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The state of men's health in Europe

Conventional primary care won't get the job done

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The European Commission's recently published report, *The State of Men's Health in Europe*, shows marked differences in health outcomes between men,[1] which are strongly related to their biology, culture, and socioeconomic realities.

The report is a huge undertaking: an attempt to describe the salient health issues of the 290 million men and boys of the 27 member states of the European Union, the four states of the European Free Trade Association, and three EU candidate countries.

Included in its findings are that working age men have significantly higher mortality rates than working age women (210% higher mortality rate in the 15-64 age range; 630 000 men per year versus 300 000 women); public health activity that benefits men's health is patchy across the EU; and working men underuse health services compared with women and unemployed men. A key conclusion of the report is that "Gender equality initiatives will have a positive impact on the way men's needs are taken into account within government health strategies and at the more local practitioner level."[1]

By 2060 there will be nearly 24 million fewer working age men than now across the 27 member states of the EU

Health ministers should be reminded by their treasury counterparts that because of lower birth rates, rising life expectancy, and the higher death rate in men in the 15-64 age group, by 2060 there will be nearly 24 million fewer working age men (aged 15-64 years) than now across the 27 member states of the EU. There will also be about 32 million more (mainly non-working) men over 65. Health ministers should then be asked what is being done in practical terms to limit this health and economic disaster, which will influence not just men but the whole of society.

The report includes a depressing review of current policy and practice: only Ireland has a national men's health policy, and in many countries a "one size fits all (sexes)" approach pinpoints the importance of the authors' call for policy makers to design and implement sex specific policies. It seems that in much of the EU men's health has not yet sufficiently entered the political, or medical, consciousness to yield meaningful changes in service delivery.

The good news, however, is that a raft of public health measures that do not specifically target men have nonetheless had a greater effect on male morbidity and mortality because of men's more flawed lifestyles. The usual suspects are to be found here, such as smoking bans, road safety legislation, and health and safety in the workplace. However, European nations continue to vary widely in, for example, restrictions on smoking in enclosed public spaces.

Although the workplace represents a key hazard for many men, it is also a key site for placing health services that men are more likely to use, a point that the report mentions only in passing. Instead it focuses on the (albeit worthy) work of major sports clubs in England in engaging with the community and carrying out match day health checks for men. Yet the evidence for a win-win situation for employers (reduced absenteeism, improved productivity, and workforce retention) and employees (happier and much healthier) in workplaces with good quality worksite health programmes is strong, with returns on investment of between 2.8 and 6.0 times; this is important knowledge for governments, employers, and unions.[2]

The report mentions the failure of educational providers to focus on men's health and men's underuse of available facilities but fails to mention the Royal College of General Practitioners' men's health curriculum or similar resources in other countries. The mere existence of a curriculum does not guarantee its use, however. Educational providers have an obligation to use such resources to help dispel the myth that men are disinterested in their health and should encourage health providers to look outside the box of traditional care to better engage with a target group that demands and deserves healthcare on its terms and on its turf.

Chastising men for underuse of existing services, which are often open only during working hours, and for not being interested in their health is simplistic, unfair (working men's taxes help fund the system), and ignores the results of studies that show men are interested in their health.[3] One local initiative to

IRISH MEN'S SHEDS ASSOCIATION

Men's sheds are a community based way of engaging men who do not access health services. Men can learn practical skills with key principles of local governance, ownership, sharing, and mentoring. Sheds have benefits across a wide range of social and health areas

improve men's access is a once or twice a week evening clinic, which attracts workers who are unable to attend during office hours (author's observation). Research is needed to determine the effect of such clinics on outcomes.

