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Informed Consent to Research with Cognitively Impaired Adults: Transdisciplinary Challenges and Opportunities

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Abstract

Introduction—Due to issues related to informed research consent, older adults with cognitive impairments are often excluded from high-quality studies that are not directly related to cognitive impairment, which has led to a dearth of evidence for this population. The challenges to including cognitively impaired older adults in research and the implications of their exclusion are a transdisciplinary issue.

Discussion—The ethical challenges and logistical barriers to conducting research with cognitively impaired older adults are addressed from the perspectives of three different fields – social work, emergency medicine, and orthopaedic surgery. Issues related to funding, study design, intervention components, and outcomes are discussed through the unique experiences of three different providers.

Clinical Implications—A fourth perspective – medical research ethics – provides alternatives to exclusion when conducting research with cognitively impaired older adults such as timing, corrective feedback and plain language, and capacity assessment and proxy appointments. Given the increasing aging population and the lack of evidence on cognitively impaired older adults, it is critical that researchers, funders, and institutional review boards not be dissuaded from including this population in research studies.

Keywords

cognitive impairment; informed consent; older adults; transdisciplinary; ethics

Introduction

An estimated 2.4 to 5.5 million older Americans live with cognitive impairment (Plassman et al., 2008) in the United States (U.S.) and that number will increase in the coming decades (Hebert, Weuve, Scherr, & Evans, 2013). A number of high-quality, rigorous research studies aimed at providing effective health services specifically to these individuals exist (Hoffmann et al., 2015; Pieper et al., 2016; Sanchez et al., 2015; Telenius, Engedal, & Bergland, 2015) but unfortunately these studies are the exception rather than the norm.

Moreover, older adults with cognitive impairment are often purposefully excluded from research that does not specifically target them due to concerns about informed consent (Taylor, DeMers, Vig, & Borson, 2012). This has led to a dearth of evidence for this population, which limits the ability to improve the healthcare experience, costs, and outcomes for this population (Teodorczuk, Mukaetova-Ladinska, Corbett, & Welfare, 2015). The challenge of including cognitively impaired older adults in research and the implications of their exclusion are a transdisciplinary issue. Transdisciplinary research is meant to serve as a complement to discipline-based research and requires researchers explore questions at the intersections of their own disciplines and pursue joint research studies (Gray, 2008). Thus if investigators are to conduct transdisciplinary research on this issue, a better understanding of how cognitively impaired older adults impact each discipline is a critical first step. And given the increased call for transdisciplinary research, (Collins, Wilder, & Zerhouni, 2014; Dankwa-Mullan et al., 2010; Gehlert et al., 2010), this article offers three distinct disciplinary perspectives representing acute care, surgical management, and transitions of care between inpatient and outpatient settings with the purpose to examine 1) the ethical challenges and logistical barriers to including cognitively impaired older adults in meaningful clinical studies, 2) the impact of this on research output and the evidence upon which organizational guidelines, educational endeavors, and future research are based, and 3) offer potential alternatives for these fields. The sections below are organized in a way that represents the flow of a patient through a possible episode of care. It is a common scenario for a cognitively impaired older adult to sustain a fracture from a fall, be brought to the emergency room, admitted for orthopaedic surgery, then transitioned to a rehabilitation facility with the help of a social worker. Using this hypothetical case study as a guide, we attempt to highlight the missed opportunities and challenges to including these patients in research from three unique perspectives – emergency medicine, orthopaedic surgery, and social work. A fourth perspective – medical research ethics – concludes this article by suggesting alternatives to exclusion for this population. Through the analysis of these four perspectives researchers can begin to come together to address this issue from a transdisciplinary perspective.

