CDA JOURNAL, VOL 50, N°5

C.E. Credit

Informed Consent in the Older Adult Population: A Mixed-Methods Study

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ABSTRACT

Background: The purpose of this pilot study is to investigate how to adequately inform older patients about dental treatment, how to secure their informed consent for the treatment and how to learn about their perceptions of dentistry. The geriatric population will probably double in the next 30 years, yet there is limited research on improving dental informed consent. Due to the COVID-19 pandemic, dental visits have become more disorienting than ever for the older adult population, therefore it is important to implement effective informed consent procedures.

Methods: Geriatric subjects were randomly assigned to read a pamphlet or watch an informational video describing implant placement. Participants then took a postcondition survey. A paired t-test and an independent t-test were used with a 95% confidence interval to determine the significance of the data. In addition, a focus group was conducted to discuss the participants' experiences with informed consent.

Results: The results reveal a statistically significant increase ($p < 0.05$) in the participants' confidence of understanding dental implants after each intervention. The focus group discussion yielded three major themes in regard to the informed consent process: The critique of a pamphlet or video, the pitfalls of assumption and the importance of building trust.

Conclusion: This study illustrates that both a video and pamphlet can improve patients' understanding of the informed consent process.

Practical implications: These adjunct materials are not a substitution for having a conversation with one's dental professional. Understanding older patients as individuals with unique past dental needs is pivotal to success in this process.

Keywords: Dentistry, geriatric, aging, informed consent

CDA JOURNAL, VOL 50, N°5

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Conflict of Interest Disclosure: None reported.

An essential practice is to obtain informed consent from the patient during clinical care. In the most basic sense, informed consent should only be confirmed when a patient feels fully comfortable in their understanding of the treatment, risks and benefits of treatment and alternatives to the proposed treatment, including refusal of treatment. However, in many instances, the informed consent process is approached only from a performative legal standpoint, leaving the patient to sign the consent paperwork without feeling fully informed about the proposed treatment.[1] Studies suggest patients often do not fully appreciate the importance of informed consent, including its purpose to protect patients through discussion and education about their dental health needs.[2]

Obtaining informed consent from older patients requires special attention. According to the U.S. Census Bureau, the population of individuals aged 65 years and older in the U.S. will double in number from 48 to 88 million by 2050.[3,4] Older adults require more health care services due to an increased number of chronic diseases including those that affect both physical and cognitive abilities (such as Alzheimer's disease).[5] Persons with Alzheimer's disease may neglect oral hygiene, and when they do present for care, may struggle to understand their treatment options. Another common condition among older adults, diabetes mellitus (DM), is known to affect both general and oral health, which demonstrates the bidirectional relationship between oral and systemic health.[6–9] Poorly controlled DM may lead to periodontal disease and tooth loss, whereas treatment of periodontal disease in individuals with DM has been shown to improve the glycemic index in these same individuals.[10,11] Timely treatment is important for systemic health, and informed consent is a key step to achieving this.

As awareness of the importance of maintaining oral health care has evolved, older adults have retained their natural teeth much later in life and thus have required more dental care for a longer period of time.[12] Older adults have seen dental practice evolve from the days of the solo practitioner, and dentistry is changing yet again during the COVID-19 pandemic. New terminologies and treatment options can challenge the health literacy of some individuals, especially those with cognitive impairment.[13] Despite the importance of studying geriatric informed consent, systemic reviews by Mukherjee and colleagues[1] and Jones and Holden[14] note that current research on this topic is limited. One thing is clear in the dental literature, namely that obtaining truly informed consent requires more than a lecture or listing of options.[15] A systematic review published by the American Dental Association concluded that providing adjunct written materials and having a conversation about the proposed procedure(s) improved informed consent outcomes.[13] However, no studies have investigated the use of adjunct materials alone, without a verbal conversation with the provider. Our study is a pilot study designed to test the effectiveness of video versus pamphlet without a patient/provider conversation.

