

The Disappearing Subject: Exclusion of People with Cognitive Impairment and Dementia from Geriatrics Research

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OBJECTIVES: To evaluate exclusion of persons with cognitive impairment from research in geriatrics by determining its frequency, method, and rationale and treatment in the resulting publications.

DESIGN: All original research articles published in 2008 and 2009 in the *Journal of the American Geriatrics Society* (n = 434) were reviewed using a structured data collection tool.

SETTING: The *Journal of the American Geriatrics Society*.

PARTICIPANTS: There were no participants in this study.

MEASUREMENTS: Data captured included recruitment method, explicit criterion for exclusion of persons with cognitive impairment, justification of exclusion criterion, reason given for exclusion, percentage of individuals excluded, and mention of exclusion as a possible limitation.

RESULTS: Of 434 articles examined, 16% used recruitment methods likely to reduce participation by persons with cognitive impairment. At least 29% of studies (n = 127) employed explicit exclusion criteria. Half used the Folstein Mini-Mental State Examination (MMSE), with variable cut points (10, 12, 17, 18, 23, 26), and 19% excluded individuals for “having dementia” without specifying how this was determined. Few (6%) provided any justification for exclusion criteria used, only 43% gave any reason for exclusion, and only 14% discussed exclusion as a possible limitation.

CONCLUSION: Persons with cognitive impairment are frequently excluded from research, often without rationale or mention of exclusion as a limitation or any discussion of its potential effect on the evidence base in geriatrics. When necessary, exclusion should be done thoughtfully

and with awareness that this may reduce the clinical utility of study findings. *J Am Geriatr Soc* 60:413–419, 2012.

Key words: exclusion criteria; research methodologies

As the proportion of older adults in the U.S. population increases from 12% in 2000 to an estimated 20% by 2050, more than 9 million will have dementia.^{1,2} Many more will have less-severe cognitive impairments that can still interfere with independent management of their medical problems and conditions;^{3–6} in this article, the term “cognitive impairment” is used broadly to include both, with the conscious intention to document the variability encompassed by this inherently imprecise term. To provide optimal care to older adults, clinicians must consider the presence of cognitive impairment when communicating with patients, making treatment decisions, weighing risks and benefits, and identifying the need for family members and others to participate in crafting and implementing care plans. Although geriatricians generally understand these concepts, operational standards for using them systematically in healthcare design have yet to emerge. This study explored to what extent clinical research in geriatrics might mirror this state of affairs.

In research as in clinical care, whether and how cognitive impairment presents problems will depend on a variety of factors. Depending on a study’s protocol, exclusion of people with cognitive impairment may or may not be appropriate; depending on its objectives, such exclusion may or may not have scientific or clinical implications. The evidence guiding clinical care of older adults is already often extrapolated from studies of younger people;^{7,8} a recent review of randomized controlled trials published in five leading journals found that more than 20% excluded subjects aged 70 and older.⁹ Geriatric research by definition does not exclude older adults, but it may enact other forms of exclusion, including exclusion of people with cognitive impairment, although such people are not

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automatically incapable of consent to clinical treatment or to research participation.¹⁰⁻¹² The present study examined the exclusion of older adults with broadly defined cognitive impairment from geriatric research and considered the scientific and clinical consequences of this.

METHODS

A systematic guided review was conducted of research studies published in *the Journal of the American Geriatrics Society (JAGS)* selected because, as the flagship peer-reviewed journal of the largest professional organization of geriatricians in North America, it features the most thoroughly vetted research in the field.

Evaluation of JAGS Articles

All research articles published in *JAGS* over a 2-year period (2008 and 2009, Volumes 56 and 57, N = 434) were reviewed. A period of 2 years (24 issues) was chosen to encompass a sufficient sample of published research articles to allow a fair assessment of current research practices. Excluded were essays, literature reviews, methodological reports, studies of healthcare professionals, clinical guidelines, case studies, letters, and review articles, because these did not involve recruitment of geriatric subjects.

