase.

Q. Right.

A. And boosted protease.

a problem with the heart, correct?
A. Correct.
Q. Are there any other contexts in which you are aware of drug-drug interactions that happen with any degree of frequency?
A. Those are the -- those are the ones I'm aware of, yes, those two, yes.
Q. Do any others come to mind that have a -- more than a de minimus frequency?
A. No, no, no.
Q. When we were talking about viral suppression, you said that continuous care -- continuous viral load suppression was important in terms of creating a situation in which a person would be noninfectious in a sexual context; is that correct?
A. Correct.
Q. Prior to that, you said that 85 percent adherence is generally sufficient to -- to reach a suppressed viral load; is that correct?
A. Correct.
Q. Would that indicate that 85 percent adherence would -- should also be sufficient to maintain the status of being noninfectious in terms of sexual transmission?

A. Yes.

Q. Do you know what level the -- of viral load the HPTN 052 study used in determining when someone would be sexually noninfectious?

A. I don't know for sure, but my -- my best guess at that is 1,000 copies.

Q. Do you know if all the studies use the same -- that -- I'm sorry, do you know if all the studies that found that people with an undetectable viral load were not infectious in terms of sexual transmission used the same level for an undetectable label?

A. There's really not a -- a thousand was established in a publication that was done from what's called the Rakai cohort from Kenya many years ago. It was confirmed in mother-to-child transmission at a thousand also. That was a cutoff that was found in women who were -- had levels of viral load at a thousand or above a thousand did or did not transmit virus to their -- to their unborn children. I don't know exactly what level they used in HPTN 052 primarily because transmissions were so rare in that. There were only three of them in the entire study, and I don't know whether they had viral loads available in all those situations or not, so I

can't give you a direct answer on that.

Q. And what about the partner study? Do you know what they considered --

A. Undetectable. In partner study, everyone was confirmed to be undetectable.

Q. My question is what did undetectable mean for purposes of that study.

A. It meant below the level of the lower limit of detection for whatever assay was being used.

Q. Do you know the number of that assay?

A. It was 50, 40 or 20. Depends upon which assay was being used in that -- in that patient's laboratory check because the study was done in many different sites throughout Europe. Not all laboratories used the same cutoff point. Well, not all laboratories used the same assay. Each assay has a different lower limit of detection. Whether it's 50, 40 or 20 probably doesn't matter though. There's really no difference as to whether a patient is -- a person is undetectable at 50 or undetectable at 20. The term "undetectable" is a term that is used based upon the assay that's being used.

Q. So --

A. Actually, let me -- let me take that back. In the partner study, they did use less than 200. I

take that back. Because of the fact that there are different levels of undetectability based upon the assay, they're all less than 200.

Q. So the study found that anyone less -- with less than a 200 copy per milliliter viral load was noninfectious in the sexual context.

A. Correct, correct.

Q. Even though 200 is not used as the current level of undetectable, correct?

A. It depends upon what context you're taking this in. In the clinical trial, the FDA most commonly uses the term less than 50, but in many clinical research studies, less than 200 is a level that is used, so it really depends on which context you're talking about.

Q. Let me pull out Exhibit 6. If you'll turn to the back side, we talked about the statements in the box at the top, and in particular, we talked about the last statement. I first want to ask you, if a person has an undetectable viral load at the time of sexual contact, does that mean that person is essentially noninfectious?

A. As -- as we best understand HIV transmission in a sexual context, the plasma viral load at the time of the sexual act is what's

important. So what U equals U is really trying to express is that it is the viral load at the time of sexual contact that's important to determine whether or not sexual transmission can or cannot happen.

Q. So let me ask another question. Does it matter when the person was last tested if they have an undetectable viral load -- let me try that again. Does the recency of the last test matter in terms of transmission risk if the person has an undetectable viral load at the time of the sexual exposure?

A. I'll try to answer this the best I can. If it's known that the patient has an undetectable viral load at the time of sexual encounter, then that's what really matters. What the viral load was two months ago, three months ago or would be in the future is not as important as what it was at the time of the sexual encounter. That's what counts.

Q. If you look at the statement that's made here that stopping therapy negates the validity of assuming that U equals U, does that say that as soon as the person stops therapy, they are no longer noninfectious?

A. It's not an immediate situation because we know it does take time for viral load to become detectable in blood after medication is stopped.

There is a period of time anywhere from as -- perhaps as short as two weeks to as long as six months or longer that it will take for viral load to become detectable once again after therapy is stopped.

Q. So if you look at the statement itself, it says that stopping therapy negates the validity of assuming that U equals U. Is it ever true that undetectable does not equal untransmittable?

A. Not based upon the concept that we have in clinical trial research.

Q. Is this statement actually saying that you can't assume that you are noninfectious or that you -- I'm sorry, does this statement actually mean that you can't assume that you have an undetectable viral load if you have stopped therapy?

A. Well, I think what U equals U is saying is once there's a correlation between taking therapy on a daily basis or at least -- as long as there's an undetectable viral load while someone's taking medication on a regular basis with regular access to it, that as long as someone is continuing that medication at the same rate and at the same kind of basis, then the viral load will stay undetectable. If the medication is stopped, it is also presumed that at some point, the large majority of people who

stop medication will once again have a detectable viral load at some point down -- into the future.

Q. And just to get a little more clarity here, if you look at the statement with me, it says that stopping therapy negates the validity of assuming that U equals U.

A. Right.

Q. Does U, undetectable, ever not equal untransmittable?

MS. CUTRI-KOHART: Objection, asked and answered.

A. Only if the person has stopped taking the medication, but when it's going to occur is unknown.

Q. I'm going to try one more time.

A. Okay.

Q. Just take the statement out of context, and maybe this is what I did before, but does an undetectable viral load --

A. Uh-huh.

Q. Regardless of whether you took your medication -- the last time you took your medication --

A. Yeah.

Q. -- always mean an untransmittable virus?

A. Yes, yes.

Q. All right. Go ahead and turn to Exhibit 7. Do you recall talking about this study discussing viral rebound?

A. Correct, yes.

Q. And it had a quicker estimate for time to detectable viral load than some of the studies that you identified in your report, correct?

A. Correct.

Q. What is the Fiebig I stage?

A. Fiebig I stage is the stage of HIV seroconversion in which -- it's the earliest stage at which any evidence of HIV transmission or infection has occurred. It's the stage at which the only test that is positive is the HIV RNA test, the viral load test. The HIV antibody test, which is commonly used to diagnose HIV infection, is still negative, and the HIV P24 antigen test is still negative. It's -- this is a stage at which only one test, the earliest test that we know detects HIV infection is positive. So it is -- it is what we would consider to be the earliest time point at which we could confirm HIV infection has occurred. It's --

Q. At what -- at what point in the progression of the immune response to HIV is the Fiebig I stage?

A. By -- by looking at this, this is a -- this

is the stage at which -- this is the stage at which the immune response has not yet occurred, because there is no antibody detected.

Q. If you provide a patient at this stage with antiretroviral treatment, what -- how does that affect the immune response?

A. Taking -- treating HIV infection at this early stage decreases the amount of virus in the blood and in other parts of the body. Therefore, it is -- it has always been a concern that treating someone at this very early stage could in fact blunt or completely abrogate the body's immune response against HIV.

Although that immune response is usually not a complete and protective immune response, it is a partial immune response, and treating this early takes away the body's target that it would respond against, and therefore, you would expect that person would have very little antibody -- immune response whatsoever. In fact, people like this may still have a negative HIV antibody test if they're treated this early.

Q. So when people who have been treated in the Fiebig I stage, then stop receiving treatment and the virus comes back, how may that affect -- how does the

nascent nature of their immune response affect viral rebound?

A. Yeah. Well, as the authors mention in here, one of their hypotheses for why they saw rebound within 14 to 42 days or average about three and a half weeks to 24 days was because when they stopped the therapy, there was no preexisting immune response to limit that viral load rebound, which makes sense based upon what we know about how immunity to HIV, albeit it impartial -- being partial immunity occurs.

So that's how they explain, and it does make sense that because their immune response was never allowed to occur because the virus was treated so quickly, that on rebound, you would expect the rebound to occur quickly as well.

Q. Can you point out in this article where that is mentioned?

A. See, on page --

Q. You can just say how many pages into the exhibit it is.

A. Second page, in the right-hand paragraph, the paragraph that -- that says reactivation down the -- about fifth sentence down, it says that the reposit, that the rapid viral rebound observed in

this study was due to the inability to achieve a small enough pool of latent cells -- of latently infected cells, excuse me, particularly in lymphoid tissues and inadequate immune control, and it references a reference here that goes into more detail about the fact that immune control in patients who are treated very early in HIV infection is oftentimes found to be lacking.

Q. You can set that exhibit aside. At one point, you referred to tenofavir, and you also referred to TAF. Is TAF a medication that contains tenofavir?

A. Yes, TAF does contain tenofavir.

Q. What do the other letters in the TAF acronym stand for?

A. TAF stands for tenofovir alafenamide difumarate.

Q. And the medication that you referred to as tenofavir, what is its full name?

A. TDF that I referred to tenofovir difumarate. It does not contain the alafenamide component.

Q. So when you refer to tenofavir in -- earlier, you were referring to TDF.

A. Correct, correct.

MR. SCHOETTES: All right, I'm done. Well, except Rebecca gets to potentially do reexamination.

FURTHER EXAMINATION BY COUNSEL FOR THE DEFENDANTS

BY MS. CUTRI-KOHART:

Q. Yeah, I'm sorry, I do have a few additional questions based on what you just said -- testified to. You've talked a lot about this -- that your adherence standard is 85 percent. What is the basis for your 85 percent number?

A. Eighty-five percent is what I'm using as what has generally been seen in clinical trials.

Q. Okay, and just help me define what 85 percent compliance mean. Does that mean taking eight to nine pills every ten days?

A. It means that usually over a three-month period, that based upon pill counts, a patient in clinical trials is usually given three months' supply of pills, 90 pills over three months, and they're asked to come back at the end of that three months, and the pills -- they're asked to bring back their pill bottle with any remaining pills in it, and there is a count that is done, and as long -- what has typically been seen is that in patients who are considered to be adherent, they have on average 85 -- taken 85 percent of the pills.

that that 85 percent is being correlated with undetectability, continuous undetectability. So whether the patient -- and this is something that is not always clearly understood or clearly defined, because whether the pills were all missed at 12 days in a row or intermittently over that 90 days, the standard for including that patient in that 85 percent was undetectability. They had to be undetectable continuously, and then those patients' adherence was then analyzed.

Q. When the CDC issued its guidance on U equals U, what did it say about the adherence requirement?

A. They did not.

Q. They did not assume consistent adherence?

A. They assumed -- they said consistent adherence, but they didn't put a number on it.

Q. How do you -- and you define consistent adherence as 85 percent.

A. I consider -- I define that from clinical trial data, which is really the only data we have.

Q. The CDC's guidance didn't say how they defined consistent adherence.

A. No.

Q. Okay.

EXHIBIT 68

Excerpts from the May 10, 2019 Deposition of
Craig Walter Hendrix, M.D.

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

Q. Okay, and your -- your detailed opinions begin on page 17, correct?
A. Yes.
Q. Okay. Could you please turn to paragraph 48? It is on page 18. In this paragraph, you're discussing the risk of transmission of HIV, correct?
A. Yes.
Q. And is HIV -- the risk of transmission of HIV through exposure to blood on the battlefield?
A. Yes.
Q. Okay. In the second sentence, you refer to wound-to-wound contact, correct?
A. Yes.
Q. Are you saying that there are no documented cases of wound-to-wound contact as a route of transmission?
MR. SCHOETTES: Objection, vague. You may answer. Just for the clarity of the transcript, you're talking about transmission of HIV?
MR. NORWAY: Correct.
THE WITNESS: So I'm not aware of documented case of wound-to-wound contact of HIV transmission on deployment -- or in a combat setting.
BY MR. NORWAY:
Q. In a combat setting. Are -- is -- are you

aware of a documented case of wound-to-wound transmission in the civilian context?

A. So as a -- there -- if there is a deep penetrating injury of a blood-coated instrument or a hollow bored needle, those are the two clearly established and highest risks of occupational transmission from patient -- an HIV positive patient to provider.

Q. Did you do any type of research to substantiate the state -- or I guess actually, let me ask you this. Do you know of any documented cases of transmission of HIV in wound-to-wound contact in the context of a car accident?

A. I'm not aware of any.

Q. Are you aware of any documented transmission events of HIV from wound-to-wound contact after a sporting event or sporting accident?

A. I'm not aware of any.

Q. Is your opinion in paragraph 48 specifically to the transmission of HIV on the battlefield?

A. Yes.

Q. And what opinion are you offering about the risk of the transmission of HIV via exposure to HIV-containing blood on the battlefield?

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

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

in one of the more recent studies when there is viral suppression.

Q. Are you a specialist in neurology?

A. I'm not a specialist in neurology.

Q. Okay.

A. What I -- The reason I was referring to this, because I'm not a specialist, but the neurologic findings in terms of abnormalities in CSF are among the publications we've done. Justin McArthur, who is a coauthor in some of these studies that were published, is a colleague of mine that I've collaborated with since I was on active duty, and the neurologic thing has been a concern that it is important, but 30 years later, people are -- is it 30 years? Thirty years later we are struggling to understand what to do with the abnormal test that doesn't seem to have a functional impact and no progression in some of the studies where we're now in the very effective antiretroviral era.

Q. Okay.

A. So I am not a neurologist.

Q. So Dr. Hardy states in his opinion that neurocognitive side effects are possible and not well documented, okay? Do you agree with those statements?

A. Yes.

Q. Okay, and he also says that some researchers are beginning to believe that they may occur, they being neurocognitive side effects, after a long-term -- let me rephrase the question.

A. Or you can quote it. I'm sorry.

Q. Right, some researchers are beginning to believe it may occur after a long-term infection, and that the side effects can and should be dealt with on a case-by-case basis. Do you agree with that statement?

A. I think it's -- I think it's smart to practice medicine on a case-by-case basis. The symptoms -- the symptoms -- abnormal test results do occur at some frequency, and when symptoms occur, if someone comes in and says I'm not thinking straight, my memory is poor, my -- I'm having trouble finding words, which are some of the -- self -- the cognitive symptomatic changes. There's also some motor changes that I don't know as well. If there -- if someone complains about those, I would deal with those.

Q. Okay.

A. But these same papers say that in the differential diagnosis, the likelihood that those symptoms is related to HIV is low. It's more likely

something else. And they also go on to list four, five or six other risk factors for these abnormal test results, the least of which in terms of impact of a variable is HIV. So the same papers that point out this -- whatever the frequency is of this occurring, whether it's -- even whether it's stable or not, is HIV is low on the list of things that will cause this, but it's the commonalities of mankind that are more common than HIV infection causing these symptoms.

Q. What -- what is meant by not well documented?

A. Well, that would mean poor evidence in the literature. I think -- that's how I would say it. I mean, I would say it -- well, the way he said it is fine. You're asking for a different use of words to -- to help understand it, and I think that's what it means. There's not much evidence for it, or the quality of the studies, if there is evidence, the quality of the studies is not good or -- or they're competing and inconsistent.

Q. Okay, when -- when you're -- when you're referring to possible and not well documented, is it because research still needs to be done in the field?

A. So -- so research needs to be done in the

field. Are these my words or --

Q. No.

A. -- or Dr. Hardy's?

Q. When -- when -- well, when either one of you -- you said -- you said that you agreed with him that it was possible and not well documented.

A. Right, but I'm just trying -- if I said it, I was going to look for where I said it so I had better context for it.

Q. Okay, I was referring to just when you agreed, so when Dr. -- when -- when you said that they're possible and not well documented, is it because research still needs to be done in this field?

A. So I think -- I think that's fair, and I think it's -- they're possible. The difficulty is that we did it in everyone because we had -- we had a small army of neurocognitive specialists, Ph.D.s that were interested in the question, and that's how we could do it routinely. I don't know if the Army and Navy did this routinely every six months for part of their -- but we had huge amounts of data. I don't think it's done anymore because we're not putting as much money into it because we didn't find a lot we could do anything about. It didn't seem to have an

impact on -- on readiness in the Air Force, so it -- I don't think it was a continued investment in that -- in that research.

Q. Okay. So are you basing sort of your opinion in this area a little bit on an opinion that sort of requires future research be done?

MR. SCHOETTES: Objection, mischaracterizes prior testimony. You can answer.

A. So I tried to refer to a number of studies that indicate there is a low frequency of the abnormal test in the asymptomatic setting, and that in the symptomatic setting, we know what to pay attention to. I mean, if something's abnormal, we deal with it. If someone's no longer fit for duty, we have ways of dealing with that, but that's manifest in the more advanced state, and that someone that's virally suppressed does not have a rate of progression -- it's either zero or very long term, those are facts that I believe are solid, and it's on that basis that I'm not very worried about asymptomatic NCI because it doesn't have a functional impact unless it progresses to a functional impact, and then -- then I'm worried about it, but it's not some occult thing other than a -- and it's -- and it's not an obscure test. They're well developed

tests, but it's not clear that we always know what to do with them. When something goes wrong, I know what to do with it, make an assessment of fitness for duty.

Q. And -- and what I'm trying to get at is is that is your opinion a predictive judgment about the risk of neurocognitive side effects, or neurocognitive -- neurocognitive effects?

A. Well, so the -- so the predictability is that there -- if someone is asymptomatic and fully suppressed, meaning they're not going to -- they will not progress, and they're in their job making it work best they can like everyone next to them, I'm not concerned. If it -- in the future they have a hard time with their job or a neurologic complaint, either a cognitive or physical disability, I'll deal with that when it occurs. I'm not -- that's when I'm worried. I'm not worried about this because I don't see that there's a functional impact.

Q. Okay, and I'm --

A. And there's a lot of data to that.

Q. And I'm asking a slightly different question, and that is is what is in your opinion the risk that there is a -- or that HIV may have a neurocognitive effect in some people?

A. Oh, I'm confident that is true in some people in this -- somewhere along this spectrum between asymptomatic, which I'm not worried about, symptomatic, which I would pay attention to, and severe, which is AIDS defining.

Q. And there's --

A. So I'm -- I -- one must pay attention to neurocognitive impairment in the overall management of HIV infection.

Q. Okay, let's turn to page 66 -- or I'm sorry, paragraph 66, and that's on page 29. So Dr. Hendrix, in paragraph 66, you state there are no geographic locations that would pose an issue for a person living with HIV so long as the individual adheres to the antiretroviral regimen, correct?

A. That's correct.

Q. And -- and is that an opinion?

A. It's an opinion based on the absence of published data that I could find to the contrary.

Q. And what type of data were you looking for?

A. Some evidence that the stressors that you helped me with the list before had a direct impact on the health of an HIV infected individual over and above the impact on any other individual.

Q. Okay.

BY MR. SCHOETTES:

Q. All right. There was just some additional discussion of nosocomial infection, correct?

A. Yes.

Q. When you were in charge of infection control while deployed, were nosocomial infections a part of your area of responsibility?

MR. NORWAY: Objection, form.

BY MR. SCHOETTES:

Q. Let me ask that a little differently. Were nosocomial infections one of the types of infections that you were tasked with helping to reduce the incidence of while you were deployed?

MR. NORWAY: Objection, form.

A. May I answer? Yes, absolutely, the -- there were -- the big concerns with nosocomial infections in -- in hospital settings have actually very little to do with viruses. They have mostly to do with bacteria and fungi, and I've actually published a number of studies, actually, a phase 3 study that we did at Hopkins looking at reducing transmission risk of fungi with prophylaxis.

So these are big risks. The ability to do that reduces the case -- these things have a case mortality rate of like 40 percent. So if that

occurs, there's a 40 percent risk of death, just to pick one, whereas if the HIV were transmitted, we're talking about with the excellent treatment you have in the Army, you have reduction of one year off of one's life with current numbers.