The first aim of this mixed-methods study was to explore the effectiveness of two different modalities for supporting older adults to make informed oral health choices: an informative pamphlet and an explanatory video. The research team developed a list of treatments with significant implications for informed consent (e.g., cost, invasiveness) and discussed which would be best suited for the study. Implant placement was

BOX 1

Informed Consent in Geriatric Patients Questionnaire

1. Please rate your previous knowledge about dental implants on a scale from 1-10 (1 being no previous knowledge and 10 being significant previous knowledge)
   1 2 3 4 5 6 7 8 9 10
2. After watching the video/reading the pamphlet, how confident are you in your understanding of dental implant placement surgery?
   1 2 3 4 5 6 7 8 9 10
3. After watching the video/reading the pamphlet, how confident are you in accepting a doctor's treatment plan of dental implant placement surgery?
   1 2 3 4 5 6 7 8 9 10
4. Please rate the helpfulness of this video in explaining the procedure:
   a. The video/pamphlet made me more confused
   b. The video/pamphlet was not helpful
   c. The video/pamphlet was somewhat helpful
   d. The video/pamphlet was significantly helpful
5. On a scale from 1-10, how confident are you in your ability to understand the risks of dental implant placement surgery after watching the video/reading the pamphlet?
   1 2 3 4 5 6 7 8 9 10
6. On a scale from 1-10, how confident are you in your ability to understand the benefits of dental implant placement surgery after watching the video/reading the pamphlet?
   1 2 3 4 5 6 7 8 9 10
7. After watching the video, how do you feel you are able to make a more informed decision about if this treatment is right for you?
   1 2 3 4 5 6 7 8 9 10

BOX 2

Guiding Questions for Focus Group

1. How has your experience at the dentist been in the past?
   a. What procedures have you had previously?
2. How well has your dentist explained various dental procedures to you?
   a. Do you feel you have the opportunity to ask questions if you have them?
   b. Does your dentist address risks, benefits, and alternatives with you during this explanation?
3. What area do you think we didn't cover well throughout this process?
4. How have your experiences changed at the dentist over the years?
5. Are there reasons why you visit the dentist often? What about not at all?
6. Are there any specific barriers that dissuade you from going to the dentist?
   a. Pain?
   b. Anxiety?
   c. Finances?
7. Do you appreciate your dental care provider?
   a. What traits make you feel this way?
   b. What traits do you look for in your provider?
8. Does your dentist use or offer any additional materials to improve the informed consent process?
   a. If so, what are they? Pamphlet, video, audio/visual tool?
   b. Was it helpful to you to have this additional resource?
9. What do you suggest could be done to change the way society views dentists and dentistry? What about the informed consent process?
10. How has this discussion been for you? Does anyone have any final comments about what we have talked about?

chosen due to it being a common, yet complex and relatively expensive procedure. We hypothesized that the video condition would be viewed by older adults as more informative and supportive of informed consent than the pamphlet-only condition.

The second aim was to document experiences and perceptions of older adults with respect to dental care and informed consent in a focus-group setting.

The study was reviewed and approved by the University of New England Institutional Review Board.

Methods

Design

To address the first aim, participants were randomly assigned to read the pamphlet or watch the video. The implant pamphlet from the American Dental Association (ADA) was chosen based on accuracy of information, concise yet comprehensive information and endorsement by the ADA.[16] An eight-minute "Dental Implant Consent Video," produced by Blue Sky Bio Dental Implant Systems Inc., was selected as the video condition due to various criteria including production quality, accuracy of information and duration of the video was realistic to be shown in a dental office.[17]

Participants for each intervention were engaged separately as a group. Participants were then provided 15 minutes to review the pamphlet or the video information. After this exposure, each group received the same follow-up survey **(BOX 1)** consisting of demographic questions and others pertaining to the participants' comprehension of the procedure and confidence for giving informed consent prior to and after the exposure. Opinions were indicated on a 1-10 Likert scale (10 = highest agreement or rating level).

To address the second aim, a focus group was conducted with all participants together to further discuss their experiences with informed consent in the dental practice setting and their general views on dentistry **(BOX 2)**.

