Informed consent in dental care and research for the older adult population

A systematic review

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Informed consent is fundamental to the ethics of clinical care and research involving people. Although it is typically the ethical responsibility and legal duty of health care professionals to obtain valid informed consent from patients and research participants, consent is not always well interpreted or well documented in practice. Previous research results show that 40% to 80% of research participants who initially were judged to be capable of giving consent did not recall 1 or more required elements of the consent information. Obtaining informed consent is more than the act of a patient signing a document. It encompasses communication between participants and their care providers or research investigators. The overarching goal is to ensure that patients or study participants have full understanding of the clinical and research procedures that will be performed, including the expected risks and benefits and alternatives that are available to them; are given the opportunity to ask questions, discuss their choice, and have time to reflect; and provide a clear indication of their eventual decision.

In dentistry, informed consent typically is viewed through a legal lens. It sometimes is seen

ABSTRACT

Background. Ethics in health care and research is based on the fundamental principle of informed consent. However, informed consent in geriatric dentistry is not well documented. Poor health, cognitive decline, and the passive nature of many geriatric patients complicate this issue.

Methods. The authors completed this systematic review according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. The authors searched the PubMed (MEDLINE), Web of Science, PsycINFO, and Cochrane Library databases. The authors included studies if they involved participants 65 years or older and discussed topics related to informed consent beyond obtaining consent for health care. The authors explored informed consent issues in dentistry and other biomedical care and research.

Results. The authors included 80 full-text articles on the basis of the inclusion criteria. Of these studies, 33 were conducted in the United States, 29 addressed consent issues in patients with cognitive impairment, 29 were conducted in patients with medical conditions, and only 3 involved consent related to dental care or research.

Conclusions. Informed consent is a neglected topic in geriatric dental care and research. Substantial knowledge gaps exist between the understanding and implementation of consent procedures. Additional research in this area could help address contemporary consent issues typically encountered by dental practitioners and to increase active participation from the geriatric population in dental care and research.

Practical Implications. This review is the first attempt, to the authors’ knowledge, to identify informed consent issues comprehensively in geriatric dentistry. There is limited information in the informed consent literature covering key concepts applicable to geriatric dentistry. Addressing these gaps could assist dental health care professionals in managing complex ethical issues associated with geriatric dental patients.

Key Words. Ethics; informed consent; competency; dental care; dental care for elderly patients; geriatrics; oral health; dental research.


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as a challenge to customary practice or is viewed with uncertainty because it may not be clear whether a person can provide valid legal consent for treatment or participation in a study. Informed consent should include 5 basic elements.

- Capacity implies the physical and cognitive ability to participate fully in the informed consent process. Capacity involves the ability to comprehend the information provided by the dentist, to weigh the treatment options on the basis of one’s beliefs and values, and to reach an independent reasonable decision or choice.4
- Information should be disclosed to the patient about his or her dental problems and the nature, risks, and benefits of the proposed treatment and other treatment alternatives available to the patient, including nontreatment.5
- Comprehension or understanding of the consent process and information provided by the dentist is necessary for valid consent. The dentist must engage the patient actively in conversation, clarify the issues, answer questions, and verify that the patient has understood the information provided.4
- Ensuring voluntariness protects the participant’s right to make his or her own decisions. A consent decision should not be coerced or manipulated either by the dentist or by family members.6 Nevertheless, if the dentist thinks that the course chosen by the patient will do more harm than good to the patient, the dentist should communicate his or her concerns and reasons in an attempt to persuade the patient to reconsider.7 If the dentist knowingly fails to do so, it is a violation of the ethical principle of beneficence.
- Final decision or choice is essential to complete the act of giving consent. The decision about whether to give consent may be communicated orally or in writing, though in many contexts written documentation is required.

Obtaining informed consent can be especially challenging when it involves geriatric patients, who constitute a substantial and growing proportion of the population. The US Census Bureau projects that by 2030, more than 20% of the population will be 65 years or older compared with 13% in 2010.8 With a growing geriatric population that increasingly will retain their natural teeth, a larger number of older people will be seeking dental care in the upcoming years.