Q. Can you give me some examples of the type of nosocomial infections that might have a high mortality rate?

A. Sure. So there could be -- oh, so one -- one example might be a super-infection of -- of an influenza virus. There could be transmission of a highly resistant Gram-negative rod. I mean, they could be Gram-positive cocci also. There's a bunch of bacteria that are increasingly resistant. The fungi I mentioned. I think those are probably the big categories, and there's a number of categories of fungi, but I think that's enough of the categories, and all of those can have a high case fatality ratio, and the drugs we're using to treat these highly resistant organisms are running out of steam, and there is a lot of pressure, the FDA is changing lots of their rules to sort of engineer industry to make more drugs to deal with this problem because it's so significant because we don't have ways to sustain lives -- these have high case fatality ratios with --

so the result of that transmission is -- is death in the hospital. They don't go home, rather than the -- the comparison of course to the HIV situation where that is not what happens. It's a chronic lifelong infection.

Q. Is ventilator-assisted pneumonia a concern in -- of nosocomial infection in a deployed setting?

MR. NORWAY: Objection, form.

A. Yeah, so ventilator-assisted pneumonia would be a -- so a ventilator would be a device that is one of the routes if it's -- if it's imperfectly cleaned between patients that use it, contaminated by one patient with a pneumonia, the second patient can be infected with that pneumonia, often highly resistant. That could lead to death, and in a deployed setting, if they're using ventilators, that would be a risk. It could be an increased risk in that setting, but -- but it is a risk. Whether -- whether it's increased or not is really irrelevant. It's -- it would be a risk, as it is in any -- in any health care facility.

Q. We talked -- you were asked questions earlier about wound-to-wound exposures to HIV. How would you define the volume of blood that is at issue in such an exposure?

EXHIBIT 69

Excerpts from the January 9, 2019 Deposition of
Lt. Col. Lisa M. Lute

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

NICHOLAS HARRISON and OUTSERVE-SLDN, INC., Plaintiffs,	
v.	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 Secretary of the Army; and the UNITES STATES DEPARTMENT OF DEFENSE, Defendants.	

Tuesday, January 9, 2019

Videotape Deposition of LT. COL. LISA M. LUTE, taken at the Law Offices of Winston & Strawn LLP, located at 1700 K Street Northwest, Washington, D.C., beginning at 9:26 a.m., before Ryan K. Black, a Registered Professional Reporter, Certified Livenote Reporter and Notary Public in and for the District of Columbia.

BY MR. SCHOETTES:

Q. Do you recall the circumstances, or do -- do you know the circumstances of what actually occurred?

MR. NORWAY: Objection. Outside the scope.

You may answer.

THE WITNESS: And before I go ahead, I want to clarify that there are two different blood bank issues here, okay?

BY MR. SCHOETTES:

Q. Okay.

A. Okay. The blood bank that would be downrange, which is already available, there's no testing. The incident that I'm aware of occurred, and it was a -- a group of individuals, the individual was aware that he was HIV-positive. He was out with his friends, and they all decided they were going to donate blood. There's a lot of camaraderie in the military. It's not cool -- you know, you kind of -- you don't want to be the -- the one man that didn't do that thing.

And so they all went to donate blood, and he did go to donate blood. It was through

one of the local blood donation sites, which then, in turn, when he came up positive on their screening, then I'm notified because I -- I, as the public health nurse, would receive the HIV-positive results for that installation, so ...

Q. So this was a blood donation through a civilian blood collection center?

A. Correct.

Q. Do you know if this person was given an opportunity during that process to anonymously -- confidentially indicate that his blood should not be used?

MR. NORWAY: Objection. Outside of scope.

You may answer.

THE WITNESS: I cannot speak to that specific organization's process, but what I can say that the standard of practice is, that there is a set of questions and -- and opportunities that are given so that anyone that has any disease process that would preclude them from donating has the opportunity to indicate such on their form or with the individual that screens them.

EXHIBIT 70

Declaration of Sergeant Nicholas Harrison in Support of Plaintiffs' Opposition to Defendants' Motions for Summary Judgment

UNDER SEAL

EXHIBIT 71

CDC, Recommendations for Preventing Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Patients During Exposure-Prone Invasive Procedures (retired), 40 MMWR 1-9 (July 12, 1991)

MMWR

Recommendations and Reports

July 12, 1991 / 40(RR08);1-9

Guidance related to HIV infection is retired. Guidance on hepatitis B is superseded. (See Updated CDC recommendations for the management of hepatitis B virus-infected health-care providers and students. 2012.)

Recommendations for Preventing Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Patients During Exposure-Prone Invasive Procedures

This document has been developed by the Centers for Disease Control (CDC) to update recommendations for prevention of transmission of human immunodeficiency virus (HIV) and hepatitis B virus (HBV) in the health-care setting. Current data suggest that the risk for such transmission from a health-care worker (HCW) to a patient during an invasive procedure is small; a precise assessment of the risk is not yet available. This document contains recommendations to provide guidance for prevention of HIV and HBV transmission during those invasive procedures that are considered exposure-prone. INTRODUCTION

Recommendations have been made by the Centers for Disease Control (CDC) for the prevention of transmission of the human immunodeficiency virus (HIV) and the hepatitis B virus (HBV) in health-care settings (1-6). These recommendations emphasize adherence to universal precautions that require that blood and other specified body fluids of all patients be handled as if they contain blood-borne pathogens (1,2).

Previous guidelines contained precautions to be used during invasive procedures (defined in Appendix) and recommendations for the management of HIV- and HBV-infected health-care workers (HCWs) (1). These guidelines did not include specific recommendations on testing HCWs for HIV or HBV infection, and they did not provide guidance on which invasive procedures may represent increased risk to the patient.

The recommendations outlined in this document are based on the following considerations:

- Infected HCWs who adhere to universal precautions and who

do not perform invasive procedures pose no risk for transmitting HIV or HBV to patients.

- Infected HCWs who adhere to universal precautions and who

perform certain exposure-prone procedures (see page 4) pose a small risk for transmitting HBV to patients.

- HIV is transmitted much less readily than HBV. In the interim, until further data are available, additional

precautions are prudent to prevent HIV and HBV transmission during procedures that have been linked to HCW-to-patient HBV transmission or that are considered exposure-prone. BACKGROUND Infection-Control Practices

Previous recommendations have specified that infection-control programs should incorporate principles of universal precautions (i.e., appropriate use of hand washing, protective barriers, and care in the use and disposal of needles and other sharp instruments) and should maintain these precautions rigorously in all health-care settings (1,2,5). Proper application of these principles will assist in minimizing the risk of transmission of HIV or HBV from patient to HCW, HCW to patient, or patient to patient.

As part of standard infection-control practice, instruments and other reusable equipment used in performing invasive procedures should be appropriately disinfected and sterilized as follows (7):

- Equipment and devices that enter the patient's vascular

system or other normally sterile areas of the body should be sterilized before being used for each patient.

- Equipment and devices that touch intact mucous membranes

but do not penetrate the patient's body surfaces should be sterilized when possible or undergo high-level disinfection if they cannot be sterilized before being used for each patient.

- Equipment and devices that do not touch the patient or

that only touch intact skin of the patient need only be cleaned with a detergent or as indicated by the manufacturer.

Compliance with universal precautions and recommendations for disinfection and sterilization of medical devices should be scrupulously monitored in all health-care settings (1, 7, 8). Training of HCWs in proper infection-control technique should begin in professional and vocational schools and continue as an ongoing process. Institutions should provide all HCWs with appropriate inservice education regarding infection control and safety and should establish procedures for monitoring compliance with infection-control policies.

All HCWs who might be exposed to blood in an occupational setting should receive hepatitis B vaccine, preferably during their period of professional training and before any occupational exposures could occur (8, 9).

Transmission of HBV During Invasive Procedures

Since the introduction of serologic testing for HBV infection in the early 1970s, there have been published reports of 20 clusters in which a total of over 300 patients were infected with HBV in association with treatment by an HBV-infected HCW. In 12 of these clusters, the implicated HCW did not routinely wear gloves; several HCWs also had skin lesions that may have facilitated HBV transmission (10-22). These 12 clusters included nine linked to dentists or oral surgeons and one cluster each linked to a general practitioner, an inhalation therapist, and a cardiopulmonary-bypass-pump technician. The clusters associated with the inhalation therapist and the cardiopulmonary-bypass-pump technician--and some of the other 10 clusters--could possibly have been prevented if current recommendations on universal precautions, including glove use, had been in effect. In the remaining eight clusters, transmission occurred despite glove use by the HCWs; five clusters were linked to obstetricians or gynecologists, and three were

linked to cardiovascular surgeons (6, 22-28). In addition, recent unpublished reports strongly suggest HBV transmission from three surgeons to patients in 1989 and 1990 during colorectal (CDC, unpublished data), abdominal, and cardiothoracic surgery (29).

Seven of the HCWs who were linked to published clusters in the United States were allowed to perform invasive procedures following modification of invasive techniques (e.g., double gloving and restriction of certain high-risk procedures) (6,11- 13,15,16, 24). For five HCWs, no further transmission to patients was observed. In two instances involving an obstetrician/gynecologist and an oral surgeon, HBV was transmitted to patients after techniques were modified (6, 12).

Review of the 20 published studies indicates that a combination of risk factors accounted for transmission of HBV from HCWs to patients. Of the HCWs whose hepatitis B e antigen (HBeAg) status was determined (17 of 20), all were HBeAg positive. The presence of HBeAg in serum is associated with higher levels of circulating virus and therefore with greater infectivity of hepatitis-B-surface-antigen (HBsAg)-positive individuals; the risk of HBV transmission to an HCW after a percutaneous exposure to HBeAg-positive blood is approximately 30% (30-32). In addition, each report indicated that the potential existed for contamination of surgical wounds or traumatized tissue, either from a major break in standard infection-control practices (e.g., not wearing gloves during invasive procedures) or from unintentional injury to the infected HCW during invasive procedures (e.g., needle sticks incurred while manipulating needles without being able to see them during suturing).

Most reported clusters in the United States occurred before awareness increased of the risks of transmission of blood-borne pathogens in health-care settings and before emphasis was placed on the use of universal precautions and hepatitis B vaccine among HCWs. The limited number of reports of HBV transmission from HCWs to patients in recent years may reflect the adoption of universal precautions and increased use of HBV vaccine. However, the limited number of recent reports does not preclude the occurrence of undetected or unreported small clusters or individual instances of transmission; routine use of gloves does not prevent most injuries caused by sharp instruments and does not eliminate the potential for exposure of a patient to an HCW's blood and transmission of HBV (6, 22-29).

Transmission of HIV During Invasive Procedures

The risk of HIV transmission to an HCW after percutaneous exposure to HIV-infected blood is considerably lower than the risk of HBV transmission after percutaneous exposure to HBeAg-positive blood (0.3% versus approximately 30%) (33-35). Thus, the risk of transmission of HIV from an infected HCW to a patient during an invasive procedure is likely to be proportionately lower than the risk of HBV transmission from an HBeAg-positive HCW to a patient during the same procedure. As with HBV, the relative infectivity of HIV probably varies among individuals and over time for a single individual. Unlike HBV infection, however, there is currently no readily available laboratory test for increased HIV infectivity.

Investigation of a cluster of HIV infections among patients in the practice of one dentist with acquired immunodeficiency syndrome (AIDS) strongly suggested that HIV was transmitted to five of the approximately 850 patients evaluated through June 1991 (36-38). The investigation indicates that HIV transmission occurred during dental care, although the precise mechanisms of transmission have not been determined. In two other studies, when patients cared for by a general surgeon and a surgical resident who had AIDS were tested, all patients tested, 75 and 62, respectively, were negative for HIV infection (39, 40). In a fourth study, 143 patients who had been treated by a dental student with HIV infection and were later tested were all negative for HIV infection (41). In another investigation, HIV antibody testing was offered to all patients whose surgical procedures had been performed by a general surgeon within 7 years before the surgeon's diagnosis of AIDS; the date at which the surgeon became infected with HIV is unknown (42). Of 1,340 surgical patients contacted, 616 (46%) were tested for HIV. One patient, a known intravenous drug user, was HIV positive when tested but may already have been infected at the time of surgery. HIV test results for the 615 other surgical patients were negative (95% confidence interval for risk of transmission per operation=0.0%-0.5%).

The limited number of participants and the differences in procedures associated with these five investigations limit the ability to generalize from them and to define precisely the risk of HIV transmission from HIV-infected HCWs to patients. A precise estimate of the risk of HIV transmission from infected HCWs to patients can be determined only after careful evaluation of a substantially larger number of patients whose exposure-prone procedures have been performed by HIV-infected HCWs.

Exposure-Prone Procedures

Despite adherence to the principles of universal precautions, certain invasive surgical and dental procedures have been implicated in the transmission of HBV from infected HCWs to patients, and should be considered exposure-prone. Reported examples include certain oral, cardiothoracic, colorectal (CDC, unpublished data), and obstetric/gynecologic procedures (6, 12, 22-29).

Certain other invasive procedures should also be considered exposure-prone. In a prospective study CDC conducted in four hospitals, one or more percutaneous injuries occurred among surgical personnel during 96 (6.9%) of 1,382 operative procedures on the general surgery, gynecology, orthopedic, cardiac, and trauma services (43). Percutaneous exposure of the patient to the HCW's blood may have occurred when the sharp object causing the injury recontacted the patient's open wound in 28 (32%) of the 88 observed injuries to surgeons (range among surgical specialties=8%-57%; range among hospitals=24%-42%). Characteristics of exposure-prone procedures include digital palpation of a needle tip in a body cavity or the simultaneous presence of the HCW's fingers and a needle or other sharp instrument or object in a poorly visualized or highly confined anatomic site. Performance of exposure-prone procedures presents a recognized risk of percutaneous injury to the HCW, and--if such an injury occurs--the HCW's blood is likely to contact the patient's body cavity, subcutaneous tissues, and/or mucous membranes.

Experience with HBV indicates that invasive procedures that do not have the above characteristics would be expected to pose substantially lower risk, if any, of transmission of HIV and other blood-borne pathogens from an infected HCW to patients. RECOMMENDATIONS

Investigations of HIV and HBV transmission from HCWs to patients indicate that, when HCWs adhere to recommended infection-control procedures, the risk of transmitting HBV from an infected HCW to a patient is small, and the risk of transmitting HIV is likely to be even smaller. However, the likelihood of exposure of the patient to an HCW's blood is greater for certain procedures designated as exposure-prone. To minimize the risk of HIV or HBV transmission, the following measures are recommended:

--All HCWs should adhere to universal precautions, including the appropriate use of hand washing, protective barriers, and care in the use and disposal of needles and other sharp instruments. HCWs who have exudative lesions or weeping dermatitis should refrain from all direct patient care and from handling patient-care equipment and devices used in performing invasive procedures until the condition resolves. HCWs should also comply with current guidelines for disinfection and sterilization of reusable devices used in invasive procedures.

--Currently available data provide no basis for recommendations to restrict the practice of HCWs infected with HIV or HBV who perform invasive procedures not identified as exposure-prone, provided the infected HCWs practice recommended surgical or dental technique and comply with universal precautions and current recommendations for sterilization/disinfection.

--Exposure-prone procedures should be identified by medical/surgical/dental organizations and institutions at which the procedures are performed.

--HCWs who perform exposure-prone procedures should know their HIV antibody status. HCWs who perform exposure-prone procedures and who do not have serologic evidence of immunity to HBV from vaccination or from previous infection should know their HBsAg status and, if that is positive, should also know their HBeAg status.

--HCWs who are infected with HIV or HBV (and are HBeAg positive) should not perform exposure-prone procedures unless they have sought counsel from an expert review panel and been advised under what circumstances, if any, they may continue to perform these procedures.* Such circumstances would include notifying prospective patients of the HCW's seropositivity before they undergo exposure-prone invasive procedures.

--Mandatory testing of HCWs for HIV antibody, HBsAg, or HBeAg is not recommended. The current assessment of the risk that infected HCWs will transmit HIV or HBV to patients during exposure-prone procedures does not support the diversion of resources that would be required to implement mandatory testing programs. Compliance by HCWs with recommendations can be increased through education, training, and appropriate confidentiality safeguards.

*The review panel should include experts who represent a balanced perspective. Such experts might include all of the following: a) the HCW's personal physician(s), b) an infectious disease specialist with expertise in the epidemiology of HIV and HBV transmission, c) a health professional with expertise in the procedures performed by the HCW, and d) state or local public health official(s). If the HCW's practice is institutionally based, the expert review panel might also include a member of the infection-control committee, preferably a hospital epidemiologist. HCWs who perform exposure-prone procedures outside the hospital/institutional setting should seek advice from appropriate state and local public health officials regarding the review process. Panels must recognize the importance of confidentiality and the privacy rights of infected HCWs. HCWS WHOSE PRACTICES ARE MODIFIED BECAUSE OF HIV OR HBV STATUS

HCWs whose practices are modified because of their HIV or HBV infection status should, whenever possible, be provided opportunities to continue appropriate patient-care activities. Career counseling and job retraining should be encouraged to promote the continued use of the HCW's talents, knowledge, and skills. HCWs whose practices are modified because of HBV infection should be reevaluated periodically to determine whether their HBeAg status changes due to resolution of infection or as a result of treatment (44). NOTIFICATION OF PATIENTS AND FOLLOW-UP STUDIES

The public health benefit of notification of patients who have had exposure-prone procedures performed by HCWs infected with HIV or positive for HBeAg should be considered on a case-by-case basis, taking into consideration an assessment of specific risks, confidentiality issues, and available resources. Carefully designed and implemented follow-up studies are necessary to determine more precisely the risk of transmission during such procedures. Decisions regarding notification and follow-up studies should be made in consultation with state and local public health officials. ADDITIONAL NEEDS

- Clearer definition of the nature, frequency, and circumstances of blood contact between patients and HCWs during invasive procedures.
- Development and evaluation of new devices, protective barriers, and techniques that may prevent such blood contact without adversely affecting the quality of patient care.
- More information on the potential for HIV and HBV transmission through contaminated instruments.
- Improvements in sterilization and disinfection techniques for certain reusable equipment and devices.
- Identification of factors that may influence the likelihood of HIV or HBV transmission after exposure to HIV- or HBV-infected blood.

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APPENDIX Definition of Invasive Procedure

An invasive procedure is defined as ``surgical entry into tissues, cavities, or organs or repair of major traumatic injuries'' associated with any of the following: ``1) an operating or delivery room, emergency department, or outpatient setting, including both physicians' and dentists' offices; 2) cardiac catheterization and angiographic procedures; 3) a vaginal or cesarean delivery or other invasive obstetric procedure during which bleeding may occur; or 4) the manipulation, cutting, or removal of any oral or perioral tissues, including tooth structure, during which bleeding occurs or the potential for bleeding exists.'' Reprinted from: Centers for Disease Control. Recommendation for prevention of HIV transmission in health-care settings. MMWR 1987;36 (suppl. no. 2S):6S-7S.

This page last reviewed 5/2/01

EXHIBIT 72

SHEA Guideline for Management of Healthcare Workers Who Are Infected with Hepatitis B Virus, Hepatitis C Virus, and/or Human Immunodeficiency, 31 Infection Control and Hospital Epidemiology 203-230 (March 2010)

INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY MARCH 2010, VOL. 31, NO. 3

SHEA GUIDELINE

SHEA Guideline for Management of Healthcare Workers Who Are Infected with Hepatitis B Virus, Hepatitis C Virus, and/or Human Immunodeficiency Virus

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EXECUTIVE SUMMARY

This guideline provides the updated recommendations of the Society for Healthcare Epidemiology of America (SHEA) regarding the management of healthcare providers who are infected with hepatitis B virus (HBV), hepatitis C virus (HCV), and/or the human immunodeficiency virus (HIV). For the reasons cited in the guideline, SHEA continues to recommend that, although some aspects of the approach to and administrative management of each of these infectious syndromes in healthcare providers are similar, separate management strategies for healthcare workers who are infected with these unrelated viruses remain appropriate. As we did in both prior iterations of this document, SHEA emphasizes the use of appropriate infection control procedures to minimize exposure of patients or providers to blood, emphasizes that transfers of blood from patients to providers and from providers to patients should be avoided, and recommends that infected healthcare providers should not be totally prohibited from participating in patient-care activities solely on the basis of a bloodborne pathogen infection. The types of procedures assessed by the panel as associated with an increased risk for provider-to-patient transmission of these pathogens are discussed in detail. For each pathogen, recommendations are graduated according to the relative viral load level of the infected provider (Tables 1 and 2). However, SHEA emphasizes that, because of the complexity of these cases, each such case will be slightly different from the next, and each should be independently considered in context.

