Appendix A. Commonwealth Secretariat, Report of a Combined Medical-Legal Workshop, Barbados 18-22 June, 1979

ITEM III : THE LAW ON MEDICAL TERMINATION OF PREGNANCY AND RELATED ISSUES: CARIBBEAN AND PACIFIC ISLANDS AND CYPRUS: CONCLUSIONS

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61. This item was dealt with in three stages, introduced respectively by Professor Michael Beaubrun, head of the Department of Psychiatry at the University of the West Indies (Trinidad campus), and by Professor Bernard Dickens and Miss Rebecca Cook, joint authors of the discussion paper Law on medical termination of pregnancy (see p.64) and of A survey of abortion laws in Commonwealth countries, contained in the Commonwealth Secretariat publication Abortion Laws in the Commonwealth (published separately and available from the Secretariat - also to be republished shortly by the World Health Organisation, Geneva, in the International Digest of Health Legislation, Vol. 30, no. 3 or 4, 1979.

General Survey

Introduction

62. Professor Beaubrun noted a world-wide trend towards more liberal abortion laws, the main reasons for which he saw as being:

(a) the recognition of a woman's right to determine her child-bearing career and how her body was used, as a matter of health and welfare;

(b) the high incidence of unwanted pregnancies and illegal abortions, with resultant high maternal mortality;

(c) improved medical technology which had made termination in the early months safer than pregnancy itself; and

(d) the world population explosion.

63. Modern technologies had blurred the distinction between contraception and abortion, and had made the old abortion laws obsolete. The "morning after" pill, the intra-uterine device (IUD), prostaglandins and menstrual regulation by vacuum aspiration before the first period was missed were instances of methods which might be technically considered abortion but which were virtually impossible to detect or control. The test-tube baby also provided an example of a situation with which the laws of most Commonwealth countries could not deal. The old laws, he observed, had become unenforceable; an unenforceable law was a bad law, leading only to disrespect and disregard, and, if only for this reason, ought to be changed.

64. Professor Beaubrun noted that there had always been a gap between law and practice. The practice of abortion was

world-wide. When laws were restrictive, the poor were pushed into the hands of back-room abortionists. Obstetrical services were overloaded with the incomplete and septic abortions which resulted. Statistics from The human problem abortion - the report of the International Planned Parenthood Federation expert panel on abortion, Bellagio, Italy, February 1978 - indicated that more permissive laws were often followed by a decrease in maternal mortality.

65. The basic law from which most Commonwealth countries derived their abortion laws was the United Kingdom Offences against the Person Act of 1861. This stemmed from an Act of 1803, passed at a time when all surgery was dangerous and intended to preserve life. Because of surgical advances, the Act was no longer relevant.

66. Even where developed laws now existed which could be interpreted by government officials, there might be uncertainty about how such interpretation would stand up in a court of law. This could lead to ambivalence on the part of doctors and reluctance to perform abortions, or even to refer cases to other doctors who were willing to do so. Such ambivalence produced delays which could be dangerous, especially in adolescence when the recognition of pregnancy was often delayed anyway.

67. Other delays were occasioned by bureaucratic referral procedures required by some categories of advanced laws. Professor Beaubrun suggested that there was no need for committees or second referral procedures for the first trimester, but that doctors should be able to perform early abortions simply on request. Excessively detailed legal restrictions as to who should perform medical termination of pregnancy, and where it could be performed, could also cause undesirable delays.

68. In any culture, the person who actually delivered health care should be licensed to terminate pregnancy in accordance with the law. Where medically-qualified personnel were in short supply, appropriately-trained health and auxiliary personnel could safely perform simple procedures, thus releasing scarce obstetric and gynaecological specialists for more complicated cases. Nor where hospital facilities essential for the termination of early pregnancies, provided this was done by skilled, licensed, supervised paramedicals.

69. In Professor Beaubrun's view, the real issue was not just the right to life, but the right to an adequate quality of life, and the right to be a wanted child. The cycle of unwanted human reproduction increasingly polluted the human resource pool. Unwanted children grew up unable to give love or to trust, and were less able than others to succeed in life. This was particularly important in developing countries, where the quality of the human resource was a critical factor in development.

