

# Evaluation of information leaflets on oral anticancer drugs: meeting the needs of patients across the health literacy spectrum?

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**Background** Oral anticancer drugs (OACD) cause a shift in responsibilities from the oncology team to the patient. Therefore, patient education, combining verbal and written information, is key to a successful treatment. However, standardized and clear written information for patients is lacking. Therefore, the EDU-CONTACT-initiative (EDUcation to support COllaborative Networks to Take responsibility for oral AntiCancer Therapy) has been set up to develop uniform pictogram-based leaflets per OACD.

**Purpose** The aim of this study was to investigate the readability of the information leaflets and to gain insight in patients' perspectives on comprehensibility, utility, and design quality. To guarantee the usability of the leaflets for patients across the health literacy spectrum, we also investigated whether the results differ according to the level of patient health literacy.

**Method** An observational cross-sectional study was conducted to evaluate a set of 3 test-leaflets. Test panels consisted of patients with cancer, patients with other chronic conditions and healthy volunteers with different levels of health literacy. Three assessments were performed: 1) general assessment of patient characteristics and health literacy using the Health Literacy Survey Questionnaire (HLS-EUQ16), 2) readability test according to the guideline from the European Commission (EC) to test patient leaflets prior to market authorization of medicines, and 3) Consumer Information Rating Form (CIRF), a direct method for measuring patients' perceptions of the comprehensibility, utility, and design quality of written medicine information.

**Findings** Each test-leaflet was evaluated by 20 participants, including 2-6 participants with inadequate health literacy, to ensure a balanced sample (according to the distribution of health literacy in Belgium) of potential users. For none of the three leaflets the readability requirements, as detailed in the EC guideline, were met. Participants mostly struggled with questions about the posology and method of administration. No relationship was found between participants' health literacy and their results on the readability test. The overall score on the CIRF was favourable. However, there was some disagreement on the topic of side effects. Some participants indicated that the list of side effects is too extensive, as opposed to others who prefer more information on this topic.

**Conclusion** In contrast to our expectations, health literacy seemed not a valid predictor for readability of the leaflets. Further optimization of the leaflets is needed to ensure their readability for patients treated with OACD and their optimal use during face-to-face education and counseling by HCPs.