CHIEF SCIENTIST OFFICE

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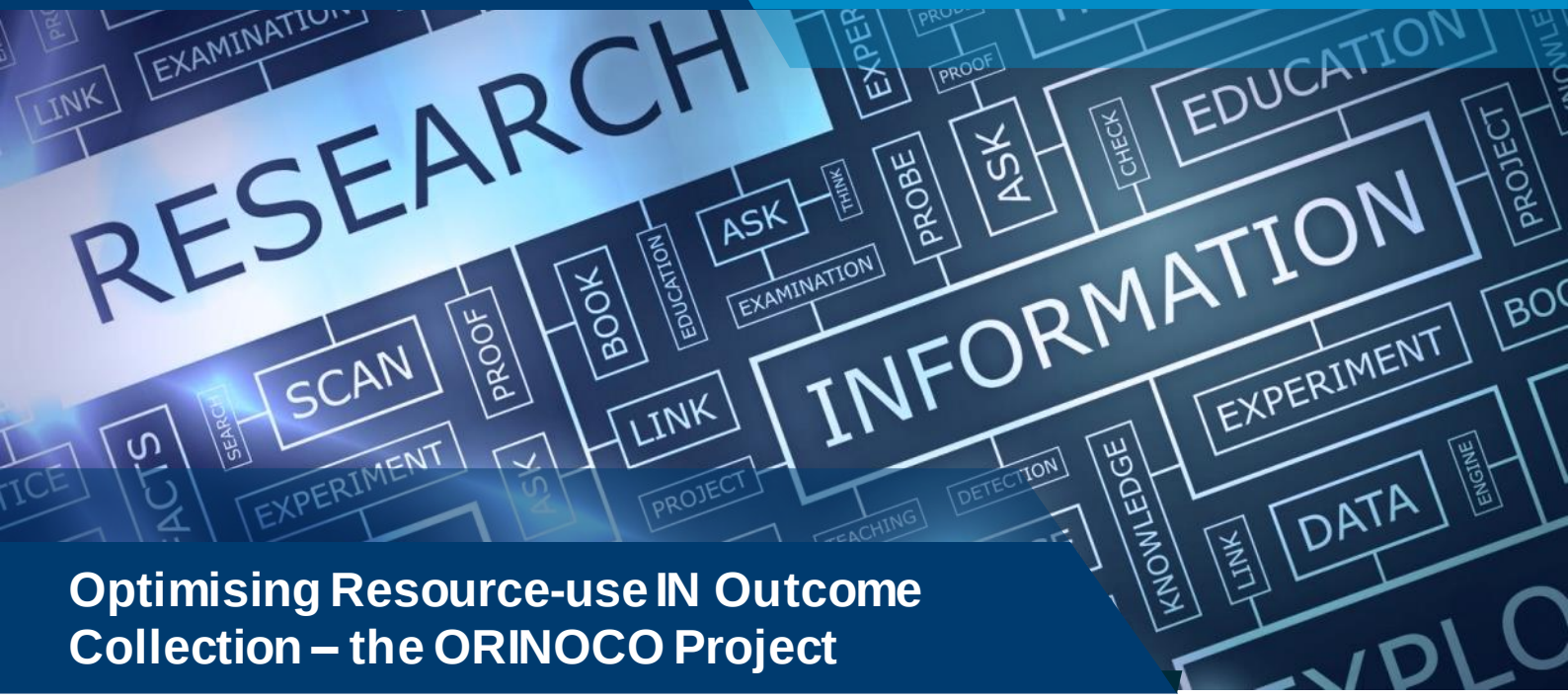
RESEARCH PROJECT BRIEFING



Optimising Resource-use IN Outcome Collection – the ORINOCO Project

USEFUL INFORMATION

In trials, data (called outcomes) are collected to see if there is a difference between the intervention and control groups. These data can come from measurements such as blood samples (e.g., cholesterol levels), or questionnaires (e.g., how you are feeling). Primary outcomes are the most important outcomes; they are used to decide how many people need to participate in the trial to see a meaningful difference between the intervention and control groups. Secondary outcomes are used to assess additional effects of the intervention.

AIMS

To explore outcome collection in trials, a process that is known to be time intensive and costly, to assess if/where efficiencies can be made.

