Practice Parameter update: Evaluation and management of driving risk in dementia

Report of the Quality Standards Subcommittee of the American Academy of Neurology

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ABSTRACT

Objective: To review the evidence regarding the usefulness of patient demographic characteristics, driving history, and cognitive testing in predicting driving capability among patients with dementia and to determine the efficacy of driving risk reduction strategies.

Methods: Systematic review of the literature using the American Academy of Neurology's evidence-based methods.

Recommendations: For patients with dementia, consider the following characteristics useful for identifying patients at increased risk for unsafe driving: the Clinical Dementia Rating scale (Level A), a caregiver's rating of a patient's driving ability as marginal or unsafe (Level B), a history of crashes or traffic citations (Level C), reduced driving mileage or self-reported situational avoidance (Level C), Mini-Mental State Examination scores of 24 or less (Level C), and aggressive or impulsive personality characteristics (Level C). Consider the following characteristics not useful for identifying patients at increased risk for unsafe driving: a patient's self-rating of safe driving ability (Level A) and lack of situational avoidance (Level C). There is insufficient evidence to support or refute the benefit of neuropsychological testing, after controlling for the presence and severity of dementia, or interventional strategies for drivers with dementia (Level U).

GLOSSARY

AAN = American Academy of Neurology; AD = Alzheimer disease; CDR = Clinical Dementia Rating; CI = confidence interval; MMSE = Mini-Mental State Examination; OR = odds ratio; ORDT = on-road driving test; QSS = Quality Standards Subcommittee; RR = relative risk.

Driving skills deteriorate with increasing dementia severity. While patients with mild dementia, as a group, are higher-risk drivers, more recent studies report that as many as 76% are still able to pass an on-road driving test (ORDT) and can safely drive. Faced with these facts, clinicians caring for patients with dementia seek to identify those patients with cognitive impairment who may be at higher risk for unsafe driving, without unnecessarily restricting those who are safe drivers.

Clinicians’ predictions of driving performance, when based primarily on the Mini-Mental State Examination (MMSE), result in no correlation or have a relatively low sensitivity for identifying an unsafe driver. When elements of the driving history and additional cognitive testing are considered along with MMSE scores, the predictions are more accurate, but still maintain only moderate degrees of sensitivity and specificity.

This parameter is an update of the 2000 American Academy of Neurology (AAN) practice parameter on driving and dementia. In addition, this parameter seeks to identify historical features that are associated with increased driving risk.

The parameter addresses the following clinical questions:

1. How strongly are global measures of dementia severity associated with decreased driving ability?
2. To what extent are patients and their caregivers able to assess driving ability and risk?
3. Which elements of the driving history are associated with decreased driving ability?
4. Which neuropsychological tests provide additional prognostic information?
5. Are there any interventions that reduce driving risk?

**DESCRIPTION OF THE ANALYTIC PROCESS**

**Panel formation and literature search.** The AAN invited neurologists, a neuropsychologist, an occupational therapist with content domain expertise, and neurologists with methodologic expertise to perform this review. Relevant articles published between 1970 and December 2006 were identified using the search strategy listed in appendix e-3 on the Neurology® Web site at www.neurology.org.

**Assessing the evidence.** All eligible articles were rated by one Quality Standards Subcommittee (QSS) member and one author panel member, using the 4-tiered scheme for rating a diagnostic study’s risk of bias (appendix e-4). Differences between reviewers were adjudicated by a second QSS member. Recommendations were linked to the strength of the evidence (appendix e-5).

The panel reviewed studies of patients with dementia of any cause or mild cognitive impairment. Population studies of aged drivers without an a priori diagnosis of dementia were accepted for analysis when studies limited to drivers with dementia were unavailable or inconclusive. The justification for this is based on the strong correlation between aging and dementia, and the fact that these studies frequently identified individuals with cognitive impairment without a previous diagnosis of dementia.7-10 To account for spectrum bias, such studies were downgraded by one evidence class, per QSS precedent.

