A multimodal assessment of driving performance in HIV infection

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Abstract—*Objective:* To examine if HIV-seropositive (HIV+) individuals are at risk for impaired driving. *Methods:* Sixty licensed drivers (40 HIV+, 20 HIV−) completed a neuropsychological (NP) test battery and driving assessments. Eleven HIV+ subjects were NP-impaired. Driving-related skills were assessed using 1) two driving simulations (examining accident avoidance and navigational abilities), 2) the Useful Field of View (UFOV) test, and 3) an on-road evaluation. *Results:* HIV+ NP-impaired subjects had greater difficulty than cognitively intact subjects on all driving measures, whereas the HIV− and HIV+ NP-normal groups performed similarly. On the UFOV, the HIV+ NP-impaired group had worse performance on Visual Processing and Divided Attention tasks but not in overall risk classification. They also had a higher number of simulator accidents (1.3 vs 2.0; $p = 0.03$), were less efficient at completing the navigation task (3.2 vs 9.2 blocks; $p = 0.001$), and were more likely to fail the on-road evaluation (6 vs 36%; $p = 0.02$). Impairment in Executive Functioning was the strongest NP predictor of failing the on-road drive test. NP performance and both simulations independently contributed to a model predicting 48% of the variance in on-road performance. *Conclusion:* HIV+ NP-impaired individuals are at increased risk for on-road driving impairments, whereas HIV+ individuals with normal cognition are not at a significantly higher risk than HIV− subjects. Executive Functioning is most strongly associated with impaired on-road performance. Cognitive and simulator testing may each provide data in identifying driving-impaired individuals.

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AQ: 1 Thirty percent to 55% of individuals with HIV infection develop neuropsychological (NP) impairment.[1,2] However, there is little research examining the impact that HIV-related NP impairments have on the ability to perform one of the most challenging and potentially dangerous of everyday activities: driving an automobile. To our knowledge, there is only one published study of driving performance in HIV-infected individuals.[3] In that study, HIV-infected persons with neurocognitive impairment had significantly more accidents on a driving simulator than HIV-seropositive (HIV+) subjects without NP impairment. This held true even though most of the NP-impaired individuals had only mild or mild to moderate levels of NP dysfunction and after controlling for immune status and disease stage. As this study only included HIV+ subjects, comparisons with uninfected individuals were not possible. In addition, it was not clear that the reduced simulator performance would translate into real world consequences (i.e., being any less safe on the road).

We sought to determine whether these earlier findings extrapolate to direct assessments of driving ability and to explore the neurocognitive impairments that are associated with worse simulator and on-road performance.

Methods. *Subjects.* Subjects consisted of 40 HIV+ and 20 HIV-seronegative (HIV−) individuals. Serostatus was determined based on ELISA with a western blot confirmation. Subjects were required to have driven an automobile within the last year and to have a current driver's license. Exclusion criteria included a history of loss of consciousness of >30 minutes, current substance dependence, psychosis, and CNS opportunistic infections or neurologic disease other than HIV infection.

Procedures. Participants completed an NP assessment as well as simulator and on-road driving evaluations. All examiners were blinded to HIV status and performance on the other measures.

NP assessment. The NP battery assessed the following cognitive domains: Verbal Fluency (Controlled Oral Word Association Test); Executive Functioning (Trail-Making Test Part B, Wisconsin Card Sorting Test [64-item computerized version], Category Test, Stroop Color–Word Interference Score); Attention/Working Memory (Wechsler Adult Intelligence Scale III [WAIS-III] Letter Number Sequencing, Paced Auditory Serial Addition Test); Speed of Processing (WAIS-III Digit Symbol and Symbol Search, Trail-

***See the Appendix on page XXX for a list of Group members.**

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Making Test Part A, Stroop Color–Word Test); Learning and Memory (Hopkins Verbal Learning Test–Revised, Brief Visuospatial Memory Test–Revised, Story Memory Test, Figure Memory Test); and Motor (Grooved Pegboard). Raw scores were converted to T scores using norms that adjust for the influence of age, education, gender, and ethnicity (whenever possible). The presence and severity of impairment were determined by a neuropsychologist who was blinded to serostatus.[4] Subjects had to be impaired in at least two domains to be classified as NP-impaired.[5]

We also applied an automated approach that yields a continuous estimate of NP functioning (the Global Deficit Score [GDS]). The GDS[1,6] emphasizes both the number and the severity of deficits, giving less weight to average and above performances. T scores on individual NP measures were converted using the following algorithm: $T \geq 40$ (deficit score [DS] = 0; no impairment), $35 \leq T \leq 39$ (DS = 1; mild impairment), $30 \leq T \leq 34$ (DS = 2; mild to moderate impairment), $25 \leq T \leq 29$ (DS = 3; moderate impairment), $20 \leq T \leq 24$ (DS = 4; moderate to severe impairment), $T < 20$ (DS = 5; severe impairment). The 17 deficit scores were then averaged to create the GDS.

