

Scottish Council on Human Bioethics

The Morning-After Pill

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KEY POINTS

Misnomer

The morning-after pill (MAP) is wrongly and misleadingly labelled “Emergency Contraception” by medical and Government bodies. It is misleading because it conceals the fact that it may work, not by preventing conception, but by preventing further survival and development of an already existing embryo.

Efficacy

Even though trials show it to be efficacious in reducing the number of pregnancies, there are more factors to be considered. As demonstrated by recent figures from Scotland, there has been no reduction in the steady rise in number of abortions.

Reservations

There is no conclusive clinical evidence that the MAP is beneficial to the psychological or physical well-being of teenagers. Nor is there any research into the long-term effects of prescribing the MAP to teenage girls. Despite this it is being promoted to teenagers.

In the light of the escalating incidence of Sexually Transmitted Infections, it is ill-advised to promote the MAP, which offers no protection against them.

Those taking the MAP as an emergency measure are already recognised to be an at risk population. Inadequate follow-up in Primary Care is a major concern.

Use of the MAP may adversely affect the pregnancies it does not prevent.

Social implications

The adverse social effects have not been fully studied.

Reduction in the fear of pregnancy produces more risk-taking behaviour, as evidenced by the spiralling increase in sexually transmitted infections.

There is now clear evidence that teenage pregnancy is associated with one-parent families and socio-economic deprivation. Both these factors should be targeted.

Ethics for health workers

Pharmacists do not have sufficient data to be able to check the age of children who ask them for the morning-after pill.

Pharmacists (or school nurses) may have incomplete information on other factors, such as other prescribed medication or family history (the teenager may not be aware, willing or be able to communicate this information), and this could lead to health complications.

Clinicians should not feel pressurised to act against their conscience.

Clinicians must realise that people who are asking for the morning-after pill are often in difficult situations and are suffering as a consequence; they need to deal with these patients with compassion and understanding

Consent cannot be considered to be fully informed and hence valid, if the possibility of endangering early life is not explained.

1. INTRODUCTION AND AIMS

The morning-after pill has been promoted as a solution to the growing teenage sexual health problem being witnessed in Scotland.

The continuing increase in sexually transmitted infections (STIs), recorded in recent reports of the Scottish Centre for Infections and Environmental Health¹, has come as a shock to members of the health profession across Scotland. Documenting a marked increase in teenage sexual activity, the report raises urgent questions about the impact of the “safe sex” message in our classrooms and the Scottish Executive’s overall approach to teenage sexual health.

One specific feature of this approach that has prompted concern from GPs, parents and educators (and others) has been the official policy on the promotion of the morning-after pill as a method of contraception. When appropriately initiated within 72 hours of unprotected coitus, emergency contraception will prevent approximately 80% of pregnancies in teens and young women who are mid-cycle and, thus, at risk of pregnancy.² But this policy has not been based on a clear and rigorous understanding of the properties, the function and the efficacy of the morning-after pill. Neither has there been adequate and in-depth research on the short and long-term safety implications of the morning-after pill.

In light of proposals to increase the availability of the morning-after pill, the overall aim of this Briefing Paper is:

1. to provide specific answers to the questions raised above, based on research evidence; and
2. to provide an independent source of information on the most recent research on the morning-after pill and STIs, for parents, teachers, politicians, members of the health and legal professions and other interested parties.

2. DEFINING AND CATEGORISING THE MORNING-AFTER PILL

In spite of the widespread availability of the morning-after pill over the past decade, considerable confusion still exists about how it actually works and its effect on the human body. Only an accurate and concise description of its nature and function can properly inform public policy on the prescription of the morning-after pill.

2.1 What is the morning-after pill?

Recommended dosage regimes

There have been two predominant brands of morning-after pill in the UK: firstly *Schering PC4TM*, and latterly *LevonelleTM* in Britain (*Levonelle -2TM* is the prescription name for the same product). *Schering PC4TM* was withdrawn in the autumn of 2001 as it was poorly tolerated and was less effective. It is no longer recommended and has been superseded by *Levonelle* and *Levonelle one stepTM*.

Schering PC4TM

This was the marketed form of the Yuzpe regime in the UK. The Yuzpe regime contained an oestrogen as well as a progesterone (ethinyloestradiol 100µg plus levonorgestrel 500µg, repeated 12 hours later).

The mechanism of action of this medication in the Summary of Product Characteristics was clearly stated as: “*Primarily aimed to prevent implantation of the fertilised ovum in the*

¹ Scottish Executive, Information and Statistics Division, *Scottish statistic 2000*, <http://www.show.scot.nhs.uk/isd/>

² Emergency Contraception. Committee on Adolescence, Policy Statement PEDIATRICS Vol.116 No.4 October 2005 (doi:10.1542/peds.2005-1877) <http://pediatrics.aappublications.org/cgi/content/full/peds.2005-1877v1>

endometrium.”³ Later, it added: “since Schering PC4 appears to affect only endometrial implantation...the effect of Schering PC4 on the conceptus in the event of failure to prevent conception is not definitely known.” Additionally, the Product Characteristics stated that Schering PC4 was aimed at the: “Inhibition of Implantation: The administration of relatively large doses of oestrogens for several days, beginning shortly after unprotected sexual intercourse, usually does not prevent fertilisation but often prevents implantation of the blastocyst.” This product was therefore not considered to have contraceptive properties.

Levonelle TM(levonorgestrel)

Levonelle does not contain any oestrogen, and due to this absence Levonelle has now gained greater acceptance. The Summary of Product Characteristics⁴ states that, ‘The precise mode of action of the Levonelle is not known. It may also cause endometrial changes that discourage implantation. Levonelle is not effective once the process of implantation has begun.’ The actual mode of action (function), in any given case, may depend on the time between administration of Levonelle and ovulation.

Table 1. Comparative doses of hormones.

Name of pill	Dose of Levonorgestrel in micrograms	Factor difference of dosage in Levonelle	Dose of Oestrogen in micrograms	Factor difference of dosage in PC4 (Yuzpe)
Combined pills				
Eugynon	250	6	30	13.3
Logynon	50-75-125	30 -12	30	13.3
Microgynon	150	10	30	13.3
Ovran	250	6	50	8
Ovranette	150	10	30	13.3
Trinordiol	50-75-125	30 -12	30	13.3
PC4	250 x 4 = 1000		100 x 4 = 400	
Progesterone only				
Microval	30	50	0	
Norgeston	30	50	0	
Levonelle	750 x 2 = 1500		0	
Levonelle one step	1500		0	

From 1998 to 2002 it was recommended that a woman took the first pill of 750µg levonorgestrel up to 72 hours after intercourse, and a second dose 12 hours later. This meant that the second dose could be as much as 84 hours after the act of intercourse that prompted the consultation, i.e. giving time for conception to occur. After that time (the "lag" period in which nothing is done) the regime was said to be less effective⁵. Since 2003 it has been recommended that a double dose be taken all at once within 72 hours of unprotected intercourse. However, it has been shown to prevent a high proportion of pregnancies even

³ Schering PC4 APBI Compendium of Data Sheets and Summaries of Product Characteristics. 1999-2000.

⁴ Levonelle, Summary of Product Characteristics. 2005. Pharmacodynamic properties <http://emc.medicines.org.uk/emc/industry/default.asp?page=displaydoc.asp&documentid=595>

⁵ Randomised controlled trial of levonorgestrel versus the Yuzpe regimen of combined oral contraceptives for emergency contraception. Task Force on Postovulatory Methods of Fertility Regulation. *Lancet* 1998; **352**: 428 – 433

up to 5 days (120 hours) after intercourse⁶. 'Levonelle one step' contains one double strength tablet. It has been phased in to replace the old Levonelle product that comprised two tablets.

As can be seen in Table 1 the dosage of hormones administered in these pills is up to 50 times greater than the normal contraceptive dose.

Mifepristone (RU486)

The US Food and Drug Administration (FDA) has issued an alert following reports of women dying after using this drug.⁷

It is licensed in the UK for use only in hospitals having approval to undertake termination of pregnancy⁸ and is no longer discussed here. It has abortifacient actions, even if given before the missed period. And *Mifepristone will significantly inhibit endometrial development*⁹, when given after ovulation.

2.2 How does it work?

*Very little is known about the exact mode of action of the morning-after pill*¹⁰, according to Dr Anna Glasier in a lecture to the Royal College of Obstetricians and Gynaecologists: *The mechanisms of action of both the Yuzpe Regimen...and levonorgestrel remain unclear. There is reasonable evidence to suggest that both will inhibit or delay ovulation – but not in all cases. The evidence for an effect on implantation is at best circumstantial despite the fact that estimates of efficacy suggest that EC (Emergency Contraception) must do more than just inhibit ovulation.*¹¹

Similarly, *'Results of studies evaluating the effect of emergency contraception on the endometrium have been conflicting. Some studies have suggested histologic or biochemical alterations in the endometrium after emergency-contraception treatment, leading to the suggestion that the pills may act by impairing endometrial receptivity to the implantation of a fertilized egg. However, other studies have demonstrated little to no effect on the endometrium and raise the question of whether the endometrial changes observed would be sufficient to inhibit implantation.'*²

Thus, even leading medical professionals in reproductive health, who advocate increased availability of the morning-after pill, have an incomplete understanding of how it works and its effect on the human body.

Is this contraception?

The Department of Health and the British National Formulary¹² officially label the morning-after pill as "Emergency Contraception", thereby implying that it acts to prevent conception. However, the standard definition of conception given in the Oxford Concise Medical Dictionary is: – *The start of pregnancy, when a male germ cell (sperm) fertilizes a female*

⁶ von Hertzen H, Piaggio G, Ding J, Chen J, et al. Low dose mifepristone and two regimes of levonorgestrel for emergency contraception: a WHO multicentre randomised trial. *Lancet* 2002;360: 1803-10.

⁷ FDA ALERT– [07/2005] FDA is aware of four women in the United States who died from sepsis (severe illness caused by infection of the bloodstream) after medical abortion with Mifeprex and misoprostol. Sepsis is a known risk related to any type of abortion. The symptoms in these cases were not the usual symptoms of sepsis.

<http://www.fda.gov/cder/drug/InfoSheets/patient/mifepristonePIS.pdf>

⁸ <http://www.emc.medicines.org.uk/> 'For termination of pregnancy mifepristone may only be administered in accordance with the Abortion Act 1967 as amended by The Human Fertilisation and Embryology Act 1990.'

⁹ Bygdeman M, Gemzell Danielsson K, Marions L, Swahn M-L. Contraceptive use of anti progesterone. *Eur J Contracept Reprod Health Care* 1999;4:103–7.

¹⁰ Glasier A., The Science of Emergency Contraception, Lecture. *Annual Symposium, Faculty Of Family Planning & Reproductive Health Care, Royal College Of Obstetricians & Gynaecologists* 18th May 2001.

¹¹ Glasier A., The Science of Emergency Contraception, Abstract. *Annual Symposium, Faculty of Family Planning and Reproductive Health Care, Royal College of Obstetricians & Gynaecologists*, 18th May 2001.

¹² British National Formulary, Section 7.3.1.