HBV

SHEA recommends that HBV-infected healthcare providers who test either positive for HBV "e" antigen (HBeAg) or negative for HBeAg but who have circulating HBV burdens of greater than or equal to 10^4 genome equivalents (GE) per milliliter of blood routinely use double-gloving for all invasive procedures, for all contact with mucous membranes or nonintact skin, and for all instances in patient care for which gloving is recommended, and that they not perform those Category III activities identified as associated with a risk for provider-to-patient HBV transmission despite the use of appropriate infection control procedures (details of the procedures identified as associated with increased risk for transmission are given in Table 2).

SHEA recommends that a healthcare provider who has a circulating HBV burden of less than 10^4 GE/mL be allowed to perform those Category III activities identified as associated with a risk for provider-to-patient transmission of bloodborne pathogens, so long as the infected provider (1) is not detected as having transmitted infection to patients; (2) obtains advice from an Expert Review Panel (the function of the Expert Review Panel is discussed in more detail in Recommendation 8, below) about continued practice; (3) undergoes follow-up routinely by Occupational Medicine staff (or an appropriate public health official), who test the provider twice per year to demonstrate the maintenance of a viral burden of less than 10^4 GE/mL; (4) also receives follow-up by a personal physician who has expertise in the management of HBV infection and who is allowed by the provider to communicate with the Expert Review Panel about the provider's clinical status; (5) consults with an expert about optimal infection control procedures (and strictly adheres to the recommended procedures, including the routine use of double gloving for Category II and Category III procedures and frequent glove changes during procedures, particularly

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TABLE 1. Summary Recommendations for Managing Healthcare Providers Infected with Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and/or Human Immunodeficiency Virus (HIV)

Virus, circulating viral burden	Categories of clinical activities[a]	Recommendation	Testing
HBV			
$<10^4$ GE/mL	Categories I, II, and III	No restrictions[b]	Twice per year
$\geqslant 10^4$ GE/mL	Categories I and II	No restrictions[b]	NA
$\geqslant 10^4$ GE/mL	Category III	Restricted[c]	NA
HCV			
$<10^4$ GE/mL	Categories I, II, and III	No restrictions[b]	Twice per year
$\geqslant 10^4$ GE/mL	Categories I and II	No restrictions[b]	NA
$\geqslant 10^4$ GE/mL	Category III	Restricted[c]	NA
HIV			
$<5 \times 10^2$ GE/mL	Categories I, II, and III	No restrictions[b]	Twice per year
$\geqslant 5 \times 10^2$ GE/mL	Categories I and II	No restrictions[b]	NA
$\geqslant 5 \times 10^2$ GE/mL	Category III	Restricted[d]	NA

NOTE. These recommendations provide a framework within which to consider such cases; however, each such case is sufficiently complex that each should be independently considered in context by the expert review panel (see text). GE, genome equivalents; NA, not applicable.

[a] See Table 2 for the categorization of clinical activities.

[b] No restrictions recommended, so long as the infected healthcare provider (1) is not detected as having transmitted infection to patients; (2) obtains advice from an Expert Review Panel about continued practice; (3) undergoes follow-up routinely by Occupational Medicine staff (or an appropriate public health official), who test the provider twice per year to demonstrate the maintenance of a viral burden of less than the recommended threshold (see text); (4) also receives follow-up by a personal physician who has expertise in the management of her or his infection and who is allowed by the provider to communicate with the Expert Review Panel about the provider's clinical status; (5) consults with an expert about optimal infection control procedures (and strictly adheres to the recommended procedures, including the routine use of double-gloving for Category II and Category III procedures and frequent glove changes during procedures, particularly if performing technical tasks known to compromise glove integrity [eg, placing sternal wires]), and (6) agrees to the information in and signs a contract or letter from the Expert Review Panel that characterizes her or his responsibilities (see text).

[c] These procedures permissible only when viral burden is $<10^4$ GE/mL.

[d] These procedures permissible only when viral burden is $<5 \times 10^2$ GE/mL.

if performing technical tasks known to compromise glove integrity [eg, placing sternal wires]); (6) agrees to the information in and signs a contract or letter from the Expert Review Panel that characterizes her or his responsibilities (discussed in more detail in Recommendation 8, below).

HCV

SHEA recommends that HCV-infected providers who have circulating HCV viral burdens of greater than or equal to 10^4 GE/mL routinely use double-gloving for all invasive procedures, for all contact with mucous membranes or nonintact skin, and for all instances in patient care for which gloving is routinely recommended, and that they not perform those Category III activities identified as associated with a risk for provider-to-patient transmission of bloodborne pathogen infection despite the use of appropriate infection control procedures. SHEA also recommends that an HCV-infected provider who has a viral burden of less than 10^4 GE/mL not be excluded from any aspect of patient care, including the performance of Category III procedures (Tables 1 and 2), so long as the infected provider (1) is not detected as having transmitted infection to patients; (2) obtains advice from an Expert Review Panel about continued practice; (3) undergoes follow-up routinely by Occupational Medicine, who tests the provider twice annually to demonstrate the maintenance of a viral burden of less than 10^4 GE/mL; (4) also receives follow-up by a personal physician who has expertise in the management of HCV infection and who is allowed by the provider to communicate with the Expert Review Panel about the provider's clinical status; (5) consults with an infection control expert about optimal infection control procedures (and strictly adheres to the recommended procedures, including the routine use of double-gloving during Category II and Category III procedures and frequent glove changes during procedures, particularly if performing technical tasks known to compromise glove integrity [eg, placing sternal wires]); 6) agrees to the information in and signs a contract or letter from the Expert Review Panel that characterizes her or his responsibilities (discussed in more detail in Recommendation 8, below).

HIV

SHEA recommends that HIV-infected providers who have circulating HIV viral burdens of greater than or equal to

5×10^2 GE/mL routinely use double-gloving for all invasive procedures, for all contact with mucous membranes or nonintact skin, and for all instances in patient care for which gloving is recommended, and that they not perform those Category III activities identified as associated with a risk for provider-to-patient transmission of bloodborne pathogen infection despite the use of appropriate infection control procedures (Tables 1 and 2). SHEA recommends that an HIV-infected provider who has a viral burden of less than 5×10^2 GE/mL not be excluded from any aspect of patient care, including the performance of Category III procedures, so long as the infected provider (1) is not detected as having transmitted infection to patients; (2) obtains advice from an Expert Review Panel about continued practice; (3) undergoes follow-up routinely by Occupational Medicine (or an appropriate public health official), who tests the provider twice annually to demonstrate the maintenance of a viral burden of less than 5×10^2 GE/mL; (4) also receives follow-up by a personal physician who has expertise in the management of HIV infection and who is allowed by the provider to communicate with the Expert Review Panel about the provider's clinical status; (5) consults with an expert about optimal infection control procedures (and strictly adheres to the recommended procedures, including the routine use of double-gloving for Category II and Category III procedures and frequent glove changes during procedures, particularly if performing technical tasks known to compromise glove integrity [eg, placing sternal wires]); and (6) agrees to the information in and signs a contract or letter from the Expert Review Panel that characterizes her or his responsibilities (discussed in more detail in Recommendation 8, below).

General Recommendations

The rationale for these recommendations is presented below (in the section Background and Rationale). SHEA argues for comprehensive education concerning bloodborne pathogens for all healthcare providers and trainees. SHEA recommends managing infected providers in the context of a comprehensive approach to the management of all impaired providers. SHEA emphasizes the importance of patient safety as well as provider privacy and medical confidentiality. The Society also emphasizes the importance of offering employees who have disabilities reasonable accommodation for their disabilities. The guideline discusses exposure management in detail and, in general, recommends adherence to existing guidelines for managing exposures to these viruses. SHEA underscores that practitioners who are institutionally based and who develop one of these bloodborne pathogen infections are ethically bound to report their infections to their institutions' occupational medicine providers and to engage in the processes outlined below. Further, practitioners who are not institutionally based and who develop one of these bloodborne pathogen infections are ethically bound to engage their public health departments (consonant with state and local laws), as described below. Finally, the society encourages routine voluntary, confidential testing of providers, emphasizing that providers who conduct Category III procedures should know their immune or infection status with respect to each of these 3 bloodborne pathogens. Specific details and the rationale for these recommendations are included in the body of the guideline.

INTRODUCTION

In 1990, in response to public and professional concern that arose in the wake of a highly publicized cluster of cases of provider-to-patient transmission of the human immunodeficiency virus (HIV) in a Florida dentist's practice,[3-8,] SHEA, in collaboration with the Association for Practitioners in Infection Control, published a position paper concerning the administrative management of healthcare providers who are infected with certain bloodborne pathogens.[9] As additional information became available, in 1997 SHEA issued an updated position paper discussing the management of healthcare workers infected with hepatitis B virus (HBV), hepatitis C virus (HCV), HIV, or other bloodborne pathogens.[10] The purpose of the present guideline is to provide updated guidance from SHEA regarding the administrative management of providers infected with these bloodborne pathogens, given the progress in the field since 1997.

Despite the widespread use of the hepatitis B vaccine, HBV remains the most commonly transmitted bloodborne pathogen in the healthcare setting. Although continued widespread administration of the vaccine should eventually mitigate this risk, any guideline for the years 2009 and beyond must include recommendations for HBV-infected providers. Similarly, the past 12 years' experience has provided insight in the factors influencing the risk for provider-to-patient transmission of HCV. Because we do not have a hepatitis C vaccine yet, and, with the prevalence of HCV infection rising around the world, this flavivirus is likely to become the most frequently transmitted bloodborne pathogen in health care in the years ahead. Provider-to-patient transmission of HIV has been extremely rare, with no cases reported worldwide since 2003. Nonetheless, the first instance of transmission of HIV from an infected provider to a patient was the driving force for the creation of guidelines and recommendations about providers infected with bloodborne pathogens.

This document provides updated information about each virus and the healthcare risks associated with infected practitioners and then addresses a series of questions relevant to the management of providers infected with each of these viruses. We then make recommendations about the management of providers infected with these bloodborne pathogens, citing the available evidence supporting the recommendations. The evidence base for these recommendations is limited at best. By the very nature of the topics being discussed, direct hypothesis-driven experimentation is virtually impossible, and may be complicated further by a low rate of voluntary

TABLE 2. Categorization of Healthcare-Associated Procedures According to Level of Risk for Bloodborne Pathogen Transmission

Category I: Procedures with de minimis risk of bloodborne virus transmission

- Regular history-taking and/or physical or dental examinations, including gloved oral examination with a mirror and/or tongue depressor and/or dental explorer and periodontal probe
- Routine dental preventive procedures (eg, application of sealants or topical fluoride or administration of prophylaxis[a]), diagnostic procedures, orthodontic procedures, prosthetic procedures (eg, denture fabrication), cosmetic procedures (eg, bleaching) not requiring local anesthesia
- Routine rectal or vaginal examination
- Minor surface suturing
- Elective peripheral phlebotomy[b]
- Lower gastrointestinal tract endoscopic examinations and procedures, such as sigmoidoscopy and colonoscopy
- Hands-off supervision during surgical procedures and computer-aided remote or robotic surgical procedures
- Psychiatric evaluations[c]

Category II: Procedures for which bloodborne virus transmission is theoretically possible but unlikely

- Locally anesthetized ophthalmologic surgery
- Locally anesthetized operative, prosthetic, and endodontic dental procedures
- Periodontal scaling and root planing[d]
- Minor oral surgical procedures (eg, simple tooth extraction [ie, not requiring excess force], soft tissue flap or sectioning, minor soft tissue biopsy, or incision and drainage of an accessible abscess)
- Minor local procedures (eg, skin excision, abscess drainage, biopsy, and use of laser) under local anesthesia (often under bloodless conditions)
- Percutaneous cardiac procedures (eg, angiography and catheterization)
- Percutaneous and other minor orthopedic procedures
- Subcutaneous pacemaker implantation
- Bronchoscopy
- Insertion and maintenance of epidural and spinal anesthesia lines
- Minor gynecological procedures (eg, dilatation and curettage, suction abortion, colposcopy, insertion and removal of contraceptive devices and implants, and collection of ova)
- Male urological procedures (excluding transabdominal intrapelvic procedures)
- Upper gastrointestinal tract endoscopic procedures
- Minor vascular procedures (eg, embolectomy and vein stripping)
- Amputations, including major limbs (eg, hemipelvectomy and amputation of legs or arms) and minor amputations (eg, amputations of fingers, toes, hands, or feet)
- Breast augmentation or reduction
- Minimum-exposure plastic surgical procedures (eg, liposuction, minor skin resection for reshaping, face lift, brow lift, blepharoplasty, and otoplasty)
- Total and subtotal thyroidectomy and/or biopsy
- Endoscopic ear, nose, and throat surgery and simple ear and nasal procedures (eg, stapedectomy or stapedotomy, and insertion of tympanostomy tubes)
- Ophthalmic surgery
- Assistance with an uncomplicated vaginal delivery[e]
- Laparoscopic procedures
- Thoracoscopic procedures[f]
- Nasal endoscopic procedures[g]
- Routine arthroscopic procedures[h]
- Plastic surgery[i]
- Insertion of, maintenance of, and drug administration into arterial and central venous lines
- Endotracheal intubation and use of laryngeal mask
- Obtainment and use of venous and arterial access devices that occur under complete antiseptic technique, using universal precautions, "no-sharp" technique, and newly gloved hands

Category III: Procedures for which there is definite risk of bloodborne virus transmission or that have been classified previously as "exposure-prone"

- General surgery, including nephrectomy, small bowel resection, cholecystectomy, subtotal thyroidectomy other elective open abdominal surgery
- General oral surgery, including surgical extractions,[j] hard and soft tissue biopsy (if more extensive and/or having difficult access for suturing), apicoectomy, root amputation, gingivectomy, periodontal curettage, mucogingival and osseous surgery, alveoplasty or alveoectomy, and endosseous implant surgery

TABLE 2. *(Continued)*

- Cardiothoracic surgery, including valve replacement, coronary artery bypass grafting, other bypass surgery, heart transplantation, repair of congenital heart defects, thymectomy, and open-lung biopsy
- Open extensive head and neck surgery involving bones, including oncological procedures
- Neurosurgery, including craniotomy, other intracranial procedures, and open-spine surgery
- Nonelective procedures performed in the emergency department, including open resuscitation efforts, deep suturing to arrest hemorrhage, and internal cardiac massage
- Obstetrical/gynecological surgery, including cesarean delivery, hysterectomy, forceps delivery, episiotomy, cone biopsy, and ovarian cyst removal, and other transvaginal obstetrical and gynecological procedures involving hand-guided sharps
- Orthopedic procedures, including total knee arthroplasty, total hip arthroplasty, major joint replacement surgery, open spine surgery, and open pelvic surgery
- Extensive plastic surgery, including extensive cosmetic procedures (eg, abdominoplasty and thoracoplasty)
- Transplantation surgery (except skin and corneal transplantation)
- Trauma surgery, including open head injuries, facial and jaw fracture reductions, extensive soft-tissue trauma, and ophthalmic trauma
- Interactions with patients in situations during which the risk of the patient biting the physician is significant; for example, interactions with violent patients or patients experiencing an epileptic seizure
- Any open surgical procedure with a duration of more than 3 hours, probably necessitating glove change

NOTE. Modified from Reitsma et al.[1]

[a] Does not include subgingival scaling with hand instrumentation.

[b] If done emergently (eg, during acute trauma or resuscitation efforts), peripheral phlebotomy is classified as Category III.

[c] If there is no risk present of biting or of otherwise violent patients.

[d] Use of an ultrasonic device for scaling and root planing would greatly reduce or eliminate the risk for percutaneous injury to the provider. If significant physical force with hand instrumentation is anticipated to be necessary, scaling and root planing and other Class II procedures could be reasonably classified as Category III.

[e] Making and suturing an episiotomy is classified as Category III.

[f] If unexpected circumstances require moving to an open procedure (eg, laparotomy or thoracotomy), some of these procedures will be classified as Category III.

[g] If moving to an open procedure is required, these procedures will be classified as Category III.

[h] If opening a joint is indicated and/or use of power instruments (eg, drills) is necessary, this procedure is classified as Category III.

[i] A procedure involving bones, major vasculature, and/or deep body cavities will be classified as Category III.

[j] Removal of an erupted or nonerupted tooth requiring elevation of a mucoperiosteal flap, removal of bone, or sectioning of tooth and suturing if needed.[2]

reporting of both infection status and high-risk provider-to-patient transmission events. Most data that we have about this subject come from documented instances of transmission. Many if not most of the conclusions from these studies are inferential. Some evidence comes from experimental laboratory studies or models. Thus, this guideline cannot have the scientific evidence-base found in many other guidelines. Nonetheless, we do have a broad experience working with these pathogens in the healthcare setting and the science base is much more robust than it was at the time the last guidance was published by SHEA in 1997.

EPIDEMIOLOGY

Provider-to-Patient Transmission of HBV

With respect to HBV transmission, through 1994, investigators at the Centers for Disease Control and Prevention (CDC) had identified 42 instances of provider-to-patient transmission of HBV (375 patients).[11] Subsequently, 2 additional clusters of provider-to-patient transmission of HBV infection were reported that involved surgeons who tested positive for HBeAg.[12,13]

In one of these more recent clusters, 4 patients acquired clinical hepatitis B infection from an orthopedic surgeon following surgeries conducted by the infected provider.[13] In a second, more recent cluster, 19 of the 144 susceptible patients whose surgical team included an HBV-infected thoracic surgery resident became infected.[12] No specific events or breaks in technique were identified in either cluster that could explain the transmissions, although the thoracic surgery resident did not wear double gloves. Since 1996, there have been an additional 10 reports of hepatitis B transmission from providers to patients. These cases have generally been associated with HBV-infected surgeons; one case was associated with an infected dentist[14,15] (I. Williams, CDC, personal communication). An important report from the United Kingdom underscored the potential for transmission from providers who are infected with so-called "pre-core" mutants of HBV.[14] Such providers are HBeAg negative but have a high circulating viral burden. This report[14] underscores the importance of directly measuring viral burden, as opposed to assaying for surrogate markers of viral burden (such as HBeAg). Only one relatively recent report is from North America: in this large outbreak, 75 patients were infected from procedures involving placement of subdermal electroencephalogram electrodes by

an HBeAg-positive technician.[16] Although infection control procedures in this electroencephalography clinic were deemed inadequate, no specific mechanism for transmission was identified.

Although such clusters continue to occur (acknowledging that the United States does not have systemic surveillance measures to detect such cases), they appear to be occurring less frequently than in the past. In contrast, the problem of patient-to-patient transmission of HBV and HCV arising from inadequate infection control precautions, such as reuse of multidose vials of medication, has become increasingly important as a cause of iatrogenic bloodborne pathogen infection.[17]

Provider-to-Patient Transmission of HCV

Provider-to-patient transmission of HCV has been extremely uncommon in the United States and has had a reasonably unique epidemiology in this county. Conversely, transmission of HCV from infected providers has been somewhat more frequently detected in Europe (Table 3). As noted above, for all of these pathogens, provider-to-patient transmission of HCV is extremely unlikely in the course of routine (ie, noninvasive) patient care. The risk for provider-to-patient transmission of HCV appears to be even smaller than the risk for HBV transmission in the course of noninvasive patient care, presumably because most individuals chronically infected with HCV have circulating viral loads that are orders of magnitude lower than those of the hepatitis B carriers who have been identified as transmitting infection to their patients.

