

treating those affected will have any impact on the incidence of preterm delivery. The results of further continuing trials are awaited.

Other investigators have concentrated on the observed association between spontaneous preterm delivery and subclinical or asymptomatic chorioamnionitis. In these women it is postulated that bacteria, from whatever source, set up an inflammatory reaction in the fetal membranes leading to the cascade of events culminating in preterm delivery. This hypothesis is currently being tested in a large randomised controlled trial, the ORACLE trial, which aims to determine whether antibiotics can improve neonatal outcome in women presenting with preterm labour or preterm pre-labour ruptured membranes.<sup>2</sup> This trial aims to recruit 10 000 women and should be completed in the year 2000.

The ORACLE trial is likely to produce results directly relevant to clinical practice and policy. The disadvantage of many trials in this area is that their main outcome measure to assess the effectiveness of antibiotics is gestation at delivery. While this may superficially appear to be appropriate, increasing gestational age may not improve neonatal or maternal wellbeing. Firstly, antibiotics may benefit mother and baby without affecting the duration of pregnancy. Secondly, lengthening gestation may not confer any benefit to the fetus/neonate and may even result in harm, as suggested by overviews of trials of tocolysis in pregnancy.<sup>3</sup>

Although advocates of the link between infection and preterm delivery may claim that antibiotics treat the cause of the condition rather than try to suppress the symptoms and are therefore fundamentally different from tocolysis, the problems of relying on gestation at delivery as an outcome measure remain.<sup>10</sup> This has been highlighted by recent evidence about the well documented link between chorioamnionitis and cerebral palsy. Work in rabbits has shown that experimentally induced chorioamnionitis treated with antibiotics and delayed delivery results in white matter lesions in the fetal brain.<sup>11</sup> Whether this damage is a consequence of the chorioamnionitis alone or the combination of chorioamnionitis and pregnancy

prolongation is not yet known. But if infection in humans does lead to preterm labour or preterm pre-labour rupture of the membranes as a consequence of chorioamnionitis, either from the vagina or elsewhere, then the best management option may be delivery. Attempts to maintain the fetus in a hostile environment may result in more harm than benefit.

Therefore any trial that evaluates the use of a treatment to prevent preterm delivery must show that the intervention benefits the baby and not just the obstetrician. Subclinical chorioamnionitis or bacterial vaginosis may well turn out to account for a substantial proportion of preterm deliveries. This has not yet been demonstrated, however, and until it has the use of antibiotics to prevent preterm delivery must continue to be seen as an experimental treatment which may result in more harm than good.

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## Public health psychiatry or crime prevention?

*Government's proposals emphasise doctors' role as public protectors*

In the wake of the recommendations of the Fallon inquiry into the personality disorder unit at Ashworth Hospital<sup>1,2</sup> the government has now announced its own solution to the problems presented by people with antisocial<sup>3</sup> or dissocial<sup>4</sup> personality disorder.<sup>5</sup> After a joint Home Office and Department of Health review which ran in parallel with the Fallon inquiry it has proposed for consultation new services and law. Although not prescriptive about the detail of its solution, both the government's philosophy and its resolve are clear. In pursuing, above all, public protection, it intends services which essentially hybridise punishment and

health care, with law that allows preventive detention of even the unconvicted.

The uncertain treatability of antisocial personality disorder,<sup>6</sup> consequent professional therapeutic ambivalence,<sup>7</sup> and inherent uncertainty about the moral status of the condition (whether individuals "suffering" from it are mad or bad)<sup>8</sup> combine sensibly to imply a hybrid service solution which is far more radical than that which emerged from the last government's attempt at a similar review.<sup>9</sup> Reflecting its close look at various European service models, the present government seems to intend a "third way," involving establishing new specialist institutions which would be

hybrids of prison and hospital and would house only people with severe personality disorder.

This contrasts with the solution proposed by Fallon<sup>1</sup> of specialised personality disorder units in both prisons and high security hospitals, with transfer to hospital according to prisoner/patient consent and treatability. But the core public policy objective is clearly public protection, and this must raise serious concern that services may be constructed and funded so as to pay inadequate attention to current treatment or to improving future understanding and treatment through research. Some reassurance is offered by the Home Secretary's announcement of substantial research funding. However, the government's estimate that only about 2700 individuals require such a service,<sup>10</sup> with the implication that the cost of the new services will be contained, clearly looks suspect given both surveys of morbidity in prisons<sup>11</sup> and the continuing public appetite for protection from "people with mental disorder."

