



## Informed Consent of Patients without Reading Skills in Ultrasound-Guided Biopsy: Beware of the Liability

LETTER  
TO THE EDITOR

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Dear Editor,

In clinical and research settings, the informed consent (IC) process starts with the disclosure of information to the patient, mostly through the use of a written document. For the consent to be valid, the information should be disclosed adequately and the patient should have the decisional capacity to integrate the knowledge.

In our image-guided biopsy practice, when we ask patients to read an IC form, some patients openly admit that they are illiterate and therefore cannot read. For these patients, some additional measures are necessary to transfer the knowledge adequately and to check if the patient has integrated the information thoroughly. However, first, one should answer the following question: What is the percentage of patients who cannot read among patients with low literacy, which is group vulnerable to legal and ethical malpractice?

For this purpose, we conducted a survey of patients who were referred to the Ultrasound Unit for aspiration biopsy of the thyroid nodules. Before the procedure, we interrogated the patients with regard to their education level and reading skills. Based on the readability categories defined in the Çetinkaya-Uzun Readability Formula, patients who had completed education up to the 9<sup>th</sup> grade or lower (i.e., who remained below the level of independent reading) were accepted as having low literacy (1). In these patients, reading skills were assessed by asking them to read the IC document aloud. Patients who admitted that they could not read were deemed as unskillful. Other patients who showed self-confidence in reading, regardless of the fluency, were deemed as reading skillfully.

Out of 130 patients, 32 females and 2 males (n=34, 26.1%) could not read. Among them, 3 patients presented with barriers due to ethnic differences and 1 patient (0.7%) had visual impairment. The education level of this group was significantly lower than that of the rest of the group (0 median years vs. 5 median years of schooling, Mann-Whitney U test, p<0.001).

Because nearly one-fourth of the low-literacy population cannot access written information, how can we cope with such a problem? Video and computer multimedia interventions may help in such cases; however, it is our view that they should be supplemented with additional test/feedback questions and/or extended discussions (2). At present, the evidence about the efficacy of various IC interventions in mitigating the effects of low literacy is limited (2, 3). One of the reasons may be the lack of established criteria to measure patients' integration of the knowledge (2, 4). However, regardless of the measurement problems, physicians need a medium to convey the knowledge to such patients because it is legally necessary to disclose the knowledge adequately and reading skills are ethically independent from the decisional capacity.

We suggest that physicians who are frequently involved in the IC practice should increase their awareness about patients who cannot read. For these patients, it is necessary to develop additional measures in order to prevent ethical and legal liability.

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