Data Analysis

Descriptive statistics and mean difference analyses (t-test) were employed to characterize the data using SPSS version 24. The focus group was recorded, transcribed and subject to grounded thematic analysis and consensus coding. All members of the research team independently reviewed the transcript, noting themes and representative quotations, and then met in small groups to

TABLE 1

Age Distribution of Pamphlet Group and Video Group

Age	Pamphlet group	Video group
55–64	2	0
65–74	3	5
75–s84	1	2
> 85	1	0

TABLE 2

Gender Distribution of Pamphlet Group and Video Group

Gender	Pamphlet group	Video group
Male	1	4
Female	6	3

TABLE 3

Education Level of Pamphlet Group and Video Group

Education level	Pamphlet group	Video group
High school	2	0
Associates	2	0
Bachelors	1	0
Graduate	2	7

determine codes that adequately described the conversations in segments.[18,19] The various agreed-upon codes were compiled into four broad themes, which were determined by the entire research team.

Results

Participants

Volunteer participants (n = 14) were recruited through a community research registry, the UNE Legacy Scholars Program, and randomly assigned to one of the two conditions. All were white residents of greater Portland, Maine, who ranged in age from 55 to 85, and nine of 14 (64%) were female. The UNE Legacy Scholars Program is open to anyone aged 55 and older and all UNE scholar enrollees were eligible to volunteer for this study. Education levels ranged from high school graduate to graduate school (**TABLE 1**). Twelve participants were volunteers for the subsequent focus group.

Survey Results

Likert scale survey responses were averaged for each question. A paired samples t-test was performed in SPSS to compare the participants' knowledge of dental implants within each group before and after the intervention. The mean confidence level of understanding dental implant placement surgery before and after reading the pamphlet/watching the video was significantly different in both groups; both reading and viewing enhanced confidence and understanding (**TABLE 2**).

In addition, an independent t-test was performed to compare the participants' confidence level in understanding the risks and benefits of dental implant placement surgery as well as in giving informed consent. The pamphlet group and the video group were not significantly different (**TABLE 3**).

Focus Group Results

Critique of Pamphlet or Video

Participants in both conditions reported enhanced understanding of dental implant surgery following exposure, but with a preference for the video. One major complaint about the pamphlet was the lack of a timeline provided for the implant process. One participant said, "It's far too basic; it doesn't go into any depth about what you should be expecting to experience, how long it's going to take for this whole process to work, etc." Overall, the participants did not perceive the pamphlet as sufficient.

While many of the participants agreed that the pamphlet was quite basic, participants noted shortcomings in the video as well. Most agreed that the video (if watched on their own time or with the dental professional) was preferred, but neither of the educational materials adequately addressed the cost and complexity of the procedure (including the time factor). Additional information would be needed to make an informed choice. Participants suggested that providing one or both educational materials prior to a scheduled appointment to prime subsequent questioning and discussion would result in, "(Having) a better idea before walking into the dentist's office, so that I don't feel totally ignorant and hesitant to even ask a question, because oftentimes, they act like it is obvious what the problem is." Throughout the focus group, participants commented on the importance of the dental team's ability to relay information clearly and with sufficient depth to promote comprehension and an informed choice.

Another option offered was that of providing the pamphlet and/or video in the dental office and allowing the patient to ask questions while reading or watching. One participant suggested, "I think … to view either the pamphlet or the video with somebody in the dental office — that way it'll be clearer for me. If you're home and watching it, you can't ask a question about what's going to happen." Participants also noted a lack of internet access (at home) as a barrier for some elders to benefit from digital materials. Paper still has a place in the informed consent process. The group noted that the video or pamphlet should supplement, not replace an interactive discussion with the provider.

