



New emergency contraceptive method ellaOne[®] — is it worth the price?

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SHORT FEATURES

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POST-COITAL emergency contraception hasn't had a "new look" for some years.

Indeed, research demonstrating that increased availability of post-coital contraception seems not to have reduced abortion rates has given it a distinctly passé feel. When discussion in expert groups began to shift the focus away from increasing its use to its role in "bridging" women to other methods, post-coital contraception seemed to have passed its prime.

However, news of the launch of *ellaOne*[®] by HRA Pharma, a young, private European pharmaceutical company, was welcomed enthusiastically by post-coital contraception supporters at the annual meeting of the International Consortium for Emergency Contraception in New York in September 2009.

The product seems to have exciting potential, not least because it is based on a compound that is new to emergency contraception, with the active ingredient ulipristal acetate (30mg), which acts by binding to the progesterone receptor. The primary mechanism of action, when taken up to 120 hours after unprotected sex, is thought to be delay or inhibition of ovulation, but it may also affect the endometrium.

Product characteristics literature distributed with launch materials on 1 October 2009 claimed comparable efficacy to levonorgestrel up to 72 hours after unprotected sex or contraceptive failure. Based on two comparative trials in women who presented for post-coital contraception between 0 and 72 hours after unprotected intercourse or contraceptive failure, efficacy was "non-inferior to that of levonorgestrel. The observed pregnancy rate was 1.5% in both studies, thereby preventing 85% and 73% of expected pregnancies". The product characteristics literature claimed that clinical trial evidence supported an observed pregnancy rate of 2.1% in women using *ellaOne*[®] between 48 and 120 hours after unprotected sex or contraceptive

failure, preventing 61% of expected pregnancies studied, according to HRA Pharma.

The main advantage of ulipristal acetate over levonorgestrel seems to be its established efficacy of up to 120 hours (five days), and its licence for this period.

Currently, statisticians and epidemiologists are pouring over the HRA Pharma efficacy data, and much debate can be anticipated. However, even as things stand *ellaOne*[®], which is now registered in the UK, France, Netherlands, Germany and Belgium, is burdened by two major, related problems: it is only available on prescription and it is expensive. In the UK, the current public sector price for *ellaOne*[®] is UK£16.95 (Personal correspondence 1 October 2009), compared to UK£5.05 for Levonelle, the licensed levonorgestrel product. This price differential raises the question of whether the added value of an extra 50 hours efficacy is worth the increased price, particularly at a time of economic recession when health services are facing pressure to ensure the cost-effectiveness of every intervention.

HRA Pharma is a company that is worthy of support. Its chairman, André Ullman, was one of the pioneers who developed mifepristone into Mifegyne, the first "abortion pill". He established HRA Pharma with the aim of designing products to fill therapeutic gaps. The company invests in niche specialist areas and commits 20% of its turnover to research and development. But, with *ellaOne*[®], it faces a crucial challenge that confronts any small company without the capacity to absorb research and development costs. Levonorgestrel is an old compound that has been used in contraception, including post-coital methods, for decades. There are those of us who would argue that even the current UK public sector price of Levonelle is scandalously high – given the minimal R&D commitment and costs incurred when Schering Health Care Ltd (now BayerSchering-Pharma) acquired the product from Gideon

Richter in Hungary. But compared with *ellaOne*, Levonelle is cheap. For *ellaOne*® to succeed in the marketplace, HRA Pharma will need to demonstrate that its value is worth its price. It will encourage future innovation if Ullman is able to succeed.

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Women's movement defends birth centres in Brazil

BRAZIL has a public health system (SUS) that provides health care for all. The rate of institutional births is over 98%.¹ Access to appropriate obstetric care for pregnant women is a key part of a comprehensive health system aimed at reducing maternal and neonatal mortality and morbidity. However, care for normal birth of healthy women and babies – the vast majority of cases – can safely be provided by a skilled attendant at the level of care that women prefer, in hospitals, birth centres or at home.²

In the last two decades, efforts to evaluate the use of technology at birth resulted in a profound change in the understanding of the safety and effectiveness of obstetric care.² Unfortunately, hospitals in Brazil, like in other Latin American countries, resist change to provide women-centred, evidence-based, humanised care. According to national data for 2006, in the SUS services, 84.6% of women having their first vaginal birth were subjected to episiotomies and only 9.6% had a companion of their choice with them (despite a national law that all women should have this right).¹

Over-intervention makes the experience of vaginal birth more painful and stressful, and increases potential harm for women and their babies. Many women “choose” a caesarean section (c-section) to escape the suffering associated with the over-interventionist model of care for vaginal birth.³ In the private sector, a doctor-centered “routine c-section” model of care was adopted, although research consistently shows that most women want a normal birth.⁴ In the absence of any regulation or systematic monitoring of outcomes, over 80% of women

in the private sector have c-sections.¹ An editorial in an obstetrics journal declared: “There is no doubt that, even when unnecessary or carrying additional risks for the mother or the baby, elective c-sections are much safer for the obstetrician.”⁵ In Brazil, several networks of consumers were organised to denounce these distortions and demand the provision of evidence-based, informed options for birth.

The now several decades-old movement for humanised care led to the creation of midwife-led birth centres in the late 1990s, whose aim was to reduce both over-intervention in vaginal birth and astronomic c-section rates. The few public birth centres in operation, in São Paulo, Minas Gerais and Rio de Janeiro, have excellent outcomes,⁶ but face aggressive resistance from the medical establishment, as well as opposition both to out-of-hospital birth and autonomous delivery practice by nurse-midwives. Doctors were prohibited, by their Medical Councils, to collaborate with such birth centres.⁷

On 5 June 2009, as part of the State Medical Council (CREMERJ) campaign against birth centres, the government of Rio de Janeiro closed the David Capistrano Centre in Realengo, a very successful birth centre and the only one in operation in Rio, for “failing to provide medical care”.⁷

Reactions were immediate. Women's networks started several demonstrations against the closure. In a few days, an on-line petition organised by the consumer's group Parto do Principio had more than 10,000 signatures from Brazil and abroad. With the support of many consumers' groups, nurse-midwives and other professional associations, the Network for the Humanisation of