After the initial review of a small sample of articles, two reviewers (JST, SMD) iteratively developed a data abstraction tool that was used to guide evaluation of individual articles, extracting information about the recruitment method used, whether individuals with cognitive impairment were excluded, reasons and criteria (with rationale) for exclusion, percentage of all potential participants excluded because of cognitive impairment (when calculable), and mention of exclusion as a possible limitation. Using the abstraction tool, two reviewers (JST, SMD) each evaluated 1 year (volume). Each also evaluated articles published in 2 months of the year assigned to the other, yielding agreement between reviewers of 96.3% (445/462 data items).

Coding of JAGS Articles

After completing the review, a coding scheme was developed for assessing studies with regard to questions not amenable to yes or no answers. Using this scheme, both reviewers coded all studies, compared their coding, and resolved discrepancies through discussion.

Evaluation of Articles Based on Prior Studies and Data Sets

Thirty-nine percent (n = 168) of all articles evaluated provided insufficient information for categorizing recruitment methods and referenced a previously published study or an existing database. Therefore the most frequently referenced sources were searched directly. Table 1 indexes the prior studies (n = 93) and databases (n = 46) most commonly cited. Two members of the research team (JST, EKV) evaluated and coded the nine most frequently referenced prior studies. Another (SB) evaluated the four most commonly

Table 1. The Most Commonly Referenced Prior Studies and Databases

Prior Studies and Databases	New Studies Using Source Data, n
Study	
Cardiovascular Health Study	11
Study of Osteoporotic Fractures	9
Health and Retirement Study	8
Health, Aging and Body Composition Study	7
Precipitating Events Project	6
Established Population for the Epidemiological Study of the Elderly and Hispanic Established Population for the Epidemiological Study of the Elderly	5
Invecchiare in Chianti Study	5
National Health and Nutrition Examination Surveys I and III	5
Women's Health and Aging Study I and II	5
Database	
Surveillance, Epidemiology, and End Results Medicare database	5
Minimum Data Set	4
Centers for Medicare and Medicaid Services	3
National Veterans Affairs inpatient, outpatient, and pharmacy databases	2

referenced of the databases (n = 18, after excluding meta-analyses and single-institution data sets, e.g., one hospital's medical records).

Data Analysis

Descriptive statistics were used to determine proportions of studies citing different recruitment methods, explicit exclusion criteria, a reason for exclusion, and the exclusion as a possible limitation. The percentage of studies that used different exclusion criteria and cited particular reasons for exclusion was also calculated. Where possible, the percentage of potential subjects excluded because of cognitive impairment was calculated. Individual studies were not assessed with regard to whether it was likely that exclusion of cognitive impairment would affect their specific goals, because the purpose was not to critique individual studies but rather to detect broad patterns of research practices within the field as a whole.

RESULTS

Results for the 434 articles evaluated are shown in Table 2 and Figure 1.

Recruitment Methods

Thirty-one percent of the 434 studies reviewed used recruitment methods with a low likelihood of excluding people with cognitive impairment (e.g., recruiting all patients in a particular setting). Sixteen percent of all articles employed recruitment methods that should be expected to exclude people with cognitive impairment, and 3% did not describe the recruitment method.

Another 39% were based on previous studies for which recruitment methods were not described in sufficient

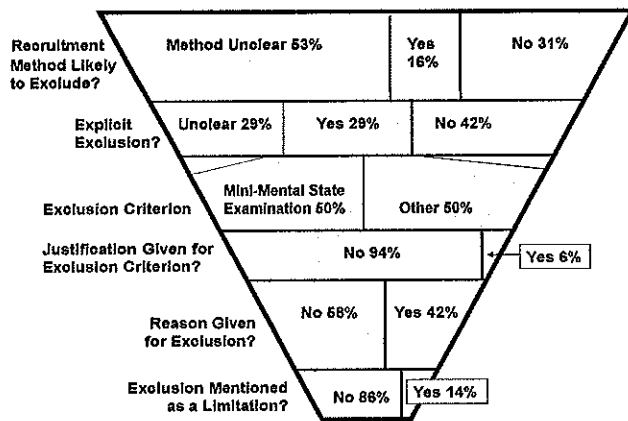


Figure 1. Overall results of guided review of research articles (N = 434).

