

DEVELOPMENTS IN MEDICAL TECHNOLOGIES
FOR FERTILITY REGULATION AND THEIR
IMPLICATIONS FOR MEDICAL LEGISLATION

prepared by

Mr. Mostyn P. Embrey, MD, FRCS, FRCOG

Nuffield Department of Obstetrics and Gynaecology,
John Radcliffe Hospital, Oxford

for

THE COMMONWEALTH SECRETARIAT

DEVELOPMENTS IN MEDICAL TECHNOLOGIES FOR FERTILITY
REGULATION AND THEIR IMPLICATIONS FOR MEDICAL LEGISLATION

by Mr. Mostyn P. Embrey, Nuffield Department of Obstetrics and
Gynaecology, John Radcliffe Hospital, Oxford.

<u>CONTENTS</u>	<u>Page</u>
<u>Summary</u>	(i)
<u>Introduction</u>	1
<u>Elements of Human Reproduction</u>	1
<u>Current Medical Practice</u>	3
<u>Emerging Trends</u>	3
<u>New Technologies</u>	4
(i) Menstrual Extraction	4
(ii) Prostaglandins	5
(iii) Post-coital Steroids - 'Morning After' Pills	6
(iv) Intrauterine Devices (IUDs)	6
(v) Possible Future Developments	7
<u>Implications of New Technologies</u>	7
(i) Status of Menstrual Regulation	7
(ii) Pregnancy Diagnosis	8
(iii) Embryological Development	9
(iv) Merits of Early Abortion	9
(v) Gestation Limits	10
(vi) Abortion Services	11
(vii) An Arbitrary Distinction	12
<u>References</u>	12

DEVELOPMENTS IN MEDICAL TECHNOLOGIES FOR FERTILITY REGULATION AND THEIR IMPLICATIONS FOR MEDICAL LEGISLATION

Summary

1. While in recent years there has been a liberalisation of some abortion laws, in many instances legislation remains restrictive. Abortion laws have not kept pace with medical developments and new technologies seem poised to overwhelm the abortion legislation in many countries.
2. Current medical practice has already adopted better and safer methods of medical termination of pregnancy - in the first trimester by vacuum aspiration and in the second trimester by using prostaglandins. Recent trends in practice reflect the realisation that the earlier in pregnancy medical termination is undertaken, the easier and safer it is.
3. New technologies, already much used, allow termination of very early 'postconceptional' pregnancy (within 14 days of a missed period) before a diagnosis of pregnancy can be verified. These methods of 'menstrual regulation' include: (i) 'Menstrual extraction' by vacuum aspiration and (ii) the use of intrauterine or vaginal prostaglandins. The development of prostaglandin gels and pessaries for vaginal administration seem likely to provide a simple, safe, medical method of early pregnancy termination of great potential.
4. Other technologies, used prior to a missed period, (e.g. developments in relation to post-coital steroids, IUDs and other effects of prostaglandins) permit the post-coital interruption of pregnancy - 'interception' by interfering with and preventing fertilisation of the ovum.
5. The recent developments in fertility regulation have implications of moral, ethical and legal importance. The legal status of the methods of menstrual regulation (by vacuum aspiration or prostaglandins) already in use, need clarification and seem capable of several interpretations under prevailing legislations. The newer methods of pregnancy interception emphasise further the arbitrary nature of the distinction between contraception and abortion. It seems evident that these and future developments will necessitate a reappraisal of the laws in relation to abortion.

DEVELOPMENT IN MEDICAL TECHNOLOGIES FOR FERTILITY

REGULATION AND THEIR IMPLICATIONS FOR

MEDICAL LEGISLATION

Introduction

The last quarter of a century has seen a gradual liberalisation of abortion laws throughout the world. In many countries laws and policies which were prohibitive or restrictive have been amended or are being reconsidered; while in some, restrictive legislation is not strictly enforced. These changes have been influenced by several factors. They include a greater appreciation of a woman's basic 'human right' to decide her child-bearing career freely and, particularly, by better recognition of the hazards of illegal abortion which remains a leading cause of maternal mortality in countries with restrictive legislation.

Yet, in many countries, abortion laws remain restrictive. Moreover, a liberal law does not guarantee that safe abortions will be available to those women in need. While it has been estimated that today approximately one-third of the world's population lives in countries with non-restrictive abortion laws¹, to date, in many parts of the world, the availability of abortion services lags behind liberal legislation and many women lack easy access to medically safe abortion.