Discussion

Emergency Medicine

Emergency medicine research often occurs in chaotic scenarios with potentially life-threatening healthcare problems occurring simultaneously in different patients spread across a department. Aging adults represent a uniquely challenging population for emergency medicine (McNamara, Rousseau, & Sanders, 1992), which has led to an increasing emphasis on quality indicators (Schnitker et al., 2015), medical education priorities (Hogan et al., 2010), policy statements (Hwang et al., 2013), and professional society guidelines (American College of Emergency, American Geriatrics, Emergency Nurses, Society for Academic Emergency, & Geriatric Emergency Department Guidelines Task, 2014). Older emergency department (ED) patients with acute delirium or unrecognized dementia represent approximately 10% and 30% of community dwelling older adults, respectively and the majority is never diagnosed (Carpenter, Bassett, et al., 2011; Carpenter, DesPain, Keeling, Shah, & Rothenberger, 2011; Han et al., 2009). Accordingly, developing feasible,

reliable, and accurate instruments and protocols to detect impaired cognition in older ED patients in order to optimize their acute management has been highlighted as top priority research by geriatric and emergency medicine organizations in conjunction with the National Institutes of Health (NIH) (Carpenter, Heard, et al., 2011; Carpenter, Shah, et al., 2011).

Since emergency medicine lacks any designated institute at the NIH, grants are often reviewed by study sections composed of content experts who have spent little time providing clinical care in the ED. This contributes to skewed perspectives of what can occur in acute care research. As a personal anecdote, the scientific review “summary sheets” for one study proposing to detect and promptly refer patients at increased risk for dementia stated the proposal “lack(ed) attention to the issues of obtaining informed consent for an intervention trial from a population who are cognitive impaired”, despite methods that followed contemporary subject assent and caregiver consent practices (Black, Rabins, Sugarman, & Karlawish, 2010). Although research involving cognitively impaired patients is challenging, these same patients receive clinical care that involves shared decision-making on a daily basis (Brindle & Holmes, 2005). Thus by rejecting studies such as the one mentioned above, the field of emergency medicine misses out on critical information about how to prepare for the increasing number of cognitively impaired older adults presenting to the ED.

One might wonder whether the emergency medicine grant experience is anomalous or rather representative of reactions to emergency research with cognitively impaired participants. Although no definitive reviews have explored the proportion of emergency medicine studies that purposely exclude cognitively impaired patients, ample evidence of such exclusions exist across studies. For example, geriatric falls are the leading cause of trauma-related mortality in older adults and the most definitive study of ED based fall prevention interventions is the Prevention of Falls in the Elderly Trial (PROFET), which excluded patients with cognitive impairment (Close et al., 1999). Although the PROFET authors do not provide a rationale for this exclusion, the assumption is that cognitively impaired patients would be less likely to remember recommended interventions, which could negatively impact compliance and limit investigators’ ability to measure a treatment benefit. In addition, falls research often depends upon self-report for subsequent falls and older adults already frequently forget falls (Cummings, Nevitt, & Kidd, 1988), so cognitively impaired patients might be expected to forget even more falls. (These possible reasons for exclusion can also be seen in orthopaedic surgery and social work research and the overarching thematic reasons for exclusion can be found in Table 1). By excluding these individuals from the trial, valuable information was lost related to what may be the common risk factors for falls in cognitively frail older adults thereby limiting research understanding about falls prevention.

Exclusion of cognitively impaired patients also occurs in emergency medicine studies of shared decision-making (Holland et al., 2016) and elder abuse (Eulitt, Tomberg, Cunningham, Counselman, & Palmer, 2014). Other studies do not exclude cognitively impaired subjects, but do not assess for it either (Koehler et al., 2009; Tanne et al., 2000), which limits clinician’s ability to extrapolate the findings to cognitively frail individuals.

Meaningful emergency research must also be generated in diverse clinical settings, including rural and urban sites, as well as academic and community hospitals (Coats & Goodacre, 2009). Undoubtedly, emergency clinicians in these diverse settings will require additional training to understand the principles and practice of ethical research (Lewis, Duber, Biros, Cone, & International Regulatory Status of Emergency Exception to Informed Consent Study, 2009). However, the need for additional training and the quick-paced, high acuity nature of emergency medicine should not dissuade researchers and medical ethicists from pursuing appropriate opportunities to better understand the path to more efficient, compassionate, and patient-centered emergency care, which is only possible through high-quality investigations. Thus as soon as our cognitively impaired older adult enters the healthcare system the barriers to including him or her in research are present.