Table 2. Results (434 Articles)

Result	n (%)
Recruitment method	
Unable to determine from published article	227 (53)
• Prior study with method not described in the article reviewed	168 (39)
• Based on database with unstated method	46 (11)
• Not described	13 (3)
Method likely to discourage participation by subjects with cognitive impairment	71 (16)
• Subjects had to volunteer (e.g., at lectures)	27 (6)
• Mailed survey	15 (3)
• Door-to-door	7 (2)
• Referral by healthcare providers	17 (4)
• Telephone contact only	5 (1)
Method more likely to include subjects with cognitive impairment	134 (31)
• All persons in a target setting (e.g., a skilled nursing facility)	134 (31)
Explicit exclusion	
Method used to exclude	127 (29)
Cognitive screen	75 (59)
• Mini-Mental State Examination	63 (50)
• Other	12 (9)
• "Have dementia" or "have cognitive impairment"	24 (19)
Unable to participate in protocol	13 (10)
Existing diagnosis of dementia	10 (8)
Reasons given for exclusion	
None given	73 (58)
Unable to follow protocol	9 (7)
Reliability of data	10 (8)
Need to isolate a condition easily confounded with dementia or cognitive impairment	13 (10)
Need to exclude at baseline (cognitive impairment an outcome variable)	11 (9)
Exclusion discussed as a possible limitation	27 (14)

detail to judge whether or how they might exclude persons with cognitive impairment. The nine prior studies most commonly referenced in this manner include three for which recruitment methods were not described, whereas the remaining six recruited subjects in ways likely to exclude many people with cognitive impairment (through

mailings alone or mailings combined with telephone contact).

An additional 11% of studies were derived from analysis of existing databases for which it was not possible to determine without further inquiry whether they were compiled in ways likely to exclude people with cognitive impairment. None of the four most commonly cited databases excluded people with cognitive impairment, although others might do so.

Exclusion Practices

Nearly one-third (n = 127) of all studies explicitly excluded people with cognitive impairment or dementia as participants. The exclusion criteria (how people with cognitive impairment were identified as being ineligible for participation) varied widely (Table 2). Of those that employed an explicit exclusion criterion, 60% relied upon a cognitive screening test. Half used the Folstein Mini-Mental State Examination (MMSE),¹³ and 9% used other cognitive screening tests (e.g., CogAt, Short Portable Mental Questionnaire). Only rarely, in 6% of the 127 articles using explicit exclusion criteria, were any reasons given for choosing the specific criterion. Cut points used with the MMSE ranged from 10 to 26 points; only 10% of the articles excluding individuals according to score gave any rationale for the specific score used.

For most studies using explicit exclusion criteria, it was not possible to calculate from the published article the percentage of potential participants excluded. When such calculations were possible (in 17% of the 127 articles), this percentage varied from a low of 0.01% to a high of 49% (median 14%).

Considering the nine previously published studies that most frequently provided source data for JAGS articles, only one clearly did not employ any exclusion criterion. In four cases, it was unclear whether explicit exclusion criteria for cognitive impairment were used. One excluded people "with dementia" if no proxy was available but did not describe how the presence of dementia was determined. The MMSE was employed as an exclusion criterion in three of the nine studies, with cut points of 17, 18, and 24.

Justifying Exclusion of Cognitive Impairment

Only 42% of the articles that employed explicit exclusion criteria offered any specific reasons for so doing; 58% offered no reason or justification. When reasons were given, they fell into several categories (Table 2).

Mention of Exclusion of Cognitive Impairment as a Limitation

Approximately one-third of all studies reviewed explicitly excluded people with cognitive impairment (using various criteria), and many of those concluded by offering recommendations that would, if adopted, presumably be implemented in a population likely to include a considerable proportion of people with varying kinds and degrees of cognitive impairment, yet only 14% of these articles actually mentioned exclusion of cognitive impairment as a possible limitation of the study.

