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GERIATRIC DISORDERS (W MCDONALD, SECTION EDITOR)

An International Approach to Enhancing a National Guideline on Driving and Dementia

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Abstract

Purpose of Review The purpose of this study was to update a national guideline on assessing drivers with dementia, addressing limitations of previous versions which included a lack of developmental rigor and stakeholder involvement.
Methods An international multidisciplinary team reviewed 104 different recommendations from 12 previous guidelines on assessing drivers with dementia in light of a recent review of the literature. Revised guideline recommendations were drafted by consensus. A preliminary draft was sent to specialist physician and occupational therapy groups for feedback, using an a priori definition of 90% agreement as consensus.
Recent Findings The research team drafted 23 guideline recommendations, and responses were received from 145 stakeholders. No recommendation was endorsed by less than 80% of respondents, and 14 (61%) of the recommendations were endorsed by more than 90%.The recommendations are presented in the manuscript.
Summary The revised guideline incorporates the perspectives of consensus of an expert group as well as front-line clinicians who regularly assess drivers with dementia. The majority of the recommendations were based on evidence at the level of expert opinion, revealing gaps in the evidence and future directions for research.

Keywords Dementia · Driving · Clinical practice guidelines · Knowledge translation

Introduction

While national-level clinical practice guidelines for physician assessments of fitness-to-drive for patients with a wide array of medical illnesses have been developed around the world, important limitations have been identified in the rigor of their development and in stakeholder involvement [1•, 2]. The Canadian Medical Association (CMA)'s Driver's Guide: Determining Medical Fitness to Operate Motor Vehicles [3] is the primary tool used by physicians across Canada to guide decision making about assessing the impact of medical conditions on driving abilities, advising patients of the risks, and

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reporting patients to transportation authorities. The CMA Driver's Guide also influences the content of national and provincial transportation policies pertaining to medical standards for drivers. The first edition of this Guide was published in 1974, and updates are provided every few years. Although the most recent publication of the CMA Guide is the 9th Edition in 2017, the present edition represented a minor opinion-based update of the 7th and 8th editions by two of our authors (F.M., M.J.R).

The term "dementia" encompasses a group of diseases (i.e., various types of dementia) that may have different effects on the functional skills required for safe driving [4]. In DSM-5, dementia was renamed major neurocognitive disorder [5]. It is known that patients with Alzheimer's dementia show an inevitable decline in cognition, with an eventual decline in driving abilities over time [6]. While to date no longitudinal studies of declines in driving ability have been conducted for other forms of dementia, certain characteristics of these dementias likely have implications for fitness to drive. For example, vascular dementia can present with abrupt periods of worsening or stepwise declines in cognition associated with accumulation of cerebrovascular lesions [7]. Parkinson's disease dementia and Lewy body dementia are often associated with motor and visuospatial dysfunction, as well as fluctuations in alertness and cognition that are inherently unpredictable and can be hazardous on the road [8•, 9•]. Furthermore, some frontotemporal dementias are associated with early executive dysfunction and behavioral changes (e.g., disinhibition, impulsivity, anger control issues) that may render driving hazardous [10•]. Insight may also be impaired in any of these illnesses, based on anatomical involvement, and thus patients' own assessment of their driving ability may be unreliable [11]. Finally, all people with dementia are more prone to delirium, an acute change in mental status with unpredictable and sudden confusion [12]. Ultimately, then, progression to unsafe driving status is difficult to anticipate for patients with dementia.

We have previously conducted a systematic review of the literature from 2005 to 2015 pertaining to the risk of motor vehicle collisions and driving impairment associated with dementia [13••]. Briefly, in that work, we found two conflicting studies on motor vehicle collision (MVC) risk. One of these studies showed a 4-fold increase in MVCs among participants with dementia compared to healthy controls in a retrospective analysis but not in their prospective analysis [14]. The other study showed no statistically significant difference between those with and without dementia on retrospectively ascertained MVCs [15]. Among the seven recent studies that examined driving impairment, six revealed medium to large negative effects of dementia on driving performance (e.g., lane observance, speed control, turning). Importantly, we found that drivers with dementia had a 10-fold increased risk of failing a performance-based on-road assessment compared to healthy controls (RR 10.77, 95% CI 3.00–38.62, $z = 3.65$, $p < 0.001$). Therefore, we concluded that older adults with even very mild or mild stages of dementia are substantially more likely to exhibit impaired on-road driving performance and fail on-road tests, but the risk of actual crashes remained undetermined.

