PAPER

Should all medical research be published? The moral responsibility of medical journal editors

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ABSTRACT

This article reinvigorates a key question in publication ethics: Is there research that it is permissible to conduct but that ought not to be published? The article raises the question in relation to two recent medical studies. It is argued (1) that the publication of these studies may cause significant harm to individuals, (2) that editors of medical journals have a moral responsibility for such harm, (3) that denial of publication is inadequate as an instrument to fulfil this moral responsibility and (4) that internationally acknowledged publication ethics codes should incorporate this aspect of editors' moral responsibility.

INTRODUCTION

A recent Danish study found that symptoms of a widespread chronic disease could be alleviated by the use of antibiotics. Getting the study published turned out to be difficult. At least one reviewer from a reputable journal noted that the study could influence the clinical practice in an undesirable way by leading to an increased use of antibiotics and thus ultimately adding to the problem of microbial multiresistance. The BMJ recently published an article suggesting that side-effects of statins may outweigh health benefits in patients at low and intermediate risk of cardiovascular disease.[1] The article sparked intense debate[2]—not least in the mass media[3–7]—and one study suggests that as many as 200 000 people in the UK have stopped taking statins as a consequence of the media coverage, potentially leading to 2000 cardiovascular events in the future.[8–10]

The two cases reinvigorate but also add important new aspects to a contested topic in publication ethics, namely whether there is medical research that is permissible to conduct but that ought not to be published.

This question is not a new one.[11] Previous considerations have, however, focused almost exclusively on cases in which medical research may be used for biological warfare and bioterrorism.[11–14] The threat of bioterrorism led a group of journal editors and authors to issue a statement in Science and Nature in 2003. In this statement, they recognised that the potential harm of publication occasionally may outweigh the societal benefits and that in such cases, 'the paper should be modified, or not be published'.[15] However, the moral responsibility of editors and reviewers to consider the potential harmful effects of publishing research is not included in two of the main publication ethics codes, the Committee on Publication Ethics' (COPE) Code of Conduct and the International Committee of Medical Journal Editors' (ICMJE) Recommendations.[16 17] The World Association of Medical Editors' (WAME) states that medical editors, 'should also take into account whether studies are ethical and whether their publication might cause harm to readers or to the public interest',[18] but this requirement only figures in their policy statement entitled 'Geopolitical Intrusion on Editorial Decisions' dealing with editorial influence from 'policies of governments or other agencies outside of the journal itself' and therefore seems likely to be interpreted as concerning only the threat of biological warfare and bioterrorism.

In this article, it is argued (1) that the publication of the Danish and UK studies may cause significant harm to individuals, (2) that medical journal editors have a moral responsibility for the potential harmful effects of publishing research, (3) that denial of publication is inadequate as an instrument for fulfilling this moral responsibility and (4) that therefore internationally acknowledged publication ethics codes should provide editors with a firm basis for evaluating and mitigating the potential effects of publishing medical research in general. The article deals solely with the publication of medical research simply because this is a field of research that is already regulated by a number of international codes. However, the points made certainly also apply to other fields of research.

RESEARCH ETHICS AND PUBLICATION ETHICS

Research ethics is concerned with the ethical legitimacy of conducting research. It provides a set of moral reasons for permitting or not permitting the conducting of certain types of research. In practice, the ethical principles and values playing a regulatory role for conducting healthcare research are laid out in the Helsinki and Taipei declarations and the Oviedo Convention.[19–21]

Publication ethics is concerned with the ethics of publishing research. It provides a set of moral reasons for permitting or not permitting the publishing of certain types of research. In practice, publication of medical research is guided by international codes such as the COPE Code of Conduct for Journal Editors, ICMJE Recommendations and the WAME Professionalism Code of Conduct with its supplementary recommendations.[16 17 22]

The principles of research ethics and the principles of publication ethics may lead to different conclusions in relation to the same research.

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Table 1 Relations between Research and Publication Ethics

Domain		Publication ethics	
		Research that ought to be published	Research that ought not to be published
Research ethics	Research that is permissible to conduct	Box 1	Box 4
	Research that is not permissible to conduct	Box 2	Box 3

Table 1 shows the possible combinations of views concerning the ethical legitimacy of conducting and publishing a certain type of research.

That there are cases of research that fit in box 1 and box 3 seems straightforward.

