Received: 4 January 2022 | Revised: 6 June 2022 | Accepted: 7 June 2022

DOI: 10.1002/emp2.12774

JACEP OPEN
JOURNAL OF THE AMERICAN COLLEGE OF EMERGENCY PHYSICIANS OPEN
A GLOBAL JOURNAL OF EMERGENCY MEDICINE
Open Access
WILEY

SYSTEMATIC REVIEW-META-ANALYSIS

Geriatrics

Inclusion of older adults and reporting of consent processes in randomized controlled trials in the emergency department: A scoping review

Lauren T Southerland MD[1] | Katherine K. Benson[2] | Austin J. Schoeffler[2] | Margaret A. Lashutka[1] | Soo Borson MD[3] | Jason J. Bischof MD[1]

[1]Department of Emergency Medicine, The Ohio State University Wexner Medical Center, Columbus, Ohio, USA

[2]The Ohio State University College of Medicine, Columbus, Ohio, USA

[3]Department of Family Medicine, Keck School of Medicine University of Southern California, Los Angeles, California, USA

Correspondence
Lauren T. Southerland, MD, Department of Emergency Medicine, The Ohio State University Wexner Medical Center, 725 Prior Hall, 376 W 10th Ave, Columbus, OH 43210, USA.
Email: Lauren.Southerland@osumc.edu

Presentations: Submitted for presentation at American Geriatrics Society, May 2022, Orlando FL.

Funding information
National Institute on Aging, Grant/Award Number: K23AG061284; College of Medicine Office of Research, Ohio State University

Abstract

Objective: Conducting research in the emergency department (ED) is often complicated by patients' acute and chronic illnesses, which can adversely affect cognition and subsequently capacity to consent for research, especially in older adults. Validated screening tools to assess capacity to consent for research exist, but neither the frequency of use nor which ones are used for ED research are known.

Methods: We conducted a scoping review using standard review techniques. Inclusion criteria included (1) randomized controlled trials (RCTs) from publication years 2014–2019 that (2) enrolled participants only in the ED, (3) included patients aged 65+ years, and (4) were fully published in English. Articles were sourced from Embase and screened using Covidence.

Results: From 3130 search results, 269 studies passed title/abstract and full text screening. Average of the mean or median ages was 55.7 years (SD 14.2). The mean number of study participants was 311.9 [range 8–10,807 participants]. A few (n = 13, 4.8%) waived or had exception from informed consent. Of the 256 studies requiring consent, a fourth (26.5%, n = 68) specifically excluded patients due to impaired capacity to consent. Only 11 (4.3%) documented a formal capacity screening tool and only 13 (5.1%) reported consent by legally authorized representative (LAR).

Conclusions: Most RCTs enrolling older adults in EDs did not report assessment of capacity to consent or use of LARs. This snapshot of informed consent procedures is potentially concerning and suggests that either research consent processes for older patients and/or reporting of consent processes require improvement.

KEYWORDS
capacity, research consent, emergency department, older adults, geriatrics

Supervising Editor: Henry E. Wang, MD, MS.

1 | INTRODUCTION

1.1 | Background

Informed consent is the cornerstone of the ethical conduct of research. Clinical research on human participants requires informed consent to ensure patients understand the purpose, risks, and benefits of studies before enrolling.[1] Requirements for informed consent are study specific and defined by the risks associated with the research. Institutional review boards (IRBs) determine whether a study (1) meets criteria for waiver of informed consent, (2) requires written or verbal informed consent, or (3) is granted an exemption of informed consent. During recruitment, study investigators must follow the consent determinations of the IRB and also consider each potential participants' individual capacity to consent.

Patients in the emergency department (ED) are at higher risk for impaired capacity to consent. Grave injury, altered consciousness, intoxication, and impaired cognitive function affect decisional capacity and are all common in ED patients.[2,3] For example, dementia affects 21%–43% of older adults in the ED.[4–6] Although cognitive impairment or dementia do not directly imply that a person has impaired capacity, they often do and, at minimum, they can complicate the understanding of consent information.[7,8] Many IRBs consider older adults (adults ≥ 65 years old) a potentially vulnerable population and may request adjustment of consent forms, formal assessment of capacity with tools, or the use of legally authorized representatives (LARs).[9–11]

1.2 | Importance

Multiple tools to assess capacity to consent to research exist. These include the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) and the University of California, San Diego Brief Assessment of Capacity to Consent (UBACC).[12] However, we do not know how often these tools are used in ED research enrollment, which tools are used, or the current practices of consent reporting and inclusion of older adults in ED research. Understanding current practice in published trials could help inform investigators in the development of ED studies that comply with the 2019 National Institutes of Health Inclusion across the Lifespan mandate.

1.3 | Goals of this investigation

In this scoping review, we assessed how randomized controlled trials (RCTs) that enrolled older patients (≥65 years) in EDs reported potential participants' capacity to consent.

2 | METHODS

2.1 | Study design

The study authors adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-SCR). The studies of interest were RCTs that enrolled patients in EDs only, were published in English from 2014 to 2019, and enrolled patients ≥65 years. The review was limited to the prior 6 publication years (2014 to 2019) both because our focus was on current practice in research and because capacity assessment tools have gained acceptance into research practice only in the past decade.[12] The review protocol was developed with the guidance of a health sciences research librarian. The articles that passed screening were analyzed to extract data on study characteristics, consent procedures, and enrollment data. Four reviewers were involved in protocol design, screening of studies, and data extraction. As this paper is a scoping review, it was not eligible for registration on PROSPERO, the international prospective register of systematic reviews.