Many older adults have multiple comorbidities, somatic and psychosocial disabilities, and impaired decision-making capacity. Scholars have suggested that many people, possibly as a result of continuing perceptions of what a proper doctor-patient relationship is, prefer not to be involved in difficult decision-making processes regarding health care.9,10 Many find it too overwhelming to comprehend diagnostic information and treatment options, to weigh risks and benefits, and to reach a decision independently. They tend to rely on their health care provider or a trusted family member or caregiver to decide on their behalf.

Typically, the topic of informed consent is introduced to predoctoral dental students as theory. However, no standardized approach to teaching dental ethics has been established, and more education does not necessarily imply better understanding or ability to deal with ethical issues in professional life.11 The topic of informed consent in geriatric populations seeking dental care or participating in dental research has not been documented or studied widely. We aimed to explore systematically important issues that affect the informed consent process applicable to a geriatric population to help inform dental health care professionals providing dental care or conducting oral health research with older adults.

METHODS

We completed this systematic review according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement.12 We developed 3 research questions to guide this systematic review:

- When is an elderly person capable of providing his or her own consent?
- Is the practice of obtaining informed consent in elderly patients for the provision of dental care or treatment different from that for other medical care?
- Is the practice of obtaining informed consent in elderly patients for participation in dental research different from that for other medical research?

Operational definitions. For the purposes of this review, we used the following operational definitions:

- Frail elderly are people with multiple comorbidities and functional disabilities at the somatic and psychosocial levels who need help with the activities of daily living.
- Capacity is the ability to understand and process the information provided and to reach an independent decision with respect to individual preferences and values.4 We classified participants as capable or noncapable on the basis of their ability to provide valid consent.
- Autonomy is self-governance, understood as the capacity to make one’s own decisions and the opportunity to do so voluntarily (without any outside coercion or manipulation).
- Comprehension and understanding is being able to understand, process, or retain the information provided by the care provider or research team.
- Geriatric assent involves actively engaging patients 65 years or older in any major decisions made by health care professionals or family members.

ABBREVIATION KEY. MacCAT: MacArthur Competence Assessment Tool. MMSE: Mini-Mental State Examination.
TABLE 1

Number of articles included in the systematic review according to article type, location, and informed consent topic for cognitive, medical, and dental conditions.

<table>
<thead>
<tr>
<th>HEALTH CONDITION OR TOPIC</th>
<th>ARTICLE TYPE</th>
<th>GEOGRAPHIC LOCATION</th>
<th>INFORMED CONSENT TOPIC</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Research</td>
<td>Survey</td>
<td>Essay</td>
</tr>
<tr>
<td>Cognitive</td>
<td>19</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>Medical</td>
<td>24</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Dental</td>
<td>2</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Both Cognitive and Medical</td>
<td>12</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>TOTAL</td>
<td>57</td>
<td>7</td>
<td>16</td>
</tr>
</tbody>
</table>

Study inclusion criteria. We selected studies if they included an elderly population (65 years or older) and discussed informed consent beyond noting that informed consent was obtained from the patient or participant. In addition, the articles’ authors had to discuss the provision of dental care or dental treatment or other medical care (question 2) or dental research or medical or biomedical research (question 3). We excluded meeting or poster abstracts. To reflect potential conceptual changes as a result of the Patient Safety and Quality Improvement Act of 2005, we excluded articles published before 2005.

Search strategy. One of the authors, a medical librarian (A.A.L.), searched the PubMed’s MEDLINE (National Library of Medicine), Web of Science, PsycINFO (American Psychological Association), and Cochrane Library (Wiley) databases in December 2015. We used a combination of controlled vocabulary terms (that is, Medical Subject Headings) and key words to search for each of the concepts of interest: geriatric population, informed consent concepts, dental or medical research, and dental or medical care. We adapted the search strategies used for each database. We limited articles to English language only. Each research question contained its own set of search results. We reviewed each research question independently, so we did not remove the citations retrieved for each of the 3 research questions. We exported search results from each database to EndNote X7 (Clarivate Analytics) for citation management and removal of duplicate citations retrieved for each question, and we used Excel (Microsoft) for citation review.

