

Appendix 2: Recommendations for the management of mild to moderate dementia, dementia with a cerebrovascular component, and for addressing ethical issues in dementia (page 1 of 7)

Mild to moderate dementia

1. Most patients with dementia can be assessed and managed adequately by their primary care physicians. However, in order to assist them in meeting the needs of patients and their caregivers, it is recommended that:
 - a. all patients with dementia and their families who consent be referred to the local chapter of the Alzheimer Society (e.g., *First Link* program where available); and,
 - b. primary care physicians should be aware of the resources available for the care of those with dementia in their community (e.g., support groups, adult day programs) and to make appropriate referrals to them [grade B recommendation, level 3 evidence].
2. The referral/consultation process is essential to the delivery of high-quality health care. In the care of a patient with mild to moderate dementia, reasons to consider referral to a geriatrician, geriatric psychiatrist, neurologist or other health care professional (e.g., neuropsychologist, nurse, nurse practitioner, occupational therapist, physical therapist, psychologist, social worker, other) with the appropriate knowledge and expertise in dementia care would include:
 - a. Continuing uncertainty about the diagnosis after initial assessment and follow-up;
 - b. Request by the patient or the family for another opinion;
 - c. Presence of significant depression, especially if there is no response to treatment;
 - d. Treatment problems or failure with specific medications for Alzheimer disease;
 - e. Need for additional help in patient management (e.g., behavioural problems, functional impairments) or caregiver support;
 - f. Genetic counselling when indicated; and,
 - g. If the patient or family, or both, express interest in either diagnostic or therapeutic research studies that are being carried out by the recipient of the consult request [grade B recommendation, level 3 evidence].
3. The care and management of patients with dementia from specific cultural groups should take into account the risk of isolation, the importance of culturally appropriate services and issues that arise in providing caregiver support [grade B recommendation, level 3 evidence].
4. Recommendations with regards to the general medical care of a patient with a mild to moderate dementia
 - a. Patients with mild to moderate dementia, when admitted to hospital, should be identified as being at increased risk for delirium. They should be offered multicomponent interventions, including orienting communication, therapeutic activities, sleep-enhancement strategies, exercise and mobilization, provision of vision and hearing aids and oral repletion of dehydration to decrease their risk of delirium [grade B recommendation, level 2 evidence].
 - b. Comorbidities of patients with mild to moderate Alzheimer disease should be appropriately managed [grade B recommendation, level 3 evidence].
 - c. The management of other chronic medical conditions may have to be modified in the setting of a dementia. In general, there should be less reliance on patient self-care and a concomitant increase in the role played by caregivers [grade B recommendation, level 3 evidence].
5. Recommendations about the use of medications in the setting of a mild to moderate dementia
 - a. Determination of how medications are being consumed and identification of any problems or concerns with medication management, including poor adherence, should be done for all patients with mild to moderate dementia. If problems are detected, in particular with adherence, the use of compliance aids or the assumption of medication management by another party will be necessary. The effectiveness of any alterations in medication management will have to be assessed [grade B recommendation, level 3 evidence].
 - b. Even when the patient is safely self-managing their medications, there should be planning for the involvement of a third party in the management of medications for all patients with a progressive dementia, since this will eventually become necessary for nearly all patients [grade B recommendation, level 3 evidence].
 - c. The use of medications with anticholinergic effects should be minimized in people with Alzheimer disease [grade D recommendation, level 3 evidence].
6. Ethico-legal recommendations
 - a. Although each case should be considered individually, in general the diagnosis of dementia should be disclosed to the patient and family. This process should include a discussion of prognosis, diagnostic uncertainty, advance planning, driving issues, treatment options, support groups and future plans [grade B recommendation, level 3 evidence].
 - b. Primary care physicians should be aware of the pertinent laws in their jurisdiction about informed consent, the assessment of capacity, the identification of a surrogate decision-maker and the responsibilities of physicians in these matters [grade B recommendation, level 3 evidence].