The report notes that consideration of the social determinants of health—especially educational level, employment, income, and social inclusion—would have the most effect on changing men's health behaviour. Challenges include finding ways to keep young men who are likely to be marginalised in an education system that often fails them, boosting men's health literacy, and engaging men of all ages who feel marginalised—with improvements in health being just one of the benefits. Research using the "plan-do-study-act" template of the UK NHS Institute for Innovation and Improvement can be inexpensive and provide relatively rapid results about the effectiveness of a new programme.[4]

A major challenge is to engage with the many men who do not access health services. One key area is the growing phenomenon of men's sheds, with more than 20 in Ireland and more than 700 in Australia, where they originated.[5 6] They provide a community based outlet for men who want to learn practical skills with key principles of local governance, ownership, sharing, and mentoring with other men in a non-judgmental setting.[7] Sheds have benefits across a wide range of social and health areas, including social inclusion, health literacy, and healthier lifestyles.

Men's health in Europe has far to go, but the report represents a springboard to an exciting future

Men's health in Europe has far to go: the challenges are immense but the potential benefits, both socially and economically, are compelling. This report represents a springboard to an exciting future.

Much adequately resourced research is needed, especially in the area of engaging with those men at greatest risk (men in lower socioeconomic groups). There is great potential in educating healthcare providers about alternatives to traditional in-hours primary care.

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MIKKEL OSTERGAARD/ PANOS

Despite early efforts to roll out antiretroviral therapy, the latest evidence shows that limited funds are available for future programmes

Antiretroviral therapy programmes in resource limited settings

Incorporating limited laboratory monitoring may lead to better outcomes and also be cost effective

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In the linked study, Mermin and colleagues assess the effect of routine laboratory monitoring on clinical outcomes in patients receiving antiretroviral therapy in Uganda; in a companion study Kahn and colleagues assess the cost and cost effectiveness of quarterly CD4 cell count measurement and monitoring of viral load in such patients.[1 2]

As a result of political commitment and major investment, more than 5 million people living with HIV in resource limited settings are now benefiting from antiretroviral therapy. Early efforts in the roll out of antiretroviral therapy decreased drug costs and made treatment both available and cost effective. Because of limited capacity and costs, treatment programmes rightly focused primarily on developing new delivery systems and not on laboratory monitoring.[3]

In contrast, in developed countries laboratory monitoring is central to patient management. For example, US guidelines recommend measuring CD4 counts and HIV-1 viral load, and performing genotyping before the start of treatment (level A evidence rating). They also recommend twice yearly measurement of CD4 counts and frequent viral load monitoring (often six times a year) in the first year of treatment (level B evidence rating).[4] Yet, despite huge differences in laboratory monitoring, observational studies have reported similar outcomes for patients in resource limited settings.[5] Laboratory monitoring is still not feasible in most resource limited settings, but—as it is incorporated—clinical outcomes and cost effectiveness must be considered. Until now, only one randomised study, the Development of AntiRetroviral Therapy in Africa (DART) trial, has compared the outcomes of clinical monitoring alone versus clinical monitoring plus twice yearly CD4 counts.[6] That study found a significant reduction in a composite end point of death, with or without stage IV World Health Organization adverse events, in the CD4 monitoring arm, but these benefits were marginal and, because of the high cost of salvage treatment, were not cost effective. Therefore, WHO did not endorse the implementation of CD4 monitoring.

In Mermin and colleagues' trial, 1094 adults who had not received ART but were eligible for antiretroviral therapy were randomised into three groups: clinical monitoring alone, clinical monitoring plus quarterly CD4 counts, and clinical monitoring plus quarterly CD4 counts and measurement of viral loads.[1] Outcomes were severe AIDS associated morbidity and mortality. The first line regimen prescribed was stavudine, lamivudine, and nevirapine or efavirenz. After enrolment, clinic visits were not scheduled; instead, trained field officers visited the participants at their homes to deliver drugs and conduct study procedures. There were 126 deaths (48% in the first three months) and 148 new AIDS defining illnesses during follow-up, and virological failure occurred in 61 (5%) of participants. Significantly more deaths and new AIDS defining illnesses occurred in the clinical monitoring arm than in the CD4 or viral load arms, but the two laboratory monitoring arms did not differ significantly.

