NIHR | Bristol Biomedical Research Centre

Surgical innovation: accurately and reliably measuring what matters to patients

Approaches to measuring and reporting the consequences of surgical procedures are often ill-defined, inconsistent, and overlook what matters to patients. Many new techniques are therefore adopted based on incomplete and unreliable information, risking patients' safety and quality-of-life.

What translational research was done?

We led international projects with the European Organisation for Research and Treatment of Cancer (EORTC), to develop and validate **patient-reported outcome measures** (PROMs) to evaluate innovative surgery for gullet, stomach, liver, bowel and bladder cancers. Our PROMs have been translated into **20+ languages** and some updated to capture new side-effects as therapies evolve.

We developed a measure to remotely assess surgical wound infections and collaborated internationally to create **new standards** (CONSORT-PRO/SPIRIT-PRO) for designing and reporting trials incorporating PROMs[1].

We designed and led **pilot studies** using the PROMs to inform the design of main trials of novel surgeries including whether innovative keyhole surgery improved patients' recovery, safety, and quality-of-life (NIHR ROMIO and VIOLET studies in gullet and lung cancer, respectively).

With the Core Outcome Measures in Effectiveness Trials (COMET) Initiative, we conceived the idea for **Core Outcome Sets** (COS); sets of scientifically defined and agreed outcomes to report in all studies evaluating a specific condition.

We led and contributed to **innovative methods** to incorporate patient-reported outcomes in COSs and set **novel standards** (COS-STAR/COS-STAD) for reporting how robustly COSs are developed. We have developed several surgical COSs, including for innovative surgery[2].

Translation into later phase research, clinical practice and patient benefit

Our EORTC PROMs are among the **most widely-used measures** in cancer surgery trials[3]. Our surgical wound infection PROM has **17 non-commercial licences** granted including NIHR trials ROSSINI-2 and TALON. The latter is testing the PROM's use in low/middle-income countries.

Our COSs are **endorsed internationally** by funding bodies, trial guidance providers, registries, regulators, clinical guidelines developers, systematic review groups and journal editors.

Implementing PROMs in trials **helps patients and clinicians understand treatment impacts** and make informed decisions.

For example, trials of new cancer treatments can now examine whether specific **patient-reported outcomes are preserved or improved** compared to standard treatments. Investigations into which PROMs are most sensitive to differences in new treatments in trials were also conducted.

We showed that patient-reported measures of symptoms and function most frequently demonstrated differences and are therefore recommended to evaluate innovative therapies.

References

1. Calvert, JAMA, 2013;DOI:10.1001/jama.2013.879
2. Avery, AnnSurg, 2021;DOI:10.1097/SLA.0000000000004975
3. Giesinger,ValueHealth, 2020;DOI:10.1016/j.jval.2020.02.007