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Cardiovascular medicine – turning people into patients: has modern medicine gone too far?

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ABSTRACT This hot topic meeting addressed the burning issue of the potential power of the medical profession and others to create disease out of cardiovascular risk factors. Cardiovascular disease remains the most common cause of morbidity and mortality in most of the western world, and in Scotland in particular. Clearly the reduction of cardiovascular disease is a critical goal but a side-effect of this can be the transformation of fit, healthy people with an increase in risk, into unwell patients labeled as suffering from disease. To prevent unnecessarily turning people into patients we need to understand the epidemiology of risk factors and have clear mechanisms for educating healthcare providers and the public. These topics were the focus of this well attended and stimulating meeting

KEYWORDS Cardiovascular medicine, risk factors, hypertension, disease mongering

LIST OF ABBREVIATIONS Association of the British Pharmaceutical Industry (ABPI), Medicines and Healthcare products Regulatory Agency (MHRA), National Institute for Health and Clinical Excellence (NICE), quality adjusted life year (QALY)

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CME

Cardiovascular disease risk factors such as hypertension are a continuum, however, arbitrary numerical values are used as cut-offs to trigger intervention. For hypertension there is robust evidence supporting the cut-off values in terms of effect on clinical outcome[1] but the issue is whether we are turning too many healthy people into patients by applying these cut-offs across the board. In addressing this issue, the meeting focused on the epidemiology of cardiovascular risk, how to advise health professionals and patients, and the role of the pharmaceutical industry.

Dr H Burns, the Chief Medical Officer for Scotland set the scene for the meeting by describing different models of health and disease such as salutogenesis (creating health by creating a supportive environment) and allostasis (a balance between an unhealthy load e.g. smoking, and resistance e.g. healthy eating).

SESSION 1

The first session focused on the epidemiology of cardiovascular risk in otherwise healthy people.

Professor L Ritchie, University of Aberdeen, addressed the key question of when a risk factor becomes a disease. He highlighted four themes: new models of health; the dangers of risk factor polarisation; key guiding principles; and key challenges in risk factor treatment. An older health model is Osler's model (a triangle of the doctor, the patient and disease) but this has largely been replaced by a patient-centered model of health involving multidisciplinary teams and accounting for cost and benefit of healthcare. Professor Ritchie highlighted the dangers of polarising risk factors vs disease. Diabetes is an example of a condition that is both a cardiovascular risk factor and a disease. In order to provide the best possible diabetic care, risk reduction and disease management need to be provided together. Therefore, Professor Ritchie proposed that risk should be considered a continuum with disease. The key principles that should guide treatment of risk factors are that the treatment should be desirable, achievable, sustainable and acceptable. For example, statin treatment of hyperlipidaemia has a strong evidence base for its desirability, but affordability and achievability will depend on the number of people treated. The number of people treated will, in turn, depend on the level of cardiovascular risk that society deems unacceptable. The lower the level of risk, the more people treated, and the higher the financial cost to the healthcare provider. Whether a treatment is acceptable must also involve discussion with the individual patient to establish personal health goals.

Professor P Hanlon, University of Glasgow, discussed what public health has to offer, and emphasised that

complex interactions lead to changes in health and disease. Professor Hanlon took an historical perspective describing changes in health resulting from social reform (e.g. civic and individual actions such as pollution reduction), focused interventions (e.g. smallpox), social justice (the Beveridge report) and technological advances (older people with chronic disease now living longer). He also speculated that the health challenges facing Scotland (e.g. increasing obesity and increasing alcohol use) may not be cured by any of these approaches, and only a profound change in society will lead to change.

Professor G McInnes, University of Glasgow, focused on the evidence base for treating cardiovascular risk in healthy people. It is estimated that 24 million people per year worldwide will die from coronary heart disease or stroke by 2030.[2] The evidence that lifestyle modification can reduce these events is disappointing. While changes in lifestyle may reduce blood pressure, clinical trials have failed to demonstrate an effect on cardiovascular events. In contrast, there is excellent evidence for drug intervention reducing cardiovascular risk, and most medications are well tolerated.[1] Blood pressure reduction reduces the risk of cardiovascular disease, and even a modest reduction gives some benefit. Lowering serum lipid levels is also beneficial in primary prevention and, like treating hypertension, the lower the better. It should be noted that the benefit of these treatments in primary prevention is modest in most groups except the elderly. Antiplatelet treatment such as aspirin is complicated by a significant risk of major haemorrhage, and has no benefit in low risk patients. If the ten-year risk of cardiovascular disease exceeds 20% Professor McInnes believes aspirin probably does more good than harm. This highlights the importance of balancing benefit against harm. A question that is still unanswered is the timescale of benefit. Does drug treatment provide a constant benefit or does the benefit only occur during early treatment? Studies have not been performed to answer this difficult question which is especially important when considering anti-hypertensive medication in young people.

SESSION 2

Session 2 focused on how to advise the medical profession about treatment of cardiovascular risk factors.