Several instances of provider-to-patient transmission of HCV have been reported in the literature.[18-32] The first documented instance of provider-to-patient transmission of HCV was reported from England in 1995 (Table 3).[23] A patient who had undergone cardiac surgery developed acute HCV infection and had no risk factors for infection. The first assistant surgeon on the operative team was found to be infected with HCV. A "look-back" study of the patients for whom the surgeon had provided care revealed that only one of the surgeon's 278 patients developed HCV infection with a strain identical to the surgeon's.[21] During the time the UK investigation was in process, an additional instance of provider-to-patient transmission of HCV was reported from Spain.[22] The detection of 2 unexpected cases of HCV infection among cardiac surgery patients participating in a study of transfusion-transmitted infections prompted a look-back study of the patients of a chronically HCV-infected surgeon. The Spanish look-back study identified an additional 4 HCV infections (ie, totaling 6 [2.7%] of the 222 patients who had been operated on by the surgeon).[22] Five of the 6 HCV strains isolated from these patients were closely related to the strain

TABLE 3. Summary of Reports of Provider-to-Patient Hepatitis C Virus Transmission from the United Kingdom

Year	Provider's occupation	Procedure	No. of patients tested	No. of probable cases	Transmission rate, % (95% CI)
1995	Cardiovascular surgery	Coronary artery bypass	270[a]	1	0.37 (0.00–1.44)
1999	Gynecology	Gynecological procedure	3,628[b]	7	0.19 (0.08–0.36)
2000	General surgery	Bowel surgery	627[c]	2	0.32 (0.03–0.91)
2000	General surgery	Bowel surgery	1,145[d]	4	0.35 (0.09–0.77)
2001	Obstetrics	Cesarean delivery	198[e]	1	0.51 (0.00–1.97)
2002	Obstetrics and gynecology	Cesarean delivery	Investigation ongoing	Investigation ongoing	Investigation ongoing
2004	Obstetrics and gynecology	Cesarean delivery	Investigation ongoing	Investigation ongoing	Investigation ongoing
Overall	…	…	5,868	15	0.26 (0.13–0.38)

NOTE. Data provided by Fortune Ncube, MD, Health Protection Agency Centre for Infections, United Kingdom (personal communication). CI, confidence interval.

[a] More than 97% of the procedures (ie, procedures in 270 of 278 patients) that the provider had participated in were classified by the incident team as "high-risk exposure-prone procedures."

[b] Patient notification was performed in 2 stages: the identification of 4 transmissions triggered an extension of the look-back exercise, resulting in the identification of 3 additional infections.

[c] All the patients included in the analysis had procedures that met investigators' definition of "high risk exposure-prone procedures," and 84% (627 of 750) of the infected provider's exposure-prone procedures were characterized as "high risk exposure-prone procedures."

[d] All these patients had undergone exposure-prone procedures. Investigators assumed that this general surgeon's workload was similar to that of the other general surgeon (ie, 84% of exposure prone procedures were "high-risk exposure prone procedures").

[e] All the patients tested and included in the table (ie, accounting for 198 of 228 of the provider's procedures) were patients who had high "high risk exposure-prone procedures."

isolated from the surgeon, and each of these patients had undergone valve replacement surgery.[22]

An HCV-infected gynecologist in the UK transmitted infection to several patients. After a single patient became infected after a gynecological procedure,[24,33] a detailed look-back study tested more than 4,500 patients, of whom 3,628 had undergone "high risk, exposure-prone procedures" that were performed by the surgeon in the previous 20 years. Seven additional patients were found to have HCV infection caused by strains of HCV closely related to the strain recovered from the surgeon (Table 3).[26]

Ross and coworkers[28] from Germany reported the results of a look-back study of 207 of the 229 patients operated on by an HCV-infected orthopedic surgeon. Three of the 207 were found to be HCV infected, but only 1 (a patient who had undergone a total hip arthroplasty with trochanteric osteotomy) was infected with a strain that was similar to the strain recovered from the HCV-infected orthopedist.[28] Subsequently, these same investigators also conducted a look-back study of the patients of an HCV-infected obstetrician/gynecologist. The look-back study was prompted by the detection of an unanticipated instance of HCV infection in a patient who had undergone a cesarean delivery. This patient was found to be infected with an HCV strain that was virtually identical to the strain infecting the obstetrician/gynecologist who had performed the procedure.[29] The investigators screened 2,286 of the obstetrician/gynecologist's 2,907 patients and found no further evidence of transmission.[29]

Three additional patient-to-provider look-back studies involving the potential for transmission of HCV from healthcare worker to patient have been reported from the United Kingdom (Table 3).[27,34,35] In the first of these studies, 3 infections (among 1,900 patients) were attributed to an HCV-infected provider. In the second, 1 infection was found among 749 patients of an HCV-infected provider.[35] In the third, a look-back study has been reported as being initiated in the United Kingdom, although no results from the study have been published;[27] letters were sent to 228 patients of an HCV-infected practitioner offering follow-up testing, after an index case was identified as linked to the practitioner following an "exposure-prone" procedure.

Several reports involve HCV-infected anesthesiologists. In the United Kingdom,[31] an HCV-infected anesthesiologist infected a patient during a procedure in which the anesthesiologist endotracheally intubated the patient, inserted a peripheral venous catheter, and provided general anesthesia. He did not participate in any procedure considered to be "exposure-prone." The anesthesiologist vehemently denied injection drug use[31]; however, in several similar cases described below, drug diversion was implicated as the cause of bloodborne pathogen transmission.

Ross and colleagues[36] reported a cluster of 5 cases of HCV infection from an anesthesia assistant. The anesthesia assistant purportedly acquired acute HCV infection as a result of an occupational exposure to an HCV-infected patient in the operating room (presumably, by contaminating an open wound on a finger of his right hand). This assistant may have presented an increased risk for transmission, since he was working while developing acute HCV infection and before having a detectable immunologic response at a time when his viral burden was likely high. In the course of 3 weeks (during which his finger was purportedly still weeping) he infected 5 patients. He vehemently denied drug abuse, but the similarity of this case to the case described by Sehulster and colleagues[37] (discussed below) is striking. An important feature of this cluster is the fact that the anesthesia assistant did not follow universal/standard precautions. He did not wear gloves (even when he had the open lesion on his right hand). Ross and colleagues[36] suggest that if the anesthesia assistant had followed universal/standard precautions, these infections would have likely been prevented.

In another highly unusual case, a child acquired HCV infection from his mother, who was functioning as his healthcare provider.[38] The child was a hemophiliac whose mother administered his frequently required clotting-factor concentrate infusions. The mother (who had chronic HCV infection) did not wear gloves and recalled several instances in which she stuck her own finger with the needle (often with her own blood visible). Sequence analysis demonstrated that the HCV isolates from the mother and the child were identical.[38]

For reasons that are not certain, look-back studies from the United Kingdom have found substantially more cases of transmission. Grouping the various studies from the United Kingdom yields a transmission rate of 0.19% (15 patients infected of 7,656 patients tested) without inclusion of index cases, and 0.26% with the inclusion of index cases. In contrast, studies from Germany have found no additional cases of transmission among more than 3,000 people tested, beyond the index cases that prompted the look-back studies. However, if one includes the index cases, the transmission rate for these studies is 0.13% (similar to the rate for the studies from the United Kingdom).

The experience in the United States is quite different. Injection drug use on the part of the infected provider appears to play a more central role in provider-to-patient HCV transmission. Williams and colleagues[39] recently reviewed the US experience, noting that 4 episodes of transmission have been detected. The first involved an HCV-infected surgical technician who infected approximately 40 of 346 patients during a 3-month period.[37,39] This healthcare provider admitted self-injecting anesthesia medications and then using the same syringe to administer drugs to patients. The second involved an anesthesiologist who acquired HCV infection from one patient and subsequently, during the anesthesiologist's acute phase of infection, transmitted the same strain of HCV to a patient; no further transmissions were identified. This anesthesiologist was also suspected to be abusing narcotics.[20,39] The third case of HCV transmission is more similar to those seen in the United Kingdom. An HCV-infected cardiac surgeon was found to have infected as many as 14 of the 937

patients who could be evaluated from over a decade of surgical practice.[39] Narcotics abuse was not suspected. Interestingly, following an expert review of the surgeon's practice, the surgeon was treated for his HCV infection and was allowed to continue to practice; he continued to perform cardiovascular procedures that would by any measure be considered exposure-prone. He made modifications to his technique, including the use of double gloves and other safety devices, and in addition, his patients were prospectively tested for HCV infection; to date no additional instances of transmission have been detected. The fourth report describes a certified registered nurse anesthetist who transmitted HCV to at least 15 of 164 patients during a 4-month period coinciding with the acute phase of his own HCV infection. The certified registered nurse anesthetist did not perform exposure-prone procedures and a specific mechanism of transmission was not identified; however, similar to the first 2 cases, the nurse anesthetist was suspected of abusing patient medications.[39] A fifth instance of provider-to-patient transmission of HCV in the United States is currently under investigation, but the details are not yet available (J. Perz, CDC, personal communication).

Although the precise mode of transmission for HCV for the majority of these cases remains unknown, the circumstances surrounding several of the cases suggest that transmission was associated with percutaneous exposures. Clearly, at least in the United States, a number of the instances of provider-to-patient HCV transmission have been associated with diversion of patients' drugs to healthcare providers who were abusing injectable narcotics. Although the contribution of injection drug use to provider-to-patient transmission of HCV has been most noticeable in the United States, 2 additional cases, one from Spain, the other from Israel, underscore its potential importance. In the cluster of cases from Spain, an anesthesiologist who was addicted to opiates was diverting some of patients' narcotics for personal use and then injecting the patients with the same syringe that he had used, thereby infecting more than 200 patients.[18,40] In the report from Israel, an injection drug–using anesthesiologist infected 33 patients by diverting some patients' drugs to himself and then using the same apparatus for injecting the drugs into the patient.[32] Detection of underlying injection drug use in these circumstances is difficult, at best, so one cannot say for certain the extent to which this behavior may have influenced the other cases reported in the literature.

Summarizing the world literature and excluding those reports in which injection drug use was considered to be a contributing factor for transmission, there were 2 gynecologists, 3 cardiac or thoracic surgeons, 1 anesthesiologist, and 1 orthopedic surgeon involved in the instances of transmission. These data lend credence to the hypothesis that "exposure-prone, invasive procedures" are likely to pose the largest risk for provider-to-patient transmission of HCV.

Provider-to-Patient Transmission of HIV

In the 25 years since HIV was first isolated, only 4 instances of HIV transmission from infected health care workers to 1 or more patients have been reported.[3-8,41-45] One cluster of infections occurred in the United States in 1990;[3-8] 2 cases occurred in France,[41,42,44,45] and 1 instance of transmission occurred in Spain.[43]

The US cluster involved a dentist who had acquire immune deficiency syndrome (AIDS); 6 of his patients became HIV infected. Their HIV isolates were linked to his, both epidemiologically and by DNA sequencing.[3-8] A thorough investigation by the CDC and viral phylogeny findings suggested practitioner-to-patient spread, though the precise mechanism or mechanisms of transmission were not determined. Although the dentist was a patient in his own practice, no infection control deficiencies were identified that would readily explain HIV transmission to the 6 patients. Additionally, the dentist did not recall occupational injuries that could have created an opportunity for cross-contamination. Despite substantial speculation, no data were uncovered suggesting intentional transmission.

The second instance of provider-to-patient HIV transmission involved an orthopedic surgeon in France who transmitted HIV to 1 patient. Transmission was confirmed through DNA sequence analysis of viral isolates obtained from the surgeon and the patient.[42,45] The surgeon was not aware of his infection until surveillance case definition AIDS was diagnosed. French investigators initiated a look-back study of the surgeon's 3004 patients since 1983. Investigators successfully contacted 2458 patients and performed HIV serologic tests on 983. One patient was found to have acquired HIV infection. This patient had 3 procedures performed by the surgeon, had a negative HIV serology before undergoing the first of the 3 procedures, and was found to be infected with HIV when she underwent testing before the third procedure.[42,45] The authors of the manuscript speculated that both the extended length of the initial procedure (10 hours) and the high likelihood that the surgeon had a high viral burden (since he had far advanced, untreated disease) contributed to the transmission. No breaches in recommended infection-control practices were identified in retrospect.

The third episode of provider-to-patient HIV transmission also was detected in France. In this unusual case, transmission of HIV is suggested to have occurred from an infected nurse to a patient, although no clear mechanism for transmission could be identified.[44] The investigators conducted a look-back study focusing on 7,580 patients for whom the infected nurse had provided care. They were able to locate 5,308 patients, and they serologically tested 2,293.[41] No additional infections were identified. The nurse was coinfected with HCV and had both a high HIV viral burden and advanced HCV-induced hepatic disease, including clotting abnormalities. HCV was apparently not transmitted to the patient, but the HIV isolates from patient and provider were closely related. The nurse was

unaware of either viral infection, though she became symptomatic enough to require hospitalization within 2 weeks of the date on which transmission was thought to have occurred. She denied injection drug use.

The fourth case occurred in Spain; a woman was infected with HIV by her obstetrician/gynecologist during cesarean delivery. Spanish officials conducted a look-back evaluation of the physician's patients. Of 275 patients on whom the practitioner had performed procedures, 250 could be tested, and none were found to be infected.[43]

More than 4 dozen look-back studies have been conducted evaluating the HIV antibody status of patients retrospectively identified as having received medical or dental care from an HIV-infected practitioner[5,46-57] (Lisa Panlilio, CDC, personal communication). None of these studies identified transmission of HIV infection. To our knowledge, only the report from France described above, in which an orthopedic surgeon infected one of his patients, identified iatrogenic transmission of HIV in a look-back study.[42,45] In the United Kingdom, no cases of HIV transmission from a healthcare worker to a patient have been detected, despite 28 patient notification exercises and testing of more than 11,000 patients between 1988 and 2006 (F. Ncube, MD, Health Protection Agency Centre for Infections, United Kingdom, personal communication). One unusual cluster of patient-to-patient HIV transmission in a surgical practice in Australia has been described in the literature;[58] however, the practitioner providing the care was not infected.

PATHOGENESIS AND TRANSMISSION RISK

HBV, HCV, and HIV are most readily transmitted either parenterally or across mucous membranes. Therefore, experts uniformly agree that the risk for transmission of these viruses from an infected provider to a patient during the provision of routine healthcare that does not involve invasive procedures is negligible. In instances in which invasive procedures, and even exposure-prone invasive procedures, are being conducted, these risks are still quite small, but are clearly elevated when compared with other routine patient-care activities. For this reason, a precise assessment of the magnitude of risk for transmission of each of the viruses—in the context of procedures associated with risks for exposing patients to the infected provider's blood or virus-containing body fluids—becomes critical to the overall risk assessment. At least in part because these transmission events occur uncommonly for each of these 3 pathogens, such information is difficult to accumulate.

Several studies have attempted to measure the risk that is associated with single discrete exposures (eg, the "needlestick" transmission rate) for transmission of these 3 pathogens. Only a few manuscripts have addressed the risk to patients who are cared for by an HBV-infected practitioner,[11,14,59-63] an HCV-infected practitioner,[22,23,64-66] or an HIV-infected practitioner[5,46-51,54,57,67] Several variables are likely to influence the transmission rate.

The first factor to influence risk is the intrinsic transmissibility of a specific pathogen. With respect to HBV, studies from the 1970s and 1980s demonstrated a risk for transmission associated with a percutaneous (ie, needlestick) exposure to blood from an HBV-infected individual that ranged from 6% to 37% (19%–37%, if the donor blood is HBeAg-positive).[68,69] The risk for transmission of HCV associated with such exposures has been estimated at 1%–2% (summarized in Henderson[65]). The risk for transmission of HIV associated with needlestick or percutaneous exposures has been estimated at 0.3% (summarized in Henderson[70]). With the exception of the HBV studies (which do make the distinction between HBeAg-positive and HBeAg-negative source patients), none of the HCV or HIV transmission studies considers the circulating viral burden of the source patient in the risk calculation.

With respect to HIV transmission from provider to patient, since the previous version of this guideline[10] was published in 1997, only 3 instances of transmission have been detected,[41-45] and in each instance only 1 patient was found to be infected, despite exhaustive look-back investigations.

A second important issue for consideration in assessing the risk for provider-to-patient transmission of bloodborne pathogens is the frequency with which providers sustain injuries that might present a risk for transmission to their patients.[71-79] Since the previous version of this guideline[10] was published, numerous strategies and interventions designed to reduce the risk for occupational exposures for providers have been implemented (discussed in more detail in the later part of this section). Many of these interventions have been shown to be efficacious in reducing risks for occupational exposures;[80-86] however, in many instances, the use of such interventions has been suboptimal.[87-89] Another set of factors that relates directly to the frequency with which exposures occur includes both the experience of the practitioner and the expertise of the practitioner. With respect to experience, clearly, students and trainees are more likely to sustain such exposures. A special problem arises when a training institution becomes aware that a trainee is chronically infected with a bloodborne pathogen. Such instances should be handled on a case-by-case basis, in consultation with the institution's legal counsel, the house staff training director, infection control professionals, the dean of the school, and others who are involved stakeholders. To date, these cases have been handled unevenly across the country, with some institutions focusing on the disability-law aspects and others focusing on liability.[90] The institution should assist the trainee in selecting a career path best suited to her or his specific situation and should provide reasonable accommodation to students and trainees who have disabling conditions. The expertise of the practitioner is more complex to measure, but may be indirectly assessed by evaluating postprocedure infection rates, bleeding and other pro-

cedure-related complications, and other adverse events associated with the performance of the practitioner.

The third issue that warrants consideration is how frequently such an exposure occurs and is then followed by exposure to a patient (ie, the so-called "recontact" or "bleedback" risk). For example, intraoperative injuries sustained by surgical care providers offer an opportunity for "recontact" to occur. In 2 studies of intraoperative provider injuries, 11.4%–29% of the sharp objects that caused injury to the provider "recontacted" the patient.[73,79] These exposures can be prevented by immediately replacing the contaminated suture needle or other sharp object before reuse. Recontacts can also occur when the provider is injured by bone spicules or materials permanently embedded in the patient's body.[73,79] These sources of potential patient exposure might be prevented by the use of safety devices or other interventions. For example, such exposures might be prevented by the use of reinforced gloves,[91,92] double-gloving, glove-liners, or other devices or materials to protect the provider's hands.[89,91,93-96] Gloves constructed of monofilament polymers or other materials resistant to tears have become available for use when manipulation of bone fragments or suture wires is needed, but their use has been associated with a decrease in tactile sensation. In addition, the use of blunted suture needles has been shown to decrease the risk of percutaneous injuries to the surgeon.[86,97-99]

A fourth factor to consider in the risk assessment is the effect of the infected provider's circulating viral burden. However, with the exception of the HBV studies (which do make the distinction between HBeAg-positive and HBeAg-negative source patients), none of the HCV or HIV transmission studies considers the circulating viral burden of the source patient in the risk calculation, although the likelihood of HIV transmission is increased if a source case patient has advanced AIDS and, presumably, an elevated HIV viral load. For HBV, 5 studies have attempted to measure the viral burden of the provider associated with transmission of infection. In these studies, source case surgeons were found to have circulating HBV DNA levels between 6.4×10^4 and 5.0×10^9 GE/mL. In a modeling study designed to assess the inoculum associated with the most common types of exposures, viral burdens equivalent to 10^4 GE/mL or less were associated with exposures to fewer than 1 virion.[100] An analysis of the technique used by one HBeAg-positive cardiovascular-thoracic surgeon implicated as the source of a cluster of HBV infections may shed some light on the risk for transmission associated with very high viral burdens.[12,101] In this study, when the surgeon repeatedly tied knots, snugging them against his index finger, shear injuries occurred through his gloves, and both the saline irrigant used to rinse the inside of his gloves and the outer surface of the gloves tested positive for hepatitis B surface antigen (HBsAg).[12,101] Despite evidence suggesting a decreased risk for contamination with blood and/or body fluids associated with the practice of double-gloving,[71] this surgeon did not wear 2 pairs of gloves—neither during clinical care nor for the experiments described above. Nonetheless, because of the extremely high viral burden associated with HBeAg positivity (100 million to 10 billion HBV particles per milliliter of blood),[102] barriers may be relatively ineffective in preventing transmission, so the establishment of some cutoff value makes implicit sense.

A fifth issue to consider is the magnitude of risk of transmission of bloodborne pathogens following various types of exposures (summarized in Henderson[70]). For HIV, this risk has been studied extensively. The average risk of transmission associated with percutaneous exposures to blood-contaminated sharp objects that have been used on HIV-infected individuals is 0.32% (21 infections associated with 6,498 exposures; 95% confidence interval, 0.18%–0.46%) (summarized in Henderson[70]). The risk for transmission of HBV from an HBeAg-positive source subject is approximately 2 $\log_{10}$ higher; the likelihood of transmission of HCV from an HCV-infected source subject is intermediate, and is estimated to be approximately 10-fold less than that for HBV (ie, approximately 1%–2% per exposure).[65] The estimated risk for transmission of HIV associated with mucocutaneous exposure is 0.03% (1 infection associated with 2,885 exposures), but this estimate is biased, because the single transmission occurred before prospective data were collected from the involved institution.[103] The risk of infection associated with intact skin exposure to blood from an HIV-infected individual is below detection in the few studies that have attempted to measure it.[104] Data estimating these latter risks are not available for either HBV or HCV, though one might reasonably assume that the risks might be higher for HCV and higher yet for HBV, given the numbers of cases infection detected for the hepatitis viruses, as well as the higher average circulating viral burdens in chronically infected individuals.