Are the results of this study substantially different from those of the DART trial? As the authors point out, the differences are more in the interpretation of the results than in the results themselves. More frequent monitoring in this trial (quarterly versus biannually) could contribute to the difference in findings. However, there may be other reasons to explain the superiority of the CD4 monitoring arm in this study. Itis surprising that the addition of monitoring for viral load did not improve outcomes. This could be because of the low rate of virological failure regardless of study arm, which was probably the result of the programme providing extensive adherence support, with frequent home visits and delivery of drugs. Thus, before disregarding viral load testing in ART programmes in resource limited countries on the basis of this one study, it should be noted that the benefits of viral load monitoring were largely negated by an adherence programme that made virological failure rare.

In the second linked study Khan and colleagues report the results of an economic analysis of the trial.[2] In this analysis quarterly CD4 testing increased the cost per 100 people by $20 458 (£12 962; €14 816) and averted 117.3 disability adjusted life years (DALYs) for an incremental cost effectiveness ratio of $174 per DALY averted. Adding viral load monitoring to CD4 testing increased the cost by $142 458 and averted 27.5 DALYs for an incremental cost effectiveness ratio of $5181 per DALY averted. On the basis of these findings the authors conclude that adding quarterly CD4 but not viral load monitoring is cost effective.

Ultimately the DART study and the new studies highlight the central problem: despite the scale up, limited funds are available for ART programmes. Is it better to start treatment in more people or to optimise outcomes in fewer? Both DART and the new studies suggest that CD4 monitoring significantly improves outcomes, although the improvement is modest when compared with the effect of clinical monitoring alone. And, although the cost of CD4 testing is low enough that it reaches cost effectiveness thresholds, more patients would be able to start on ART with clinical monitoring alone.[7] Viral load testing, at five times the expense of CD4 monitoring, is not cost effective. Continued innovation is needed to develop inexpensive point of care testing for viral load that is cost effective and can be implemented in resource limited settings.

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RESEARCH, pp 1134, 1135

Why do the results of randomised and observational studies differ?

Statistical theory conflicts with empirical findings in several areas of research

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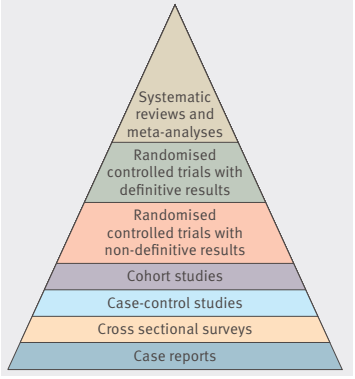
In the linked study, Tzoulaki and colleagues found that cardiovascular risk markers show less predictive power in secondary analyses of data from randomised controlled trials (RCTs) than in observational studies that were set up to investigate these markers.[1] Why would this be?

For decades the question of "which are better?"—randomised trials or observational studies—has been debated. We now have not only theory, but also evidence in three different areas—effects of treatment, adverse effects, and biomarkers. Theory predicts that randomised trials are superior when investigating the hoped for effects of treatments. In daily practice, treatment depends on the perceived prognosis of a patient, so any effect of treatment becomes inextricably intermingled with prognosis. Therefore, data from daily medical practice cannot be used to investigate the intended effects of treatments. Trials with concealed randomisation are needed to obtain the right answers. However, empirical proof that observational studies of treatment are widely off the mark has been surprisingly elusive.[2] Four meta-analyses contrasting RCTs and observational studies of treatment found no large systematic differences (Benson 2000, Concato 2000, MacLehose 2000, Ioannidis 2001).[2] The first and second found no difference, with RCTs showing larger variation in the second; the third found no differences for higher quality studies; the fourth found a high correlation coefficient, with a slight tendency for larger estimates and somewhat more heterogeneity in observational studies. A systematic difference was found in an older study on historical controls.[3] A semi-simulation showed average similarity but larger variation for observational studies.[4] Thus, the notion that RCTs are superior and observational studies untrustworthy, except when looking at dramatic effects,[5] rests on theory and singular events—discrepancies in the effects of vitamins[6] and hormone replacement therapy. For hormone replacement therapy, however, discrepancies between RCTs and observational studies were shown to have little to do with assumed advantages of randomisation but to be the result of different time axes in the analysis.[7]



The evidence pyramid: are randomised trials or observational studies better?

