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Parallel Researching with Online Collaboration (PROC), a new cost effective model for multicentre multinational research

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The traditional model of multicentre multinational studies is a costly exercise that limits its feasibility for resource limited settings. We propose an alternate model for such studies named Parallel Researching with Online Collaboration (PROC). If implemented, this hypothetical model will make multicentre trials feasible in many resource limited settings. PROC can be summarized in five phases; phase I – academics using free access social networking sites to collaborate and develop research questions, phase II – further consolidation of an idea and expansion of it with online contributions from experts, identification of key persons to carry out the study in parallel at different centres, phase III – drawing up a common research protocol and study tools, phase IV – each satellite centre functioning independently to carry out the common protocol, Phase V – pooling of data in a common summarized format and writing up the findings.

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Background

The concept of multinational multicentre studies is often associated with the notion of a costly exercise in which peripheral research centres are centrally regulated by an overseeing authority. This is often (if not always) true [1]. The study hypothesis, methodology and budgeting are decided by a central authority (usually a centre in a developed country which has sufficient funds) and only the instructions on the protocol flow down to the peripheral units that enrol patients and collect data [1]. This is reflected by in the discrepancies of the number of clinical trials in progress between developed and developing countries in the world [2]. Some concerns and restrictions of the current model can be summarized as follows:

1. The contribution of the peripheral stations is usually weighted towards data transferring rather than changes in study protocol or design.

2. Most research questions addressed in current trials may not address the pressing health care issues of developing nations that are involved [1,3,4].

3. Multicentre multinational studies based on the traditional model are a costly exercise which prevents them from being planned by centres in developing countries [2,4] .

It can be reasonably argued then, that the current model: (a) may not always address the more relevant healthcare needs of developing nations [4]; (b) is considerably more costly even to be carried out with available research grants in affluent countries [5] and (c) is becoming increasingly difficult to execute with the global economic depression. This has led to fears of restriction of research funds especially when results are not supported by cost effective data [6-8].

We propose an alternative model to enable research relevant to developing countries which would not carry the heavy overheads required by the traditional model of

multicentre multinational studies. We propose that this would enable the following:

1. Research could be carried out in resource limited settings tailored to the needs of these settings.
2. Audits and small scale clinical studies that are not addressed by the current model can be executed with this model.
3. Research output is not hindered despite predicted cost cuts in research and development funding.

The hypothesis

Using the freely available resource of online communication can dramatically reduce costs in research. The proposed model of Parallel Researching with Online Communication (PROC) will help to create a more interactive environment for planning and executing multicentre multinational studies.

Online access has become far easier as we have moved from desktops to laptops and from stationary broadband connections to mobile broadband connections; this is the case even in developing countries. Furthermore, the internet is currently accessible by 'common accessories' such as mobile phones and personal digital assistants. The methods of communication has also moved forward from emails that provide personalized channels of communication between small groups of individuals to broader online idea exchanges via social forums (Facebook, Myspace, Twitter) [9,10]. Nowadays anyone can make their voice heard by masses at click of a button. These influences sometimes extend as far as facilitating regime change. Communication has never been so easy yet complicated, and has never had such impact and consequences in history.

How this resource can be harnessed to revolutionize research methodology is an interesting idea to explore. The traditional way of doing multicentre multinational studies are encountered by many logistical difficulties (legal constraints, language, travel and transport issues) and associated cost concerns. These pose limitations for these trials to be successfully completed. As a result, especially for disease conditions affecting developing countries, much of the best evidence comes from meta-analyses of small studies. The methodological quality of these smaller studies shows wide variation.

Our alternate model i.e., PROC, for planning such trials can be elaborated in five phases:

Phase I: Freely accessible social networking sites can be used to create web pages or forums that can be used as portals for academics to generate, refine and discuss ideas and hypothesis for research. This phase does not require any financial commitments. It only requires participation of colleagues. Rather than being restricted to the viewpoints of few colleagues serving in associated institutions, this enables ideas to be exchanged from different settings all over the world.