2.2 | Information source

We selected Embase to source articles because it covers studies in international and drug/pharmacy journals as well as Medline. As this is a scoping review, no additional databases or repositories (such as grey literature) were included. The search was performed on June 21, 2020 using a strategy designed to broadly locate all English language RCTs involving EDs within the publication years 2014–2019, while excluding conference abstracts. The search string used in Embase was: [("emergency department"/exp OR "emergency department" OR "emergency room"/exp OR "emergency room" OR "emergency unit"/exp OR "emergency unit" OR "emergency ward"/exp OR "emergency ward") AND [english]/lim AND [2014–2019]/py AND ("randomized controlled trial"/exp OR "randomized controlled trial") NOT "conference abstract"/it]. After sourcing the raw pool of studies from the Embase search, we imported them into Covidence (Veritas Health Innovation Ltd, VIC Australia) for screening.

2.3 | Eligibility criteria and definitions for article screening

The eligibility criteria were: design (RCT); online or print publication date (January 1, 2014–December 30, 2019); full text available in English; completeness (full publications, not method only or abstract only); enrollment location (patients enrolled from EDs); and subjects (studies including significant numbers of older adults, see exclusion criteria). For the purposes of this scoping review, an "RCT" was any randomized trial where one or more interventions was prospectively compared to 1 or more standard therapies or placebo in the care of human patients. Additionally, we defined "emergency departments" (EDs) to include any studies that consented participants exclusively in emergency rooms, emergency fast track units, trauma bays, cardiac catheterization labs (if part of the ED), or any other wing of an emergency medicine care unit. This excluded ICUs, inpatient hospital wings, in-ambulance care, primary care community centers, outpatient clinics, urgent care centers, nursing homes, and so on. Any study in which some or all patients were enrolled outside of an ED setting was excluded. The

location of the study interventions could be in the ED or elsewhere as long as consent occurred in the ED setting.

We developed quantifiable criteria to evaluate whether studies included at least some older adults. Studies that did not exclude older adults in their methods were included in the review if (A) the age range of participants in the methods was reported and extended to >65 years, or (B) the age range of participants was *not* reported in the methods but the upper age range of the study group was >65. When no age ranges were reported, the study team developed an estimation of whether older adults were included using the mean or median age of participants. We assumed that if the mean + 1 SD of ages was ≥55 years and the study had no exclusions to enrolling older adults, then likely some participants >65 were enrolled. Similarly, if median and interquartile range (IQR) only were reported, then studies with median + IQR ≥55 were included. Our goal was to include any RCT that probably recruited older adults. No study that explicitly excluded older adults was included.

2.4 | Title/abstract screening

We first identified possible duplicates using the duplicate detection feature in Covidence and then manually excluded duplicates. The remaining studies were sent to title/abstract screening. The exclusion criteria for title/abstract screening were "not fully published" (eg, article was a conference abstract or a study protocol); "wrong study design" (article was not reporting an original RCT study; secondary data analyses of RCTs were excluded, but these papers were examined to ensure inclusion of the primary publication if indicated); "wrong publication years" (eg, study was not published 2014–2019); "wrong setting" (the study was not enrolling patients exclusively within an ED setting); "wrong age group" (eg, the title or abstract explicitly excluded adults over 65); and/or "not published in English" (although studies published in both English and other languages were included).

At the start of title/abstract screening, 3 reviewers (LS, KB, and AS) performed group screening decisions on ~100 articles to ensure interrater consistency. The reviewers all had training in reading medical literature (LS is an emergency physician and KB and AS are medical students). After this initial meeting, the remaining studies were divided among the 3 reviewers for title/abstract screening (one reviewer per study). If a reviewer found a study with unclear eligibility, a second reviewer provided input. If it was unclear whether to exclude the study based on title and abstract alone, the article was included for full text screening.

2.5 | Full text screening protocol

We had university access to Embase, Ovid, Scopus, and multiple journals through our institution to find and upload full text PDFs into Covidence. If a full text PDF for a study could not be located online after searching these and using PubMed, Google searches, and online hosting sites (such as author's institutional webpage), we contacted the corresponding author via email to request it. If no response was received from the author after 2 weeks, the article was excluded from the review. Only 6 articles were excluded from the final analysis for lack of full text availability.

Each article was independently reviewed by 2 reviewers. If there was disagreement about whether to include a study *or* which exclusion criterion should be used to exclude a study, a third reviewer independently resolved the conflict. Articles that passed full text screening proceeded to data extraction.

2.6 | Data extraction

All reviewers underwent an hour of training on data abstraction using a standardized data abstraction sheet. During training a data dictionary was created. We reviewed the entire manuscript as well as any supplemental data, appendices, or previously published study protocol manuscripts. Ten percent of studies were reabstracted independently. Data extraction variables included study name, first author, year of publication, country where the study was performed, age range of study participants, mean or median age of study participants, whether informed consent procedures were reported, whether informed consent was waived or exempt, reason for waiver/exemption if applicable, whether informed consent was verbal or written or both, whether a decisional capacity assessment tool was reported, and the type of assessment tool used (if applicable). Additionally, the abstractors dichotomized the studies into higher and lower risk. Higher risk studies randomized patients to a medication, drug, or invasive device or intervention. An invasive device or intervention was defined as a device, surgical, or procedural intervention that involved more than minimal risk. Variations on a normal clinical procedure that did not increase the baseline risk of that procedure were not included. For example, a comparison of 2 tourniquet techniques for peripheral venipuncture would be a lower risk study. If there was no SD, IQR, or age range available for extrapolation, the corresponding authors were contacted via email to request additional age information. If there was no response after 2 weeks, the reviewers were unable to extract an age range for those studies (n = 5 studies).