For adverse effects, the same theory predicts that observational studies based on records from daily practice can give the right answers. Adverse effects are diseases that are different from those being treated; they have different risk factors, and they are always unintended and often unpredictable (or analyses can be restricted to patients for whom the adverse effect is unpredictable). Hence, there is no confounding by indication.[8] This idea has been supported by one small and one larger meta-analysis,[9 10] both of which showed that estimates of adverse effects from randomised trials and observational studies are similar. The similarity was most clearly shown in a funnel plot.[10] Thus, on the basis of comparisons where both types of study were available, results from observational studies are reliable. This is fortunate because randomised trial data do not exist for many adverse effects, especially those that are rare or occur late. The greatest benefit of being able to use data from daily practice for research into adverse effects is that the frequency of adverse effects can be much higher in daily practice than in the superselected population of trials.

Theory is silent, however, about a potential difference between secondary analyses of randomised trials versus observational studies for the predictive power of biomarkers. Indeed, almost all advantages of RCTs disappear when trial data are used to assess a biomarker. Biomarkers are not randomised and any alleged advantage of advance protocol specification of end points and analyses does not apply because biomarkers are often analysed as an "afterthought" to publish something extra from an RCT. Researchers doing biomarker analyses might be expected to "data dredge" in the same way in a dataset that came originally from an RCT as they would for observational data.

Tzoulaki and colleagues discuss three potential explanations for their finding that the predictive power of biomarkers is lower in RCTs than in observational studies: data dredging, individual patient data analyses, and spectrum bias. The authors admit that the question whether secondary analyses of data from randomised trials lead to less or more data dredging than for observational studies can be argued either way. Meta-analyses of individual patient data and meta-analyses based on aggregate results did differ, but the authors dismissed this as a possible explanation because markers studied in individual patient meta-analyses were probably different. Lastly, patients in RCTs may have a more limited range of risk profiles, but the authors did not think that this could explain their findings. However, RCTs have a restricted range of patients because inclusion criteria aim to reduce any risk to participants or sponsors. The enrolment of patients in trials is even more selective than can be gleaned from the stated inclusion and exclusion criteria.[11 12] Sensitivity and specificity will differ between studies because of the inclusion of a different range of patients, a phenomenon known as "spectrum bias." Spectrum bias is a good candidate to explain differences in results for prognostic markers in trials versus observational studies. If spectrum bias is the explanation, credibility should be given to observational studies that include a wider range of patients from daily practice.

As a solution, Tzoulaki and colleagues propose to register all study populations with acceptable data quality and to reanalyse all studies for each novel emerging biomarker of interest. But this might not be feasible because the biomaterial from older studies may no longer exist, the material was not stored in the right way, or it is not financially or logistically possible. Before we search for solutions, we ought to know what the problem is. Can Tzoulaki and colleagues' findings be replicated and, most importantly, if they can, what is the underlying mechanism? Understanding the mechanism will determine which studies to trust.

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Exercise helps prevent excessive weight gain, and women who exercise during pregnancy are more likely to exercise after the birth and lose the weight gained during pregnancy

Exercise during pregnancy

Eat for one, exercise for two

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With the start of the London 2012 Olympics less than a year away, athletes such as Paula Radcliffe and the Canadian heptathlete, Jessica Zelinka, remind us that it is possible not only to return to world class competition after having a baby but also to continue training—albeit with some modifications—throughout pregnancy. The prevalence of obesity is increasing: in 2007, 24% of women in the United Kingdom aged 16 and over were obese compared with only 16% in 1993. One of the aims of the London 2012 Olympic bid was to encourage the whole population to become more physically active. This should include pregnant women too.