KEY FINDINGS

- We collected full primary and secondary outcome timing data for 130 out of 161 trials. For every 1 minute spent collecting primaries, 3 minutes were spent on secondaries. These data are available to others in a database.
- The biggest difference was for a cardiology trial where for every minute spent on primary outcome data, 401 minutes were spent on secondaries. The smallest was for a rheumatoid arthritis trial where for every minute on primary data, 0.03 were spent on secondaries.
- In 29 qualitative interviews participants focussed on primary and secondary outcome selection, describing factors that drove selection such as: interplay between stakeholder groups, research culture, and the need for meaningful patient and public involvement.
- When discussing how data to support outcomes should be collected, participants described using the existing literature and experienced trial team members to support their decisions.

WHAT DID THE STUDY INVOLVE?

1) **Identifying trials and outcomes.** We searched PubMed, a database of scientific publications, for academically led, Phase III trials evaluating interventions that aimed to impact on a health-related outcome, and indexed between 2014 and the project start date in 2019. From this search, we randomly selected 120 Phase III trials and 20 trials evaluating a public health intervention. We also included trials that used the established rheumatoid arthritis core outcome set.
2) **Obtaining timings for each outcome.** If outcome timing data was not reported in the trial publication or registration, we emailed the trial team. If the team did not respond, we used web-based resources such as the Shirley Ryan AbilityLab Rehabilitation Measures Database, and a crowd-funding approach with trialists and clinical professionals – contacting individuals in our networks that have hands-on experience of collecting the outcomes.
3) **Stakeholder consultation.** We conducted 29 semi-structured interviews with trial stakeholders, to explore their views and experience of outcome selection and collection. We then worked with a group of 18 individuals with expertise in outcome selection, collection, and research waste, to develop guidance for trial teams to use to steer their decisions about primary and secondary outcome selection and collection.

WHAT WERE THE RESULTS AND WHAT DO THEY MEAN?

We identified 230 primary outcomes and 688 secondary outcomes from 161 trials. Full primary and secondary timing data were obtained for 130 out of 161 trials; we used these data to calculate how much more (or less) time was spent collecting primary to secondary outcome data, which is called the ratio. The average (median) ratio was 1 to 3.1 minutes. The ratio varied slightly between the types of trial: Phase III trials were 1 to 3.2; public health trials 1 to 2.2; core outcome set trials 1 to 3.4.

Our qualitative work explored the decisions involved in selecting and collecting outcome data. Participants described their experience of selecting outcomes as *"probably the most important and the most difficult thing to do",* which demonstrates just how difficult this process can be. Various factors that contribute to outcome selection were reported, including the interplay between different stakeholder groups and potential pressures as a result of research culture, including *"how many papers they can get out of this piece of work".* Meaningful patient and public involvement was discussed at length, with trialists reporting various degrees of involvement and success, and patients recounting how their experiences differ based on the trial team's actions, *"it's all about power and hierarchies because I can only get involved if people choose to involve me."*

In contrast, deciding on methods to collect outcome data seemed much less challenging; participants explained that they tend to use the literature to lead their decisions, which results in core outcome sets being used regularly, but this approach has the potential to perpetuate mistakes in outcome selection and collection.

WHAT IMPACT COULD THE FINDINGS HAVE?

Our findings demonstrate that most trial teams spend more time collecting outcome data to support secondary outcomes than primary outcomes. This is not a problem if these activities are planned and budgeted for, but previous work shows that time and budget extensions are common. For participants, this may mean that trials are rushed, staff are stretched thin and the quality of the data collected is not as good as it could be. For patients after the trial is complete, this may mean that trial results are not as impactful on healthcare as they could be, potentially missing important information about the effects of an intervention.

Our qualitative work explores outcome-related decision-making, and combined with further stakeholder consultation we have developed guidance for trial teams to use while planning their trial to steer their decisions about outcome selection and collection.

We anticipate trial teams using this guidance to support budgeting, and to ensure that the outcomes being measured are important to patients, and do not contribute to research waste.

HOW WILL THE OUTCOMES BE DISSEMINATED?

We are currently drafting three manuscripts to disseminate the findings from the timing data work, the qualitative interviews and the guidance. These will be submitted to the open-access journal, *Trials*. We will submit two abstracts from this project for presentation at the 6th International Clinical Trials Methodology Conference which is planned for October 2022. We will also use platforms such as Trial Forge, the UK and Irish Trials Methodology Research Networks, and NIHR Clinical Research Networks to disseminate results of this work to the wider trials community through a series of webinars and talks. We will be working closely with our public contributor, Annabel Dawson, to ensure that our presentations are accessible.

CONCLUSION

Data collection is a lot of work and time spent on one outcome may take time away from another. Our guidance incorporates the views and experiences of various stakeholders to ensure that trial teams can select and collect outcome data that are meaningful to patients and the research and clinical communities, are focused, within budget and without research waste.

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Additional Information

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