The Pitfalls of Assumptions

When discussing the experiences individuals had with informed consent, many brought up the tendency of the dentist to assume patient comprehension. Dental terminology is not easy for the layperson to understand. Many of the participants noted that both the pamphlet and the video used words that were

TABLE 4

Survey Participants' Knowledge on Dental Implant Before and After Reading the Pamphlet or Watching the Video

	Pamphlet group (n = 7)		Video group (n = 7)	
	Mean (std. deviation)		Mean (std. deviation)	
	Previous	After reading the pamphlet	Previous	After watching the video
Confidence level of understanding dental implant placement surgery	3 (2.38)	9 (0.816)	5.43 (2.76)	8.86 (1.07)
Sig. (2-tailed)	p < 0.001		p = 0.039	

Participants had a higher level of understanding dental implant surgery after reading the pamphlet (p < 0.001) or watching the video (p = 0.039).

unfamiliar and neither explained them effectively. One participant stated, "There are some terms in there, some appropriate medical (or) dental terms that you all understand and make the assumption that we understand what edentulous or periodontal is, and so remember the audience."

Building Trust Is Essential

Participants emphasized the importance of mutual trust between the patient and the provider as a crucial aspect of giving true informed consent. Encouraging mutual discussion about dental treatment is seen as key. One participant noted his previous experience, "This individual who was doing the implant informed consent had zero chairside ability at all. They were rude, didn't want to answer questions, nothing, and I just was so turned off by it, so consequently … never followed through with it."

All the participants agreed that the process should be collaborative; one stated, "It goes to the doctor's relationship with the patient and making the patient feel comfortable to show that they're not stupid, you know, that they can say 'I don't get it,' 'What's it mean?' 'What are you doing and why?'" Another participant requested for the professional to "talk to me about what's going on in my mouth in a way I can understand … that makes all the difference in the world to me," while another participant stated, "I would start asking questions and kind of get half answers, and … it was like 'why are you bothering me with these questions?'"

These concerns all relate to the development of mutual trust or lack thereof. Participants noted the importance of involvement of the entire dental team (dental assistants and dental hygienists) in the informed consent process, not just the dentist. Some group members expressed that they have a positive relationship with their dentist and hold a high degree of mutual trust. Others felt the opposite. One participant stated, "I think there's an awful lot of the trust that used to happen between the dentist and the patient (that) is disintegrating, unfortunately, so that the informed consent process is a lot more important now." One participant stated, "Dentists should not get too comfortable with the fact that … the patient signed the informed consent. Don't assume that 'I may have forgotten to tell so-and-so something, but I have this informed consent paper, so I don't have to worry.' That's not a good way to go into this. You want to ensure that people really do understand … and have a calm way to ask questions. Trust is paramount in any profession. It is crucial."

Discussion

This mixed methods study explored the relative effectiveness of learning about dental implant treatment through a written pamphlet versus a training video. Broader perceptions of dental care, particularly those related to informed consent, were examined through a subsequent focus group with the same participants. Our results indicate that educational materials are helpful in an informed consent process, but they cannot substitute for interactive questioning and dialogue with a provider.

This study demonstrated that both the pamphlet group and the video group reported enhanced confidence in their ability to give informed consent. Both modalities served to improve the level of understanding of the implant procedure, and interestingly, although several participants had undergone the procedure, they felt they did not have adequate knowledge coming into the study. After the intervention, they had a better understanding of the risks and benefits. This finding indicates that both the pamphlet and the video are effective supplemental resources that can be used in the dental setting to increase a patient's knowledge base and confidence in giving informed consent. However, note the word supplemental. Neither the pamphlet nor the video are recommended as substitutes for frank discussions between practitioner and patient.

Participants overall felt that they needed to be given the time to read or watch the adjunct resource materials

TABLE 5

Survey Participants' Understanding Level of the Risks and Benefits of Dental Implant Before and After Reading the Pamphlet or Watching the Video

Confidence level	Pamphlet group (n = 7)	Video group (n = 7)	
	Mean (Std. Deviation)	Mean (Std. Deviation)	P-value (2-tailed)
Participants' confidence in understanding risks of dental implant placement surgery	6.86 (2.73)	8.71 (0.95)	0.131
Participants' confidence in understanding benefits of dental implant placement surgery	8.86 (0.90)	9.14 (1.22)	0.626
Participants' confidence in ability to give informed consent	8.29 (1.80)	8.57 (1.27)	0.738

There was no significant difference in understanding of risks or benefits of dental implant surgery after watching the video or reading the pamphlet.

independently. Yet the timeline for this process did not reach consensus. One suggested that this should take place prior to the office visit, while others preferred viewing the video during the visit with time set aside for the provider to answer questions. Participants all felt that having the time to read the informed consent document and ask questions prior to the procedure would improve their confidence in giving informed consent for a treatment plan.