Recognising the beneficial effects of exercise during pregnancy is not new. In 1900, J M Ballantyne, who helped pioneer antenatal care—or as he put it pre-maternity care—in Edinburgh, designed a card to make sure essential advice during pregnancy was remembered and recorded by his pre-maternity nurses. This included a tick box regarding exercise and rest.[1] In 1945, the textbook *Williams Obstetrics* advised 30 minutes of exercise twice a day.

Recent recommendations suggest that, in the absence of medical or obstetric complications, either 30 minutes or more of moderate exercise a day on most, if not all, days of the week,[2] or 30 minutes of moderate intensity activity a day,[3] should be the targets in pregnancy. This recommendation slightly exceeds but is not dissimilar to the most recent advice to UK adults of at least 150 minutes of activity a week.[4] Not all women achieve these levels of activity before pregnancy, and activity often decreases during pregnancy.[5 6] The amount of exercise performed is often proportional to the woman's concerns about safety.[7]

Both the Royal College of Obstetricians and Gynaecologists and American College of Obstetricians and Gynecologists have excellent patient information leaflets that cover which types of exercise are recommended in pregnancy and which should be avoided.[8 9] Precise guidance is given on the level of exertion and relevant precautions. Exercise in pregnancy has the same beneficial health outcomes as in non-pregnant women. It also relieves many of the minor ailments of pregnancy, such as tiredness, leg oedema, back pain, constipation, and nausea. It does not increase the risk of miscarriage and can help prevent and control gestational diabetes. Exercise also helps prevent excessive weight gain in pregnancy, and women who exercise during pregnancy are more likely to exercise after the birth and therefore lose the weight gained during pregnancy. Return to pre-pregnancy weight between pregnancies helps reduce the risk of obesity later in life.

There seems no doubt that moderate intensity exercise during pregnancy is safe for uncomplicated pregnancies, but there is continuing debate about vigorous and longer periods of exercise. A study in a Danish cohort of 85 139 pregnant women found a significant link between high levels of exercise in early pregnancy (>270 minutes a week) and the risk of severe pre-eclampsia, although the absolute risk was still low at 1.1-1.3%. There was no link between exercise at the currently recommended levels (210 minutes a week) and severe pre-eclampsia.[10]

There is also increasing interest in measuring the effects of maternal exercise on the fetus.[11] The effect of maternal exercise on birth weight is not consistent between studies. Obese women and women who gain excessive weight during pregnancy have bigger babies. If maternal exercise results in a small reduction in birth weight in babies in the high end of normal or large for gestational age range, childhood obesity may be reduced and the risk of metabolic disease in later life lessened, consistent with the Barker hypothesis.[11] More research is also needed about the effects of exercise on overweight and obese women because many studies were conducted on normal weight women or women who were already physically active before pregnancy.[12]

Since the advent of antenatal care in the early 1900s, the list of advice and tests that need to be discussed during this important period of a woman's life has increased greatly. Discussions about the amount and type of exercise that is recommended during pregnancy may be seen as less important than screening for Down's syndrome or deciding whether or not to screen for gestational diabetes. But the beneficial effects of exercise during pregnancy to both the mother and developing baby need to be emphasised, and women need reassurance that they are doing no harm as long as their pregnancies are progressing normally. The challenge for the future will be to encourage all women with uncomplicated pregnancies to attain at least the currently recommended exercise levels while continuing to research what type, what intensity, and how much exercise in pregnancy will give the best maternal and fetal outcomes.

