August 2015

Royal College of Surgeons

Position Statement

ADVANCING SURGICAL STANDARDS

Clinical Trials Transparency

Background

Well-designed clinical trials are arguably the most effective means of determining the efficacy and side effects of a medical intervention. Trial findings are therefore the main information source on which treatment decisions are based. Publication of only a subset of all clinical trials on an intervention leads to 'publication bias', where results of published studies are systematically different from results of unpublished studies.[1] 'Selective reporting' of positive outcomes within a trial also introduces bias. Publication bias and selective reporting can skew the overall evidence base for an intervention, usually making it appear more effective than it actually is and hiding its side effects. This leads to flawed treatment decisions, detrimentally affecting patient care and patient outcomes, and in some cases jeopardising patient safety.[2]

Despite this, around half of clinical trials, including a third of surgical trials,[3] are not published, and trials with positive results are twice as likely to be published as those with negative results[1]. Moreover, one in five surgical trials are discontinued early[3] and selective reporting of positive outcomes has been found to be prevalent in surgical journals[4].

The RCS and Surgical Trials

The Royal College of Surgeons strongly supports the use of surgical trials to assess the efficacy of surgical procedures, with the aim of developing breakthroughs in treatments for patients. To this end in 2013 the College and partners launched a Clinical Trials Initiative, establishing a UK-wide network of Surgical Trials Centres. By early 2015 these centres were running 53 trials, with 26 in set up. In addition the College funds around 30 surgical trainees annually, to participate in research through the RCS Research Fellowship scheme.

The College recognises that the publication of surgical trial results is required for trials to fulfil their potential to transform surgical care. Our *Good Surgical Practice* (2014) says:

'All clinical trials should be registered and all trial results should be published, including negative results or results where the outcome is different to what was expected.'[5]

While we do not formally regulate trials, the College expects all researchers conducting trials, including those supported by the College, directly or indirectly, to:

1. Register the trial in a publicly accessible trial database, such as ClinicalTrials.gov,[6] the ISRCTN registry,[7] or another register listed on the WHO International Clinical Trials Registry Platform,[8] within six weeks of recruiting the first patient or, for trials of medical devices, within the timeline determined by the current registration and publication decision trees.[9]
2. Submit for publication the trial's full study report, including methods and unbiased reporting of results (i.e. no selective reporting of positive outcomes).
3. Share anonymised participant-level trial datasets where appropriate, through pre-existing free online resources such as FigShare[10] or ResearchGate,[11] to facilitate ancillary research and independent reanalysis of study results.
4. Provide continuity of access to data if a trial is discontinued.

For further information please contact Grace Gottlieb, RCS Policy Officer, at ggottlieb@rcseng.ac.uk

References

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