Box 2 has received some attention in the literature. It has been argued that although certain types of research are not permissible—because they cause harm to research participants or violate requirements of informed consent—the results of such research may be of such importance for public health that it should be published if it has been conducted.[23 24]

Box 4 is the object of this article. Clearly, otherwise valuable research may fit in this category if the reporting of this research violates principles of for example, scientific integrity. Research may also, however, fit in this category because of the potential harmful effects following publication of such research. Research that may be used for bioterrorism could be one such example. The Danish and UK studies raise the question whether research may fit into this category because the publishing of this research may have harmful effects other than those associated with bioterrorism.

THE MORAL RESPONSIBILITY OF EDITORS FOR THE HARMFUL EFFECTS OF PUBLISHING RESEARCH

The harmful effects of publishing research

If we have moral reasons to consider rejecting publication of research that may be used for bioterrorism, we certainly also have moral reasons to consider rejecting publication of the Danish and UK studies. Thus, they are similar to research posing a security/safety risk in at least two ways:

1. They may lead to significant harmful effects to a significant number of people.
2. Publishing the research significantly increases the likelihood of these harmful effects.

The Danish study may lead to an increased use of antibiotics ultimately increasing the problem of microbial multiresistance. The UK study could lead to increased numbers cardiovascular events due to undertreatment or due to patient incompliance. In both cases, the harmful effects are the potential outcome of changes in clinical practice. In the latter case, the harmful effects could also follow unwarranted changes in patient behaviour.

As in the case of research that may be used for bioterrorism, it is the publishing of these studies in a scientific journal that significantly increases the likelihood of the harmful effects. Isolated research into the effects of antibiotics on a chronic disease and the effects of statins on levels of cholesterol without exposure in scientific journals and mass media seem unlikely to really affect clinical practice and patient behaviour.

It may be objected that publication does not make such effects likely in absolute terms. However, the publishing of an article on the possibility of artificially synthesising a live poliovirus does not make bioterrorism likely in absolute terms. It still requires a number of persons with significant expertise, access to appropriate facilities and funding and arguably also limited morality. Likely or not, there are important differences between this type of study and the Danish and UK studies. Differences that seem to make the harmful effects of publishing the latter studies considerably more likely:

- They are of direct relevance to the clinical practice.
- They hold promise of novel and significant healthcare benefits.
- These potential health benefits are in the interest of large groups of patients/people.

These features will make the publishing of these studies attract the attention of researchers and healthcare professionals. They will also, however, increase the likelihood of exposure in the mass media (the Danish and UK study both received attention in the mass media), which in turn may come to fuel a clinical, political and public demand to further develop and implement these new treatment options and findings into healthcare policy and practice or it may simply lead to changes in patient behaviour, all of which pave the way for the potentially harmful effects suggested above.

The moral responsibility of editors

An adequate account of the moral responsibility of journal editors should make editors morally accountable for the harmful effects of publishing research for at least two reasons:

1. Editors make the decision to publish research that may have harmful effects.
2. Editors are in a position to foresee the potential harmful effects.

For an agent to be morally responsible for certain harmful effects, the agent must be the cause of these effects. Editors make the decision on whether or not to publish research. This means that they influence whether or not the harmful effects of publishing obtain, and in this sense they may be said to be part of the set of conditions causing or not causing the harmful effects.

For an agent to be morally responsible for certain harmful effects, the agent must reasonably be able to foresee these effects. Editors are arguably in a very good position with respect to foreseeing the potential harmful effects of publishing research because:

- They understand medical research,
- They have insights into the interests of various stakeholders and
- They know about the role of different media in the dissemination of research.

Most if not all editors have a background in research and therefore must be expected to be able to understand and critically engage with the content of research publications. And, very importantly, they are aided in these efforts by the reviewers, who may have a firmer grasp of specific areas within a particular field of medical research.

Surely editors also have insight into the interests of researchers and research groups, healthcare professionals and organisations, decision-makers and the wider public as these interests are reflected in the ongoing discussions in medical journals and in the broader healthcare-related dialogue in the mass media. And, most certainly, editors have substantial experience of the role of medical journals in the wider dissemination chain from researcher to the public. They have seen how scientific studies

may get picked up—perhaps distorted or one-sidedly represented—by mass media and how this may influence public opinion and debate, individual behaviour as well as political decision-making.

These insights—at least *in certain cases*—place editor's in a good position in terms of foreseeing the potential harmful effects of publishing research.

Dismissing the moral responsibility of editors I: benefits of publishing and academic freedom

The moral responsibility of editors for such effects may be considered negligible for at least two reasons:

1. The benefits of publishing always outweigh the harm it can cause.
2. The value of academic freedom outweighs the harm caused.