Accepted outcome measures included ORDT performance, driving simulator performance, crash data, and caregiver reports. The panel considered standardized ORDTs to be the most valid measure. State-administered ORDTs are the de facto legal determinant of driving ability. Driving simulator studies can evaluate driving behavior in (simulated) dangerous circumstances, but have varying degrees of standardization and validity.11 Crash data are somewhat insensitive, because not all certifiably unsafe drivers have had a crash, and nonspecific, because not all drivers with an at-fault crash are unsafe drivers.

Cohort studies were judged to have a narrow spectrum if they excluded subjects based upon the value of a predictor variable (e.g., a study of the predictive ability of the MMSE that excluded subjects with MMSE scores less than 25). Case-control studies were judged to have a narrow spectrum if they excluded equivocal outcomes (e.g., a study of at-fault crashes that excluded crashes with indeterminate at-fault status).

**ANALYSIS OF EVIDENCE**

**Clinical Dementia Rating.** In a Class I study,3 relative risk (RR) for failing an ORDT was 82.7 (confidence interval [CI] 5.1–1333) for Clinical Dementia Rating (CDR) 0.5 (table) and 88.67 (CI 5.4–1444) for CDR 1, compared to drivers with CDR 0 (note wide CIs). However, 85% of the CDR 0.5 group and 76% of the CDR 1 group still passed the ORDT, compared to 100% of CDR 0. In a second Class I study,12 drivers with a CDR of 1 were more likely to be judged unsafe on 6-month follow-up ORDTs than drivers with a CDR of 0 (RR 2.68, CI 1.4–4.8; NS for CDR of 0.5 vs 0 and CDR 1 vs 0.5). A Class II study13 reported that drivers with a CDR of 0.5 had an RR of 9.67 (CI 2.3–40.7) for being judged unsafe in comparison to drivers with a CDR of 0; drivers with a CDR of 1 had an RR of 12 (CI 2.8–50.1). Yet 67% of the CDR 0.5 group and 41% of the CDR 1 group still passed the ORDT, vs 78% of controls. In a second Class II study,2 drivers with a CDR of 0.5 or 1 had an RR for unsafe driving of 25 (CI 1.5–384) compared to drivers with a CDR of 0; however, there was no difference in CDR between safe and unsafe drivers (p = 0.90), and 45% of drivers with a CDR of 0.5–1 passed the ORDT.

**Conclusions.** The CDR is established as useful for identifying patients at increased risk for unsafe driving (2 Class I and 2 Class II studies); however, a substantial number of patients with a CDR of 0.5–1 (41%–85%) will be found to be safe drivers by an ORDT.

**MMSE.** Studies evaluating the MMSE have reported conflicting results. In a Class II study,14 MMSE was strongly correlated with ORDT score (r = 0.63). In a second Class II study,5 64% of subjects with an MMSE of 24 or less failed an ORDT, and MMSE was significant in logistic regression modeling. In a Class III study,15 MMSE was also correlated with ORDT scores (r = 0.72, p < 0.01).

However, in a Class II study,2 MMSE score (mean = 24) was not correlated with ORDT score.
### Table Clinical Dementia Rating*