It is apparent, and a matter of increasing concern, that abortion laws have not kept pace with medical developments and thinking, and recent advances in medical technology seem poised to overwhelm the abortion legislation of most if not all countries. It is therefore appropriate to review the new technologies and examine their possible influence on future legislation.

Elements of Human Reproduction

Ovulation is the process whereby each month at mid-cycle a mature follicle in the ovary ruptures casting out the ovum (egg cell) which is swept up into the fallopian tube. The remaining follicle develops into the corpus luteum (yellow body) which secretes the hormone progesterone.

In the absence of fertilisation the corpus luteum degenerates shortly before the succeeding menstrual period. If fertilisation of the ovum occurs the corpus luteum persists during the early months of pregnancy producing the progesterone which is essential for the continuation of the pregnancy. By the third month manufacture of progesterone is taken over by the placenta.

Following intercourse, sperms travel upwards through the uterus to the fallopian tubes. Fertilisation of the ovum (or conception) takes place in the outer end of the fallopian tube. The fertilised ovum normally takes approximately seven days to travel down the fallopian tube to the uterus. Early cell division has been occurring during this time resulting in a solid 'clump' of cells (the morula) which later becomes vacuolated (the blastocyst). The ovum reaches the uterus in the morula or blastocyst stage.

Implantation (or nidation) is the process by which the fertilised ovum now 'digests' its way into and becomes embedded in the uterine mucosa (endometrium) previously prepared to form the decidua of pregnancy. Further cell division is now rapid and soon leads to the demarcation of the three primary layers of the 'embryonic plate' from which the various tissues and organs are ultimately developed.

'Quickening' is the appreciation of fetal movement by the mother or the 'feeling of life'. It is usually noted, with some variation, at about mid-pregnancy - at approximately 20 weeks in a first pregnancy and about 18 weeks in a subsequent pregnancy. But quickening does not mean that the fetus is viable at this time.

It should be recognised that development is a gradual process. There is not, as is sometimes surmised, a "moment of conception"; fertilisation is a complex process which takes time. Implantation or embedding of the ovum, similarly, is a process which is accomplished gradually and which can be said to be complete only after several days. While differentiation of the embryonic layers commences early on, complete development of the body systems takes much longer. Although with modern methods of management a fetus may occasionally survive if born a little (3 or 4 weeks) earlier, traditionally and usually it is held - and it is often thought that the law assumes - that the fetus is 'viable' i.e. capable of being born alive, at or after the 28th week of pregnancy. In fact this is a misconception. Legally the time of viability is not defined; the law protects the fetus from whenever it is viable.

Fertility regulation or family planning methods include a variety of techniques which can either prevent or interrupt pregnancy. Although it is sometimes used in a wider context, in the strict sense contraception means, and should be reserved for, the prevention of fertilisation of the ovum by the sperm. The interruption or termination of pregnancy subsequent to fertilisation is an abortion.

However, modern techniques now permit termination at the very earliest stage of pregnancy, immediately after or even before the first missed menstrual period. Abortion at this stage is, in effect, clinically almost indistinguishable from contraception. Implantation may not yet be quite complete; the conceptus is minute and its expulsion along with seemingly normal menstrual loss would go unnoticed. In these circumstances the terms "contraception" and "abortion" and the sharp distinction the law makes between them seem less appropriate than they once were. In consequence, a new terminology is emerging to describe the new techniques, though some of the names proposed are sanctioned more by common usage than by semantic accuracy.

For the purposes of this paper the term "interception" of pregnancy is interpreted as meaning the postcoital interruption of pregnancy, from the time of conception until the first missed menstrual period, and implies the use of methods which (by whatever means) interfere with and prevent the fertilised ovum from fully implanting in the uterus (c.f. Tunkel - Intercepting Methods).

Other recently available techniques, which operate after implantation, are increasingly used for the interruption or termination of very early pregnancy, usually within one to two weeks of a missed period. These methods include vacuum aspiration or so-called menstrual extraction (also

called menstrual regulation) and the administration of prostaglandins, (sometimes also called menstrual regulation). Employing a terminology which has been accorded some general acceptance the use of these procedures within fourteen days of the first missed menstrual period is referred to here as termination of 'postconceptional' pregnancy. (c.f. Tunkel - Disimplanting Methods).

Current Medical Practice

In the nineteenth century, the laws restricting the practise of abortion protected women from what was at that time a dangerous operation. Surgical evacuation of the uterus, performed without the modern benefits of antibiotic therapy, blood transfusion and sophisticated anaesthesia, was a hazardous procedure associated with a high mortality and morbidity from trauma, haemorrhage and sepsis. Nowadays, the risks of legal abortion, especially in early pregnancy, are less than those of pregnancy continuing to term.