Certainly most, if not all, research may provide new and useful knowledge—at least in the weak sense of leading to the evolution of science. It is not, however, self-evidently true that these benefits always outweigh the harm caused. The Danish and UK studies both yielded novel insights that in turn may lead to more effective treatments/less overtreatment, but it is not self-evidently true that these potential benefits outweigh the harm of increased microbial multiresistance and the risk of undertreatment of high levels of cholesterol. To determine this requires a cost-benefit analysis on a case-by-case basis—it cannot be established a priori.

It may be objected that providing an adequate cost-benefit analysis is impossible since it requires both an adequate catalogue of benefits and harms and an adequate prediction of the course of the world following publication of research. The former is not readily available and the latter seems unrealistic. However, there are no compelling reasons to believe that international or journal-specific publication ethics codes could not—through open and transparent processes involving relevant stakeholders—be amended to take into account the potential harmful effects of publishing in a way that is adequate for all practical purposes.

The potential benefits of publishing may be claimed to outweigh the harms and so may the right to academic freedom. Academic freedom may tentatively be defined as the right of researchers to freely choose their object and methods of research and to communicate their findings to the wider public without being censored or sanctioned. Certainly academic freedom is valuable. However, it cannot reasonably be thought to be an absolute right. As Mill realised, rights to liberty may only be exercised to the extent that such exercise do not cause harm to others.[25] From this viewpoint, it is the risk of harm that outweighs academic freedom. The fact that harm may outweigh academic freedom is already reflected in international research ethics codes such as the Helsinki Declaration.

Most importantly, however, even if we maintain that 1. and 2. hold for all cases, it still does not follow that the moral responsibility of editors is negligible. It may at best provide editors with a strong case for publishing research, but it does not mean that they are not morally responsible for taking steps to minimise or entirely avoid the harmful effects. If, on balance, we believe that the Danish and UK studies should be published, this does not mean that editors and reviewers should not call attention to the potential harmful effects of publishing these studies and try to avoid or at least mitigate such effects.

Dismissing the moral responsibility of editors II: distribution of moral responsibility

The moral responsibility of editors may also be considered negligible on the grounds that:

3. The moral responsibility for the harmful effects must be distributed between several agents

There is a problem of 'many hands' in relation to the potential harmful effects of publishing research.[26] Several other agents—the researchers, the mass media, the healthcare professionals, decision-makers to mention but a few—play a causal role in producing harmful effects that could be foreseen by any of them. Hence, they all have moral responsibility. The cardinal question, therefore, becomes how the moral responsibility should be distributed among the relevant agents. What is a reasonable distribution of moral responsibility for the harmful effects of publishing?

First of all, it should once again be noted that, even if we accept 3., it does not entail that editors are not morally responsible or that their moral responsibility is negligible. Second, there are good grounds for thinking that editors should be assigned responsibility beyond the negligible. Editors are in a good position with respect to *foreseeing* the potential harm of publishing. But they are in a unique position with respect to *acting* on their moral responsibility in two ways:

- Editors are capable of strongly influencing the reception of research.

They can block publication and can also in and through the publication process influence both the *content* of research publications and the *context* of the publication and thereby shape the broader reception of the research among the various healthcare stakeholders including the research community, healthcare professionals and organisations, mass media and decision-makers. More on this below.

- Although editors may have various interests in publishing a specific piece of research beside the quality of the study, it seems that they would generally be less biased in making publishing decisions about the specific research than researchers.

Evidently, researchers may also strongly influence what is published—and hence may be argued to have moral responsibility for the harmful effects of publishing[27–29]—but they can hardly be expected to serve as impartial judges of the potential harmful effects of publishing their research and to act accordingly.[11 13 30]

SHOULD ALL MEDICAL RESEARCH BE PUBLISHED

The moral responsibility of editors for the harmful effects of publishing research may be exercised in different ways. An obvious instrument for exercising moral responsibility is to deny publication. But is this an adequate instrument? A guiding principle in law-making and policy-making is the principle of proportionality, which requires of a law or policy (1) that it should be an effective way of achieving a desired goal and (2) that the goal should be desirable and (3) that there should be no less invasive, alternative ways of achieving the same goal.[31] The proportionality principle thus suggests three criteria for evaluating the adequacy of any instrument of moral responsibility.