Because the risks for provider-to-patient transmission of these 3 bloodborne pathogens are apparently quite different (albeit there is a small risk for each of the 3 viruses), SHEA decided in the previous version of this guideline in 1997 to consider them individually.[10] This updated version also follows that approach.

In 1991, the US Public Health Service published guidelines designed to prevent provider-to-patient transmission of HBV and HIV.[105] Since that document was published, we have gained substantial insight into the factors that contribute to the risks for healthcare-associated transmission of these pathogens; we have witnessed substantial progress in the management of HBV, HCV, and HIV infection; we have seen the development of sensitive molecular tests designed to measure circulating viral burdens for these infections; and we have implemented a variety of interventional strategies designed to reduce these risks.

More than 20 infectious diseases have been transmitted by needlestick injuries.[106] However, HBV, HCV, and HIV infections remain overwhelmingly the most important diseases to consider in provider-to-patient transmission. Other blood-

borne diseases remain of hypothetical concern only. For this reason, this guideline will focus only on HBV, HCV, and HIV.

CLINICAL PROGRESS SINCE PUBLICATION OF THE 1997 SHEA GUIDELINE

HBV

The previous version of this SHEA guideline[10] relied on the presence of HBeAg as a surrogate marker of infectivity and did not consider direct measurement of the HBV DNA viral burden in making recommendations about practice restrictions. One major advance since the publication of the previous guideline is the recognition that presence of HBeAg is not a sensitive marker for HBV infectivity. Indeed, several instances of provider-to-patient transmission of HBV have involved providers who were infected with strains of HBV that did not produce HBeAg (so-called "pre-core" mutants).[14,107] The use of HBeAg as a surrogate marker for infectivity has been effectively replaced by molecular tests that measure a patient's circulating viral burdens with precision. A third major advance is the availability of antiviral medications and other approaches to treat HBV infection. The past decade has seen the development of treatment strategies that, for the first time, offer some hope of reducing patients' viral burdens, and also of producing durable remissions, if not cures. The US Food and Drug Administration has approved 7 antiviral agents (interferon-α, peg interferon, lamivudine, telbivudine, adefovir, tenofovir, and entecavir) for the treatment of chronic hepatitis B in the United States; others (eg, emtricitabine and clevudine) are currently under evaluation. Of patients who received monotherapy with one of the approved agents for 1 year, 14%–30% became negative for HBeAg, and 21%–67% developed undetectable HBV DNA levels.[108] The role of combination therapies is at too preliminary a stage to judge their efficacy; however, some studies have suggested that therapy with combinations of some of the newer nucleoside and nucleotide analogues (eg, truvada) are superior, or preferable, to monotherapy for patients who have HBeAg or high circulating levels of HBV DNA.[108] Although the evidence base for the use of antiviral and/or immunological therapy for hepatitis B is not yet fully adequate (ie, current therapy for chronic hepatitis B infection most often does not eradicate HBV and most studies demonstrate limited long-term efficacy), the role of therapy, the impact on the potential transmission risk, and the impact on practice restrictions have not yet been fully investigated.

HCV

As is the case with HBV, in the past decade we have gained more sophistication and precision in our ability to measure the circulating viral burdens of patients infected with HCV. In addition, new antiviral agents and combinations of agents have been employed with increasing success to treat individuals who have acute and chronic HCV infection. A National Institutes of Health Consensus Development Conference and 2 academic professional societies have published congruent treatment guidelines for individuals who are chronically infected with HCV.[109-112] These guidelines emphasize that individuals who have chronic hepatitis C infection who are 18 years of age or older, have detectable HCV RNA in serum, and evidence of chronic hepatitis (either elevated serum alanine aminotransferase levels or active hepatitis and/or fibrosis) should be treated, assuming they are willing to participate in the therapy and that there are no contraindications to the use of the indicated antiviral agents. Also of importance are the several published studies that suggest that acute HCV infection can be treated with nearly 100% success.[113-116] Whether these recommendations might apply to HCV-infected practitioners who want to be able to perform exposure-prone invasive procedures (whether or not they have evidence of chronic hepatitis) is not addressed in this guideline.

HIV

Substantial progress also has been made for HIV. Tests to monitor HIV RNA viral load are now routine, and highly active antiretroviral therapy has been routinely given for more than a decade. None of the existing guidelines have incorporated treatment of the infected practitioner into the decision about practice restriction for HIV-infected providers who wish to continue performing exposure-prone invasive procedures.

CURRENT PUBLISHED GUIDELINES

In the United States, in the aftermath of the national and international publicity surrounding the instances of iatrogenic HIV infection linked to the Florida dentist,[3-8] the CDC issued guidelines for HIV-infected and HBV-infected providers[105] in July of 1991. From an implementation perspective, 3 aspects of these guidelines were problematic: (1) the need to classify a subset of invasive procedures as "exposure-prone," (2) the requirement that an infected practitioner notify prospective patients of her or his infection status, and (3) the legal and administrative implementation strategies concerning the establishment and workings of the Expert Review Panel, an administrative requirement of the guidelines. Although we have witnessed substantial clinical progress and much has been written about these issues, these problems remain largely unresolved 18 years after publication of the original CDC guideline.[105]

The anxiety associated with the publicity surrounding the Florida dentist case-cluster prompted Congressional scrutiny of the 1991 CDC guideline,[105] and, ultimately, resulted in the US Congress passing Federal legislation (PL. 102–141) requiring states to certify that they have implemented the July 1991 CDC guideline[105] or "equivalent" guidelines. Interestingly, since the 1991 CDC guideline[105] was published, the United States has identified no additional instances of provider-to-patient HIV transmission and only rare instances of

either HCV or HBV transmission. The fact that only a small number of cases have been detected is attributable to a variety of factors, including less aggressive case-finding by the CDC and other local and state public health officials (ie, no active ongoing surveillance), the use of primary strategies to prevent exposure, and the efficacy of highly active antiretroviral therapy, which has lowered the viral burden in HIV-infected "source patients," has reduced the likelihood of hospitalization, and has decreased the need for and the numbers of invasive procedures that place healthcare workers at risk for exposure. To date, the management of infected practitioners therefore appears to have been effectively managed at the individual, the institutional or at the state level.

Although no new US Public Health Service guidelines regarding infected providers have been published since 1991, guidelines have been published outside the United States, and several articles have been published that argue differing points of view about this complex issue. The issue remains controversial for several complicated reasons. First, at least in part because of the manner in which HIV infection first presented in society, American public opinion has consistently reflected a "zero-risk" stance. Second, although most guidelines have focused on practice restrictions for infected providers who conduct exposure-prone procedures, a panel of experts convened by the CDC was unable to come to consensus about which invasive procedures are "exposure-prone," at least in part because of the substantial variability from provider to provider. The United Kingdom guidelines detail their definition of "exposure-prone" procedures.[117] Also, recently, a group convened at the University of Virginia created a table of procedures, divided into 3 categories: (1) procedures with de minimis risk of viral transmission, (2) procedures for which viral transmission is theoretically possible but unlikely, and (3) procedures that are associated with a definite risk of viral transmission or that are directly characterized as exposure prone procedures.[1] We have included a similar table in this guideline (Table 2), modified slightly from the table created by the University of Virginia group; the committee that drafted this guideline also expressed the strong opinion that some procedures listed under Category III might well be moved to Category II if the practitioner follows recommended work practice controls and uses appropriate safety devices. Third, this topic offers a unique confluence for the disciplines of epidemiology, medicine, ethics and law, and experts in these disciplines express widely divergent views about the optimal approach. Each of these issues deserves additional discussion.

Despite the fact that experts uniformly agree that infected providers who are not conducting invasive procedures present virtually no risk to their patients, as recently as 2005, a study found that 89% of respondents acknowledged that they would want to know whether their doctor or dentist is infected with HIV; 82% agreed that disclosure of HBV or HCV infection in a provider should be mandatory; and only 38% thought that infected providers should be allowed to provide patient care of any kind.[118] Some have argued that by not completely restricting providers infected with bloodborne pathogens, the discipline of medicine has betrayed its responsibility to patients.[119] Because public opinion is far from aligned with the existing science base, a major issue becomes "What level of risk will society tolerate?"

ETHICAL ISSUES

A useful perspective is to consider the accommodations society has made for medical or psychiatric conditions in the healthcare worker, or a history of substance use, which also could put patients at risk. In certain cases, these conditions may necessitate restriction of the healthcare worker from certain aspects of healthcare practice. Restriction is not viewed as justified, however, when these conditions are well treated and the healthcare provider is able to practice in a safe and competent way.

Similarly, we feel that infection with a bloodborne pathogen does not itself justify restriction on the practice of an otherwise competent healthcare provider. As with providers who have medical, psychiatric, or substance-use problems, healthcare providers infected with bloodborne pathogens should seek ongoing care and treatment. SHEA recommends the additional protection of restricting health care providers from performing Category III procedures if the healthcare provider is infected with a bloodborne pathogen and meets other criteria, as delineated in this document.

The ethics of this issue are also complex. Healthcare providers have an ethical, professional and fiduciary responsibility to act in the best interests of their patients. Healthcare providers have a duty to ensure patient safety. The fact that healthcare providers are bound by the principle of nonmaleficence, which requires them to do no harm to patients and to do what is possible to prevent harm, is widely accepted. Nonetheless, this simple formulation of the principle of nonmaleficence provides limited guidance, because many beneficial interventions also present risks to patients. Consistent with the principle of nonmaleficence or "do not harm," healthcare providers are expected to act in accordance with the standards of their profession to prevent harm in the practice of patient care. Accordingly, healthcare providers have an obligation to follow the accepted standards of practice to prevent the transmission of bloodborne pathogens to patients. These standards include knowledge about and diligent utilization of infection control procedures, as well as careful attention to individual factors that can be controlled to reduce any risk of transmission.

Over the last 2 decades, considerable progress has been made in our understanding of HIV, HCV, and HBV infections. Sensitive tests to measure levels of circulating virus have been developed, as well as an impressive armamentarium of interventions to control the infections, including effective antiviral therapies for each disease. We know that when individuals are treated so that their viral load becomes and re-

mains low or undetectable, the risk of transmission to others is greatly decreased. Technological and other advances in equipment and infection control procedures, as well as work-practice controls that have reduced the risk of occupational injuries to healthcare providers and, therefore, indirectly improved patient safety, have further reduced the risk of transmission in healthcare settings.

The accumulated experience and data provide reassuring evidence that the magnitude of risk for provider-to-patient transmission of HIV, HCV and HBV, although not zero, is exceedingly small. At the same time, the burdens of certain restrictions that have been placed on healthcare providers out of concern for patient safety have been disproportionately high. Qualified and experienced healthcare providers have suffered from discrimination, loss of privacy, liability, and loss of their jobs and their livelihoods. These burdens, associated with highly personal and stigmatizing diagnoses, seem unjustified in the face of an extremely low risk that can be further reduced by reasonable accommodations in the workplace and the diligence of healthcare providers and institutions.

All healthcare providers should comply with institutional policies and procedures designed to protect patients. Healthcare providers have an ethical responsibility to promote their own health and well being, and a responsibility to remove themselves from care situations if it is clear that there is a significant risk to patients despite appropriate preventive measures.

Infection with a bloodborne pathogen does not itself justify restriction on the practice of an otherwise competent healthcare provider. Healthcare providers infected with bloodborne pathogens should seek ongoing care and treatment. Restrictions may be justifiably imposed when a healthcare provider has a physical or mental impairment that affects his or her judgment and/or jeopardizes patient safety. Examples might include exudative lesions or weeping dermatitis; a history of poor infection-control technique or adherence to proper technique; mental confusion; or a prior incident of transmitting a bloodborne pathogen to a patient.

LEGAL ISSUES

From the legal perspective, the courts have been relatively unsupportive of infected healthcare providers. Although some authorities have argued that proscriptive state regulations are responding "to a problem that does not exist,"[120] many legal actions were filed against infected healthcare providers and their institutions, based either on the CDC guidelines of July 1991,[10] professional societies' adoption of these guidelines, or both. In many, if not most of these actions, a practitioner was sued, not for infecting patients, but rather for inflicting mental anguish, for causing "pain and suffering," for assault, for the practitioner's failure to comply with the "duty to warn" the patient of risk, or for various other legal issues. Virtually all of these suits were filed because of the possibility that patients may have been unnecessarily exposed to the risk for infection, not because the patients were infected with bloodborne pathogens. Outcomes for these cases have been highly variable, and have not, to our knowledge, established a definitive precedent.

HBV

Existing US guidelines, published in 1991 and not, to date, ever revised,[105] recommend that "healthcare providers who perform exposure-prone procedures and who do not have serologic evidence of immunity to HBV from vaccination or from previous infection should know their HBsAg status and, if that is positive, should also know their HBeAg status. If infected with HBV (and HBeAg positive) providers should not perform exposure-prone procedures unless they have sought counsel from an Expert Review Panel and been advised under what circumstances, if any, they may continue to perform these procedures. Such circumstances would include notifying prospective patients of the healthcare worker's seropositivity before they undergo exposure-prone invasive procedures."[105]

Several countries have issued modified guidelines for the management of HBV-infected providers based on the infected provider's circulating viral burdens. Unfortunately, the evidence base for these recommendations is minuscule, and the existing recommendations are quite disparate.

In the United Kingdom, HBV-infected providers who are HBeAg positive may not conduct exposure-prone invasive procedures; HBV-infected providers who are HBeAg negative but have HBV DNA levels of greater than 10^3 GE/mL may not conduct exposure-prone invasive procedures; and HBV-infected providers who are HBeAg negative and have HBV DNA levels of less than 10^3 GE/mL may conduct exposure-prone invasive procedures but must be retested at least every 12 months to ensure that the level of viremia remains below 10^3 GE/mL.[121] More recently, authorities in the United Kingdom have also recommended[122] that HBV-infected healthcare providers who are HBeAg negative and who have pretreatment HBV DNA levels of 10^3–10^5 GE/mL could be allowed to perform exposure prone procedures if they are receiving suppressive oral antiviral therapy and if their viral loads have decreased to below 10^3 GE/mL. The major challenge associated with this latter recommendation is the development of an effective monitoring strategy to make certain that the circulating viral burden remains less than 10^3 GE/mL.[122] The availability of various testing systems further complicates monitoring.

A European consortium was convened to create recommendations for HBV-infected providers and reached slightly different conclusions.[123] In their recommendations, HBV-infected providers who are HBeAg positive are instructed that they may not perform exposure-prone procedures.[123] HBV-infected providers who are HBeAg negative but have HBV DNA levels of less than 10^4 GE/mL may conduct exposure-

prone invasive procedures but must be retested at least annually to make certain that the circulating viral burden remains below 10^4 GE/mL.[123] These guidelines also emphasize that providers who are detected as having transmitted HBV should not perform exposure-prone procedures, and HBV-infected providers who have been treated and whose post-treatment DNA levels have fallen to less than 10^4 GE/mL may conduct exposure-prone procedures but must be retested every 3 months to ensure that the viral burden remains below 10^4 GE/mL.[123]

Scientists from the Netherlands published a third set of recommendations suggesting that HBV-infected providers who have HBV DNA levels of less than 10^5 GE/mL may conduct exposure-prone invasive procedures, but must be retested at least annually.[124]

In a thoughtful analysis, van der Eijk et al[125] listed the challenges to standardizing recommendations for practice restrictions for HBV-infected providers, emphasizing that guidelines have to strike a balance between excluding providers unnecessarily and patient safety. More recently, the Viral Hepatitis Prevention Board, a European consortium whose mission is to contribute to the control and prevention of viral hepatitis, convened a meeting of international experts from the public and private sectors to try to harmonize these recommendations.[126] This meeting identified a number of issues that the contributors felt needed to be addressed before development of standardized recommendations, and consensus could not be achieved.[126] Included in this list of issues are the following: (1) the variability of HBV DNA levels among chronically infected individuals; (2) the paucity of data linking levels of viremia to risk for transmission; (3) the variable reliability and reproducibility of the molecular tests used to measure HBV DNA, as well as the variability between the differing test systems; (4) the lack of standardization among the different tests used to detect HBV DNA; and (5) the variability and durability of therapeutic antiviral effects and, specifically, the length of time viremia can be effectively suppressed before "escape" mutant viruses emerge.

HCV

No US Public Health Service guidelines address the management of providers infected with HCV, including the 1991 CDC recommendations.[105]The UK guidelines[109] are quite proscriptive regarding hepatitis C, stating that HCV-infected providers who have circulating HCV RNA may not conduct exposure-prone invasive procedures. Further, trainees found to have circulating HCV RNA should be restricted from starting training in exposure-prone invasive procedures.[127] The UK guidelines also address treatment, noting that HCV-infected providers who have circulating HCV RNA who receive antiviral treatment and become HCV RNA negative for a period of 6 months can be permitted to return to performing exposure-prone invasive procedures but must be retested in 6 months to confirm the durability of the response.[109]

The European Consortium could not reach consensus about the management of HCV-infected providers, concluding that "on balance it is not recommended that exposure-prone procedures be forbidden for HCV-infected healthcare workers."[123] Similarly, the scientists from the Netherlands addressed only HBV infection, and did not discuss HCV-infected providers.[124] Furthermore, the findings of the Viral Hepatitis Prevention Board with respect to HBV (eg, variable HBV DNA levels, paucity of data linking levels of viremia to risk for transmission, variable rates of reliability and reproducibility of molecular tests used to measure HBV DNA, variability and lack of standardization of the differing test systems, variability and durability of therapeutic antiviral effects, and length of time viremia can be effectively suppressed before "escape" mutant viruses emerge) also apply to individuals chronically infected with HCV.

HIV

The UK guidelines[117] recommend restriction of the practice of HIV-infected providers.[105] The US guidelines recommend that HIV-infected practitioners, "not perform exposure-prone procedures unless they have sought counsel from an Expert Review Panel and been advised under what circumstances, if any, they may continue to perform these procedures. Such circumstances would include notifying prospective patients of the HCW's seropositivity before they undergo exposure-prone invasive procedures."[105] Neither guideline bases recommendations on the clinical status of the infected provider or on the viral burden of the HIV-infected provider.

CURRENT ASSESSMENT

SHEA emphasizes that, more than 20 years after the publication of the "Universal Precautions" guidelines,[128] blood and potentially contaminated body fluids (eg, cerebrospinal fluid, peritoneal fluid, amniotic fluid, pleural fluid, synovial fluid, pericardial fluid, semen, vaginal secretion, and any blood-contaminated fluid) from any patient must be considered to have the potential to transmit bloodborne pathogens, irrespective of the patient's primary or secondary diagnosis. Although this principle was initially intended to apply to patients, we find it equally relevant to healthcare providers who may be infected with HIV, HBV, HCV, and/or another bloodborne pathogen. The magnitude of risk for provider-to-patient transmission of bloodborne pathogens may never be known with precision; however, the additional experience gained over the past 20 years provides reassuring evidence that these risks are extremely small.