DISCUSSION

This systematic review of 434 JAGS research articles published in 2008 and 2009 reveals a pattern of frequent, often unexplained, and usually unacknowledged exclusion of people with cognitive impairment from geriatric research. The large majority used recruitment methods that would discourage participation by persons with cognitive impairment or provided too little information to determine what recruitment methods were used and whom they might exclude. One-third of studies reviewed explicitly excluded individuals with cognitive impairment, but fewer than half of these gave any reason for this exclusion, and few mentioned this exclusion as a possible limitation. Given that all articles had multiple coauthors and were reviewed by experts in the field before publication in JAGS, hundreds of investigators were involved in producing the body of scholarship considered here.

The authors of the current review believe that this is the first study to assess the exclusion of individuals with cognitive impairment from research studies in geriatrics. The findings, based on review of a large sample of specific studies, raise broad questions about how cognitive impairment should be handled in research in geriatrics. Research methods used in JAGS articles are state of the art, but this art deserves critical appraisal and continuous updating and improvement.

One striking finding of the research is how seldom it is possible to determine, while reading a published article, whether or how exclusion of people with cognitive impairment may have taken place, for what reasons, and how this might limit the generalizability of results or the clinical applicability of recommendations. Some simply made no mention of recruitment methods. For more than half of the articles reviewed, recruitment methods could not be found without digging into past publications (which most readers are unlikely to do). When numerous articles are based on the same primary or source study—some addressing questions not considered in the original study or database—any critical omissions may be multiply compounded. To illustrate: using the search tool on JAGS home page, the names of the nine “prior” studies most often serving as sources for published articles were searched for; 3,948 results were achieved. The practice of citing a prior study as the basis for the present one, without describing original methods (common across medical disciplines), has the ironic consequence that the more influential a study has become, the more difficult it is to evaluate whether the original methods might undermine the validity and generalizability of the results of new work derived from it.

Many studies effectively exclude people with cognitive impairment by using recruitment methods that are likely to miss many or most of them. Every recruitment method has its costs and limitations, and no method will capture all individuals, nor must every study include a comment about dementia simply because it is a “geriatric” study, but it should be acknowledged that recruitment methods requiring the exercise of a high-level of cognitive capacity and initiative will predictably exclude many people with cognitive impairment. For example, people with cognitive impairment are less likely to call and volunteer for a study

after reading a description of it on a flyer posted in a public area. Studies that recruit subjects by telephone or through a letter or survey sent in the mail also may exclude many people with cognitive impairment, for similar reasons. Studies that recruit subjects through provider referrals are also likely to exclude people with cognitive impairment, because physicians may not consider them to be suitable research participants.¹⁴

One-third of studies reviewed explicitly excluded people with cognitive impairment from participation in the research. Those excluding individuals with cognitive impairment did so using a variety of criteria. Half used the MMSE, a tool never intended for this purpose, and cut-points used ranged from 10 to 26, mostly without clear rationale or empirical support for the choice. Existing data indicate that research participation can be possible with individuals scoring as low as 13^{15–17} (and lower for some types of studies), and there is no identified cut point below which capacity to give consent or assent, or to participate in research, is always impossible. One study referenced experience with a prior study to justify the cut point used,¹⁸ and in another, investigators conducted pilot work to determine appropriate cut points for their particular design.¹⁹