<http://www.bnf.org/WeBNF/form1/scripts/display2.dll/mpanel?ID=4568>

*germ cell (ovum) in the fallopian tube...*¹³. The word 'contraception' is therefore insufficient to describe the full effect of the morning-after pill, which may act to prevent *implantation* (attachment of the embryo to the wall of the uterus), which occurs approximately seven days after conception has taken place. The word *contraception* clearly means a specific measure to *prevent conception*, not *implantation*. Acts which are post-conceptive (after conception) cannot reasonably be included in the definition of contraception.

Confirmation of the facts can be found in standard textbooks on embryology, which affirm that: *...human development begins after the union of male and female gametes or germ cells during a process known as fertilisation (conception)*.¹⁴ And further that: *Fertilisation thus results in a restoration of the diploid number of chromosomes, the chromosomal sex of the new individual and the initiation of cleavage*.¹⁵ The sexual and other human characteristics are thus already determined genetically from the moment of conception (fertilisation). Indeed, implantation has been described as the *fourth* stage of human embryonic development.¹⁶ By this time it has undergone eight of the forty-one cell doublings that occur before birth.

Unfortunately, these facts seem to be ignored by scientists engaged in the family planning industry, who have initiated a subtle campaign against the established and scientifically proven definition of conception.

The full, self-contradictory nature of this view can be seen in a publication of the Family Planning Association (FPA) which asserts that: *...the egg is wafted down the fallopian tube to the ready prepared womb. Here it settles and attaches itself to the thick, nutritious lining. Implantation has now taken place, conception is complete and pregnancy begins*. The document goes on to state that: *An average pregnancy lasts 280 days*¹⁷, i.e., just over 9 months. As they are making a woman count from 21 days later than prevailing customs, it would come as a surprise to most mothers, that following on from such distortion of definitions, this leaflet would suggest counting 10 months from the last period!

Dr John Ling, formerly of the Institute of Biological Sciences at Aberystwyth University, refers to the government's position 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*'.¹⁸

Assisted conception units acknowledge that we are dealing with a complex being: '*Before implantation the blastocyst is a highly organised mass of approximately one hundred cells*'¹⁹. They measure their success by '*the chemical pregnancy rate*'; which is a blood measurement of a hormone produced by the chorion (tissues surrounding the embryo, which becomes the placental tissue and membranes). The test is positive 5-7 days after fertilisation. IVF centres thus diagnose pregnancy in the time **before** implantation.

It is significant that scientists who have no vested interest in the family planning industry – i.e. the substantial body of medical opinion – are quite clear on the difference between conception and implantation: '*Implantation represents the remarkable synchronisation between the development of the embryo and the differentiation of the endometrium*'.²⁰ In other words, the existence of a separate life prior to implantation is acknowledged.

¹³ Oxford Concise Medical Dictionary 1980.

¹⁴ Moore KL. *Essentials of Human Embryology*, Blackwell/Decker 1998.

¹⁵ Williams PL, Wendell-Smith CP. *Basic Human Embryology*, Pittman 1978;2nd Edition (reprint):36.

¹⁶ Moore KL. *The Developing Human: Clinically Oriented Embryology*. 1976.

¹⁷ Contraceptive Education Service *Body Works, a rough guide to eggs, sperm and conception*. Family Planning Association (FPA)

¹⁸ Ling JR. *Responding to the Culture of Death*, London: Day One, 2001, courtesy of Family Education Trust.

¹⁹ Blastocyst culture and transfer. *Glasgow Nuffield Newsletter* Summer 2001

²⁰ Horne A., White J., Lalani E. *The endometrium and embryo implantation* *BMJ* 2000;321:1301-2

It is therefore incorrect and misleading for the Department of Health to categorise the morning-after pill as “Emergency Contraception”, as it conceals the fact that it may work to prevent further survival and development of an already existing embryo.

Is this abortion?

Another disagreement is about when an action can be called abortifacient. Some would say that this is only after implantation, as a pregnancy is not carried up to this stage, using the argument that a ‘*pregnancy with an IVF baby is not celebrated until after implantation*’.²¹ Here, the terms matter less than the facts: the life is present and vulnerable.

Leading advocates of this position include the process of implantation, which occurs a week after conception, under the general definition of conception. One such scientist, Dr John Guillebaud, repeatedly advanced the argument that: “...*before implantation the process of conception is not complete; there is not true “carriage” of a pregnancy, because only thereafter is the woman’s physiology made aware of the blastocyst’s presence.*”²² The fundamental flaw in his argument, however, is that the essential nature of the embryo (conceptus), that it is a distinct entity from that of the mother, is *unchanged* by implantation; only the *position* of the embryo is affected. We are distracted by the attempt to re-define pregnancy, which is peripheral.

A case was brought against the government by the Society for the Protection of Unborn Children (SPUC) to contest the above. The morning-after pill is sold without prescription on the basis that it is simply a contraceptive. The 18 April 2002 decision of the High Court to allow this rested on a distinction between the legal meaning of pregnancy and the reality of conceiving and bearing a child. The case focused on the status of the newly conceived embryo, and the judge (Mr. Justice James Munby) decided, in essence, that a mother is not pregnant until the embryo implants in the womb. Before that, although an embryonic child is present, she is not legally pregnant, the judge said.²³ This judgement has supported the idea that conception includes implantation, and hence pregnancy is not legally recognised until that event; but this does not change the facts that a life is already present before implantation.

Feminist author Germaine Greer also recognises the abortifacient nature of the morning-after pill and 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.*’²⁴

The ‘Task Force on Postovulatory Methods of Fertility Regulation’ carried out the main study to date on the morning-after pill²⁵. The title of this Task Force is in line with the idea that the main action is post-ovulatory, even if attempts to lessen the unacceptability are made in subsequent publications.

²¹ Grimes, David A. MD; Raymond, Elizabeth G. MD, MPH Emergency Contraception, Letters Annals of Internal Medicine 138(3) 238

²² Guillebaud J. *Update*, p.417, 19th March 1977 & *Update*, p.575, 23rd April 1997. Margaret Pyke Centre.

²³ <http://www.spuc.org.uk/news/releases/2002/april18>

²⁴ Greer G. *The Whole Woman*, London: Doubleday, 1999, pp92-93, courtesy of Family Education Trust

²⁵ Randomised controlled trial of levonorgestrel versus the Yuzpe regimen of combined oral contraceptives for emergency contraception. Task Force on Postovulatory Methods of Fertility Regulation. *Lancet* 1998; **352**: 428 – 433

Understanding scientific terms used for the cycle

It may be helpful to understand the stages of the menstrual cycle for the following discussion. A graphic representation may be found in physiology textbooks and on several websites²⁶. A helpful one is reproduced below (Figure 1) and a summary diagram (Figure 1a) follows which may be helpful in understanding some of the terms used interchangeably in the various papers referred to.

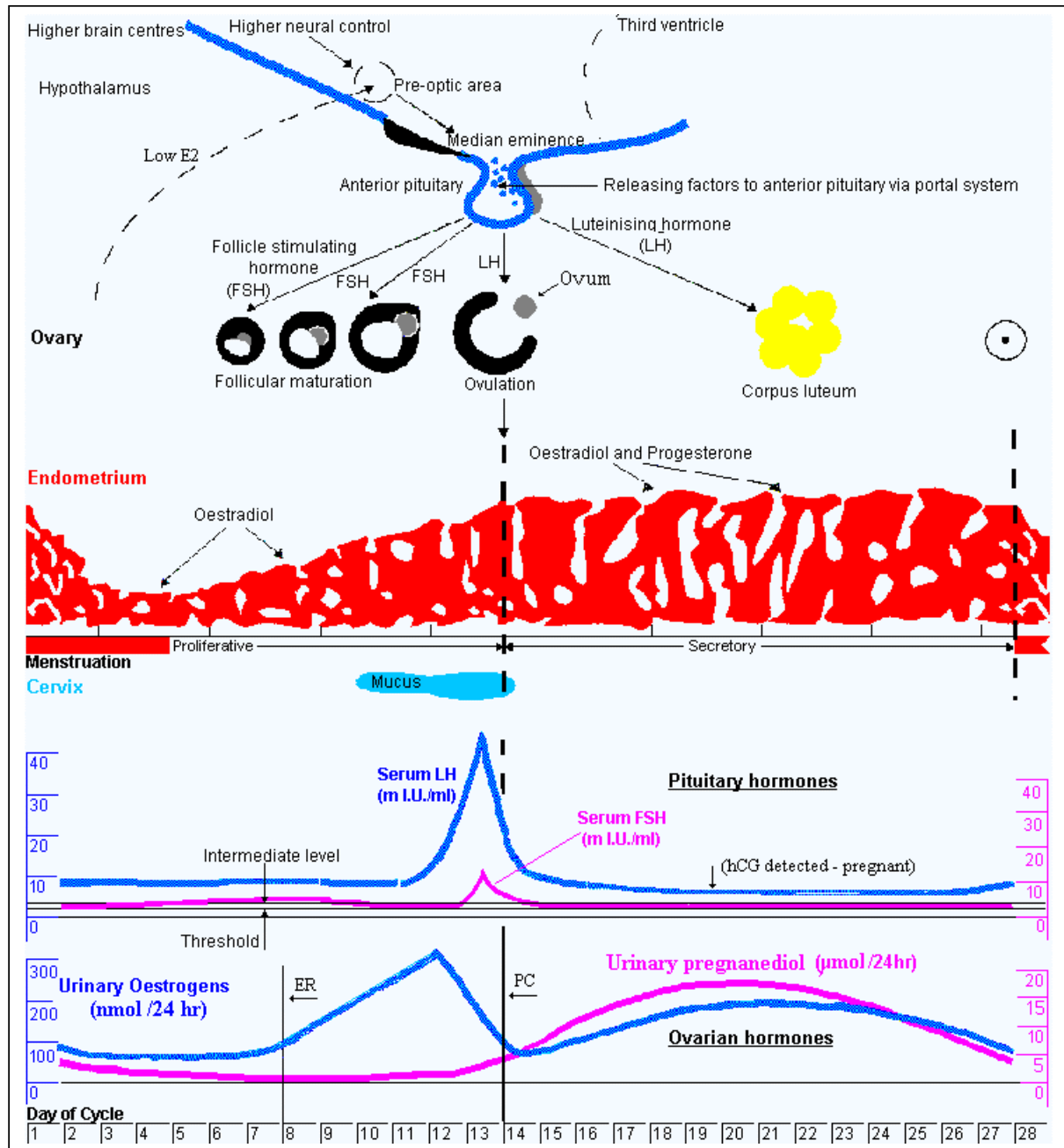


Figure 1: Menstrual cycle.

²⁶ www.holistic-online.com/Remedies/hrt/hrt_mens
<http://www.woomb.org/bom/hormones/index.html>
www.wisc.edu/ansci_repro/lec/lec_11/lec11fig.html

		1st part of cycle												2nd part of cycle														
Endometrial phase	Proliferative phase													Secretory phase														
	Follicular Phase													Luteal Phase														
Ovarian	Pre-ovulatory													Post-ovulatory														
	Oestrogen peak													Progesterone and Oestrogen rise														
Relation in days to LH peak	Ovulation													•														
Cycle day*	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
											LH -2	LH -1	LH	LH +1	LH +2													

Figure 1a. *The cycle is traditionally depicted as 28 days with ovulation at 14 days; but variation most commonly occurs in the first part of the cycle; in fact, only 13-17% of women have a 28-day cycle.²⁷ Therefore, the days can be more accurately numbered by their relationship to ovulation or in relation to the peak in Luteinising Hormone (LH peak), (e.g., 2 days before or after the LH peak designated LH-2 or LH+2).