Although motor vehicle collisions are predicted by the World Health Organization to become the 3rd leading cause of disability-adjusted life years lost by 2020 [16], physicians are wary of advising their patients to stop driving because of potentially negative impacts on autonomy, health outcomes, quality of life, and the doctor-patient relationship [17–21]. This has led to under-reporting of patients with medical conditions that may impair driving to transportation authorities [20, 22], despite a demonstrated increased risk of collision [20, 22] that may be reduced by physician reporting [23]. A well-executed knowledge synthesis may increase confidence of clinicians using the guidelines [24], inform transportation policy, and provide a model for updating other international guidelines for medical illness and driving. In 2014, the Canadian Medical Association Journal published the Guidelines International Framework [25••] that outlines a systematic process of developing guidelines in a rigorous manner and involving stakeholders in the process. Our group sought to use this framework to update the CMA Driver's Guide on the topic of dementia.

Methods

We followed the 2014 CMAJ Guidelines International Framework [25••] and the"ADAPTE" process for updating clinical practice guidelines [26]. The ADAPTE collaboration was "an international collaboration of researchers, guideline developers, and guideline implements who aimed to promote the development and use of clinical practice guidelines though the adaptation of existing guidelines." [27].

Our team of authors includes researchers from Canada, Australia, Belgium, Ireland, England, and the USA, and representatives of geriatric psychiatry, geriatric medicine, neurology, family practice, occupational therapy, rehabilitation science, psychology, and pharmacology, as well as Canadian transportation administrators.

In April of 2016, the team met in Toronto, Canada, to complete the literature review [13••], and to review the existing clinical practice guideline recommendations on driving with dementia. Conflicts of interest were declared and authors were not allowed to make decisions pertaining to article inclusion, data extraction, or guideline recommendations for content areas on which they had contributed evidence. We reviewed 104 recommendations from 11 different national-level guidelines [3, 28–37]. We drafted a preliminary set of guidelines based on the review of the literature, the existing

guidelines that were retrieved, and the clinical experience of the team. Each recommendation was assessed for level of evidence using the New Zealand Guideline Group Grading of Recommendations [38]. At the meeting, we voted on whether each recommendation (i.e., course of action) was supported by good evidence (Class A), fair evidence (Class B), expert opinion only (Class C).

The preliminary draft recommendations were further refined by two of the investigators (MJR and DC), and were then sent out for voting by the full team of investigators in July 2016. After an iterative process of electronic debate and discussion for those with less than 100% consensus, unanimous agreement was achieved for 23 guideline recommendations. For stakeholders, we focused on Geriatric Medicine, Geriatric Psychiatry, Neurology, Family Medicine, and Occupational Therapy. From November 2016 to March 2017, the revised guidelines were sent in an electronic survey to members of the Canadian Geriatrics Society (CGS), Canadian Academy of Geriatric Psychiatry (CAGP), and Canadian Association of Occupational Therapists (CAOT), the Canadian Neurological Sciences Federation (CNSF), and the Women's College Family Practice (WCFP) for voting. We set an a priori definition of consensus as 90% agreement with the guideline recommendations.

Results

The research team generated 23 guideline recommendations with consensus (Table 1). We received 145 responses from stakeholders, which included 51 from CGS members, 51 from CAGP members, 25 from CAOT members, 1 from a CNSF member, 1 from a member of the WCFP, and 16 from other sources (e.g., colleague invitations). These responses included a total of 17 family physicians, 49 geriatricians, 35 geriatric psychiatrists, 8 general psychiatrists, 4 internal medicine specialists, 1 emergency medicine physician, and 31 occupational therapists.

