



## COVER STORY

# Informed consent comprehension and recollection in adult dental patients

## A systematic review

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People have the right to self-determination through the informed consent process.<sup>1,2</sup> Despite the importance of legal aspects of informed consent,<sup>3,4</sup> attention also should be given to providing patients with appropriate information needed to make an autonomous choice that best represents their own interests.<sup>5</sup> Important issues related to the patient's treatment, including risks, benefits, treatment alternatives, and costs, have to be explained fully by the health care professional and understood by the patient, so the patient can make an informed decision.<sup>1</sup> However, available evidence shows that even after being informed, a high proportion of patients do not understand fully the proposed treatment explanations and associated risks and benefits.<sup>6</sup> The patient's or guardian's complete comprehension of information shared during the informed consent process is of paramount importance<sup>6,7</sup>; otherwise, the signed document may represent the patient's acceptance of a partially comprehended procedure.<sup>5</sup>



This article has an accompanying online continuing education activity available at: <http://jada.ada.org/ce/home>.

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## ABSTRACT

**Background.** Patients' ability to recollect and comprehend treatment information plays a fundamental role in their decision making.

**Types of Studies Reviewed.** The authors considered original studies assessing recollection or comprehension of dental informed consent in adults. The authors searched 6 electronic databases and partial gray literature and hand searched and cross-checked reference lists published through April 2015. The authors assessed the risk of bias in the included studies via different validated tools according to the study design.

**Results.** Nineteen studies were included: 5 randomized clinical trials, 8 cross-sectional studies, 3 qualitative studies, 2 mixed-methods studies, and 1 case series. Conventional informed consent processes yielded comprehension results of 27% to 85% and recollection of 20% to 86%, whereas informed consent processes enhanced by additional media ranged from 44% to 93% for comprehension and from 30% to 94% for recollection. Patient self-reported understanding ranged positively, with most patients feeling that they understood all or almost all the information presented. Results of qualitative data analyses indicated that patients did not always understand explanations, although dentists thought they did. Some patients firmly stated that they did not receive any related information. Only a few patients were able to remember complications related to their treatment options.

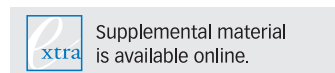
**Conclusions and Practical Implications.** Results of this systematic review should alert dentists that although patients in general report that they understand information given to them, they may have limited comprehension. Additional media may improve conventional informed consent processes in dentistry in a meaningful way.

**Key Words.** Informed consent; decision making; dentist-patient relations; evidence-based dentistry.

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Although comprehensive reviews about this topic in the medical literature point to an overall unsatisfactory patient understanding<sup>8,9</sup> and recollection<sup>9</sup> of the information presented during informed consent processes, investigators in only a few empirical studies in dentistry<sup>10-12</sup> have explored these issues. Although results of these studies suggest that similar problems occur in the dental field during the informed consent process, the reality is that the informed consent process in dental settings is not necessarily similar to that in medical settings. Several relevant factors are different: multiple oral health problems may occur simultaneously,<sup>13</sup> there often is an aesthetic effect, and there is a fee-for-service aspect of dental services. To our knowledge, no attempt has been made to synthesize available evidence of the effectiveness of the informed consent process in dentistry. In this systematic review, we assess available evidence regarding adult dental patients' ability to comprehend effectively the



oral health treatment information provided during informed consent processes and to

recall that information immediately or more than 1 week after the informed consent process was completed.

## METHODS

This systematic review adheres to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement.<sup>14</sup> We registered this systematic review protocol at PROSPERO under the protocol number CRD42015020345.

**Eligibility criteria.** Inclusion criteria were as follows:

- original studies, regardless of the methodology used, in which the investigators assessed adult patients' ability to comprehend effectively the oral health treatment information provided during informed consent processes and to recollect that information immediately or more than 1 week after the informed consent process was completed;

- studies in which the investigators compared standard informed consent processes with different kinds of information delivery, such as multimedia or smart consents;
- no language restriction.

During phase 2, the reviewers added 1 extra inclusion criterion:

- Studies in which the investigators included personal interaction between the dental care provider and patient before an assessment of their informed consent comprehension or recall was completed.

Exclusion criteria were as follows:

- studies in which the investigators analyzed informed consent for participation in research trials and exclusively assessing readability of consent forms;
- studies in which the investigators included patients with cognitive deficit or impairment, as well as letters, reviews, and personal opinions.

**Information sources.** We comprehensively searched the following databases: MEDLINE via OvidSP, PubMed, Cochrane Library, Embase, LILACS (Literatura Latino Americana em Ciências da Saúde), and Web of Science up to the first week of April 2015; we used detailed individual search strategies for each database. We performed a partial gray literature search by using Google Scholar and limited it to the first 100 most relevant articles. We also checked reference lists of included articles and conducted hand searches for additional citations that were not identified during the electronic searches.

**Search.** We adapted truncation and word combinations according to each specific database search (eTable 1, available online at the end of this article). We managed all references by using reference manager software (RefWorks-COS, ProQuest) and removed all duplicates.

**Study selection.** We completed study selection in 2 phases. In phase 1, 2 of us (N.C.F.M., C.P.P.) independently assessed the titles and abstracts of all identified electronic database citations. We selected all abstracts that met the inclusion criteria and retrieved full-text articles for phase 2. Whenever abstracts did not provide enough information to make a decision, we obtained the full-text articles to support a final decision. In phase 2, the same 2 reviewers independently reviewed the full-text articles and applied the same selection criteria to confirm eligibility. In both phases, disagreements about whether a study met the inclusion criteria were settled by discussion between the 2 reviewers. A third author (C.F.M.) was involved when an initial agreement was not possible.

**Data items.** We extracted the following data elements from each included study: authors, year of publication, sample size, study objectives, methods, dental procedure performed or dentistry area (when the procedure was not clear), results related to outcomes of interest, methodology of standard informed consent within the study, experimental informed consent method of comparison (when applicable), and time frame for information recall. If any required data were not available, we tried to contact the authors to retrieve any missing information.

**Data collection process.** One author (N.C.F.M.) collected all required information from each selected article. A second author (C.P.P.) cross-checked the retrieved information. Following a systematic process, we resolved any disagreement by means of discussion. The third author (C.F.M.) was involved when an agreement could not be reached.

**ABBREVIATION KEY.** DB: Decision board. EndoDB: Endodontic decision board. LILACS: Literatura Latino Americana em Ciências da Saúde. NHS: National Health Service. WTL: Wisdom Tooth Leaflet.

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