Evidence-based reproductive medicine

Madam

I look forward to the arrival of the Journal. It is always a good read, full of relevant and practical information – much more ‘user-friendly’ than most journals I receive these days. July’s edition seems particularly interesting with a number of interesting articles.

However, my interest was quickly replaced by irritation. There is a lot to be said for evidence-based practice. The CEU is always worth reading but it is always worth having a look at who is writing a new article. In my mind, it is always worth having a look at who is writing a new article. The CEU is always worth reading but it is always worth having a look at who is writing a new article. In my mind, it is always worth having a look at who is writing a new article.

The Clinical Effectiveness Unit (CEU) product review of the desogestrel-only pill is another example of EBMs being unhelpful to our clinical practice. It states: ‘an evidence-based recommendation cannot be made that the desogestrel-only pill is different from other POPs in terms of efficacy, nor that it is similar to combined oral contraception (COC) in this respect.’

The recommendation is based on insufficient evidence to support lower failure rates with the desogestrel-only pill. This is despite another study showing that the desogestrel-only pill was sufficient to inhibit ovulation in 97% of cycles and that this is its primary mode of action. The evidence-based medicine (EBM) must be subjected to informed clinical judgement, based on all available evidence (including the reported pharmacology of the product) and – dare I say it? – clinical common sense.

The statement of the DTB is inaccurate when it states (in nearly the same words as the CEU) ‘There is insufficient evidence on whether it (Cerazette) is a more effective contraceptive than other POPs in terms of efficacy.’ The evidence-based practice must equally be assured that none of those women in the (desogestrel) arm, who were undertaking the desogestrel-only pill review have any relevant associations with the manufacturers of other progesterone-only pills (POPs), who are unlikely to be independent.

I am not denying the need for more unbiased clinical trial evidence; I am just despairing at our sudden inability to put the information to practical use. Non-scientists, it seems, are rarely supposed to tell women that a POP that inhibits ovulation in 97% of cycles is no more effective than currently available POPs.

One final point refers to the FPFRHC Guidance on Contraceptive Choices for Women with Inflammatory Bowel Disease which includes the repeated comment that WHO 3 implies cannot use, e.g. ‘Women with primary sclerosing cholangitis should not use the POP (WHO Category 3 – risks outweigh the benefits).’ I am concerned that the CEU is perpetuating this misinterpretation of the WHO 3 category that does not absolutely contraindicate use, although other methods should be the first choice.

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References
2. Foy R, Colly H, Brechin S. Evidence-based reproductive

CEU New Product Review of the desogestrel-only pill

Madam

The Clinical Effectiveness Unit (CEU)’s product review of the desogestrel-only pill1 and the recent article ‘Is Cerazette the minimill of choice?’ in the Drug and Therapeutics Bulletin (DTB)2 are both good reviews of the literature. But in my opinion they are marred by their surprisingly negative conclusions.

What do we do when the evidence from clinical trials and epidemiology is not as complete as we would all like, but we have clients sitting in front of us wanting our help in choosing from the available options? It is then not sufficient just to provide the ‘evidence’ from an ivory tower. A decision has to be made, at present. Pending more data, evidence-based medicine (EBM) must be subjected to informed clinical judgement, based on all available evidence (including the reported pharmacology of the product) and – dare I say it? – clinical common sense.

In my view, the New Product Review1 provides an utterly objective summary of currently available evidence concerning the desogestrel pill. I stand by our statement that ‘on theoretical grounds and as yet there is no evidence that the desogestrel-only pill will be more effective than existing progesterone-only pills ... but we do not have trial evidence to support this’. The evidence-based reproductive health paper by Foy et al.1 is commended by your first correspondent but reaches the same conclusion as our New Product Review: ‘You cannot tell if the DSG pill is superior to inferior to other POPs.’

Dr MacGregor mentions ‘the suggestion that the data provided by the manufacturers may not be credible’. Nowhere in our New Product Review is an expression of discrediting made relating to claims or data provided by the manufacturers. She goes on to seek assurance ‘that none of those undertaking the desogestrel-only pill review have any relevant associations with manufacturers of other progesterone-only pills’.

The New Product Review from the CEU does not include an explicit statement of interests. Hence, it is almost impossible to know if the CEU is adequately guided by a formal code of practice on ‘Relationships with the Pharmaceutical Industry’, which was drawn up in consultation with the FPFRHC Clinical Effectiveness Committee and formally established. This eight-point code of practice includes the following statements: ‘In all aspects of the work of the CEU, staff will be required to appraise the relative benefits of individual contraceptive products and groups of products. Such appraisals will always be conducted in an impartial manner, and be based on available research evidence.’

Such appraisals will always be conducted in an impartial manner, and be based on available research evidence. The CEU staff should not accept any honoraria or consultancy payments from pharmaceutical companies – either for their personal accounts or for CEU funds’. Dr MacGregor also comments on the FPFRHC Guidance on Contraceptive Choices for Women with Inflammatory Bowel Disease3 developed by our Unit and included in the same issue of the Journal. She feels that we have misrepresented ‘Category 3’ (risks outweigh benefits) as described in the WHO publication Medical Eligibility Criteria for Contraceptive Use4 giving the impression that ‘Category 3’ equates to absolute contraindication. This is certainly not our intention, and I fully agree with Dr MacGregor’s interpretation that ‘Category 3’ indicates that a method should not be advised as a woman’s first choice, but may be used after appropriate counselling. I can only apologise if, in the interests of brevity, this distinction was unclear in this particular FPFRHC Guidance.