Phase II: Several interested academics agree on a research hypothesis or a clinical question that needs to be explored further. They then form a group and invite more experts from different countries to participate in the study. With online collaboration, the core research question can be further refined to reach specific objectives that are acceptable to all participants, as appropriate to the clinical settings in the countries they represent.

Phase III: This entails the development of a detailed research protocol and study tools such as questionnaires through online collaboration. This effort would need a core person or a 'secretary' within the group for coordination. Consensus is reached on the research protocol, and the participating researchers agree to adhere to a common protocol, and to share any deviations encountered during implementation.

Phase IV: From this point onwards, the individual academics start to function more independently in their settings to conduct parallel studies in their localities (based on the same protocol). The funding for the functioning of each centre should be secured by lead coordinators at each station. There will be a significant time gap between phases III and IV till all centres are financially equipped and some stations may drop out due to inability to secure funding. Once the work starts, individual centres should maintain regular online communications and adhere to the common research protocol. These units should function independently in getting ethical clearance, setting up logistics, recruiting patients, carrying out procedures, collecting data, summarizing it according to an agreed protocol and managing their own financing in this regard. Since travel costs, exchanges in foreign currency, moving stationary and equipment from a central location to periphery across borders are avoided, cost reduction becomes a reality. As the key researcher is a local person in each independent unit, dealing with local authorities, clearing legal issues and gaining ethical clearance will be easier.

Phase V: This entails convergence again as the summarized data (according to a uniform consensus) are pooled together and analysed by statisticians. The pattern recognition, statistical analysis, refining of results and writing of the paper can be done by all authors communicating via the online forum.

The advantages of PROC

1. Making significant cost cuts while maintaining the quality of research (large sample sizes, diverse cohorts, better statistical power, increased validity and better applicability of findings to different settings).

2. The ability to address many research questions that would otherwise go unnoticed due to lack of finances (for example, efficacy of low cost measures in preventing snakebites).

3. Enabling academics of developing countries to initiate multicentre multinational studies on issues pertinent to their settings (e.g. studies on tropical problems such as filariasis, snakebites leishmaniasis and malaria).

4. Allowing better international collaboration between colleagues with 'scientific networking' than mere 'social networking'.

5. Enhancing the capacity to increase the volume of research per available amount of funding in any setting by cuts on travel, stationary, mailing, bureaucratic and legal, logistical and employee expenses (Supplementary Information, Table 1).

6. Ability to increase the research volume on diseases with low incidence and prevalence by engaging diverse cohorts from around the world (e.g. research on inherited rare conditions such as spinocerebellar ataxia).

The PROC model has similarities with meta-analysis. Meta-analyses are considered the highest level of evidence in the hierarchy of the evidence based medicine, because they collate data from smaller studies to produce cohorts of data which are large with high power. Meta-analyses are often plagued by clinical and methodological diversity, and statistically heterogeneity [11,12]. The prospective nature of the individual studies in the PROC model provides the opportunity to reduce clinical and methodological diversity and statistical heterogeneity which adversely impact on the results of most meta-analytical results. The PROC model is akin to a meta-analysis which has been prospectively planned.

The disadvantages and limitations

1. Risk of plagiarism – since the ideas are posted online initially, researchers who do not choose to join the collaboration could potentially plagiarize these ideas.

2. Lack of physical cohesion between centres. Attrition or delays in some centres may jeopardize the entire project.

3. The flow of ideas within a social network page may be chaotic and difficult to maintain in an orderly fashion.

4. Difficulties in harnessing the prowess of less 'tech savvy' academics.

5. Since funding should be secured by individual stations, there could be a considerable delay between stages III and IV and some stations may drop out at this transition.

Some limitations such as confidentiality and risk of plagiarism can be guarded to an extent by communicating through groups and messaging systems that are not visible to those outside the group. However, the risk cannot be completely eliminated.