We broadly defined "reporting of informed consent procedures" as any mention of obtaining consent, procedures to obtain consent (such as "consent was obtained during the ED stay"), waiver of consent, or mention that patients were excluded if they declined to consent. Informed consent procedures could be mentioned anywhere in the article and were not restricted to the methods section. The reviewers also extracted whether the study documented excluding subjects who lacked capacity to consent. This was considered documented if (1) lack of decisional capacity was part of exclusion criteria; (2) capacity to consent was part of the inclusion criteria; (3) if anywhere in the text, the CONSORT patient diagram or other study flow diagrams patients were excluded for delirium, dementia, or lack of capacity to consent; or (4) LARs were used to include patients who lacked capacity to consent. The use of LARs in the consent process was considered reported if a study mentioned approaching LARs or seeking proxy consent from a family

member or next of kin to provide consent for those who lacked capacity to consent.

2.7 | Data analysis

The data were analyzed using Stata (version 17, StataCorp LLC). The primary outcomes for this scoping review are counts or proportions of studies in each category. We performed a subgroup analysis of the studies conducted in the United States to assess for possible between-country differences in research regulation.

3 | RESULTS

3.1 | Study selection

The search strategy identified 3130 studies for potential inclusion. Twenty-nine duplicates were excluded. The remaining 3101 studies underwent title/abstract screening (Figure 1). The reviewers excluded 2387 studies not meeting inclusion criteria, and the remaining 709 studies underwent full text screening. We identified 465 RCTs that recruited only in the ED. Out of these studies, around a fifth (19.6%, n = 91) were designed to exclude older adults (age limit extended to < 65 years). In 22.6% (n = 105), older adults were not included to any significant degree (no age range was given and mean + SD or median + IQR was <55 years). The remainder (57.8%, n = 269) included older adults and, therefore, met inclusion criteria for this review (listed in Appendix A). For a list of studies excluded at the full text screening level and rationale for exclusion, see Appendix B.

The reviewers met serially during data abstraction to ensure consistency and resolve any queries. The IRB determination was independently double extracted for every study. Agreement was 98% with a kappa of 0.86. Forty studies (15%) underwent independent dual review to assess interrater reliability on all variables. Abstractors had excellent agreement on whether consent information was present and on whether a capacity screening tool was used (39/40, or 97.5%). Agreement on mean/median age was 97.3% (36/37 that included extractable mean age). Kappa values were not computed for these outcomes due to high agreement. Agreement on country of study origin was 87.5% (35/40), and disagreement was mainly due to 1 reviewer mistaking journal country of origin for country in which the study was conducted, which was then corrected.

3.2 | Study description

The 269 studies were conducted in EDs worldwide: 33.5% (n = 90) were from North America, 21.9% (n = 59) from Africa and Middle East, 21.6% (n = 58) from Europe, 10.7% (n = 29) from Australia and Pacific Islands, 8.9% (n = 24) from Asia, 1.5% (n = 4) from South America, and a few (1.9% n = 5) spanned multiple countries and continents (Figure 2). Study participants ranged in age from 0.3 to 102 years. Average of the mean or median ages was 55.7 years (SD 14.2). The mean number of study participants was 311.9 [range 8–10,807 participants].

3.3 | Study consent procedures

Consent was waived for 8 studies due to minimal risk[13–20] and 5 studies (1.9%) were given exception from informed consent due to research on time-sensitive, life-threatening conditions (Table 1).[21–25] In 1 study with waiver due to minimal risk, if patients were alert or an LAR was available consent was obtained.[13] In total, 13 studies (4.8%) did not require informed consent and 4 of these still reported attempts to obtain consent if possible.[13,22,24,25]

Nine studies (3.3%) did not describe consent procedures. These articles were presumed to have required consent and included in the analysis as informed consent. For example, although 2 of these studies did not report any information on the consent process, they did report lack of capacity to consent as an exclusion criterion.[26,27] Similarly, another study did not report consent procedures but did list a low Mini-Mental State Exam (MMSE) score as an exclusion criterion.[28] It was not reported whether this was found during screening of medical records or performed by the research team at the time of attempted consent.

Of the 256 studies requiring consent, 70.7% (n = 181) reported written consent, 1.2% (n = 3) both written and oral consent, 1.6% (n = 4) oral consent only, and 26.5% (n = 68) did not specify the type of consent. Thirteen (5.1%) allowed for proxy consent by LAR. One of these did not document excluding anyone for lack of capacity to consent or discuss criteria for use of an LAR.[29]

3.4 | Capacity to consent

Of the 256 studies without a waiver or exemption, 73.0% (n = 188) did not document excluding patients who lacked capacity to consent. Only 11 (4.3%) documented use of a formal screening tool (Table 2). General cognitive screening tools were the most commonly used: the MMSE[30] (4 studies used the full version[28,31–33] and one used an "abbreviated" version[34]), the Three Step Command Test[35] (1 study[36]), and the General Practitioner Assessment of Cognition (GPCOG)[37] (1 study[38]). Four studies used tools designed to identify decisional capacity issues for research: the Decision-making Capacity and Comprehension Assessment[39] (1 study[40]) and the Six-Item Screener[41] (3 studies[42–44]).

3.5 | Subgroup analyses

To reduce concerns of variability in research consent requirements across countries, the 81 studies completed in the United States were analyzed as a subgroup. Three (3.7%) did not report any consent information.[45–47] Five (6.2%) were done under a waiver of consent for minimal risk and 1 study of patients seizing with altered mental status

