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 medicine (EBM) but it is always worthwhile to have a review of the current evidence available in order to provide women with accurate information when discussing contraception. However, it is not sufficient just to provide the ‘evidence’. EBM must consider that clinicians need practical guidance with decision making.

The Clinical Effectiveness Unit (CEU) of the FFPRHC and the Clinical Effectiveness Unit of the FFPRHC (FFPRHC) is its primary mode of action. Since when was ‘is its primary mode of action’. Since when was it not sufficient just to provide the ‘evidence’ from a double-blind controlled trial in basic clinical pharmacology not ‘evidence’?

The main collaborative European multicentre study was indubitably underpowered, as regards efficacy, in the levonorgestrel POP comparator arm. However, among more than 600 women in the other (desogestrel) arm, who were not breastfeeding and with known gross non-compliance excluded, the Pearl failure rate was only 0.17 (CI 0.004–0.928) per 100 woman-years. Such a low rate (with an upper bound of 1) in any clinical study of a POP ovulating with only 61–64% of cycles (i.e. with the levonorgestrel-progestogen-only pill (POP)), which (in the CEU review’s own words) ‘is its primary mode of action’. Since when was it not sufficient just to provide the ‘evidence’ from a double-blind controlled trial in basic clinical pharmacology not ‘evidence’?

The author adds that pharmaceutical industry-funded trials tend to report more favourable results in terms of efficacy, nor that it is similar to the evidence-based ‘evidence’. EBM must consider that clinicians need practical guidance with decision making.

One final point refers to the FFPRHC 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

Claim by CEU New Product Review of the desogestrel-only pill

Madam

The Clinical Effectiveness Unit (CEU)’s product review of the desogestrel-only pill and the recent article ‘Is Cerazette the minipill of choice?’ in the Drug and Therapeutics Bulletin (DTB) are both good reviews of the available evidence. 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.

The statement of the DTB is not inaccurate when it says (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 ‘is its primary mode of action’. Since when was it not sufficient just to provide the ‘evidence’ from a double-blind controlled trial in basic clinical pharmacology not ‘evidence’?

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Dr MacGregor mentions ‘the suggestion that the data provided by the manufacturers may not be credible raises an additional concern. In the same edition an excellent article on evidence-based reproductive health by Robbie Foy quotes a Chinese proverb: “Be careful what you wish for: it may come true”.’

We also welcome the opportunity to respond to the letter from Anne MacGregor concerning two articles in the July 2003 issue of the Journal relating to the desogestrel-only pill. I am sorry that your correspondent found the New Product Review from our Unit irritating, rather than clinically useful.

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References

Reply

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On behalf of the FFPRHC Clinical Effectiveness Unit (CEU), I thank you for the opportunity to respond to the letter from Anne MacGregor concerning two articles in the July 2003 issue of the Journal relating to the desogestrel-only pill. I am sorry that your correspondent found the New Product Review from our Unit irritating, rather than clinically useful.

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Therefore I consider this product a useful addition to the range of contraceptives, particularly for a young, non-breastfeeding woman wanting a pill method but recommended, or wishing, to avoid the combined oral contraceptive (COC). It is likely likely (though again this is not yet fully established) to be more forgiving of late pill-taking than other POPs. But users will, as usual for all POPs, need forewarning about the occurrence of irregular bleeding. And I see no special reason to use it in those situations where the combination with a cheaper old-type POP is already virtually 100%, such as in lactation, or in older women, especially those aged over 45 years.