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- c. While patients with Alzheimer disease retain capacity, they should be encouraged to update their will and to enact both an advance directive and an enduring power of attorney [grade B recommendation, level 3 evidence].
7. Recommendations for nonpharmacologic interventions for the management of the cognitive and functional limitations arising from mild to moderate Alzheimer disease
 - a. There is insufficient research evidence to come to any firm conclusions about the effectiveness of cognitive training/cognitive rehabilitation in improving and/or maintaining cognitive and/or functional performance in people with mild to moderate dementia [grade C recommendation, level 1 evidence].
 - b. Further research is required to be able to conclude that cognitive training/cognitive rehabilitation is effective in improving cognitive and/or functional performance in persons with mild to moderate dementia [grade B recommendation, level 2 evidence].
 - c. Although there is some indication of a beneficial impact on IADL and ADL, there is insufficient evidence to make firm conclusions about the effectiveness of environmental interventions in promoting functional performance in persons with mild to moderate dementia [grade C recommendation, level 1 evidence].
 - d. There is good evidence to indicate that individualized exercise programs have an impact on functional performance in persons with mild to moderate dementia [grade A recommendation, level 1 evidence].
 - e. For other non-pharmacological therapeutic interventions, there is insufficient evidence to allow any conclusions being made about their efficacy in improving or maintaining functional performance in persons with mild to moderate dementia [grade C recommendation, level 1 evidence].
8. Primary care physicians should be able to administer and interpret brief measures of functional activities and cognitive abilities, or refer to health care professionals with the required knowledge and expertise [grade B recommendation, level 3 evidence].
9. After treatment has been started, patients should be reassessed regularly by the appropriate health care professional involved in their care [grade B recommendation, level 3 evidence].
10. Records should be kept such that stabilization, improvement, or persisting deterioration in treated patients will be determinable [grade B recommendation, level 3 evidence].
11. In monitoring the response to therapy of patients with dementia, the input of caregivers (where available) should be sought. They can provide information on the patient's cognition, behavior, and social and daily functioning [grade B recommendation, level 3 evidence].
12. If the attending primary care physician is unable to perform the assessments required to gauge response to therapy, referral to another health care professional with knowledge and expertise in dementia care (e.g., other physician, nurse, occupational therapist) or a service (e.g., memory clinic) willing to perform such assessments is advised [grade B recommendation, level 3 evidence].
13. Primary care physicians should be able to communicate appropriate information concerning dementia, including realistic treatment expectations to their patients and their families [grade B recommendation, level 3 evidence].
14. Recommendations regarding the use of cholinesterase inhibitors:
 - a. All 3 cholinesterase inhibitors available in Canada are modestly efficacious for mild to moderate Alzheimer disease. They are all viable treatment options for most patients with mild to moderate Alzheimer disease [grade A recommendation, level 1 evidence].
 - b. Although all 3 cholinesterase inhibitors available in Canada have efficacy for mild to moderate Alzheimer disease, equivalency has not been established in direct comparisons. Selection of which agent to use will be based on adverse effect profile, ease of use, familiarity and beliefs about the importance of the differences between the agents in their pharmacokinetics and other mechanisms of action [grade B recommendation, level 1 evidence].
 - c. All physicians prescribing these agents should be aware of the contraindications and precautions with the use of cholinesterase inhibitors [grade B recommendation, level 3 evidence].
 - d. If adverse effects occur with a cholinesterase inhibitor, the agent should either be discontinued (if the side effects are judged to be disabling or dangerous), or the dose of the agent should be decreased with an option to retry the higher dose after 2–4 weeks if the lower dose is tolerated (if the side effects are judged to be minor in severity) [grade B recommendation, level 3 evidence].
 - e. If nausea or vomiting, or both, occur with the use of a cholinesterase inhibitor, review how the medication is being taken (e.g., dose, frequency, with or without food, evidence of an unintentional overdose) and consider: modifying the prescription (e.g., lower dose); the responsibility for administration (e.g., caregiver taking over from the patient); the directions given to the patient (e.g., with food); or stopping the agent. Although antiemetics can be used for nausea and vomiting, a number of them (e.g., dimenhydrinate, prochlorperazine) have anticholinergic properties that can lead to adverse cognitive effects [grade B recommendation, level 3 evidence].

