Electronic informed consent: the need to redesign the consent process for the digital era

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BACKGROUND

The Electronic Informed Consent (eIC) was introduced with the aim of optimizing time and costs, providing the essential characteristics of a clinical study in an easy-to-use format thus enhancing patient understanding.

METHODS

During the second quarter of 2020, the Working Group "Clinical Research Coordinators" of the Medical Oncology Italian Association (AIOM) has developed a survey on the knowledge, use and opinion of eIC.

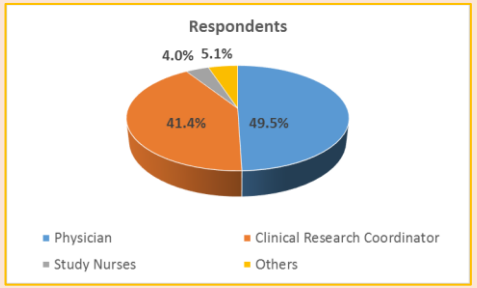
The questionnaire was an anonymous web-based survey, consisting of 16 multiple-choice questions, aimed at clinical research stakeholders and disseminated through AIOM social channels.

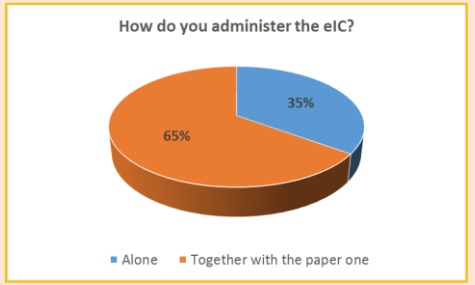
RESULTS

- The survey was completed by 99 stakeholders.
- Only 17% of the total participants had a personal experience with eIC (67% for direct use at the center, 33% through theoretical training).
- The most used tool (69%) is the tablet.
- eIC was almost always (86%) administered by the physician.
- 40% did not express any difference in dealing with the eIC compared to the paper version.
- 41.4% reported initial perplexity of patients, that in most cases was overcome after an interview with the physician while in 6% of cases were persistent throughout the study.

Possible reasons for the difficulties in approaching the eIC

-Patients' age and computer skills
-Reduced attention of physician and patient
-Reduced awareness compared to the paper version
-Perplexity and misunderstanding of the patient





- According to participants' experience, the use of eIC has little influence on patient's possible refusal to participate in the study (average score 3.5 on a scale of 0 not at all - 10 a lot).
- At a regulatory level, the use of eIC seems to have some negative effects, such as longer time frames for study approval (26% of respondents) and the need for additional information in order to express an opinion (48%).
- On a scale of 0 to 10, participants expressed a median score of 6 with respect to the possibility that the eIC can completely replace the paper form.

What is the patient's approach to the eIC?	
No difference compared to the use of paper consent	41.4%
Some initial concerns	40.4%
Total lack of experience	12.1%
Concerns that remain during the study	6.1%

CONCLUSIONS

The experience of Italian centers with respect to the use of eIC is still very limited, although there are no major hesitations from clinicians or patients. Surely the tool could be very useful in cases where, as during the pandemic, patient access to the hospital may not be the best option for his well-being and safety.

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