When other methods for excluding persons with cognitive impairment were used, empirical rigor was similarly rare (Table 2). In one laudable example, the investigator screened each potential participant for eligibility in a face-to-face interview, evaluating understanding of the study purpose and ability to execute test procedures as the basis for determining eligibility. Studies that excluded people “who have dementia” or “who are cognitively impaired” (19%) appear to treat the heterogeneous types and manifestations of cognitive disorders as a single entity with a uniform effect on study participation, often giving no rationale pertinent to the particular study being reported. It is possible that researchers’ expectations regarding the informed consent requirements of institutional review boards lead many to consider, from the outset, that inclusion of people with cognitive impairment is difficult or impossible. Furthermore, it may in many cases seem evident to the researchers that persons with cognitive impairment should be excluded from their intervention or protocol, but this judgment needs careful scrutiny; it might reflect unfounded biases or assumptions. Previous research has documented that individuals who are less familiar with persons with cognitive impairment tend to rate them as less capable than those who know them best.²⁰ Judgments regarding capacity to consent to and participate in research are as complex as judgments of decisional capacity more generally.²¹ For cognitive impairment as for other conditions affecting mental functioning, such as schizophrenia, no single measure or diagnosis will capture all relevant dimensions.^{22,23}

Of studies that employed exclusion criteria and provided a reason, most cited matters relating to the design and intent of the study: dementia was excluded because it might confound assessment of another condition or symptom, such as Parkinson’s disease or delirium, or because the onset of dementia was an outcome variable; advanced cognitive impairment was excluded because the study concerned early or mild cognitive impairment; or people with

cognitive impairment were excluded because they were judged or assumed to be unable to follow the study protocols. One-tenth of articles that employed explicit exclusion criteria gave as a reason concerns about the reliability of the information or the stability of preferences obtained from individuals with cognitive impairment. Two studies cited the need for a control group free from cognitive impairment, and one study stated that people with cognitive impairment were excluded because the study was of no benefit to them.²⁴

There are situations where exclusion of individuals with cognitive impairment is entirely appropriate (Table 3). Scientifically valid situations might include studies, for example, of a self-administered treatment known to be too complex for a person with cognitive impairment to manage safely and reliably or of the effect of a dietary supplement on incident cognitive decline in cognitively normal persons. Even when such exclusion is appropriate, it may still limit clinical applicability and generalizability of research findings, yet nearly 90% of studies excluding cognitive impairment did not mention this as a limitation (Table 3). In some cases, exclusion of cognitive impairment directly affects the researchers' chosen outcome. For example, a study evaluating the association between depression and disability after a myocardial infarction excluding patients with cognitive impairment will miss a significant comorbidity that may have diverse effects on the relationship between the primary predictor (depression) and outcome (disability) and may be important for clinical practice. Likewise, studies of interventions to reduce falls or to improve advanced directives that do not evaluate cognitive impairment or exclude individuals with cognitive impairment seriously limit the ability to judge the clinical usefulness of such interventions. Many nonetheless con-

clude with recommendations intended for implementation in a population likely to include many people with varying kinds and degrees of cognitive impairment, in whom the intervention was never tested.

The current study also has limitations. The review was limited to a single journal and to articles published only during 2 years. *JAGS* was selected because the authors believe that it publishes the best and most broadly conceived research in the field, and every effort was made to track down relevant prior studies and databases to find methods unreported in these articles, but some of this information was unavailable. Had it been possible to review additional documents, such as study protocols or human subject applications, it might have been possible to arrive at more-nuanced assessments of individual studies. Despite its limitations, the study highlights a missing element in geriatric research: rigorous standards for determining when, how, and for what types of research older persons with cognitive impairment can be excluded without risking degradation of the evidence base that research in geriatrics seeks to build. Poorly reasoned exclusion of persons with cognitive impairment can lead to unrepresentativeness²⁵ of results and adversely affect dissemination of important advances in clinical care for real-world populations, in which cognitive impairment is often a factor. The pattern of widespread, unexplained, and unacknowledged exclusion documented here amounts to an active, albeit unwitting, production of ignorance about cognitive impairment within the field of geriatrics.²⁶

There are some research questions and study designs that must exclude people with cognitive impairment,²⁷ but inclusion may often be possible using alternative research approaches. For instance, there exist social scientific methods that allow researchers to study how people with cognitive impairment express preferences, values, emotions, and knowledge even when verbal abilities are limited.²⁸⁻³⁰ When research tools familiar to biomedical researchers do not succeed in answering important questions in geriatrics, the challenge is to identify and use more-suitable tools. After all, clinicians would never simply give up on taking blood pressure readings in obese patients simply because standard cuffs give false readings. One uses a larger cuff.