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Up to a billion women worldwide have been beaten, coerced into sex, or otherwise abused in their lifetime

Seeking a better world for women and girls

A moral and political movement is needed to end gendered oppression

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GMB AKASH/PANOS

One of the great injustices of our times is the insidious, systemic, and widespread oppression of women and girls. Gendered violence and avoidable complications of pregnancy and childbirth are associated with increased risk of depression, anxiety, suicidality, chronic diseases, disabling injuries, and death.[1 2] They are also infringements of basic human rights and freedoms.[1 2] For several decades these problems have been documented, and programmes, campaigns, policies, laws, conventions, and treaties have been devised to eliminate them.[1 2] Despite some successes, American journalists Nicholas Kristof and Sheryl WuDunn argue in their 2009 book, *Half the Sky: Turning Oppression into Opportunity for Women Worldwide*, that it will take an incipient movement to emancipate women fully from what is the "equivalent of slavery."[3] *Half the Sky* is an impassioned call for action to stop routine abuse and neglect.

The statistics are grim. Up to a billion women worldwide have been beaten, coerced into sex, or otherwise abused in their lifetime.[4] Four out of five of the estimated 800 000 people trafficked across borders annually are women and girls, most of whom are targeted for sexual exploitation.[5] More girls have been killed simply because they were girls in any single decade than people were murdered in all the genocides of the 20th century.[3] Furthermore, the claim that childbirth is almost as deadly as ever remains true.[3] In 2008, 358 000 maternal deaths were reported globally, 99% of which occurred in developing countries.[6] Because of a lack of available appropriate health services, for each woman who dies, 20 others endure long term ill health.[2] Population level strategies, in combination with cause specific interventions, show promise for reducing maternal mortality and morbidity, but they require the staunch support of relevant stakeholders.[7]

These facts are not new to those who work in these areas but may be a stark revelation for others. By highlighting violations such as forced prostitution, rape, honour killings, female genital cutting, and acid attacks through personal accounts of tragedy and triumph, popular media can inform and inspire citizens. Exposure to the efforts of ordinary people's attempts to tackle such devastating problems could help engage people in meaningful change (www.halftheskymovement.org/). *Half the Sky*'s reference to the successes of small microfinance operations is—for example, supported by research showing that specific initiatives such as the Intervention with Microfinance for AIDS and Gender Equity in South Africa can reduce intimate partner violence.[3 8] However, other effective programmes for preventing and dealing with violence against women and girls are desperately needed.

How can a call to action to end gendered oppression be put most effectively into practice? Representatives of state organisations could capitalise on the interest generated by a book such as *Half the Sky* to give the problem a higher priority on national, regional, and international agendas in resource poor and resource rich countries. Because gender inequality lies at the core of oppression, the focus should not be solely on women as victims of injustice and agents of change responsible for their own emancipation,[9] but also on men and cultures of masculinity through which the unjust balance of power is generated and reproduced. Those who harm women and girls must be held accountable, and all men and boys must be fully engaged with interventions that promote equality and prevent violence.[8] Moreover, this action must avoid ethnocentrism, support the growth and activities of local leaders, and begin to attend to the Western economic power that can keep women and girls in the developing world impoverished.[9]

Any movement intended to alter societal structures and attitudes requires political will. Building political will requires collective resolve and coordinated action across nations. With this, it is more likely that—for example, the United Nation's millennium development goals' focus on promoting gender equality, empowering women, educating girls, and improving maternal and child health is achieved.[10 11] Although a multisectoral strategy is essential, the health sector has the potential to take the lead in this regard,[1 8 11] and further investing in the health of women and girls, as Ban Ki-moon, the United Nations secretary general, has commented, is "not only the right thing to do," but an important means to create more peaceful and productive societies.[12] "When we deliver for every woman and every child, we will advance a better life for all people around the world," he added at a recent UN headquarters event.[13]

It is strikingly clear that the oppression of women and girls is a profound moral and political concern.[3] Now is the time to act to end the deplorable state of so many lives in both developing and industrialised countries. We must challenge indifference and cast a wide net across all levels of societies to harness the energies of those concerned. The task is immense but not insurmountable.[11]

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