

people, which is often reinforced by legislation, such people are marginalised and endangered. It is our historical treatment of prostitutes that has made them vulnerable to violence and abuse.

Criminalising prostitution denies people, in this case mainly women, choices and the right to control their own bodies. There has been debate as to whether prostitutes have choices; our duty is to increase their relatively few options, not reduce them further.

It is abuse of human beings, no matter what their occupation, that must be combated. The "evil" that Due points to consists of activities that are crimes and morally and ethically unacceptable in any walk of life, and we are bound to apply the protections of society from abuse to every person equally.

Health professionals have to adopt morally neutral positions if they are to work with and help every member of society equally. Whether abolition of prostitution is a realistic or desirable goal is irrelevant to a duty, collectively and individually, to care for prostitutes. Due's position is an example of confusing morals with ethics. *The Lancet* is correct in stating that the health profession's ethic mandates the protection of the vulnerable, and that only by providing them the full protection of the law and the resources of our society will that mandate be fulfilled.

Prostitutes are a group of people who have greater than average health and social needs and the health professions have, by and large, failed them abysmally. *The Lancet* joins other medical journals such as the *CMAJ*³ and criminologists⁴ in calling for the decriminalisation and protection of prostitutes. As one of us has stated, "the criminal law is a rather ineffective custodian of moral norms, especially when these are disobeyed by many and disagreed with by many more".⁵ Only by making our society completely inclusive will we achieve true distributive justice. Prostitutes are

indeed people too, with real needs. If we forget this fact, we betray our commitment to caring.

We declare that we have no conflict of interest.

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Screening for oral cancer

Deciding whether an oral cancer screening programme should be established depends on the balance between the potential benefits of screening in terms of improved outcome for patients, the harms of screening resulting from testing and investigating the healthy population, and the resources required. Publication of the final round of the only randomised controlled trial (RCT) on oral cancer screening (June 4, p 1927)¹ provides fair evidence for its effectiveness in high-risk populations in India, where oral cancer is one of the most common forms of malignant disease. However, we have identified some methodological weaknesses in Rengaswamy Sankaranarayanan and colleagues' RCT according to the high standards of the Cochrane Collaboration and the CONSORT statement on cluster randomised trials.^{2,3}

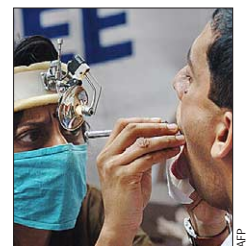
These weaknesses include lack of allocation concealment and the small number of clusters randomised, which increases the potential for imbalance

across treatment groups; indeed, Sankaranarayanan and colleagues themselves recognise that variations in risk factors at baseline were confounding to some extent. In addition, the close geographical proximity of the clusters could lead to contamination. No data were provided on quality of life, costs, or lead time that can result in length bias. Some assumptions seem to have been made about the sensitivity and specificity of the screening test itself and it seems that the ability of the health workers to discriminate significant oral lesions was not measured.

More importantly for decision makers, there was no hard information on the harms of screening. In particular, no data were provided for the overall specificity of the programme. False-positive screening can cause distress, and unnecessary investigations can be a huge drain on scarce resources. The number of false-positive screens tends to increase as the prevalence of the disorder in the population decreases, so if false-positive rates were high in Kerala, it could be a major consideration for those planning trials in populations where oral cancer is less prevalent.

Lessons from existing screening programmes should be taken into account when planning future trials. In cervical cancer screening programmes, adjunctive methods to visual examination have proved pivotal for detection of early lesions using risk markers. More research is needed to understand the natural history of oral cancer at the molecular level, and to develop objective clinical methods for identification of early oral lesions.

The results of Sankaranarayanan and colleagues' study do not change the conclusion of our earlier Cochrane review² that there is insufficient evidence to support or refute the introduction of population-based screening programmes for oral cancer worldwide. However, theirs is an invaluable contribution nevertheless and should stimulate further oral cancer screening



trials using more rigorous methods and perhaps aided by sophisticated adjunctive techniques.

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Authors' reply

Our study was designed in 1994 when no CONSORT guidelines existed for cluster randomised trials. Thus we had no opportunity to refer to CONSORT at that time; however, the study fulfilled almost all requirements.

The randomisation scheme depends to a large extent on local circumstances. Randomisation was done by a statistician independent of our study and the allocation was done randomly using restricted block randomisation, ensuring almost equal distribution of clusters into the study groups.

The number of clusters must again reflect the local circumstances. A small number of clusters was used in our study to minimise contamination in view of the high population density in Kerala; a greater number of smaller clusters would have resulted in closer geographic proximity. Two previous interim analyses ignored the cluster design so the differences in risk factor prevalence were significant.^{1,2} The final analysis took into account the cluster design, and the study groups were well balanced for age, sex, religion, socioeconomic status, pan-tobacco chewing, and alcohol use, but the proportion of

smokers was slightly higher in the intervention group.

The sensitivity and specificity of oral visual inspection in our study were reported in a previous publication;³ the approximate programme sensitivity and specificity can be estimated from the data provided in the paper.

No specific quality of life measurements were used in our study, nor are we aware of any randomised screening trials that report this outcome specifically. Improved survival in the intervention group is due to downstaging; the effect size and duration of follow-up argue against lead-time bias. No major or minor harms from screening were seen in our study. We are currently instituting cost measurements for cost-effectiveness analysis.

It is a challenge to incorporate any molecular markers such as ploidy, retinoic acid receptor β , P53, genetic instability, loss of heterozygosity, and cyclin D1 as adjunctives in population-based screening, even in the most advanced settings. In reality, all existing cancer screening programmes including those of the breast, cervix, and colorectum rely heavily on clinical and histomorphological assessments of potential malignant and premalignant lesions, and oral cancer screening is no exception.

We have assessed a simple, clinical screening tool that can be used easily in all settings, including developed and developing countries, and we provide fair evidence, as agreed by Omar Kujan and colleagues, and valid data that oral screening by visual inspection can lead to a significant reduction in mortality in high-risk individuals. It is important to realise the potential benefits of early clinical detection and appropriate treatment in reducing the devastating worldwide consequences of oral cancer rather than waiting for validated and feasible molecular interventions to become available. Nevertheless, such adjunctive developments, if they occur, and more randomised trials, if they can be organised, are always welcome.

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Department of Error

Oransky I. Norman Horowitz. *Lancet* 2005; **366**: 116—In this Obituary (July 9), the date of birth should have been March 19, 1915.

Jefferson T. Peer review and publishing: it's time to move the agenda on. *Lancet* 2005; **366**: 283–84—In this book review (July 23), the author of the book (noted in the last sentence of the third paragraph and beneath the image of the book cover) should have read "Elizabeth Wager".