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Morning-after pill

Many governments believe that the best way to stem rising numbers of unwanted pregnancies, especially amongst teenagers, is to make emergency contraception, or the morning-after pill, freely available. Ethically and medically, this is very misguided, argues Dr **Anne Williams**, a British family doctor.

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What is the morning-after pill?

The morning-after pill (MAP), sometimes called emergency contraception, has been marketed extensively as an answer to the problem of unwanted pregnancy. This has been directed especially at the young who may not have anticipated or prepared for the consequences of a sexual encounter.

The progesterone-only method is the most common. Two tablets Levonorgestrel 0.75mg are given up to 72 hours after intercourse. Up until 2003, the two dosages were separated by 12 hours. Recently it has been recommended that the double dose should be taken all at once within 72 hours of unprotected intercourse. It is thought to be more effective the earlier it is taken, although it has been shown to be effective up to 120 hours. The initial MAP, or Yuzpe regime, contained an oestrogen also, but was poorly tolerated and was less effective. It is no longer recommended.

In a 2005 policy statement the American Academy of Pediatrics proposes the use of multiple doses of the more common contraceptive pills. Although they refer to this as a non-labeled use, this indicates an unlicensed use. This is surprising, as the combination pills are highly unacceptable in terms of side effects of nausea and vomiting.

Current controversies

A number of questions surround the use of the morning-after pill. The first and most basic is a question of fact: whether the MAP is an **abortifacient**. There is also the question of its **efficacy**, which is only estimated. So far, it has not reduced unwanted pregnancies, nor have its **risks** been fully evaluated. Despite these unknowns, some governments have adopted policies for **easy access**, which have great implications for both the family and society.

There is a range of weighty ethical issues about the MAP. There are other issues, as well. Unless people are fully informed – for example, about the pill's abortifacient aspect – **consent** may be invalid. Could the use of MAP be ethical in extreme cases such as **rape**? And what is the position of **health workers with ethical objections** to this pill? Can **public funding** be justified, given its controversial nature?

The following sections deal with each of these issues. Although there are many references to the British experience, the general principles apply to other countries like the United States, Canada and Australia.

Is the contraceptive an abortifacient?

The MAP is officially labelled as "emergency hormonal contraception", implying that it acts to prevent conception. However, its activity includes effects on events after conception, which would require classification as a substance which could cause an abortion.

Scientifically, "human development begins after the union of male and female gametes or germ cells during a process known as fertilization (conception)" 1. Many human characteristics are already laid down genetically from the moment of conception. We can already determine whether the new being is male or female.

Implantation has been described as the fourth stage of human embryonic development.2 By this time it has undergone eight of the forty-one cell doublings that occur before birth. The nature of the embryo (conceptus), which

is human and alive, is unchanged by implantation; only the position of the embryo is affected.

Proponents of the term "emergency hormonal contraception" have changed the definitions by saying, "before implantation the process of conception is not complete".3

Dr John Ling, formerly of the Institute of Biological Sciences at Aberystwyth University, refers to this as a "new biology" whereby, contrary to centuries of biological scholarship, conception has been separated from fertilisation. It is, he says, an example of lexical engineering preceding social engineering.4

Feminist author Germaine Greer also recognises the abortifacient nature of MAP. She considers that to conceal this fact is deceptive and undermines the dignity of women:

> These days, contraception is abortion because... pills cannot be shown to prevent sperm fertilising an ovum... Whether you feel that the creation and wastage of so many embryos is an important issue or not, you must see that the cynical deception of women by selling abortifacients as if they were contraceptives is incompatible with the respect due to women as human beings.5

Possible modes of action

"Very little is known about the exact mode of action of the morning-after pill" 6. Its action may vary, depending on several factors:

- the exact time in the menstrual cycle of the woman
- the time delay between intercourse and fertilization
- the formulation used
- the exact time delay between intercourse and the administration.
- the act of intercourse which prompted the consultation may or may not be, the only act which may cause impregnation.

Theoretically, MAP could inhibit or delay ovulation if given early in the cycle. Administration at this time would not be necessary, if the woman were to know and understand her menstrual cycle, as intercourse at this stage would not be likely to result in a pregnancy anyway.