Some of the medical developments of recent years in relation to abortion are already well established and current clinical practice can be summarised quite briefly.

In the first trimester of pregnancy (less than 12 weeks) termination is now usually carried out by vacuum aspiration. Compared with orthodox uterine evacuation with ovum forceps and curette, suction does not need the same degree of cervical dilatation and bleeding tends to be less so that it is generally regarded as preferable and safer than the older methods.

In the second trimester of pregnancy (after 12 weeks) because of the fetal size, the risks of injury to the uterus and of excessive bleeding are considerable so that traditional surgical evacuation of the uterus becomes increasingly dangerous as gestation advances, and is not recommended. Abdominal hysterotomy (miniature Caesarean Section) which leaves a scar in the uterus, also carries considerable risk to the mother and is best avoided, while the alternatives practised in recent times - intraamniotic (intrauterine) injection of hypertonic solutions of saline or glucose - have their own hazards and mortality.

In the past few years therefore the prostaglandins (PGE_2 and $\text{PGE}_2\alpha$) have been increasingly used for the induction of second trimester abortion (vide infra). Administered locally (by intraamniotic or extraamniotic injection into the uterus) they have been shown to be more efficacious and safer than other methods, while recently some synthetic prostaglandin analogues have been found to be effective by the vaginal route.

Emerging Trends

For several reasons (vide infra) a considerable proportion of second trimester terminations still have to be performed, but medical experts continue to emphasise that the hazards associated with pregnancy termination increase with gestation; mortality rates show that the risks of pregnancy termination in the first trimester are much fewer than those associated with second trimester abortion or of carrying a pregnancy to term, and much less than most surgical procedures. Recent research in fertility regulation

has therefore explored new ways of preventing or interrupting pregnancy at the earliest possible stage while, as a short term goal, the highest priority has been given to the development of simple, safe abortifacients for use in early postconceptional pregnancy (within 14 days of a missed period).

New Technologies

New technologies for the termination of very early post-conceptional pregnancy have been developed and already two methods - Menstrual Extraction and Prostaglandin Therapy - have been used widely. Such methods require especial scrutiny because their legal status remains unclear. Additionally, some other potential uses of prostaglandins, developments in intrauterine devices (IUDs) and the post-coital use of steroid hormones ('morning after' pills) are further examples of fertility regulation procedures which have obscured the previously accepted boundary between contraception and abortion.

(i) Menstrual Extraction:

Menstrual extraction or regulation is also variously called mini abortion, mini suction, menstrual induction. It is a relatively simple, safe and inexpensive outpatient procedure in which the uterine contents are aspirated within 14 days of a missed menstrual period. It can in some cases be carried out without any anaesthesia but commonly local anaesthesia (e.g. paracervical block) is employed. A small plastic catheter of the Karman type (4, 6 or 8 mm) is used and introduced into the uterus usually without preliminary dilatation of the cervix. An electric or hand pump or even a large 50 ml syringe provides the suction. Self-contained menstrual regulation kits are available.

Menstrual extraction has been used in many thousands of cases for the termination of pregnancy with good results. Serious complications are infrequent but a complication rate of 2 - 3 percent (from uterine perforation, haemorrhage, sepsis) has commonly been quoted and there is a 2 - 3 percent failure rate. Follow up is therefore essential.

In the absence of facilities for sophisticated β -subunit HCG (i.e. Human Chorionic Gonadotrophic Hormone) assays it is inevitable that up to one-third of the patients treated by menstrual extraction within 14 days of a missed period may not be pregnant at the time. The percentage of non-pregnant patients treated is in fact inversely proportional to the duration of amenorrhoea. When aspiration (menstrual extraction) is performed within 35 days of the last menstrual period pregnancy may only be confirmed in 30 - 40 percent of patients but when aspiration is done at 35 - 42 days the proportion of pregnant patients rises to 60 - 70 percent⁵.

It should be realized that apart from termination of early pregnancy the technique of uterine aspiration is nowadays put to a number of other diagnostic and therapeutic uses. As an alternative to conventional dilatation and curettage (D and C) - in some respects a superior alternative - it is increasingly used in the diagnosis of abnormal menstrual bleeding, endocrine dysfunction and infertility while it is also used for the treatment of incomplete abortion and hydatidiform mole.

