an overall increased risk for birth defects with first-trimester exposure to any selective serotonin reuptake inhibitors but later studies with more efficient designs such as the case–control approach started showing low-to-moderate increased risks for the more commonly occurring birth defects such as heart defects, neural tube defects and oral clefts. Therefore, using a cohort approach would have resulted again in a null finding, contrary to Rajkumar & Jacob's comments.

We excluded pregnancies ending with abortion or miscarriage per design since malformation outcomes of these foetuses were not available in the Quebec Pregnancy Registry. We agree that this resulted in prevalent cases of malformations in our study but this is highly comparable to studies performed in similar populations. We do not, however, agree that this methodological choice resulted in biasing our study estimates towards the null. Indeed, although Hemels *et al*[3] reported an association between antidepressant use during pregnancy and risk of spontaneous abortion, this was based on women's self-report and likely resulted in an overestimation of the rate of miscarriage and an underestimation of the rate of abortion, hence a significant association.

Major congenital malformations are structural abnormalities that affect the way a person looks and require medical and/or surgical treatment. Minor defects are abnormalities that do not cause serious health or social problems. Major defects were the focus of interest in our study and, although the risk of minor malformations is interesting, it is a different research question. Several other authors have previously made this distinction.[4,5]

We agree that results from observational studies always need to be interpreted with caution. However, given that from an ethical point of view it is almost impossible to randomise pregnant women to receive medications not known to be safe for the foetus, the collection and follow-up of observational data is the only ethical way to close the knowledge gap between the limited value of animal studies and human pregnancy exposures.

Finally, our study was not designed to look at the effect of the duration of specific antidepressants on the risk of specific major congenital malformations. Therefore, we only looked at duration of antidepressant use during the first trimester of gestation and its risk for major congenital malformations, all types and all malformations combined. Results should be interpreted in this context.

Declaration of interest

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Structural equation modelling in developmental psychiatry

The paper Green & Dunn[1] may prove to be of merit in the interpretation of causal relationships between interventions and outcomes. In particular, the recommendation that randomised controlled trial (RCT) methodology should be embedded within statistical methods from observation studies is long overdue. Such an approach would greatly assist in the interpretation of results which seem completely counterintuitive to those in everyday clinical practice. One such result is the finding of Byford *et al*[2] that cognitive–behavioural therapy provides no added or separate advantage to selective serotonin reuptake inhibitors in the treatment of adolescent depression.

I have a quibble with the length of time it has taken for basic concepts on causality introduced by Green & Dunn to appear in psychiatric research. These concepts have been commonplace in social science research for more than 20 years and their section on causal inference in analysis is little more than a primer. For a more complete coverage of principles of causality, I can recommend Judea Pearl's book, *Causality: Models, Reasoning and Inference*.[3]

Is there any particular reason why Green & Dunn, having put their toes in the water by introducing basic concepts on causality, have not taken their paper further or are we to await a follow-up? In particular, why is there no mention of structural equation modelling, otherwise known as covariance structure analysis? Structural equation modelling has been extensively used in social science research for the past 20 years and adaptations of the method such as multiple-indicator, multiple-cause (MIMIC) seem to address the issues on confounding variables adequately without the need to revert to RCT methodology. It would be interesting to hear from Green & Dunn their thoughts as to how necessary would RCT methods be in developmental psychiatry research whenever a structural equation model is being employed.

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Authors' reply: We thank Dr MacFarlane for his favourable comments on our views. The development of research designs that can rigorously test the complexities of mental health intervention and also have face validity to clinicians is at the centre of our concern. In a brief editorial we could do no more than whet the readers' appetites. There was no mention of structural equation modelling because of lack of space, and not because we do not have sympathies with the technique. In fact, one of us (G.D.) has taught structural equation modelling for nearly 20 years.[1] When used wisely and with correctly specified models, structural equation modelling approaches can be very powerful – but they do not obviate the need for good design (including the randomisation in an RCT). In particular, MacFarlane is mistaken when he suggests that the use of structural equation modelling (MIMIC)

models can successfully address issues of hidden confounding in the absence of appropriate design. Although enthusiasts in the social and behavioural sciences have used structural equation models and 'causal models' interchangeably for many years, their naïvety has frequently brought structural equation modelling into disrepute. Pearl's book covers structural modelling in the appropriate way, but many readers of this journal will find it a bit heavy going. We do indeed plan to publish on these issues in much greater detail in the near future.