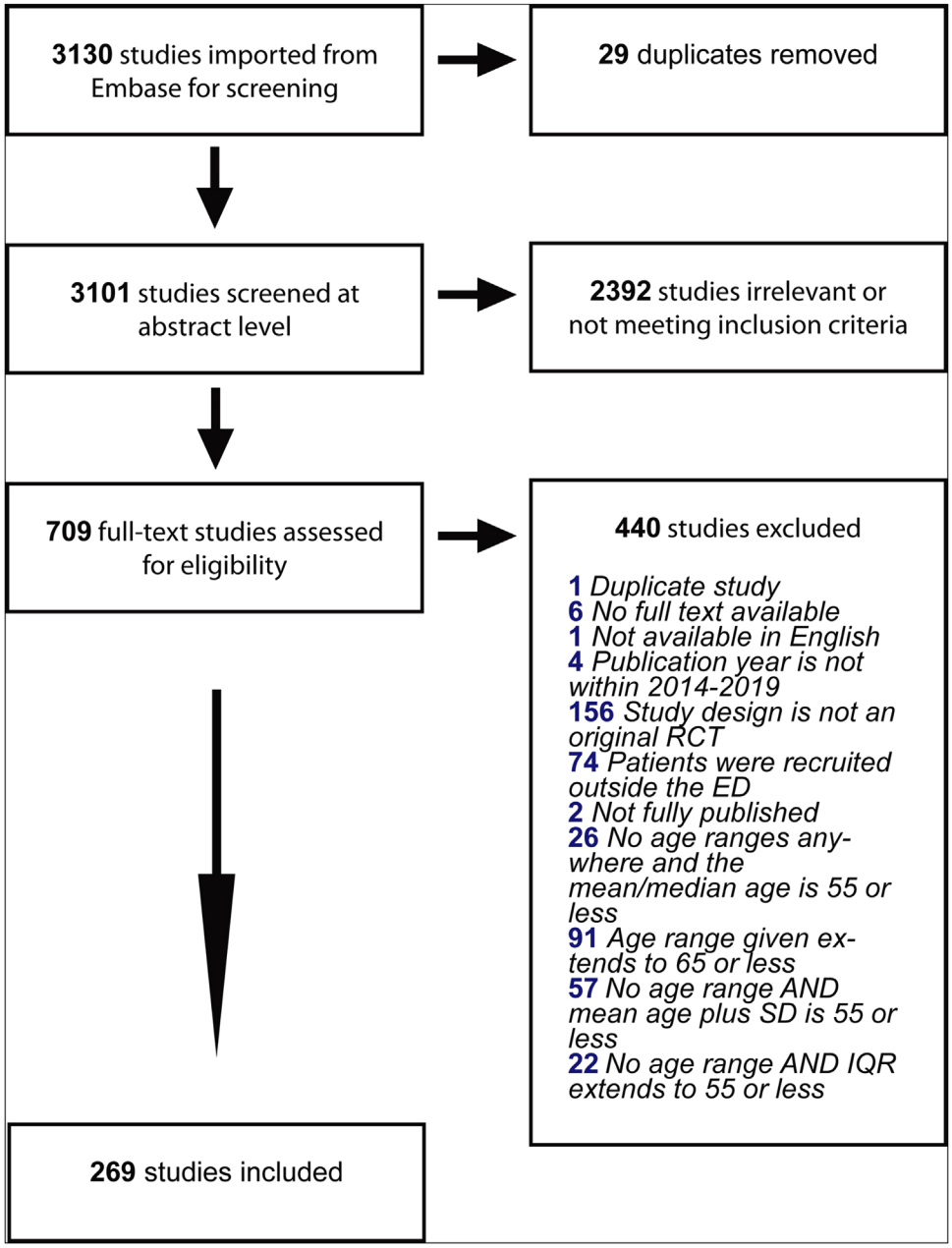

FIGURE 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) review flow diagram

TABLE 1 Documentation of the use of capacity screening tools and legally authorized representatives in consent process of randomized controlled trials that recruited older adults in the emergency department

Type of consent required	Number of studies	Studies reporting excluding patients who lack capacity to consent [n, %]	Studies that used a capacity screening tool [n, %]	Studies allowing consent by legally authorized representative [n, %]
Informed consent	256	68 (26.5%)	11 (4.3%)	13 (5.1%)
Waiver of consent for minimal risk	8	1 (12.5%)	0	1 (12.5%)
Exemption from informed consent	5	2 (40%)	0	3 (60%)
Total	269	71 (26.4%)	11 (4.1%)	17 (6.3%)

