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Reviewer recommendations: collaborative research

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Collaborative research describes medical projects involving partnerships between different researchers, including within and between medical specialties, across disciplines, and between researchers and stakeholder [1]. Collaboration offers the opportunity to examine complex phenomena, with different groups bringing distinctive areas of expertise and broadening the scope of studies by extending research outwith one particular discipline. Research questions that are generalisable; require large numbers of patients; or aim to complete promptly often require collaborative approaches. Modern research design and delivery usually require broader stakeholder engagement; collaborating with these groups improves research quality.

The COVID-19 pandemic highlighted the importance of collaborative research to meet global challenges. Studies such as COVIDSurg [2], the Randomised Evaluation of Covid-19 Therapy (RECOVERY) Collaborative [3], intubateCOVID [4] and the Randomised, Embedded, Multi-Factorial, Adaptive Platform Trial for Community-Acquired Pneumonia (REMAPCAP) [5] highlighted how collaboration could be harnessed rapidly to have significant implications for healthcare throughout the pandemic. Whilst well-funded collaborative studies delivered by experienced academics are likely to be successful, trials with modest or no funding can also influence clinical practice, such as those conducted by trainee research networks [6,7]. However, there are no clear guides to support researchers in successfully conducting collaborative research studies. Rather than describe the well-defined clinical research processes in general or be a comprehensive guide, we aim to provide specific principles that apply to collaborative studies.

Research design and delivery

Designing collaborative studies is more complex than non-collaborative studies. They involve more people, often from a range of professional, geographic and socio-economic backgrounds. Given the complexity of delivering collaborative studies, investigators must first determine if collaborative research is appropriate and feasible for the research question and team involved. If a collaborative approach is appropriate, conduct can broadly be split into four stages: preparation, design, delivery, and analysis and publication (Table 1). We will use this structure to describe how to successfully realise a collaborative research project.

1. Preparation

The first step is to build the team. This will include a core Executive Committee, a Steering Committee, a wider Advisory Panel and Collaborators. The Executive Group should include the individuals who conceived the research idea and members with expertise in particular areas, such as a statistician and a clinical trial manager. The chief investigator holds ultimate responsibility, but the core team should consist of members with a range of skills, time and resources to take responsibility for all study design and implementation collectively. Executive Committee members should hold a range of allocated roles, such as communication, governance, approvals or data management. Ownership of each team member in their designated role ensures that all aspects of trial management receive full attention. It is often beneficial to have patients involved in the executive committee. The chief investigator's institution is usually the sponsor, and having full institutional approvals, engagement and support is critical.

The Steering Committee is a group that provides guidance to the Executive Committee on study design and delivery and should include experts in their field relevant to the different areas the

collaborative research aims to include. It is imperative to have patients involved in this Steering Committee. If appropriate, a wider Advisory Group should be formed. This can include stakeholders in the particular research topic of interest, including a lay committee (e.g. patient advisory groups), allied health professionals (e.g. nursing or midwifery groups) or representatives of stakeholder organisations (e.g. specialist societies). Teams should reflect the wider collaborative group and be multi-disciplinary and representative of the essential groups. All members of the teams need to have the time and expertise to commit to the project. Established collaborative networks are a resource that should be utilised if possible. Examples include the Research and Audit Federation of Trainees (RAFT) in anaesthesia and Surgical Research Collaboratives (SRCs) within surgery.

Collaborators are people who will actively contribute to the delivery of collaborative studies locally. This often includes a lead or local coordinator at each institution or region participating. In clinical research, these are often referred to as principal investigators. This person is responsible for ensuring local governance and ethical approvals are obtained, organisation of local training and organisation of all aspects of local study delivery. This ensures that sufficient local collaborators are involved, supervised and trained. They work to support both the study and their local collaborators. If collaborative research is international in scope, having a national principal investigator or coordinator is highly recommended. Encouraging principal investigators to recruit suitable, named, role-allocated team members locally to recruit to studies is beneficial.