Modes of action

The evidence on this subject has been of particular interest because of the concern that the morning-after pill may cause an early abortion. Those involved in the research and development of these methods have naturally carried out most of the studies on the morning-after pill. Some of the papers that are regularly quoted are based on small numbers and from unrepresentative populations. They have been published in journals dedicated to contraceptive and abortion methods²⁸. Most of the mainstream research on fertility has been done specifically for IVF requirements, and so may not clarify what happens in nature and when administered hormones disrupt this.

Although there remains much uncertainty about the mode of action, researchers have not been able to exclude entirely risk to the new life in all cases.

‘To be effective, postcoital treatment should inhibit or delay ovulation or inhibit implantation. If sexual intercourse takes place shortly before or at the time of ovulation, and treatment is given after ovulation, an inhibitory effect on embryo development or implantation is necessary to prevent pregnancy.’²⁹ This latter effect is abortifacient.

‘It is not fully understood how this medicine prevents pregnancy. It is thought to work by preventing ovulation and fertilisation and also by altering the lining of the womb, depending on which stage of the menstrual cycle the woman is at.’³⁰

²⁷ Treloar AE, Boynton RE, Behn BG, Brown BW. Variation of the human menstrual cycle through reproductive life. Int J Fertil. 1967 Jan-Mar;12(1 Pt 2):77-126. PMID: 5419031

²⁸ Contraception <http://www.arhp.org/healthcareproviders/onlinepublications/arhpjournal/journal.cfm?ID=300>

²⁹ Bygdeman M, Gemzell Danielsson K, Marions L, Swahn M-L. Contraceptive use of anti progesterone. Eur J Contracept Reprod Health Care 1999;4:103-7.

³⁰ <http://www.netdoctor.co.uk/medicines/100004487.html>

Variables:

- i) We do not know the exact time-relation intercourse bears to fertilisation in the particular woman seeking advice (possible range 1/2 hr to 4 or 5 days).
- ii) Hence it is not possible, at present, to calculate the exact time-relation of ovulation or fertilisation to the administration of the pills.
- iii) The above may be affected by the exact time in the menstrual cycle of the woman.
- iv) We do not know if the act of intercourse, which prompted the consultation, is the only act which may cause impregnation.

Possible modes of action to be studied here are as follows:

- inhibition of ovulation
- alteration of hormonal function
- altered transport of gametes (pre-conception)
- prevention of fertilisation
- altered transport of zygote (post-conception)
- an effect on implantation and the endometrium
- effects after implantation

1) Inhibition of ovulation

There is some evidence to suggest that if levonorgestrel is administered at a very specific time in the women's cycle it can suppress the LH peak and will inhibit or delay ovulation, if ovulation has not yet occurred.

However levonorgestrel needs to be given within a very narrow window of time to inhibit ovulation; and even then the effect is "not guaranteed".^{31, 32} The time available is on the day, 2 days before the LH peak (LH -2). Only doses given on the precise day, consistently inhibited ovulation.³³

Administration at other times in the cycle would not have this effect. '*It is possible that... the treatment was initiated closer to the LH peak, when LH had already started to rise, at a time when it no longer was possible to influence follicle development and the LH surge.*'³⁴

2) Alteration of hormonal function

In all 12 women in the study³⁵ using the Unipath™ monitor '*the luteal (postovulatory) phase was significantly shortened following treatment with levonorgestrel compared to the placebo cycles.*' This suggests a post-ovulatory effect. Short luteal phases are associated with subfertility³⁶, because there is neither the time nor conditions for adequate implantation.

3) Altered transport of gametes (pre-conception)

There is a theoretical possibility that levonorgestrel may enhance the 'barrier' effect of cervical mucus to the passage of sperm through the cervical canal. However, an effect on cervical mucus is unlikely to be important as the morning-after pill is sought and administered **after** intercourse has taken place. The effects on cervical mucus arise within 24 hours of

³¹ Gemzell-Danielsson, K. 1; Marions, L. Mechanisms of action of mifepristone and levonorgestrel when used for emergency contraception. *Human Reproduction Update*. 10(4):341-348, July/August 2004.

³² Marions L, Cekan C, Bygdeman M and Gemzell Danielsson K (2004) Preovulatory treatment with mifepristone and levonorgestrel impairs luteal function. *Contraception* 69, 373–377. [[CrossRef](#)][[ISI](#)][[Medline](#)]

³³ Müller AL, Lladós CM and Croxatto HB (2003) Postcoital treatment with levonorgestrel does not disrupt postfertilization events in the rat. *Contraception* 67, 415–419.

³⁴ Hapangama D, Glasier A, Baird DT. The effects of peri-ovulatory administration of levonorgestrel on the menstrual cycle. *Contraception* 2001;63:123–9.

³⁵ Hapangama D, Glasier A, Baird, D. *Contraception* 63 (2001)123-129

³⁶ Evelyn and John Billings Teaching the Billings Ovulation Method Part 2. Variations of the cycle and reproductive health. Chapt 14. Infertility, Short Luteal Phase.

administration³⁷. In another study³⁸, 'the sperm penetration into the cervical canal was not affected until 9 hours after ingestion of the medication.' (postcoital levonorgestrel in an oral dose of 400µg). This time delay is likely to be too long to allow any prevention of conception. The Summary of Product Characteristics used to indicate that: *Emergency hormonal contraception is thought to work mainly by preventing ovulation and fertilisation by altering tubal transport of sperm and ova.*³⁹ However, this has been deleted as it has not been observed and any evidence is incomplete.

The 'data indicate that levonorgestrel ... in doses relevant for emergency contraception have no direct effect on sperm function'⁴⁰.

4) Prevention of fertilisation

Early pregnancy factor (EPF)⁴¹ may be detected in sera of pregnant women well within 24-48 hours of conception; later studies even suggest 12-16 hours after fertilisation⁴². This could be used in the future to detect if fertilisation has taken place. No studies have yet been carried out.

5) Altered transport of zygote (post-conception)

'Diethylstilbestrol, given daily in high dosage for 5 to 6 days, may also accelerate passage of the dividing zygote along the uterine tube.'⁴³ This could reduce the possibility of implantation but these doses were not used in the Schering PC4TM.

6) An effect on implantation and the endometrium

The process of implantation starts 4 to 5 days after fertilisation and is established around day 7. Levonorgestrel can still work after 120 hours (5 days) delay. The drug stays in the blood for 15 - 25 hours after administration⁴⁴. The blood distributes it to other parts of the body. After that, the chemical effect on the newly fertilised egg and endometrium may endure several days. It is therefore recognised that levonorgestrel has a prolonged action. In a study by Durand⁴⁵ those women treated immediately before the LH pre-ovulatory surge and in whom ovulation occurred, all had lower luteal progesterone serum concentrations and had a significant shortening of the luteal phase. In a small study⁴⁶, at least 50% of women had a disruption in the second part of the cycle when administered levonorgestrel in the post ovulatory phase. It cannot therefore be correctly concluded, that levonorgestrel has no effect on the luteal phase.

³⁷ Cyclic changes of cervical mucus in normal and progestin-treated women. *Fertil Steril* 1966;17:63.

³⁸ Kessler E, Garmendia F, Westphal N, Parada J. The hormonal and peripheral effects of dl-norgestrel in postcoital

contraception. *Contraception* 1974;10:411-24.

³⁹ Levonelle, Summary of Product Characteristics. 1999.

⁴⁰ Gemzell-Danielsson, K. 1; Marions, L. Mechanisms of action of mifepristone and levonorgestrel when used for emergency contraception. *Human Reproduction Update*. 10(4):341-348, July/August 2004.

⁴¹ Morton H, Rolfe B, Clunie G J. An early pregnancy factor detected in human serum by the rosette inhibition test. *Lancet* 1977;8008:394-7.

⁴² Haq A, Mothi B A, Al-Hussein K, et al. Isolation, purification and partial characterisation of early pregnancy factor (EPF) from sera of pregnant women.. *Eur J Med Res* 2001 29;6(5):209-214.

⁴³ Kalant et al., 1990. Best R., Emergency abortion – Pharmacology. *Life Research and Communications Institute*.

⁴⁴ Rodrigues and Grou, elimination half-life, *Am J Obstet Gynecol* 1994 Dec;171 (6):1529-34

⁴⁵ Durand M, del Carmen Cravioto M, Raymond EG, Duran-Sanchez O, De la Luz Cruz-Hinojosa M, Castell-Rodriguez A, Schiavon R and Larrea F (2001) The mechanism of action of short term levonorgestrel administration in emergency contraception. *Contraception* 64,227-234.

⁴⁶ Marions L, Hultenby K, Lindell I, Sun X, Stabi B and Gemzell Danielsson K (2002) Emergency contraception with mifepristone and levonorgestrel: mechanism of action. *Obstet Gynecol* 100, 65-71.

7) Effects after implantation

Effects on existing pregnancies

All women had a pregnancy test at entry to the Task Force trial⁴⁷, but only those found to be pregnant (42 women) at the end of the trial had their enrolment pregnancy results published: 4 of the 42 women were already pregnant before the morning-after pill administration, for another 5 women, pregnancy status on admission was unknown. It is not known how many of the other women (1956 women) were pregnant, and if the morning-after pill caused them to lose their pregnancy.

Effects on subsequent acts of intercourse

742 women (38%) had additional acts of intercourse after taking either the Yuzpe regime or levonorgestrel, and in both groups, those who had further acts of intercourse after treatment, had higher pregnancy rates than women without further intercourse. However the pregnancy rates in the 2 groups were markedly different (5.3% in the Yuzpe group compared to 1.6% in the levonorgestrel group). This would suggest that levonorgestrel was more effective in reducing pregnancy from intercourse after administration.

Summary

It seems very unlikely that the 85% effectiveness rates achieved in the Task Force trial⁴⁸ could have been possible if the only mechanism of action of levonorgestrel was the inhibition of ovulation. This effect is only present for one or two days per cycle, and many women would have presented at other times including the post-ovulatory phase. This is well recognised: “estimates of efficacy suggest that EC (morning-after pills) must do more than just inhibit ovulation”⁴⁹, as already quoted above.

Therefore:

- either levonorgestrel inhibits or delays ovulation if it is given at a very specific time (the ‘window’ for this effect for levonorgestrel seems to be rather narrow at 2-3 days prior to ovulation);
- or levonorgestrel produces abnormal luteal function, which may affect the stability of the endometrium where implantation takes place;
- or levonorgestrel has some other effect as yet unknown which adversely affects the further progress of the pregnancy.

3. ASSESSING THE RISKS OF THE MORNING-AFTER PILL

The lack of scientific understanding of the function of the morning-after pill raises significant issues about safety and risk management in its prescription.