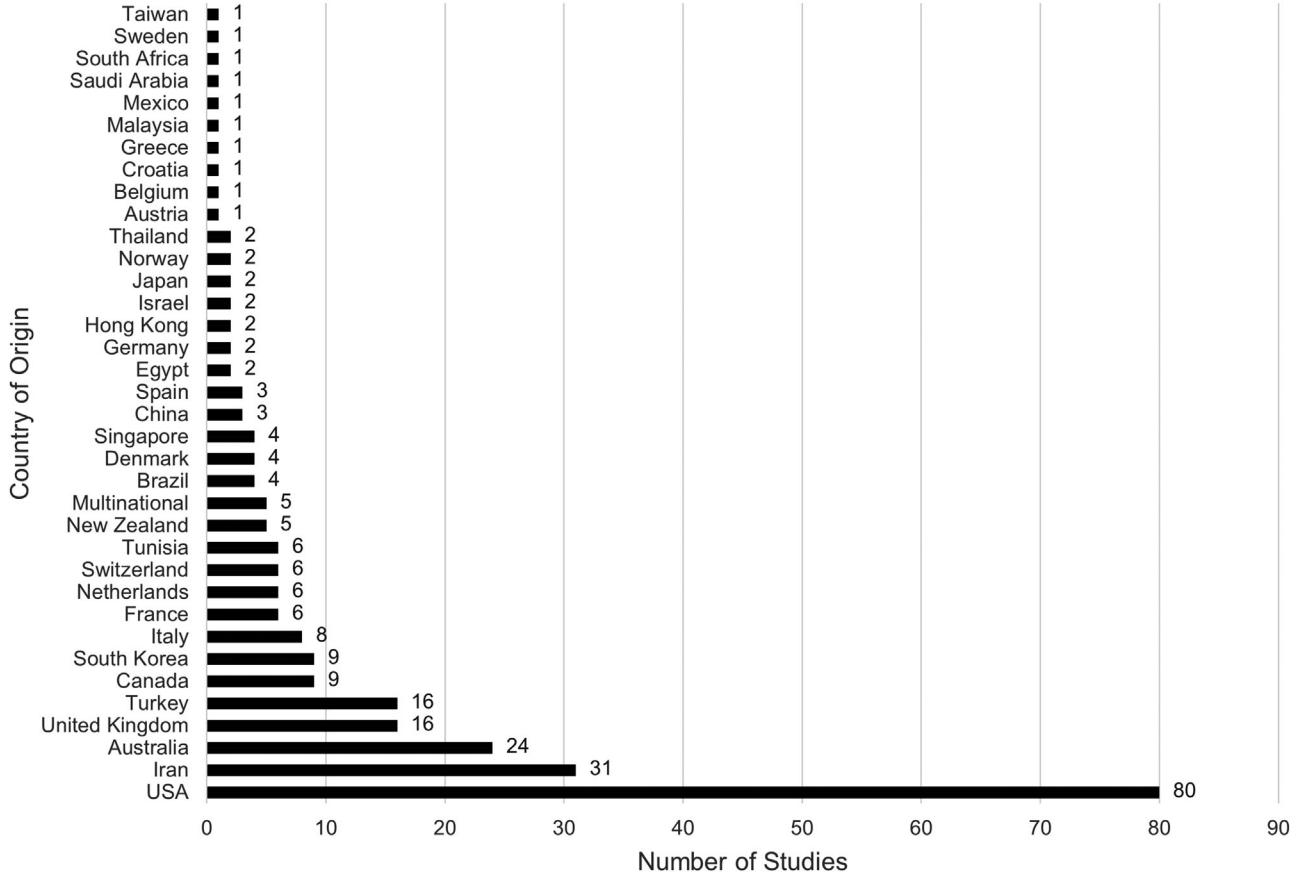

FIGURE 2 Country of origin of randomized controlled trials recruiting older adults in the emergency department, 2014–2019

was done under exception from informed consent.[25] Of the US studies requiring consent (n = 74), 5 (6.8%) documented use of a capacity screening tool and 4 (5.4%) documented use of a LAR for patients without capacity to consent. Non-US studies (n = 182 required consent) were similar, as 6 (3.3%) documented use of a capacity screening tool (chi square $p = .23$) and 9 (4.9%) documented use of a LAR (chi square $p = .88$).

Within the 256 studies requiring informed consent, higher risk studies (n = 134) were not more likely to use a capacity screening tool (5.0% vs. 4.0% for lower risk, chi square $p = .74$) or report excluding potential participants who lacked capacity (27.2% vs. 26.0%, chi square $p = .82$). There was also no difference in the lack of consent information (3.0% vs. 3.7%, chi square $p = .79$).

4 | LIMITATIONS

This scoping review provides only a snapshot of RCTs enrolling in the ED. Our search strategies could have missed studies, but as the original search collected >3000 potential studies, we feel that our strategy was not overly narrow. Additionally, although the study team made every effort to reach out to authors to confirm data and obtain full texts, 6 studies were excluded due to lack of access to full text articles. However, this does not limit our main conclusions because even assuming all 6 articles used LARs and capacity assessment tools, the overall proportion of studies meeting these criteria would still be low.

5 | DISCUSSION

This is the first study analyzing the general practice of ED research consent. Even though most RCTs recruiting older adults did not have a waiver or exemption (and therefore were obtaining informed consent), formal assessment of capacity to consent was rarely reported. Documented use of cognitive or formal capacity screening tools or LARs was very low (5% of studies). This snapshot of informed consent procedures in emergency research is potentially concerning and suggests that either consent processes for older patients and/or reporting of consent processes requires improvement. A potential solution could be to include reporting of consent procedures and capacity assessment processes as part of the next update of the Consolidating Standards of Reporting Trials (CONSORT) guidelines.[48]

We must make clear that no evidence of unethical inclusion of research subjects was found in this scoping review. This review can only describe what was reported in manuscripts, which does not contain all the standard procedures of a study. Also because the differences in reporting were not attributable to 1 geographic area, study type (higher or lower risk), or specific research team, we suspect that the

TABLE 2 Screening tools used during the consent process in randomized controlled trials from 2014 to 2019 recruiting older adults in the emergency department

Screening tool name	Studies using the tool	Description of tool and considerations for use	Score required for study participation
MMSE (Mini-Mental State Exam)[30]	n = 4; Hao 2019; Chaudet 2015; Monti 2014; Barker 2019	Tests orientation, attention, memory, language, and visual-spatial skills. Requires a paid license to use for research.	Varied by study: • ≥17 • ≥18 • ≥23 • ≥27
Abbreviated MMSE	n = 1 Reavley 2015	Not described.	≥8/10
Six item screener[41]	n = 3 Biese 2014; Platts-Mills 2018; Morrison 2016	Tool designed to identify cognitive impairment among potential research subjects. Asks about year, month, day, and 5-min recall (Apple, Table, Penny) for a total of 6 pts possible. Score <4 is likely impairment.	≥4 required for consent, <4 required LAR.
General Practitioner Assessment of Cognition (GPCOG)[37]	n = 1 Fayyazi 2018	Tests date, clock draw, 5 min recall, and asks the person to relay a recent event in the news. Nine points total.	Score ≥5 included.
Three step command test[35]	n = 1 Matchar 2017	Asks the patient to do a 3-step command that crosses the midline. Considered a neurological test rather than a cognitive test.	Scoring not listed.
Decision-making capacity and comprehension assessment based on the aid to capacity evaluation[39]	n = 1 Bowers 2017	A semistructured clinical interview designed to assess the 4 elements of capacity when a patient is facing a medical decision. Instructions and training materials are available online.	≥80% or higher included.