Responses from an additional 33 individuals were excluded because they consisted of missing data (e.g., all blank responses) or duplicate entries; or they were completed by professionals who either chose to withhold their area of practice ($n = 6$) or specialized in areas outside the scope of this analysis (i.e., residents, nurses, therapists, social workers, transportation stakeholders ($n = 15$)).

Of the 23 recommendations, more than 90% of respondents agreed with 14 (61%), and the remaining nine (39%) were endorsed by more than 80% but less than 90% of respondents.

In Table 1, we present the revised guideline recommendations for driving with dementia, along with the level of evidence and the percent of endorsement by the group. Recommendations with 80 to 89% endorsement, i.e., those falling below our a priori definition of consensus, include a summary of the comments of the respondents. Narrative comments from the research team follow some of the guideline recommendations as well for areas where the research team felt additional information was warranted, not necessarily based on the percentage of endorsement of the stakeholders.

Discussion

The development of these new guideline recommendations involved a much more rigorous process than prior editions of the CMA Driver's Guide, which were rated poorly with respect to rigor of development and stakeholder involvement [1•]. Based on work on other clinical guidelines, we anticipated that enhancing the quality of the CMA guideline on driving with dementia may ultimately have a positive impact on patient outcomes [39], be more likely to be used in clinical practice [40], and increase the confidence of clinicians using the guidelines [41]. Rather than expert opinion of one or two authors (FM and MR authored the last 3 editions), we used a rigorous process of reviewing the literature, expert consensus, and stakeholder engagement for feedback. The stakeholders include multidisciplinary health care professionals who are involved with the clinical management of patients with dementia. Incorporating the perspectives of these professionals into the process of updating clinical guidelines on driving can [1] supplement the limited research by providing valuable opinion not available in the published literature [42](2) help to resolve conflicts over competing principles during the revision of specific recommendations from a multi-faceted approach [43, 44], and [3] enhance ownership of the recommendations and help to foster acceptance among clinicians [26, 43].

It is notable that only 8 of the 23 guideline statements were thought to have fair or good evidence to support them, while the remainder were still at the level of expert opinion. This gap in evidence is shared by many other areas of medical fitness to drive, such as various psychiatric conditions [45] and reflects the professional neglect of the healthcare professions of the importance of transport, and in particular the private automobile, to health and social inclusion. One barrier to enhancing understanding of these matters is that the effects of illnesses on driving crosses many different professional domains, and is not seen to specifically fall within any particular academic or clinical specialty. This problem is in turn is matched by a lack of education in traffic medicine at undergraduate [46], graduate, and postgraduate levels of medicine [47]. This paper may help promote a stronger evidence base for guidance on medical fitness to drive, one which is belatedly being recognized by funding bodies through the funding of studies that link databases of health records with police and crash data [48]. A particularly important focus for future research will be to gain a sense of the relative impact of combinations of co-

Table 1 The proposed new evidence-informed recommendations on Driving with Dementia for consideration for the Canadian Medical Association Driver's Guide as well as other national guidelines