Depression was assessed with the Beck Depression Inventory (BDI).

Driving simulations. Subjects completed two interactive driving simulations (Systems Technology, Inc., Hawthorne, CA), consisting of three networked Pentium-based computers, three side-by-side monitors (135° field of view), a steering wheel, and brake and accelerator pedals. Subjects were trained to criterion to minimize the effect of novelty on performance.

Simulation 1: Advanced Routine and Emergency Driving. The Advanced Routine and Emergency Driving (ARED) task consisted of a 15-minute drive along multilane highways and congested city streets. It included curves and hills, and subjects were required to pass cars, drive around stalled vehicles, and adjust to fog. Six accident-avoidance scenarios, such as a pedestrian darting across the road, were included. To ensure adequate sensitivity in detecting driving impairments, the simulation was designed to be sufficiently challenging so that even safe drivers might experience an accident. The primary outcome was the number of accidents on the simulation.

Simulation 2: Virtual City. To assess navigational abilities, we developed a five-by-six-block Virtual City comprising residential and commercial sections bisected by a park. The roadway included one-way streets, four-lane thoroughfares, and stop signs. There were no pedestrians or traffic. Subjects were given a map (figure 1), placed at an intersection, and instructed to find the most efficient route to a designated location (general store) while obeying all traffic signs. They could consult the map freely and generate written directions. Upon arrival at the store, they were to drive back to the starting point. Subjects unable to complete the task (n = 3) were assigned scores of 1 block greater than the highest score generated by the remainder of the cohort (thus including them in the analyses, but not giving their scores excessive weight). The primary outcome was the number of excess city blocks beyond optimal performance (12 blocks to the store and 10 blocks for the return trip, for a total of 22 blocks).

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Useful Field of View. Participants completed the Useful Field of View (UFOV),[7] a computer-based measure of Visual Processing Speed, Divided Attention, and Selective Attention that has been used with various neurologic disorders[8-10] and is associated with prior and future accidents in the elderly.[11,12] In Part I, participants identified a target stimulus (car/truck) presented from 16 to 325 milliseconds in a 1 × 1-in box located in the center of the monitor. In Part II, participants had a similar task but were to also localize a simultaneously presented stimulus (car) displayed in the periphery of the screen. Part III was identical to Part II, except that the peripheral object was embedded among distractors. The program assigns a risk level for driving-related problems, ranging from very low to very high, based on an older sample. Data were not available for two subjects (both of whom were HIV+ NP-normal and safe during the on-road drive).

On-road driving evaluation. The on-road evaluation was designed by a driving rehabilitation instructor in consultation with a field office of the California Department of Motor Vehicles and included a number of tasks from the department's Driver Performance Evaluation (road test).

The evaluation (12 mi, 35 minutes) was conducted by the instructor, who rode in the front passenger seat, and a research assistant, riding in the right rear seat. The vehicle included an accelerator and brake pedals on the passenger side for use by the instructor. Subjects drove in a parking lot, through residential and commercial districts, across intersections (regulated and unregulated), and on freeways (with lane merges). The drive included single- and multistep directions (e.g., "Make the first available right turn. At the next street, make an immediate left turn"). The primary performance criteria were the ability to perform traffic checks, maintain lane position and speed, and yield when appropriate. Driving performance was scored (0 for adequate, 1 for inadequate performance) at specific locations, yielding a possible total score of 77 points. Critical driving errors (requiring intervention by the examiner or making a dangerous maneuver) counted as 15 points. If a drive was aborted owing to safety concerns, the participant was assigned a score that was 1 point higher than the highest score of those who completed the drive. The original protocol called for the evaluators to provide independent scores. However, impaired drivers required the undivided attention of the instructor, and thus the evaluators provided a consensus score.