Identifying and initially approaching the correct people to be involved can be challenging. Communication and networking are vital in identifying the experts and people you want on your team who can guide and provide invaluable advice. In the same way a literature review is performed to crystallise a research question, a review of the people already involved in your area of research is helpful.

2. Design

In terms of study design itself, collaborative research is similar to non-collaborative research. It must follow the same standards of protocol design, trial registration, funding, ethical approval, contractual agreements, advertising, site training and data monitoring [8]. However, one consideration with collaborative research is the variation in governance and approval regulations across sites. For example, requirements in Scotland may differ from those in England, and similarly, regulations in different countries are highly variable. Relying on national coordinators to ensure contractual agreements and national and local regulations are adhered to is recommended.

Before rolling out across collaborative networks or wide geographical regions, a smaller, possibly local, pilot would be performed to assess the feasibility of widening the project's context and identify any potential problems [9]. The Executive Committee should iteratively and collaboratively develop a protocol, including a statistical analysis plan, reviewed by the Steering Committee and Advisory Panel. Several collaborative tools can be used in protocol development and review, and having a system to achieve this is important to maximise efficiency. One example is having shared folders (e.g. Microsoft SharePoint, Teams, Dropbox) where files are managed centrally, but simultaneous editing is currently less reliable. Another is to use a service such as Google Docs (Alphabet, Inc., Mountain View, CA, USA) to allow simultaneous reading, commenting and editing by several collaborators. Numerous project management services are available (e.g. Basecamp), but researchers should determine which tool is most suitable to their needs and meets institutional governance requirements.

Another vital step is designing data management and case record forms (CRFs). Whilst this is often done in conjunction with protocol development, collaborative studies require electronic databases with sufficient capacity to handle large numbers of collaborators inputting data and large numbers of data points. Efficient design of CRFs can make or break effective study delivery; thus, selecting the provider (e.g. REDCap, Castor EDC, OpenClinica) and trialling the design is critical. These data management platforms can also be used to conduct surveys of recruiting sites and manage information on authorship by collecting names, Open Researcher and Contributor IDs, and contributions of all people involved in any aspect of the study.

One of the essential elements of the formulation of collaborative study is how the research teams will communicate between executive, steering, advisory and collaborator groups. It is useful for each executive committee to allocate at least one person to lead all communication. This involves advertising to recruit sites, disseminating study documentation, and providing regular study updates, often in newsletters. Producing a website for the study, either as a standalone site or embedded within an existing institutional website, may provide a repository for relevant files and information. During this stage of collaborative trials, producing online training videos that can be accessed by all collaborators, creating frequently asked questions documents, as well as coordinating approvals by principal investigators is essential. Social media is increasingly influential in this regard.

At this stage, it is also vital to confirm and communicate the authorship of any final publications directly arising from the study and data collected by any contributor. The International Committee of Medical Journal Editors (ICMJE) suggests that authorship requires:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Simply put, authors are people who have contributed to the initial study design and/or the writing of the final product of dissemination [10]. Collaborators tend to be people who have provided expertise in designing and performing the research with possible guidance towards the final publication. Contributors tend to help with data collection and more ‘on the ground’ work. Both Collaborators and Contributors meet fewer than all four criteria suggested by the ICMJE. Some studies publish lists of tens or hundreds of authors, but the exact contribution of each is unclear. However, group authorship is also possible whereby a collective group is named as the author [2,11], with the individual names of the group being published elsewhere, such as in the supplementary material. This is increasingly seen as an essential demonstration of democratic collaboration within research. Researchers can request that all contributors receive named authorship or members of different groups within the study (e.g. Executive Committee only). The difference in these groups is how they contribute towards citations and authorship for individual researchers. It also represents an important tool to achieve buy-in from collaborators and contributors and recognition for all who warrant it.

3. Delivery

After preparing the study, patient recruitment and data collection represent the next critical step. Again, organisation and communication are key. During the delivery stage, there must be clear lines of communication with prompt turnaround. At least one member of the Executive Committee should always be available to answer queries from collaborators collecting data, ideally via a dedicated email address. A separate team member should be available to deal with technical queries, particularly if using an electronic database for data input. Data collection will stall if collaborators encounter problems and do not feel that those problems are addressed quickly. The Chief Investigator needs to be immediately contactable to deal with any issues that arise.