<table>
<thead>
<tr>
<th>Categories</th>
<th>Impairment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Memory (major category)</td>
<td>No memory loss or slight inconsistent forgetfulness</td>
</tr>
<tr>
<td></td>
<td>0.5</td>
</tr>
<tr>
<td>Category</td>
<td>Consistent slight forgetfulness, partial recollection of events, “benign” forgetfulness</td>
</tr>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Category</td>
<td>Moderate memory loss; more marked for recent events; deficit interferes with everyday activities</td>
</tr>
<tr>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Category</td>
<td>Severe memory loss; only highly learned material retained; new material rapidly lost</td>
</tr>
<tr>
<td>Secondary categories</td>
<td></td>
</tr>
<tr>
<td>Orientation</td>
<td>Fully oriented</td>
</tr>
<tr>
<td></td>
<td>0.5</td>
</tr>
<tr>
<td>Category</td>
<td>Fully oriented except for slight difficulty with time relationships</td>
</tr>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Category</td>
<td>Moderate difficulty with time relationships; oriented for place at examination; may have geographic disorientation elsewhere</td>
</tr>
<tr>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Category</td>
<td>Severe difficulty with time relationships; usually disoriented to time, often to place</td>
</tr>
<tr>
<td>Judgment and problem solving</td>
<td></td>
</tr>
<tr>
<td>Slight impairment in solving problems, similarities, and differences</td>
<td>Moderate difficulties in handling problems, similarities, and differences; social judgment usually maintained</td>
</tr>
<tr>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Category</td>
<td>Severely impaired in handling problems, similarities, and differences; social judgment usually impaired</td>
</tr>
<tr>
<td>Community affairs</td>
<td>Independent function at usual level in job, shopping, and volunteer and social groups</td>
</tr>
<tr>
<td></td>
<td>0.5</td>
</tr>
<tr>
<td>Category</td>
<td>Unable to function independently at these activities although may still be engaged in some; appears normal to casual inspection</td>
</tr>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Category</td>
<td>No pretense of independent function outside home; appears well enough to be taken to function outside a family home</td>
</tr>
<tr>
<td>Home and hobbies</td>
<td>Life at home, hobbies, and intellectual interests are well-maintained</td>
</tr>
<tr>
<td></td>
<td>0.5</td>
</tr>
<tr>
<td>Category</td>
<td>Mild but definite impairment in function at home, more difficult chores abandoned, more complicated hobbies and interests abandoned</td>
</tr>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Category</td>
<td>Only simple chores preserved; very restricted interests, poorly maintained</td>
</tr>
<tr>
<td>Personal care</td>
<td>Fully capable of self-care</td>
</tr>
<tr>
<td></td>
<td>Needs prompting</td>
</tr>
</tbody>
</table>

*Impairment is the decline from the subject’s usual level of functioning. Clinical Dementia Rating (CDR) – Memory score unless 3 or more of the secondary categories score above or below the Memory score, in which case the CDR – the majority of the secondary categories. For complete instructions, see Morris.41*

Three additional Class III studies reported no correlation with ORDT scores16,17 or crashes.18

**Conclusions.** An MMSE score of ≤24 is possibly useful in identifying patients at increased risk for unsafe driving (1 Class II study). Otherwise, the correlation between MMSE scores and driving performance is unclear, as data are conflicting.

**To what extent are patients and their caregivers able to assess driving ability and risk?** Patients who rate themselves as poor or fair drivers have usually either begun to restrict their driving or have stopped entirely (Class II).19 Those who continue to drive with self-imposed restrictions have a fivefold increased risk of crashes (Class III).18

In a Class I study of patients with mild Alzheimer disease (AD) (CDR 0.5 to 1),3 94% rated themselves as safe, but only 41% passed an ORDT (specificity for safe 10.7%). In another Class I study of patients with mild AD,20 all patients who failed the ORDT considered themselves to be safe drivers. A third Class I study of patients with mild AD21 also reported significant discrepancies between self-rating as safe and ORDT performance.

Caregiver ratings correlate modestly with ORDT performance. A Class I study of patients with mild AD3 reported a sensitivity of 47.8% and a specificity of 81.8% for a caregiver’s rating of marginal or unsafe, vs an experienced neurologist’s sensitivity of 60.7% and specificity of 90.9%. A second Class I study of patients with mild AD21 reported that, while there was no significant difference between informant ratings and patient performance in most categories of an ORDT, informants overrated performance in nearly every category.

**Conclusions.** A caregiver’s rating of marginal or unsafe is probably useful in identifying unsafe drivers (1 Class I study). A patient’s self-rating of safe is established as not useful for determining that the patient is safe to drive (3 Class I studies).

**Which elements of the driving history are associated with decreased driving ability? Crashes and traffic citations.** Because of the association across all age groups between crashes or citations and unsafe driving, these events are the basis for the demerit point system used by insurance and licensing agencies to quantify driving risk.22,23

**Evidence from studies of dementia.** A Class II study14 of drivers with dementia reported a correlation of −0.38 between crashes and violations (combined) and ORDT score (p < 0.0001).

**Evidence from studies of aged drivers or mixed populations (downgraded 1 evidence class).** A Class III study7 of drivers over age 65, which included people with cognitive impairment, reported a correlation between self-reported crashes in the previous 12 months and lower ORDT scores (r = 0.29, p < 0.007). A second
Class III study\textsuperscript{24} of drivers over age 60 reported a correlation between a crash in the previous 3 years and a crash in the following 3 years ($r = 0.09–0.11$, $p < 0.0001$).