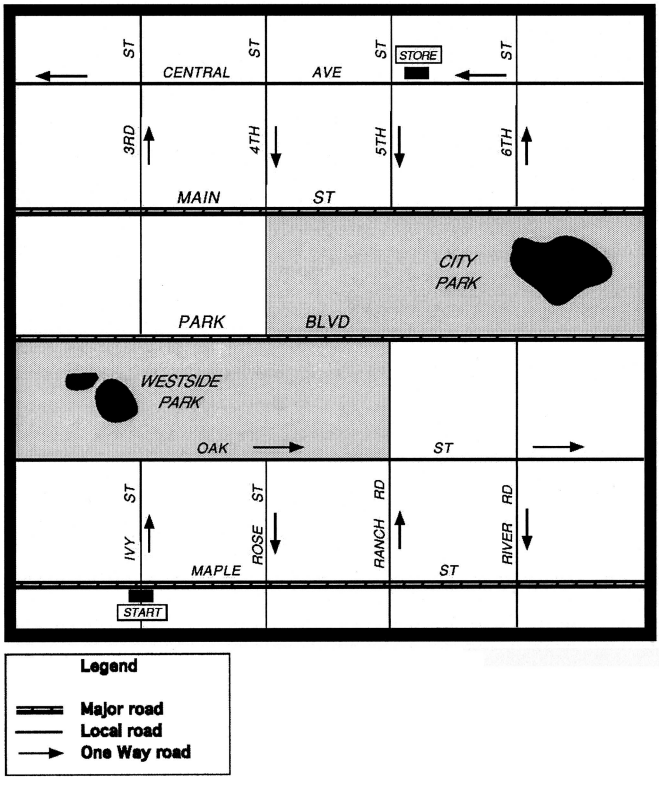

Figure 1. Map of the Virtual City.

At the conclusion of the drive, prior to discussing the drive score, the examiners independently rated subjects as to whether they were safe, marginal (some concerns, but probably does not need to be taken off the road), or unsafe (should not be driving). They then arrived at a consensus evaluation (the primary outcome). The examiners independently disagreed on three individuals, yielding an excellent[13] level of agreement ($\kappa = 0.86$). By consensus, 7 subjects were rated as unsafe, 5 were marginal, and 48 were safe. The marginal and safe groups were combined for analyses. Subjects failing the on-road drive (and significant others, if available) were counseled regarding their performance and referred to a community driving rehabilitation specialist.

Statistical analysis. Independent t-tests were used for continuous variables and χ^2 or Fisher exact tests for categorical variables. The Mann–Whitney U and the Kruskal–Wallis tests were used when dependent variables were not normally distributed. Because power for three-group comparisons was limited owing to the small sample size, we performed follow-up comparisons when omnibus tests were $p < 0.15$. As our a priori hypothesis was that HIV+ NP-impaired subjects would have greater difficulty on the driving tasks than NP-normal subjects, these analyses were per-

Table 1 *Demographic and medical characteristics of the three subject groups*

	A: HIV−, n = 20	B: HIV + NP-normal, n = 29	C: HIV + NP-impaired, n = 11	*p*
Age, y	42.5 (10.5)	42.1 (6.3)	40.4 (2.9)	0.75
Education, y	14.6 (2.9)	13.8 (2.3)	12.5 (1.4)	0.06
Gender, % male	71.4	89.7	81.8	0.25
Ethnicity, % white	52.4	75.9	45.5	0.11
CD4 cell count		308.4 (281.9)	362.1 (212.0)	0.57
AIDS, %		79.3	90.9	0.65
BDI				
Total	6.7 (7.9)	8.1 (7.4)	8.3 (5.7)	0.46
Cognitive items	4.2 (5.5)	4.6 (4.7)	4.2 (3.8)	0.77
Years driving	25.0 (9.5)	26.0 (7.1)	24.8 (4.2)	0.86
Miles driven last year	12,296 (11,798)	7,850 (5,828)	4,013 (4,362)	0.03, A > C

NP = neuropsychological; BDI = Beck Depression Inventory.

formed using a one-tailed test. A series of multiple logistic regressions were used to predict driving performance (pass vs fail). The effect of demographic factors (age, education, gender, and ethnicity), medical factors (HIV status, CD4 cell count, and AIDS/non-AIDS status), depressive symptomatology (BDI cognitive/mood items), and recent driving history (miles driven in the last year) on driving performance were tested in separate regressions. Education and miles driven in the last year, the only significant predictors of on-road failure, were entered into the model as controlling covariates, and NP and simulator predictors were entered as detailed in Results. Analyses were performed using S-Plus (Insightful, New York, NY) and JMP (SAS, Cary, NC) statistical software.

