delivery modes. Any harm caused by nicotine replacement must be compared with that caused by continued smoking—which is extremely harmful to both the woman and her child. Clear evidence of effectiveness and safety is required. We need definitive randomised, placebo controlled, clinical trials of a range of doses and administration routes for nicotine replacement in pregnancy.

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# Making public health interventions more evidence based

## *TREND statement for non-randomised designs will make a difference*

The movement towards evidence based public health policy has been gaining momentum over the past decade. It takes an important step forward with the recent publication of the TREND statement (transparent reporting of evaluations with non-randomised designs).[1] Its aim is to improve the quality of reporting of non-randomised evaluations so that the conduct and findings of such research are transparent and information that is critical for research synthesis is not missing, and to do for public health evaluations what the CONSORT statement has done for randomised controlled trials.[2]

The publication of the TREND statement reflects the increasing recognition that successful evaluation of public health interventions will necessarily entail the use of research designs other than controlled trials[3–5] and various types of evidence, often in combination.[4 6] The reasons for using such interventions include the following.

Firstly, the intervention is already well established or its delivery is by nature widespread—for example, evaluation of the efficacy of BCG in different settings[3] or of the current advertisement campaign in the United Kingdom to encourage adherence to speed limits in built up areas. No control groups exist; the evaluations need to be based on comparisons before and after the intervention and on comparisons of adopters with non-adopters.

Secondly, the intervention has been shown to be efficacious or effective in small scale studies, conducted under ideal conditions, but its effectiveness needs to be shown when scaled up and carried out under routine conditions.[6]

Thirdly, the intervention is multifaceted and the pathways to impact are complex. Victora et al argue that an impact achieved in randomised controlled trials will not convince policy makers unless it is accompanied by additional evidence showing changes in intermediate process outcomes and differences between adopters and non-adopters of the intervention.[6]

Fourthly, ethical issues in the use of a control group, such as occurs when the intervention has known benefits but its efficacy against an important outcome is not known, or when patient choice needs to be factored in.[7] This issue was overcome in the Gambia hepatitis B vaccine trial of the long term impact on liver cancer, by using a "stepped wedge design," with the vaccine introduced district by district on a staggered basis and the order of introduction chosen at random.[8]

The TREND statement follows the exact format of the revised CONSORT statement, retaining the same 22 items, with revised descriptions relevant to non-randomised designs. Some important enhancements have been made that are also relevant to randomised controlled trials evaluating public health interventions. Item 2 (background) now includes the underlying behavioural or social science theory used to develop the intervention, and item 4 (interventions) encourages a more detailed description of both the content and the delivery of the intervention.

The authors' vision is that adoption of the TREND reporting guidelines will ensure that comparable

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information across studies can be consolidated and translated into generalisable knowledge and practice more easily.[1] Have they got it right?

The answer is both yes and no. The authors rightly say that this is work in progress and that improvements might be necessary. With this publication they aim to start a dialogue; they invite comments and feedback. Their decision to follow rigidly the 22 items of the CONSORT statement is a major limitation—this is not a case where one size fits all. Although I strongly endorse the suggestion that alternative ways, such as linked web pages, are needed to tackle fully the level of detail needed if an intervention is to be reproducible,[9] I encourage a rethink and expansion to include named items relating to the development of interventions, and additional items for process and confounding variables. I would also redo item 8 (renamed assignment method), which attempts to capture the evaluation design used. This is the weakest part of the TREND statement, and it needs to be expanded to capture the whole range of evaluation designs; at present it is biased towards the evaluation of newly introduced interventions. I recommend an entry called evaluation design, including separate items for the two main dimensions[4]: comparisons to be used (before and after, adopters *v* non-adopters, intervention *v* control and whether randomised or not,) and design of data collection (longitudinal, cross sectional, case-control).

However, this is an excellent and encouraging start and an important milestone in public health research. Having the TREND statement of agreed reporting standards for non-randomised designs increases their scientific credibility and draws attention to the scientific rigour involved in their conduct and design. It should challenge the prejudice that evaluation research is second rate and encourage more to do such research. We should look forward to its continuing development and evaluation.

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# Pathogenesis and treatment of varicoceles

## *Controversy still surrounds surgical treatment*

The varicocele is an enigma in the treatment of male infertility. Despite over 30 years of evidence that repair of varicoceles results in improved fertility,[1] the retrospective nature of most of these reports has led to controversy regarding the utility of treatment. This is compounded by the fact that not all varicoceles cause infertility. Varicocele is present in approximately 15% of men, and, although it is the most commonly diagnosed cause of male infertility, nearly two thirds of men with varicoceles remain fertile. The reason for this discrepancy remains unknown, although it is postulated that the cause of infertility is related to both temperature and time.[2] The anatomical and physiological principles of the testicular vasculature and the evidence base regarding surgical treatment are outlined here.

The blood supply to the testis, as well as the resulting counter current heat exchange, results in cooler intratesticular temperatures compared with body temperature.[3] Disruption of this system can result in hyperthermia of the testes.[4] As the left side drains into a system with higher resistance, small venules may persist or open during embryogenesis. Testicular blood flow remains low before puberty, and therefore these veins do not become clinically apparent until adolescence when testicular blood flow increases, which explains the appearance of most varicoceles around puberty.[5] Endocrine dysfunction may contribute to varicocele related infertility. Studies have shown altered function of the Leydig, Sertoli, and germ cells in men with notable varicoceles.[6] Whether this is due to the increased intratesticular temperature or other factors is unknown.

Treatments vary from radiological ablation to surgical ligation of the varicocele, although most urologists reserve the radiological approach for the rare surgical failures. Numerous studies have examined various operative methods, attempting to show a difference in efficacy and outcome. Although most of these methods result in similar short term results, the open microsurgical methods tend to yield fewer long term complications, such as recurrences and hydroceles.[7] Although laparoscopic varix ligation was once touted as a minimally invasive method compared with open surgical repair, several authors have shown similar recovery rates, equal efficacy, fewer complications, and the advantage of not having to enter the abdomen.[7] Most experts agree that only clinically apparent varicoceles should be treated. Although subclinical varicoceles (those identified by imaging studies only) may result in improvement in some seminal variables, evidence of efficacy is lacking regarding pregnancy rates.[8]

A Cochrane review identified five randomised controlled trials that examined the outcomes in couples with male factor infertility and varicoceles and

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