A history of previous crashes portends a higher risk of future crashes than does the presence of mild dementia alone. A Class II study of drivers aged 55 through 87\textsuperscript{a} reported that the RR of a crash was higher for drivers with a crash in the previous 5 years vs no crash (RR 2.0; CI 1.06–3.79, $p = 0.03$), while a comparison of crash risk for those with and without cognitive impairment yielded no significant difference (RR 1.17; CI 0.61–2.27). A Class III study of drivers over age 65\textsuperscript{b} reported that the odds ratio (OR) for an at-fault crash in the final year of the study was higher for drivers with one or more at-fault crashes in the first 4 years of the study (OR 2.1; CI 1.5–3.0) than for drivers with mild cognitive impairment (OR 0.8; CI 0.5–1.4). Another Class III study of drivers over age 65\textsuperscript{c} reported that the OR for a future crash was higher for drivers with a crash in the previous 2 years (OR 2.0; CI 1.1–3.7) than it was for drivers with mild cognitive impairment (RR 0.6; CI 0.3–1.2).

A Class II study of drivers age 79 or older\textsuperscript{d} reported an OR for an injury crash of 2.1 (CI 1.1–4.1) in the following 2 years among drivers with a citation in the previous 2 years.

A large Class III study\textsuperscript{24} of drivers over age 60 (n = 426,408) reported a correlation between citations in the previous 3 years and in the following 3 years ($r = 0.08–0.10$, $p < 0.0001$). Another large Class III study\textsuperscript{23} of a random sample of all-aged drivers (n = 144,710) reported that, for drivers over age 60, each traffic citation in the previous 3 years resulted in an additional RR of 0.54–0.77 for a crash in the following 3 years. For drivers over age 70, 2 or more citations result in RR of a crash that exceeds that of any other age group.

Conclusions. A history of a crash in the previous 1 to 5 years or a traffic citation the previous 2 to 3 years is possibly useful in identifying patients with decreased driving ability (1 Class II and 5 Class III studies). A history of a crash is possibly more useful in identifying patients at risk for subsequent crashes than the presence of mild dementia alone (3 Class III studies).

Reduced mileage and situational avoidance. Evidence from studies of aged drivers or mixed populations (downgraded one evidence class). Class I and Class II studies\textsuperscript{9,20,25} have reported that driving mileage is significantly reduced in patients with mild dementia, due to external and self-imposed restrictions. In a Class II mixed-population study\textsuperscript{28} of people over age 55 and patients with mild AD, the mean weekly mileage of the group failing the ORDT was 64.6 (SD 51) vs 210 (SD 165) for the passing group ($r = -7.22$, $p < 0.001$). Using logistic regression, reduced mileage was the only predictor of failure on an ORDT ($\chi^2 = 12.84, p = 0.0003$). In a Class III study of drivers over age 65\textsuperscript{e} that included drivers with cognitive impairment, reduced mileage was moderately correlated with worse scores on the ORDT (standardized $\beta = 0.281$, $t = 3.185$, $p = 0.002$, $r = 0.334$).

A Class II mixed-population study of drivers over age 60 and medically referred drivers (including cognitively impaired drivers)\textsuperscript{29} found correlations between a self-report of always avoiding driving in the rain or at night and failing an ORDT ($r = 0.33–0.35$, $p \leq 0.01$). In a Class III study,\textsuperscript{18} drivers over 65 who reported changing their driving habits because of safety concerns had an RR of 5.3 (95% CI 0.63–44.65; note CI extends below 1) of a crash in the following 2 years. In a Class III study of aged drivers that included those with cognitive impairment,\textsuperscript{30} drivers referred to licensing agencies were 3 times as likely to report that they always avoided driving in the rain or at night. However, in a Class II\textsuperscript{29} and a Class III study,\textsuperscript{30} drivers who failed an ORDT or had an at-fault crash were just as likely to report never avoiding these situations as reporting always avoiding them.

Conclusions. In mixed-population studies of aged drivers and drivers with mild dementia, reduced driving mileage is possibly associated with an increased risk of poor driving performance (1 Class II, 1 Class III study). In aged drivers, self-reported avoidance is possibly useful to identify drivers at increased risk (1 Class II study). The absence of self-reported avoidance is possibly not useful for identifying safe drivers (1 Class II and 1 Class III study).