In the previous version of this guideline, SHEA expressed the opinion that most of the issues applicable to HBV-infected providers would generally apply to providers who are infected with HIV and might also hold for providers infected with HCV. In this revised version, SHEA decided to deal with each of the pathogens individually—at least with respect to setting policies for infected providers. This decision was made for a

TABLE 4. Definitions of the Strength of Recommendations and the Quality of the Evidence Supporting Them

Category and grade	Definition
Strength of recommendation	
A	Good evidence to support a recommendation for use
B	Moderate evidence to support a recommendation for use
C	Poor evidence to support a recommendation for or against use
D	Moderate evidence to support a recommendation against use
E	Good evidence to support a recommendation against use
Quality of evidence	
I	Evidence exists from at least one properly randomized, controlled trial
II	Evidence comes from at least one well-designed clinical trial without randomization, from cohort or case-controlled analytic studies (preferably from more than one center), from multiple time-series studies, or from dramatic results in uncontrolled experiments
III	Evidence comes from opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

NOTE. The classification scheme is that developed by the Infectious Diseases Society of America,[134] which are adapted from the Canadian Task Force on the Periodic Health Examination.[135]

variety of reasons. First, the "average" risk for transmission following a single parenteral exposure is at least 10-fold and probably 100-fold higher for HBV than for HIV. The risk for HCV transmission appears to be intermediate between those for HIV and HBV.[65] Second, chronic carriers of these 3 viral pathogens typically exhibit substantial differences in viral burden (ie, the number of intact virions per milliliter of blood); thus, circumstances that might involve a measurable risk for transmission of HBV may not necessarily be associated with a measurable risk for transmission of HIV. Third, postexposure management strategies, including treatment, have evolved considerably, and treatment for each of these diseases since the previous version of this guideline was published. Pre-exposure receipt of hepatitis B vaccine has led to a dramatic decrease in the incidence of HBV infection in healthcare personnel. Further, postexposure prophylaxis for HBV infection using hepatitis B immune globulin and/or hepatitis B vaccine is both safe and highly effective. Although its efficacy has not been proven in a clinical trial, postexposure prophylaxis for HIV infection using 2-drug or 3-drug combinations has likely contributed to the dramatic decrease in occupationally acquired HIV infection in healthcare workers in the United States. The last such case documented by the CDC occurred in 1999.[70,129] Unfortunately, neither pre-exposure nor postexposure prophylaxis exist for HCV.

For these reasons, the version of this guideline will continue to consider each pathogen individually. The following recommendations are based on the following information: (1) available scientific information about the magnitude of risk for provider-to-patient transmission of the bloodborne pathogens; (2) clinical hospital epidemiology and infection control experience and management of HBV, HCV and HIV related problems in the healthcare setting since 1981; and (3) experience with the implementation and interpretation of prior recommendations and guidelines, including those issued previously by the US Public Health Service.[102,130-133] The recommendations are classified according to the scheme developed by the Infectious Diseases Society of America[134] (Table 4).

GUIDELINE RECOMMENDATIONS

BACKGROUND AND RATIONALE

These recommendations are based on the thorough consideration of the risks for provider-to-patient transmission of these pathogens, from the information provided by (1) the past 50 years' experience with these pathogens in the healthcare setting; (2) the reported experience with HBV-infected providers and their patients[11-16,61-63,136] (I. Williams, CDC, Personal Communication), HCV-infected providers and their patients,[18-32,35,37,39,40,64] and HIV-infected providers and their patients[3-8,41-57]; (3) studies of the frequency of various types of occupational exposures[65,71-79,137,138]; (4) studies of the magnitude of risk of transmission of bloodborne pathogens following various types of exposures[70,104,139,140]; (5) the substantial progress biomedical science has made in accurately measuring viral burden as an indicator of disease activity, and, possibly, infectivity, for all 3 viral infections; (6) the availability of an effective vaccine for HBV; (7) the development of effective postexposure management strategies, as well as therapy that can substantially suppress HIV and HBV infection and can suppress and even cure HCV infection; (8) progress made in modifying procedures and devices to create a safer healthcare environment; and (9) the resources required to develop a unique administrative approach for the management of providers infected with these 3 bloodborne pathogens.

The major changes in the risk calculus since the publication of our prior set of recommendations are, first, that effective antiviral therapeutic interventions have been developed for

all 3 pathogens, and, second, that a number of engineering and work-practice controls have been introduced into the healthcare environment that have contributed substantially to decreasing the risk for occupational injuries to healthcare providers and, therefore, indirectly, to improving patient safety.

I. PRACTICE ISSUES

1. Should healthcare providers who are infected with HBV be allowed to practice? If so, under what clinical, serological, or viral burden parameters?

Recommendation

All blood and potentially blood-containing fluids (ie, cerebrospinal fluid, peritoneal fluid, amniotic fluid, pleural fluid, synovial fluid, pericardial fluid, semen, vaginal secretion, and any blood-contaminated fluid) from patients and providers must be regarded as potentially infectious for HBV (A-III). All providers should follow the tenets of Standard Precautions (A-III). Only the following body fluids have been implicated in the transmission of bloodborne viruses: blood, blood products, semen, cervical secretions, cerebrospinal fluid, peritoneal fluid, pleural fluid, synovial fluid, pericardial fluid, and amniotic fluid. Transfers of blood or other potentially infectious materials from providers to patients must be avoided (A-III). Tears, saliva, vomitus, sputum, urine and stool are not considered to be capable of transmitting bloodborne viruses unless contaminated with blood. Nonetheless, healthcare providers should practice Standard Precautions and avoid contact with these fluids, as they are potentially infectious for additional pathogens (eg, saliva for herpes simplex virus, stool for hepatitis A virus).

HBV-infected healthcare providers should not be prohibited from participating in patient-care activities solely on the basis of their HBV infection (A-III). HBV-infected providers should not be restricted from participating in Category I or Category II Procedures (Table 2) (A-III). Providers infected with HBV who are either HBeAg positive or who have circulating viral burdens greater than or equal to 10^4 GE/mL should refrain from performing Category III procedures (A-III). Healthcare providers who have circulating HBV burdens of less than 10^4 GE/mL should be allowed to perform those Category III activities identified as associated with a risk for provider-to-patient transmission of bloodborne pathogens, so long as the infected provider (1) is not detected as having transmitted infection to patients; (2) obtains advice from an Expert Review Panel about continued practice; (3) undergoes follow-up routinely by Occupational Medicine staff (or an appropriate public health official), who tests the provider twice per year to demonstrate the maintenance of a viral burden of less than 10^4 GE/mL; (4) also receives follow-up by a personal physician who has expertise in the management of HBV infection and who is allowed by the provider to communicate with the Expert Review Panel about the provider's clinical status; (5) consults with an expert about optimal infection control procedures (and strictly adheres to the recommended procedures, including the routine use of double-gloving for Category II and Category III procedures and frequent glove changes during procedures, particularly if performing technical tasks known to compromise glove integrity [eg, placing sternal wires]); and (6) agrees to the information in and signs a contract or letter from the Expert Review Panel that characterizes her or his responsibilities (discussed in more detail in Recommendation 8, below) (A-III).

Discussion. We have chosen a cut-off of 10^4 GE/mL to separate providers who can and cannot perform Category III procedures. This level was chosen in the absence of data that definitively associate a given level with either a clear risk for transmission or, more importantly, an absence of risk. As noted above, one modeling experiment suggested that the most common types of exposure to a provider who had a viral burden of 10^4 GE/mL would be associated with an exposure to less than 1 virion.[100] In addition to that modeling experiment, another important piece of evidence that supports this threshold is the fact that, in all of the instances of transmission from an HBeAg-negative provider to a patient in which the source provider's viral burden has been measured, the implicated provider had a circulating viral burden in excess of 10^4 GE/mL,[123] except in one case,[141] and the validity of that one case has been questioned, because the sample was taken from the provider more than 3 months after the transmission occurred.[124] Setting the cutoff for the circulating HBV viral burden at 10^3 GE/mL would have resulted in restricting the practices of 58% of the HBV-infected providers in the United Kingdom and nearly 95% of such providers in the Netherlands.[126]

These guidelines suggest a cutoff of 10^4 GE/mL and allow an individual who has a circulating viral load of less than 10^4 GE/mL to continue to conduct Category III procedures as long as the individual (1) is not detected as having transmitted infection to patients; (2) obtains advice from an Expert Review Panel about continued practice; (3) undergoes follow-up routinely by Occupational Medicine staff (or an appropriate public health official), who tests the provider twice per year to demonstrate the maintenance of a viral burden of less than 10^4 GE/mL; (4) also receives follow-up by a personal physician who has expertise in the management of HBV infection and who is allowed by the provider to communicate with the Expert Review Panel about the provider's clinical status; (5) consults with an infection control expert about optimal infection control procedures (and strictly adheres to the recommended procedures, including the routine use of double-gloving for Category II and Category III procedures, use of puncture-resistant gloves, use of blunted surgical needles,[86,97-99] use of "hands-free" technique,[142] and other work practice controls, among many others); and (6) agrees to the information in and signs a contract or letter from the Expert Review Panel that characterizes her or his responsibilities (discussed in more detail in Recommendation 8, below). If a provider is receiving treatment for this infection, the efficacy of the treatment should be considered in the

context of the specific infection being treated. In general, because of their very high viral burdens, providers who have acute HBV infection and those who have HBV infection in the absence of immunological responses should not perform Category III procedures. Providers whose infections have resolved and who have no evidence of circulating virus should not be restricted in any way.

Individuals relying on these guidelines must keep in mind that each such case must be evaluated on its own merit and that the molecular testing strategies discussed in the document are subject to several limitations. These include (1) the fact that infected individuals' HBV DNA levels may vary over time, (2) there are limited scientific data linking levels of viremia to risk for transmission, (3) the fact that the different currently marketed test for measuring HBV viral burden may produce variable results (4) the varying level of reproducibility of these molecular tests, (5) the fact that antiviral therapy may produce transient or limited responses (particularly with respect to monotherapy for HBV), and (6) the variety of virological and patient-related factors (eg, adherence to the recommended antiviral regimen) that may contribute to the development of "escape" mutants. SHEA underscores that these guidelines are, of necessity, malleable and modifiable as more information becomes available.

Antiviral therapy clearly reduces the circulating HBV viral burden to levels below acceptable cutoff values.[143] Since, to date, therapies have been suppressive and not curative, this approach is associated with the clear possibility of antiviral agent–related toxicity, as well as the theoretical possibility of fostering resistance among viruses from the infected provider. The effect of therapy should be considered carefully by the Occupational Medicine physician and the Expert Review Panel, as well as by the provider's personal physician who has expertise in the management of HBV infection.

2. Should healthcare providers who are infected with HCV be allowed to practice? If so, under what clinical, serological or viral burden parameters?

Recommendation

HCV-infected providers should not be prohibited from participating in patient-care activities solely on the basis of their HCV infection (A-III).

HCV-infected providers should not be restricted from participating in Category I or Category II Procedures (A-III); providers infected with HCV who have circulating viral burdens of greater than or equal to 10^4 GE/mL should refrain from performing Category III procedures (B-III).

Healthcare providers who have circulating HCV burdens of less than 10^4 GE/mL should be allowed to perform those Category III activities identified as associated with a risk for provider-to-patient transmission of bloodborne pathogens, so long as the infected provider (1) is not detected as having transmitted infection to patients; (2) obtains advice from an Expert Review Panel about continued practice; (3) undergoes follow-up routinely by Occupational Medicine staff (or an appropriate public health official), who tests the provider twice per year to demonstrate the maintenance of a viral burden of less than 10^4 GE/mL; (4) also receives follow-up by a personal physician who has expertise in the management of HCV infection and who is allowed by the provider to communicate with the Expert Review Panel about the provider's clinical status; (5) consults with an expert about optimal infection control procedures (and strictly adheres to the recommended procedures, including the routine use of double-gloving for Category II and Category III procedures and frequent glove changes during procedures, particularly if performing technical tasks known to compromise glove integrity [eg, placing sternal wires]); and (6) agrees to the information in and signs a contract or letter from the Expert Review Panel that characterizes her or his responsibilities (discussed in more detail in Recommendation 8, below) (B-III).

Discussion. These guidelines recommend that HCV-infected healthcare providers who have circulating viral burdens of less than 10^4 GE/mL not be restricted from any aspect of health care so long as the infected provider follows the detail of the recommendation. Specifically, the provider must be willing to consult with, and follow the recommendations of, an infection control expert. The infected provider must strictly adhere to the recommended procedures (eg, routine use of double-gloving for Category II and III procedures, frequent glove changes during procedures, particularly if performing technical tasks known to compromise glove integrity [eg, placing sternal wires], use of puncture-resistant gloves, blunted surgical needles,[86,97-99] "hands-free" technique[142,144] and other work practice controls, among many others). Finally, the infected provider must agree to the information in, and sign, a contract or letter from the Expert Review Panel that characterizes her or his responsibilities. One might have easily argued for no restrictions whatsoever for HCV-infected providers, on the basis of the experience in the United States alone.

The selection of a practice-restriction-threshold of 10^4 GE/mL is arbitrary, but, as noted above (in the section Legal Issues), some European guidelines have taken a far more restrictive tack. Because there have been virtually no such cases in the United States, we have, nonetheless, chosen a conservative cutoff for restricting practitioners. We have recommended practice restrictions for providers who perform Category III procedures whose viral burdens are 10^4 GE/mL or greater. We have based this decision on the in vitro HBV data cited above (in the section Pathogenesis and Transmission Risk), as well as the clinical experience with patient-to-provider transmission of HCV in the United Kingdom. In addition, we note that therapy for HCV is becoming increasingly effective, so that many providers who are identified as infected with HCV can have their infections eradicated. Studies of the efficacy of the treatment of acute HCV infection often demonstrate cure rates in excess of 95%, with studies of the treatment of chronically infected individuals demon-

strating cure rates of up to 70% or 80%, particularly for individuals infected with a treatment-favorable genotype.[145-147]

Individuals relying on these guidelines must keep in mind that each such case must be evaluated on its own merit and that the molecular testing strategies discussed in the document are subject to several limitations. These include (1) the fact that infected individuals' HCV RNA levels may vary over time, (2) the paucity of scientific data linking levels of viremia to risk for transmission, (3) the fact that the different currently marketed test for measuring HCV viral burden may produce variable results, (4) the varying level of reproducibility of these molecular tests, (5) the fact that antiviral therapy may produce transient or limited responses, and (6) the variety of virological and patient-related factors (eg, adherence to the recommended antiviral regimen) that may contribute to the development of "escape" mutants. SHEA underscores that these guidelines are, of necessity, malleable and modifiable as more information becomes available.

3. Should healthcare providers who are infected with HIV be allowed to practice? If so, under what clinical, serological or viral burden parameters?

Recommendation

HIV-infected healthcare providers should not be prohibited from participating in patient-care activities solely on the basis of their HIV infection (A-III). HIV-infected providers should not be restricted from participating in Category I or Category II procedures; providers infected with HIV who have circulating viral burdens equal to or in excess of 5×10^2 GE/mL should refrain from performing Category III procedures (A-III). Healthcare providers who have circulating HIV burdens of less than 5×10^2 GE/mL should be allowed to perform those Category III activities identified as associated with a risk for provider-to-patient transmission of bloodborne pathogens, so long as the infected provider (1) is not detected as having transmitted infection to patients; (2) obtains advice from an Expert Review Panel about continued practice; (3) undergoes follow-up routinely by Occupational Medicine staff, who test the provider twice per year to demonstrate the maintenance of a viral burden of less than 5×10^2 GE/mL; (4) also receives follow-up by a personal physician who has expertise in the management of HIV infection and who is allowed by the provider to communicate with the Expert Review Panel about the provider's clinical status; (5) consults with an expert about optimal infection control procedures (and strictly adheres to the recommended procedures, including the routine use of double-gloving for Category II and Category III procedures and frequent glove changes during procedures, particularly if performing technical tasks known to compromise glove integrity [eg, placing sternal wires]); and (6) agrees to the information in and signs a contract or letter from the Expert Review Panel that characterizes her or his responsibilities (discussed in more detail in Recommendation 8, below) (B-III).

Discussion. These guidelines recommend that HIV-infected healthcare providers who have circulating viral burdens of less than 5×10^2 GE/mL not be restricted from any aspect of health care, so long as the infected provider follows the detail of the recommendation. Specifically, the provider must be willing to consult with, and follow the recommendations of, an infection control expert. The infected provider must strictly adhere to the recommended procedures, (eg, routine use of double-gloving for Category II and III procedures; frequent glove changes during procedures, particularly if performing technical tasks known to compromise glove integrity [eg, placing sternal wires]; use of puncture-resistant gloves blunted surgical needles,[86,97-99] and "hands-free" technique,[142,144] and other work practice controls, among many others). Finally, the infected provider must agree to the information in, and sign, a contract or letter from the Expert Review Panel that characterizes her or his responsibilities.

As is the case for our recommendations for HBV-infected practitioners and HCV-infected practitioners, we acknowledge that the selection of a practice-restriction-threshold of 5×10^2 GE/mL is arbitrary; however, as noted above (in the section on Legal Issues), European guidelines have taken a far more restrictive tack. Because no provider-to-patient transmissions of HIV infection have been detected in the United States since the initial cases involving the Florida dentist (discussed in more detail in the sections Epidemiology and Current Published Guidelines, above), we have chosen to recommend permitting an HIV-infected practitioner to conduct Category III procedures if his or her viral burden is suppressed below 5×10^2 GE/mL. We chose 5×10^2 GE/mL as the threshold, in part, because individuals who typically have their viral burdens suppressed to the "undetectable" range (generally <50 copies/mL) occasionally have levels that spike to 5×10^2 GE/mL, despite ongoing effective antiretroviral therapy. We have recommended practice restrictions for a provider who performs Category III procedures and has a viral burden of 5×10^2 GE/mL or greater. Because this recommendation represents a substantial departure from other similar guidelines, we have recommended a relatively low threshold for restriction. Since data do not exist to provide evidence for the most appropriate threshold, this lower threshold was selected solely on the basis of opinions of the committee that drafted this guideline. This threshold should be revisited on a regular basis and modified on the basis of additional accumulating experience. Our committee also noted that highly active antiretroviral therapy is continuing to improve to the point that most HIV-infected providers can have their infections suppressed to this level or below. SHEA underscores that these guidelines are, of necessity, malleable and can be modified as more information becomes available.

Individuals relying on these guidelines must keep in mind that each such case must be evaluated on its own merit and that the molecular testing strategies discussed in the document are subject to several limitations. These include (1) the fact that infected individuals' circulating HIV levels may vary over time, (2) the paucity of scientific data linking levels of

viremia to risk for transmission, (3) the fact that the different currently marketed test for measuring viral burden may produce variable results, (4) the current variability in the level of reproducibility of these molecular tests, (5) the fact that antiviral therapy may produce transient or limited responses, and (6) the variety of virological and patient-related factors (eg, adherence to the recommended antiviral regimen) that may contribute to the development of "escape" mutants. In general, because of their very high viral burdens, providers who are experiencing the HIV seroconversion illness should not perform Category III procedures.

4. For providers who are infected with HBV, HCV, and/or HIV and who have circulating viral burdens greater than the recommended cutoff values, which procedures should they be precluded from performing?

Recommendation

HBV, HCV, and HIV infected providers should not be restricted from participating in Category I or Category II Procedures solely on the basis of their bloodborne pathogen infection (A-III). HBV-infected providers who are either HBeAg positive or who have circulating HBV burdens greater than or equal to 10^4 GE/mL should refrain from conducting procedures listed in Category III (A-III). HCV-infected providers who have circulating viral burdens greater than or equal to 10^4 GE/mL should refrain from conducting procedures listed in Category III (B-III). HIV-infected providers who have circulating viral burdens greater than or equal to 5×10^2 GE/mL should refrain from conducting procedures listed in Category III (A-III).

Discussion. Historically, the concept of "exposure-prone" procedures has been a point of controversy, though several more recent guidelines and manuscripts have suggested that "exposure-prone" procedures can be defined.[1,109,117,121] In the previous version of this guideline, SHEA suggested that "exposure-prone" procedures might be defined as those that have been "epidemiologically implicated" in patient-to-provider transmission. This approach has proved to be flawed; for example, one recent case-cluster of provider-to-patient transmission of HBV suggested that the implantation of electroencephalography electrodes was implicated in the transmission of HBV.[16] No guideline would include implantation of electroencephalography electrodes as an "exposure-prone" procedure. Some authorities have suggested that providers, rather than procedures, might be exposure-prone, suggesting that technical expertise and experience may play a more substantive role in the risk for provider-to-patient exposure, rather than the procedures themselves. We favor a modification of the approach taken by Reitsma et al[1]; namely, 3 tiers of procedural risk (Table 2). Most guidelines do not consider the impact of the introduction of safer devices and safer work practice controls to the risk calculus for infections with these 3 pathogens. As noted above in the section Pathogenesis and Transmission Risk, the use of reinforced gloves,[91,92] double gloves, glove-liners, or other devices or materials to protect the provider's hands,[89,91,93-96] and use of blunted suture needles,[86,97-99] as well as a variety of other safer devices and work practices, have been shown to decrease the risks for percutaneous injuries. The members of the committee drafting this guideline emphasized that the consistent use of safety devices by a practitioner should be one factor considered by the Expert Review Panel when deciding about practice restrictions. Some members of the committee felt that consistent use of these procedures and techniques might move some procedures from Category III to Category II for individual practitioners.