However, the crucial issues for mental health professionals relate to the intended law reform. This goes far beyond the "hospital and limitation direction," or "hybrid order," of the Crime (Sentences) Act 1997, which allows courts to pass a prison sentence with an immediate direction to hospital.<sup>12</sup> Even that provoked major ethical concern among psychiatrists,<sup>13</sup> partly because of the likelihood of prisoner-patients being detained in hospital long after they needed treatment and partly because of concern that psychiatrists would become too involved in the punitive sentencing process. The new proposals, however, sideline the hybrid order in favour of a solution which necessarily uses health professionals even more directly in public protection.

Hence, there will be an indeterminate but reviewable order imposed by a court on evidence from psychiatrists (and perhaps psychologists) which will remain in place so long as the person is deemed, again on expert evidence, sufficiently dangerous to warrant it. This goes beyond even the Fallon proposal of a "renewable sentence" since the order will also apply to people who have not been convicted of any offence. The order will also apply to the untreatable. Indeed, a new order would be unnecessary for the treatable since they can already be detained under the Mental Health Act 1983.

Why make the new order a health order at all? The answer lies in the European Convention on Human Rights. Except in the event of an immediate risk of serious violence, the only means of preventively detaining unconvicted people lies in article 5 of the convention. This allows the detention of anyone of "unsound mind" on a fairly unrestricted basis. Hence, a "health order" is the only route available to the government to secure its goal. As a result, doctors (and perhaps psychologists) will be required to "diagnose" the new legal concept of severe personality disorder and advise on whether the "grave danger" threshold for the order is met where the effect of such recommendations will often not be treatment but punishment, or preventive detention. This raises serious professional ethical issues, going beyond even those implied by the suspect reliability of diagnosis and risk assessment.

Under the new order both the convicted and the unconvicted, as well as both the treatable and the untreatable, will be detained in a specialist secure

service which must necessarily be legally a "hospital," since unconvicted people cannot be imprisoned. However, the regime will emphasise management rather than treatment, since many of the "patients" will be untreatable. Hence, for many detainees, health professionals will operate much more as public protectors than as therapists.

Such a solution represents apparent victory of the Home Secretary<sup>14</sup> over the psychiatric establishment<sup>15</sup> in his assertion that doctors must return to a "sensible" approach to public protection via patient control. He justifies this on the twin bases of there being many untreatable medical conditions for which doctors accept a responsibility to continue to care for the patient and the avoidance of therapeutic nihilism. However, since both the new service and legal measures require doctors to offer care to people with untreatable disorders against their wishes, ultimately it is the public to whom the care is therefore offered. Although doctors are properly required to apply public health measures to protect the public in relation, for example, to infectious diseases, the new measures go beyond a public health model. At least patients who are restricted because of their infection also receive validated and effective treatment.

Although only described very generally, the government's service proposals for dealing with antisocial personality disorder per se are sensible, since they reflect the scientific uncertainty about applying the medical model, perhaps even including the notion of treatability, to those suffering from the disorder. However, its legal proposals challenge both the civil liberties of the unconvicted and those designated untreatable and the ethical nature of public health psychiatry. They also imply the risk of long term hopeless detention, especially if services are inadequately resourced. They must serve therefore to initiate a long overdue debate about the social definition and role of forensic psychiatry, which, in the face of pressures from an increasingly risk averse society, prone to moral panic,<sup>16</sup> must go beyond the narrow confines of severe personality disorder. The fragility of the distinction between public health psychiatry and crime prevention has never before been so starkly represented as it is now in this proposal. However, all doctors should note the subtle but growing social requirement that medical practice should be applied towards public protection.<sup>17</sup> That requirement is not restricted to the practice of forensic psychiatry.