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- f. Clinicians should consider the possible contributing role of cholinesterase inhibitors in new-onset or worsening medical presentations, and the potential risk of co-prescribing cholinesterase inhibitors and other drugs to patients with dementia [grade B recommendation, level 2 evidence].
 - g. Patients can be switched from one cholinesterase inhibitor to another. A decision to make a switch is based on the judgment of the prescribing physician and the patient (or their proxy) about the relative benefits and risks of making a change in the patient's pharmacotherapy [grade B recommendation, level 3 evidence].
 - h. Patients can be switched from a cholinesterase inhibitor to memantine (see the next recommendation, part b). The decision of when to make a switch is based on the judgment of the prescribing physician and the patient (or their proxy) [grade B recommendation, level 3 evidence].
15. Recommendations regarding the use of memantine
- a. Memantine is an option for patients with moderate to severe stages of Alzheimer disease [grade B recommendation, level 1 evidence]. Its use in mild stages of Alzheimer disease is not recommended [grade D recommendation, level 1 evidence].
 - b. Combination therapy with a cholinesterase inhibitor and memantine is rational (since the medications have different mechanisms of action), appears to be safe and may lead to additional benefits for patients with moderate to severe Alzheimer disease. This would be an option for patients with Alzheimer disease of a moderate severity [grade B recommendation, level 1 evidence].
16. Medications for the treatment of cognitive and functional manifestations of Alzheimer disease should be discontinued when:
- a. The patient (or their proxy) decides to stop;
 - b. The patient refuses to take the medication;
 - c. The patient is sufficiently nonadherent with the medication that continued prescription of it would be useless, and it is not possible to establish a system for the administration of the medication to rectify the problem;
 - d. There is no response to therapy after a reasonable trial;
 - e. The patient experiences intolerable side effects;
 - f. The comorbidities of the patient make continued use of the agent either unacceptably risky or futile (e.g., the patient is terminally ill); or
 - g. The patient's dementia progresses to a stage where there is no significant benefit from continued therapy [grade B recommendation, level 3 evidence].
17. After therapy for Alzheimer disease is stopped, patients should be carefully monitored. If there is evidence of a significant decline in their cognitive status, functional abilities, or the development or worsening of behavioural challenges, consideration should be given to reinstating the therapy [grade B recommendation, level 3 evidence].
18. Recommendations with regards to supplements, herbal preparations and other medications for the cognitive and functional manifestations of dementia:
- a. High-dose (i.e., ≥ 400 IU/d) vitamin E supplementation is not recommended for the treatment of Alzheimer disease [grade E recommendation, level 1 evidence].
 - b. The use of the synthetic antioxidant idebenone is not recommended for the treatment of Alzheimer disease [grade E recommendation, level 1 evidence].
 - c. The administration of vitamin B₁, B₆, B₁₂ and folic acid supplements to people with Alzheimer disease who are not deficient in these vitamins is not recommended [grade D recommendation, level 3 evidence].
 - d. There is insufficient evidence to allow for a recommendation either for or against the use of ginkgo biloba in the treatment of dementia. Further methodologically sound trials are required [grade C recommendation, level 1 evidence].
 - e. The use of an anti-inflammatory drug is not recommended for the treatment of the cognitive, functional or behavioural manifestations of a dementia [grade D recommendation, level 1 evidence].
 - f. The use of an HMG-CoA (3-hydroxy-3-methylglutaryl-coenzyme A) reductase enzyme inhibitor is not recommended for the treatment of the cognitive, functional or behavioural manifestations of a dementia [grade D recommendation, level 3 evidence].
 - g. Hormone replacement therapy (estrogen combined with a progestagen or estrogen replacement therapy (estrogen alone) is not recommended for the cognitive impairments of women with Alzheimer disease [grade D recommendation, level 1 evidence].
 - h. There is insufficient evidence to recommend the use of androgens (e.g., testosterone) to treat Alzheimer disease in men [grade C recommendation, level 1 evidence].
 - i. There is negative, inconclusive or conflicting evidence for a number of other agents proposed as potential therapies for the cognitive and behavioural manifestations of Alzheimer disease. Their use cannot be recommended at this time [grade C or D recommendation, levels 1–3 evidence; varies between agents].