70. He took the view that the old basic law was now unworkable and counter-productive and should be repealed. If, instead of repeal, it was decided to develop new advanced laws, then the mistakes made in some countries should be borne in mind. Consent procedures should be simple or should not be included in laws at all. Ideally, only the consent of the woman herself should be needed. Existing laws which were first enacted to promote health now endangered it, Professor Beaubrun considered. He invited participants in the workshop to share with each other their problems of practice under the existing laws.

Discussion

71. In the discussion, it was generally acknowledged that a woman with an unwanted pregnancy was likely to turn to any means available to abort, if no legal and acceptable procedure were available. The frequent outcome was that she needed to be treated later in hosptial for complications resulting from the unhygienic and unskilled surgery.

72. Poorer women suffered most, since they could not afford to travel to other countries where advanced laws were in operation, nor could they afford to buy a safe abortion from a medical practitioner. They were thus obliged to resort to illegal abortionists or to dangerous, self-induced miscarriage.

73. Religious opposition to abortion was seen by some participants as a signficant obstacle to reform in certain countries, but existing cultural and social attitudes also presented obstacles.

74. Concern was expressed about abortion performed outside hosptials and approved clinics, as standards in doctors' surgeries in some areas would be difficult to control.

75. Problems of adolescent pregnancy were recognised as common to many countries. Participants in the workshop were unanimous in expressing their grave concern at the increasing incidence of teenage conception. Discontinuation of education, resulting in future unemployment and consequent lack of economic independence, was referred to. It was noted that adolescents tended to delay seeking help, both because they failed to recognise that they had conceived and because they feared to admit to sexual activity. The question of parental consent to abortion on a minor extended the problem of termination still further.

76. It was suggested that consideration should be given to de-criminalising abortion, and to the repeal of prohibitive language in laws, so leaving abortion to the medical and legal controls governing all other forms of surgery. In this event, there would be no need for new abortion legislation.

The Law on Abortion

Introduction

77. Professor Dickens, introducing the paper of which he and Miss Cook were the joint authors (see p.64), identified three types of Commonwealth law on abortion:

(a) basic law, which absolutely prohibited abortion in all circumstances - this might conform to the preference of some jurisdictions, although such a law cost lives which might be saved;

(b) developed law, which was based on the English 1938 Bourne decision permitting abortion to preserve life or physical or mental health - although such law was implicit in basic law, it often required to be made explicit by declaration of the courts or of a senior law officer, or possibly a health minister.

(c) advanced law, which set out in detail the conditions under which abortion was lawful.

78. Professor Dickens outlined the characteristics of an advanced law, beginning with the indications upon which such a law permitted abortion. These included strict necessity (to save life), the therapeutic indication (regarding serious danger to life or to physical or mental health), the fetal or eugenic indication (concerning serious handicap to the prospective child) and the juridical indication (rape and incest). Some of these were alternatives for others; for instance, the mental health indication might be applied to a rape victim where no rape indication was adopted.

79. Control of delivery of abortion services might be by various and alternative means. Practitioners with specified qualifications might be given authority to perform abortions, perhaps with a requirement of higher qualifications for later, more complex procedures, and permission of less specialisation for earlier procedures, which might be undertaken by paramedicals. A condition of authorisation might be service in public sector facilities, to aid equitable social distribution of services and to prevent concentration in the fee-paying sector.

80. Alternatively, control might be through facilities such as hospitals and approved clinics, which might be relied upon to employ personnel with appropriate qualifications. Again, facilities might be authorised for performance of procedures within specified gestational limits.

81. Professor Dickens emphasised that approval procedures, such as second or further medical opinions, could be a source of health-threatening delay and could be difficult to implement in practice where resources and personnel were limited. Similarly, consent of third parties, such as spouses or parents, might cause delay and loss of confidentiality for the patient. Nevertheless, some cultures might require an approach through the family structure rather than through an individual patient in isolation.