Screening. Two reviewers (A.M., S.C.) completed a title and abstract screening of all retrieved citations in December 2015 by using the inclusion criteria for each research question. We selected those marked yes by both the reviewers for full-text review. A third reviewer (S.B.) reviewed citations marked yes by either of the 2 reviewers and no or “don’t know” by the second reviewer to determine inclusion. We included articles marked yes by the third reviewer for full-text review. Using the inclusion criteria, 1 of the reviewers and another 1 (A.M., B.A.D.) retrieved and reviewed the full text of the included articles.

Data abstraction and management. For studies eligible for full-text review, 2 reviewers (A.M., B.A.D.) extracted data in the form of 5 data abstraction tables. Table 1 presents information about the article type, geographic location of the population, health condition, and consent topics discussed. Table 2 presents the issues of capacity assessment and declining capacity. In Table 3, we extracted data regarding elements and concepts of consent that included autonomy or voluntariness. In Table 4, we extracted data on patient understanding. In Table 5, we collected data on surrogates and geriatric assent. We used Excel (Microsoft) for data abstraction.

RESULTS

Study identification and inclusion. We identified 14,448 articles through electronic database searches (Figure). We excluded articles published before 2005 (n = 3,575). We screened titles and abstracts for 10,873 articles, and we excluded 10,768 on the basis of the inclusion criteria. Of the 105 remaining articles, we excluded 25 either for being duplicates or for not satisfying the inclusion criteria, resulting in a final set of 80 articles for full-text review (Table 1). We present an expanded description of the articles reviewed in eTables 1-5 (available online at the end of this article). eTable 6 (available online at the end of this article) provides a detailed description of the search strategy.

Article characteristics. Of the 80 articles, 16 were essay-type articles; 17 were surveys; and 57 were research articles consisting of case studies and case reports, follow-up studies, cross-sectional studies, case-control and

ORIGINAL CONTRIBUTIONS
The studies reviewed were from a variety of geographic locations: United States (n = 33); United Kingdom (n = 7); France (n = 5); the Netherlands (n = 5); Spain (n = 3); and Canada, Sweden, Finland, Germany, Switzerland, Turkey, Hong Kong, Scotland, Norway, Italy, South Africa, Israel, South Korea, Austria, and Nigeria (n = 27). Investigators in 29 studies discussed consent in patients with only medical conditions, 29 in patients with cognitive impairments only, and 19 in patients with both medical and cognitive issues or frail or vulnerable elderly (eTable 1, available online at the end of this article). Investigators in only 3 studies discussed consent issues related to dentistry (Table 1). Rubinos Lopez and colleagues70 discussed elements and understanding in a Spanish dental care unit; Taiwo and Kass78 discussed elements and concepts of informed consent and patient understanding of oral health research in Nigeria; and Van and colleagues81 focused on elements, capacity, surrogates, and assent in a group of cognitively impaired geriatric patients seeking dental care in the United States.

Investigators in 39 articles discussed capacity; 19 were in research settings, 15 were in clinical care settings, and 5 involved both research and care (Table 2). Investigators in 24 articles discussed decision-making capacity, and investigators in 33 articles discussed capacity assessment topics. Mini-Mental State Examination (MMSE) and MacArthur Competence Assessment Tool (MacCAT) were the most commonly used capacity assessment tools, with MMSE mentioned in 23 articles and MacCAT in 13 articles (eTable 2, available online at the end of this article). The investigators mentioned declining capacity in 20 of the 39 articles with major emphasis on the concept of advance directives. Only 1 dental-related article focused on capacity.81 The authors discussed the importance of capacity evaluation in the dental office and suggested that a patient’s history and a long-standing patient–dentist relationship might help in detecting possible cognitive decline.