Abbreviation: LAR, legally authorized representative.

lack of discussion of consent processes is a result of manuscript formats and word count limitations. Should editors trust that IRB approval sufficiently addresses the inclusion of adults with cognitive deficits, or should this be reported openly? We believe that the impact on internal validity of the research is great enough that this should be reported openly in research manuscripts.

Cognitive impairment in patients is frequently missed clinically, which suggests that it could also be missed during study recruitment. Delirium affects >10% of ED patients and is missed by clinicians in 50%–80% of cases[49,50] Cognitive impairment, which is different from acute delirium, also frequently goes unrecognized or unaddressed by emergency physicians.[51] In 1 study, 5.6% of older adults in the ED had a prior diagnosis of dementia, but 21.5% qualified as having dementia based on cognitive testing during their visit.[4] Unrecognized cognitive impairment in participants could affect participant recruitment, data validity, follow-up, patient-reported outcomes, and external generalizability.

This review does confirm that there is no clear standard or tool to assess capacity in use. Our review identified 5 different tools, only 2 of which were designed to assess capacity (Decision-making Capacity and Comprehension assessment and the Six Item Screener, Table 2). The others are assessments of cognition, which does not automatically translate into valid consent determinations.[52] However, assessments of cognition rather than capacity may be more informative as inclusion criteria for some types of studies, such as studies reliant on recall or educational interventions. Similarly, use of an LAR may not be appropriate for all studies. In an educational study, the patient will need to understand the education or recall events. Therefore, it is appropriate that we found differences in study design and risk reflected in the tools and consent processes. We recommend researchers report why (or why not) an assessment was chosen and how it was used to better describe the study population and improve reproducibility and generalizability.

A cognition or capacity tool for clinical research in the ED needs to have construct validity for its purpose and be feasible in a busy ED setting. Research consent may be interrupted by clinical care needs, or it may have to be swift because of the study timeline. Many ED interventions are time sensitive, especially for conditions such as stroke, infection, or trauma. The MMSE and Decision-Making Capacity and Comprehension Assessments are very lengthy (Table 2). The Six Item Screener and GPCOG are considerably shorter and test recall and orientation. We expected to find the MacCAT-CR, the UBACC, and the Mini-Cog in use, but no studies in our review used these tools.[2,53] Most of the studies using a tool (8/11) recruited only older adults, suggesting that researchers focused on this population may be more likely to understand and use capacity or cognitive tools. There is currently no standard decisional capacity assessment tool for research consent in the ED setting.

Older adults are already disproportionately excluded from clinical trials.[54] We do not want discussion on this topic to cause researchers to further unreasonably exclude cognitively impaired individuals from studies. That would reduce generalizability, potentially conflate cognition with decisional capacity, and bias results. Many IRBs have ethics consultants or participant protection teams to help guide researchers in designing studies that include older adults safely and transparently.

One limitation of this review is that we can only conclude that capacity assessments are rarely reported, not that they are rarely done in practice. It is possible that study authors and journal editorial boards feel that reporting consent practices in the manuscript is unnecessary as long as studies are listed in a clinical trial registry or have undergone review by an IRB. However, IRB practices can vary considerably from institution to institution and from country to country.[10,55–57] Reporting how studies protect vulnerable participant populations is also valuable information for study replication.

In conclusion, about half of ED RCTs include older adults, but there does not appear to exist a standard protocol for consent processes and most studies do not report how they assess capacity to consent. Researchers in the ED use a variety of tools to assess cognition or capacity, but further research is needed to see how these tools can best be incorporated into consent procedures.

ACKNOWLEDGMENTS

The authors recognize Stephanie J. Schulte, MLIS, Assistant Director of Research and Education at the Health Sciences Library at The Ohio State University, for her research librarian advice and services. Lauren T. Southerland was funded by NIA K23AG061284. Katherine K. Benson was supported in part by The OSU College of Medicine (Samuel J. Roessler Fund) Medical Student Research (MDSR) Scholarship program and the OSU Health Sciences Library for the use of Covidence.

CONFLICT OF INTEREST

The authors report no conflict of interest.

AUTHOR CONTRIBUTIONS

Lauren T. Southerland: Conceptualization, investigation, data collection, writing, formal analysis. Katherine K. Benson: Funding acquisition, methodology, data collection, writing, formal analysis. Austin J. Schoeffler: Conceptualization, methodology, data collection. Soo Borson: Conceptualization, expert opinion. Jason J. Bischof: Conceptualization, investigation, methodology. All members contributed to the review and editing process. Lauren T. Southerland and Katherine K. Benson are responsible for data integrity. Dr. Southerland takes final responsibility for the article.