82. Conscientious objection to abortion should be accommodated, where compatible with preservation of the patient's life and health. In particular, the convictions of nursing personnel should be taken into consideration, although equally

they should not be permitted to place abortion patients at a disadvantage.

Discussion

83. A number of participants stressed difficulties due to the consent requirement, particularly regarding minors. It was also noted that women needed protection from third-party pressure to have abortions they did not want. This could be a source of subsequent maladjustment to having been aborted. Parental pressure on a minor might be particularly dangerous.

84. It was recognised that liberalisation of abortion law involved the issues both of the legal status of adolescents and of their capacity to give independent consent to contraceptive assistance. Legal doctrine on the mature and the emancipated minor might make legitimate treatment of minors more available than might at first appear, but clarification was needed for the satisfaction and protection of physicians and appropriate paramedical personnel.

85. Some participants considered that the linking of abortion services to general family planning counselling and service delivery was essential. They thought that abortion should be brought within government health services, and that where necessary the law should be changed to make this possible. It was considered that family planning guidance should involve males as well as females.

86. It was noted that abortion services might be more easily rendered under a developed law than under an advanced law, but that this might expose the practitioner to greater insecurity, risk and anxiety. An advanced law, specifying qualifications, facilities, approval procedures and possibly residence tests, might be more restrictive than a simple developed law.

87. The workshop noted that prohibitive abortion laws remained unenforced by prosecution even in the face of clear evidence of repeated violation. The value of such laws was thus open to question, especially when they prevented access to safe medical therapy. The effect was to send women to unskilled practitioners and to deny them continuing care and introduction to contraceptive information. Also, restrictive laws tended to affect only the poor, as women of financial means could easily evade them.

88. It was pointed out that the rape indication for abortion could raise difficulty, since rape was a juridical conclusion rather than a medical diagnosis. Evidence of rape had both legal and social aspects; physicians tended to respond to the latter rather than the former. However, the mental health therapeutic indication could be used to justify abortion in cases of rape.

89. The indication for abortion of failure of a conscientiously-used means of reasonably reliable contraception was seen as regarding abortion as a back-up or fail-safe service for contraception, not as an alternative, and as offering an incentive to use contraceptive means.

90. The need for simple procedures to obtain medical approval for abortion was stressed by a number of participants. Legally-compelled procedures which caused delay and anxiety were regarded as counter-therapeutic.

91. Some participants favoured toleration of conscientious objection to the peformance of abortion, but considered that the onus should be on the objector to show good faith and not to prejudice care of the patient. The possibility of a conflict arising between the objector's right to non-discriminatory advancement and the government's duty to make services available was noted. Applicants for appointments might be required to be prepared to carry out the full range of services offered.

Strategies for Interpretation or Reform

Introduction

92. Miss Cook outlined principles of law which might be applied in countries where legal reform was not yet possible, and suggested strategies which doctors might adopt to engage lawyers in a combined effort to interpret the law more broadly.

93. Doctors might attempt to get Attorneys-General or Directors of Public Prosecution to make statements clarifying how they would interpret existing laws. Although not an ideal solution, this might be the best that could be achieved in some countries. Doctors had an interest in persuading lawyers to clarify the law and to find creative ways of interpreting it, so that medical duties could be properly undertaken.

94. Efforts should be made to find common ground for discussion of fundamental principles with religious groups which were opposed to abortion, with the aim of developing a dialogue and mutual respect. Church groups, Miss Cook suggested, might respond to arguments based on the United National Declaration of Human Rights, and to the recent statement in Poland by Pope John Paul II on freedom of conscience.

95. The decriminalisation of abortion law might be sought through the repeal of specific provisions concerning early termination of pregnancy, and the control of illegal abortion might be effected through statutes governing the unqualified practice of medicine. Doctors should seek to be consulted by lawyers when medical statutes were re-drafted.

96. Miss Cook also suggested various methods of protecting and reassuring providers of abortion care. Physicians could be made aware that they could not withhold appropriate care from their women patients lawfully entitled to termination of pregnancy. Furthermore, treatment of incomplete abortion did not usually fall under abortion statutes but rather under the provisions of medical statutes and general law, and was usually considered a legitimate medical procedure. Consequently, failure to give treatment for incomplete abortion could constitute negligence.