Table 3 presents key concepts of consent and autonomy discussed in the reviewed studies. Investigators in 48 articles discussed disclosure of risk, benefits, and alternatives. Investigators in 43 articles discussed patient autonomy; 3 were in dental settings.70,78,81 Arias15 and Basta16 stated that patients’ decisions always should be respected, and Davies and colleagues22 stated that patients should be made aware that they may withdraw from the research or treatment at any time, without any legal binding or penalty. Clayman and colleagues32 discussed autonomy-enhancing and autonomy-deterring behaviors of patient companions. Of the 3 studies in which the investigators discussed consent in dental settings, Taiwo and Kass33 stated that most of the patients in oral research settings in Nigeria were not aware of the concept of autonomy.

Investigators in more articles discussed patient understanding in the context of research (n = 28 articles) than did those in the context of patient care (n = 15 articles), and 7 articles were applicable to both research and care. Researchers most often used questionnaires to assess patient understanding (Table 4). Investigators in 3 studies mentioned use of the MacCAT understanding scale.80,62,66 Information provided to patients, physicians’ communication with patients, role of medical staff, and patient companions are some of the factors that affect patient understanding.21,22,35 Investigators in 5 studies suggested educational intervention or computer-based...
TABLE 3  
Number of articles included in the systematic review according to elements and concepts of informed consent for cognitive, medical, and dental conditions.

<table>
<thead>
<tr>
<th>HEALTH CONDITION OR TOPIC</th>
<th>CONCEPTS OF INFORMED CONSENT DISCUSSED</th>
<th>KEY INFORMATION REQUIREMENTS FOR CONSENT DISCUSSED</th>
<th>AUTONOMY DISCUSSED</th>
<th>CONSENT URGENCY</th>
<th>APPLIED TO RESEARCH, USUAL CARE, OR BOTH</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Disclosure of Risk, Benefits, and Alternatives</td>
<td>Assessment of Decision-Making Capacity</td>
<td>Voluntariness or Choice Without Coercion</td>
<td>Morbidity and Mortality</td>
<td>Quality of Life</td>
</tr>
<tr>
<td>Cognitive</td>
<td>12</td>
<td>11</td>
<td>13</td>
<td>4</td>
<td>11</td>
</tr>
<tr>
<td>Medical</td>
<td>19</td>
<td>9</td>
<td>17</td>
<td>6</td>
<td>13</td>
</tr>
<tr>
<td>Dental</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Both Cognitive and Medical</td>
<td>14</td>
<td>9</td>
<td>10</td>
<td>6</td>
<td>9</td>
</tr>
<tr>
<td>TOTAL</td>
<td>48</td>
<td>32</td>
<td>43</td>
<td>16</td>
<td>36</td>
</tr>
</tbody>
</table>

* Autonomy primarily focuses on the right to refuse.


tutorials to improve patient understanding. Other aids to decision making that could improve patient understanding are visual aids, audiowritings, and photographs, diagrams, and vignettes. Investigators in 6 studies discussed readability and level of vocabulary used in informed consent forms. Investigators in 1 dental research article and 1 dental care article discussed patient understanding.

Table 5 presents details of studies presenting issues regarding the role of surrogates and assent in the decision-making process. Investigators in 38 articles discussed proxy decision making. Investigators in 28 articles discussed the effect of relatives or companions on decision making. Investigators discussed advance care planning, advance directives, and shared decision making under the topic of geriatric assent. Coverdale and colleagues proposed a 4-step approach to obtaining geriatric assent: identifying patient’s values and preferences, assessing plans of care in terms of safety and the patient’s values, protecting remaining autonomy, and cultivating the professional virtues of making decisions under conditions of risk.