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The most undeserving poor?

The Secretary of State for Work and Pensions, James Purnell, proposes removing payment of benefits from unemployed persons with addiction to crack cocaine and heroin.[1,2] The proposed Green Paper[3] sets a remarkable precedent in terms of official, inter-agency response to that common mental disorder described as 'drug addiction'. It focuses on benefits (to an estimated 267 000 individuals in England alone) for those 'dependent on drugs' or 'problematic drug users'.[4] Little attempt is made to distinguish between degrees of dependence or recreational use. The Green Paper claims that 'this is around three-quarters' of all the people who are 'dependent on these drugs'.[3]

It states 'we believe that drug misuse is a serious cause of worklessness and that individuals have a responsibility to declare it and take steps to overcome it' (section 2.40). At present only 0.05% of people on jobseekers allowance declare an addiction.[3]

All applicants will be required 'to declare whether they are addicted to heroin or crack cocaine' (section 2.39) with investigations for fraud against those who 'mislead' and they will 'be required to enter treatment' (section 2.41–2.43). Proposals include new powers to force agencies such as 'drug workers' (section 2.38) to disclose clinical information. It seems inevitable that at least forensic and prison doctors will have to 'share information', and National Health Service psychiatrists will become complicit in informing job centres as part of multidisciplinary teams.

Given the known morbidity of addiction,[5] we know of no other psychiatric disorder that excludes citizens from access to statutory services!

For practising clinicians, the proposed legislation strikes at the core of the doctor–patient relationship, destroying medical confidentiality and grossly interfering in treatment. Therapy is often episodic and incremental but in future doctors will hesitate to end an episode of failing treatment for fear of depriving their patients of food and sustenance. How will clinicians establish working relationships with their patients while simultaneously policing the state benefit system? Politicians, high on prejudice, are driving a coach and horses through the subtle art of treatment. Where is the dissenting outcry from the profession and the Royal College of Psychiatrists? If doctors do not speak up for their most vulnerable patients, who will?

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Wake-up call for British psychiatry: responses

The paper by Craddock *et al*[1] and the subsequent eLetters illustrate the variety of opinions that attracted me to psychiatry. I work in a multi-agency service and our assessments and interventions can be carried out by professionals in Mind, in social services and in the National Health Service (NHS). In our service we share responsibilities. This allows me (a consultant psychiatrist) to pursue a resurgent interest in psychopharmacology, treatment adherence and the harm caused by side-effects of medication. Although I appreciate the academic endeavours in biomedical science, I believe it is very important to contextualise them for non-academics. Randomised controlled trials don't speak to clinicians as well as naturalistic studies. I have noticed that some of my psychiatric colleagues (and myself at times) shy away from precise diagnosis, acutely aware of how diagnoses are deliberately used to stigmatise people by individuals outside mental health services (as well as within). This is happening at a time when case definitions are becoming important to health service managers. Perhaps some psychiatrists are uncomfortable in their traditional territory. However, if psychiatrists step back too far, then others will move in. I expect that senior managers, rather than other clinicians or service users, are likely to move into the spaces that we vacate. Psychiatrists should not support the replacement of 'doctor knows best' with 'manager knows best'. New Ways of Working may end up doing exactly that. Instead of being a shot in the arm, it may be a shot in the foot. Four trusts in the north of England are already constructing their own diagnostic systems to use alongside or instead of existing diagnostic schemes as a currency for payment by results. Assigning patients to pseudo-diagnostic 'care clusters' could be something all staff do, not just the doctors. If psychiatrists step back from diagnosis, then diagnosis may change from a clinical concept with an associated evidence base, to a financial planning tool. There are other drivers of change too. In the prevalent atmosphere of anxiety and blame, risk assessment, not diagnosis, is now arguably the main gateway into acute mental health services. This means that some very ill people may have to wait for treatment, while people who seem to be at acute risk are attended to first.

Times change and if psychiatrists of any persuasion want to retain some influence they have to put up, not shut up; so well done for making the biomedical case. Biomedical psychiatry complements psychosocial psychiatry and is uniquely part of