The Task Force on Postovulatory Methods of Fertility Regulation carried out the main study on the method for the World Health Organisation. The title of this project (hereafter referred to as the WHO task force study) displays the mainstream thought on how these pills work, even if attempts to lessen the unacceptability are made in subsequent publications7. In the WHO task force trial, menses was postponed in 28 per cent of women. This may reflect that ovulation was delayed, but this was not measured. "Studies so far have demonstrated no effect on ovulation" 8.

There is also a theoretical possibility that it could alter the transport of the gametes (sperm or ova). It does enhance the barrier effect of cervical mucus, but as administration is after intercourse and the sperm can be found in the uterus as soon as 30 minutes after intercourse, this is unlikely to be a way it can work.
It is also possible that the MAP works after conception. A study using the Unipath monitor found "the latter part of the cycle to be shortened following treatment with the morning-after pill".9 This would give insufficient time or conditions for implantation and therefore would result in the loss of a new life. "It may also cause endometrial changes that discourage implantation." 10 The endometrium (womb lining) may not have the same receptivity11. This will adversely affect implantation and further progress of the pregnancy. Levonorgestrel had a continuing effect on the stability of the womb lining where implantation must take place. This will affect the durability of implantation. Thus, the pregnancy will be lost.

The AAP policy acknowledges such action: "Emergency contraception primarily inhibits ovulation, disrupts follicular development, and/or interferes with the maturation of the corpus luteum. These are the same mechanisms by which other hormonal methods of contraception prevent pregnancy." The research cited by the AAP suggests there is a lot of evidence that the combination of oestrogen and progesterone has a definite effect on the endometrium.

How well does the MAP work?

In the WHO task force trial, it was estimated that Levonelle™ prevents 85 per cent of expected pregnancies. However, "Calculations used to arrive at estimates of efficacy are inevitably based on poor quality data."12 There was no control group, and there are several reasons why the trial may not be applicable to the daily reality, where there is less control:

- The average age of the women was 27 years, so the accuracy of the history of the last menstrual period and the last episode of sexual intercourse, understanding, compliance and reliability would be very much better than the history given by teenagers.
- It was a multi-centre trial with 21 different teams of observers and some of the data was suspect.13

The results were based on the assumption of accurate verbal histories from the participants, but other studies have shown how notoriously inaccurate women are at recalling the date of their last menstrual period.14

It is impossible to tell if a pregnancy developing after administration of MAP originated from the act of intercourse for which the pills were taken.

The results of the initial pregnancy tests of most of those entering the trial were not revealed. This calls into question the good ethical standing of the trial.

The third dose prescribed in cases of vomiting would not have been available in real life (especially if this had occurred overnight). The results would therefore have differed significantly outside of trial conditions.

The chance of pregnancy for an individual woman who has intercourse at her most fertile time may be considerably higher.

Does the MAP reduce unwanted pregnancies?

Experience so far does not suggest that the number of unwanted pregnancies falls with increasing access to the MAP. One health economist has said: "The UK experience does not provide evidence that improving access to family planning will, in itself, be successful in reducing the rate of underage conceptions.15 Alison Strath, General Secretary of the Royal College of Pharmacists, has admitted: "We don't know if the free distribution of the morning-after pill] reduces teenage pregnancy."16 Prescribing rates of MAP have multiplied while there has been no observed decline in the rate of abortions.17

The condom has been promoted widely and statistics show its use to be increasing especially among the young. This is evidenced by it being the preferred method in family planning clinics. Teenagers who opt for condom use to avoid pregnancy are clearly at a greater risk of pregnancy than those who abstain from sexual intercourse. Condom mishaps account for half of the requests for the MAP.18 However, not all of teenage pregnancies are unwanted, and many teenagers opt to keep their pregnancies rather than abort19.

Perhaps policy makers should be looking at alternative ways to reduce unwanted pregnancies. Poland has witnessed a dramatic reduction in the number of abortions since the fall of communism, with no increase in maternal deaths or still births and no evidence of back-street abortion.20

There is clear evidence that teenage pregnancy is associated with one-parent families21 and socio-economic deprivation 22. Primary prevention could be aimed at tackling the problem of deprivation. Both these factors could be targeted by family friendly legislation.

What are the risks of MAP?