3.1 What are the adverse effects of the morning-after pill?

A balanced view of the health risks of the morning-after pill can be obtained only through consideration of what has been established in clinical trials and by what otherwise remains unproven.

Effects on the woman

The prevalent idea that *Levonelle* is just a reformulation of Norgeston™ (levonorgestrel 30 µg, a form of mini-pill) hides the magnitude of the dose disparity. The daily dosage of levonorgestrel given in *Levonelle* compared to Norgeston is 1500µg compared to 30µg⁵⁰: i.e.,

⁴⁷ Task Force on Postovulatory Methods of Fertility Regulation. *Lancet* 1998; **352**: 428 - 433.

⁴⁸ Task Force on Postovulatory Methods of Fertility Regulation. *Lancet* 1998; **352**: 428 - 433.

⁴⁹ Glasier A., The Science of Emergency Contraception, Abstract. *Annual Symposium, Faculty of Family Planning and Reproductive Health Care, Royal College of Obstetricians & Gynaecologists*, 18th May 2001.

⁵⁰ mcg = 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 doses).

The side effects of *Levonelle* are listed from the Task Force trial⁵¹ (expressed as percentage of women) as nausea 23.1, low abdominal pain 17.6, fatigue 16.9, headache 16.8, dizziness 11.2, breast tenderness 10.8, vomiting 5.6, all other undesirable effects 13.5 (mostly diarrhoea, irregular bleeding and spotting). Norgeston in addition lists 'migraine, depressive moods, changes in body weight and libido, and allergic reactions can occur. Amenorrhoea and changes in the pattern of the menstrual cycle have also been observed.'⁵²

The British National Formulary highlights that the doctor should explain to the patient: 'the need to return promptly if any lower abdominal pain occurs because this could signify an ectopic pregnancy (and also in 3 to 4 weeks if the subsequent menstrual bleed is abnormally light, heavy or brief, or is absent, or if she is otherwise concerned).'⁵³

The contraindications listed for Norgeston⁵⁴ are numerous, but are dismissed in the Data sheet for *Levonelle*. "*Since exposure to levonorgestrel with Levonelle is brief, the risks of pregnancy in all women, including those with pre-existing medical conditions, are almost certainly greater than those associated with Levonelle*". This fails to take into account the simple fact that the dangers of pregnancy to a woman have fallen drastically. The maternal death rate UK-wide is only 11.4 per 100,000 maternities.⁵⁵

Also it is important to state that the probability of pregnancy with one completely random act of unprotected intercourse was found to be 3.1%⁵⁶ i.e. 97% would not become pregnant. Consequently many women are being exposed to these hormones unnecessarily.

Effects on the foetus

Animal experiments with levonorgestrel have shown virilisation of female fetuses at high doses.⁵⁷

Despite the use of levonorgestrel, in the World Health Organisation multi-centre Task Force trial, reported in the *Lancet*⁵⁸, 1% of women were found to be pregnant after treatment with *Levonelle*. 10% of these pregnancies were thought to have been already in existence before administration of the drugs. (A further 2% were lost to follow-up, so the outcome was unknown.) In real life, rather than in a carefully conducted trial, the pregnancy rate may be much higher.

If there is uncertainty about the timing of the unprotected intercourse or if the woman has had unprotected intercourse more than 72 hours earlier in the same menstrual cycle, conception

⁵¹ Task Force on Postovulatory Methods of Fertility Regulation. *Lancet* 1998; **352**: 428 - 433

⁵² APBI Compendium of Data Sheets and Summaries of Product Characteristics 1999-2000

⁵³ British National Formulary Section 7.3.1 <http://www.bnf.org/bnf/bnf/current/openat/>

⁵⁴ Summary of Product Characteristics <http://www.emc.medicines.org.uk/> The Data sheet for Norgeston lists the contraindications to Levonorgestrel 30 micrograms as: – pregnancy, severe disturbance of liver function, jaundice or persistent itching during a previous pregnancy; Dubin-Johnson syndrome; Rotor syndrome; previous existing liver tumours; a history of herpes of pregnancy; mammary carcinoma or a history of this condition; undiagnosed abnormal vaginal bleeding; history of existing thrombo-embolic process (e.g. stroke or myocardial infarction); severe diabetes with vascular changes; sickle cell anaemia or hypersensitivity to any of the components of the drug.

⁵⁵ *Why Mothers Die 1997-1999* Royal College of Obstetricians and Gynaecologists

⁵⁶ Wilcox AJ, Dunson DB, Weinberg CR, Trussell J, Baird DD. Likelihood of conception with a single act of intercourse: providing benchmark rates for assessment of post-coital contraceptives. *Contraception*. 2001 Apr;63(4):211-5.

PMID: 11376648 [PubMed - indexed for MEDLINE]

⁵⁷ Summary of Product Characteristics 2005 <http://www.emc.medicines.org.uk/>

⁵⁸ Task Force on Postovulatory Methods of Fertility Regulation. *Lancet* 1998; **352**: 428 - 433

may have occurred. Treatment with Levonelle following the second act of intercourse may therefore be ineffective in preventing pregnancy.⁵⁹

Based on these figures, if approximately one million packs of the morning-after pill are prescribed annually⁶⁰, 10,000 pregnancies will be exposed in Britain alone⁶¹, in one year. Although the doses are much lower than in the animal experiments referred to above, such exposure could risk masculinisation of a female foetus i.e., gender ambiguity and foetal malformation.⁶²

3.2 What are the adverse effects of repeated use?

Repeated use and exposure to the morning-after pill has become an issue of great concern⁶³ due to the increasing availability of the morning-after pill through GPs, family planning clinics and over the counter in pharmacies. In seven family planning clinics, over half the women had used the morning-after pill at least once that year, and 25% had used it three or more times.⁶⁴ The WHO Task Force⁶⁵ trial found that 1 in 5 participants had used 'Emergency Contraception' before. This is important because of the evidence that repeated use has significant health implications: "Menstrual complaints were reported by 70% of women (leading problems). Other complaints included (in decreasing order) nausea, breast tenderness, weakness, dizziness, headache, abdominal bloating, loss of libido, depression and vomiting. High dose levonorgestrel pills are unsuitable for regular postcoital contraception", according to the WHO Task Force report⁶⁶.

However, this does not tell the full story. The *short-term* effects of repeated use may well be adequately documented, but much less is known about the *long-term* health implications. The initiatives to provide the morning-after pill free of charge over the counter (and other schemes designed to increase the availability of the morning-after pill on the open market), will increase repeated use of a drug for which there is evidence of health risks in the short term and evidence of perhaps even greater risk in the long term. It is notoriously difficult to track *repeated* use of the morning-after pill. This will be especially difficult with the use of different sources. A woman may be listed as a single user at each source.

In the Task Force trial⁶⁷, there is no data relating to teenagers, as the average age of the women was 27 years. Of these women, two thirds had proven fertility. There is no data on subsequent fertility when a young and developing body is exposed to such high doses of hormones.

3.3 Other health risks

Sexually Transmitted Infections show an alarming rise among young people. Teenage pregnancies and STIs arise from teenage intercourse. This may seem obvious, but it needs to be highlighted. Also, whilst the Government target to reduce pregnancies in the under 16s

⁵⁹ Summary of Product Characteristics 2005 <http://www.emc.medicines.org.uk/>

⁶⁰ *Pharmacy Magazine* Feb 2000

⁶¹ The Joint Medico-Legal Committee on bioethics On the proposed reclassification of levonorgestrel as a pharmacy medicine for 'Emergency Contraception' by the Medicines Control Agency June 2000

⁶² There are 2 main groups of progestogen: a) Progesterone and its analogues (dydrogesterone, hydroxyprogesterone and medoxyprogesterone) And b) Testosterone analogues (norethisterone and norgestrel). "levonorgestrel is the active isomer of norgestrel and has twice its potency. Progesterone and its analogues are less androgenic than the testosterone derivatives" British National Formulary, Section 6.4.1.2. <http://www.bnf.org/bnf/bnf/current/openat/>

"Vigorous progestogen therapy during pregnancy can virilise female fetuses seriously." Laurence, DR, Bennet, PN. *Clinical Pharmacology*, Churchill Livingstone 5th Edition;771.

⁶³ Fertility Care, Glasgow. Minutes 6.3.2001

⁶⁴ *Journal of Family Planning and Reproductive Health Care* 2001;27:197-202

⁶⁵ Task Force on Postovulatory Methods of Fertility Regulation. *Lancet* 1998; **352**: 428 - 433.

⁶⁶ Von Hertzen H. Task Force on Postovulatory Methods of Fertility Regulation. *Contraception*. 61(5): 303-8, 2000 May.

⁶⁷ Task Force on Postovulatory Methods of Fertility Regulation. *Lancet* 1998; **352**: 428 - 433.

is a commendable objective, it is not the only problem. Use of the morning-after pill will do nothing to protect against STIs; but in fact due to changed expectations, may only serve to worsen the situation. Looking at the figures below, a woman is much more likely to get a STI than get pregnant.

Inadequate follow-up in Primary Care is a major concern. Those taking the morning-after pill as an emergency measure are already recognised to be an “at risk population”, requiring to be screened for Chlamydia. Teenagers are also vulnerable because they are more prone to contracting infections.

According to the Alan Guttmacher Institute, there are biological factors which heighten the risk of STIs for young women in their teens: ‘Young women contract STIs more easily than adults because they have fewer protective antibodies and the immaturity of their cervix facilitates the transmission of an infection.’⁶⁸ Younger sexually active people are also more likely to have more than one partner.⁶⁹

According to “Teenage Pregnancy”⁷⁰ “In a single act of unprotected sex with an infected partner, teenage women have a 1 per cent chance of acquiring HIV, a 30 per cent risk of getting genital herpes and a 50 per cent chance of contracting gonorrhoea.” Despite the Swedish tradition of a liberal and supportive approach towards adolescent sexual relations, and a network of youth health clinics, teenage abortion rates and chlamydial infections are rising steeply in Sweden.⁷¹

In Scotland:

- 23.3 per cent of STIs diagnosed in females were in patients aged under 20 years old.⁷²
- The latest figures from the Scottish Health Statistics show that 73.4% of STIs diagnosed in females were in patients aged under 25 years old.⁷³

Table 2. Diagnoses in women, in Scotland, July to September 2004.

	All	age <25
Chlamydia	2494	1885
Gonorrhoea	50	35
H Simplex	255	134
Total	2799	2054

In Scotland there has been a doubling of the rates of Herpes and Gonorrhoea and a four-fold increase in Chlamydia in the past ten years (1993-2003)⁷⁴, see Table 3 and Figures 1 & 2. Only in Chlamydia is it thought that the rise may be partly due to improved diagnostic techniques.⁷⁵

⁶⁸ Alan Guttmacher Institute. *Sexually Transmitted Diseases Hamper Development Efforts*. AGI, 1998 http://www.agi-usa.org/pubs/ib_std.html

⁶⁹ Dawe F, Meltzer H. *Contraception and Sexual Health*, 1999. London:HMSO, 2001

⁷⁰ Report by the Social exclusion Unit June 1999 Cm 4342 7.1 page 49

⁷¹ <http://sti.bmjournals.com/cgi/content/full/78/5/352>

⁷² ISD Scottish Statistics 2000 <http://www.show.scot.nhs.uk/isd/>

⁷³ <http://www.show.scot.nhs.uk/scieh/>

⁷⁴ <http://www.show.scot.nhs.uk/scieh/PDF/pdf2004/0446.pdf>

⁷⁵ Indeed, it should be noted also that only limited comparisons of the data, spanning the previous ten years, can be made because of a change in test technology. Almost all laboratories adopted the use of nucleic acid-based tests in the late 1990s; this initiative resulted in increased detection rates. <http://www.show.scot.nhs.uk/scieh/>

Table 3. Diagnoses in Scotland 1993 to 2003 (see Figures 2 & 3).