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19. Assessment of patients with mild to moderate Alzheimer disease should include measures of behavior and other neuropsychiatric symptoms [grade B recommendation, level 3 evidence].
20. The management of behavioural and psychological symptoms of dementia should include a careful documentation of behaviours and identification of target symptoms, a search for potential triggers or precipitants, recording of the consequences of the behaviour, an evaluation to rule out treatable or contributory causes, and consideration of the safety of the patient, their caregiver and others in their environment [grade B recommendation, level 3 evidence].
21. Recommendations with regard to the management of depressive symptoms in the setting of mild to moderate dementia:
 - a. Because depressive syndromes are frequent in patients with dementia, physicians should consider diagnosing depression when patients present with the subacute development (e.g., weeks, rather than months or years) of symptoms characteristic of depression, such as behavioural symptoms, weight and sleep changes, sadness, crying, suicidal statements or excessive guilt [grade B recommendation, level 3 evidence].
 - b. Depressive symptoms that are not part of a major affective disorder, severe dysthymia or severe emotional lability should initially be treated nonpharmacologically [grade B recommendation, level 3 evidence].
 - c. If the patient had an inadequate response to the nonpharmacologic interventions or has a major affective disorder, severe dysthymia or severe emotional lability, a trial of an antidepressant should be considered [grade B recommendation, level 3 evidence].
 - d. If an antidepressant is prescribed to a person with Alzheimer disease, the preferred choice would be an agent with minimal anticholinergic activity, such as a selective serotonin reuptake inhibitor [grade B recommendation, level 3 evidence].
22. Recommendations with regard to sleep problems in the setting of mild to moderate dementia:
 - a. Patients with Alzheimer disease who experience sleep problems should first undergo a careful assessment for medical illnesses (including pain), psychiatric illnesses (especially depression), potentially contributing medications, environmental factors and poor sleep habits (e.g., daytime naps) that may be adversely affecting sleep. Any identified secondary cause should be managed [grade B recommendation, level 3 evidence].
 - b. The presence of a REM sleep behaviour disorder in the setting of a dementia would be suggestive of dementia with Lewy bodies and related conditions. Treatment options would include clonazepam [grade B recommendation, level 2 evidence].
 - c. Nonpharmacologic approaches to sleep disturbances can be effective for patients with Alzheimer disease, but a combination of these approaches will likely be required [grade B recommendation, level 1 evidence].
 - d. When considered clinically necessary, pharmacologic interventions for insomnia, including short- to intermediate-acting benzodiazepines and related agents, can be used at the lowest effective doses and for the shortest possible time [grade B recommendation, level 3 evidence].
23. Recommendations with regard to the management of behavioural and psychological symptoms of dementia in the setting of mild to moderate dementia:
 - a. Nonpharmacologic treatment of behavioural and psychological symptoms of dementia should be considered first. Nonpharmacologic interventions are often used in combination with pharmacotherapy [grade C recommendation, level 1 evidence].
 - b. Although there is insufficient evidence regarding the effectiveness of the interventions to strongly advocate for their routine use in the management of behavioural and psychological symptoms of dementia, some people with dementia may benefit from the following: music; Snoezelen (multi-sensory stimulation); bright-light therapy; reminiscence therapy; validation therapy; aroma therapy; and massage and touch therapy [grade B recommendation, level 2 evidence].
 - c. Pharmacotherapy for behavioural and psychological symptoms of dementia should be initiated only after consideration, and usually a trial where appropriate, of nonpharmacologic interventions [grade B recommendation, level 3 evidence].
 - d. The presence of visual hallucinations in the setting of mild dementia would suggest that the patient has dementia with Lewy bodies. Patients who have dementia with Lewy bodies are abnormally sensitive to antipsychotics. If pharmacotherapy is required for the visual hallucinations, a cholinesterase inhibitor should be tried first, if possible. If control of acute symptoms is required or the cholinesterase inhibitor is ineffective, a cautious trial of an atypical antipsychotic (e.g., very low dose of quetiapine) can be attempted [grade B recommendation, level 2 evidence].
 - e. Medications for behavioural and psychological symptoms of dementia should normally be initiated at a low starting dose and then subsequently titrated carefully based on the patient's response and the presence of adverse effects [grade B recommendation, level 3 evidence].
 - f. There should be periodic attempts to taper and withdraw medications after a period of 3 months of behavioural stability [grade B recommendation, level 3 evidence].