Effects of the medication on the foetus

Worldwide, hundreds of thousands of pregnancies a year are exposed to a drug for which there is little evidence of safety and for which there are health risks. In real life, rather than in a carefully conducted trial, the pregnancy rate would be much higher. Such exposure could lead to masculinisation of a female foetus – that is, gender ambiguity and foetal malformation 23.

Short and long-term effects on women

The daily dosage of levonorgestrel given in Levonelle™ compared to Norgeston (a form of mini–pill) is 1500mcg compared to 30mcg (micrograms) - 50 times the dose! It is significant that before the release of Levonelle, many women who were prescribed Norgeston required counselling to persuade them of the safety of taking a single course (50 tablets in two parts).

The short-term side effects are listed as nausea, abdominal pain, fatigue, headache, dizziness, breast tenderness and vomiting. Official guidelines highlight the need for the doctor to explain that the patient should return "promptly if any lower abdominal pain occurs because this could signify an ectopic pregnancy".24

There is no research into long-term safety, frequency of ectopic pregnancy, or safety in pregnant women. Repeated use and exposure to MAP has become an issue of great concern due to its increasing availability through GPs, family planning clinics and over the counter in pharmacies.

The WHO task force trial found that 1 in 5 participants had used "emergency contraception" before, but concluded that high-dose levonorgestrel pills are unsuitable for regular post-coital contraception". Women are effectively being used as guinea pigs until these research issues are resolved25.

Risks of sexually-transmitted diseases

MAP does nothing to protect against sexually transmitted infections (STIs). In fact, due to changed behaviour, it may serve only to worsen the situation. According to one official report, "In a single act of unprotected sex with an infected partner, teenage women have a 1% chance of acquiring HIV, a 30 % risk of getting genital herpes and a 50% chance of contracting gonorrhoea."26

Many countries have seen an explosion of STIs such as gonorrhoea and chlamydia in the past decade. Only in chlamydia is it thought it to be partly due to improved diagnostic techniques. Women asking for MAP are seen as an at-risk population and a screening test for chlamydia may be recommended.

A cancer specialist says: "A sharp rise in rates of pre-cancer of the cervix among young women is probably the result of increased sexual activity since the sixties... Without screening, we would probably be seeing an epidemic. We estimate that by 2025 screening could prevent 5000 cancers a year" 27.

Should there be easy access to MAPs?

Improving access to health education and contraceptive services is seen as the principal way to reduce teenage pregnancy. Teenagers who choose MAP, however, may be more at risk of unintended pregnancy, possibly because it is a marker of "risk taking" in sexual activity. They may also be putting their health at risk.

Regulations that came into effect in the UK the year 2000 enable nurses, pharmacists and other "health professionals" to administer or supply medicines to groups of patients who may not be individually identified. This will not help those who need counselling and support to address long-term needs – not only for issues surrounding their physical health, such as infection, but also for emotional support following cases of rape or for women in abusive relationships.

The distribution of MAP over the counter is likely to severely curtail follow-up. There will be no monitoring if agencies have no need to report back to the patient's GP.

There is the further danger that removing the fear of pregnancy may bring about a casual approach to entering a sexual relationship, with little excuse for a young woman to refuse. MAP appeals psychologically because it requires neither a conscious decision to remain abstinent nor advance planning for a sexual act.28 The consequences of any irresponsibility may not need to be faced. Potential sexual partners will exploit these perceptions to exert increased pressure upon abstinent youth. It may be more difficult to say 'No'.

The effects of the MAP on families

Any policy which attracts minors to use a service by promising confidentiality, threatens what has long been considered a vital safeguard against child abuse: the principle of parental consent. At present a fully trained nurse cannot give paracetamol or apply a dressing without parental consent.29 But the role of nurses is being extended.

If MAP were to be available at school to under-16s this would be a further erosion of parental rights. The argument of personal autonomy seems to override good clinical practice in the areas of sexual health in a way not seen in other areas, such as when clinicians try to educate patients and refuse prescriptions of antibiotics for viral sore throats.

