we suspect we would live in a very different world, one in which the science had lagged far behind what actually has been achieved. Philosophers still disagree over the rules for how science is conducted. One of them eschewed the existence of any method in science, "[G]iven any rule, however 'fundamental' or 'necessary' for science, there are always circumstances when it is advisable not only to ignore the rule, but to adopt its opposite."[9] This view may be extreme. But who would suggest that any set of guidelines for a process as complicated as the scientific method would offer perfect guidance? At the very least, guidelines need frequent updating to keep pace with the evolution of research methods.[10]

As Hemingway and colleagues note, good quality data are important for valid research. They acknowledge, however, that it might be more fruitful to use secondary data sources, such as registries, than to incur the costs of collecting expensive primary data and following the cohort over a long time. But should all study protocols that are or could be conducted within such secondary sources be registered, along with guidelines for reporting the results from such studies? We hope not.

The strongest argument for imposing guidelines is to help researchers reduce both systematic and random error. To accomplish this end, guidelines would require keen understanding of research methods and a development of basic concepts. Such development is lagging behind in the area of prognosis research. For example, few attempts have been made to conceptualise overall determinants of disease outcomes. Five groups of determinants have previously been suggested: the illness, diagnostic tests, potential treatments, clinical performance, and patient compliance.[11] Unfortunately, neither these nor the suggested 10 steps from Hemingway and colleagues include comorbidity, often a powerful determinant of prognosis.[12] The formulation of guidelines might be best deferred until their conceptual basis is further developed.

Surprisingly, improved training of researchers was not on the list of suggested solutions. We think improved training would ultimately bring greater benefits than any measure on the list, although these benefits would be deferred. Meanwhile, consider the crucial role of the gatekeepers of published research. Any published research, including the low quality work that Hemingway and colleagues bemoan, has survived the scrutiny of peer reviewers and of the ultimate gatekeepers, journal editors. Perhaps the priority should be continuing education efforts focused on journal editors. We believe that step would improve the quality of published research faster than any other intervention.

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Registration of observational studies

The next step towards research transparency

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Observational studies, such as cohort and case-control studies, are an important form of medical research, but they are also vulnerable to bias and selective reporting.[1] They often produce large datasets that can be subjected to multiple analyses. Researchers may then craft a paper that selectively emphasises certain results, often those that are statistically significant or provocative. These decisions may reflect strong financial or academic interests and prior beliefs. At present, consumers of observational research cannot easily distinguish hypothesis driven studies from exploratory, post hoc data analyses. Researchers do not routinely disclose the number of additional analyses performed. Nor is there any satisfactory way to know whether the research questions or methods of statistical analysis diverged from those initially planned. It has been observed that there is "little or no penalty" for data dredging and selective reporting. Rather than attracting censure it can "get you into the *BMJ* and the Friday papers."[2]

In the linked article, Hemingway and colleagues reinforce many of these arguments, particularly with respect to studies of prognosis, because these can be important clinically but are often flawed.[3] This group, which includes two of the *BMJ*'s statistics editors, Doug Altman and Richard Riley, recommends that "all research on humans should have a protocol." Such calls for registries of observational research are gathering pace, and indeed an international meeting held in London last September was devoted entirely to the discussion of such registries and other efforts to improve the credibility of observational research.[4 5]

The *BMJ* publishes a large amount of observational research and has an important stake in its quality. We are now actively supporting the registration of observational

study protocols and results in publicly accessible registries. Although the *BMJ* does not advocate one particular registry, we note that around 14 000 observational studies are already registered with clinicaltrials.gov, and that the results of such studies can be posted there too, as is already the case for clinical trials.[6] The development of registries for randomised trials was driven by several ethical and scientific concerns, not just by the desire to prevent suppression of unfavourable results (box).[7] We feel strongly that most of these points also apply to observational studies.

We recognise the lack of consensus on this proposal. In a linked editorial, Sørensen and Rothman express concerns that the insistence of journals on protocols and registration would be too restrictive, and they argue that peer reviewers and editors are as much to blame as researchers for the publication of low quality work.[8] There are legitimate worries, too, that prioritising protocol driven studies might discourage publication of genuinely important results that emerge from data mining or that it might have other unintended negative effects because "subgroups and multiple analyses are a necessary part of observational research: otherwise, one cannot make new discoveries, nor quickly check discoveries by others."[9] We agree that exploratory observational research is important. Many new ideas arise from unexpected findings in observational research, and many researchers learn their skills from examining available datasets. However, that is not the sort of research the *BMJ* usually aims to publish; rather, we give highest priority to studies that provide strong support for inferences applicable to clinical practice. We think the case against data driven observational studies is particularly compelling under these circumstances.

We understand concerns that extending these rules to observational studies might encourage editors—particularly of general journals—to be overzealous or clumsy in their application. The STROBE statement has improved reporting of observational studies by asking authors to spell out in their papers exactly what they did during their studies.[10] It asks authors to "explain the scientific background and rationale for the investigation being reported" and "state specific objectives, including any prespecified hypotheses." As journal editors, we have probably not paid enough attention to emphasising these points, but we aim to do so from now on. However, like most reporting statements, STROBE is aimed at improving the clarity of study reporting and comes too late to influence study design.

For these reasons, we will now ask authors of papers reporting observational studies submitted to the *BMJ* to tell us more about the origins, motivations, and data interrogation methods of that work. This may not be appropriate for all observational studies, and we aim to apply the policy in a flexible and thoughtful manner. We would not reject an observational study just because it did not have a prespecified hypothesis, but we would want the exploratory nature of its research question, and its design, to be fully reported.

Among other things, we will be asking authors to report in their papers a clear statement of whether the study hypothesis arose before or after inspection of the data (and, if afterwards, we will need an explanation of steps taken to minimise bias); we will ask to see study protocols if they exist; and we will add to the papers' abstracts their registration details, if they have been registered. If the study is registered we will ask whether the protocol was registered before data acquisition or analysis began.

Registration of observational studies is just one of many changes needed to increase confidence in observational research, but we believe it is the crucial next step. The aim is to facilitate the design and reporting of observational research, not to hinder it. Trial registration has had a substantial and important positive effect on the design, conduct, and reporting of randomised clinical trials, and we believe it is time to extend those benefits to observational research.

Rationale for registration of clinical trials[7]

Ethical

Respect the investigator-participant covenant to contribute to biomedical knowledge by making trial methods and results public
Provide global open access to information
Reduce unnecessary duplication of invested research resources through awareness of existing trials
Assure accountability with regard to global standards for ethical research
Enable monitoring of adherence to ethical principles and processes

Scientific

Increase the reliability and availability of evidence on which healthcare decisions are based
Improve trial participation
Increase opportunities for collaboration
Ensure transparency of trial design and methods
Provide open review of protocols to improve trial quality and refine methods
Provide means for identification and prevention of biased under-reporting or over-reporting of research
Accelerate knowledge creation

Competing interests: The authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare that: (1) None of the authors received external support for the submitted work; however, all three work as editors for the *BMJ* and EL is an unpaid associate editor for two subspecialty journals; (2) No author has had a relationship in the previous three years with a private company that might have an interest in the submitted work; (3) Their spouses, partners, and children have no financial relationship that may be relevant to the submitted work; and (4) No author has a non-financial interest that may be relevant to the submitted work.

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