	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003
Chlamydia	2973	2937	2685	3181	3705	4928	5690	7654	10636	12392	14407
Herpes	634	695	820	816	740	788	937	910	1033	940	1310
Gonorrhoea	463	326	424	503	455	469	539	848	817	821	825

One STI, Chlamydia, affects teenage girls more than any other age group. It is the biggest cause of ectopic pregnancy, and can lead to infertility. The disease may be symptomless in up to 70% of infected women, and in 4-11% of infected men. The protocol for the management of Chlamydia recommends that 'all women requiring Emergency Contraception should be tested /screened for the infection'. They are seen as an 'at risk' population⁷⁶. The distribution of the morning-after pill over the counter is likely to severely curtail follow-up. An Edinburgh study based in primary care identified prevalence rates of chlamydia of between 5.3% and 7.6% in women attending for emergency contraception (Kettle *et al.*, 2002).

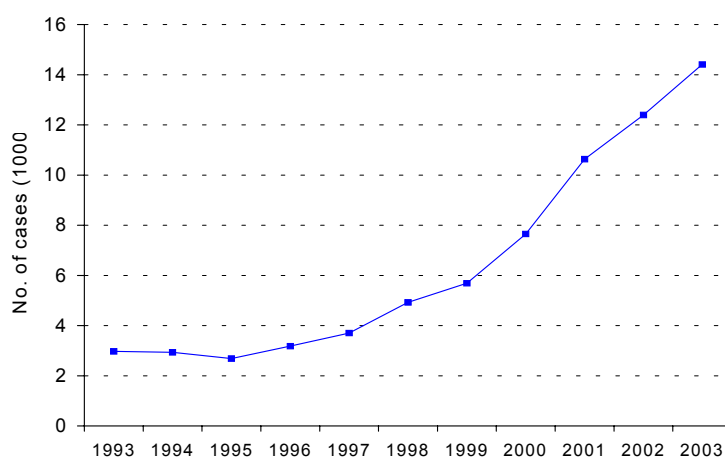


Figure 2: Incidence of Chlamydia infections, 1993 to 2003.

Gonorrhoea: Numbers of diagnoses of gonorrhoea dropped dramatically between 1985 and 1994; from 4,691 to 272. But since 1994 there has been a sudden increase in this disease among teenagers, particularly among girls under 16⁷⁷. Sixteen- to nineteen-year-olds have the highest rate of increase in gonorrhoea of any age group, with a 45% increase in new cases in 1995-1997 alone.⁷⁸ It is a disease associated with transmission between people who change partners frequently (core groups: teenagers and homo/bisexuals).

Genital Herpes continues to rise dramatically. This can be a devastating disease due to the pain and its lifelong recurrence, in the same way as cold sores.

Genital Warts: The highest age specific incidence of this disease is found in girls' aged 16-19. The prevalence of genital warts among teenagers has increased by a quarter between 1995-1997. Infection with certain strains of Human Papilloma Virus (HPV) has been linked to cervical abnormalities and the development of cervical cancer. It is also linked to early sexual activity.

⁷⁶ Dr S Ahmed et al, Management of Genital Chlamydia Trachomatis infection in Glasgow, April 2001

⁷⁷ ISD Scottish Statistics 2000 <http://www.show.scot.nhs.uk/isd/>

⁷⁸ Genitourinary Medicine April 1997

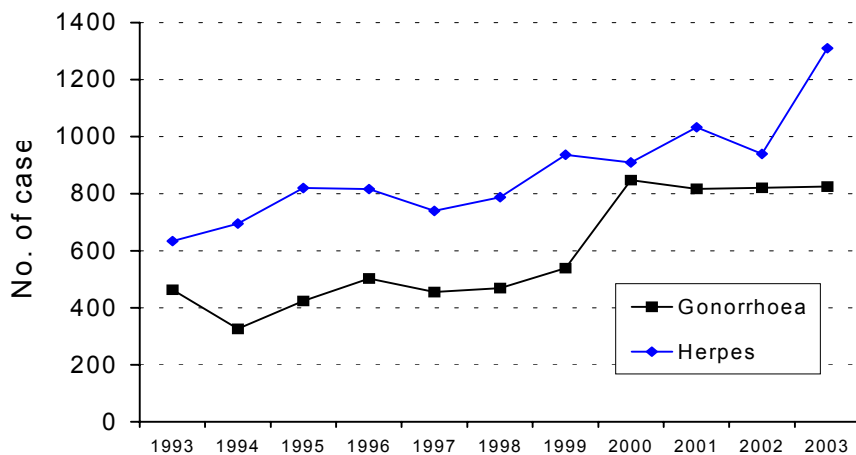


Figure 3: Incidence of Gonorrhoea and Herpes, 1993 to 2003.

HIV: The spread of this disease has far exceeded expectations, (see Figure 4).⁷⁹ More people are vulnerable to infection as it spreads to the heterosexual population.

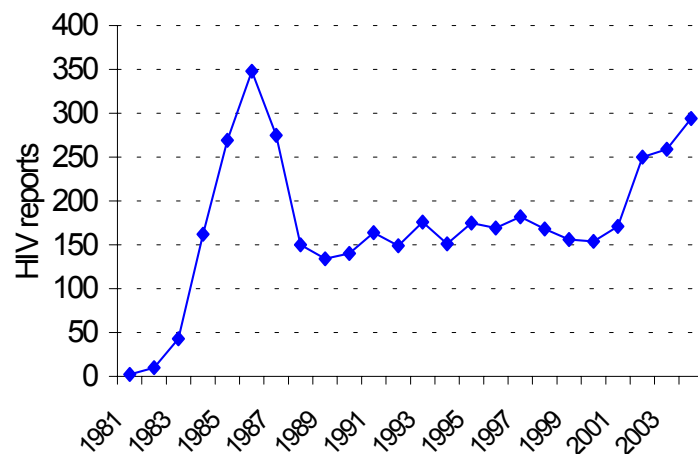


Figure 4: New HIV diagnoses

There is a fear that the epidemic currently hitting some African countries, which is linked to having multiple sexual partners, will arrive here. It is interesting to note that the epidemic is not affecting all countries in Africa. Muslim countries, where there is less extra-marital intercourse, are not affected. In 1991, the infection rate in Uganda was 21%. Now, after years of a simple, low-cost program called ABC, it has dropped to about 6%. ABC stands for Abstain, Be faithful, or use Condoms if A and B are not practised.⁸⁰

Sperm have a diameter of 50 microns. Naturally occurring holes in the wall of a latex condom have a diameter of 1 micron. The HIV retrovirus, which causes AIDS, has a diameter of 0.1 microns. To illustrate the difference in size between a sperm and the infective agent, the graphic comparison of an ant crawling on a basketball has been made⁸¹. AIDS viruses swim

⁷⁹ data taken from <http://www.show.scot.nhs.uk/scieh/> Table A1 HIV reports, Scotland by transmission category and year of report; as at 31 December 2003 [A1 2003.pdf] and 25 January 2005 Volume 39 No. 2005/03 ISSN 1357-4493 [0503.pdf]

⁸⁰ <http://www.mercatornet.com/content/view/86/0/>

⁸¹ <http://www.Abortionfacts.com>

freely through the holes in a condom⁸². That is a fact that should be widely publicised. This is substantiated by the fact that, following the recent drive to promote condom use, the prevalence of STIs caused by large bacteria such as Gonorrhoea has stabilised, whereas that of smaller organisms such as Chlamydia, Herpes and HIV have not (see Figures 1-4). It seems that size does matter.

Cervical Cancer⁸³ As the teenage cervix is not fully developed, there are possible health risks to the immature cervix. We do not know what risks the younger generation are exposing themselves to by engaging in early sexual intercourse and increased possibility of multiple partners (see Figure 5).

“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.”

Dr Anne Szarewski (Imperial Cancer Research Fund)⁸⁴

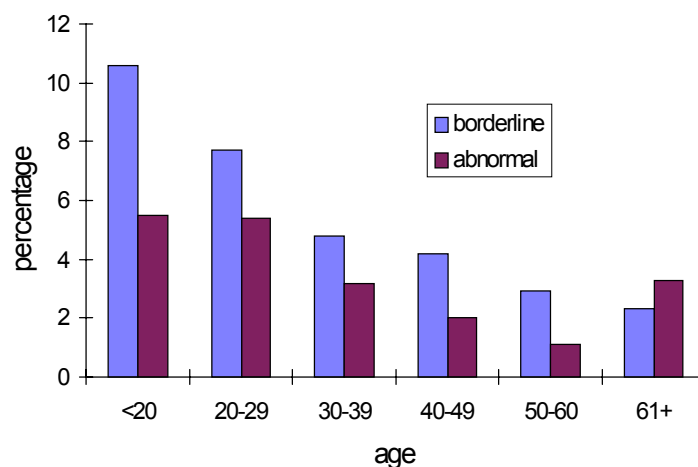


Figure 5: Borderline and abnormal cervical smears GGHB 1998.

4. THE MEDICAL AND SOCIAL EFFICACY – DOES IT WORK?

‘The need to visit a doctor imbued the morning-after pill with a gravity which was both medical and moral.’⁸⁵ The increased ease of availability may create a more relaxed and less premeditated approach to sexual encounters. This may lead to increased promiscuity.

4.1 Medical efficacy

“It is very difficult to gain precise figures about the number of people who have used Emergency Contraception and if they have used it properly. There has never been a placebo-controlled trial of emergency contraception, so its efficacy can only be estimated. Calculations used to arrive at estimates of efficacy are inevitably based on poor quality data.”⁸⁶ In the Task Force trial, it was estimated that *Levonelle* prevents 85% of expected pregnancies⁸⁷. The study only compared two types of morning-after pill and it is not known

⁸² Kelly J. Using condoms to prevent transmission of HIV. *BMJ* 1996; 312:1478a-1478.