ORCID

Lauren T Southerland MD https://orcid.org/0000-0002-3561-8332

TWITTER

Lauren T Southerland MD https://twitter.com/@LSGeriatricEM

REFERENCES

1. World Medical Association. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *JAMA*. 2013;310:2191-2194.
2. Martel ML, Klein LR, Miner JR, et al. A brief assessment of capacity to consent instrument in acutely intoxicated emergency department patients. *Am J Emerg Med*. 2018;36:18-23.
3. Smithline HA, Mader TJ, Crenshaw BJ. Do patients with acute medical conditions have the capacity to give informed consent for emergency medicine research? *Acad Emerg Med*. 1999;6:776-780.
4. O'Sullivan D, Brady N, Manning E, et al. Validation of the 6-Item Cognitive Impairment Test and the 4AT test for combined delirium and dementia screening in older emergency department attendees. *Age Ageing*. 2018;47:61-68.
5. Ke YT, Peng AC, Shu YM, et al. Prevalence of geriatric syndromes and the need for hospice care in older patients of the emergency department: a Study in an Asian Medical Center. *Emerg Med Int*. 2020;2020:7174695.
6. Carpenter CR, Banerjee J, Keyes D, et al. Accuracy of dementia screening instruments in emergency medicine: a diagnostic meta-analysis. *Acad Emerg Med*. 2019;26:226-245.
7. Black BS, Brandt J, Rabins PV, et al. Predictors of providing informed consent or assent for research participation in assisted living residents. *Am J Geriatr Psychiatry*. 2008;16:83-91.
8. Karlawish J. Measuring decision-making capacity in cognitively impaired individuals. *Neurosignals*. 2008;16:91-98.
9. West E, Stuckelberger A, Pautex S, et al. Operationalising ethical challenges in dementia research-a systematic review of current evidence. *Age Ageing*. 2017;46:678-687.
10. Ries NM, Mansfield E, Sanson-Fisher R. Ethical and legal aspects of research involving older people with cognitive impairment: a survey of dementia researchers in Australia. *Int J Law Psychiatry*. 2020;68:101534.
11. Hunold KM, Goldberg EM, Caterino JM, et al. Inclusion of older adults in emergency department clinical research: strategies to achieve a critical goal. *Acad Emerg Med*. 2021;29(3):376-383.
12. Gilbert T, Bosquet A, Thomas-Anterion C, et al. Assessing capacity to consent for research in cognitively impaired older patients. *Clin Interv Aging*. 2017;12:1553-1563.
13. Atkinson PR, Milne J, Diegelmann L, et al. Does point-of-care ultrasonography improve clinical outcomes in emergency department patients with undifferentiated hypotension? An international randomized controlled trial from the SHoC-ED investigators. *Ann Emerg Med*. 2018;72:478-489.
14. Begaz T, Elashoff D, Grogan TR, et al. Initiating diagnostic studies on patients with abdominal pain in the waiting room decreases time spent in an emergency department bed: a randomized controlled trial. *Ann Emerg Med*. 2017;69:298-307.
15. Bobb MR, Van Heukelom PG, Faine BA, et al. Telemedicine provides noninferior research informed consent for remote study enrollment: a randomized controlled trial. *Acad Emerg Med*. 2016;23:759-765.
16. Caputo N, Azan B, Domingues R, et al. Emergency department use of apneic oxygenation versus usual care during rapid sequence intubation: a randomized controlled trial (The ENDAO Trial). *Acad Emerg Med*. 2017;24:1387-1394.
17. Driver BE, Prekker ME, Klein LR, et al. Effect of use of a bougie vs endotracheal tube and stylet on first-attempt intubation success among patients with difficult airways undergoing emergency intubation: a randomized clinical trial. *JAMA*. 2018;319:2179-2189.
18. Hohl CM, Partovi N, Ghement I, et al. Impact of early in-hospital medication review by clinical pharmacists on health services utilization. *PLoS One*. 2017;12:e0170495.