Aggressive personality characteristics. In patients with mild to moderate dementia (mean MMSE = 21.9), a Class II study\textsuperscript{31} reported that agitation and aggression were predictive of a refusal to discontinue driving (hazard ratio for driving cessation = 0.54, 95% CI 0.32–0.90). In a Class III study of all-aged drivers (downgraded one evidence class),\textsuperscript{32} deliberate violations of driving laws, across all ages, correlated with future crashes ($\beta = -0.12$, $p < 0.001$).

Conclusions. Aggressive or impulsive personality characteristics are possibly useful to identify patients with increased driving risk (1 Class II and 1 Class III study).

Which neuropsychological tests provide additional prognostic information? Given the association between global measures of cognitive impairment and driving impairment, one would expect driving impairment to be associated with impairment in individual cognitive domains. Numerous studies confirm...
PUTTING THE EVIDENCE IN A CLINICAL CONTEXT Clinicians have professional and, in some cases, legal obligations to identify conditions, such as potentially unsafe driving, that may risk their patients’ or the public’s health. Because there is no test result or historical feature that accurately quantifies driving risk, clinicians are only capable of making qualitative estimates of driving risk.

Clinicians may present patients and their caregivers with the data showing that, as a group, patients with mild dementia (CDR of 1) are at a substantially higher risk for unsafe driving and thus should strongly consider discontinuing driving. At the very least, patients and their caregivers should prepare for the eventuality of driving cessation as dementia severity increases.

However, advocates for maintaining driving privileges may cite the wide CIs for relative risk and ORDT pass rates of 41% to 76% as evidence against a categorical recommendation for patients with mild dementia to cease driving. Such advocates do not want truly capable drivers to negatively impact themselves or their caregivers by premature driving cessation.

In that case, one may look for evidence of increased risk in an individual patient—concerns from the patient or caregiver, restricted driving, crashes, tickets, and aggressive or reckless driving. Consideration of these additional issues can result in a more accurate prediction of driving performance. The questionnaires in Appendices 1 and 2 include these issues and may be useful as a starting point for obtaining pertinent information.

A clinician may wish to integrate this information into an algorithm, such as that in the figure, to obtain a qualitative estimate of driving risk. Given the current state of evidence, this algorithm should only be considered supplementary to the clinician’s judgment.

Patients at higher risk may agree to surrender privileges. For those who wish to continue driving, clinicians may consider referral for a professional or governmental driving evaluation, depending on state
reporting laws. Patients who continue to drive should be reassessed at 6-month intervals.14

Dementia specialists typically go beyond the MMSE or CDR in determining dementia severity. Neuropsychological testing offers a means of assessing memory, spatial cognition, and executive functioning that is more sensitive than the MMSE or CDR. While it seems intuitive that a more accurate determination of impairment in specific cognitive domains would result in a more accurate estimate of driving risk, there are no data at this time to support or refute this approach.

Additional medical conditions (e.g., visual defects, immobility) may also be relevant, but those issues are beyond the scope of this review.

Qualitative risk estimates, based on imperfect data, are a familiar part of clinical practice. However, clinicians may be less comfortable making such judgments in a legal context; for example, to comply with mandatory state reporting of dementia that “could” (Pennsylvania), “may” (Oregon), or “is likely to” (California) result in driving impairment.e7 When the threshold for “likely” impairment is low (e.g., CA: “inability to perform one or more functions of daily living”)e8 or unclear, some clinicians may choose to report borderline cases. In some states, doing so may leave them open to civil litigation.e7 This practice parameter cannot operationalize these types of subjective statutory requirements; it is intended for use in a clinical setting to assist in an evidence-based estimate of driving risk.

RECOMMENDATIONS FOR FUTURE RESEARCH
Future studies may wish to evaluate the appropriate weighting of risk factors using, for example, discriminant function analysis14,e9 to develop a composite method of rating risk in patients with mild dementia.

