STUDY DESIGN MONITORING PAUL GLASZIOU pdf

1: Problems of stopping trials early. â€” Mayo Clinic

To realise the full value of his legacy, research funders, research regulators, research organisations, journals, and the many people Doug taught and inspired must act together to design, conduct, and report better research done for the right reasons.

Paul Glasziou and Iain Chalmers: Our own first reaction was similar: It seems a problem worthy of serious analysis and attention. But how can we estimate the waste? The easiest fraction to understand is the fraction wasted by failure to publish completed research. If the results of research are never made publicly accessibleâ€”to other researchers or to end-usersâ€”then they cannot contribute to knowledge. The time, effort, and funds involved in planning and conducting further research without access to this knowledge is incalculable. Publication is one necessary, but insufficient, step in avoiding research waste. Published reports of research must also be sufficiently clear, complete, and accurate for others to interpret, use, or replicate the research correctly. Measured endpoints are often not reported, methods and analysis poorly explained, and interventions insufficiently described for othersâ€”researchers, health professionals and patientsâ€”to use. New studies are frequently developed without a systematic examination of previous research on the same questions, and they often contain readily avoidable design flaws [Yordanov,]. And even if well designed, the execution of the research process may invalidate it, for example, through poor implementation of randomization or blinding procedures. Given these essential elementsâ€”accessible publication, complete reporting, good designâ€”we can estimate the overall percent of waste. Let us first consider what fraction of research projects DO satisfy all these criteria? Of projects, 50 would be published. Of these 50 published studies, 25 would be sufficiently well reported to be usable and replicable. And of those 25, about half Hence the percent of research that does NOT satisfy these stages is the remainder, or Although the data on which our estimates were based came mainly from research on clinical research, particularly controlled trials, the problems appear to be at least as great in preclinical research [Macleod. Additionally, our estimate did not account for waste in deciding what research to do and inefficiencies in regulating and conducting research. These were covered in the Lancet series on waste, but it is harder to arrive at a justifiable estimate of their impact. If research was a transport business, we would be appalled by these data. Half the goods carried would be badly designed, half lost in shipping, and half of the remainder broken by the time they arrivedâ€”a truly heart breaking waste. These salvage and repair operations may be the most cost-effective way of improving the yield from research: However, we need to press on with that salvage: We certainly should, and must, attend to thatâ€”indeed it seems both an economic and an ethical imperativeâ€”but we also need to improve the processes and incentive systems in research. The Alliance is currently working with funders, regulators, publishers, organisations, and others to reduce waste and add value. If you are concerned about the correlation between steps, first note that the studies of reporting were of the published studies only, so the dependence in those steps is accounted for. His research focuses on improving the clinical impact of research. As a general practitioner, this work has particularly focused on the applicability and usability of published trials and systematic reviews. IC declares no competing interests other than his NIHR salary, which requires him to promote better research for better healthcare.

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2: OCEBM Levels of Evidence - CEBM

Acknowledgment: The authors thank Tim James for local cholesterol level testing data; Katy Bell, Jorgen Hilden, Martin Turner, Andrew Hayen, and members of the LIPID management committeeâ€"David Sullivan, Harvey White, Paul Nestel, and David Colquhounâ€"for helpful comments; and Rhana Pike for editorial work.

Investigators stop trials early when they consider it is no longer ethical to enroll patients in a control group. The goal of this systematic review is to determine how investigators of ongoing or planned RCTs respond to the publication of a truncated RCT addressing a similar question. Reviewers will determine in duplicate the similarity between the truncated and subsequent trials. We will analyze the epidemiology, distribution, and predictors of subsequent RCTs. We will also contact authors of subsequent trials to determine reasons for beginning, continuing, or prematurely discontinuing their own trials, and the extent to which they rely on the estimates from truncated trials. Discussion To the extent that investigators begin or continue subsequent trials they implicitly disagree with the decision to stop the truncated RCT because of an ethical mandate to administer the experimental treatment. The results of this study will help guide future decisions about when to stop RCTs early for benefit. Randomized controlled trials stopped early for benefit, RCT, Systematic review, Protocol Background The decision of whether to stop a randomized control trial RCT for apparent benefit before its planned completion is complex and requires consideration of ethical, statistical, and practical issues [1]. The main rationale for stopping is to avoid denying current and future control group participants a beneficial treatment, and to ensure rapid dissemination of that treatment [2]. A correct decision requires the wise judgment of the study investigators and, preferably, of an independent data monitoring committee DMC typically including trialists with both clinical and statistical expertise [3]. The DMC needs to attend to the interests of future patients and society at large, while considering the impact of their results on the wider community of clinicians, researchers, and evidence users [2]. Considerations include the risk of disseminating an overestimation of the treatment effect on the primary outcome and ensuring that the optimal information regarding toxicity and secondary outcomes is also captured, particularly if adverse events occur late in the course of the trial [4]. A systematic review Study of Trial Policy of Interim Truncation-1 STOPIT-1 developed by our group to evaluate the epidemiology and reporting quality of RCTs stopped early for benefit truncated RCTs tRCTs found that this type of trial was becoming more common, and often failed to adequately report relevant information about the decision to stop early [5]. Moreover, almost two thirds of the pooled effects of the non-tRCTs failed to demonstrate benefit [6]. These results raise serious concerns about the potential impact of stopping trials early on the body of evidence and therefore on current health policies. First, investigators have disseminated an estimate of effect that is, on average, substantially overestimated; how stakeholders best incorporate this evidence in generating subsequent best estimates of effect is uncertain. Second, this represents a lost opportunity to generate more precise and higher quality evidence about benefits and harms. Third, the publication of a trial stopped early for benefit may stop further research addressing the same question, which may distort the effect size overestimating the effect and making it more imprecise of the whole body of evidence [7]. First, they may be unaware of the existence of the tRCTs. This seems unlikely, given that researchers are usually aware of ongoing research in their field, and that tRCTs are commonly published in high impact journals, and often receive appreciable media attention [5 , 6]. A second possibility is that investigators are aware of the findings of the tRCT but remain unconvinced of the observed large benefit even of whether there is any important benefit and thus deem it ethical to allocate patients to not receive the new treatment. The decision to continue a current trial or start a new one answering a similar research question may represent an implicit different judgment with the previous decision to stop early and to the body of evidence in general. If sRCTs are common, it suggests that current practice of stopping RCTs for apparent benefit might not be acceptable by many other scientists and not sufficiently conservative either by reaching different conclusions than the body of evidence or showing highly unreliable estimates. Understanding the decisions to initiate, continue, or begin sRCTs is likely to provide insights that ultimately improve the policies and procedures of clinical trial oversight and the credibility of clinical