When discussing experiences individuals had with informed consent, participants brought up the tendency for the dentist (or dental professional) to assume patient comprehension. Examples ranged from assumptions of understanding dental terminology, the dental procedure itself, treatment options, risks and benefits of each option and the cost of dental procedures. The discussion about assumptions led to further concerns about the omission of important information about time involved and high monetary cost. One example given was the need for both implant placement and restoration of the implant with an implant-supported crown. Assuming the patient knows both steps are necessary without explanation or discussion can negatively affect patient satisfaction.

Providers automatically may speak in dental jargon, not realizing the patient may not be fully comprehending. This was noted by participants both when discussing treatment with the provider and also in the adjunct materials. For example, both included the term "osseointegration." Although the provider may use these materials to aid the informed consent process, it is still ultimately the responsibility of the provider or the provider's staff to use appropriate "plain language" that can be easily understood by the patient. Offering the patient the opportunity to pose questions by asking, "What questions do you have?" versus "Do you have any questions?" invites follow-up inquiries.[20] Avoiding assumptions of comprehension benefits both the provider and the patient by setting clear expectations on actual procedures, healing times, number of appointments and cost. Some dentists may not feel they have the time to sit and answer questions posed by patients. Yet to promote best practice, making time for mutual discussion is a necessity. If the dentist cannot provide the time, training other office staff members, such as implant coordinators and assistants, to answer questions within their scope of practice may provide an alternative solution.

Participants emphasized the importance of mutual trust between the patient and the provider as a necessary prerequisite component of giving true informed consent. Only a few participants expressed that they had a strong mutually trusting relationship with their dentist.

The focus group discussion included the importance of younger providers especially building trusting relationships with older patients, as many of the older patients had gone to the same dentist for decades prior to their dentist retiring. One participant went as far as to say trusting relationships between patients and providers were "disintegrating" and pointing out informed consent is more important now than ever. Participants felt that to build trust the provider must take the time needed to discuss the treatment, seek trust and gain understanding from the patient prior to signing the informed consent. The focus group concluded that the signing of the consent form should not be the goal of providers; the goal should be to ensure a high degree of understanding of the dental procedures.

Providing a high-quality pamphlet or video prior to the appointment would be a way to allow the patient to come to their appointment prepared with questions for the dentist. The consensus seemed to be that the adjunct materials were helpful, but only in addition to discussion with a dentist. These materials cannot, and should not, replace a valuable discussion with the dentist about a treatment. This discussion needs to take as long as necessary for each patient to achieve an

adequate level of understanding. The "teach-back" method can be helpful to ensure adequate comprehension.[21]

Limitations

This clinical research project aimed to begin the conversation about informed consent in dentistry. The first limitation was our small sample size largely because this was a pilot study. Furthermore, although the participants were randomly assigned to the pamphlet group or video group, the groups' education level may have been significantly different: The groups were too small to establish this for sure. While the focus group yielded important information for dental professionals, the results were from a small number of somewhat like-minded participants and may not be transferable to a larger more diverse older population, although this study does offer a place to start. Another limitation was being limited to the use of one pamphlet and one video, which were chosen as the most appropriate by the research team. Participants may have reacted differently had alternate videos or pamphlets been chosen. Many other videos and pamphlets outlining the dental implant process are available. We chose to focus on the informed consent process of dental implant placement due to the growing popularity of the treatment, but there are many other treatments in the dental office where informed consent would need to be obtained.

The results from our study can only be applied to patients being more confident to provide informed consent for implant placement. We could have analyzed pre- and postsurvey scores for more of the questions (rather than just confidence level), but the results would not have been conclusive anyway due to the fact that these educational materials, while likely to improve knowledge base, would not be recommended as the primary procedure for garnering informed consent.