There are many harmful consequences from the free availability of contraception to the young, including spiralling STIs. There has been no effect on the abortion rate since the availability of MAP and we have many disillusioned, unhappy youngsters who have not learnt to form relationships, other than sexual. Early sexual activity, especially among those who initiate sex under the age of 16 years old, is associated with more sexual partners during a lifetime. There is also a greater likelihood of psychological harm and regret.30

There is a great emphasis on protecting the confidentiality of the young and on the fact that they may be shy to buy things over the counter in case their parents should find out. Policy documents do not ask why the young may want to hide their activities from their parents. Presumably they know they are going against their wishes. In what other instances do laws encourage this undermining of trust? Does the state want to encourage minors to hide their activities? Should people not be proud of all they do and if they are not, why are they doing it?

The effects of the MAP on society

The adverse social effects have not been fully studied. The ready availability of these emergency methods may increase the chaos of people's lives. One leading public health official commented: "The answer is not more contraception or emergency contraception, but a change in attitude towards sexual behaviour."31 The widespread promotion of contraceptive education seems only to have resulted in increased teenage sexual activity.
Reducing the fear of pregnancy is only serving to produce changes in behaviour patterns and more risk-taking behaviour as evidenced by the spiralling increase in STIs. The effect on behaviour and attitudes towards family planning in the population needs to be assessed.

Have users given informed consent?

Due to the uncertainty of the mode of action in any particular case, there is a possibility that MAP may act by preventing implantation - that is, as an abortifacient. This possibility should be clearly stated in the patient information leaflet. True informed consent cannot take place with incomplete information. The prescribing doctor has the opportunity to fully inform a woman of abortifacient action of this medication during the consultation, which, in turn, allows her to object to its use. Pharmacists or other agencies may not have the privacy or time to discuss this fully.

What about rape?

The use of MAP in a girl who has been raped has been discussed as an extraordinary circumstance. The victim has suffered an attack on her integrity and may not even know her aggressor. She has not contemplated nor considered a pregnancy before this event, but knows this is a possible outcome of the attack. She is suffering after the trauma and will not be happy at the possibility of having conceived in such a violent way.

We cannot say that any ensuing pregnancy is evil, as a new life can never be perceived as such. However, under the circumstances it does not seem to be the best plan, as she is likely to be unsupported by the father of the child. A pregnancy may seem a disaster but it may be possible to encourage acceptance. Time can dispel the initial horror and even reverse the situation so that a child is awaited with joy. In a case of rape this is obviously more difficult.

She does seem to have a right to protect herself from a pregnancy resulting from a violation. A means to this end may be the administration of hormones but, in the present formulation, can the use of the MAP be justified, since there is a risk of causing an abortion?

The principle of double effect and medical ethics

Some have recourse to the principle of double effect, stating that because the intention is to prevent pregnancy not to abort it, the action can be justified32. This holds that, in the context of actions that have both good and bad effects, an action that has a bad effect is morally permissible if:

the action itself is good,

its perpetrator's intention is solely to produce the good effect,

the good effect is not achieved through the bad, and

there is sufficient reason to permit the bad effect.

However, if there is reasonable doubt about the mode of action of the medication this principle may not apply. The possible abortifacient effect cannot be classified blithely as an "unforeseen" effect of its use.

The desired effect of a pregnancy not coming to fruition is legitimate if the pregnancy is truly prevented. However, the effect of the administered hormones is not good if it terminates a pregnancy. The bad effect may not be intended as the means, but it may end up being the mechanism (means). The end does not justify the means. To focus on the intention and ignore the means is a bit careless, like saying, "I have to get to work on time and it is just too bad if I run down a few people on the way."

It is often said, as a way to assuage a conscience, "she may not have been pregnant anyway". But if a life has been taken it remains a fact, even if this is never known by the perpetrators to be the case.

The greater the risk of some negative consequence, the less ethical is the action. If the only negative consequence of MAP was that a person would have to remain in hospital for 48 hours, most people would accept the procedure. However, with MAP the negative consequence is often the killing of a person and its use can therefore be seen as unacceptable, and disproportionate to the benefits. In this case, not having a child cannot compensate for the negative action of killing a person.

It has been suggested that, if it is used before ovulation, there will be more chance of preventing a pregnancy rather than interrupting it. "Once the woman has started to ovulate, she should not use this method of avoiding pregnancy because of the increased risk of there being a fertilized egg," says a bioethicist.33 There is an ovulation-testing method that attempts to ascertain whether any new conception is likely to result from the recent assault.34 "In this method, 'emergency contraception' is offered only if the pregnancy test is negative, and if empirical and personal data indicate that the woman is not at or near the time of ovulation. The simple testing method gives medical staff the information to know whether they can safely intervene to prevent the release of a woman's ovum, or prevent the sperm from reaching the egg. In this way, any child conceived is exposed to very little risk indeed and a woman treated can be reassured that she was not pregnant."35

In reality, few women know their cycle sufficiently well to be able to determine the time of ovulation. Science would have to advance before we can be certain in each particular case.