5. If restricted from performing certain types of procedures, should providers who are infected with HBV, HCV, and/or HIV be restricted on the basis of (A) clinical status, (B) laboratory parameters of disease activity and/or progression (and, if so, at what specific "set-points" for each infection), and/or (C) clinical performance (eg, technical skill or lack of adherence to important infection control procedures); and if so, who measures and who decides, and what are the criteria for restriction?

Recommendation

Healthcare practice restrictions should be based on several factors, including (1) evidence of transmission of infection to patients; (2) advice from the Expert Review Panel about continued practice, (3) advice from the Occupational Medicine specialist who is following up the provider, (4) advice from the provider's physician who has expertise in the bloodborne pathogen infection, (5) viral burden measurements of greater than or equal to 10^4 GE/mL (for HBV or HCV infection) or greater than or equal to 5×10^2 GE/mL (for HIV infection), (6) lack of adherence to recommended infection control procedures, and (7) inability to safely provide patient care (eg, development of another contagious disease such as tuberculosis or development of a bloodborne pathogen–associated disorder, such as HIV-associated neurological disease) (A-III).

Discussion. SHEA recommends that restrictions should be based on various combinations of these data. Anyone clearly implicated in the transmission of one of these organisms should become the subject of scrutiny. The factors listed above (ie, clinical status, laboratory parameters, and clinical performance) all contribute to the assessment of the individual's ability to practice safely. This ongoing assessment is one of the important roles that should be assumed by the Expert Review Panel (discussed in detail in Recommendation 8, below). The expert review panel and the occupational medicine physician should also consider the possibility of narcotics diversion in the transmission of these infections. Providers identified as acutely infected with any of these pathogens should be carefully evaluated for viral burdens and

should engage the expert review panel through their occupational medicine and/or public health practitioners.

6. Should students, residents, fellows, and other trainees who are infected with HBV, HCV, and/or HIV be discouraged from entering certain specialties and/or subspecialities? How and by whom should these decisions be made?

Recommendation

Healthcare institutions should make certain that students and trainees are fully educated about the risks associated with testing of themselves for, and management of patients with, bloodborne pathogen infections (A-III). All providers who are at risk for occupational exposure to blood should be immunized with the hepatitis B vaccine, unless it is contraindicated (A-I). All healthcare providers should know their serological status with respect to antibody to HBsAg, which should be measured 1–6 months after the completion of their HBV immunization series (A-III). Institutions should assist students and trainees who are determined to be infected with bloodborne pathogens in identifying and selecting career choices that will be the least influenced by their infection(s) (A-III). Healthcare institutions should maintain the privacy and medical confidentiality of students and trainees identified as infected with bloodborne pathogens (A-III). HBV-infected students and trainees who are either HBeAg positive or who have circulating HBV burdens greater than or equal to 10^4 GE/mL should refrain from training in or conducting procedures listed in Category III (A-III); HCV-infected students and trainees who have circulating viral burdens in excess of 10^4 GE/mL should refrain from training in or conducting procedures listed in Category III (B-III); HIV-infected students and trainees who have circulating viral burdens greater than or equal to 5×10^2 GE/mL should refrain from conducting procedures listed in Category III (B-III). Students and trainees who are not receiving optimal therapy for their bloodborne pathogen infection(s) should seek such treatment (A-I).

Discussion. A special problem arises when a training institution becomes aware that a trainee is chronically infected with a bloodborne pathogen. Each of these instances should be handled on a case-by-case basis, in consultation with the institution's legal counsel, the house staff training director, infection control professionals, the Dean of the school, and others who are involved stakeholders. To date, these cases have been handled unevenly across the United States, with some institutions focusing on the disability-law aspects and others focusing on liability.[90] The law concerning these issues is changing rapidly and is relatively untested in the higher courts. The institution, however, does have responsibility to make certain that the trainee is fully informed about the risks—both to the trainee and to his or her patients—associated with clinical practice. The institution should underscore the importance of appropriate treatment and the importance of adherance to infection control recommendations. The institution should assist the trainee in selecting a career path best suited to her or his specific situation and should provide reasonable accommodation to students and trainees who have disabling conditions. By adopting the modification of the position initially proffered by Reitsma et al[1] (ie, the 3-tiered risk schema), SHEA advocates encouraging trainees who are infected with HBV, HCV, and/or HIV and whose infection(s) cannot be effectively cleared or whose infections cannot be suppressed below the thresholds identified in Recommendations 1, 2, and 3 (above), to select career paths that do not involve the highest-risk procedures. In instances in which the decision is made to continue training, SHEA advocates having the student be closely supervised by an attending provider who is aware of the student's status when the student is learning or performing Category II procedures.

7. Should providers infected with HBV, HCV, and/or HIV be subject to specific monitoring programs, and, if so, how and by whom and to whom should the data be reported?

Recommendation

Providers infected with HBV, HCV, and/or HIV who perform Category III procedures should have their circulating viral burdens measured at least every 6 months by an engaged occupational medicine practitioner and should undergo periodic evaluations (at a minimum, twice per year) by a physician selected by the provider who has demonstrated expertise in the management of the provider's infection. Results of the viral burden tests should be reviewed by the Occupational Medicine physician, should be reviewed with the provider's personal physician, and should be evaluated by the provider's Expert Review Panel (A-III).

Discussion. Because the guidelines recommend viral burden cutoffs for practice restrictions, SHEA believes that an ongoing monitoring program is essential. Most molecular assay results are reproducible only within about half an order of magnitude. A fraction of infected individuals have fluctuating viral burdens. SHEA recommends a major role for the Occupational Medicine practitioner in supervising the monitoring program. This role would include, but not be limited to, measuring the provider's circulating viral burden at least twice annually and providing advice to the Expert Review Panel about the provider's progress and ongoing clinical status. For independent practitioners working only from an office, these functions should be fulfilled by the city, county or state health department (consonant with state and local laws). Elements of follow-up are summarized in Table 5.

TABLE 5. Functions of the Expert Review Panel

1. Evaluation of the infected provider's clinical status
2. Assessment of the provider's viral burden data
3. Assessment of the provider's experience and expertise
4. Assessment of the procedures performed by the provider and the specific techniques used to perform these procedures
5. Determination of the extent to which the provider adheres to accepted infection control precautions
6. Provision of recommendations about the use of specific barriers, work practice controls, and infection prevention strategies for the conduct of specific procedures and assess the provider's willingness to adhere to these recommendations
7. Provision of counseling to the provider about her or his ethical obligation to report a patient exposure, should one occur, and about the appropriate procedures to follow, should an exposure occur
8. Develop and execute a contract between the infected provider and the Expert Review Panel and/or institution (see Table 5)
9. In instances in which transmission is suspected, consider the potential for narcotics diversion
10. Notify Risk Management should a breach in procedure or a patient exposure occur
11. Notification of the appropriate licensure board for breaches of the signed contract with the Expert Review Panel (if required by state regulations)

NOTE. In instances in which an infected provider is not institutionally based, this responsibility should fall to the local or state health department (consonant with existing state laws).

8. Prior recommendations have suggested the creation of an Expert Review Panel for assisting institutions in managing providers infected with bloodborne pathogens. Is there a role for such a panel in 2009 and beyond? If so, what is that role, and at what level should the committee be convened (eg, at the institutional, city, or state level), who should comprise such a committee, what should be the committee's charge, and how and by whom should the committee be managed? Do committee members accept liability for participation?

Recommendation

Healthcare providers infected with HBV, HCV, and/or HIV should have their clinical status and laboratory data reviewed by an Expert Review Panel (A-III). Such a panel could exist at a state, regional, county, city, or institutional level, consonant with the individual provider's circumstance and with state and local laws. The review panel should include, but not necessarily be limited to, individuals who have expertise in the infected provider's specialty or subspecialty, Healthcare Epidemiology, Infectious Diseases or Hepatology (specifically with expertise in the bloodborne pathogen[s] being discussed), Occupational Medicine, and/or hospital administration; the infected provider's physician; a public health official (in states in which this issue is managed at the state level); a human resources professional; and, perhaps, an individual with legal and/or ethics expertise. The review panel will advise the healthcare provider, the Occupational Medicine physician, and/or the patient's primary physician about the provider's practice and about the advisability of her or his performing Category III procedures, as well as about the use of infection control interventions (A-III). The panel will create a contract or letter detailing the provider's responsibilities and those of the panel (Figure 1). Before the provider returns to practice, this document must be agreed to and signed by the provider and the panel chair (A-III). The panel should reconsider the provider's performance in the event any of the following occurs: the provider's viral load increases to above the recommended level for consideration of restrictions from performing Category III procedures; the provider develops another contagious disease (eg, tuberculosis); the provider develops another condition that might adversely effect patient safety (eg, HIV-associated neurological impairment or hepatic encephalopathy); the provider fails to strictly adhere to recommended infection control practices; a patient is exposed to a potentially contaminated body fluid of the provider; and/or if there is evidence of provider-to-patient transmission (A-III). The entity chartering the panel should indemnify the panel members against any legal risks and/or costs (A-III).

Discussion. SHEA believes that the creation of an Expert Review Panel to assist in the management of these providers is an important aspect of a patient safety program. Such a program could exist at a state, county, city or institutional level. We believe that the fact that no such cases have received publicity in the United States since the early part of this decade is an indirect reflection of the efficacy of this approach. The basic functions of the Expert Review Panel are described in Table 5. The panel, at a minimum, should include representation from Hospital Epidemiology, Infectious Diseases, the provider's specialty or subspecialty, Occupational Medicine (ie, the individual involved in monitoring the provider), hospital administration, and, perhaps, legal representation. Each case will be slightly different from the next, and each should be considered independently in context. These subtle differences underscore the importance of the Expert Review Panel. The panel should develop a formal letter or contract delineating its specific recommendations regarding the provider's performance, training in infection control, conduct of specific procedures, follow-up, and management, among other issues (Figure 1). Table 6 provides a list of issues for the infection control professional and the Expert Review Panel to consider when providing advice to infected providers regarding the performance of various procedures. Table 7 provides detail concerning the elements of this letter or contract. The requirement for a twice-annual meeting of the panel may be met by a confidential conference call or secure electronic communication. The Occupational Medicine physician, the infection control professional, and/or the state epidemiologist can serve as gatekeepers for the twice-annual review. So long as the contract is being fulfilled and no guideline violations are identified, additional face-to-face meetings

Date

Dear Dr. [Name]:

[Hospital or Health Department name]'s Expert Advisory Panel on Infected Healthcare Workers met on [date], to discuss your case. The Panel reviewed the medical literature relevant to healthcare workers infected with [HBV, HCV, HIV]. In addition, we reviewed guidelines, including the 1991 CDC Guideline pertaining to healthcare workers infected with bloodborne pathogens and the position statements of selected medical professional societies pertaining to the guideline. The Panel concluded the following:

You are permitted to continue your [specialty/subspecialty] training or practice at [hospital name]. If you agree to the Panel requirements below, it is mutually understood that you will comply with the following guidelines:

- You must double-glove for all [discipline] procedures, whether those procedures are carried out in the operating room, in an imaging suite, at the bedside, or in a treatment room.
- You must change gloves approximately every 2-3 hours, or in the event that glove damage occurs during a procedure. Glove damage has been shown to occur more frequently during longer procedures, and has been specifically associated with certain activities, (e.g., tying sternal wires). You are encouraged to increase your frequency of glove changes under such circumstances.
- You should avoid digital palpation of needle tips and blind probing in poorly visualized or highly confined anatomic sites.
- If you suffer an injury which penetrates your gloves and skin, but during which you do not observe contact of your blood with the surgical field, you should check your hands to be certain you are not bleeding. If you are not bleeding, you may rejoin the case after changing gloves. If you are bleeding, you should withdraw from the case. If the device that injured you recontacted the patient, you must notify [your representative to the expert review panel] who must assure that the patient is made aware of the potential exposure and is treated appropriately.
- If you suffer an injury that causes you to bleed during a procedure and your blood contacts the surgical field, you must withdraw from the case and contact [your representative to the expert review panel], immediately. She/he will assure that the patient will be informed that a possible [HBV/HCV/HIV] exposure has taken place and the patient will be offered appropriate postexposure management, including immuno-/chemoprophylaxis and follow-up, as appropriate. To the extent possible, your identity will be protected.
- The Panel requests that you continue under the care of a physician with expertise in [HBV/HCV/HIV] medicine in order to appropriately monitor and manage your illness.

If you agree to the outlined restrictions on your practice, please sign below.

Signature:_____ Date:_____

Witness:_____ Date:_____
[Name, Expert Advisory Panel Representative]

FIGURE 1. Sample contract letter between an Expert Review Panel and a healthcare provider infected with a bloodborne pathogen. The letter delineates the specific recommendations of the panel and the responsibilities of the panel and of the infected provider. Table 7 provides more detail on the elements of such a letter or contract.

TABLE 6. Issues for the Hospital Epidemiologist and the Expert Review Panel to Consider When Providing Advice to Infected Healthcare Providers Regarding the Performance of Various Procedures

1. The precise procedures for which permission is sought, the historical risks for provider-to-patient bloodborne pathogen transmission associated with these procedures, the provider's experience with such procedures, and the likelihood of patient exposure to provider blood during these procedures
2. Gather evidence of the infected provider's skills, practices, and adherence to the institutional infection control plan (particularly with respect to standard precautions)
3. Investigate and discuss with the provider the availability of safer devices that will reduce the risk for patient exposures (eg, spring-loaded retractable needles, guards that shield dangerous tips, and blunted surgical needles)
4. Investigate and discuss the availability of barriers that will reduce the risks for exposures (eg, reinforced gloves,[91,92] double gloves, gloves constructed of monofilament polymers or other materials resistant to tears, glove-liners, and other devices or materials to protect the provider's hands[89,91,93-96])
5. Discuss work process controls, such as the "hands free" technique in the operating room[142]
6. Emphasize the need and ethical obligation to notify the hospital epidemiologist, immediate supervisor, or other individual, as detailed (or identified) in the contract, should a breach and/or patient exposure occur
7. Emphasize a detailed description of the process to be used in the event of breach of infection control procedures or a patient exposure

of the Expert Review Panel may not be needed. In instances in which guideline violations are identified or in instances in which the provider's clinical status has changed significantly, the entire review panel should meet to consider the new information. The committee emphasizes that the Expert Review Panel should not advise the practitioner about his or her health and treatment options; this responsibility falls to the provider's personal physician.

II. DISCLOSURE ISSUES

9. Are there any medical settings in which a healthcare provider infected with HBV, HCV, and/or HIV should be routinely required to notify patients of his or her bloodborne pathogen status; and, if so, what are the specific types of circumstances requiring notification?

Recommendation

Providers infected with HBV, HCV, and/or HIV who are adhering to the guidelines above should not be required to disclose their infection status to any patient (unless the provider has been the source for an exposure for a patient, as discussed in Recommendation 11A, below) (A-III).

Discussion. Societal views of patients' rights are strong, and most patients feel that they have a right to know if their physician or other healthcare provider is infected with a potentially transmissible bloodborne pathogen (irrespective of the magnitude of risk).[118,148,149] A national survey conducted in 2004 demonstrates little change in public views of this issue.[118] Case law has generally concluded that informed consent includes disclosure of risks that may be perceived by patients as being important even if, by rational consideration, they are negligible. These positions aside, in both previous versions of this guideline, we concluded that a requirement for such disclosure would very likely require a provider to abandon or substantially modify his or her practice—an unwarranted outcome in light of our current understanding of the risks for provider-to-patient transmission of these bloodborne pathogens. The existing 1991 US Public Health Service guidelines[105] require that patients who are to have "exposure-prone invasive procedures" performed by HIV-positive or HBeAg-positive, HBV-infected practitioners be notified of the practitioner's infection status prior to the procedure. On the basis of the substantial changes in the risk profile since the previous version of this guideline was published (eg, new safety devices, new infection control strategies, better techniques for monitoring diseases, effective postexposure management, and effective therapy), SHEA feels even more strongly that such a position is unwarranted. If practitioners adhere to the components of this guideline with respect to modifying their practices when an increased level of risk is present, in the absence of an adverse patient exposure to blood or blood-containing body fluids (discussed in Recommendation 11, below), the risk for provider-to-patient transmission is so small that it cannot be accurately measured. SHEA's position on these issues remains essentially unchanged. An earlier iteration of the American Hospital Association Patients' Bill of Rights argues for disclosure of relevant information to patients,[150,151]although this "Bill of Rights" has subsequently been replaced by a plain-language document that does not directly address this issue. The American Medical Association Council on Judicial Affairs also includes a general statement in favor of patient disclosure.[152]

10. Are there circumstances for which an infected healthcare provider should be required to obtain informed consent that includes disclosure of the provider's serostatus from a patient prior to a procedure?

Recommendation

Providers infected with HBV, HCV, and/or HIV who are adhering to the guidelines above should be required to obtain informed consent for a procedure but should not be required to disclose

TABLE 7. Elements of the Contract between an Infected Healthcare Provider and the Expert Review Panel

Responsibilities of the healthcare provider

1. Agrees to twice yearly follow-up by Occupational Medicine, including measurement of viral burden using tests specified by the panel
2. Agrees to twice yearly evaluations by a private physician who has expertise in the provider's specific bloodborne pathogen infection and agrees to have this physician discuss the results of these evaluations with the provider's Expert Review Panel
3. Agrees to formal training in infection control via a course identified by the infection control expert, or, alternatively agrees to counseling by the infection control professional concerning the use of appropriate infection control procedures, safety devices and work practice controls
4. Agrees to follow the recommended procedures and practices identified in the previous item (responsibility 3)
5. Agrees to notify the occupational medicine or the public health authority participating in the panel regarding any change in provider status that may increase risk to the patient (eg, new neurological findings, development of another contagious disease [eg, tuberculosis])
6. Acknowledges the ethical obligation to do so, and agrees to report instances immediately in which a patient exposure may have occurred to the hospital epidemiologist or to appropriate institutional/public health authorities identified in the contract, so that the potentially exposed patient may receive appropriate postexposure management and counseling
7. If receiving treatment, agrees to continue treatment as prescribed and agrees to notify occupational medicine if the treatment regimen is modified for any reason
8. Agrees to re-evaluation by expert panel and revision of contract should clinical status or viral burden change

Responsibilities of the institution and/or public health authorities

1. Agrees to convene Expert Review Panel at least twice annually (see text) to assess provider's clinical and virologic status as well as the provider's ongoing performance and her or his ability to continue to perform requested procedures
2. Agrees to maintain provider's medical privacy and confidentiality
3. Agrees to develop and follow institutional or provider-based follow-up procedure for potential patient exposure that makes every effort to ensure practitioner confidentiality
4. Panel participants should have no liability
5. Develops process for notifying hospital Risk Management

NOTE. Some aspects of this contract may be mandated by state laws, so the contract should carefully consider the legal requirements for the state in which the contract is being issued. A sample contract letter is shown in Figure 1.

their serostatus as part of the process of informed consent from patients on whom they are about to perform a procedure (A-III).

Discussion. If a practitioner adheres to the guidelines outlined in detail above, SHEA concludes that the risk for transmission would be so small that informed consent about the risk of transmission would not be required. In special circumstances associated with a known or anticipated increased level of risk (eg, a provider who has previously transmitted infection to a patient or a provider who has a viral burden in excess of those listed in these guidelines is performing a Category III procedure), obtaining informed consent is rational, prudent, and advised.

III. EXPOSURE MANAGEMENT

11. How should a provider-to-patient blood exposure or other hazardous body fluid exposure to HBV, HCV, and/or HCV be managed?

11A. Should a provider who is the source of a patient exposure be required to undergo testing for bloodborne pathogen infection?

Recommendation

A provider who is aware that he or she is the source of a significant patient exposure to his or her blood or hazardous body fluid should undergo testing for infection with bloodborne pathogens, even if not known to be infected with HBV, HCV, and/or HIV (A-III). Healthcare institutions should develop specific policies to deal with such exposures and should establish sanctions for providers who refuse testing for bloodborne pathogens in these circumstances (A-III). Such policies should be formally drawn and approved by institutional attorneys and governing boards (A-III).