The obvious advantage of the method is its potential as an outpatient or 'office' procedure. Its general acceptance as a diagnostic measure will

finally be determined by its reliability. A still greater experience is needed but in some comparative studies results have compared well with conventional curettage.

The chief therapeutic use of uterine aspiration is in cases of incomplete abortion. When the cervix is already dilated aspiration can often be performed without any anaesthesia or with simple premedication and is generally safe and associated with little blood loss. When the abortion occurs after the eighth week of gestation a mechanical or electrical suction pump is essential. Uterine aspiration is also used in cases of septic incomplete abortion but adequate antibiotic cover is obviously wise before proceeding to aspiration.

The fact that uterine aspiration is used for the treatment of a variety of menstrual disorders as well as the termination of early pregnancy has important practical implications (vide infra).

(ii) Prostaglandins⁶:

The notable impact of prostaglandins (PGs) on human reproduction depends on their ability to interrupt pregnancy at any stage of gestation. They are a group of naturally occurring hormone-like chemicals found in many tissues, two of which (PGE_2 and $\text{PGF}_2\alpha$) are of importance in reproduction. They are very rapidly metabolised in the bloodstream. In consequence, oral administration is not satisfactory so far because the dosage needed results in unpleasant gastro-intestinal side-effects (vomiting and diarrhoea). The prostaglandins, however, are locally acting and, by producing uterine contractions, they can cause expulsion of the fetus at any stage of pregnancy. They are already widely used to procure late (second trimester) abortion (vide supra), and to induce labour.

The prostaglandins are currently being used in multicentre clinical trials for the termination of early postconceptional pregnancy (i.e. up to 14 days after a missed period). Initially, vaginal administration was disappointing and it was found that success in the interruption of post-conceptional pregnancy required intrauterine injection. While, prescribed vaginally, the natural prostaglandins are not very effective some synthetic derivatives or analogues are (e.g. 15 methyl $\text{PGE}_2\alpha$, 16:16 dimethyl PGE_2), and administered in a vaginal pessary or gel, offer - as an alternative to menstrual extraction - a medical method of menstrual regulation or mini-abortion of considerable potential. As with menstrual extraction, of necessity some women treated will not be pregnant. There are as yet a few failures calling for uterine evacuation, and side effects (vomiting and diarrhoea) are a little troublesome, but it is likely that more specific analogues and/or better delivery vehicles will be developed. It is probable that these developments will soon result in a simple, safe, non-surgical method of early pregnancy termination of great potential and this is a priority area of fertility regulation research.

The prostaglandins also have other potential (though as yet undeveloped) roles in reproduction. In animals the prostaglandins - apart from stimulating uterine contractions - have powerful luteolytic effects; they can prevent or interrupt pregnancy by bringing about regression of the corpus luteum and therefore withdrawal of the hormone progesterone which is essential in pregnancy. At least two prostaglandin analogues are very powerful luteolytics in domestic animals and of great promise in the veterinary field. However, in the human there seem to be differences in

the mechanism of luteolysis and the prostaglandins have so far been rather disappointing. Nonetheless, because of its potential, attempts are being continued to harness this luteolytic effect for fertility control in the human. The prostaglandins also have effects on the contractility of the fallopian tubes and it has been shown in laboratory animals that some prostaglandins can speed the transport of ova presumably as a result of tubal contractions. Studies of tubal motility in the human are still limited but there is the prospect that by influencing tubal motility and hastening passage of the ovum along the tube implantation could be prevented so that administration of prostaglandins before nidation could provide an interceptive fertility control method. Prostaglandin effects on sperm transport and on the synthesis and release of steroid and gonadotrophic hormones may also be important and the contraceptive potential of the prostaglandins is still largely unexplored.

(iii) Post-coital Steroids - 'Morning After' Pills⁷:

The post-coital administration of large doses of oestrogen (e.g. diethyl stilboestrol 25 mg b.d. or ethinyl oestradiol 0.5 mg b.d. for 5 - 7 days) has been used over several years as a means of preventing pregnancy. The mode of action is not clear. The published data available indicate that as a non-recurrent method after an isolated act of unprotected intercourse it usually provides effective protection against conception. Treatment is mostly followed in a few days by menstrual bleeding but such bleeding is not proof of success and there are a few failures.

A serious disadvantage of the method is that very large doses are required, so that recurrent use cannot be contemplated, and there is a high incidence of side effects, particularly nausea and vomiting, and also menstrual disturbance to limit the method's applicability. Additionally there is concern about the high incidence of fetal abnormality should the pregnancy continue after oestrogen therapy⁷.