Orthopaedic Surgery

As the U.S. population ages, falls and resulting orthopaedic injuries are projected to increase as well (Holroyd, Cooper, & Dennison, 2008). Population-based studies in this country are limited secondary to lack of a high-quality national database, but other countries with similar socioeconomic structures suggest a bleak picture for older adults who sustain falls and concomitant fractures with dementia (Wiklund et al., 2015). Recently, it has been suggested that up to 90% of hospitalizations in patients with dementia are related to falls (Harvey, Mitchell, Brodaty, Draper, & Close, 2015). Fractures about the hip are commonly studied, and for patients with dementia who sustain a hip fracture, dementia is independently associated with hip fractures (Wang et al., 2014). Thirty-day mortality is doubled (Khan, Hossain, Ahmed, Muthukumar, & Mohsen, 2013), and one-year mortality rates are roughly 1.5 times higher in patients with dementia than their comorbidity and age-matched peers without dementia (Maceroli, Nikkel, Mahmood, & Elfar, 2015).

Despite the significant burden of these injuries, many orthopaedic studies have excluded patients with cognitive impairment. For example, numerous randomized trials comparing two surgical treatments often exclude patients with cognitive impairment yet the results of these studies related to treatment selection are then applied clinically for patients with dementia (Hebert-Davies, Laflamme, Rouleau, Health, & investigators, 2012). Trials testing the effect of interventions to improve adherence post-surgery have also excluded cognitively impaired older adults (Rosal et al., 2011) meaning the field also lacks evidence to inform best-practices in post-op care. Although there is ample evidence that cognitively impaired older adults can report their preferences and quality of life (Jefferson et al., 2012; Johnson & Karlawish, 2015; S. Y. Kim, Appelbaum, et al., 2011; Miller, Whitlatch, & Lyons, 2014; Palmer et al., 2013; Reamy, Kim, Zarit, & Whitlatch, 2011, 2013), researchers' often believe these patients cannot accurately and reliably report quality of life outcomes and choose to exclude them based partly on this assumption (Hebert-Davies, Laflamme, Rouleau, Health, & investigators, 2012; Mundi, Chaudhry, & Bhandari, 2014). An interest in improving care in this population has prompted the development of multi-disciplinary inpatient teams to manage fragility fracture hospital admissions. Early outcomes are promising (Kelly & Kates, 2015), but long-term effects with meaningful functional outcomes are decidedly lacking, mostly secondary to study design. Many of these studies focus on cohorts of database-driven mortality results (Wiklund et al., 2015). Other studies are based on standard-of-care

paradigm shifts in consecutive patient cohorts (Della Rocca et al., 2013), focusing on in-hospital mortality, complications, and re-admissions. These types of study design avoid the need for individual patient and caregiver consent; but they cannot replace randomized controlled trials. To develop the highest levels of evidence for orthopaedic surgery (e.g., Cochrane's level I), it will be necessary to conduct studies requiring prospective informed consent (Prestmo et al., 2015). Again, our hypothetical patient is unlikely to be included in research at this stage in his or her episode of care and because patients are often identified for research by their presenting illness or injury this is a critical stage to miss patients.

