Barriers and facilitators to data sharing of individual patient data (IPD): A randomised control trial. Poster presented in the *25th Cochrane Colloquium*, September 2018, Edinburgh, UK.

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Background

Individual participant data (IPD) meta-analysis is considered the 'gold standard' for exploring the effectiveness of interventions in different subgroups of patients. However, it is time consuming to contact authors of original randomized controlled trials (RCTs) to obtain IPD. To date, there are no studies evaluating strategies to optimize the process for retrieval of IPD from RCTs.

Objectives

To examine the impact of providing a financial incentive to RCT authors that are eligible for a systematic review versus usual contact strategies to obtain IPD. To describe potential barriers and facilitators associated with the data sharing process.

Methods

We used RCTs identified through 2 systematic reviews and contacted both study authors and sponsors to obtain IPD. Eligible authors were randomized to either the intervention or control group using a 1:1 procedure. The intervention group included contacting authors via email, mail, and phone, along with a financial incentive. The control group included the same contacting author process with no financial incentive. Primary outcome: the proportion of authors who provided complete IPD. Secondary outcomes: time taken to obtain IPD between initial request and authors' provision, and completeness of IPD received. Descriptive analysis was conducted for characteristics abstracted from RCTs or collected through author/sponsor contacting process.

Results

Of the total 138 trials, we were unable to locate contact information for 8 trials. Of the 130 authors, we were able to obtain 83 (64%) responses (38 [29%] positive and 45 [35%] negative responses). In total, one author provided complete IPD (control group) within 472 days. Of the 138 studies, 107 reported at least one industry-sponsored funder in their publication. We contacted 17 sponsors for 137 studies (83 studies were funded by 1 sponsor, 23 studies by 2 sponsors, and 1 study by 5 sponsors), 3 (18%) of which did not respond to any of our contacting attempts. To date, we have 2 complete IPD datasets from a single sponsor. For study sponsors, data sharing agreements were required and the time to clarify the process ranged between 0 and 24 days.

Conclusions

Important barriers were encountered in obtaining study IPD threatening the validity of an IPD meta-analysis. These include study identification, data ownership, and limited data access.