# Cancer patients struggle with key aspects of clinical trial methodology

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Clinical trials are fundamental to the development of new treatments for cancer, yet the annual accrual to cancer clinical trials worldwide is low, estimated at three to five percent. A nationwide study in Ireland, the preliminary results of which are to be presented at the ESMO 2017 Congress in Madrid, shows that although most oncology patients consider it important to have clinical trials available, many struggle with the central concepts that underpin trial methodology.

"As a medical oncologist, I have experienced situations where patients have declined clinical trial options because of misconceptions about them," said study author Dr. Catherine Kelly from Mater Misericordiae University Hospital in Dublin, Ireland. "To improve participation in clinical trials, we need to understand the factors influencing patients' decisions about taking part."

In the course of the study, 1090 adult patients with a diagnosed malignancy and being treated at one of 14 participating oncology centres across Ireland filled out anonymised questionnaires in which they were asked to evaluate statements about clinical trials and research.

"Consistent with previous studies, the concepts of chance and randomisation posed difficulties to a significant proportion of patients. Over half of previous medical trial participants and 73 percent of those who had never been on a cancer clinical trial did not understand that in a randomised trial, the treatment given was decided by chance," Kelly reported.

"We also found that most patients did not understand clinical equipoise: the fact that no one knows which treatment is best. Surprisingly, this was more marked in previous clinical trial participants, 60 percent of whom believed that their doctor would know which study arm was best," she said.

"To provide informed consent when participating in a trial, patients need to understand these key concepts - and doctors explaining them well is essential to alleviating any fears that might prevent patients from participating. For example, many didn't realise that clinical trials are not just an option for when standard treatment has failed," she observed.

"Doctors have a responsibility to properly inform their patients in this regard, because they are the ones patients trust the most," Kelly said. "As we analyse the data further, we will be able to offer physicians a more detailed picture of the questions patients need answered and the factors that influence their decision-making according to age group, cancer type, educational background and other demographics."

Dr. Bettina Ryll, Chair of the ESMO Patient Advocates Working Group (PAWG), commented: "The question of whether patients understand clinical trial methodology is a very valid one, and what makes this study so interesting is that more than a quarter of the patients questioned had actually been on clinical trials before," she said.

"However, I was surprised at the median age of the cohort: 60 years. It would be interesting to compare the data collected here with younger patient groups, who access information in a very different way," Ryll observed. "I would also expect to see differences across tumour groups: among breast cancer patients, for instance, who make up almost a third of the study cohort and for most of whom there is a well-established standard of care, clinical trials are likely to be of less interest than among lung cancer patients, for whom the standard treatment is less effective."

Ryll further cautioned: "When we talk about understanding, it is important to consider that patients and physicians approach clinical trials from different perspectives: For example, the concept of randomisation is one that many patients question from a moral standpoint. Equipoise, by contrast, may be a laudable moral concept, but it is difficult to uphold if the results of earlier trials are already known: finding out whether a treatment is, say, 51 percent better or only 49 percent, may matter to an Health Technology Assessment (HTA) assessor - but not to a patient. This undermines the conclusion that patients simply do not understand equipoise."

Trial design is a complex issue - one of many that cancer patients can face in the course of their treatment. Complementing the educational role of doctors, ESMO's Patient Advocates also play a crucial part in making sure that patients are well-informed and giving them the opportunity to take part in research that can truly benefit them.

**More information:** Abstract 1465P_PR 'Do oncology patients understand clinical trials? A nationwide study by Cancer Trials Ireland' will be presented by Catherine Kelly during the Poster Display Session on Sunday, 10 September

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