Progestogens have been used similarly for postcoital protection. Their true value as postconceptional contraceptives for recurrent use is not clear for definitive data are lacking but known reports suggest the method is not sufficiently reliable.

(iv) Intrauterine Devices (IUDs):

Intrauterine devices continue to play a major role in contraception. More than a decade of experience has shown that, if not quite the ideal contraceptives, they nevertheless, have important merits and are highly effective. Despite their widespread use over many years the mode of action of intrauterine devices (IUDs) is still not fully understood and they appear to affect different phases of the reproductive process in different species. In the human several explanations are possible but they are commonly supposed to interfere in some manner with implantation of the ovum. The recent hypothesis that prostaglandin production may be responsible for this contraceptive or interceptive effect has been partially substantiated in animal experiments⁶.

The postcoital insertion of an IUD has recently been proposed as an effective method of preventing pregnancy after unprotected coitus. In a relatively small trial group of women who had unprotected intercourse in the fertile phase of the menstrual cycle, no pregnancies occurred although the risk of pregnancy was estimated at 10 - 20 percent⁶. Further

corroboration of the method is needed but it has the advantage of providing continuing contraceptive protection. Moreover the method is not associated with the nausea and vomiting of the alternative massive oestrogen therapy.

Recently, some data emanating from the U.S.A. concerning HCG levels in women wearing IUDs, suggested that perhaps such women frequently conceive and undergo 'mini-abortions'. However, the view has not been substantiated and other investigators have failed to corroborate the experimental findings⁴.

(v) Possible Future Developments:

Mention should be made, too, of some more speculative medical developments which might in the future provide new and better methods of fertility regulation.

Reverting to the prostaglandins, it is increasingly realized that they are implicated in the process of ovulation. Thus it has been shown in experimental animals that ovulation can be blocked by administration of 'prostaglandin synthetase inhibitors', e.g. aspirin or indomethacin, though some uncertainty remains whether the inhibition is at pituitary or ovarian levels. The development of more effective inhibitor agents is awaited but implementation of this research in the human could result in an inhibitor of ovulation of great potential as a contraceptive method.

Other means of controlling ovulation or events subsequent to it may also be developed. Knowledge of some fundamental physiological systems is incomplete, but as the inter-relationships between ovarian steroids and pituitary gonadotrophins, rupture of the ovarian follicle, fertilisation and nidation are elucidated new methods of controlling the reproductive cycle will doubtless emerge.

Blocking essential hormone pathways (e.g. HCG or progesterone) by biochemical means is one possibility, and at least one 'antiprogestosterone' has been recently under investigation.

Immunisation against hormones is also possible and is an attractive goal, especially immunisation against the β -subunit of HCG⁴. Already in experimental animals, including primates, active immunisation has suppressed fertility; fertility is suppressed for about one year but when antibody titres decline subsequent pregnancies end in abortion.

Implications of New Technologies

The foregoing developments in fertility regulation raise some controversial religious, ethical and moral issues as well as having important legal implications in that the hitherto accepted distinction between contraception and abortion has become blurred. What constitutes an abortion is no longer clearly defined.

(i) Status of Menstrual Regulation:

Most existing restrictive abortion laws were inherited from the British Offences Against the Person Act of 1861 - itself chiefly a re-statement of statutes going back to 1803 - in some instances supplemented by the

Infant Life (Preservation) Act of 1929 and clarified by judicial decisions such as the celebrated R. v. Bourne case. The interpretation of the abortion laws, from the beginning of the nineteenth century, seems to have been based on the premise that pregnancy begins at fertilisation or conception. It is noteworthy that this represented a shift from the medieval view that life did not begin until quickening - a view which persisted up to the 1803 Act. Medical scientists have recently questioned the nineteenth century view and tended to define life as beginning with nidation or implantation of the fertilised egg. Indeed, medical authors have suggested that some judicial opinions, such as the U.S. Supreme Court decision in 1973 which legalised abortion during the first trimester and on grounds of maternal health during the second trimester, give some renewed support to the concept of quickening - but this is questionable. In fact, the law does not state when life begins - the duration of pregnancy is calculated from the last menstrual period - although under some recent enactments, e.g. the Austrian and German laws, abortion is regulated from the time of nidation.

Menstrual regulation [whether by vacuum extraction (menstrual extraction) or prostaglandins] is normally undertaken within one to two weeks of a missed menstrual period and, of course, after nidation.