Instruments of moral responsibility I: rejection of publication

Denying the publication of research may at first sight seem an ineffective instrument for avoiding the harmful effects of publishing research. After all, there are numerous both printed and online journals in a competitive market, and a multitude of online platforms providing access to both the wider research community and the public. However, denying publication of a paper may still play a regulatory role by 'cooling off' the desire to seek publication of a certain type of research. Researchers

have various interests. They have an interest in getting their research published and to get it published in particularly relevant and prestigious scientific journals with rigorous peer review, access to a large research community and so forth.[14] These secondary interests confer on editors the power to influence what researchers seek to publish. Moreover, if the rejection of publication is based on an internationally adopted of publication ethics, then the 'cooling off' effect will gain some impetus, and the rejection of publication may be effective in some degree in avoiding the harms of publishing. Criteria (1) of the proportionality principle may thus be satisfied, if only partially.

That effectiveness comes at a price. The rejection of publication by editors may lead to the self-censoring of research by researchers. That is, it seems likely that the stronger the 'cooling off' effect on the desire to publish a certain type of research, the stronger the 'cooling off' effect on the desire to conduct this research. After all, why conduct research that one may not be able to get published in journals that are considered attractive. This will obviously not pose a problem in those cases where the research seems unlikely to generate any benefit, but there are very few, if any, clear-cut cases of such research. Most medical research may be argued to generate insights that eventually will benefit patients and society. It seems undeniable that the Danish and UK studies provided valuable insights that, if applied in the right way, may come to benefit patients. This ultimately goes to show that the denial of publication fails as a means to achieving what is ultimately the desired goal, namely gaining the benefits from publishing research while avoiding the harms. Criteria (2) of the proportionality principle is thus only partially satisfied.

Instruments of moral responsibility II: influencing content and context of publications

Finally, denying publication fails as an adequate instrument because of the availability of alternative instruments that may achieve the truly desired goal of avoiding the harmful effects while preserving the benefits of publishing research. These alternative instrument may even promote academic freedom.

Arguably, the harmful effects following the publication of medical research are in many cases due to one-sided communication of research findings to the various stakeholders as well as insufficient regulation of the uses of these findings in research and clinical practice. The Danish and UK studies are prototypical examples of this. The potential harmful effects of publishing these studies only obtain if the dissemination of these studies leads to undesirable changes in clinical practice or to unsolicited changes in patient compliance. Clinical practice may, however, be regulated through policy and law, and patient compliance may be influenced through information (as the follow-up study of the effects of publishing the UK study shows). Thus the harmful effects of publishing these studies may to a large extent be avoided if the relevant clinical practices become properly regulated and if the public is provided with balanced and rounded information. If so, then certainly there is a pivotal role for editors to play in avoiding the harmful effects of publishing. They may raise awareness of the potential harmful effects of publishing research and of the need for proper regulation and they may take steps to ensure balanced information to all relevant stakeholders. And they are in unique position to do so, as they may influence both the *content* and the *context* of research publications.

Editors may influence the content of publications with the aim of avoiding harmful effects in a variety of ways. They may require authors to explicitly describe and address the potential harmful effects and the need for regulation, and they may ask authors to revise unnecessarily strong, one-sided, unbalanced statements that are likely to be picked up and communicated uncritically by the mass media.

Editors may also influence the context of publications by inviting reviewer or open peer comments or by an editorial comment. They may choose to include such research in special thematic issues with a special emphasis on the wider effects of publishing this research. They may highlight the sensitive issues in their advertising on social media and in potential press releases to the mass media. They could even ask a panel of healthcare organisations and relevant decision-makers to comment in the journal on the potential harmful effects and the need for regulation. The dampening effect on the motivation to conduct valuable research would presumably be non-existent or very small. The wider implication being that the denial of publication also fails to satisfy criteria (3) of the proportionality principle.

Policy implications

The previous arguments have provided a basis for suggesting that publication ethics codes should:

1. Acknowledge moral responsibility for the effects of publishing.
2. Define benefits and harms of publishing.
3. Specify a range of actions an editor may take.

An internationally adopted and enforced code of publication ethics with these elements would serve as a guide for editors and thus secure consistency in the relevant editorial decisions. It would also be an important step towards creating transparency and thus underpinning accountability in such decisions.

Could such a code of publication ethics reasonably be journal-specific? Could each medical journal make up its own standards and sanctions? Needless to say, the preventive effect would be limited, and it would generate uncertainty among researchers about submission requirements. Hence, there are good grounds for seeking an international code of publication ethics with the suggested elements.

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