One of the main concerns about PROC is the mechanism used to monitor methodological quality at different centres, in order to ensure uniformity of data quality. The whole purpose of PROC is to decentralize the research process to individual centres and therefore it is not cost effective for a central office to keep tabs on the quality and validity of data collection. The monitoring mechanisms must be as stringent as for multicentre trials and maintaining them should be the responsibility of each centre. It must be stressed that each study centre must adhere to Good Clinical Practice (GCP) guidelines when conducting clinical trials involving human subjects. The only difference in PROC is that at phase IV, the whole process is decentralized so it is the responsibility of each centre to maintain adherence to GCP guidelines (e.g. obtaining ethical clearance and monitoring from an accredited local ethics review committee). Additional support in maintaining standards can be provided by organizing a common workshop for all data collectors or a representative from each of the centres. It would even be possible to conduct these workshops online, using low cost video-conferencing technology such as Skype. Each study coordinator or lead researcher must take care to ensure quality of randomization, blinding, and data collection and storage. Data collection could be centralized using online tools to share data, such as Google Docs or Dropbox. The lead coordinator's role would also include monitoring the progress of the project in his/her centre, and reporting back to the group if shortcomings arise. Agreement among the group must be made at the start of the project as to what action could be taken in case a particular study centre does not adhere to the defined standards of methodological quality or GCP guidelines; if the difficulties cannot be overcome then the study group may recommend the removal of that centre from the project. Standard tests used to evaluate heterogeneity in meta-analysis could be utilized to compare the data from the different centres. The monitoring of adherence to accepted ethical standards and GCP guidelines during phase IV can be done in three ways at each centre: by subject to scrutiny by visiting peer review team, surveillance by a local accredited ethics review board or by commissioning a local independent body to oversee the functioning of each centre with regard to GCP guidelines.

It has to be appreciated that in current context where cost cutting is creeping into research budgets worldwide and free online communication is available to all, novel methods and models of researching have to be developed and adopted. This should be the way forward for more relevant, valid, cost effective and globally coherent researching in future.

An example of PROC and a cost comparison between

the traditional model and PROC is presented in the Supplementary Information.

Summary

This article explains an alternate model for multicenter multinational studies named Parallel Researching with Online Collaboration (PROC).This hypothetical model will make multicenter trials feasible in many resource limited settings as it will enable considerable cost cutting compared to the traditional model. PROC can be summarized in five stages and involves extensive incorporation of online communication in to clinical research. This model may also be considered to be a type of meta-analysis which has been prospectively planned.

References

1. Friedman LM, Furberg CD, Demets DL. *Fundamentals of Clinical Trials. 4th Edition*. London: Springer Science+Business Media, 2010.
2. US National Institutes of Health. *Clinical Trials locations by region*, 2011.
3. Maiti R, M R. Clinical trials in India. *Pharmacol Res* 2007; **56**(1): 1-10.
4. Siegel AW. *Kantian ethics, exploitation and multinational clinical trials.* In: Emanuel EJ, Hawkins JS, editors. Exploitation and developing countries: the ethics of clinical research. Princeton: Princeton University Press, 2008: 175-205.
5. Choi HY, Ko JW. Facilitating large-scale clinical trials: in Asia. *Urol Oncol* 2010; **28**(6): 691-2.
6. Rivero-Arias O, Gray A. The multinational nature of cost-effectiveness analyses alongside multinational clinical trials. *Value Health* 2010; **13**(1): 34-41.
7. Marshall DA, Hux M. Design and analysis issues for economic analysis alongside clinical trials. *Med Care* 2009; **47** (7 Suppl 1): S14-20.
8. Revicki DA, Paramore C, Rentz AM. Incorporating pharmacoeconomic and health outcomes into randomized clinical trials. *Expert Rev Pharmacoecon Outcomes Res* 2005; **5**(6): 695-703.
9. Raacke J, Bonds-Raacke J. MySpace and Facebook: applying the uses and gratifications theory to exploring friend-networking sites. *Cyberpsychol Behav* 2008 **11**(2): 169-74.
10. Jones S, Fox S. *Generations online 2009*. Washington D.C.: Pew Internet & American Life Project, 2009.
11. Higgins JP, Thompson SG, Deeks JJ, Altman DG. Measuring inconsistency in meta-analyses. *BMJ* 2003; **327**(7414): 557-60.
12. Walker E, Hernandez AV, Kattan MW. Meta-analysis: Its strengths and limitations. *Cleve Clin J Med* 2008; **75**(6): 431-9.