DISCUSSION

The investigators in the 80 articles included in this systematic review discussed informed consent substantively—that is, beyond noting that consent was obtained from the patient or participant. However, investigators in only 3 of the 80 articles discussed consent related to dentistry in the geriatric population. Most of the studies included in this review focused on capacity assessment and patient understanding. Decision-making capacity, 1 of the principal pillars of valid informed consent, has 4 essential domains: understanding relevant information, appreciating and applying the information to one’s personal needs and circumstances, rational reasoning, and communicating a clear and consistent choice. Even though the MMSE and MacCAT were the most studied capacity assessment tools, investigators in few studies reported using them in everyday practice. The tools were time-consuming to use and insufficient to determine the degree to which patients possess the capacity to provide valid consent. Investigators also have reported that agreement between methodology and use is poor. Overall, the practicality, efficiency, acceptability, affordability, and sustainability of capacity assessment tools in dentistry remain unexplored.

In addition to the lack of proper assessment tools, patient passivity and questionable, inconsistent capacity further complicate capacity assessment in the geriatric population. Cognitive impairments such as dementia, Alzheimer disease, Parkinson disease, and brain damage and medical conditions such as chronic comorbidities, terminal illness, aphasia, and visual and hearing impairments were some of the factors known to interfere with a patient’s ability to provide consent. The potential for declining capacity is another important issue in geriatric dental care and research. Investigators recommended initiatives such as advance care planning, shared decision making, and advance directives to address susceptibility to declining capacity. Van and colleagues discussed decision-making capacity, capacity assessment, and declining capacity in a dental care setting and recommended a medical referral for capacity evaluation if the dentist was unsure of the patient’s ability to consent to treatment. Assessing a patient’s ability to provide consent can be challenging for dentists under a variety of circumstances, including when capacity is affected by mental health status or is transient. The extent to which dental practitioners...
Patients’ preferences and values have emerged as important considerations in the consenting process. Investigators identified communicating knowledge and proper understanding of the treatment or research procedures as factors essential to patient autonomy. In patients with mild cognitive impairment, investigators recommended geriatric assent, which entails engaging the patient in decision making to the maximum extent possible, to preserve patient autonomy. 

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Investigators in only 2 articles addressed autonomy in the dental care setting, and investigators in 1 article addressed autonomy in dental research. Taiwo and Kass reported that oral health research participants in Nigeria had a poor understanding of the consent process. Most participants were unaware of the purpose or duration of the trial and the concept of patient or participant autonomy. Similar to findings about dental care among adults regardless of age, results of a 2015 survey administered to 52 patients in the United

<table>
<thead>
<tr>
<th>HEALTH CONDITION OR TOPIC</th>
<th>CONCEPTS OF UNDERSTANDING DISCUSSED</th>
<th>ASSESSING UNDERSTANDING AS IT RELATES TO INFORMED CONSENT</th>
<th>APPLIED TO RESEARCH, USUAL CARE, OR BOTH</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Presubmission Information Provided</td>
<td>Decision Aids to Improve Understanding</td>
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<tr>
<td>Both Cognitive and Medical</td>
<td>12</td>
<td>9</td>
<td>1</td>
</tr>
</tbody>
</table>

| TOTAL                     | 49                                   | 23                                                      | 5                                      |

<table>
<thead>
<tr>
<th>HEALTH CONDITION OR TOPIC</th>
<th>ROLE OF SURROGATES</th>
<th>GERIATRIC ASSENT DISCUSSED</th>
<th>APPLIED TO RESEARCH, USUAL CARE, OR BOTH</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Proxy Decision Making: Best Interest Versus Substituted Judgment</td>
<td>Effect of Relatives or Companions on Decision Making and Understanding</td>
<td>Acquire Directly or Advance Directives</td>
</tr>
<tr>
<td>Cognitive</td>
<td>13</td>
<td>11</td>
<td>10</td>
</tr>
<tr>
<td>Medical</td>
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</tr>
<tr>
<td>Dental</td>
<td>1</td>
<td>0</td>
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</tr>
<tr>
<td>Both Cognitive and Medical</td>
<td>10</td>
<td>7</td>
<td>10</td>
</tr>
</tbody>
</table>

| TOTAL                     | 38                 | 28                        | 29                                     | 20                                     | 21       | 19   | 9    |
Kingdom indicated that most patients remained unaware that the consent process was intended to promote their autonomy and interests.\textsuperscript{94}