97. Physicians should also be made aware that it had to be shown that there was a wrongful intention as well as a wrongful act for a conviction of a crime to be secured. If a doctor could show that an abortion had been performed in good faith, with proper regard and care, to preserve the woman's life or health, it would be very difficult to prove wrongful intent.

98. Good faith could be shown through openness as to the fact that such care was being provided for the community, directed to meeting the health needs of women, through consultation with colleagues; through maintaining proper medical records, evidence of which could be shown by the completion of a medical check list; and through charging reasonable fees, consistent with patients' financial means.

99. Physicians faced two questions regarding abortion, arising from its criminal and its welfare aspects respectively. The first was whether they could legally perform an abortion; the second, which there had been a tendency to ignore, was whether they could refuse to perform an abortion to which a patient was entitled. As the welfare aspect of abortion counselling and care developed, this second question might become the more important in guiding medical practice.

Discussion

100. The workshop noted that some existing advanced laws might be more inhibiting than developed law. Reference was made to bureaucratic delays resulting from the law in force in Canada and in Britain. It was agreed that there were lessons to be learned from the British and Canadian experience, and that these should be borne in mind when new legislation was being drafted.

101. There was some agreement that the options for decriminalisation should be considered, and also that statutes regulating the functions of health and auxiliary personnel needed some re-definition.

102. A number of participants expressed the view that medical termination of pregnancy during the first twelve weeks of gestation should be available on request.

103. In relation to parental consent to medical termination of pregnancy, lawyer-participants referred to the legal duty of parents to provide health services for their children, and saw this as constituting an overriding legal obligation which could be used in the particular case of pregnant adolescents. Participants were agreed on the principle that a minor had a right to privacy and confidentiality.

Conclusions

104. The following were the general conclusions reached.

National

(a) The material before the workshop, and the experience of participants, suggested that existing laws in many countries may be out-dated and in some instances may even create health

risks. Where this situation exists, legislative reform is the only remedy. The options which emerged are simple repeal, which may be unacceptable, or the introduction of an advanced law. Those concerned with the drafting of advanced laws could learn much from the experience of countries which already had advanced laws, and in this way avoid repeating some of their faults.

(b) It was desirable for the legal formalities in advanced laws to be kept to a minimum, to allow procedures for termination at the earliest possible stage of pregnancy.

(c) Notwithstanding the desirability that termination should be at an early stage, care should be taken to ensure that it is the woman's real and considered wish that her pregnancy should be terminated, and also to ensure her protection from undue pressure.

(d) Consideration might be given to decriminalising abortion during the first twelve weeks of pregnancy.

(e) It was considered important that abortion services should be rendered by adequately-qualified, but not over-qualified, personnel. In principle, it seemed that the person providing general health care for the community should be responsible for providing abortion services. If this person were a registered medical practitioner, there did not appear to be any reason why other qualifications should be sought unless they were required for specialised procedures.

(f) Consideration should be given to authorising suitably-trained paramedical personnel to provide early abortion services under appropriate supervision.

(g) It was considered appropriate for abortion for adolescents to be regulated under comprehensive provisions for fertility control and education. Ideally, parental concurrence should be sought, but when this is not available or is refused and the minor seeking abortion is left in jeopardy to life or health then naturally the patient's interest should prevail. In such cases there might be an alternative source of permission: perhaps the minor and her physician might have immediate access to an independent public officer, such as an Official Guardian or Children's Ombudsman, to present evidence and apply for legal authorisation by this officer in loco parentis.

(h) In the case of adult patients - and also minors, subject to (g) above - it was seen as desirable to minimise the need for third-party consents in legislation. Most participants felt that only the informed voluntary consent of the patient, competent to give consent, on whom the procedure is to be performed should have to be obtained.

(i) Pending possible implementation of an advanced law, measures should be considered which would ease physicians' fears of acting under existing laws. These could include the

development of a check-list of items which physicians could show they had taken into account in their decisions, in order to demonstrate their good faith. Emphasis on physicians' good faith directed to the welfare of patients might do much to remove the criminal taint from abortion procedures.