#	Recommendation	Class of Evidence	Agreement (N^a, %)
1	Dementia often has a direct effect upon fitness to drive, and clinicians should address cognitive compromises that may impact fitness to drive.	C	140, 96.6%
2	Diagnosis of dementia alone is not sufficient to withdraw driving privileges.	A	136, 93.8%
3	Severe dementia is an absolute contraindication to driving.	C	140, 96.6%
4	It is unlikely that safe driving can be maintained in the presence of moderate dementia (e.g. the additional presence of basic ADL impairments) and is to be strongly discouraged. If the patient desires to drive, they should be formally assessed and monitored very carefully. *Narrative Comments on Recommendation #4 from the Research Team:* *Only one study to date (Berndt et al.)[50] to our knowledge where patients with moderate dementia (as measured by CDR 2) were tested on the road, and in that study 18/19 failed the road test. While our experts recognize that a CDR of 2 is generally inconsistent with safe driving, clinicians do not often use the CDR, it is mainly a research-based tool. The group recognizes that some patients with dementia who score in the "moderate range" on a global cognitive test may be safe to drive, but there are no evidence-based cut-offs on these tests that point toward safe or unsafe driving. Hence, although drivers with moderate dementia as labelled by a global cognitive screen may be successful in a road test, close monitoring for any degradation in cognitive status is essential.*	B	134, 92.4%
5a	People with dementia with progressive loss of two or more IADLs due to cognition (but no basic ADL loss) are at higher risk of driving impairment.	A	138, 95.2%
	5b A formal assessment and ongoing monitoring of fitness to drive is recommended in this situation if the patient wishes to continue driving.	B	136, 93.8%
6a	No in-office test or battery of tests including global cognitive screens (e.g. MMSE, MOCA) have sufficient sensitivity or specificity to be used as a sole determinant of driving ability *in all cases*.	A	141, 97.2%
	6b. However, abnormalities on these tests may indicate a driver at risk who is in need of further assessment.	B	139, 95.9%
	6c. Substantially impaired scores which are typically associated with moderate to severe dementia may preclude safe driving. • *Additional commentary from stakeholders on recommendation 6c focused around the difficulty establishing cut-offs and the need to review the cognitive test scores in light of the full clinical picture (including history, ADL, IADL impairment, insight, and factors like aphasia, low education, non-fluency with English that may lead to artificially low scores on such tests).*	C	122, 84.1%
	6d. If concerns or uncertainty still exists, a specialist opinion should be sought. • *Additional commentary from stakeholders on recommendation 6d focused around lack of clarity on which type of specialist, the value of a road test over a specialist opinion, and problems with accessibility of specialist care.* *Narrative Comments on Recommendations #4, 5 and 6 from the Research Team:* *Some, but not all, members of the group suggest that in the circumstance of patients with moderate dementia or with loss of IADLs, that physicians mandate holding off on driving until reassessment can occur, and to err on the side of public safety.*	C	118, 81.4%
7	Patients with dementia who are deemed fit to continue driving should be re-evaluated every 6 to 12 months or sooner, if indicated. *Narrative Comments on Recommendations 7 from the Research Team:* *Our group emphasized that there are limitations to the evidence about the frequency of re-testing. Furthermore, there are some practical concerns: 1) some patients may deteriorate sooner than 6 months; 2) some patients and family members may be unreliable about seeking clinical attention if deterioration should occur, and this may include cancelling or not appearing for scheduled follow-up. The group therefore advises that clinicians be cognizant of these factors, and attend to issues of compliance with*	B	135, 93.1%