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- g. Patients who have mild to moderate Alzheimer disease and neuropsychiatric symptoms can be considered for a trial of a cholinesterase inhibitor or memantine, or both, for these symptoms [grade B recommendation, level 3 evidence].
 - h. Treatment of behavioural and psychological symptoms of dementia with cholinesterase inhibitors or memantine should persist until clinical benefits can no longer be demonstrated [grade B recommendation, level 3 evidence].
24. For the following community-based programs for the management of behavioural disturbances, there is limited high-quality evidence regarding effectiveness. The recommendations are based on 1 to 2 randomized controlled trials for each program:
- a. Adult day care (greater involvement of the caregiver may decrease problem behaviours in the care recipient) [grade B recommendation, level 2 evidence];
 - b. Support groups that focus on the management of behavioural problems and extend over several months [grade B recommendation, level 1 evidence];
 - c. In-home systematic, comprehensive support by a health care provider with advanced training in dementia care over an extended period (i.e., couple of years) [grade B recommendation, level 1 evidence];
 - d. In-home psychoeducational intervention that teaches caregivers how to manage behavioural problems [grade B recommendation, level 1 evidence];
 - e. Nonpharmacologic approaches to sleep disturbances can be effective for patients with Alzheimer disease, but a combination of approaches will likely be required [grade B recommendation, level 1 evidence].
25. Recommendations with regard to driving a motor vehicle and individuals with mild to moderate dementia:
- a. Clinicians should counsel people with a progressive dementia (and their families) that giving up driving will be an inevitable consequence of their disease. Strategies to ease this transition should occur early in the clinical course of the disease [grade B recommendation, level 2 evidence].
 - b. No single brief cognitive test (e.g., Mini-Mental State Examination [MMSE]) or combination of brief cognitive tests has sufficient sensitivity or specificity to be used as a sole determinant of driving ability. Abnormalities on cognitive tests such as the MMSE, clock-drawing test and Trails B should result in further in-depth testing of driving ability [grade B recommendation, level 3 evidence].
 - c. Driving is contraindicated in people who, for cognitive reasons, have an inability to independently perform multiple instrumental activities of daily living (e.g., medication management, banking, shopping, telephone use, cooking) or any of the basic activities of daily living (e.g., toileting, dressing) [grade B recommendation, level 3 evidence].
 - d. The driving ability of people with earlier stages of dementia should be tested on an individual basis [grade B recommendation, level 3 evidence].
 - e. A health professional-based comprehensive off- and on-road driving evaluation is the fairest method of individual testing [grade B recommendation, level 3 evidence].
 - f. In places where comprehensive off- and on-road driving evaluations are not available, clinicians must rely on their own judgment [grade B recommendation, level 3 evidence].
 - g. For people deemed safe to drive, reassessment of their ability to drive should take place every 6–12 months, or sooner if indicated [grade B recommendation, level 3 evidence].
 - h. Compensatory strategies are not appropriate for those deemed unsafe to drive [grade B recommendation, level 3 evidence].
26. Recommendations with regard to caregivers:
- a. The clinician should acknowledge the important role played by the caregiver in dementia care. The clinician should work with caregivers and families on an ongoing basis and schedule regular appointments for patients and caregivers together and alone [grade B recommendation, level 3 evidence].
 - b. The clinician should: enquire about caregiver information and support needs; provide education to patients and families about dementia; and assist in recruiting other family members and formal community services to share the caregiving role. If available, refer patients to specialized dementia services (e.g., Alzheimer Society, community-based dementia programs, memory clinics) that offer comprehensive treatment programs including caregiver support, education and training [grade A recommendation, level 1 evidence].
 - c. The clinician should: enquire about caregiver health (both physical and psychiatric); offer treatment for these problems (including individual psychotherapy or medications as indicated); and refer to appropriate specialists [grade B recommendation, level 3 evidence].
 - d. The clinician should enquire about problem behaviours of the dementia patient and the effect these behaviours are having on the caregiver. If these are causing significant caregiver distress, refer the caregiver and patient to specialized dementia services that can offer treatment to the patient and assist the caregiver in modifying his or her interactions with the patient [grade A recommendation, level 1 evidence].