research. Objective The present study aims to examine how often randomized trials are launched or continued after the publication of a tRCT asking the same or sufficiently similar research question. We will also analyze trials that were stopped in response to such external evidence. Our study involved two primary research questions. First, what is the proportion of tRCTs that are followed by a sRCT addressing the same or closely similar research question?

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3: Table of contents for Evidence-based laboratory medicine

Objectives: To evaluate the optimal lipid to measure in monitoring patients, we assessed three factors that influence the choice of monitoring tests: (1) clinical validity; (2) responsiveness to therapy changes and (3) the size of the long-term 'signal-to-noise' ratio.

Paul Glasziou and Iain Chalmers: While both issues have gathered considerable attention, they are usually written about separately, as if they are separate problems. Replication in healthcare research is already common. But without systematic search and review, the replications can be overlooked. The figure below shows the results of eight studies, in chronological order, asking whether antenatal corticosteroids in preterm labour can reduce early neonatal death. Meta-analysis of trials before of corticosteroid therapy in premature labour and its effect on early neonatal death From Cochrane. However, analysis of these differences is often hindered by poor reporting of methods and results, and by unpublished studies. Hence wasteful research practices hinder understanding of replicability. Each of these phases of research production and waste has an impact on replicability. Relying on informal knowledge, or even an unskilled search of the global literature, are poor guarantees for finding all previous similar studies: If we examine the number of studies included in systematic reviews of studies ordered chronologically such as in the figure , it is evident that some degree of replication is already quite common. Replication of the exact study methods would merely replicate those flaws and, at best, confirm the biased results. Hence good replication should be preceded by a critical appraisal of the previous studies, preferably in systematic reviews of all previous similar studies. This would allow researchers to use the best methods and improve on design flaws before attempting replication. Again, reduction of waste in research and replication have a goal in common: Hence a critical element of attempts at replication is to ensure that 1 all trials are registered at inception, and 2 their results are reportedâ€”at least within that registry, even if not published in a journal. Of course, this two step call by AllTrials needs to be extended to all types of studiesâ€”clinical and pre-clinicalâ€”if we are to avoid inadequately informed replication. Again, reduction of waste in research and replication have a goal in common. If these conditions remain unfulfilled, we will remain uncertain as to whether any failure to replicate reflects differences in methods or differences in findings. Unfortunately, a large proportion of studies have poorly described study populations and methods. It is helpful to distinguish three types of reproducibility: The latter twoâ€”results and inferential reproducibilityâ€”were illustrated in the figure above: Even identically conducted studies will never give exactly the same results the squares in the figure , nor are they all likely to lead to the same statistical inference based on statistical significance. However, to explore the sources of any results and inferential differences between studies requires replicability of methods, and doing that will depend on adequate reporting of methods of previous studies. Paul Glasziou is professor of evidence based medicine at Bond University and a part time general practitioner. IC declares no competing interests other than his NIHR salary, which requires him to promote better research for better healthcare. Our thanks to Anna Scott for preparing the figure. Nature Human Behaviour 1, Article number: Avoidable waste of research related to inadequate methods in clinical trials. What does research reproducibility mean?

4: Paul Glasziou and Iain Chalmers: Is 85% of health research really â€œwastedâ€•? - The BMJ

Improving research processes and reporting - poor quality research reporting hampers clinicians' use of research evidence. Research in this area is examining the descriptions of non-drug interventions in trials, difficulties in synthesising and using complex interventions, and ways to improve the quality of systematic review abstracts.

5: "Which lipid measurement should we monitor? An analysis of the LIPID study" by Paul Glasziou

Paul Glasziou, professor (paul flow monitoring or monitoring only at times of symptoms.8 The study showed that peak flow monitoring is helpful but that the less.

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6: Early stopping of randomized clinical trials for overt efficacy is problematic â€” Mayo Clinic

Paul Glasziou is professor of evidence based medicine at Bond University and a part time general practitioner. Competing interests: None declared. Between and , Iain Chalmers helped to establish the National Perinatal Epidemiology Unit and the Cochrane Collaboration.

7: Professor Paul Glasziou - CREBP

Which lipid measurement should we monitor? An analysis of the LIPID study Paul P Glasziou,1 Les Irwig,2 Adrienne C Kirby,3 Andrew M Tonkin,4 R John Simes3 To cite: Glasziou PP, Irwig L, Kirby AC.

8: SelectedWorks - Paul Glasziou

Paul Glasziou FRACGP, PhD is Professor of Evidence-Based Medicine at Bond University and a part-time General Practitioner. He was the Director of the Centre for Evidence-Based Medicine in Oxford from

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