Suggestions for Researchers

From these findings follow several suggestions for research practice. First, during the process of designing a study involving older individuals, researchers should proactively consider that cognitive impairment is a common comorbidity and think carefully about what cognitive abilities are required for participation in the planned research. A concern for clinical applicability of recommendations and guidelines would seem to demand that researchers in geriatrics not exclude people with cognitive impairment out of hand. Second, when researchers exclude individuals with cognitive impairment from healthcare research, they should give sound reasons for doing so. Third, criteria for exclusion should be scientifically valid and meaningful and should be included in the description of study methods. Researchers should make clear what they mean by "cognitive impairment" or "dementia" in ways that others can understand and operationalize. Fourth, when there is

Table 3. Examples of Exclusion and No Exclusion, with Effect on Aim of Study

Exclusion, appropriate to the aim	Study aims to determine whether a particular intervention prevents progression from mild cognitive impairment to dementia and so excludes individuals who already have dementia.
No Exclusion, no effect on the aim	Study aims to assess correlation between blood pressure measures and a certain vitamin, uses large Veterans Affairs database of blood pressure measures and pharmacy records (no exclusion for cognitive impairment)
Exclusion, negative effect on applicability of findings	Study aims to develop a tool to help older adults talk with their doctors about advanced care planning and excludes all individuals with "cognitive impairment"
Exclusion, negative effect on applicability of findings	A study of an intervention addressing urinary incontinence excludes people with dementia, using Mini-Mental State Examination score as criterion. Potential applicability of the intervention to incontinence problems in geriatrics is limited, because urinary incontinence is frequently associated with cognitive impairment in older adults
No Exclusion, negative effect on the aim	Study seeks to determine whether there is a relationship between presurgical depression and development of postsurgical delirium and makes no assessment of baseline cognition in participants, even though baseline cognitive impairment is a primary risk factor

exclusion, this should be explicitly addressed as a possible scientific or clinical limitation in the discussion of research findings.

Suggestions for Geriatrics as a Field

There is a need for consensus in geriatrics with regard to when, how, and why exclusion of people with cognitive impairment as research participants is and is not appropriate. Such consensus should offer a coherent theoretical framework and specify the empirical support that justifies investigators' choice of methods with regard to inclusion of persons with cognitive impairment. Such standards relating to exclusion of cognitive impairment and dementia could establish benchmark methods for handling other conditions that may be similarly subject to inadvertent exclusionary practices.

Research on clinical interventions—from “proof of concept” pilot studies through randomized-controlled trials—requires careful evaluation of whether the planned intervention is likely to be used with persons with cognitive impairment as well as cognitively intact seniors, and participants should be selected appropriately. Consideration of cognitive impairment may also influence the choice of outcome measures.

Professional journals, together with professional societies, scientific organizations, and funding agencies, help to shape scientific inquiry. Journals publishing research in geriatrics can help set new standards for inclusiveness and transparency with respect to dementia and cognitive impairment. For example, when assessing an article for publication, reviewers and editors might ask whether the criteria used for exclusion are valid with regard to the study under consideration. Reviewers and editors might also ask that, whenever possible, a new study using data derived from prior work or an existing database report sufficient detail about recruitment methods to allow clinicians to evaluate the applicability of its findings and recommendations to the populations with whom they work. Table 4 gives examples of specific articles that addressed the issue of exclusion well.

Many recent initiatives aim to improve the care of older adults generally^{31,32} and of the significant proportion

with cognitive impairment in particular.³³ Geriatric research plays a vital role in these developments. Research that handles cognitive impairment thoughtfully and addresses questions of exclusion explicitly will best equip geriatricians to serve the people for and about whom they care. Rethinking exclusion of people with cognitive impairment from research in geriatrics stands to improve research and clinical care. There are already many ways, in our world, that elderly people with dementia and other forms of cognitive impairment are made to disappear from view,^{34,35} geriatrics research should not be one of them.