	recommendations.		
8a	Any clinician who has concerns but is uncertain whether a patient's cognitive problems may adversely affect driving, should refer the patient for a functional driving assessment, either through an occupational therapy evaluation or directly to the licensing authority. *Narrative Comment from the Research Team Regarding Recommendation #8a:* *Our group emphasized that there is regional variability in what happens when a "functional driving assessment" is requested, and different standards may be applied, and suggest strongly that this include an on-road evaluation.* • *Additional commentary from stakeholders on recommendation 8a focused around the cost and lack of accessibility of driving assessments, regional variations in related legislation, procedures or policies, as well as the differential value of driving assessments done by occupational therapists or the licensing authority.*	C	124, 85.5%
	8b. If there are clear aspects of the history, physical examination and cognitive examination that place the patient and public at high risk for crash or impairment, the patient and informant/caregiver should be advised not to drive, and this conversation (including date and participants) should be documented in the clinical record. *Narrative Comment from the Research Team Regarding Recommendation #8b:* *It is important when this occurs that all efforts be made to share the recommendations with family members or caregivers even if they do not attend the medical appointment.*	C	140, 96.6%
	8c. Clinicians should be aware of the legal reporting requirements in their jurisdiction, mindful of their professional ethical imperatives, and strive to ensure that mechanisms to remove unsafe drivers from the road are sensitive, timely and effective. • *Additional commentary from stakeholders on recommendation 8c focused around the fact that clinicians have little ability to address challenges in the mechanisms pertaining to removal of medically unsafe drivers.*	C	124, 85.5%
9a	Caregivers are able to predict driving safety more accurately than can the patients themselves, although in some circumstances, the caregivers may have a vested interest in preserving the patient's autonomy beyond a safe window... • *Additional commentary from stakeholders on recommendation 9a focused around the fact that caregivers may report on driving safety and inform the assessment of driving safety, but are not typically expected to predict safety. Some participants also commented that caregivers may alternately have a vested interest in earlier cessation rather than preserving the autonomy.*	C	119, 82.1%
	9b ...Hence, caregiver concern about driving impairment should be taken seriously…	B	140, 96.6%
	9c...and the possibility of a conflict of interest in preserving driving autonomy must be taken into consideration if such caregiver concern is absent.	C	134, 92.4%
10	Medical comorbidities, physical frailty and the use of multiple medications are also factors that must be taken into consideration when assessing fitness to drive.	C	135, 93.1%
11	We recommend a formal evaluation if behavioural disturbances (e.g. agitation, personality change, psychosis) are concerning for interfering with safe driving. • *Additional commentary from stakeholders on recommendation 11 focused around the fact that in some cases, behavioural disturbances may be so severe that immediate cessation will be warranted, whereas in other cases, the impact may be less certain. Some also commented on the lack of clarity of what this formal evaluation would entail.*	C	124, 85.5%
12	Patients with prominent language impairment, e.g. primary progressive aphasia or other aphasia in the context of dementia, cannot be adequately screened with typical language-based tests and require a specialized assessment possibly from a speech therapist or neuropsychologist, functional assessment (IADL's, ADL's) and/or a formal driving assessment. *Narrative Comment from the Research Team Regarding Recommendation #12:* *Such patients may also have problems with road signs.* • *Additional commentary from stakeholders on recommendation 12 surrounds disagreement as to whether a neuropsychological or functional assessment would be suitable in the absence of a formal driving assessment, as well as concerns about the cost and accessibility of the recommended assessments.*	C	122, 84.1%
13	As with many disabling progressive diseases that lead to driving cessation, conversation	C	129, 89.0%

	regarding eventual retirement from driving should be held as early as possible. *Narrative Comment from the Research Team Regarding Recommendation #13:* *The issue of driving adds yet another layer of emotional complexity when patients and their families/ caregivers are still experiencing challenges emotionally processing the dementia diagnosis itself[51].* • *Additional commentary from stakeholders on recommendation 13 focuses on the potential impact of such discussions on the doctor-patient relationship, as well as practical and emotional challenges of timing of this discussion.*		
14a	Driving cessation has been associated with social isolation, depression and other adverse health outcomes.	C	131, 90.3%
	14b Therefore, after a person with dementia has stopped driving, it is important to monitor for these problems longitudinally. • *Additional commentary from stakeholders on recommendation 14b surrounds lack of clarity as to who would monitor for these problems, and a lack of resources to monitor for them and address such concerns as they arise.* *Additional Narrative Comment from the Research Team About Dementia and Driving:* *Recent crashes and voluntary self- restriction of driving to less complex situations are also considerations that should raise concern that a patient with dementia may be no longer safe to drive. Having said that, depending on circumstance, it may be an appropriate adaptive behavior and one to be encouraged as reflecting insight/judgment,*	C	127, 87.6%

[a] *N* is the number of respondents who agreed with the recommendation out of the total number of respondents (N_{total} = 145).

Note: recommendations with < 90% agreement are shaded, and additional comments from the research team and stakeholders are presented

morbidity, as exemplified by the additive effect of co-existing vision and hearing impairment [49].