The legal status of menstrual regulation needs clarification and medical authorities have expressed concern and are perplexed that several interpretations of its status seem possible.⁸ Thus it might be supposed that menstrual regulation would be legal in countries with an advanced law (permitting abortion when specified justifications are satisfied) providing the requirements of the Act are complied with. Yet this is not certain for it should be noted that in the U.K. the Lane Committee has expressed doubt whether "the wording of the Abortion Act is apt to cover a speculative abortion procedure..... on a woman who may or may not be pregnant at the time". The Committee felt that the Act did not envisage any such speculative procedure. In countries where abortion is prohibited or restricted it would seem there could be two legal interpretations. In some (e.g. some Commonwealth countries) where the intent to procure an abortion is a crime, whether or not in fact the woman is pregnant, menstrual regulation would risk criminal proceedings. However since it is performed before a diagnosis of pregnancy can be verified clinically or by the normally available pregnancy tests and/or to regulate menstrual problems, prosecution would perhaps be unlikely. In other countries (e.g. some Latin American countries) the law implicitly requires pregnancy as an element of the offence and unless it could be established that the woman was pregnant, menstrual regulation would not violate abortion statutes.

(ii) Pregnancy Diagnosis:

The use of Menstrual Regulation techniques ponders the matter of pregnancy diagnosis. Within 14 days of a missed period, when menstrual regulation is performed, verification of pregnancy is not usually possible by clinical examination or by ordinary immunological pregnancy test. But diagnosis can be made by a highly sensitive β -subunit HGC assay within a few days of implantation and even before a menstrual period has been missed. The test, however, is expensive, requires special equipment and expertise, is time-consuming, and is not likely to be generally available for a long time. Indeed, bearing in mind the simplicity, safety and relatively low cost of the menstrual regulatory method, it is arguable

whether the introduction of such sophisticated tests for clinical use would be justifiable on a cost-benefit basis. More rapid, simpler tests of very early pregnancy will probably be developed - but for the time being menstrual regulation must be performed without precise diagnosis and inevitably, therefore, on a proportion of women who are not pregnant. Scientific progress will no doubt eventually resolve this dilemma but in the meantime it can be argued that diagnosis is not essential and could even have disadvantages. Bearing in mind the other non-pregnant indications for menstrual regulation, it would seem, in countries where restrictive abortion laws require proof of pregnancy, that lack of diagnosis would give menstrual regulation a legal status. There is, moreover, an additional viewpoint. Several medical authorities stress that the rationale of menstrual regulation is based on human needs as well as medical considerations. Menstrual regulation is seen as a humanitarian response to the anxiety of a woman who is aware of a late menstrual period and worried about an unwanted pregnancy.

Reference must be made to the use of large doses of oral oestrogens as a diagnostic test of pregnancy. Because of their lack of reliability, high incidence of side effects and risk of fetal abnormality (vide supra) such tests are not to be recommended and immunological tests should be preferred.

(iii) Embryological Development:

When life begins is of course the fundamental question at the root of much of the controversy which has existed concerning medical termination of pregnancy. Ardent opponents of medical abortion base their arguments on the view that life begins at the time of conception; others, less antagonistic, assume that human life or human personality begins at some time later in the gestation - the old notion being that it began with quickening - and that, in the very early stages of pregnancy at least, only a potential human being exists.

In many ways these arguments are specious. From a biological stand point, life is certainly present from the time of conception - but equally life is present before conception; the ovum was alive before fertilisation, and so was the sperm. On the other hand the concept that human life begins with quickening is also unbiological. It must be emphasised that embryological development is a progressive process and a more meaningful 'milestone' biologically is the time at which the fetus, if born, is capable of separate existence, and this is several weeks later on.

(iv) Merits of Early Abortion:

Of the greatest importance from the medical standpoint is the realization that the earlier in pregnancy medical termination is undertaken, the easier and safer it is. This is a matter of experience to most gynaecologists, but it is also well-documented that the physical hazards and complications of abortion increase as pregnancy advances. Moreover, there is little doubt that the interruption of very early pregnancy, before the major developments of embryology, is much more acceptable emotionally and psychologically, both to the mother and the operator than is late abortion.