Recommendation

In the event of possible or documented patient exposure to blood or potentially hazardous body fluids from an infected provider, the involved provider is ethically obligated to notify immediately either the Occupational Medicine physician who is conducting follow-up for the provider or the chair of the provider's Expert Review Panel (A-III). Whoever is notified should immediately engage the infection control team, the hospital administration, and institutional risk management team to ensure there is appropriate follow-up and medical management for the potentially exposed patient (A-III). In the event of possible or documented patient exposure to blood or potentially hazardous body fluids from an infected provider who is not institutionally based, the provider is ethically bound to contact the official in the public health establishment who is providing Expert Review Panel oversight (A-III). This individual, in turn, should immediately ensure that there is appropriate follow-up and medical management for the potentially exposed patient (A-III).

Discussion. State laws and State policies and procedures vary substantially with respect to testing for bloodborne path-

ogens. Healthcare institutions electing to develop policies that compel testing of the source individual should make certain that such polices are legal in their jurisdictions and should apply such policies only to exposures for which scientific precedent establishes that HBV, HCV, or HIV transmission could occur.

11B. Should an inadvertently exposed patient be notified of the exposure?

Recommendation

A patient who has been exposed (ie, by way of percutaneous, mucous membrane, or nonintact-skin exposure) to the blood or potentially contaminated body fluid of any provider should be notified of the exposure promptly and given clear options for follow-up testing and management (A-III). An exposed patient (1) should be notified about the exposure promptly; (2) should subsequently be notified of the outcome of the source provider's HBV, HCV, and HIV test results; (3) should receive expert counseling regarding the implications of the event; and (4) should be offered effective postexposure treatment appropriate for the exposure in instances in which an exposure to a bloodborne pathogen is documented (consistent with current CDC guidelines[153,154]) (A-III). Institutions should establish policies requiring self-reporting to the infection control program or occupational health program and to the exposed patient's primary physician of provider-to-patient blood or hazardous body fluid exposure (A-III). The exposed patient should not be notified of the source provider's name or of the exact circumstances of the exposure but should be provided with enough information to understand the implications of the exposure fully (A-III).

Discussion. For a variety of reasons, in instances in which a provider-to-patient blood exposure occurs, the patient has a right to know that the exposure has occurred, irrespective of whether the provider is known to be infected with a bloodborne pathogen. The patient must be notified about the exposure and presented with options for postexposure treatment (as appropriate), as well as appropriate follow-up.[153,154] In addition, the patient must receive counseling about the risk for transmission and the strategies that are effective in preventing subsequent transmission of the bloodborne pathogen to which the patient was exposed. Since any exposure to blood may place patients at risk for acquiring a bloodborne infection, patients should always be notified of such occurrences. The identity of the source (ie, the infected provider) should not be disclosed. Needlestick transmissions (as well as mucous membrane and nonintact-skin transmissions) of HBV, HCV, and HIV infection have all been amply documented. Since negative serologic test results do not completely eliminate the possibility of transmission of bloodborne pathogens, any blood exposure creates a requirement for notification of the exposed patient. Notification also allows the exposed patient to have the option of receiving recommended postexposure management (eg, appropriate chemoprophylaxis or immunoprophylaxis). Institutions should designate a responsible person for informing an exposed patient and ensuring patient follow-up. Ultimate responsibility for follow-up should be assigned to the patient's physician, even if the physician is the source of the exposure. The physician providing the follow-up should receive expert guidance from a member of the Infection Control and/or Occupational Health staff. SHEA would not recommend that the source of the exposure be involved in counseling, informed consent, or test explanation, in light of the potential for conflict of interest. The hospital epidemiologist, infection control practitioner, or other staff knowledgeable both about the risks and routes of transmission of bloodborne pathogens, as well as the counseling of individuals exposed to bloodborne pathogens, should be available for support and consultation.

11C. Should an inadvertently exposed patient be required to undergo baseline serologic testing?

Recommendation

The exposed patient and his or her physician should be asked for consent to perform baseline testing for bloodborne infections (when consonant with state and/or local laws) (A-III). If consent is obtained, the patient's serum should be tested for evidence of HBV, HCV, and HIV infection (A-III). If the patient refuses testing, the institution should seek the permission of the patient or the patient's representative to store available baseline serum from the patient (A-III). If neither testing nor storage can be accomplished, the patient or the patient's proxy should be asked to sign a formal declination emphasizing that these services were offered and declined (A-III).

Discussion. Although the exposed patient cannot be compelled to have and may clearly choose not to have such testing performed, such testing would help establish the basis (and some of the best evidence) for a claim against the institution and/or the practitioner. Exposed patients should be made aware of the potential value and detriment of negative and positive test results. For patients who refuse testing (and consonant with state and local laws regarding testing), institutions should attempt to obtain informed consent from the patient to allow the institution to preserve a carefully labeled and dated baseline serum sample from the exposed patient. Although such samples cannot be tested against the patient's will, these samples ultimately represent important evidence in such a case. Patients refusing to consent to serum storage should be asked to sign a form noting their declination for both serologic testing and serum storage.

11D. How (and by whom) should an inadvertently exposed patient be followed and, if appropriate, treated?

Recommendation

Exposed patients should be counseled regarding the risks for infection and the symptoms of acute HBV, HCV, and HIV infection (A-III), should be offered postexposure chemoprophylaxis and/or immunoprophylaxis as is characterized in current CDC guidelines for an exposed healthcare worker[153,154] (A-II), and should be

followed in a manner analogous to the existing CDC guidelines for providers who sustain occupational exposures to HIV or other bloodborne pathogens.[153,154] Institutions and/or providers involved in such exposures should provide testing at no cost to the patient and should provide the details of appropriate follow-up to the patient and her or his physician (A-I).

IV. TESTING ISSUES

12. Should any, or perhaps all, providers be routinely tested for HIV infection?

Recommendation

Mandatory HBV, HCV, or HIV screening of healthcare providers is not recommended (A-III). A provider who conducts Category III procedures is ethically obligated to know his or her infection status with respect to HBV, HCV, and HIV (A-III). Institutions should provide voluntary confidential testing for their employees (A-III). A provider who knows that he or she is the source of a patient exposure (ie, as defined by the CDC—a percutaneous, mucous membrane or nonintact-skin exposure) to his or her blood or hazardous blood or body fluid should report the exposure and should undergo testing for infection with bloodborne pathogens (A-III).

V. LOOK-BACK STUDIES

13. If an infected provider is identified, under what circumstances should a look-back study be conducted?

Recommendation

Look-back studies should be conducted only on a case-by-case basis in instances in which compelling evidence for increased risk for provider-to-patient transmission is identified (A-III). A decision to initiate a look-back study should be made in collaboration with the infected provider's Expert Review Panel, institutional leadership, and appropriate local and/or state public health authorities (A-III).

Discussion. Although look-back studies may occasionally provide useful information, most look-back studies have yielded no useful information, and all such investigations are extremely labor-intense and resource-intense.[48,57] SHEA recommends that such studies be conducted only when factors are identified that suggest an increased risk for provider-to-patient transmission of one of these bloodborne pathogens.

A variety of circumstances may prompt initiation of a look-back study. These include (1) if an infected healthcare worker is identified during the investigation of a possible instance of healthcare-associated transmission of one of these viruses, (2) if provider-to-patient transmission infection is documented or presumed, (3) if there is disclosure of a bloodborne pathogen infection associated with a viral burden higher than the thresholds defined in Recommendations 1, 2, and 3 (above), by a healthcare worker who has been conducting Category III procedures, or (4) if an ongoing screening program identifies an infected healthcare worker who has been conducting Category III procedures and who has a viral burden in excess of the thresholds noted in Recommendations 1, 2, and 3 (above). The goals for such an investigation include (1) the provision of information to patients regarding the nature and magnitude of risks to which they may have been exposed, (2) the identification of patients who may have become infected with one or more of these bloodborne pathogens as a result of healthcare interventions and who may benefit from treatment, (3) the prevention of additional instances of transmission, (4) the management of institutional risks, and (5) the reassurance of the public.

The decision about whether to conduct a look-back study should be made on a case-by-case basis. Factors that would suggest an increased risk for provider-to-patient transmission that would prompt such a study include (1) identification of an infected patient in the practice of an infected provider (and the demonstration of that the patient's and the provider's viral isolates are related), (2) the healthcare provider's clinical specialty and the types of procedures performed are among those associated with increased risk for transmission, (3) concern that a given provider fails to follow recommended infection control procedures, (4) evidence of substandard clinical practice (eg, high postoperative infection rates or frequent occupational exposures), and (5) comorbid medical diagnoses in the infected provider that might elevate risk (eg, conditions resulting in, for example, nonintact skin or early dementia).

The identification of a documented instance of provider-to-patient transmission of one of these 3 bloodborne pathogens should invariably result in a thorough look-back exercise. In the absence of a documented instance of provider-to-patient transmission, the Expert Review Panel should evaluate the risk for transmission on a case-by-case basis. If a look-back study is implemented, every effort should be made to preserve the privacy and medical confidentiality of the infected provider.

In instances in which the infected provider is institutionally based, the provider's institution should be responsible for the notification program, with appropriate collaboration with the local and state public health authorities. In instances in which the provider is not institutionally based, local or state public health authorities should decide about the need for such a study. If the decision is made to initiate such a study, the decision should be made, and the study conducted, by the appropriate public health authorities.

SUMMARY

SHEA favors a comprehensive approach to managing healthcare providers who have been identified as being infected with HBV, HCV, and/or HIV in the broader context of all institutional health and credentialing programs. Such an ap-

proach allows the assessment of the provider-to-patient transmission risks in appropriate perspective. Thus, reasons for broadly restricting practice should be consonant with existing impaired-provider and disability guidelines, and should be based on the following criteria: (1) the provider has a viral burden above the recommended threshold for the relevant virus, (2) the provider has a medical condition or conditions resulting in the provider's inability to perform assigned tasks, (3) the provider has documented untoward events (ie, the provider is known to have transmitted HBV, HCV, or HIV), (4) the provider refuses or is unable to follow recommended guidelines to prevent transmission of infectious diseases, and/or (5) the provider is unable to perform regular duties, assuming that "reasonable accommodation" has been offered for the disability.

AUTHORSHIP STATEMENT

A subcommittee of the Guidelines Committee of The Society for Healthcare Epidemiology of America drafted this guideline. The SHEA Board of Directors approved the final draft. This consensus statement represents SHEA's position on these controversial issues, and does not represent the opinions of the individual contributors to the document or of individual members of the organization.

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EXHIBIT 73

Excerpts from the March 7, 2019 Deposition of Sergeant Nicholas Harrison

IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF VIRGINIA

NICHOLAS HARRISON, et al., Plaintiffs,	:	
v.	:	Civil Action No.
PATRICK M. SHANAHAN, in his official capacity as Acting Secretary of Defense, et al., Defendants.	:	1:18-cv-641-LMB-IDD

Deposition of NICHOLAS HARRISON, a Plaintiff herein, at the offices of United States Department of Justice, 1100 L Street, N.W., Washington, D.C., commencing at 9:38 a.m. on Thursday, March 7, 2019 and the proceedings being taken down by stenotype and transcribed by Catherine B. Crump, a Notary Public in and for the District of Columbia.

"informal"?

A. Informal in that, I mean, they basically decided that that weekend, they were going to fill their JAG slots and they reached out and found several people who were interested in that position and sort of conducted the interviews sitting around a conference table in their JAG office.

Q. How did they communicate to you that they have a slot for you?

A. They told me verbally on the phone and then I believe they reached out to my commanding officer in the military police unit, Captain Harvey at the time and informed him they wanted to let him know that they were interested in me as well and asked him if that was all right and to get his recommendation and his approval, which he did, and they told him at that time that, given my service, given that I've served as a previous NCO, they were try to get me commissioned directly as a captain rather than me having to go through the initial first lieutenant position.

Q. So they asked your commanding officer

for his recommendation at this point?

A. Right. I mean, it wasn't a formal recommendation. They didn't say will you write something up, will you recommend him. They basically went and talked to my commanding officer to let him know they were interested and, of course, make sure, more or less, that you don't have issues with his guy, this guy isn't a problem, what you do think about him; and they went and sat down, talked to him, said we're considering him for a JAG position; we want to offer him this position. My commanding officer was like, Yes, he's a great person, a great NCO; I think he would be an exceptional candidate for this position.

So that was sort of their interaction or the conversation.

Q. So you say they said they want to offer you a position. Had you been formally given a position at this point?

A. I mean, I hadn't been formally given a position because they didn't commission me.

Q. Had you been formally given an offer at

that point?

A. He gave me an offer. He said that he was going to reach out to my commanding officer, but yes. He said he wanted me.

I'm sure the offer could have been withdrawn if they reached out to my commanding offer and my commanding officer said, No, he's a -- for lack of a better word, he's a shit bag, don't take him, but they were very interested in me. They basically had given me a tentative offer.

That formalized as soon as they talked to my commanding officer and they said, Okay, that's fine.

Q. How was it formalized?

A. I mean, my commanding officer in formation that day got up in front of the entire unit and said Sergeant Harrison here has been offered a JAG commission; we're going to miss him, but they're going to bring him as a captain because of his record of service. He made a big deal about it because he liked me. He was very impressed with my record and how I was as an NCO.

He thought that it was also an inspiration for

EXHIBIT 74

Excerpts from the March 15, 2019 Deposition of Kevin Cron

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION
NO. 1:18-CV-00641-LMB-IDD

NICHOLAS HARRISON and
OUTSERVE-SLDN, INC.,

Plaintiffs,

vs.

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.
_____/

201 North Franklin Street
Tampa, Florida
9:00 a.m. to 3:41 p.m.
March 15, 2019

VIDEO-RECORDED DEPOSITION OF KEVIN CRON

Taken on behalf of the PLAINTIFFS before Kim Auslander, RPR, CRR, Notary Public in and for the State of Florida at Large, pursuant to Notice of Taking Deposition in the above cause.

A I talked to my command surgeon to notify him that I would be participating in this regard. He notified the CENTCOM legal department that we would -- that I would be participating in this regard to ensure that that was acceptable.

Q Okay. And did you talk to anyone else?

A No.

Q Did you talk to anyone to prepare yourself to testify on any of the topics that you've been designated to address?

A I should mention I did, and this would actually contradict my previous answer. I did contact the -- my counterparts within the service components of CENTCOM, which would be ARCENT, AFCENT, MARCENT, and NAVCENT.

So, within the Combat and Command, you have the Combat and Command headquarters, which is who I represent. Then we have service components that represent their affiliated armed services, both geographically and operationally within the organization. So, ARCENT is the Army Central Command, consisting of Army personnel who work through Army issues and so on and so on.

Because of our waiver program, we handle at the headquarters level behavioral health waivers,

waivers for personnel that are not affiliated to any particular service, and then appeals.

We've deferred authority to arbitrate medical waivers on medical issues -- purely medical issues -- down to the service components, so it's conceivable that they may have issued a determination on an HIV waiver without notifying us.

I had -- in order to properly advise my surgeon, I had to contact them and ensure that they had not actually done that, and additionally make sure that when we put forth our initial opinions, but for that earlier letter I mentioned, that we had not granted any waivers, I was speaking truthfully.

Q Okay. So, just to see if I understood your response, are you saying that it isn't you who would grant the waiver for someone who was HIV and seeking to deploy, it would be handled by the Service?

A We all work on behalf of the CENTCOM command surgeon. He has delegated authority to me to handle those waivers that come to the Central Command headquarters. Other waivers would go through the service components, and they would usually -- and when it's become an issue, they would contact us to notify us that they had an issue that is unusual.

However, it's conceivable that they did not,

and as a staff officer, you quickly learn that you verify your facts before you go on record, so in order to properly address the question, I was asked for my surgeon -- I had to confirm with them that they had not in fact approved any, and the response that I got back from all of them was uniformly that they did not.

Q Was there anyone else that you talked to to prepare yourself to testify on any of the topics that you were designated to address today?

A No.

Q I want to go back to the statement that you said was issued in February 2019 by CENTCOM public affairs. I don't mean to mischaracterize your testimony, so correct me if I'm wrong.

As I understood, just the gist of the statement was it was very unlikely, although possible, for someone who was HIV positive to deploy to CENTCOM, then you enumerated the concerns you had with such a deployment; is that right?

A Yes.

Q And, to the best of your recollection, what were the concerns that were enumerated in that February 2019 statement?

A Our concerns are that the service members who are HIV positive and managed on therapy are vitally

A That's correct.
Q Okay.
A It's worth clarifying, I have either issued the determination or basically cosigned the determination.
Particularly with some of our components, they will tell us what they think they should do, and we will just agree or disagree; so I don't want to take credit for their work --
Q Okay.
A -- but it is my -- I am acting on my authority to act as the final authority, similar to a doctor cosigning a note for one of their students.
Q The number here, the over 14,000 are all applications that you've been personally involved with --
A That's correct.
Q -- either as the sort of sole determinant or as a codeterminant of what should be done?
A That is correct, yes.
Q You were telling me a few minutes ago about the persons from the individual services who were also involved in making --
A Yes.
Q -- waiver decisions; is that right?

A Correct.

Q If they make a decision -- let me ask it differently.

For example, what are those people called?

MR. NORWAY: Objection to form. Vague.

THE WITNESS: They are also called waiver action officers, although the services will sometimes term the position differently according to their own traditions.

BY MS. BAUER:

Q Okay. But, for example, can the waiver action officer for the Army determine whether someone in the Army can deploy to CENTCOM by themselves?

A They have the ability to make a determination, although in some -- once again, we cannot contradict Army policy, so, if Army policy said it was okay for that person to come into or to deploy at all, then that surgeon -- for the Army, it's typically the ARCENT surgeon who serves in that capacity -- could authorize them to go, could endorse the waiver, because he's basically using delegated authority from the CENTCOM surgeon.

Q Okay. So, in other words, that person could make a determination on their own, and that's not included in your number of over 14,000; is that right?

A That's correct. The number including those is substantially more.

Q Do you know what the number is if I included the waiver action officer for the services?

A It's -- I don't know an exact number, because it's -- our components are geographically isolated from us. We have two of our components co-located at MacDill, two of them are 500 miles north of us at Shaw Air Force Base, and then the NAVCENT surgeon's office is in the country of Bahrain, so we don't maintain contiguous data systems with them.

They operate more or less autonomously. We have constant informal communications back and forth checking with each other as to how we feel about different things.

Q Okay.

A All of this is in our written policy; this entire chain of authority.

Q And which two components are located at MacDill?

A That's the Air Force component -- I'm sorry -- at MacDill. I apologize. The MARCENT and SOCCENT.

Q And what's SOCCENT?

A Special Operations Command Central.

Q Which two are located at Shaw Air Force Base?

EXHIBIT 75

Excerpts from the February 22, 2019 30(b)(6) Deposition of Defendants Given by Andrew Wiesen

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

NICHOLAS HARRISON and OUTSERVE-SLDN, INC., Plaintiffs, vs. 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. No. 1:18-cv-00641 LMB-IDD

RICHARD ROE, VICTOR VOE, and and OUTSERVE-SLDN, INC., Plaintiffs, vs. 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. No. 1:18-cv-01565

VIDEOTAPED 30(b)(6) DEPOSITION OF DEFENDANTS
GIVEN BY ANDREW WIESEN

DATE: Friday, February 22, 2019
TIME: 9:14 a.m.
LOCATION: Winston & Strawn
1700 K Street, N.W.
Washington, D.C.

attachment A and it is -- it doesn't have page numbers. It's attachment A. It's the first page. And it's paragraph 4. Are you there?

A Yes.

Q All right. So if you look to paragraph 4, do you understand that you are here today to provide testimony regarding the factual bases for DODI 6490.07 in general, and specifically for the DOD policies set forth in section 4 in enclosure 3, medical conditions usually precluding contingency deployment, section (e), infectious diseases?

A Yes.

Q If you look to paragraph 7, do you understand that you are here to provide testimony on behalf of the Department of Defense regarding the factual basis for defendants' contention that a person living with HIV is not fit or capable of performing his or her duties in the military?

A Yes.

Q If you look to paragraph 21, do you understand that you are here today to provide testimony on behalf of the Department of Defense regarding the process by which service members requiring daily medication are provided with that

EXHIBIT 76

Excerpts from the March 20, 2019 Deposition of
Lt. Col. Jason Okulicz, M.D.

UNDER SEAL