(j) It was desirable that providers of health who claim conscientious objection to being involved in abortion should be required to refer patients to personnel or agencies known not to be averse to the procedure. However, the workshop saw no room for conscientious objection in cases of emergency or post-abortion care.

(k) Ideally, abortion services should be rendered in facilities offering general female health services, including contraception counselling and services, sterilisation and breast self-examination.

(l) Consideration should be given to accommodating abortion primarily in laws focussing not upon crime and punishment but upon health and welfare.

(m) A continuing dialogue should be maintained between doctors and lawyers on the impact of legislation upon medical practice, and the impact of medical technology upon the relevance and application of laws.

(n) National documentation of proposals for legislative reform and copies of legislation enacted should be sent to the Commonwealth Secretariat, in order to ensure that other jurisdictions might benefit from collective experience in this difficult field.

Regional

(o) Regional groups of countries should explore the possibility of regional collaboration to improve the legal availability of abortion services, to make means of fertility control more freely available, to determine the appropriate qualifications of paramedical personnel involved, and to clarify and, where necessary, reform relevant legislative provisions, including those concerning adolescents. The provision of a consultant, on request, to assist governments of the region in this connection, and to advise on how recommendations of the workshop might be implemented, should be considered.

(p) Regional groups should also promote the training and monitoring of appropriate health care providers, on a regional basis, in the light of the workshop's recommendations.

Commonwealth Secretariat

(q) The Secretariat should, where requested, assist in whatever way it can governments and regional groups seeking to implement recommendations of the workshop.

(r) The Secretariat should from time to time circulate to member governments documentation on proposals for legislative reform and copies of relevant national legislation. A periodic list of relevant health legislation in the Commonwealth should also be made available, possibly by

extracting references and citations from the Commonwealth Law Bulletin.

(s) The Secretariat should seek to arrange further workshops and continue to promote discussion to improve understanding between doctors and lawyers on abortion, contraception, adolescent health care and associated matters.

Appendix B Commonwealth Secretariat, Report of a combined Medical-Legal Workshop, Malawi, October 1979

ITEM III : THE LAW ON MEDICAL TERMINATION OF PREGNANCY AND RELATED ISSUES: AFRICAN AND ASIAN COUNTRIES: CONCLUSIONS

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63. This item was introduced by three speakers. Dr. Nimrod Mandara, formerly head of the Muhimbili UMATI clinic in Dar es Salaam and medical director of the Tanzania Family Planning Association, and now working as a gynaecologist in Swaziland, dealt with medical issues relating to the medical termination of pregnancy. Professor Bernard Dickens, Director of the Law and Health Care Programme of the Faculty of Law, University of Toronto, Canada, and also Associate Professor in the Faculty of Medicine of that university, analysed the main features of various types of law governing abortion. Miss Rebecca Cook, formerly head of the Law Programme, International Planned Parenthood Federation, outlined options for doctors. Miss Cook and Professor Dickens are the joint authors of the discussion paper Law on medical termination of pregnancy (see p.69) and of A survey of abortion laws in Commonwealth countries, contained in the Commonwealth Secretariat publication Abortion laws in the Commonwealth (published separately and available from the Secretariat - also to be re-published by the World Health Organisation, Geneva).

Medical Issues

64. Dr. Mandara said that, in general, about ten per cent of all pregnancies aborted before the twenty-fourth week. A large proportion of these sponteneous abortions (about 80 per cent) were incomplete and required medical attention. Complications such as bleeding and sepsis were the common reasons for seeking medical treatment, and even with good medical attention some abortion cases died, usually because of delay in seeking treatment.

65. In many African countries numerous hospital beds were taken up by abortion cases. In the main medical centre in Dar es Salaam, for instance, over 4000 (two-thirds) of the total of 6000 gynaecological admissions in 1978 were diagnosed as abortion cases. Of these, it was estimated that 85 per cent were spontaneous abortions and 5 per cent had been interfered with before admission; as for the remaining 10 per cent, it was difficult to ascertain whether there had been any interference or not. Complications, usually bleeding and sepsis, were common and had resulted in nine deaths (a mortality rate of over 2 per 1000). A study in Khartoum, Sudan, in 1975 had shown that the ratio of admissions of incomplete abortions to other admissions of maternity cases was 1:1. The pattern in other centres in Africa was similar.