Social Work

The field of social work is often dedicated to working with marginalized patient populations and linking patients to community resources, which has led social work to play an integral role in discharge planning and care transitions (Whitaker, Weismiller, Clark, & Wilson, 2006). Facilitating care transitions for cognitively impaired older adult patients is vital for the well being of patients and their caregivers. Cognitively impaired older adults are at higher risk than their counterparts for hospital readmission and negative outcomes during a care transition (Daiello, Gardner, Epstein-Lubow, Butterfield, & Gravenstein, 2014). This is in part due to the unique needs of these patients and the unique challenges of providing transitional care for them. Patients and their caregivers report the need for transitional care that addresses not only the acute problem but also the cognitive impairment (Naylor et al., 2007; Naylor, Stephens, Bowles, & Bixby, 2005). This includes managing agitation, resistance, confusion, and memory loss, all of which may result in difficulty adhering to the discharge plan (Epstein-Lubow, Fulton, Gardner, Gravenstein, & Miller, 2010). Some common challenges to providing transitional care for cognitively impaired older adults include the patient's limited understanding of discharge instructions and difficulty arranging and implementing aftercare services that will accommodate the patient's cognitive impairment and possible associated behavioral disturbances. Again, these issues are summarized in Table 1 below. Transitional care interventions reduce readmission rates and medication errors, and improve patient and caregiver satisfaction (Shepperd et al., 2013). These interventions often include educational components such as reviewing medication instructions and symptom recognition (Hansen, Young, Hinami, Leung, & Williams, 2011) and work to engage patients in taking an active role in their transitions and health management (Coleman, Parry, Chalmers, & Min, 2006).

However, a majority of studies evaluating these interventions excluded cognitively impaired older adults from their samples. And while the issues mentioned earlier relate to social work practice, the field of social work is dedicated to providing evidence-based practice and thus if the evidence excludes this population then social work practitioners cannot provide evidence-based care to this population.

A report by the Agency for Healthcare Research and Quality found that among transitional care interventions one of the most common reasons for exclusion was the presence of cognitive impairment or dementia (Rennke et al., 2013). These exclusions have numerous implications. The specific and complex needs of this population mentioned above are not being addressed in the design of these interventions and the efficacy of these interventions is

not being tested with this population. If these interventions have been designed to only address patients' acute illness needs they will not be reliably effective for cognitively impaired older adults in whom dementia-related issues also need to be addressed. Likewise, if key components to effective interventions include patient engagement and education then it should be no surprise when these interventions fail to demonstrate similar outcomes among cognitively impaired older adults.

Furthermore, while these issues relate directly to the field of health social work and transitional care, they are emblematic of the broader challenge of providing high-quality, effective care to cognitively impaired older adults and their caregivers. This challenge plagues other facets of social work such as clinical practice, where the caregivers of cognitively impaired older adults often seek help for anxiety and depression caused by their caregiving burdens (Covinsky et al., 2003; Eters, Goodall, & Harrison, 2008; Schulz & Martire, 2004; Schulz, O'Brien, Bookwala, & Fleissner, 1995), and community social work, where social workers must identify and refer, organize, and manage services for cognitively impaired older adults. One of the hallmarks of social work practice is the biopsychosocial assessment (National Association of Social Workers, 2005), a holistic assessment of a person's major physical, psychological, and social issues, and it is evident that social workers in these and other roles must acknowledge and address a cognitive impairment as it relates to these issues not only for the person with the impairment but also the caregiver. Thus the need for generalizable evidence that social workers can use to effectively treat and advocate for their clients is clear. And once again, as our hypothetical patient exits the hospital they are excluded from research studies and given that these patients are at an increased risk for readmission and that interventions targeting discharge planning can reduce readmissions, this failure on the part of the researcher and academic institution has significant consequences.

Clinical Implications

Exploring Ethical Solutions for Consent

Understanding and appreciation of information about a treatment or study is essential to voluntary informed consent (Grisso & Appelbaum, 1998). When individuals fail to understand and appreciate consent information, one option is to exclude them from participation. However, as the above sections on emergency medicine, orthopaedic surgery, and social work interventions indicate, such an approach may deny individuals access to potentially beneficial research studies and may compromise the quality of data about aging populations limiting external validity.

One commonly used approach to addressing this dilemma involves screening potential participants for decisional capacity. The University of California, San Diego, Brief Assessment of Capacity to Consent (UBACC) is one example of a validated instrument for assessing understanding and appreciation of study information. It requires only 5 minutes to administer; research assistants can be trained to use it with excellent inter-rater reliability; and it correlates strongly with other measures of decisional capacity, including expert ratings of psychiatrists. (Jeste et al., 2007) When using such an instrument, individuals who score below a threshold (e.g., a 14 on the UBACC) may be excluded from participation. Other

validated instruments for assessing capacity to consent to research exist (Dunn, Nowrangi, Palmer, Jeste, & Saks, 2006; Karlawish, 2008), including the MacArthur Competence Assessment Tool for Clinical Research, which uses hypothetical vignettes that may reduce relevance when screening participants for enrollment in a study, but enhances the ability to compare findings across diverse clinical research settings (Appelbaum & Grisso, 2001).