Ethics dilemmas for health workers

If a doctor has an ethical objection to a particular intervention, it is only fair that he/she states this with clarity and openness. The doctor may ask a woman about the precise timing of her cycle, first, to try to assess the risk of pregnancy, but then, to try and work out if he/she can prescribe the hormones without risk to a pregnancy. This is bound to affect the consultation. The distressed patient in this scenario would indeed wonder why there are so many questions, if the ethical question was not was not made clear.

Perhaps some doctors will not feel able to prescribe until a more exact method of diagnosis of pregnancy can be developed.

British medical guidelines advise doctors to "make sure that your personal beliefs do not prejudice your patients' care"36. This position has not been tested with MAP, and the case would not normally arise due to the availability of

a second opinion. In general medical practice doctors rarely work alone and it will be clearly stated in the practice leaflet which services are provided. The doctor should not feel pressurised to act against his/her conscience in order not to "impose" his/her own moral values on a patient.

In a country such as Malta, where the culture and law do not allow for provision of MAP, tourists may be surprised. Perhaps the travel agents should inform them they cannot get the medication in such places - in the same way that people know they cannot drink alcohol in Saudi Arabia. When visiting a country it is good to respect local customs. With today's large tourist industry this may be difficult.

Pharmacists in the UK as in North America have been put under duress with the advent of MAP. As at April 2005, only four states in the United States have "conscience clauses" allowing pharmacists to opt out of dispensing certain items, while another four states are considering bills which would require them to fill all prescriptions.

In the UK, the professional code of ethics now requires: "Before accepting employment, pharmacists must disclose any factors, which may affect their ability to provide services." This change has had severe and immediate implications for those who have a conscientious objection (whether practical or ethical) to MAP, in eliminating the legal status of the official conscience clause that all medical professionals have the right to invoke.

Apart from the greater ethical problems posed by MAP, there is the question of the legal age of consent to sexual intercourse. Guidelines urge pharmacists supplying this medication OTC to "make every reasonable effort to satisfy themselves that women are aged 16 years or over", but the pharmacist or other agent may not have access to records to check the age of the client.

Pharmacists (or school nurses) may overlook factors such as other prescribed medication or family history and this could lead to health complications.

Should MAPs be government funded?

Another ethical problem to consider is that of public funding. This forces taxpayers who object in conscience to abortifacients to subsidise MAP's routine use. Economically, the use of this medication makes no sense. For example, the rate of MAP use soared to four times that of the abortion rate in Scotland in 2003, at a cost of £222,488, yet made not the slightest dent on the continued increase in the number of abortions.

Conclusion

A look across the landscape at the evidence-base for the prescription of the morning-after pill reveals that little is known or understood about it. In a culture that rightly places considerable value on empirical research evidence as the basis of effective public policy, there is an alarming scarcity of rigorous, independent research on this medication. In fact, the evidence accumulating shows that the main rationale for the promotion of MAP - a reduction in the abortion rate – is groundless. The policy makers, doctors and pharmacists involved need to ask themselves what has been achieved.

Glossary

Conception: "The start of pregnancy, when a male germ cell (sperm) fertilises a female germ cell (ovum) in the fallopian tube…"37.
Contraceptive: An agent working against conception
Endometrium: The lining of the womb, which provides the blood supply and supports a pregnancy
Fertilisation: Union of a sperm and egg to form a new being (zygote, conceptus etc)
GP: general practitioner, or family doctor.
Implantation: Attachment of the new life into wall of the womb for continued nutrition and blood supply at about day 7 after conception
Oestrogen: A hormone which prepares a woman for fertility. Synthetic preparations may have different effects.
Ovulation: Release of the ovule (egg), or female gamete, from the ovary.
Progesterone: A hormone which is found in women and prepares the womb for (pro)gestation. As with oestrogens, the synthetic versions may actually block the natural hormone.
STIs: Sexually transmitted infections

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