66. Dr. Mandara pointed out that induced abortions had been carried out for a variety of reasons in almost every culture before proper medical services had been established. In parts of Africa, such procedures had been carried out before the Western medical and legal systems had been established, and even to this day cases of abortion complications frequently arose, caused by the use of herbs or crude instrumentation, often with grave results.

Indications for pregnancy termination

67. Indications for the medical termination of pregnancy varied, depending on the law governing abortion in particular countries. On the whole, however, the law was imperfectly understood by those carrying out terminations. Common indications included:

(a) risk to the life of the woman;

(b) risk to the physical or mental health of the woman if the pregnancy were allowed to continue;

(c) some degree of likely physical or mental impairment of the child;

(d) pregnancy resulting from rape or incest, or some other unaccpetable sexual union;

(e) socio-economic reasons, where the pregnancy would affect the welfare of existing members of the family;

(f) failure of routine contraceptive use.

68. In most African countries, Dr. Mandara explained, legal justifications for abortion were restrictive, and allowed only for the first two of these indications, risk to life and risk to health. A woman seeking abortion for any other reason was consequently obliged to consult a back-street abortionist. The expertise of such abortionists was questionable and they often employed unsafe procedures which put women in grave danger of serious complications and even death. This was one important reason why abortion was becoming a serious problem in so many countries.

69. The deaths of all the nine abortion cases who had died in the Dar es Salaam medical centre in 1978 had resulted from illegally induced abortions. Of the surviving cases, a high proportion of those who had developed sepsis would not be capable of bearing children in the future because of obstructed fallopian tubes. Infertility was a common problem in Africa; infertility management was not only time-consuming and expensive, but gave disappointing results even when surgery had been attempted. And few infertile women were fortunate enough to be able to consult a physician, let alone undergo surgery.

Current medical practice

70. Medical developments in recent years had changed this gloomy picture to the extent that the risks of legally performed abortion, especially in early pregnancy, were less than

those of allowing the pregnancy to continue to its full term. During the first few weeks of a missed period, termination of pregnancy could be easily and safely carried out by vacuum aspiration - either as a simple menstrual extraction or regulation without an anaesthetic or with only a local anaesthetic and as an outpatient procedure (a "lunchtime" abortion); or by means of vacuum aspiration apparatus in the operating theatre under local or general anaesthetic during the first twelve weeks of pregnancy. Routine dilation and curettage (D and C) could also be employed during this early period. Complications arising from apsiration termination were few, and without any deaths in many centres.

71. More recently, vaginal prostaglandin tablets had been tried and "morning after" pills were also under trial, in some countries with promising results.

72. Surgical evacuation of the uterus became increasingly dangerous during the second trimester of pregnancy because of the risk of injury to the uterus and excessive bleeding. Intra-amniotic or extra-amniotic prostaglandins were safer and more effective than first trimester abortions. The aim should therefore be to carry out the medical termination of pregnancy before the twelfth week of pregnancy, or, better still, as a simple menstrual extraction as soon as the woman missed a period. Where second trimester terminations were unavoidable, prostaglandins were much safer than hysterotomy, which was not only costly in terms of personnel and hopsital beds but also involved risks associated with scarred uterus.

The need to review abortion law

73. Despite the fact that medical developments had made pregnancy termination such a safe procedure, Dr. Mandrara observed, legal developments had lagged behind. The consequence was that induced abortion, which was known to occur frequently, was still being performed by persons not trained to carry out the procedure - secretly, in places with very poor facilities, and often with serious complications resulting.

74. Besides pointing to the need for a complete reappraisal of the laws governing abortion, Dr. Mandara suggested that attention should also be focused on the moral, cultural and legal aspects of contraception, with the aim of making contraceptives available to all who needed them. If existing laws could be modified to allow easier access to legal abortion, the use of contraceptives might even be made mandatory after every pregnancy termination.