⁸³ A Report from the Department of Public Health GGHB CERVICAL SCREENING PROGRAMME ANNUAL REPORT 1998,(distributed May 2000)

⁸⁴ *Cytopathology* & Dr Anne Szarewski, Imperial Cancer Research Fund

⁸⁵ The Problem Pill, Editorial, *The Daily Telegraph* 2.1.01

⁸⁶ Glasier A., The Science of Emergency Contraception, Abstract. *Annual Symposium, Faculty Of Family Planning & Reproductive Health Care, Royal College Of Obstetricians & Gynaecologists* 18th May 2001

⁸⁷ Task Force on Postovulatory Methods of Fertility Regulation. *Lancet* 1998; **352**: 428 - 433.

what the pregnancy rate would have been in the diverse populations studied if the morning-after pill had not been used, as there was no control group. There are several reasons why the trial may not be applicable to the daily reality, where there is less control:

1. The average age of the women was 27 years and so the accuracy of the history of the last menstrual period and the last episode of sexual intercourse, understanding, compliance and reliability will be very much better than the history given by teenagers.
2. It was a multi-centre trial with 21 different teams of observers and some of the data was suspect.⁸⁸
3. The results were based on the assumption of accurate verbal histories from the participants – however other studies have shown how notoriously inaccurate women are at recalling the date of their last menstrual period.^{89 90}
4. It is impossible to tell if a pregnancy resulting from failed morning-after pill originated from the act of intercourse for which the pills were taken.
5. The results of the pregnancy tests of the majority of those entering the trial were not revealed. This calls into question the good ethical standing of the trial.
6. 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.
7. The chance of pregnancy for an individual woman who has intercourse at her most fertile time may be considerably higher.

Professor Anna Glasier, NHS Lothian's clinical director for sexual health, says that the FPA, formerly known as the family planning association, have overstated the effectiveness of the morning-after pill by emphasising that it is effective in 95 per cent of cases. She also hit out at the wide availability of the drug, and the willingness of doctors to prescribe it, which she says has encouraged young girls in particular to view it as an alternative method of contraception⁹¹.

The results of a recent study suggest that widespread distribution of advanced supplies of the morning-after pill through health services may not be an effective way to reduce the incidence of unintended pregnancy in the UK⁹². No effect on abortion rates has been demonstrated.

4.2 Social efficacy

Another commonly held view for which there is no documented evidence is that improving knowledge about and access to Emergency Contraception will reduce the number of teenage pregnancies. 'The UK experience does not provide evidence that improving access to family planning will, in itself, be successful in reducing the rate of under-age conceptions.'⁹³ Alison Strath, General Secretary of the Royal College of Pharmacists recently made a tacit admission of this fact when she said that: "We don't know if (the free distribution of the

⁸⁸ Glasier A., The Science of Emergency Contraception, Lecture. *Annual Symposium, Faculty Of Family Planning & Reproductive Health Care, Royal College Of Obstetricians & Gynaecologists* 18th May 2001

⁸⁹ Stirling, A 2000. University of Edinburgh.

⁹⁰ Vollmann 1977 University of Edinburgh.

⁹¹ Wed 3 Aug 2005 Health body 'too positive' about effects of morning after pill. Michael Blackley <http://thescotsman.scotsman.com/index.cfm?id=1720052005>

⁹² A. Glasier, K. Fairhurst, S. Wyke, S. Ziebland, P. Seaman, J. Walker, and F. Lakha. Advanced provision of emergency contraception does not reduce abortion rates. *Contraception* 69 (5):361-366, 2004.

⁹³ Paton D, The Economics Of Family Planning And Underage Conceptions *Journal of Health Economics*, 2002, 21, 2 (March), 27-45)

morning-after pill) reduces teenage pregnancy⁹⁴ (our emphasis). Experience of use so far does not give any evidence of effectiveness. Prescribing rates of the morning-after pill have multiplied steadily in Scotland while there has been no observed decline in the rate of teenage pregnancies or abortions (Figure 6).⁹⁵

Analysis of data on contraceptive practice for women aged 16-49 years in the period 2000-2 was carried out in the Omnibus Survey, a multipurpose survey in which around 7600 adults living in private households are interviewed each year. One striking development was the change in where women obtained the morning-after pill. The proportion of women reporting that they obtained it from pharmacies increased to a third, and the proportion who said they obtained it from other sources fell.⁹⁶ The total rate of use was unchanged.

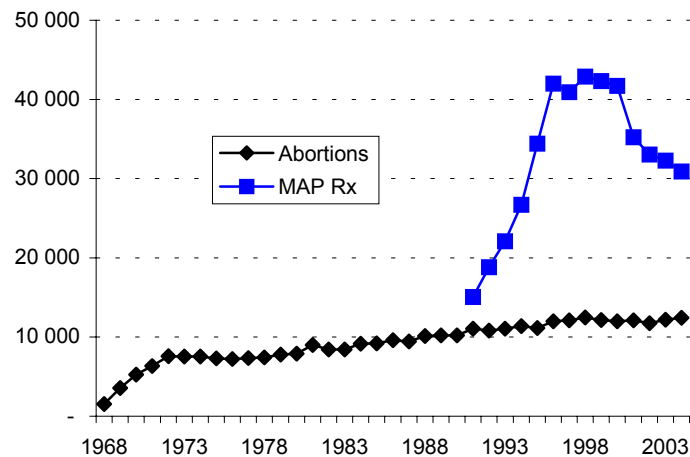


Figure 6: Numbers of abortions and prescriptions for the morning-after pill.

Figure 6 clearly shows there has been a steady rise in the annual number of abortions in Scotland. It also shows that the substantial increase in prescription of morning-after pill since 1990 has had almost no effect on the overall number of teenage pregnancies. The decrease in the number of prescriptions for the morning-after pill in recent years is due to its increased availability over the counter and other sources (see the Omnibus survey below).

Similar statistics are emerging Britain-wide.

The interpretation of these results could be that there are more failures in contraception (see above) with increased use of condoms. Alternatively it could be that people are taking part in more unpremeditated sexual activity.

The condom has been promoted widely and statistics in Scotland show its use to be increasing especially among the young. This is evidenced by it being the preferred method in family planning clinics in Scotland.⁹⁷ Contraceptive failures are more common in the young. Indeed, research from the Alan Guttmacher Institute (run by the Planned Parenthood Federation) recently confirmed that 57.5% of a control group of 10,000 women, who had had abortions, were using a contraceptive the month they became pregnant. It is not surprising

⁹⁴ The Daily Mail 18th September 2001 (My Italics): "We don't know if this reduces teenage pregnancies, but other pilot schemes have shown that women like the pharmacist as a point of access for emergency contraception, and that it should therefore be freely available."

⁹⁵ *Prescribing of Levonelle, Levonelle2 and Schering PC4 in Scotland - calendar years 1989 to 2003* Bill Gold, Healthcare Information Group, Information Services, Gyle Square, 1 South Gyle Crescent, Edinburgh, EH12 9EB
Abortion Statistics: http://www.isdscotland.org/isd/files/mat_aas_chart1.xls

⁹⁶ Cicely Marston, Howard Meltzer, and Azeem Majeed Impact on contraceptive practice of making emergency hormonal contraception available over the counter in Great Britain: repeated cross sectional surveys *BMJ* 2005; 331: 271

⁹⁷ ISD Scottish Statistics 2000 <http://www.show.scot.nhs.uk/isd/>

that teenage girls accounted for a large percentage of this group.⁹⁸ Condom mishaps account for half of the requests for the morning-after pill⁹⁹.

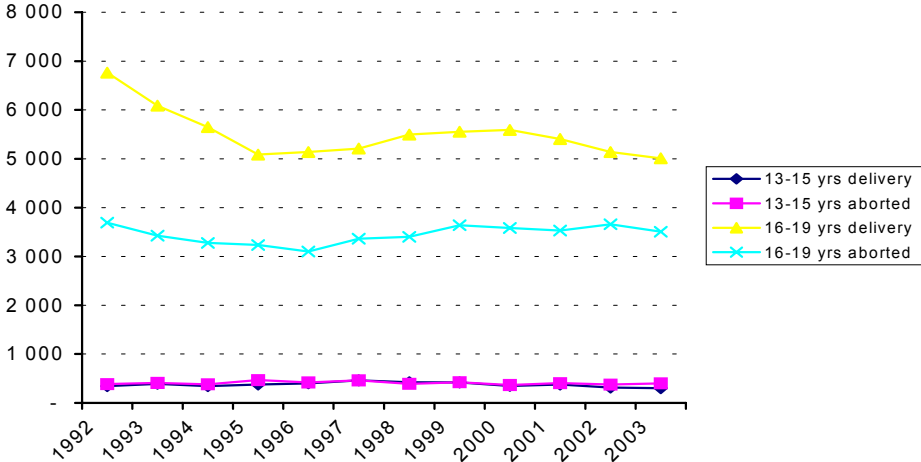


Figure 7: Teenage pregnancy outcome.

Despite policy focus in the white paper *Towards a Healthier Scotland* and a headline target to reduce teenage pregnancy among 13-15 year olds by 20% between 1995 and 2010, there has been little change so far. Not all teenage pregnancies are unwanted. In fact the figures show that more teenagers opt to keep their pregnancies rather than abort¹⁰⁰.

The ISD reports ‘teenage pregnancy’ for two age groups, 13-15 years and 16-19.

The delivery rate among the 16-19 age group went down before, but not since, the introduction of the morning-after pill. There has been no reduction in the abortion rate. The abortion and delivery rates have remained steady for the 13-15 year-olds who were targeted by the policy. Perhaps policy makers should be looking at alternative ways to reduce the small numbers of unwanted pregnancies in 13-15 year-olds.

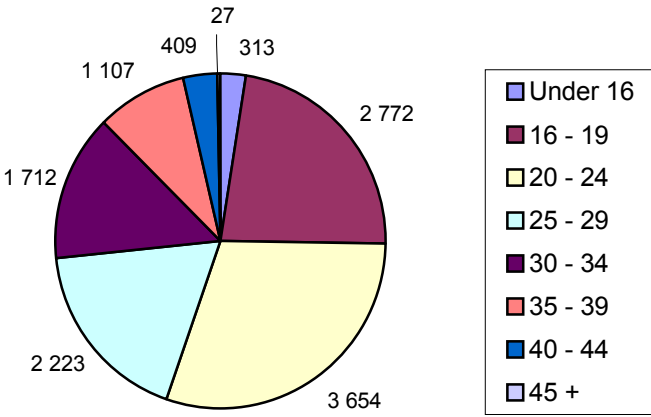


Figure 8: Number of abortions in Scotland in 2003, by age.

⁹⁸ S. Henshaw, *Fam. Plan. Perspect.* Vol. 28, No. 4, July/Aug. 1996.
⁹⁹ *Journal of Family Planning and Reproductive Health Care* 2001;27:197-202
¹⁰⁰ ISD Scottish Statistics 2004 <http://www.isdscotland.org/isd/>

Much is made of teenage unwanted pregnancies in the press and by those promoting the morning-after pill; but when compared to total abortions, those in the under-16s form a very small percentage.¹⁰¹ (Figure 8)¹⁰²

Most unwanted pregnancies are in 20-30 year-olds.

There is clear evidence that teenage pregnancy is associated with one-parent families^{103, 104} and socio-economic deprivation.¹⁰⁵ Primary prevention could be aimed at tackling the problem of deprivation. Both these factors could be targeted by family-friendly legislation. Poland has witnessed a dramatic reduction in the number of abortions since the fall of communism, with no increase in maternal deaths or stillbirths and no evidence of back-street abortion.¹⁰⁶

5. THE IMPLICATIONS OF INCREASING ACCESS TO THE MORNING-AFTER PILL

5.1 Lack of follow-up

Until recently the ability of GPs to give follow-up medical advice and support to women who use the morning-after pill has been the principal means adopted by the Government Committee on the Safety of Medicines of monitoring the short- and long-term effects of all 'prescription only medication'.