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- e. Pharmacotherapy for Alzheimer disease can decrease caregiver burden and the time required of caregivers to support the care-recipient. It should be considered as a means to help support caregivers [grade B recommendation, level 1 evidence].
 - f. Future studies of medications for the treatment of Alzheimer disease and dementia should examine the impact of these agents on caregiver burden and the time required to support the care-recipient. There is a need to ensure consistency in the measurement of these outcomes [grade B recommendation, level 3 evidence].
27. Recommendations with regard to education:
- a. All clinicians caring for patients with mild to moderate Alzheimer disease have to acquire the core knowledge and skills required to manage this condition (note: see recommendations 1, 13, 20 and 28 for specific educational needs of primary care physicians) [grade B recommendation, level 3 evidence].
 - b. A multifaceted educational program should be implemented to promote adoption of the recommendations of the Third Canadian Consensus Conference on the Diagnosis and Treatment of Dementia by practitioners [grade B recommendation, level 1 evidence].
28. Recommendations with regard to the organization and funding of care for those with dementia:
- a. Every community should examine the services locally available for the management of those with a dementia, assess their adequacy, and implement plans to deal with identified deficiencies [grade C recommendation, level 3 evidence].
 - b. There is a need to modify the prevailing model of chronic disease management (i.e., less reliance on promotion of patient self-management coupled with greater caregiver involvement) for dementia. The efficacy and efficiency of modified chronic disease management for dementia should be explored [grade C recommendation, level 3 evidence].
 - c. Shared care models for the management of patients with mild to moderate Alzheimer disease and dementia should be developed and evaluated. This will require the acceptance of joint responsibility on the part of primary care practitioners and specialty services in delivering care to patients with dementia [grade C recommendation, level 3 evidence].
 - d. Dementia care must to be adequately funded and reimbursed. Inadequate remuneration should not be a barrier to the delivery of good dementia care [grade C recommendation, level 3 evidence].

Dementia with a cerebrovascular component

Use of nonpharmacologic interventions

1. There is currently (as of March 2006) insufficient evidence to recommend the use of cognitive training for vascular dementia [grade C recommendation, level 2 evidence].

