Offline: Lessons from the controversy over statins

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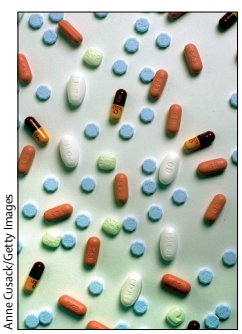

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Controversy over the safety and efficacy of statins has harmed the health of potentially thousands of people in the UK. After publication of disputed research and tendentious opinions about statin use among people at low risk of cardiovascular disease in 2013, patients already taking statins were more likely to stop their medication both for primary prevention (an 11% increased risk of stopping treatment) and secondary prevention (a 12% increased risk). Over 200 000 patients were estimated to have stopped taking a statin in the 6 months after adverse media coverage. More than 2000 additional cardiovascular events across the UK can be expected over the next decade. Some observers have likened this statin scare to that of MMR, where false claims about the safety of a vaccine, made (incorrectly) on the basis of a now retracted research paper, led to widespread vaccine hesitancy. One lesson of MMR was that, in the face of an unjustified claim that could harm public health, the scientific community, including journals, should respond quickly and robustly to counter that claim. That is why we are this week publishing a comprehensive scientific Review about the efficacy and safety of statin therapy by researchers who have made substantial contributions to the science of statins. The purpose of this Review is to help doctors and patients make informed decisions about the use of this important drug class. The Review also makes a larger point—that non-randomised evidence (of the kind used to undermine confidence in statin use) has severe limitations.

Committee on Publication Ethics

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One difficulty in addressing the claims about statins has been the absence of any institutional mechanism to review the contrasting evidence offered by different parties. An "independent statins review panel" was established in 2014. Its Chair had previously written critically about overuse of statins among older people, calling into question the independence of the panel's judgments. In October, 2014, a year after the original articles questioning the safety and efficacy of statins were published, a group of concerned scientists, including several authors on the Review we publish today, wrote to the Chair of the UK's Committee on Publication Ethics (COPE). COPE provides guidance to editors and publishers about questions of publication ethics. The concerned scientists pointed to publication of incorrect claims about statin side-effects, inaccurate editorial and media statements, and inappropriate peer review. After 2 years of frustrating exchange, including a direct request that COPE conduct an independent investigation, COPE declined to act further, emphasising that it is a charitable member organisation, not a regulatory authority. Although it is true that COPE is not a statutory regulator, it does investigate the conduct and processes of journals and editors. COPE's refusal to investigate the growing concerns of senior UK scientists was surprising and disappointing. The Committee's decision points to a serious gap in UK science—the lack of a central institution where scientists who wish to question the actions or ethics of other scientists or scientific institutions can go. Allegations of research misconduct are best investigated by the institution where the original research took place. But that principle does not apply for some organisations, such as scientific or medical journals. With no independent tribunal to consider allegations of research or publication malpractice, a damaging dispute has been allowed to continue unresolved for 2 years, causing measurable harm to public health.

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The debate about statins, as for MMR, has important implications for journals. Some research papers are more high risk to public health than others. Those papers deserve extra vigilance. They should be subjected to rigorous and extensive challenge during peer review. The risk of publication should be explicitly discussed and evaluated. If publication is agreed, it should be managed with exquisite care. Authors and editors should be aligned on the messages they wish to convey, and every effort must be made to avoid misinterpretations and misunderstandings in the media. Editors also have to separate their roles as gatekeepers and campaigners. It is tempting to publish science that confirms pre-existing beliefs, especially if those beliefs underpin a campaign. Two ongoing campaigns—against Too Much Medicine and for Statin Open Data—continue to imply that statins are overused and that hidden harms remain to be exposed. As the Review we publish makes clear, the best available evidence indicates that neither statement is true.

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