Improving access to health education and contraceptive services is seen as the principal way to reduce teenage pregnancy.¹⁰⁷ The distribution of the morning-after pill 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. Regulations that came into effect in 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"¹⁰⁸. This will not help those who need counselling and support. This may not be just for issues surrounding their physical health, such as infection, but also for emotional support following cases of rape or women in abusive relationships.

The recommendations were tested in a pilot study in the Manchester area under a protocol, known as a *Patient Group Direction*. This comprised a series of basic personal and lifestyle questions designed to assess the suitability of the morning-after pill for women and girls over 16 years old.

The basic assumption that teenagers are reluctant to seek advice on the morning-after pill from their own GP, due to embarrassment or fears over confidentiality, is totally unproven. Indeed, of the scant research evidence available on the use of General Practice services by teenagers, in a study published in the British Medical Journal, Churchill¹⁰⁹ confirmed that:

1. Most teenagers who become pregnant *do* access general practice in the year before pregnancy, suggesting that potential barriers to care are less than often supposed.

¹⁰¹ ISD Scottish Statistics 2000 <http://www.show.scot.nhs.uk/isd/>

¹⁰² Abortions performed in Scotland -year ending 31 December 2003(provisional) http://www.isdscotland.org/isd/info3.jsp?pContentID=1919&p_applic=CCC&p_service=Content.show&

¹⁰³ Social Exclusion Unit. *Teenage pregnancy*. London: Stationery Office, 1999:33, fig 19.

¹⁰⁴ Blake SM, Simkin L, Ledsky R, Perkins C, Calabrese JM. Effects of parent-child communications intervention on young adolescents' risk for onset of early intercourse. *Fam Plan Perspect* 2001; 33: 52-61[[Medline](#)].

¹⁰⁵ Ref. Teenage mothers and their peers: a research challenge BJGP Oct 1998, **48**, 1685-1686

¹⁰⁶ Pro-life times Jan 2002

¹⁰⁷ NHS Centre for Reviews and Dissemination. Preventing and reducing the adverse effects of unintended teenage pregnancies. *Effective Health Care* 1997; 3: 1-12.

¹⁰⁸ Statutory Instrument No.3231 The Prescription Only Medicines (Human Use) Amendment (No.3) Order 2000

¹⁰⁹ Churchill D, Consultation patterns and provision of contraception in general practice before teenage pregnancy: case-control study, *BMJ* 2000;321:486-489 (19 August)

2. Teenagers who become pregnant have higher consultation rates than their age-matched peers, and most of the difference is owing to consultation for contraception.
3. Teenagers whose pregnancies end in terminations are more likely to have received emergency contraception before conception, emphasizing the need for adequate follow-up.

Teenagers who choose the morning-after pill, 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. This emphasizes the importance of appropriate follow-up to address long-term needs whenever a teenager consults for this reason. It also raises questions about the possible supply of emergency contraception by agencies that are unable to provide such follow-up.

5.2 Family implications

This policy 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. The role of nurses is also being extended.¹¹⁰ If the morning-after pill were to be available at school to the under 16s this would be a further erosion of parental rights.

If a nurse prescribed the morning-after pill to a child without parental knowledge or consent, and the child became ill or died as a result, the nurse might be open to prosecution or to legal action for negligence¹¹¹, particularly since the drug would be prescribed without access to the child's medical records. This raises questions of indemnity. Health ministers have stated that in the event of medical complications arising as a result of its supply by school staff, potential liability would be covered by the arrangements of the NHS body operating the Patient Group Direction under which it was being dispensed.¹¹² The availability of the morning-after pill in schools runs counter to the government's good practice guide with regard to the supply of any other medical treatment in schools.

Official guidance states that:

- 'Parents or guardians have prime responsibility for their child's health and should provide schools with information about their child's medical condition.'
- 'Parents' cultural and religious views should always be respected.'
- There should be 'prior written agreement from parents or guardians for any medication, prescribed or non-prescription, to be given to a child'.
- 'School staff should generally not give non-prescribed medication to pupils [e.g. aspirin and paracetamol]. They may not know whether the pupil has taken a previous dose, or whether the medication may react with other medication being taken.'
- 'No pupil under the age of 16 should be given medication without his or her parent's written consent.'¹¹³

This guidance is completely overlooked concerning supply of the morning-after pill in a school context.

Clearly, teenagers who opt for contraception to avoid pregnancy are at an even greater risk of pregnancy than those who abstain from sexual intercourse, especially with the apparent unreliability of the condom as discussed above.

¹¹⁰ Nursing for Health, Scottish Executive. A Review of the contribution of Nurses Midwives and Health Visitors to improving the Public's Health in Scotland. 20.3.2001

¹¹¹ if there was no valid consent under The Age of legal Capacity (Scotland) Act 1991

¹¹² HC Debate (2000-01) 363, written answers, col.31.

¹¹³ Department for Education & Employment, Department of Health. *Supporting Pupils with Medical Needs: A good practice guide*. London:HMSO 1996.

With programs already promoting the morning-after pill in schools there is a danger of embarking on an experiment, which could have lasting adverse effects on the lives of young people and their future relationships. Many sex education programmes do not limit themselves to promoting contraception but are also giving information about what is called 'emergency contraception'. The message, which gets transmitted to youngsters, is that there is no need to 'say NO', but that they are being responsible, as long as they do not get pregnant. The reduction in 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 more we provide safeguards the more risks and unpremeditated sexual encounters take place. The ready availability of these emergency methods may increase chaos in some people's lives.

5.3 Social implications

From 1981-5 to 1991-5 rates of teenage pregnancy in Scotland increased more rapidly in areas of greater socioeconomic deprivation. In the 1990s socioeconomic deprivation explained more than 50% of local variation in rates of teenage pregnancy, more than double the amount explained by it in the 1980s¹¹⁴. These findings were independent of variations in provision of contraceptive services.

There is a well-established link between one-parent families and teenage pregnancy, which is graphically illustrated by (although not highlighted in the text of) the 1999 social exclusion report on teenage pregnancy^{115, 116}. Young people aged 14-17 who live in a two-parent family are less likely to have ever had sexual intercourse than young people living in any other family arrangement, even after adjusting for potentially confounding factors such as race, age, and socioeconomic deprivation.¹¹⁷

Further research on indicators of deprivation showed that teenage pregnancies correlate with these indicators:¹¹⁸

- 5 or more members in the family
- unemployed person in house
- rented home
- no car owner at home
- parents separated or divorced
- less than 7 GCSE passes
- smoker

Britain's rate of teenage pregnancy is usually described as being "the worst in Europe". The new guidelines from the UK Department of Education and Employment place the emphasis on contraception rather than encouraging abstinence, which is not even mentioned.¹¹⁹

Some try to compare our situation to that of the Dutch; but they are very different to us in many ways. The nature of family life in Holland means that youngsters tend to stay at home longer than in Britain. The Dutch also employ heavy disincentives to teenage parenthood, as the state provides neither housing nor benefits for the unmarried mother. There are no state-funded contraception services either¹²⁰. This may be one reason for the disparity between teenage pregnancy rates in Holland and the U.K.

¹¹⁴ McLeod, A Changing patterns of teenage pregnancy: population based study of small areas *BMJ* 2001;323:199-203 (28 July)

¹¹⁵ Social Exclusion Unit. *Teenage pregnancy*. London: Stationery Office, 1999:33, fig 19.

¹¹⁶ Letters, Teenage pregnancies are influenced by family structure *BMJ* 2002;324:51 (5 January).

¹¹⁷ Blake SM, Simkin L, Ledsky R, Perkins C, Calabrese JM. Effects of parent-child communications intervention on young adolescents' risk for onset of early intercourse. *Fam Plan Perspect* 2001; 33: 52-61 [[Medline](#)].

¹¹⁸ Ref. Teenage mothers and their peers: a research challenge *BJGP* Oct 1998, **48**, 1685-1686

¹¹⁹ The Sex & Relationships Guidance (D. of E. E. 0116/2000) (2.1 0)

¹²⁰ Family Planning Perspectives March/April 1996

There is a 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. The consequences of any irresponsibility may not need to be faced. 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.¹²¹ There is a danger of increased pressure upon abstinent youth. The morning-after pill appeals psychologically because it requires neither a conscious decision to remain abstinent nor advance planning for a sexual act.¹²²

The effect on behaviour and attitudes towards family planning in the population needs to be assessed. One leading Director of Public Health Medicine commented: "The answer is not more contraception or emergency contraception, but a change in attitude towards sexual behaviour."¹²³ The widespread promotion of contraceptive *education* seems only to have resulted in *increased* teenage sexual activity.

In New York this has now become a political issue and Governor George Pataki vetoed legislation that would have allowed pharmacists to dispense the so-called 'morning-after pill' without prescriptions. "We can do better [than this bill]," Pataki said. "I happen to think that it is simply wrong that a 12 or 13-year-old girl would have access to prescription medication with no medical supervision at all, which would be the case under this bill." The Governor said he wanted a limit on the number of pills that could be dispensed at one time and did not want men to be able to get them, as would have been permitted under the vetoed legislation.¹²⁴

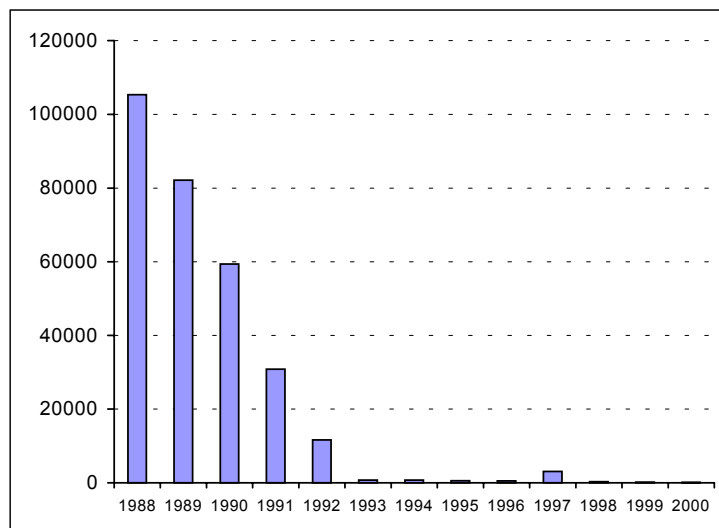


Figure 9: Legal abortions in Poland.

Poland has witnessed a dramatic reduction in the number of abortions (See Figure 9). In 1988 there were over 100,000 abortions in Poland. However, after the fall of communism and before the change in the legal situation, the number began to decline markedly so that by 1992, the year before new anti-abortion laws, there were only 11,640 abortions. When the restrictive abortion law was abolished for one year in 1997, the climate had changed to such an extent that only 3,047 women obtained abortions even though the procedure was available virtually on demand. In 2000, there were only 138 legal abortions performed in Poland. There has been no increase in maternal deaths or stillbirths and no evidence of

¹²¹ Mellanby AR, Phelps FA et al Schools sex education:an experimental programme with educational and medical benefit *BMJ*. 1995, 311 p414-417

¹²² Emergency Contraceptive Pills," Population Reports, Series A, Number 9. Available at: www.infoforhealth.org/pr/a9/a9ecp.shtml

¹²³ Williams ES. The contraceptive failure may be a major factor in teenage pregnancy. *BMJ* 1995; 311:806-7.