19. Pevnick JM, Nguyen C, Jackevicius CA, et al. Improving admission medication reconciliation with pharmacists or pharmacy technicians in the emergency department: a randomised controlled trial. *BMJ Qual Saf*. 2018;27:512-520.
20. Zimmerman FS, Karameh H, Ben-Chetrit E, et al. Modification of blood test draw order to reduce blood culture contamination: a randomized clinical trial. *Clin Infect Dis*. 2020;71:1215-1220.
21. Ahn S, Kim YJ, Sohn CH, et al. Sodium bicarbonate on severe metabolic acidosis during prolonged cardiopulmonary resuscitation: a double-blind, randomized, placebo-controlled pilot study. *J Thorac Dis*. 2018;10:2295-2302.
22. Anantharaman V, Tay SY, Manning PG, et al. A multicenter prospective randomized study comparing the efficacy of escalating higher biphasic versus low biphasic energy defibrillations in patients presenting with cardiac arrest in the in-hospital environment. *Open Access Emerg Med*. 2017;9:9-17.
23. Lee DK, Cha YS, Kim OH, et al. Effect of automated simultaneous sternothoracic cardiopulmonary resuscitation device on hemodynamics in out-of-hospital cardiac arrest patients. *J Emerg Med*. 2018;55:226-234.
24. Takeda Y, Kawashima T, Kiyota K, et al. Feasibility study of immediate pharyngeal cooling initiation in cardiac arrest patients after arrival at the emergency room. *Resuscitation*. 2014;85:1647-1653.
25. Zehtabchi S, Abdel Baki SG, Omurtag A, et al. Effect of microEEG on clinical management and outcomes of emergency department patients with altered mental status: a randomized controlled trial. *Acad Emerg Med*. 2014;21:283-291.
26. Okere AN, Renier CM, Tomsche JJ. Evaluation of the influence of a pharmacist-led patient-centered medication therapy management and reconciliation service in collaboration with emergency department physicians. *J Manag Care Spec Pharm*. 2015;21:298-306.
27. Taylor DM, Grover Johnson O, Lee M, et al. The effect of provision of pain management advice on patient satisfaction with their pain management: a pilot, randomised, controlled trial (pain advice trial). *Emerg Med J*. 2016;33:453-457.
28. Hao J, Dong B, Zhang J, et al. Pre-emptive analgesia with continuous fascia iliaca compartment block reduces postoperative delirium in elderly patients with hip fracture. A randomized controlled trial. *Saudi Med J*. 2019;40:901-906.
29. Trethewy CE, Doherty SR, Burrows JM, et al. Ideal cricoid pressure is biomechanically impossible during laryngoscopy. *Acad Emerg Med*. 2018;25:94-98.
30. 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.
31. Chaudet A, Bouhours G, Rineau E, et al. Impact of preoperative continuous femoral blockades on morphine consumption and morphine side effects in hip-fracture patients: a randomized, placebo-controlled study. *Anaesth Crit Care Pain Med*. 2016;35:37-43.
32. Monti PM, Colby SM, Mastroleo NR, et al. Individual versus significant-other-enhanced brief motivational intervention for alcohol in emergency care. *J Consult Clin Psychol*. 2014;82:936-948.
33. Barker A, Cameron P, Flicker L, et al. Evaluation of RESPOND, a patient-centred program to prevent falls in older people presenting to the emergency department with a fall: a randomised controlled trial. *PLoS Med*. 2019;16:e1002807.
34. Reavley P, Montgomery AA, Smith JE, et al. Randomised trial of the fascia iliaca block versus the '3-in-1' block for femoral neck fractures in the emergency department. *Emerg Med J*. 2015;32:685-689.
35. Molloy DW, Standish TI. A guide to the standardized Mini-Mental State Examination. *Int Psychogeriatr*. 1997;9(Suppl 1):87-94; discussion 143–150.
36. Matchar DB, Duncan PW, Lien CT, et al. Randomized controlled trial of screening, risk modification, and physical therapy to prevent falls among the elderly recently discharged from the emergency department to the community: the steps to avoid falls in the Elderly Study. *Arch Phys Med Rehabil*. 2017;98:1086-1096.
37. Brodaty H, Pond D, Kemp NM, et al. The GPCOG: a new screening test for dementia designed for general practice. *J Am Geriatr Soc*. 2002;50:530-534.
38. Fayyazi SMTM, Nabizadeh-Gharghozar Z, Javadzadeh H, Mahmudi S, Heidari K. Effectiveness of intravenous promethazine and diazepam in the treatment of peripheral vertigo in emergency department visits. *Physiol Pharmacol (Iran)*. 2018;22:213-218.
39. Etchells E, Darzins P, Silberfeld M, et al. Assessment of patient capacity to consent to treatment. *J Gen Intern Med*. 1999;14:27-34.
40. Bowers KJ, McAllister KB, Ray M, et al. Ketamine as an adjunct to opioids for acute pain in the emergency department: a randomized controlled trial. *Acad Emerg Med*. 2017;24:676-685.
41. Callahan CM, Unverzagt FW, Hui SL, et al. Six-item screener to identify cognitive impairment among potential subjects for clinical research. *Med Care*. 2002;40:771-781.
42. Biese K, Lamantia M, Shofer F, et al. A randomized trial exploring the effect of a telephone call follow-up on care plan compliance among older adults discharged home from the emergency department. *Acad Emerg Med*. 2014;21:188-195.
43. Platts-Mills TF, Hollowell AG, Burke GF, et al. Randomized controlled pilot study of an educational video plus telecare for the early outpatient management of musculoskeletal pain among older emergency department patients. *Trials*. 2018;19:10.
44. Morrison RS, Dickman E, Hwang U, et al. Regional nerve blocks improve pain and functional outcomes in hip fracture: a randomized controlled trial. *J Am Geriatr Soc*. 2016;64:2433-2439.
45. Dailey SK, Miller AR, Kakazu R, et al. The effectiveness of mini-c-arm fluoroscopy for the closed reduction of distal radius fractures in adults: a randomized controlled trial. *J Hand Surg-Am*. 2018;43:927-931.
46. Kline JA, Fisher MA, Pettit KL, et al. Controlled clinical trial of canine therapy versus usual care to reduce patient anxiety in the emergency department. *Plos One*. 2019;14:e0209232.
47. Okere AN, Renier CM, Tomsche JJ. Evaluation of the influence of a pharmacist-led patient-centered medication therapy management and reconciliation service in collaboration with emergency department physicians. *J Manag Care Spec Ph*. 2015;21:298-306.
48. Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. *BMJ*. 2010;340:c869.
49. Kennedy M, Enander RA, Tadiri SP, et al. Delirium risk prediction, healthcare use and mortality of elderly adults in the emergency department. *J Am Geriatr Soc*. 2014;62:462-469.
50. Lee S, Gottlieb M, Mulhausen P, et al. Recognition, prevention, and treatment of delirium in emergency department: an evidence-based narrative review. *Am J Emerg Med*. 2020;38:349-357.
51. Hustey FM, Meldon SW. The prevalence and documentation of impaired mental status in elderly emergency department patients. *Ann Emerg Med*. 2002;39:248-253.
52. Taylor JS, DeMers SM, Vig EK, et al. The disappearing subject: exclusion of people with cognitive impairment and dementia from geriatrics research. *J Am Geriatr Soc*. 2012;60:413-419.
53. Wilber ST, Lofgren SD, Mager TG, et al. An evaluation of two screening tools for cognitive impairment in older emergency department patients. *Acad Emerg Med*. 2005;12:612-616.
54. Sedrak MS, Freedman RA, Cohen HJ, et al. Older adult participation in cancer clinical trials: a systematic review of barriers and interventions. *CA Cancer J Clin*. 2021;71:78-92.
55. Millum J, Beecroft B, Hardcastle TC, et al. Emergency care research ethics in low-income and middle-income countries. *BMJ Glob Health*. 2019;4:e001260.

56. Petersen LA, Simpson K, SoRelle R, et al. How variability in the institutional review board review process affects minimal-risk multisite health services research. *Ann Intern Med*. 2012;156:728-U120
57. Scott AM, Kolstoe S, Ploem MC, et al. Exempting low-risk health and medical research from ethics reviews: comparing Australia, the United Kingdom, the United States and the Netherlands. *Health Res Policy Sy*. 2020;18:11.

SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Southerland LT, Benson KK, Schoeffler AJ, Lashutka MA, Borson S, Bischof JJ. Inclusion of older adults and reporting of consent processes in randomized controlled trials in the emergency department: A scoping review. *JACEP Open*. 2022;3:e12774. https://doi.org/10.1002/emp2.12774