Providing regular updates throughout the delivery stage helps maintain impetus; this could be via social media posts or regular email updates. These updates also reinforce that the Executive Committee is involved and working hard to facilitate the delivery of the collaborative research throughout all sites and can address amendments or changes that need to be widely distributed. Regular reminders of the resources created during the design stage (e.g. frequently asked questions) can also be useful to reduce unnecessary questions and make the data collection easier. If the preparation and design stages of the collaborative study have been performed well, the delivery aspect should run smoothly and only involve troubleshooting during data collection.

4. Analysis and Publication

Due to the nature of collaborative research, there is likely to have been a large volume of data collected with variable completeness. Part of the planning stage needs to have allowed time for data cleaning to take place before analysis can begin. Within the study design, it needs to be decided who will perform data cleaning, be it members of the Executive Committee who will go on to analyse the data, or local sites. If the latter, a high degree of buy-in and incentivisation is needed for data cleaning to be effective and timely.

Data analysis should follow the statistical methodology of non-collaborative studies but the volume of data collected may necessitate the use of large computational power and external statistical help. The statistical analysis plan within your study design should have encompassed these needs.

Collaborative manuscript preparation should follow the same processes as study design, in terms of role allocation and the use of shared documents or folders. Authorship will have already been decided; it is important to remember that all authors hold responsibility for the final manuscript.

Once the collaborative study is complete, the results need to be published to ensure that the hard work contributes to the literature and, ultimately, to the progression of science. Choosing the correct journal is critical to ensure that your research findings are disseminated correctly. When selecting a journal, consider the readership, impact, area of dissemination and speed of publication. Decisions on the target journals ultimately lie with the Chief Investigator and Executive Committee, but these discussions may gauge feedback from other study contributors. Once agreed upon, authors should communicate and work with the chosen journal to get the best out of their work for patient benefit. This may work best if you make initial contact with relevant journals at the planning stage. Dissemination of the work is critical, and agreed publication strategies and launch plans should be discussed and agreed with journals to maximise impact.

Collaborative research studies can produce multiple publications at different stages of the research: the protocol should be published before study commencement; key results should be published as the primary manuscript; and secondary results could be published as secondary

manuscripts. This needs planning (ideally at the design stage of the research with careful database design) to ensure that findings published in separate manuscripts are different and there is no inappropriate duplication of work.

Conclusion

Collaborative research takes a vast amount of time, planning and organisation to be successful. However, as evidenced by recent large collaborative studies within anaesthesia and critical care, they can have a considerable impact on patient care and should be encouraged where appropriate, regardless of study design. This article provides a structure and guide on successfully conducting a collaborative study. These principles should aid the standardisation of collaborative research, making it more achievable and of more significant impact.

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Table 1. Checklist to consider when planning collaborative research

Preparation

• Formulation of research question
• Forming teams
  ○ Executive Committee
  ▪ Chief investigator
  ▪ Trial manager
  ▪ Statistician
  ▪ Communication
  ▪ Data management
  ▪ Governance and approvals
  ○ Steering committee:
  ▪ Experts
  ▪ Patients
  ○ Advisory group
  ▪ Lay committee
  ▪ Allied health professionals
  ▪ Stakeholder organisations
  ○ Collaborators
  ▪ Principal investigators at local sites
  ▪ Local collaborators

Design
• Pilot study • Determine governance and approval requirements for involved jurisdictions • Iterative and collaborative protocol and CRF design • Create training materials • Set up study website with access to information and documents • Determine authorship structure
Delivery
• Allocated member of executive team easily available for support • Dedicated email address • Prompt communication to address any queries • Allocated technical lead especially if using an electronic database • Regular updates
Analysis and publication
• Data cleaning and analysis • Collaborative manuscript preparation • Agreement on destination Journal • Collaboration with Journal of choice • Publication of protocol, primary manuscript and secondary analyses