¹²⁴ www.cnn.com/2005/POLITICS/08/05/pataki.veto.ap/

back-street abortion.¹²⁵ Perhaps the social environment, which encouraged this change should be studied so that this phenomenon can be followed elsewhere.

6. ETHICS AND THE MORNING-AFTER PILL

6.1 How are GPs and pharmacists affected?

Recent changes made to the Code of Ethics governing the work of pharmacists require that: "Before accepting employment, pharmacists must disclose any factors which may affect their ability to provide services."¹²⁶ This change has had severe and immediate implications for those who have a conscientious objection (whether practical or ethical) to the morning-after pill, in eliminating the legal status of the official Conscience Clause that all medical professionals have the right to invoke. In theory, it may be possible for a pharmacist (or a GP for that matter) to refer the request to a colleague who has no objection to dispensing the morning-after pill. However the new Guidelines make it *practically* impossible to opt out when the role of dispensing is included in the official job description for the position. In other words, opting out is now a "sackable offence".

The Guidance¹²⁷ to pharmacists sets out to address the specific issues that should be explored with the client to ensure safe and appropriate supply in accordance with the required professional standards. This is edited below:

Pharmacists:

- Must deal with the request personally.
- Only in exceptional circumstances ... supply the product to a person other than the patient ... not normally ... where ... suspects abuse or non-consensual sex.
- Should use their professional judgement to decide whether they believe the supply is both necessary and in the woman's best interest.
- Make every reasonable effort to satisfy themselves that women are aged 16 years or over.

Despite these precautions there is an obvious risk of giving falsified personal information to a pharmacist, demonstrated in the high profile case of a 14-year-old who was able to obtain the morning-after pill over the counter¹²⁸.

In Illinois, a Governor who issued an executive order forcing all pharmacists to fill all prescriptions for legal drugs, including the morning-after pill, faces three lawsuits from several pharmacists in the state seeking to overturn the order.¹²⁹

Other professionals are also affected. In the United States, a nurse has filed a Federal lawsuit, contending she was demoted because she refused to dispense Emergency Contraception.¹³⁰

Clinicians must realise that people who are asking for the morning-after pill are often in difficult situations and are suffering as a consequence; they need to deal with these patients with compassion and understanding. If a clinician has an ethical objection to prescribing any

¹²⁵ Pro-life times Jan 2002

¹²⁶ Code of Ethics Part 2A.1k *Pharmaceutical Journal* 28th April 2001.

¹²⁷ *Practice guidance on the supply of emergency hormonal contraception as a pharmacy medicine* Practice Division of the Royal Pharmaceutical Society of Great Britain (RPSGB). September 2004 Lorraine Fearon <http://www.rpsgb.org.uk/pdfs/ehcguid.pdf>

¹²⁸ Pro-Life Times Nov 2000

¹²⁹ Gov. Rod Blagojevich *July 26, 2005 Congress Holds Hearing on Pharmacists and Morning After Pill* <http://www.lifenews.com/nat1478.html>

¹³⁰ Nurse sues parish hospital June 29, 2005 The Times-Picayune <http://www.nola.com/news/t-p/frontpage/index.ssf?base/news-3/112002454775100.xml>

medication, which may work by causing an abortion, he or she has an obligation to inform the patient and not to misguide. This may just be a matter of clarifying the position adopted, but does not require a full explanation of the ethical or moral reasons to the patient.

A prescribing doctor has the opportunity to fully inform a woman of the possible abortifacient action of the morning-after pill during the consultation, which, in turn, allows her the possibility to withdraw or give consent. Pharmacists or other agencies may not have the privacy or time to discuss this fully.

6.2 Valid consent

The law governing the age for consent is different in different countries, those for the UK are set out below.

In the UK, people under the age of 16 years can consent to medical treatment if they have sufficient maturity and judgment to enable them to fully understand what is proposed.

In England and Wales, it is lawful to provide contraceptive advice and treatment without parental consent, provided that the practitioner is satisfied that the following **Fraser Guideline criteria**¹³¹ are met:

- The young person understands the practitioner's advice.
- The young person cannot be persuaded to inform his or her parents or allow the practitioner to inform the parents that contraceptive advice has been sought.
- The young person is likely to begin or to continue having intercourse with or without contraceptive treatment.
- Unless he or she receives contraceptive advice or treatment, the young person's physical or mental health or both are likely to suffer.
- The young person's best interest requires the practitioner to give contraceptive advice, treatment, or both without parental consent.

In Scotland, statutory provision by way of The Age of Legal Capacity Act 1991 applies similar criteria. The Act actually appears to assign more legal rights to children under 16 years, in that parents cannot authorise procedures a competent child has refused.¹³²

6.3 Informed consent

Due to the uncertainty of the mode of action in any particular case, there is a possibility that the morning-after pill 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. It is certainly the doctor's or nurse's obligation to inform patients of choices available. Patient empowerment and the principle of respecting autonomy are based on the simple principle of giving the information that a reasonable person in the circumstance would want to know or should be in a position to know in order to make a properly informed choice.

6.4 Use in extreme cases for those not wanting to cause an abortion

The use of the morning-after pill in a girl who has been raped has been discussed as an extra-ordinary 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

¹³¹ Teenage Pregnancy Unit (2001) Guidance for the field social workers, residential social workers and foster carers providing information and referring young people to contraception and sexual health services. Department of Health. www.dh.gov.uk [Accessed: 29-4-2004]. [Full text]

¹³² <http://www.prodigy.nhs.uk/guidance.asp?gt=Contraception - emergency>

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, therefore, seeks help to protect herself from pregnancy. 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 morning-after pill be justified, if there is a risk of causing an abortion?

Some will 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 justified.

The principle of double effect and medical ethics.¹³³

The doctrine 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:

- a) the action itself is good,
- b) its perpetrator's intention is solely to produce the good effect,
- c) the good effect is not achieved through the bad, and
- d) there is sufficient reason to permit the bad effect.

However, if there is reasonable doubt about the mode of action of the medication, this may be difficult to justify. The 'possible abortifacient effect of the "morning-after pill" cannot be classified blithely as an "unforeseen" effect of its use'.¹³⁴ It has to be admitted at the present state of knowledge that the possibility of it causing an abortion is real.

The desired effect of a pregnancy not coming to fruition is legitimate if the pregnancy is truly prevented. However the administered hormones may not produce a good effect if the action is to terminate a pregnancy. In fact, if the latter happens, the effect achieved is bad. The bad effect may not be intended as the means but it may end up being the mechanism (means). Whilst it is true that a woman, in taking a 'morning-after pill' following a recent rape, need not *intend* to cause an abortion, in bringing about a fatally inhospitable environment for any newly conceived child she, and those who treat her, are morally obliged to take into account the risk at which they place such a child.¹³⁵

An action cannot simply be justified by saying we are intentionally 'trying to prevent a pregnancy'. This is because, in reference to the principle of double effect, the good effect will be achieved by the bad. It 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, that 'she may not have been pregnant anyway'. The fact that a life has been taken remains a fact, even if this is never known to be the case, by the woman or clinician.

The greater the risk of negative consequences, the less an action becomes ethical. If the negative consequence of the morning-after pill were only the fact that a person would have to remain in hospital for 48 hrs then most people would accept the procedure. However, with the morning-after pill the negative consequence is often the killing of a person and is therefore seen as unacceptable (and disproportional) to the benefits. In this case, not having a child cannot compensate the negative action of killing a person.

¹³³ Gillon R. The principle of double effect and medical ethics. Br Med J (Clin Res Ed). 1986 Jan 18;292(6514):193-4.

http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=3080130&dopt=Abstract

¹³⁴ <http://www.linacre.org/frames.html>

¹³⁵ id

In order for her action, or the action of her doctor to be legitimate, she must not do something evil to obtain the good, but has to consider the possibility of a new life and the consequent human rights. For this reason, efforts should be made to reduce this risk as much as possible.

It has been suggested that, if it is used at a precise time before ovulation, there will be more chance of preventing a pregnancy rather than interrupting it. 'Once she has started to ovulate, then she should not use this method of avoiding pregnancy because of the *increased* risk of there being a fertilized egg.'¹³⁶ The clinician may therefore start to enquire about the timing of her cycles in order to establish the timing of ovulation. It is only fair for the clinician to tell the patient *why* he or she is asking so many questions.

The 'ovulation-testing method'¹³⁷ attempts to ascertain whether any new conception is likely to result from the recent assault. 'In this method, "emergency contraception" is offered only if the pregnancy test is negative *and* empirical and personal data indicate that the woman is not at or near the time of ovulation. The simple testing 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.'¹³⁸ If the timing is right it may be possible to prescribe, but if on the other hand she has either already ovulated or if she is about to, then the position is made more difficult.

In reality, few women know their cycle sufficiently well to be able to determine the time of ovulation. The clinician may not wish to take the risk if she sincerely does not know. Science would have to advance before we can be certain in each particular case.

Another aspect to consider is that if someone is desperate to receive the morning-after pill, this is creating an opportunity for the girl to give a 'wise' answer.

6.5 Funding

Another ethical problem to consider is that public funding is used to fund these policies. This forces taxpayers who object in conscience to abortifacients, to subsidise the morning-after pill's routine use.¹³⁹

Economically, the use of this medication makes no sense. Rate of morning-after pill 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.

7. CONCLUSION

A look across 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 the morning-after pill.

There is now clear evidence that teenage pregnancy is associated with one-parent families and socio-economic deprivation. Current medical practice is evidence based and, through protocols, aims at excellence. Any method suggested for solving the problem of teenage unwanted pregnancy, needs to be properly evaluated. Primary prevention could be aimed at tackling the problem of deprivation. Places where a reduction in the number of abortions has occurred should be studied.

¹³⁶ Mallia, P., Email: pmallia@synapse.net.mt The use of emergency hormonal contraception in cases of rape personal communication. To be published in July 2005 in the *European Bioethics Review Reproductive and Genetics Ethics*.

¹³⁷ Details of a widely adopted protocol on ovulation testing are outlined in St Francis Medical Centre, "Interim Protocol, Sexual Assault: Contraceptive Treatment Component", Peoria, IL, (October 1995).

¹³⁸ <http://www.linacre.org/frames.html>

¹³⁹ Julie Wheeland, *Under The Table* Population Research Institute http://www.pop.org/under_the_table.pdf

The assumption that teenagers are going to engage in sexual intercourse before the age of consent, in itself makes it more likely. More should be done to help them delay sexual activity until they develop a certain level of physical and social maturity. This will enable them to form a mature and enduring relationship.¹⁴⁰

The policy adopted by Family Planning Agencies, of promoting the morning-after pill, could endanger the psychological well-being and family stability of the young generation. The doctors and pharmacists involved need to ask themselves what has been achieved.

¹⁴⁰ Informing choice - an SCHB report on sex education <http://www.schb.org.uk/>