Such a screening approach can be appropriate when used correctly, but there are at least two potential risks. First, it is stigmatizing to screen for decisional capacity when screening is done only with groups deemed likely to lack decisional capacity (DuBois et al., 2012). Second, those who score low on an assessment of decisional capacity are often capable of demonstrating adequate understanding if researchers would take the time to pursue options other than exclusion (Flory & Emanuel, 2004; Nishimura et al., 2013). Such options may at once respect the need for informed consent, avoid stigmatizing groups, and enable research participation under a broad range of conditions.

Option 1: *Timing*—Cognitive impairments—particularly those associated with aging—frequently wax and wane. Accordingly, one option is to time the informed consent discussion for a “good day,” a time when the individual demonstrates adequate understanding (DuBois, 2008). This approach is well suited to short-term interventions. However, it may prove inadequate in longer-term studies that require ongoing consent for interventions that might require re-consenting patients as new information about risks and benefits becomes available. It may also be unfeasible in emergency medicine settings because patients are often seen only once for a brief period of time (Cairns et al., 2010). It may also be complicated when participants refuse participation (or dissent on a “bad day”) after having provided informed consent; this is particularly problematic, as informed consent for ongoing participation is generally understood to be something an individual can withdraw at any time in a study, and most informed consent forms explicitly grant this right to participants (Prentice, Applebaum, Conley, & Carpenter, 2007).

Option 2: *Corrective Feedback and Plain Language*—Sometimes we blame a lack of understanding on participants, when in fact the communication process was inadequate. Studies have found that use of a simplified consent form—one using figures and plain language—can improve understanding (Dunn & Jeste, 2001; Kim & Kim, 2015). Others have found that an iterative process of assessing understanding, identifying areas of misunderstanding, and providing corrective feedback can lead to significant improvements in the understanding and appreciation of information (DuBois, Bante, & Hadley, 2011; Nishimura et al., 2013). However, as cognitive impairments grow more severe, such an approach may be inadequate.

Option 3: *Assess Capacity to Appoint a Proxy*—A final approach involves appointing a proxy decision-maker, frequently a family member or caregiver. Studies have found that a majority of older adults support allowing a proxy to make decisions for them regarding research participation (De Vries et al., 2013; Kim, Karlawish, et al., 2011; Kim et al., 2009). Moreover, a recent study of participants with Alzheimer’s disease found that 55% of those incapable of deciding to participate in a neurosurgical trial retained the capacity to appoint a surrogate; this makes sense because such a decision involves significantly less

complicated information than a clinical trial (Kim, Karlawish, et al., 2011; Kim & Appelbaum, 2006). Proxy permission ordinarily also requires patient assent—or at least the absence of dissent, which as discussed above, can complicate matters (Alzheimer's Association, 2004; Black et al., 2010; De Vries et al., 2013). However, IRBs may allow continued participation in research, particularly if risks are only a minor increase over minimal risk or if the study presents the prospect of direct benefit and a legally authorized representative has granted consent for participation (Saks, Dunn, Wimer, Gonzales, & Kim, 2008).

These options and when they may be appropriate alternatives when faced with the general reasons for exclusion highlighted earlier are summarized in Table 1.