In New York State, for example, in two years following the liberalisation of its abortion law, a study of abortion-related death rates

showed that the risk of death in second trimester abortions was seven times higher than in first trimester abortions. Data for abortions performed in England and Wales in the years 1968 - 1973 similarly showed that the risks were related to the duration of gestation. Another U.S.-based study, by the National Academy of Science Institute of Medicine, showed that legal abortion in the first trimester carried a lower mortality rate - of the order of 2:100,000 - than when abortion was performed in the second trimester and that it was still less hazardous than delivery at term and most operative procedures. Based on data from the U.S.A. and U.K. it has, moreover, been computed that the mortality from legal abortion in the first trimester compares well with the risk of death associated with the use of common contraceptive methods such as the contraceptive pill and the IUD.

To some extent similar consideration concerning safety apply to spontaneous abortion. In the first weeks of pregnancy (up to 6 - 8 weeks) the products of conception are often expelled in their entirety - the abortion is 'complete'. Bleeding is rarely excessive, normality of the pelvic organs is soon restored, and the abortion causes the patient little physical or emotional upset. On the other hand, when abortion occurs in the late first or second trimester, after the formation of the placenta, the fetus is first expelled and the placenta not infrequently retained - the abortion is 'incomplete'. Retention of the placenta may well be complicated by haemorrhage while there are increasing risks of infection. Hospitalization and surgical removal of the placenta are often necessary in such cases.

It has been realized in recent times, moreover, that many spontaneous abortions occur at this very early stage of pregnancy - there is a very considerable natural wastage of defective early embryos. Precise figures are difficult to obtain but careful study of abortuses has shown that in about 60 percent of abortions the ovum is defective or the embryo malformed ('blighted ovum') while, in consequence, in a further 15 percent there are defects of implantation. In many cases the defect occurs before or at conception and chromosome studies of first trimester abortions have shown that up to 40 percent have chromosomal abnormalities. The proportion could well be higher and embryologists have estimated from studies of very early embryos that one in three or possibly one in two of all fertilised ova are destined to be lost by abortion or reabsorption.

(v) Gestation Limits:

So strong are the arguments in favour of early (as opposed to late) termination of pregnancy that medical experts continue to emphasise the importance of early referral for treatment, and concentrate their efforts on improved technologies for use in early pregnancy. Commendable as it may seem, however, there are objections to any restriction of legal abortion to the early months of pregnancy, particularly abortion carried out on eugenic grounds.

Progress has been made in the diagnosis of fetal abnormality, and recent advances (e.g. alpha feto protein testing) have extended the number of abnormalities which can be demonstrated in pregnancy. But the methods so far available only permit diagnosis relatively late in the second trimester of pregnancy, and presently an increasing number of second trimester abortions are being performed on this account.

Nonetheless, there should be cogent reasons for the performance of late second trimester abortions. There will probably continue to be some women who, through ignorance or being ill-advised, seek late abortion, but every effort should be exerted to reduce their number.

It is a matter of concern that not infrequently these are young women. At present teenagers account for about one quarter of all the legal abortions in England and Wales (and in the U.S.A. the proportion is somewhat higher), and regrettably a significant proportion of these girls tend to be aborted late in pregnancy. The reasons for the delay are several but include such factors as a failure or unwillingness to recognise the signs of pregnancy, wishful thinking that the pregnancy "will go away", and a reluctance to confide in the parents or seek other help. What is important - quite apart from the particular problems of the teenager - is that statutes or regulations which lead to unnecessary procedural delays in a woman obtaining treatment are medically undesirable and must be avoided.

(vi) Abortion Services:

The liberalising trends of past years have resulted in some conspicuous improvements in maternal health. In nearly all countries with reliable data, including Great Britain, U.S.A., Canada, Cuba and some East European countries, the increase in the total number of abortions following liberalisation has been associated with a decline in maternal mortality.¹⁷

However, legalising abortion does not necessarily ensure that all the women in need have access to safe abortion and it is clear that in many parts of the world the availability of abortion services has not kept pace with liberal legislation. The requisites to assure availability and full utilisation of abortion services must include a sufficient number of medically-trained personnel, readily accessible medical facilities, and a widespread communications network to inform all women, (including those in rural or remote areas) that services are available.

The educational function is an important role of the Family Planning Services. Medical termination of pregnancy is to be seen alongside the various methods of contraception and sterilisation in the wider context of "family planning" or "fertility regulation" as a necessary "back-up" to contraception. Fears that easy access to legal abortion would lead to couples abandoning or neglecting contraception are not supported by the available data. Indeed, there is some evidence that better or more effective contraception is practised after pregnancy termination, which provides a unique degree of motivation for contraceptive counselling.