Results. NP impairment was identified in 11 of 40 HIV+ subjects (28%) and in no HIV− subjects. Based on our initial hypotheses, we classified subjects into one of three groups: HIV− (n = 20), HIV+ NP-normal (n = 29), and HIV+ NP-impaired (n = 11). There were no significant demographic differences among the three groups (table 1), although the HIV+ NP-impaired group had somewhat fewer years of education. The two HIV+ groups were well matched in terms of disease/immune status and depressive symptomatology (BDI scores). Four of the HIV+ NP-impaired participants had mild impairment, six had mild to moderate levels of impairment, and one was moderately impaired. All groups had similar years of driving experience, although the HIV+ NP-impaired group drove fewer miles in the last year.

Simulator performance. In a three-group comparison, there was a trend for group differences in the number of ARED accidents ($p = 0.12$). As shown in figure 2A, the HIV− and HIV+ NP-normal groups appeared to perform similarly, and the combined NP-normal group had fewer accidents than the HIV+ NP-impaired group (mean of 1.3 [SD = 1.0] vs 2.0 [1.6] accidents; $p = 0.03$). The three groups had different results on the Virtual City performance (see figure 2B; $p = 0.01$), with the HIV+ NP-impaired group taking a greater number of city blocks to complete the task than the other two groups. As expected, the HIV+ NP-impaired group had worse performance than the combined NP-normal groups (average of 3.2 [4.8] vs 9.2 [6.8] blocks; $p = 0.001$). The three groups were similar in the number of blocks it took to get to the store ($p = 0.75$) but differed in the number of blocks beyond the optimum (of 10) it took on the return trip ($p = 0.02$). The HIV− group (2.1 [4.6] blocks) and HIV+ NP-normal group (2.3

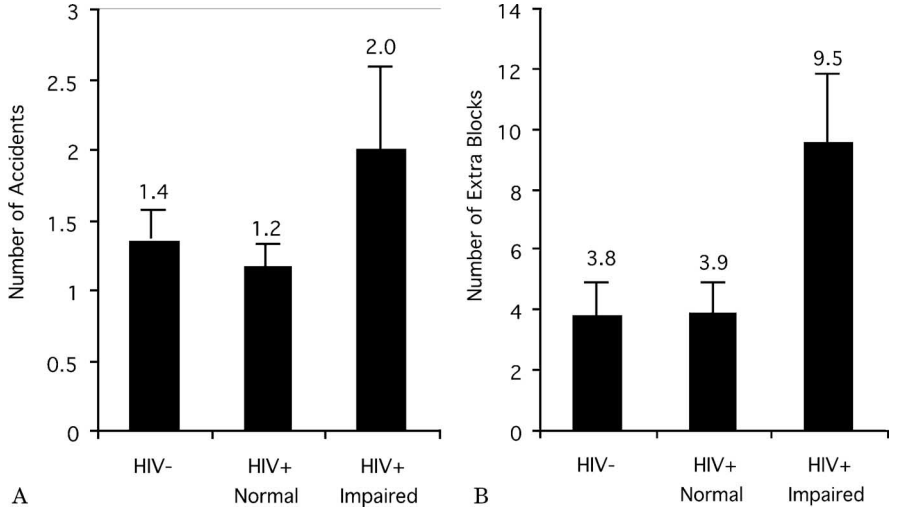

Figure 2. Comparison of group performance on number of simulator accidents (A) and number of city blocks beyond optimal performance on the Virtual City (B).