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Author Contributions: All authors participated in the design of the study, collection of data, analysis and interpretation of findings, and writing of this article.

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Table 4. Examples of Studies that Addressed Exclusion or Limitations Well

Exclusion, criteria developed carefully

A study correlating muscle endurance to fatigue and to levels of inflammatory cytokines in blood in nursing home residents excludes individuals unable to understand and execute test instructions. Mini-Mental State Examination tested as exclusion criterion in pilot study and found to be insufficiently useful; investigators used face-to-face interview instead to determine whether participants could follow protocol¹⁹

Exclusion, possible effect on the aim but handled appropriately

A study of visual acuity and contrast sensitivity that compared large database findings with direct examination of residents of long-term care facilities. Because participants had to be able to reliably read letters during eye examination, researchers excluded persons with Mini-Mental State Examination scores less than 13, cited references in support of this cut point, and mentioned this exclusion as a possible limitation in their discussion¹⁸

No Exclusion, exemplary discussion of limitations

Study of care preferences of nursing home residents that does not exclude people with dementia but includes thoughtful discussion of difficulties related to use of caregiver proxies, especially when their concerns and interests may be distinct from, or even opposed to, the wishes of the person with dementia³⁶

Study of fall prevention intervention in nursing homes that does not exclude people with dementia but notes the possibility that recruitment might systematically miss some people with dementia and explicitly addresses this in discussion of limitations and in recommendations³⁷