It now seems likely that the recent development of vaginal pessaries and gels containing prostaglandin analogues will soon (with suitable medical safeguards) result in a simple, effective, non-invasive (i.e. medical) method of early pregnancy termination which could have far-reaching implications. Traditionally, as a matter of practice, legal abortions have been performed by medical practitioners and mostly in hospital or clinic. But the vaginal prostaglandin makes feasible termination of early pregnancy as an out-patient procedure, not requiring anaesthesia, and is a method which, with little training, nurses and para-medical personnel could readily undertake under medical supervision. (Menstrual extraction, too, can be performed on an outpatient basis).

More particularly, the prostaglandin developments could open the way for possible self-administration. This would clearly pose serious moral and ethical as well as legal issues. "Black market" abuses could even be envisaged. This would mean that the whole concept of procreation would have to be reconsidered. Meantime, medical scientists see it as an advance capable of making a major contribution to fertility regulation in those parts of the world where there is a scarcity of medical practitioners.

(vii) An Arbitrary Distinction:

The recent advances in fertility regulation technology, particularly the newer methods of menstrual regulation, used before a diagnosis of pregnancy can be established, have already drawn attention to the arbitrary nature of the boundary between contraception and abortion. Furthermore, some newer developments reviewed, which can either prevent or interrupt pregnancy, emphasise the obscurity of this distinction. For example, the prostaglandins are effective agents for the interruption of very early pregnancy if administered within a few days of a missed period. But additionally, there is evidence from research trials that prostaglandins suitably administered postcoitally, before nidation (and, of course, before a missed period) could effectively prevent implantation of the ovum and be used as a fertility regulation method. The postcoital but pre-implantation use of prostaglandins (interception) might therefore be construed as contraceptive and might be acceptable in countries where abortion is illegal. To many medical scientists there is little difference between preventing the fusion of the male and female cells, and preventing the fertilised ovum lodging in the uterus.

With this clouding of the previously accepted boundary between contraception and abortion it becomes more and more illogical to take an entrenched conservative (or liberal) stance on one, and not also on the other. Increasingly, it becomes evident that these and future medical advances will not only influence moral and ethical thinking but call, in many countries, for a reappraisal of the laws and policies in relation to contraception and abortion.

References

1. Tietze, C. and Lewit, S.
Legal Abortion, Scientific America 1977, 236, No. 1.
2. Berger, G., Tietze, C., Pakter, J. & Katz, S.
Maternal Mortality Associated with legal abortion. New York State Obst. & Gynae 1974, 43 (3), 315.
3. National Acad. of Science Inst. Med. Legalized Abortion under Public Health Washington, D.C. 1975 (167p).
4. U.S. Dept. Health Ed. & Welfare (Centre for Disease Control) 1975 (Data for 1972-1973).

5. Goldsmith, S., Margolis, A. - Menstrual Induction Medical Aspects.
In Lewit, S. - Advances in Planned Parenthood. Vol. 9, Amsterdam.
Excerpta Medica, 1974, 7.
6. Embrey, M.P., Hillier, K. Recent Advances in Obstetrics and
Gynaecology, Churchill Livingstone, Ed. Stallworthy, J.S. &
Bourne, G. London, 1977.
7. Shearman, R.P.
Contraception 1973, Vol. 7, 59.
8. Janerich, D.T. et al.
British Medical Journal, 1977, Vol. 1, 1058.
9. Nora, J.J. and Nora, A.H.
Lancet 1973, Vol. 1, 941.
10. Lippes J., Malik, T. & Tatum, H.J.
International Family Planning Digest, 1975, No. 3.
11. Short, R.V. Personal Communication.
12. Meeting of Royal Society in London - Research in Reproduction
1976, Vol. 8 No. 2
13. Lee, L., Poxman, J.M.
Menstrual Regulation : Legal Implications, Menstrual Reg.
Conference; Honolulu, Hawaii, 1973, 7 pg.
14. Tietze, C., Murstein, M.C. 1975
Induced Abortion 1975 - A Fact Book - Reports on Population/
Family Planning No. 14 (2nd Edition)
15. Tietze, C., Bongaarts, J., Schearer, B.
Mortality Associated with Control of Fertility, Family Planning
Perspectives, 1976, Vol. 8, No. 1.
16. Llewellyn-Jones, D.
Fundamentals of Obstetrics and Gynaecology, Faber and Faber
Ltd. London 1970.
17. Van der Tak, J.
Abortion, Fertility and Changing Legislation, Lexington,
Mass. D.C. 1974, 141 pg.