Professor M Brown, University of Cambridge, discussed how hypertension treatment guidelines are created. A key message was that although there is robust evidence, there is still scope for interpretation and this leads to different guidelines in different countries. The British Hypertension Society guidelines[1] were reviewed, as were the NICE guidelines,[3] and it was interesting to note the difference in the composition of the expert panels with NICE including more input from non-physicians. Professor Brown also touched upon the question of when to start treatment for young people with hypertension and suggested that a calculation of lifetime cardiovascular risk may help in determining the timing of commencement of treatment.

Dr A Walker, University of Glasgow, then discussed the cost-effectiveness of health intervention. Within this calculation the cost, opportunity cost (i.e. what else cannot be funded if money is spent on an intervention) and the value of an intervention must be considered. This lecture focused on the difficult balance between what is best for the individual patient and what is best for society. Bad decisions cost money and cost-effective healthcare can be promoted by introducing targets, incentives and structures. For example, QALYs allow powerful comparisons across diseases and could form the basis for new healthcare targets. The use of this approach may allow governments to set targets which maximize the number of QALYs gained per money spent.

Finally Dr R Williams, a GP from Edinburgh, gave a view of guidelines from a primary care perspective. He felt that compliance could be increased if guidelines were evidence-based, gave precise definitions, were non-controversial and easy to put into practice. The Lothian Lipid Guidelines were highlighted as an example of an easy to use, effective guideline.[3]

SESSION 3

Whereas Session 2 focused on advising professionals the theme of Session 3 was how we advise patients about cardiovascular risk.

Dr S Maxwell, Edinburgh University, opened Session 3 by reminding us that only about half of newly diagnosed patients with hypertension persist with their medication three years after diagnosis. The level of risk that patients are willing to accept before wanting treatment is very variable. We, as doctors, receive very little formal training in explaining risk and it is a complex issue at the centre of successful therapy. Dr Maxwell focused on ways of supporting the decision-making process. It is important to involve the patient in making decisions but this is difficult as the balancing of benefit vs harm is often complex. There are a number of decision aids based on words, numbers and visual aids that can be used. The Cochrane Library has an inventory of over 400 decision aids.[4] Aids based on words and numbers can be problematic as they are open to interpretation. Visual aids such as 'smiley faces' and 'donut charts' may be more useful. It is important that aids use appropriate language, consider all risks, are specific to the patient, based on good quality evidence, clarify the options and are achievable within the time constraints of modern clinical practice.

The role of the media in advising the public was discussed by Dr R Smith, former editor of the *British Medical Journal*. He cited the example of restless legs syndrome as a

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disease in which the media were complicit in exaggerating claims of prevalence and seriousness ('disease mongering').[5] This demonstrated that the media can be manipulated by the pharmaceutical industry, and Dr Smith provided further examples of how certain newspapers can print stories promoting medicalisation (urging the reader to seek more medical input than is required). The media is a critical interface between the healthcare service and people, and it is worrying that disease mongering and medicalisation are published instead of balanced argument.

M Coles gave the perspective of the patient. Her story of being diagnosed with hypertension at a young age reminded the audience of the profound effects of labeling a healthy person as a patient. Ms Coles was symptomless, but once treatment for hypertension was initiated, she became worried about health issues that were not, at least at first, addressed by her doctors. This highlights the importance of clear discussion about the meaning of risk reduction.

The final session was an interactive debate chaired by Professor DJ Webb. The motion was 'this house believes that the pharmaceutical industry is turning people into patients in the drive to treat more cardiovascular risk factors'. Before the debate, the audience voted and 25% strongly agreed with the motion, 40% agreed, 17% were undecided and only 18% disagreed.

The case for the motion was presented by Dr I Heath, a GP from London. She argued that there is a universal fear of ill-health and death and, therefore, there is money to be earned by persuading the healthy they are sick. Pharmaceutical companies want to increase the number of patients treated to maximise profits. Treating risk factors is particularly attractive as the drugs may be taken life-long. For example, Dr Heath claimed drug companies promote a new treatable condition 'prehypertension' in the hope of increasing drug sales.

The argument against was made by Dr D Gillen, Medical Director, Wyeth. He argued that the main problem is a lack of trust of the pharmaceutical industry. While the industry is responsible for bringing effective and safe drugs to the marketplace (e.g. statins) that have contributed to the reduction in cardiovascular death in Scotland, there is a trust issue. While recent incidents, such as Vioxx being withdrawn, have damaged the reputation of big pharmaceuticals, the public need for new drugs remains. In the UK, industry spends £3·2 billion on research and development and employs 73,000 people with the aim of improving the nation's health. To improve the pharmaceutical industry's reputation, Dr Gillen suggested more direct discussion between industry and patients but more distance between industry and doctors. This is highlighted in the tougher new MHRA and ABPI Codes.

A second vote showed a very slight shift of opinion with 24% of people strongly agreeing, 32% agreeing, 24% undecided and 20% disagreeing.

This stimulating meeting attracted an audience with a wide variety of backgrounds and was covered by the media.[6] Hopefully this will lead to further debate around the treatment of risk factors.

CME

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