Given that our review uncovered a limited number of articles in which the investigators discussed consent issues in geriatric dentistry, comparing geriatric consent issues between dentistry and medicine is difficult. Of the 3 studies in which the investigators discussed informed consent in geriatric dentistry, investigators in 2 focused on consent in dental care,\textsuperscript{70,81} and investigators in 1 discussed ethical issues in a dental research setting.\textsuperscript{78} Assessing the cognitive function of patients in a dental office could be challenging because of lack of appropriate assessment tools and time constraints. As with older patients in medical care settings, older patients in dental care settings more frequently chose to decline additional information about their treatment procedures.\textsuperscript{20} Rubinos Lopez and colleagues\textsuperscript{70} suggested that the patient should have 24 hours before any routine dental procedure to process the information provided in the consent form. Quality and quantity of information provided was also important. To ensure that patients have understood the relevant information, dental health care professionals were encouraged to ask questions to assess comprehension.\textsuperscript{81} Moreover, dental practitioners could pay attention to signs such as visible confusion and inconsistencies in the patient’s behavior, and if the patient’s decision-making capacity appeared questionable, family members or caregivers should be involved in the decision-making process.

There were a number of differences in how the 5 key concepts of informed consent (capacity, information, understanding, voluntariness, and choice) were addressed between the dental and medical articles we reviewed. Contrary to articles we found in the dental literature, articles involving patients with medical conditions generally addressed capacity assessment by comparing the different assessment tools available.\textsuperscript{13,15,32,38,87} The authors in most of these articles favored the MMSE and MacCAT over others. Investigators discussed concepts related to declining capacity and advance directives more thoroughly in the medical literature\textsuperscript{20,23,39,42,61,67} than in the dental literature. Investigators identified decision making and preserving patient autonomy as substantial ethical concerns arising in cases of medical emergencies.

Preserving autonomy by means of geriatric assent, advance care planning, surrogates and legal proxies, and shared decision making during medical emergencies were a number of the concepts discussed in the medical literature. Investigators rarely discussed these concepts as important issues affecting patient treatment during a dental emergency. Although investigators in some articles addressed issues arising from a conflict of interest between a patient with a medical or cognitive condition and his or her surrogate or proxy,\textsuperscript{55,72,74} there were no articles in which the investigators discussed these issues in the geriatric dentistry literature. Overall, in our review we found a paucity of articles discussing the topic of informed consent in geriatric dentistry. A limitation to this review is possible publication bias; however, we addressed this limitation by searching multiple databases and reviewing the bibliographies of key articles to ensure we had a collection of international research on these topics.
CONCLUSIONS

Although health care professionals and researchers recognize the importance of respecting patients’ personal beliefs, values, and preferences, findings from our review suggest that the topic of informed consent in geriatric dentistry rarely is studied or discussed in the literature. Furthermore, available information is insufficient to compare consent issues adequately in dental settings with those in other medical settings. Topic areas that could benefit from additional study and substantially improve knowledge in the field of dentistry include concepts of geriatric assent, shared decision making, and proxy decision making in dental care and research; factors affecting decision making and capacity among geriatric patients and study participants; practicality, acceptability, and affordability of the existing capacity assessment tools for use in dentistry; and appropriate involvement of medicolegal professionals in determining patients’ and participants’ decision-making capacity. Expanding information in these areas could assist dental health care professionals not only in understanding the ethical and legal issues regarding informed consent but also in increasing awareness of concepts that could facilitate active participation among the elderly in dental research and care.

SUPPLEMENTAL DATA

Supplemental data related to this article can be found at: http://dx.doi.org/10.1016/j.adaj.2016.11.019.

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