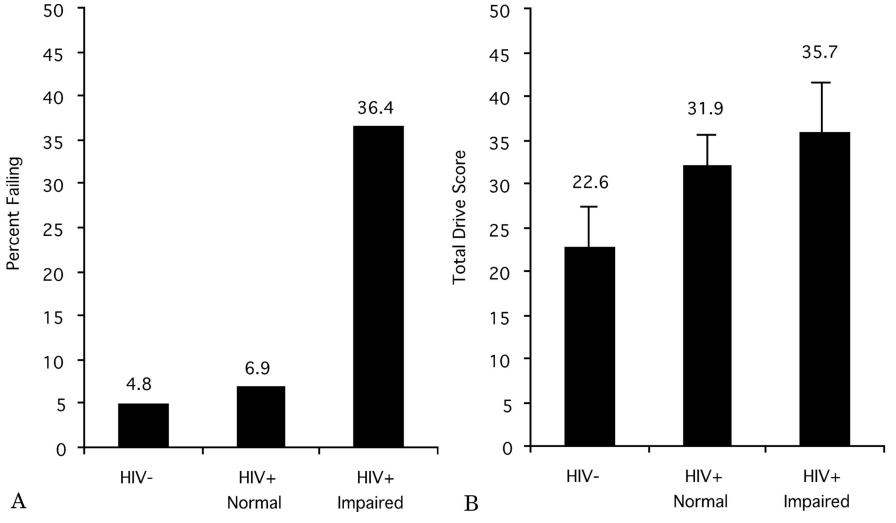

Figure 3. Comparison of group performance on percentage of subjects failing the on-road driving evaluation (A) and total on-road drive score (B).

[4.7]) again performed equivalently, whereas the HIV+ NP-impaired group (6.8 [7.1]) had the greatest difficulty. In this latter scenario, subjects drive toward themselves on the map (if the map is held with north facing away from the participant), requiring them to mentally rotate their position (i.e., a right turn would move them to the left on the map).

UFOV. The three-group comparison trended toward significance on the Visual Processing and Divided Attention tasks (both $p = 0.07$) but not on the Selective Attention test. On the Visual Processing test, the large majority of participants performed within the normal range, although the HIV+ NP-impaired group did slightly worse (median of 16; interquartile range [IQR] 16, 23) than the HIV+ NP-normal group (median 16; IQR 16, 16). On the Divided Attention task, the HIV+ NP-impaired group performed the worst (median 66; IQR 23, 166), with the HIV− (median 23; IQR 16, 33.5) and HIV + NP-normal (median 23; IQR 16, 36) performing similarly. As would be expected, when the HIV− and HIV+ NP-normal samples were combined as a cognitively normal group, the HIV+ NP-impaired group performed worse on both the Visual Processing (NP-normal median 16; IQR 16, 16; $p = 0.02$) and the Divided Attention (NP-normal median 23; IQR 16, 36; $p = 0.02$) tests. All HIV− subjects were classified as either very low (n = 18) or low (n = 2) risk, as were 90% of the HIV+ NP-normal group and 73% of the HIV+ NP-impaired group. Three participants were at low to moderate risk (all HIV+ NP-impaired). Two participants (both HIV+ NP-normal) were at very high risk.

On-road evaluation. Seven individuals were classified as unsafe drivers. As seen in figure 3A, 4 of 11 (36.4%) HIV+ NP-impaired subjects were unsafe compared with 1 of 20 (5.0%) HIV− subjects and 2 of 29 (6.9%) HIV+ NP-normal subjects ($\chi^2 = 6.3$, $p = 0.04$). Failure on the exam was due to maneuvers such as cutting off cars during lane changes and pulling out in front of pedestrians. The HIV− individual who failed the test drove recklessly, and the examiner attributed it to personality issues. Figure 3B shows that although the three-group differences were not significant ($p = 0.20$) using the Kruskal–Wallis test, HIV+ NP-impaired participants had the highest driving scores (35.7 [25.2]), and HIV− participants had the lowest score (22.6 [13.3]), with the HIV+ NP-normal group scoring in between (31.9 [18.9]).

Three of the drivers who failed the on-road evaluations lacked awareness regarding their poor performance. All of these individuals were HIV+ NP-impaired, had mild to moderate level of impairment, and were impaired in Executive Functioning and Learning.

Predictors of on-road driving performance. To determine which laboratory measures were most predictive of on-road performance, we divided the entire cohort into those who passed and those who failed the on-road drive. The groups were relatively well matched in terms of demographics, although the group that failed the on-road drive was slightly less educated and drove fewer miles within the last year (table 2).

NP measures. A significantly higher proportion of unsafe drivers than safe drivers were cognitively impaired (57.1 vs 13.2%; $p = 0.02$) (see table 2). To determine whether specific NP impairments were associated with poor driving, after including education and miles driven in the last year, we conducted a series of logistic regressions where overall binary impairment for each NP domain was the main predictor and pass/fail on the road was the outcome. In individual models, impairment in Executive Functioning ($p = 0.03$) was the only significant predictor of on-road pass/fail, although Attention/Working Memory ($p = 0.05$), Verbal Fluency ($p = 0.06$), and Learning ($p = 0.06$) trended toward significance. We therefore performed a stepwise regression including education, miles driven, and these NP domains. Executive Functioning ($p = 0.002$), Attention ($p = 0.15$), and miles driven in the last year ($p = 0.07$) entered the model, which accounted for 34% of the variance in on-road performance.