Other therapeutic interventions

2. Investigations for vascular risk factors. It is recommended that vascular risk factors are identified in all patients with vascular cognitive impairment [grade C recommendation, level 3 evidence].
3. Treating hypertension. There is some evidence that treating hypertension may prevent further cognitive decline associated with cerebrovascular disease. There is no compelling evidence that one class of agent is superior to another; calcium channel blockers or ACE-inhibitors may be considered. (Grade B, Level 1). Treatment for hypertension should be implemented for other reasons, including the prevention of recurrent stroke [grade A recommendation, level 1 evidence].
4. Antiplatelet therapy with acetylsalicylic acid (ASA): There is currently no evidence to support the use of ASA to specifically treat dementia associated with cerebrovascular disease [grade C recommendation, level 3 evidence]. ASA or other antiplatelet therapies should be used for the prevention of recurrent ischemic stroke in appropriate patients [grade A recommendation, level 1 evidence].
5. Nimodipine in vascular dementia: There is insufficient evidence for or against the use of nimodipine for vascular dementia [grade C recommendation, level 1 evidence].
6. Use of memantine: There is some evidence of small magnitude of cognitive benefit that is not captured in global measures for patients with vascular dementia. There is insufficient information to recommend memantine for the treatment of vascular dementia [grade C recommendation, level 1 evidence].
7. Use of cholinesterase inhibitors in dementia due to combined Alzheimer and cerebrovascular disease: There is fair evidence of benefits of small magnitude for galantamine in cognitive, functional, behavioural and global measures in Alzheimer disease with a cerebrovascular component. Galantamine can be considered a treatment option for mixed Alzheimer with cerebrovascular disease [grade B recommendation, level 1 evidence].
8. Use of cholinesterase inhibitors in probable or possible vascular dementia using the NINDS–AIREN diagnostic criteria:
 - a. There is insufficient evidence for or against the use of galantamine [grade C recommendation, level 1 evidence].
 - b. There is fair evidence of benefits of small magnitude for donepezil in cognitive and global outcomes, with less robust benefits on functional measures. Donepezil can be considered a treatment option for vascular dementia [grade B recommendation, level 1 evidence].

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Ethical issues in dementia

Disclosure

1. The process of diagnostic disclosure for persons with cognitive impairment or dementia must begin as soon as the possibility of cognitive impairment is suspected [grade A recommendation, level 3 evidence].
2. Both the diagnosis of dementia and the disclosure of the diagnosis must be considered processes that provide opportunities for education and discussion [grade A recommendation, level 3 evidence].
3. The potential for adverse psychological consequences must be assessed and addressed through education of the patient and family/caregivers [grade B recommendation, level 3 evidence].
4. Once a diagnosis is established, this must be disclosed to the patient and their family/caregivers in a manner that is consistent with the expressed wishes of the patient [grade B recommendation, level 3 evidence].
5. Follow-up plans must be made and discussed at the time of diagnostic disclosure [grade A recommendation, level 3 evidence].

Consent for therapy

1. Provision of the best standard of care for the patient must always remain the priority [grade A recommendation, level 3 evidence].
2. Drawing a clear distinction between research participation and clinical care is essential for both the patient and their family/caregiver. The distinctions between the clinician's role in the management of the individual's health care and his/her potential role in the conduct of research must be clearly understood by everyone, as must the procedures that represent standard care and research. In research settings, the availability of a physician other than the research physician to provide general care is recommended in order to ensure that decisions regarding treatment are made in the best interests of the patient [grade A recommendation, level 3 evidence].
3. A diagnosis of dementia, or other forms of cognitive impairment, does not preclude competence to provide informed consent, whether it be for treatment decisions, for participation in clinical trials or for participation in non-therapeutic research. Competency must be considered as the ability to make an informed decision about participation in the particular context of the specific treatment or research study [grade A recommendation, level 3 evidence].
4. For studies, it is reasonable to expect that the procedures that will be used to evaluate the ability of the potential subject to understand the nature of the research, the consequences of participation (i.e., potential risks and benefits) and alternative choices are described. However, at present there is insufficient evidence available to recommend the use of a specific standardized method for determining competency for decision-making either for treatment or research [grade B recommendation, level 3 evidence].
5. Even in the absence of a legal determination of the competency of the patient with cognitive impairment or dementia, it is important that the clinician and researcher consider the consent process as one that should involve both the patient and their family/caregiver for treatment and research decision-making. In research settings, research ethics boards may explicitly require that consent/assent be obtained from both parties [grade B recommendation, level 3 evidence].
6. The potential that competency for treatment and research decision-making will change over time must be recognized. This may lead to a change from one of obtaining the patient's ongoing consent to one of obtaining ongoing assent. Assent is almost invariably required, and the decision to discontinue treatment, whether it be therapy or research, must always be an option [grade A recommendation, level 3 evidence].
7. To the best of their ability, clinicians and researchers must ensure that the decisions made by proxies regarding treatment and research are based on the prior attitudes and values of the patient. Proxies have a responsibility to represent the patient and all parties must recognize the challenges of doing so [grade A recommendation, level 3 evidence].