Researchers develop new standards for quality of life measurement in cancer

February 3 2020

Patients filling forms. Credit: @eortc

For the first time, recommendations for the analysis of patient-reported outcomes (PROs) in cancer clinical trials have been developed by an international group of experts. The recommendations will help to

determine more consistent and comparable quality of life (QoL) results from clinical trials.

In a paper published in *The Lancet Oncology* today, the international SISAQOL consortium, led by Dr. Andrew Bottomley, EORTC Assistant Director and Head of the Quality of Life Department, EORTC, Brussels, Belgium, together with colleagues from 10 countries, set out their blueprint for achieving consistent, standardised PRO reporting. Cancer patients' own reporting of their QoL is an important factor in understanding treatment risks, benefits, and tolerability, they say.

Although some standards already existed for assessing QoL in trial protocols, there was previously no unified approach to analysing the data obtained in trials. Hence, in the past, very similar trials may have reported different results. The adoption of these new standards will mean that results from trials that measure QoL will be more reliable and consistently conducted and that the direct benefits for patients will be clearly seen.

"The SISAQOL consortium includes all the major players in cancer QoL; PRO experts, statisticians, regulators (including the EMA and FDA), and representatives from international academic societies, industry, cancer institutes, and patient organisations. "For the first time it has been possible to get all these people together and achieve agreement on the best practices and standards," says Dr. Bottomley, "and we are delighted that we have done it."

"These new guidelines will be invaluable to everyone planning, conducting and analysing clinical trials and will set new standards for academic and industry researchers to follow," said a co-author of the publication, Dr. Ingolf Griebsch, responsible for Market Access Oncology at Boehringer Ingelheim. Dr. Dan O'Connor, a co-author from the UK Medicines and Healthcare Products Regulatory Agency (MHRA)

said: "Heterogeneity in how PROs are measured and analysed has hampered the utility of PRO data. The output from the SISAQOL initiative provides an important first step towards fostering a more scientifically rigorous approach to PRO measures."

The consortium's recommendations will enable standardised analyses of PROs in randomised controlled trials of cancer treatments. In addition to benefiting patients, doctors, and regulators, this will also help to ensure that limited research resources are not wasted, the researchers say. The new guidelines are already being disseminated extensively, and a new, larger consortium is being set up to monitor their use in the future and to develop more detailed standards.

"Although our standardised guidelines were developed specifically for cancer, we think that the majority of them could be used elsewhere," says Dr. Bottomley. "QoL is important for everyone, and we hope that researchers and patients across other disease areas will adapt them to their particular fields."

"SISAQOL's work highlights the vital importance of including PROs in all cancer research studies and will also help ensure that the issues which really matter to patients, and significantly impact them, are part of treatment decision-making in a much more consistent and accurate manner," commented co-author Kathy Oliver, Chair of the International Brain Tumour Alliance.

More information: International standards for the analysis of quality-of-life and patient-reported outcome endpoints in cancer randomised controlled trials: recommendations of the SISAQOL Consortium, *Lancet Oncol* 2020; 21: e83-96.

Provided by European Organisation for Research and Treatment of Cancer