Driving simulations. Unsafe drivers had a twofold greater number of accidents on the Routine and Emergency Driving test (2.57 vs 1.26) ($p = 0.004$) (see table 2) and took a greater number of blocks to complete the Virtual City task (9.4 vs 3.6; $p = 0.01$). The two groups performed similarly on the drive toward the store ($p = 0.67$), but the unsafe group had much greater difficulty on the return drive (9.4 vs 2.2 blocks; $p = 0.005$).

UFOV. Very few participants were identified as at risk according to the UFOV (see table 2), and there were

Table 2 *Comparison of subjects who were classified as safe or unsafe on the road*

	Safe, n = 53	Unsafe, n = 7	*p*
Age, y	42.6 (7.7)	38.4 (3.5)	0.16
Education, y	14.2 (2.4)	12.1 (1.5)	0.03
Gender, % male	83	71	0.60
Ethnicity, % white	66	43	0.40
HIV+, %	64.2	85.7	0.40
AIDS (HIV+ only), %	82.4	83.3	0.95
BDI			
Total	7.2 (7.2)	11.4 (7.2)	0.14
Cognitive Items	4.2 (4.8)	6.3 (4.4)	0.18
Years driving	26.4 (7.3)	21.0 (5.9)	0.07
Miles driven in last year	9,552 (8,895)	2,953 (4,193)	0.004
% with NP impairment	13.2	57.1	0.02
ARED accidents	1.26 (.96)	2.57 (1.7)	0.004
Virtual City			
To segments	1.8 (2.6)	2.6 (5.6)	0.94
Return segments	2.2 (4.4)	9.4 (8.3)	0.005
Total segments	3.4 (6.4)	12.0 (12.0)	0.01
Useful Field of View			
% ≥ moderate risk	3.9	0.0	0.44
Visual Processing (Part I; median ms)	16	16	0.98
Divided Attention (Part II)	23	26	0.48
Selective Attention (Part III)	166	153	0.69

Fisher exact test was used when expected cell frequency was <5.

BDI = Beck Depression Inventory; NP = neuropsychological; ARED = Advanced Routine and Emergency Driving.

no significant differences between the safe and unsafe drivers on the individual subtests.

Combined behavioral measures. To examine the relationship between the on-road drive and the laboratory assessments, we constructed a model incorporating the three measures that were significantly associated with on-road performance (NP GDS, simulator accidents, and number of blocks on the return trip) as well as years of education and miles driven within the last year. This model predicted on-road pass/fail and accounted for 51.5% of the variance ($p < 0.001$) . However, education ($p = 0.30$) and miles driven ($p = 0.67$) no longer neared significance. The most parsimonious model ($p < 0.001$) included only the NP GDS ($p = 0.017$), simulator accidents ($p = 0.029$), and Virtual City return blocks ($p = 0.070$) and explained 47.6% of the variance in on-road performance.

Discussion. The current study, utilizing a multimodal method of assessing driving abilities (NP testing, driving simulations, UFOV, and on-road evaluations), suggests that a subset of individuals with HIV infection is at increased risk for impaired driving abilities. Importantly, it appears that neurocognitive dysfunction imparts the increased risk, and not the infection itself; that is, the majority of HIV-infected participants (especially those with normal NP status) demonstrated normal driving abilities.

On-road assessments are considered the reference standard for addressing driving abilities.[14] We designed a 12-mi, standardized road course that the HIV+ NP-impaired subjects failed at a higher rate than the HIV− and HIV+ NP-normal groups. The continuous drive score for the HIV+ NP-normal group fell between the other two groups, suggesting a slight decline, albeit one that does not significantly impact on-road safety. Unlike on-road tests, simulators are ideal for assessing responses to unanticipated events. HIV+ NP-impaired participants had significantly more accidents than the cognitively intact group, consistent with previous findings.[3] Taken together, these findings indicate that HIV+ NP-impaired individuals may be unsafe drivers under difficult, though not unusual, driving conditions. Both the test drive and the simulations were designed to be challenging to ensure sensitivity to important group differences, and this is likely the reason why a small fraction of cognitively normal subjects failed the on-road test and had simulator accidents.

