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SP-0519 Collecting PROs in clinical practice to assess radiotherapy toxicity and develop normal tissue complication probability models

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The initial part of this presentation will focus on an overview of the literature and theory around the collection and use of patient reported outcomes (PROs) in oncological clinical practice. The second part will focus on the use of PROs to collect symptomatic radiotherapy toxicity data and develop normal tissue complication probability (NTCP) models using examples from RCTs and clinical practice.

Improvements in cancer survival have led to an increasing number of patients with significant long-term adverse events/toxicity. The multiple modalities used to treat cancer make monitoring toxicity challenging and a systematic method of documenting acute and late adverse events has yet to be used in routine care. Increasingly PROs have been included in clinical trials as a standard data source for subjective patient experience. Research shows good concordance between patient and clinician evaluated toxicity with patients providing data on a wider range and milder toxicities.

The integration of PRO results for use in routine practice has been found in multiple RCTs to improve patient-clinician communication and symptom management without lengthening the duration of the consultation. Increasingly, electronic systems have been used to collect and integrate PRO results within existing electronic health records systems. Electronic methods are acceptable to patients and provide better quality data. They also provide the opportunity for remote monitoring of symptoms. However, there are a number of technical and procedural barriers that must be considered when implementing a complex intervention. International examples will be presented alongside experiences from our research group.

The international committee QUANTEC (Quantitative Analysis of Normal Tissue Effects in the Clinic) aimed to establish best practice guidelines to help clinicians and treatment planners to determine acceptable dose/volume constraints to minimise toxicity to normal tissue. One of the key recommendations was the inclusion of PROs in toxicity assessment alongside clinician-reporting in routine clinical practice to define clinically relevant endpoints and aim to standardise outcome measures. Development of predictive models for normal tissue complications requires a detailed evaluation of the relationship between dosimetric, patient and clinical factors, as well as accurate measures of toxicity. Illustrative examples where PRO data has been incorporated within NTCP models from RCTs and observational study experience from our research group will be presented.

SP-0520 PROs instruments used in clinical trials

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The utilization of Patient Reported Outcomes (PROs) in clinical trials have become widespread but data collection from such studies is not always consistent or fully reported leaving gaps in our knowledge of treatment consequences and quality of life. PROs focus on physical symptoms, treatment toxicities, psychosocial problems or global health related quality of life and the impacts of the disease and treatment from the patient's perspective. PROs are therefore critical to understanding the consequences of radiotherapy from a 'whole-person' perspective and the impact of treatment on people's lives [1]. To this end PROs have become an important tool for clinical trials to reflect not only the differences between therapies from the personal perspective but also predictors of health and treatment factors that may influence cancer outcomes. In view of their importance there is a need to ensure rigorous PRO data collection and analysis within clinical trials.

Despite their importance PROs have not always been able to demonstrate significant long-term changes in QOL when evaluating new radiotherapy techniques. In reviewing radiotherapy clinical trials PRO generic quality of life tools tend to be more widely used [2]. These generic tools provide population based data that are useful for comparison in large studies but can be strongly influenced by environmental factors. Improving diversity of PROs by combining a range of instruments to demonstrate granularity can improve sensitivity of PROs to change. It is important to target measures and review the sensitivity of current measures to detect PRO changes as emerging radiotherapy treatments evolve. Furthermore, PROs can be influenced by non-radiotherapy factors such as comorbidities, other cancer treatments, age, health status as well as health care provided. Over time there is a so called 'response shift' as patients become used to chronic symptoms and adapt their lives improving QOL scores despite symptom occurrence. These effects should be mitigated within randomization.

Improving the rigor of how PROs are used in clinical trials is essential for good data capture and the credibility of future radiotherapy evidence. A survey of PRO research staff found that the timing of PRO measures within UK clinical trials varies substantially i.e. prior to the participant's clinical consultation or after, by post or via help from a research nurse. These small differences can impact on participant's responses and subsequent data quality [3]. Use of reminders and digital capture