The rigorous approach we used should be used to inform other national efforts in different countries, with international collaboration. Other national dementia and driving guideline development groups can use these findings to enhance the evidence base upon which their own guidelines are built. This will lend all guidelines greater validity and credibility to the developed guideline. This project has already fostered international collaborations, for example with researchers and clinicians in the UK who are developing similar Guidelines through a Delphi process. By working from a common internationally derived evidence-based foundation, it is hoped that the various national guidelines will share many common elements while still retaining the ability to adapt to unique local circumstances. There are many benefits to such an approach. First, this research produces guideline revisions that are not jurisdiction-specific, as they are based on the international scientific evidence. Secondly, it entails the establishment of a multinational collaboration of researchers and clinicians (e.g., the USA, Canada, Ireland, Belgium, and the UK), which functions to (a) incorporate a wide range of perspectives into the newly-revised recommendations and (b) facilitate the dissemination and adoption of the updated recommendations into clinical practice and public policy, utilizing the existing networks of the research team within each of the nations involved in the guideline revision process.

It is worth noting some limitations to this work. First, the guideline development process is limited by the quality of the evidence reviewed. Guidelines include not only evidence-informed recommendations but, given the weak or lacking evidence in some areas, also include authors' guidance based on clinical practice, a form of evidence albeit less rigorous and more prone to bias. Second, our process was also limited by a lack of broader input of family physicians, and the input of those most affected by the guidelines, i.e., drivers with mild dementia and their caregivers, and we did not seek input from representatives of driving authorities, and organizations such as the Alzheimer Society. The time frame of the study did not permit us to get permission to send the survey to the national organization of Family Physicians, and we relied on a small convenience sample of local family physicians only. Third, lower levels of agreement are not necessarily indicative of the lower levels of evidence. In fact, low agreement may pertain to practical concerns about how the recommendations would be implemented or concerns with impact on the relationship between the clinicians and their patients.

As further evidence emerges, the most effective manner to incorporate the new evidence into guidelines in a timely manner would be via the development of a standing working group that continuously updates the evidence informing driving guidelines. Unfortunately, most countries cannot afford to fund such groups especially when all other medical conditions are considered. The present study, funded by a research

granting agency for a limited period of time, illustrates that point. A funded international consortium of researchers and guideline developers to continuously update the evidence for driving guidelines would have international benefits, including harmonizing an approach to these problems, despite different legislative structures.

Conclusion

The proposed guidelines listed in this paper are not meant to be prescriptive. Rather, they serve as a list of evidence-based elements that dementia and driving guideline developers should consider for inclusion in their national guidelines. This research represents the next step in the evolution of evidence-based guidelines. The adoption of a rigorous scientific approach to guideline development will enhance the credibility of future national guidelines on fitness to drive among patients with various medical conditions.

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Compliance with Ethical Standards

Conflict of Interest Several of the authors have publications on the topic that were included as part of the review. To mitigate the associated risk, the authors were not involved in the screening or data extraction of their own publications (MJR, DBC, SC, NH, JD, JC, SM, JPT). Several co-authors disclosed research grants/funding for their work (MJR, DBC, SC, NH, JD, JC, KL, SM, FM). Potential COIs were declared by MJR (Canadian Academy of Geriatric Psychiatry (CAGP) board president; consultancy at the Canadian Medical Association(CMA)), DBC (board membership for Memory Care Home Solutions, Dementia Organization, and the Advocacy Committee for the Alzheimer's Association; consultancies at ADEPT, MEDSCAPE, Traffic Injury Research Foundation, and AAA Foundation for Traffic Safety; legal cases on medical conditions and driving), SC (honoraria from National Institutes of Health (NIH) and Canadian Association of Occupational Therapy (CAOT)), NH (research support from Lundbeck and Roche; consultancies at AbbVie, Astellas, and Merck; honouraria from Pfizer, Lundbeck, and Novartis), JC (board membership for BrainLink; consultancies at the Royal College of Physicians of Ireland, and National Transportation Commission), SM (consultancies at the CMA, the Ministry of Transportation of Ontario (MTO), and from physicians; expert testimony on TBI; honouraria for peer-reviewed speaking activities), FM (consultancy at the CMA).

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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