Conclusion

Obtaining informed consent is a required process for many dental procedures. The process can be completed in a quick, careless manner just to meet the regulations or mindfully to ensure that the patient truly understands prior to signing. Adjunct materials such as videos or pamphlets may enhance levels of understanding but can never replace the vital discussion between the dental professional and patient. When working with older adults, perhaps even more care must be taken to ensure trust and facilitate the desired level of comprehension. Older adults may have conditions such as decreased sensory awareness and cognitive decline that necessitate additional attention. Dental professionals can use this information about the informed consent process to create positive changes in their practices that will enhance the experience for both patients and professionals. ■

ACKNOWLEDGMENT

This project was supported by Dr. Yang Kang's grant from the Center for Excellence in Aging & Health at the University of New England. Student Research Scholarship was provided by the University of New England College of Dental Medicine. The authors thank Jane Page, Kelly Abrams, Brenna McNally and Lori Rand of the Student Academic Success Center for their help. In addition, they extend their appreciation to Mohamed ElSalhy, BDM, PhD, research coordinator at the University of New England Research Department.

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C.E. CREDIT QUESTIONS

May 2022 Continuing Education Worksheet

This worksheet provides readers an opportunity to review C.E. questions for the article "Informed Consent in the Older Adult Population: A Mixed-Methods Study" before taking the C.E. test online. You must first be registered at cdapresents360.com. To take the test online, please click here. This activity counts as 0.5 of Core C.E.

1. Which of the following statements about informed consent is incorrect:
a. It is primarily a legal process that requires the patient to read and sign a consent-to-treatment document.
b. It must discuss the risks and benefits of treatment.
c. It must include alternatives to treatment including treatment refusal.
d. Its main purpose is to protect patients through discussion and education about their dental health needs.

2. True or False: A systematic review published by the American Dental Association concluded that providing adjunct written materials and having a conversation about the proposed procedure(s) improved informed consent outcomes.

3. In this study, which compared providing the information for informed consent in a pamphlet with providing that information in a video, the primary feedback on the pamphlet was which of the following:
a. The information it contained was thorough and easy to understand.
b. It was simpler and less time consuming than watching a video.
c. The diagrams were instructive.
d. It was considered too basic and insufficient to make an informed decision.

4. Feedback on the video included which of the following:
a. It failed to address the cost and complexity of the procedure.
b. It did not discuss the treatment timeline.
c. Participants felt additional information was necessary to make an informed decision.
d. All of the above

5. Which of the following statements was not part of the focus group discussions on informed consent:
a. Dental terminology is often difficult for the layperson to understand, though it is frequently used by dentists and the educational materials they provide.
b. The process should be collaborative.
c. To reduce confusion, the dentist should be the only one involved in informed consent discussions and to answer patient questions.
d. Trust is paramount to the informed consent process.

6. True or False: This study demonstrated that both the pamphlet and the video served to improve the level of understanding of the implant procedure group, and both groups reported enhanced confidence in their ability to give informed consent.

7. Which of the following suggestions did focus group members make to improve the informed consent process:
a. Use plain language; avoid dental jargon.
b. Ask "What questions do you have?" versus "Do you have any questions?"
c. Include healing times, number of appointments and cost in the discussion.
d. All of the above

8. Which of the following was not a conclusion of the focus group:
a. Providing a high-quality pamphlet or video prior to the appointment might be a way to allow the patient to come to their appointment prepared with questions for the dentist.
b. The informed consent discussion needs to take as long as necessary for each individual patient to achieve an adequate level of understanding.
c. The "teach-back" method can be helpful to ensure adequate comprehension.
d. The ultimate goal of informed consent is the patient's signature on the consent form.

9. This study's limitations included all but which of the following:
a. Small sample size.
b. Homogeneity of the groups' education level.
c. Results may not be transferable to a larger, more diverse older population.
d. Use of just one pamphlet and one video.

10. True or False: The study results indicated that educational materials are helpful in an informed consent process but cannot substitute for interactive questioning and dialogue with a provider.