



Protocols

Describing the first 2000 registrations to the Research Registry[®]: A study protocolAlexander J. Fowler^{a,*}, Chris Limb^b, Daniyal J. Jafree^c, Riaz A. Agha^{d,e}^a Critical Care Research Department, Royal London Hospital, London, UK^b St Helier Hospital, Surrey, UK^c MBPhD Programme, Faculty of Medical Sciences, University College London, London, UK^d Department of Plastic Surgery, Guy's and St. Thomas' NHS Foundation Trust, London, UK^e Balliol College, University of Oxford, Oxford, UK

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ABSTRACT

Background: In 2013, the Declaration of Helsinki was updated and required the registration of all research studies involving human participants. Prior registries focussed on the registration of clinical trials and systematic reviews, and we estimate that only 10% of observational research is registered in a publicly accessible registry. The Research Registry[®] was established to provide a venue of registration for any study, prospectively or retrospectively, involving human participants. This protocol describes the analysis for the first 2000 registrations received to the Research Registry[®].

Methods and analysis: Data for each registration to the Research Registry[®] (www.researchregistry.com), adapted from the World Health Organisation minimum data set, has been collected since the launch of the registry in 2015. A weekly curation process ensures that inappropriate registrations, such as duplicate studies or those not involving human participants, are removed from the registry. We will present the characteristics of the first 2000 registrations and how they have changed overtime. A quality score will be calculated for each registration by two independent teams, and inter-rater reliability will be calculated. Funding sources of work registered will also be presented. This process will also be performed for the systematic review portion of the registry ('The Review Registry'), which will be considered separately.

Ethics and dissemination: Ethical approval is not required for this study as it involves no human participants. The findings will be presented at international conferences and published in a peer reviewed journal.

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Background

Registration of clinical trials has long been identified as best practice [1]. Amongst its various advantages, registration of research reduces the risk of publication bias, as a discrepancy between study registrations and published studies is a clear indicator of such bias. It also reduces the risk of reporting bias, whereby outcomes are reported selectively based on their significance, and not based on *a priori* definitions [2]. It also reduces the risk of waste in biomedical research by having a clear record of studies that have been, and are being, undertaken [3].

Whilst emphasis on registration has traditionally been placed on clinical trials and systematic reviews, there is an increasing recognition of the importance of registering all research. In 2013,

the Declaration of Helsinki was modified to ensure that not only clinical trials were registered, but all studies involving human participants. Despite these efforts, there is increasing acceptance that observational research is seldom registered [4], and that there are limited venues to register research that has already begun recruiting participants. This was the basis for the foundation of the Research Registry[®] [5]. This provides free and immediate registration of any study type involving human participants. Its development has been outlined previously [4], and we have reported the first 500 registrations; finding that a majority of these to be retrospective cohort studies, case series or first-in-man case reports, fulfilling a previous unmet need for the registration of these study types, that the quality of the registrations improved over time and that ~16% of studies were incorrectly registered [6].

The aim of this study is to describe the first 2000 registrations received to the Research Registry[®], and to separately report the first 200 registrations of systematic reviews received to the Review Registry.

* Corresponding author.

E-mail address: alexjfw@ic.ac.uk (A.J. Fowler).

Methods

This will be retrospective database analysis, and involves no human participants, so is not registered. No reporting guidelines exist for study types of this design.

Data source

Data will be extracted from the Research Registry® (www.researchregistry.com) database when 2000 complete registrations have been received. Characteristics to be extracted include: study design; country of origin; date of registration; number of patients anticipated or included in study; source of funding for study and study phase at which registration was made. Curation reports for these 2000 registrations will be collected, and the process curation of the registry has been described previously; involving a weekly process of screening for inappropriate registrations by trained curators [5]. Any registrations missing these data will be excluded by list-wise deletion, and their characteristics compared to included registrations. Separate analyses will be performed for the Review Registry, the part of the Research Registry® designated for the registration of systematic reviews and meta-analyses.

Data quality score

To establish the quality of the registrations received at the Research Registry®, we have previously described a quality score that was developed based on Sir Austin Bradford Hill's criteria for what a research study should convey [5]. Each registration is marked by providing an appropriate answer for each of the following: primary investigator, participating institutions, countries recruiting, key questions and objectives, patient population, intervention, control or comparator, primary outcomes (and secondary, if used) and dates of enrolment. Each of these items scores one point, and therefore each registration can score a maximum of 9. If any of these items are inapplicable, such as the use of a control or comparator for first-in-man case reports, then the item is marked as such and the denominator of the quality score for that registration decreases. Each registration will be marked by two researchers independently. Where consensus is not reached on the correct score for a given registration, the decision will be raised to a senior author.

Statistical analysis

All records will be held in a Microsoft Excel 2007 (Microsoft, Redmond, WA) database. Data will be cleaned and descriptive statistics will be used. Continuous data will be presented as either mean or median (with standard deviations and interquartile ranges respectively), and categorical data as a number (with percentages). The quality score will be compared between different time points (divided by month) with an independent samples Kruskal–Wallis test, with post hoc comparisons to compare quality scores between months. To compare continuous data, we will use student's *t*-test if parametric, and a Mann Whitney *U* test if non-parametric. χ^2 tests will be used to compare categorical variables. All statistical tests will be performed within R [7] and the analysis code will be provided.

Ethics and dissemination

As no human participants will be included in this study, no ethical approval was required. Findings will be disseminated by the team working on Research Registry® as soon as data are available. The data will be published in a peer reviewed journal and presented at international conferences.

Funding

No funding was received for this work.

Conflicts of interest

RAA is the Director and Founder of the Research Registry; AJF is the Assistant Director of the Research Registry; CL is the Director of Quality of the Research Registry, DJJ is the Director of Usability of the Research Registry.

Author contribution

AJJ, DJJ – drafting, study design, RAA – concept, study design and critical appraisal, CL – critical appraisal. All authors approved the final version of the submitted manuscript.

Guarantor

Riaz Agha

Research registration UIN

This is not a human study.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <http://dx.doi.org/10.1016/j.isjp.2017.08.002>.

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