Next Steps

While this article presents the disciplines representative of the authors, other disciplines have struggled with this issue for decades and as a result have more guidance on how to overcome the issue and we encourage the professionals in our own fields of emergency medicine, orthopaedic surgery, and social work to seek out and employ when applicable the evidence put forth by these other disciplines. For example, the fields of neurology and nursing, for example, certainly face this challenge and have published a great deal of literature on ways to assess capacity and provide and obtain informed consent from this population (Buckles et al., 2003; Karlawish et al., 2013; Marson, Dymek, & Geyer, 2001; Mayo & Wallhagen, 2009; Rikkert, Lauque, Frolich, Vellas, & Dekkers, 2005; Slaughter, Cole, Jennings, & Reimer, 2007; Stocking, Hougham, Baron, & Sachs, 2003). This issue is also a central focus, perhaps even more so than the previously mentioned fields, of the fields of psychology and psychiatry, which have done significant work in the area (Dunn, Nowrangi, Palmer, Jeste, & Saks, 2006; Edelstein, 2000; Lai & Karlawish, 2007; Moye & Marson, 2007; Moye, Marson, & Edelstein, 2013). These professions not only face this issue in conducting their own research but also are best suited for identifying the necessary tools for assessing individuals' capacity to provide informed consent (Moye et al., 2007; Palmer et al., 2005) and assisting individuals' in understanding instructions and directions of interventions and reporting follow-up outcomes (Logsdon, Gibbons, McCurry, Teri; 2002). There is also information available from the Alzheimer's Association that provides investigators and human subjects protection officers with guidance on how to handle this issue (Alzheimer's Association, 2004).

However, despite the evidence put forth by these other fields and organizations, the fields of emergency medicine, orthopaedic surgery, and social work continue to struggle with this issue, which suggests a lack of dissemination and uptake of the solutions proposed by these other fields and organizations. This is confirmed by the variation in IRBs practices related to surrogate consent processes (Gong, Winkel, Rhodes, Richardson, & Silverstein, 2010).

We note a shortage of articles that explicitly state the challenges researchers have faced on this issue with regard to specific studies and the unique solutions they used to overcome them. In order to improve the process of assessing for capacity and obtaining informed consent from cognitively impaired older adults, it is critical that common challenges and solutions are identified and reported in detail so that other studies can learn from and

replicate successes. One potential place to report this information is study protocols, which an increasing number of journals are beginning to publish to aid in the overall transparency and replication of research. This would also serve to educate grant reviewers and other gatekeepers of the research enterprise.

Conclusions

The exclusion of cognitively impaired older adults from research is a transdisciplinary issue that has left a vulnerable population without a strong evidence base from which providers can draw. While a fundamental shift in the perspectives of funders and IRBs is needed, until that shift happens investigators can advocate for the inclusion of this population in studies by proposing alternatives to exclusion such as the options outlined above. Furthermore, as investigators and funders aim to conduct transdisciplinary research, a better understanding of how this issue distinctly affects different disciplines can help investigators collaborate and overcome these challenges. The authors hope this article will bring attention to the detrimental repercussions of excluding cognitively impaired older adults and spark discussion on how to include these individuals in future research.

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Table 1

Possible Reasons for Excluding Cognitively Impaired Older Adults from Research Studies and Potential Alternatives

Reason	Examples	Potential Alternatives
Inability to consent to participate in research study	Patient has dementia or other cognitive impairment listed in medical history thus researchers automatically exclude patient.	<ul style="list-style-type: none"> • Screen patient for decisional capacity before deciding to exclude. • If there is time, try screening and assessing capacity at different times of the day to avoid the possible fluctuation of cognitive impairment. • Ask the IRB prior to beginning the study for the option to allow for the appointment of a proxy if it is deemed the patient cannot consent for themselves.
Inability to follow intervention instructions	Patient has cognitive impairment and it is assumed he or she will not be able to follow the intervention instructions.	<ul style="list-style-type: none"> • Ahead of time adapt intervention protocol and/or materials using plain language • Use procedures such as corrective feedback and teach-back to ensure patient understands intervention
Inability to report outcomes	Patient has cognitive impairment and it is assumed he or she will not be able to complete follow-up assessments and report outcomes.	<ul style="list-style-type: none"> • Ahead of time choose alternative outcome measures that have been adapted for cognitively impaired individuals such as the Bristol Activities of Daily Living Scale (Bucks, Ashworth, Wilcock, & Siegfried, 1996).