It is recommended that future studies of individual cognitive domains (e.g., attention, executive function) 1) emphasize simple bedside tests (e.g., Trail Making Test), 2) control for both the presence and severity of dementia to identify independent pre-
dictors of unsafe driving, 3) report results in terms of relative risk based on the presence of a risk factor or cutoff score, rather than in terms of correlation coefficients,10 and 4) report using STARD-D criteria.

Rules for determining when to revoke driving privileges are ultimately made by society through the legislative process. By accurately quantifying risk with well-designed prospective studies using validated outcome measures, researchers can ensure that legislators are provided with the best science with which to inform their decisions.

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DISCLOSURE
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DISCLAIMER
This statement is provided as an educational service of the American Academy of Neurology. It is based on an assessment of current scientific and clinical information. It is not intended to include all possible proper methods of care for a particular neurologic problem or all legitimate criteria for choosing to use a specific procedure. Neither is it intended to exclude any reasonable alternative methodologies. The AAN recognizes that specific patient care decisions are the prerogative of the patient and the physician caring for the patient, based on all of the circumstances involved. The clinical context section is made available in order to place the evidence-based guideline(s) into perspective with current practice habits and challenges. No formal practice recommendations should be inferred.

CONFLICT OF INTEREST
The American Academy of Neurology is committed to producing independent, critical and truthful clinical practice guidelines (CPGs). Significant efforts are made to minimize the potential for conflicts of interests to influence the recommendation of this CPG. To the extent possible, the AAN keeps separate those who have a financial stake in the success or failure of the products appraised in the CPGs and the developers of the guidelines. Conflict of interest forms were obtained from all authors and reviewed by an oversight committee prior to project initiation. AAN limits the participation of authors with substantial conflicts of interest. The AAN forbids commercial participation in, or funding of, guideline projects. Drafts of the guidelines have been reviewed by at least three AAN committees, a network of neurologists, Neurology® peer reviewers, and representatives from related fields. The AAN Guideline Author Conflict of Interest Policy can be viewed at www.aan.com.

APPENDIX 1: PATIENT QUESTIONNAIRE
This questionnaire addresses historical features with Level A, Level B, or Level C evidence of relevance to driving competency, as well as selected items from the Manchester Driver Behavior Questionnaire. It is only intended to be used in the qualitative determination of driving risk in elderly patients and patients with dementia, and has not been validated for use in the quantitative determination of driving risk.

1. How many times have you been stopped or ticketed for a traffic violation in the last three years? (0, 1, 2, 3, 4 or more)
2. How many accidents have you been in, or caused, within the last three years? (0, 1, 2, 3, 4 or more)
3. In how many accidents were you at fault in the last three years? (0, 1, 2, 3, 4 or more)
4. I have concerns about my ability to drive safely.
5. Others have concerns about my ability to drive safely.
6. I avoided driving in the rain.
7. I avoided driving in busy traffic.
8. I will run a red light if I think that I won’t be caught.
9. I will drive faster than the speed limit if I think that I won’t be caught.
10. I will drive after drinking more alcohol than I should.

Use this scale to answer the following questions: 1 = strongly disagree; 2 = disagree; 3 = no opinion; 4 = agree; 5 = strongly agree.

APPENDIX 2: FAMILY OR CAREGIVER QUESTIONNAIRE
1. How many times has the patient been stopped or ticketed for a traffic violation in the last three years? (0, 1, 2, 3, 4 or more)
2. How many accidents has the patient been in, or caused, within the last three years? (0, 1, 2, 3, 4 or more)
3. In how many accidents was the patient at fault in the last three years? (0, 1, 2, 3, 4 or more)
4. I have concerns about the patient’s ability to drive safely.
5. Others have concerns about the patient’s ability to drive safely.
6. The patient has limited the amount of driving that he/she does.
7. He/she avoids driving at night.
8. He/she avoids driving in the rain.
9. He/she avoids driving in busy traffic.
10. He/she avoids driving after drinking more alcohol than he/she should.

Use this scale to answer the following questions: 1 = strongly disagree; 2 = disagree; 3 = no opinion; 4 = agree; 5 = strongly agree.
How many miles a week does the patient drive?

Note: The treating physician must comply with the relevant rules implementing HIPAA, such as 45 C.F.R. § 164.502(g), before disclosing a patient’s protected health information to family members or caregivers.

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