

## 世界权威医学期刊真的就权威吗？

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临床研究存在这样一个众所周知的问题：刚开始研究人员声称他们将寻找一个特定的解决方案，但当他们公布结果时，总会对结果做一些过度的解读。这种做法可以使研究的药物或治疗看起来比实际情况更安全或更有效。针对这一问题，一项系统性的调查研究试图查明各大期刊是否遵守了自己的承诺，即确保结果得到正确报道。

该项目负责人、英国牛津大学 (University of Oxford) 医生、支持药物研究透明化的本·戈尔达克尔 (Ben Goldacre) 说：“当期刊和研究人员被要求纠正研究结果时，他们的回答既有趣又令人担忧。编辑和研究人员经常误解正确的试验报告是什么样子。”

从4年前开始，他的团队所在的循证医学结果监测项目中心 (COMPare) 开展了一个项目，研究了在5种世界知名医学期刊（《内科医学年鉴》(Annals of Internal Medicine)、《英国医学杂志》(BMJ)、《美国医学会杂志》(JAMA)、《柳叶刀》(Lancet) 和《新英格兰医学杂志》(NEJM)）上发表了6周以上的所有试验结果。

这项研究选定的主题从糖尿病患者饮酒对健康的影响到两种肾癌药物的比较。所有五种期刊都认可了很早就建立的联合试验报告标准 (CONSORT) 指南。CONSORT 规则之一，就是作者应该在试验开始前描述他们计划要研究的结果，并在发表试验结果时仍然坚持最初的计划列表。

COMPare 团队的研究在2月14日报道，发表在上述5份世界权威医学期刊上的67项试验中，只有9项正确地报道了研究结果。四分之一的试验没有正确报告他们最初检测的主要结果，45%的试验

没有正确报告所有次要结果；其他试验则添加了新的结果。（与 NEJM 的试验有 96% 试验是正确的相比，内科学年鉴中只有 44% 的试验正确报告了主要结果）

当 COMPare 团队就这些有问题的论文给上述期刊写信时，58 封信件中只有 23 封信被发表。内科学年鉴和 BMJ 都发表了，柳叶刀接受了 80% 的信件，而 NEJM 和 JAMA 都拒绝了。NEJM 的编辑解释说，他们的编辑和同行审稿人决定报告哪些结果。他们写道，虽然有些 CONSORT 规则是有用的，但作者不一定需要遵守。如果试验中的研究人员披露了变化，他们就能改变最初的结果。JAMA 和 NEJM 表示，杂志有时不一定有足够的版面公布所有的试验结果。

COMPare 团队在一篇论文中发现，当试验的作者回复那些最终被打印出来的信件时，他们的观点中充满了不准确或有问题的陈述和误解。与编辑一样，许多作者误解了 CONSORT 规则以及公共注册中心在共享试验计划中的作用。有一些人对批评不屑一顾，抱怨他们的工作有多难，还有一些人否认他们遗漏了任何结果，而更有一些人甚至攻击 COMPare 项目在研究范畴之外。

COMPare 团队希望期刊能受到启发，更好地执行 CONSORT 规则，并重新审视它们发布信件内容的标准。Goldacre 说：“我们希望编辑们对我们的发现做出积极、建设性和深思熟虑的回应。”

### 参考文献

- [1] Scientific Community. doi:10.1126/science.aax0350.
- [2] <http://compare-trials.org/wp-content/uploads/2016/01/protocol.pdf>.
- [3] <http://www.consort-statement.org/>.

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# THE COMPARE PROJECT

CENTRE FOR EVIDENCE-BASED MEDICINE OUTCOMES MONITORING PROJECT:  
TRACKING SWITCHED OUTCOMES IN CLINICAL TRIALS

## THE PROBLEM

Before carrying out a clinical trial, all outcomes that will be measured (e.g. blood pressure after one year of treatment) must be pre-specified in a trial protocol and on a clinical trial registry (e.g. [clinicaltrials.gov](http://clinicaltrials.gov)). This is because if researchers measure lots of things, some of those things are likely to give a positive result by random chance (a false positive). A pre-specified outcome is much less likely to give a false-positive result. In the trial report, all pre-specified outcomes must then be reported, to ensure a fair picture of the trial results.

However, pre-specified outcomes are often left *unreported*, while novel outcomes that were not pre-specified *are* reported. This is an extremely common problem that distorts the evidence we use to make real-world clinical decisions.

## OUR APPROACH

The COMPare project takes a new approach. We are monitoring all trials published in the top five medical journals (NEJM, JAMA, The Lancet, Annals of Internal Medicine, BMJ). We are analysing each trial for outcome switching, by comparing the clinical trials registry and trial protocol with the trial report. For any trial where we find that outcomes have been switched, we

图为循证医学结果监测项目中心 Centre for Evidence-Based Medicine Outcome Monitoring Project (COMPare) 项目。

CONSORT TRANSPARENT REPORTING OF TRIALS

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## Welcome to the CONSORT Website

CONSORT stands for Consolidated Standards of Reporting Trials and encompasses various initiatives developed by the CONSORT Group to alleviate the problems arising from inadequate reporting of randomized controlled trials.

### The CONSORT Statement

The main product of CONSORT is the **CONSORT Statement**, which is an evidence-based, minimum set of recommendations for reporting randomized trials. It offers a standard way for authors to prepare reports of trial findings, facilitating their complete and transparent reporting, and aiding their critical appraisal and interpretation.

The CONSORT Statement comprises a 25-item **checklist** and a **flow diagram**. The checklist items focus on reporting how the trial was designed, analyzed, and interpreted; the flow diagram displays the progress of all participants through the trial. The CONSORT "Explanation and Elaboration" document explains and illustrates the principles underlying the CONSORT Statement. We strongly recommend that it is used in conjunction with the CONSORT Statement. In addition, **extensions of the CONSORT Statement** have been developed to give additional guidance for RCTs with specific designs, data and interventions.

CONSORT 2010 Key Documents

- CONSORT 2010 Checklist
- CONSORT 2010 Flow Diagram
- CONSORT 2010 Statement
- CONSORT 2010 Explanation and Elaboration Document

图为 Consolidated Standards of Reporting Trials (CONSORT) 官方网站页面。