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EDITORIALS

Mass treatment with statins

True informed choice will require wholesale changes to the way we gather and communicate evidence

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In broad terms, statins are cheap and more likely to do good than harm. But broad terms may no longer be sufficient. The UK National Institute for Health and Care Excellence (NICE) now recommends offering a statin to anyone with more than a 10% 10 year risk of a cardiovascular event, estimated to be 25% of the population aged 30-85 years.[1] When we offer a preventive drug to such large numbers of healthy people, we are a long way from the doctor treating a sick patient. In some respects, we are less like doctors and more like a life insurance sales team: offering occasional, possibly life changing, benefits, many years from now, in exchange for small ongoing inconvenience and cost. This represents a new kind of medicine, and delivering informed choice that reflects differing patient preferences will require wholesale structural improvements in how we gather and communicate research evidence.

The current data on statins have many avoidable shortcomings. Important questions on comparative efficacy, and efficacy in different risk strata, have never been adequately answered.[2 3] We still do not know the difference, for example, in mortality benefits and side effects between high and low dose atorvastatin treatment in the new primary prevention population at 10% risk. Perhaps more importantly, we lack reliable information from randomised trials on common symptomatic side effects of statins.[4-6]

This persisting uncertainty about the precise risks and benefits of statins is a serious barrier to informed patient choice; after two decades of widespread statin prescription, it also shows that we have so far failed to implement the core principles of evidence based medicine. Cardiovascular disease is the most common cause of death in the United Kingdom, the outcomes are comparatively straightforward to ascertain, and statins are the most commonly prescribed class of drug in the NHS. That should be enough motivation and clinical experience to resolve any uncertainty.

Gathering evidence of benefit from modestly effective preventive treatments in low risk participants poses specific challenges for researchers. It requires large numbers of participants and long follow-up times, which both drive up costs. Here, however, the NHS offers a unique opportunity for innovation.[7] When comparing widely used treatments that are known to be safe and effective, it should be trivial to embed randomised trials unobtrusively into routine clinical activity, using cheap, routinely collected electronic health record data for outcomes. A comparison of high and lower intensity statin treatment in a low risk population would be one such example. We recently attempted a similar trial but faced numerous expensive regulatory barriers that were disproportionate to the risks.[8]

There are also important challenges around communicating evidence effectively. Here, even NICE falls short. Although doctors are told they must give clear information to patients on the benefits of treatment, at high and low intensity, at each level of risk, this information cannot be found in the 302 page guideline. Yet such data are vital, because different people give differing weights to different aspects of risk and benefit: some want longevity at any cost, for example, while others regard even mild side effects as an affront.

The best solution is likely to involve decision making tools[9 10]—numerical printouts that are tailored to patients' own risks—if these can be integrated seamlessly into electronic health record systems, validated, and made into attractive and helpful products.[11] Sadly, such tools do not receive funding or attention on the same scale as even generic drugs. Consequently, their use is patchy and often requires laborious manual data entry. If NICE recommended the information as clearly as it recommends the pill, this might help create a demand, a market, and funding within the NHS.

Currently, however, NICE seems ambiguous about its core recommendations. The press release and promotional activity around the guideline emphasised lifestyle changes and the need for patients to receive clear information on the benefits of treatment.[12] However, the guideline itself has a different emphasis: of eight "key priority recommendations" for implementation, four focus on which tool best identifies patients for treatment, and four focus on atorvastatin. None mentions lifestyle or communicating evidence on treatment options. NICE summarises large numbers of randomised trials on interventions that target individuals to improve diet and encourage exercise, most with negative results, yet it still recommends these interventions. Lifestyle change is likely to deliver large health

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benefits well beyond lipid lowering, but there is no good evidence that people eat better diets, or do more exercise, simply because they are told to. They are more likely change their behaviour when changes in their economic, social, and cultural context make it easy for them to do so. This requires major shifts in—for example—national policy, driven by public health. Such shifts are harder to deliver and fund than drugs or advice.

There are similar challenges in delivering the information revolution necessary for informed choice on mass prescription. Doctors are unlikely to start giving patients clear numerical information simply because they are told to do so. They might do so if NICE can recommend information tools with the same force as when it recommends drugs, and if it becomes as easy to give contextual numerical advice as it is to print a prescription. Similarly, history shows that trials on important difficult questions will not appear simply because we need knowledge. They will flow more freely if we can remove disproportionate regulatory barriers, reduce the cost of information, and make trial participation convenient and uncomplicated.

Mass prescription for modest individual benefit is new. Truly informed choice will require more than good intentions. We will need better data, from bigger trials, and better risk communication than for conventional medical treatment. Delivering this will require us to embed the gathering, communication, and implementation of evidence as seamlessly and cheaply as possible into the everyday routine of medicine. Without such innovation in the use of medical data, we can say only that statins are—broadly speaking—likely to do more good than harm. That is not good enough.

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