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 so far 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 helpful 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) product review of the desogestrel-only pill1 is particularly interesting. The CEU study 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.”2 The recommendation is based on insufficient evidence to support lower failure rates with the desogestrel 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.3 The current 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 is provided by Foy et al4 which quote a Chinese proverb: “Be careful what you wish for: it may come true.”2 The author adds that pharmaceutical industry-funded trials tend to report more favourable findings than those funded by other means, noting that one of the trial authors for the desogestrel-only pill studies is affiliated to the company that manufactures the pill. If this is an issue, then we must consider whether none of those undertaking the desogestrel-only pill review have any relevant associations with the manufacturers of other progestogen-only pills (POPs), who are unlikely to welcome this new competitor. We must equally be assured that none of those manufactures the pill. If this is an issue, then we need practical guidance with decision making.

‘Be careful what you wish for: it may come true’.5

In my view, our New Product Review6 of the desogestrel-only pill provides an utterly objective summary of currently available evidence concerning the desogestrel pill. I stand by our statements that ‘on theoretical grounds, it is reasonable to expect that the desogestrel pill to be more effective than existing progestogen-only pills … but we do not have trial evidence to support this’. The evidence-based reproductive health paper by Foy et al.7 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 or 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 suggestion or suggestion 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 progestogen-only pills’.8

The New Product Review from the CEU does not include an explicit statement of interests. However, the CEU staff are bound by a formal code of practice on ‘Relationships with the Pharmaceutical Industry’, which was drawn up in consultation with the FPFRHC Clinical Effectiveness Committee. Dr MacGregor also comments on the CEU’s interpretation that ‘Category 3’ is unclear in this particular FFPRHC Guidance. This eight-point code of practice includes the following statements: ‘In all aspects of the work of the CEU, staff will be required to operate in an impartial manner, and be based on available research evidence,’ and ‘CEU staff should not accept any honoraria or consultancy payments from pharmaceutical companies – either for their personal accounts or for CEU funds’.

Moreover, the CEU statement concerning the recommendations on the FPFRHC Guidance on Contraceptive Choices for Women with Inflammatory Bowel Disease9 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 Use: giving the impression that it equates to absolute contraindication. This was 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.

John Guilbeault, FRCS, FRCOG
Emeritus Professor of Family Planning and Reproductive Health, University College London, London, UK

References


LETTERS

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 minipill of choice?’2 in the Drug and Therapeutics Bulletin (DTB)3 are both good reviews of the evidence available. But in my opinion they are marred by their surprisingly negative conclusions.

What do we do when we 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 DTB3 is not inaccurate when it states that the DTB ‘is not evidence on whether it (Cerazette) is a more effective contraceptive than other POPs in terms of efficacy’. The evidence presented by the DTB study states: ‘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 is provided by Foy et al4 which quote a Chinese proverb: “Be careful what you wish for: it may come true.”2 The author adds that pharmaceutical industry-funded trials tend to report more favourable findings than those funded by other means, noting that one of the trial authors for the desogestrel-only pill studies is affiliated to the company that manufactures the pill. If this is an issue, then we need practical guidance with decision making.

‘Be careful what you wish for: it may come true’.5

In my view, our New Product Review6 of the desogestrel-only pill provides an utterly objective summary of currently available evidence concerning the desogestrel pill. I stand by our statements that ‘on theoretical grounds, it is reasonable to expect that the desogestrel pill to be more effective than existing progestogen-only pills … but we do not have trial evidence to support this’. The evidence-based reproductive health paper by Foy et al.7 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 or 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 suggestion or suggestion 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 progestogen-only pills’.8

The New Product Review from the CEU does not include an explicit statement of interests. However, the CEU staff are bound by a formal code of practice on ‘Relationships with the Pharmaceutical Industry’, which was drawn up in consultation with the FPFRHC Clinical Effectiveness Committee. Dr MacGregor also comments on the CEU’s interpretation that ‘Category 3’ is unclear in this particular FFPRHC Guidance. This eight-point code of practice includes the following statements: ‘In all aspects of the work of the CEU, staff will be required to operate in an impartial manner, and be based on available research evidence,’ and ‘CEU staff should not accept any honoraria or consultancy payments from pharmaceutical companies – either for their personal accounts or for CEU funds’.

Moreover, the CEU statement concerning the recommendations on the FPFRHC Guidance on Contraceptive Choices for Women with Inflammatory Bowel Disease9 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 Use: giving the impression that it equates to absolute contraindication. This was 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.

References


64

Journal of Family Planning and Reproductive Health Care 2004; 30(1)

Downloaded from http://jfprhc.bmj.com/ on June 18, 2017 - Published by group.bmj.com