HIV+ NP-impaired subjects also performed poorly on the navigation task (Virtual City), particularly on the return trip (which required mental rotation). Map-reading difficulties have previously been noted with diseases disrupting frontostriatal connections.[15,16] The current results are consistent with findings that egocentric spatial abilities, route finding, and mental rotation involve the basal ganglia and frontal and parietal cortices,[17,18] which are also sites of HIV pathology.[19-22]

What cognitive abilities differentiate safe and unsafe drivers? HIV+ individuals failing the on-road evaluation generally had greater than mild impairment (though short of dementia), suggesting that the most mild impairments do not result in marked driving difficulties. Our sample size precluded detailed analysis of NP profiles. Nonetheless, unsafe drivers were more often impaired in Executive Functioning, which encompasses abilities such as planning and decision making. Three of these individuals lacked awareness of their performance; thus, one should be cautious when relying on self-reported driving ability in these patients. The relationship between Executive Functioning and driving is surprisingly understudied. Focused assessment of these abilities may improve detection of impaired drivers.[23]

We found significant NP-impaired/unimpaired group differences on the UFOV subtests, consistent with reports of reduced visual attention in HIV infection.[24,25] Unlike other studies, however, the two UFOV high-risk subjects performed safely during the on-road test. The UFOV was designed for use

with older adults, and perhaps younger HIV+ individuals are able to compensate for their impaired attention, at least during a structured on-road drive.

Three primary measures used in this study (NP testing, accident avoidance simulation, navigation simulation) independently predicted on-road failure, suggesting that a multimodal assessment of driving behavior may be the most informative laboratory-based approach. Simulations may provide information on real world behaviors that are not captured by NP testing,[14] such as one's ability to perform a task requiring anticipation, perception, judgment, and action under time pressure (accident avoidance) or to compensate for impairments (e.g., by driving slowly).

This study is limited by sample size. Although we had 40 HIV+ subjects, only 11 had cognitive impairment, and it would be premature to extrapolate the findings to the larger population. In fact, not all HIV+ NP-impaired individuals failed the drive; only a subset of the more impaired individuals appeared to be at greatest risk. In addition, some individuals may self-limit their exposure to conditions such as those in our on-road evaluation (e.g., freeway driving) and thus, despite their test performance, be at less risk in the real world than it appears.

Loss of driving privileges can significantly impact quality of life, and this decision should be made only following careful assessment of driving abilities. Unfortunately, laboratory evaluations still have significant limitations in accurately classifying impaired drivers. In the meantime, clinicians may want to consider the findings reported here: that greater than mild neurocognitive impairment and, in particular, deficits in Executive Functioning may warrant an on-road evaluation. In future work, it will be important to determine whether reversal of HIV neurocognitive impairment, which can occur with highly active antiretroviral therapies, leads to improvement in previously compromised driving performance.

Appendix The San Diego HIV Neurobehavioral Research Center Group is affiliated with the University of California, San Diego, the Naval Hospital, San Diego, and the San Diego Veterans Affairs Healthcare System, and includes the following: director: Igor Grant, MD; co-directors: J. Hampton Atkinson, MD, and J. Allen McCutchan, MD; center manager: Thomas D. Marcotte, PhD; Naval Hospital San Diego: Mark R. Wallace, MD (principal investigator); Neuromedical Component: J. Allen McCutchan, MD (principal investigator), Ronald J. Ellis, MD, Scott Letendre, MD, Rachel Schrier, PhD; Neurobehavioral Component: Robert K. Heaton, PhD (principal investigator), Mariana Cherner, PhD, Julie Rippeth, PhD, Joseph Sadek, PhD, Steven Paul Woods, PsyD; Imaging Component: Terry Jernigan, PhD (principal investigator), John Hesselink, MD, Michael J. Taylor, PhD; Neuropathology Component: Eliezer Masliah, MD (principal investigator), Dianne Langford, PhD; Clinical Trials Component: J. Allen McCutchan, MD, J. Hampton Atkinson, MD, Ronald J. Ellis, MD, PhD, Scott Letendre, MD; Data Management Unit: Daniel R. Masys, MD (principal investigator), Michelle Frybarger, BA (data systems manager); Statistics Unit: Ian Abramson, PhD (principal investigator), Reena Deutsch, PhD, Deborah Lazzaretto, MA.

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