REFERENCES

- Breitner JC. Dementia—epidemiological considerations, nomenclature, and a tacit consensus definition. *J Geriatr Psychiatry Neurol* 2006;19:129–136.
- Alzheimer's Association. 2011 Alzheimer's disease facts and figures. *Alzheimer's Demont* 2011;7:208–244.
- Cooper C, Carpenter I, Katona C et al. The AdHOC Study of older adults' adherence to medication in 11 countries. *Am J Geriatr Psychiatry* 2005;13:1067–1076.
- Insel KC, Cole L. Individualizing memory strategies to improve medication adherence. *Appl Nurs Res* 2005;18:199–204.
- Royall DR, Cabello M, Poik Mf. Executive dyscontrol: An important factor affecting the level of care received by older retirees. *J Am Geriatr Soc* 1998;46:1519–1524.
- Okonkwo OC, Griffith HR, Copeland JN et al. Medical decision-making capacity in mild cognitive impairment: A 3-year longitudinal study. *Neurology* 2008;71:1474–1480.
- Mody L, Miller DK, McGloin JM et al. Recruitment and retention of older adults in aging research. *J Am Geriatr Soc* 2008;56:2340–2348.
- Hardy SE, Allore H, Studenski SA. Missing data: A special challenge in aging research. *J Am Geriatr Soc* 2009;57:722–729.
- Zulman DM, Sussman JB, Chen X et al. Examining the evidence: A systematic review of the inclusion and analysis of older adults in randomized controlled trials. *J Gen Intern Med* 2011;26:783–790.
- Rubright J, Sankar P, Casarett DJ et al. A memory and organizational aid improves Alzheimer disease research consent capacity: Results of a randomized, controlled trial. *Am J Geriatr Psychiatry* 2010;18:1124–1132.
- Karlawish J. Measuring decision-making capacity in cognitively impaired individuals. *Neurosignals* 2008;16:91–98.
- Beattie E. Research participation of individuals with dementia. *Res Gerontol Nurs* 2009;2:94–102.
- Folstein MF, Folstein SE, McHugh PR. 'Mini-mental state'. A practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res* 1975;12:189–198.
- Carr SA, Davis R, Spencer D et al. Comparison of recruitment efforts targeted at primary care physicians versus the community at large for participation in Alzheimer disease clinical trials. *Alzheimer Dis Assoc Disord* 2010;24:165–170.
- Brod M, Stewart AL, Sands L et al. Conceptualization and measurement of quality of life in dementia: The Dementia Quality of Life instrument (DQoL). *Gerontologist* 1999;39:25–35.
- Simmons SF, Schnelle JF. Strategies to measure nursing home residents' satisfaction and preferences related to incontinence and mobility care: Implications for evaluating intervention effects. *Gerontologist* 1999;39:345–355.
- Logsdon RG, Gibbons LE, McCurry SM et al. Assessing quality of life in older adults with cognitive impairment. *Psychosom Med* 2002;64:510–519.
- Swanson MW, McGwin G Jr, Elliott AF et al. The nursing home minimum data set for vision and its association with visual acuity and contrast sensitivity. *J Am Geriatr Soc* 2009;57:486–491.
- Bautmans I, Njemini R, H Predom H et al. Muscle endurance in elderly nursing home residents is related to fatigue perception, mobility, and circulating tumor necrosis factor-alpha, interleukin-6, and heat shock protein 70. *J Am Geriatr Soc* 2008;56:389–396.
- Stocking CB, Hougham GW, Danner DD et al. Variable judgments of decisional capacity in cognitively impaired research subjects. *J Am Geriatr Soc* 2008;56:1893–1897.
- Sessums LL, Zembrzuska H, Jackson JL. Does this patient have medical decision-making capacity? *JAMA* 2011;306:420–427.
- Kim SYH, Appelbaum PS, Kim HM et al. Variability of judgments of capacity: Experience of capacity evaluators in a study of research consent capacity. *Psychosomatics* 2011;52:346–353.
- Kaup AR, Dunn LB, Saks ER et al. Decisional capacity and consent for schizophrenia research. *IRB* 2011;33:1–9.
- Tannenbaum C, Brouillette J, Korner-Bitensky N et al. Creation and testing of the geriatric self-efficacy index for urinary incontinence. *J Am Geriatr Soc* 2008;56:542–547.
- Epstein S. *Inclusion: The Politics of Difference in Medical Research*. Chicago Studies in Practices of Meaning. Chicago: University of Chicago Press, 2007.
- Proctor R, Schiebinger LL. *Agnology: The Making and Unmaking of Ignorance*. Stanford: Stanford University Press, 2008.
- Hoffmann DE, Schwartz J, DeRenzo EG. Regulating research with decisionally impaired individuals: Are we making progress? *DePaul J Health Care Law* 2000;3:547–608.
- Pols AJ. Enacting appreciations: Beyond the patient perspective. *Health Care Anal* 2005;13:203–221.
- McLean AH. Coherence without facticity in dementia: The case of Mrs. Fine. In: Leibing A, Cohen L, eds. *Thinking About Dementia: Culture, Loss, and the Anthropology of Senility*. New Brunswick: Rutgers University Press, 2006, pp 157–179.
- Kontos PC. Embodied selfhood: An ethnographic exploration. In: Leibing A, Cohen L, eds. *Thinking About Dementia: Culture, Loss, and the Anthropology of Senility*. New Brunswick: Rutgers University Press, 2006, pp 195–217.
- IOM committee calls for complete revamping of health care system to achieve better quality. *Qual Lett Healthc Lead* 2001;13:14–15.
- Institute of Medicine. *Retooling for an Aging America: Building the Health Care Workforce*. Washington, DC: National Academies Press, 2008.
- Reuben DB, Roth CP, Frank JC et al. Assessing care of vulnerable elders—Alzheimer's disease: A pilot study of a practice redesign intervention to improve the quality of dementia care. *J Am Geriatr Soc* 2008;58:324–329.
- Sweeting H, Gilhooly M. Dementia and the phenomenon of social death. *Sociol Health Ill* 1997;19:93–117.
- Taylor JS. On recognition, caring, and dementia. *Med Anthropol Q* 2008;22:313–335.
- Nishita CM, Wilber KH, Matsumoto S et al. Transitioning residents from nursing facilities to community living: Who wants to leave? *J Am Geriatr Soc* 2008;56:1–7.
- Rapp K, Lamb SE, Buchelle G et al. Prevention of falls in nursing homes: subgroup analyses of a randomized fall prevention trial. *J Am Geriatr Soc* 2008;56:1092–1097.