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## Effect of vitamin A and $\beta$ carotene supplementation on women's health

*Evidence from Nepal suggests benefits—but raises further questions*

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Much research has been devoted to child health in populations deficient in vitamin A<sup>1,2</sup> but much less to maternal health. On p 570 West et al present a report based on a large field trial in Nepal which examines the health benefits to women of supplementation with vitamin A or  $\beta$  carotene.<sup>3</sup> Vitamin A is found only in foods of animal origin, whereas  $\beta$  carotene is the main vitamin A precursor of plant origin. The authors used a hard endpoint—all-cause maternal mortality—in a strong design, and they found that both vitamin A and  $\beta$  carotene were effective. More work needs to be done, however, before supplementation is recommended for populations such as Nepal's.

Women of childbearing age were allocated according to area of residence, by cluster randomisation, to one of three dietary interventions: a single weekly oral supplement of either placebo, vitamin A, or  $\beta$  carotene. Female field workers gave participating women their assigned supplement and recorded health related information during weekly home visits.

Among the 44 646 participating women, 20 119 became pregnant once and 2070 twice. The main endpoint was maternal deaths from any cause during pregnancy or within 12 weeks of delivery. They occurred at rates of 704 per 100 000 pregnancies in the placebo group (51/7241), 426 in the vitamin A group (33/7747), and 361 in the  $\beta$  carotene group (26/7201). The corresponding preventive effects, expressed as relative risks, were 0.60 (95% confidence interval 0.37 to 0.97) for vitamin A and 0.51 (0.30 to 0.86) for  $\beta$  carotene.

What is the scientific strength of these findings? The researchers selected a strong design to test two hypotheses which, according to the protocol, had been defined a priori. They provided evidence that the doses given could affect serum retinoid concentrations, and they conducted a trial with a statistical power sufficient to study outcomes as rare as maternal mortality. This involved weekly personal contacts with over 44 000 women over three and a half years in a poor and uneducated population. The organisers should certainly be complimented for what they did accomplish.

Limitations of the study include the completeness by which numerators and denominators were assessed, the efficacy of masking, and some aspects of the analytic strategy. Among participating women in whom pregnancy had been identified all deaths during pregnancy were ascertained. However, 157 women were lost to follow up during the postpartum period (70 in the vitamin A group, 43 in the  $\beta$  carotene group, and 44 in the

placebo group). If these women disappeared because they had died, this would spuriously decrease mortality in the vitamin A group compared with the placebo group. If, on the other hand, mortality among the 157 women was similar to that of the average population this differential loss would play no role.

The authors provide no data on ascertainment of deaths among participants with unidentified pregnancies (expected in around 10% of pregnancies), but it is unlikely to have been complete. This could have biased the results if there were differential ascertainment of such deaths across the three groups. Blinding should have avoided this problem, but there are some doubts about the blinding. The three types of capsules were identical in appearance, but opening them would reveal that the  $\beta$  carotene supplement had a different colour and consistency from the other supplements. What this meant for ascertainment of pregnancies and maternal deaths is difficult to know with certainty, unless it was addressed in a specific substudy.

Pregnancy related mortality, defined above, was selected as the primary endpoint, rather than conventional maternal mortality, which is limited to the first 42 days after delivery and excludes deaths due to injuries and accidents. This choice, made a priori, was justifiable because pregnancy-related mortality may occur later than 42 days and because of the difficulties of getting reliable information on causes of death. The authors did actually collect such information and, interestingly, injuries seemed to be the single group of causes which showed the greatest risk reduction when expressed in relative terms.<sup>7</sup> However, these analyses had little statistical power, and conventional maternal mortality was in fact reduced by 40% ( $P=0.02$ ) in the combined treatment groups compared with placebo ( $P=0.08$  for vitamin A and  $P=0.04$  for  $\beta$  carotene).

What of the adverse effects of supplementation and endpoints other than deaths related to pregnancy? Vitamin A is a known teratogen, but the dose-response relations are debated.<sup>4-7</sup> One single observational study has suggested that daily amounts as low as 10 000-15 000 IU may be enough to cause malformations,<sup>5</sup> though other evidence suggests that these doses are safe.<sup>4</sup> The Nepal trial used doses of 23 310 IU (7000 :g) retinol, but on a weekly basis. High exposures in fetal life have also been hypothesised to cause schizophrenia.<sup>8</sup> Obtaining reliable information from the Nepal trial on malformations is likely to be difficult, let alone obtaining information on schizophrenia or its childhood prodromes. These other