75. Dr. Mandara ended his presentation with the warning that the present system for the delivery of medical care in many countries, particularly in Africa, would be hard pressed to meet the demand that could be expected to follow the introduction of liberal abortion laws. It was therefore necessary to move carefully, and to try to balance the law against the medical availability of abortion services.

The Law on Abortion

Types of abortion law

76. Professor Dickens opened his presentation by distinguishing three types of law governing abortion in the jurisdictions represented at the workshop, namely:

(a) basic law,

(b) developed law,

(c) advanced law.

77. Basic law had emerged from section 58 of the English Offences against the Person Act, 1861, and was expressed in simply prohibitive language. Professor Dickens read the section verbatiam, and emphasised that it used the word "unlawfully" on four occasions to define the prohibition; at no point, however, did the section say when abortion might be undertaken "lawfully".

78. Developed law demonstrated that, as an exception to the criminal prohibition, abortion might be lawfully performed where necessary to preserve a woman's life or health. The development of the law had been established by the judgement in the celebrated 1938 English case, R. v. Bourne. In that case, the pregnancy of a young girl made pregnant by rape had been terminated lest she might become a "mental wreck". In instructing the jury that abortion performed in good faith on this ground justified acquittal, the judge had recognised the legality of both physical and mental health indications for abortion.

80. While every basic law was inherently developed when construed, cases leading to clarification were few. Professor Dickens observed that development could be achieved not only by legislatures and by judicial rulings, but also by senior members of the executive, such as attorneys-general and ministers of health, presenting their understanding of the law. This would not be legislative, nor would it bind the judiciary; it would in fact be nothing more than a clarifying statement of what the law already was.

81. Advanced law specified indications upon which abortion was lawful, and provided machinery for the prior establishment of legality. Specific indications included the indication of strict necessity, concerning risk to life and grave risk to permanent health, and the therapeutic indication incorporating the Bourne test of serious danger to physical or mental health. Other indications included the fetal or eugenic indication, relating to the fetus and its prospect of serious handicap; the juridical indication, where rape or incest had caused the pregnancy; and the social, socio-medical or socio-economic indication.

82. A number of advanced laws included such indications, but the therapeutic indication could be quite comprehensive, so that an advanced law excluding a rape indication as such

might permit termination of a victim's pregnancy resulting from rape on the ground of danger of mental health, compatibly with the Bourne cases.

Considerations for legal reform

83. Professor Dickens noted the evolution from crime-control laws (basic), through laws recognising medical exceptions (developed), to laws focusing upon health and welfare (advanced). He stressed the desirability, for purposes of public comprehension and health providers' protection, of the law being at least developed, and expressed in language clearly stating what was lawful. Where legislators did not address the issue, attorneys-general and ministers of health might be requested or encouraged to offer clarification.

84. He observed that a gap existed between the restrictiveness of the written law and its very rare enforcement, although breach was obviously frequent. He further observed that women with means could meet or evade the law with skilled, safe medical attention; the poor, the young and the uneducated bore the health hazards of unskilled, unqualified interference. This was the more tragic when grounds existed for lawful treatment.

85. Laws governing abortion were silent as to the point in time when pregnancy might be said to commence, but evolving methods of contraception - particularly by "hindsight" methods such as "morning after" pills - might blur the distinction between contraception, which was lawful, and abortion. Accordingly, however abortion was defined, the law should not be applicable in such a way as to obstruct means of legitimate contraception. Indeed, the case was worthy of consideration to revert to the position of the historic Common Law, where pregnancy was first evidenced by "quickening", which was taken to occur at the end of the first trimester.

86. In conclusion, Professor Dickens noted the obstacles that might exist to enacting an advanced law. He also pointed out that certain forms of advanced law could in fact be restrictive, by introducing mechanisms for approval which depended on the use of personnel who might not be available. A clear statement that national law was in developed form might well be adequate to serve the health needs of the majority of women.

The Position of Doctors

Options

87. Miss Cook began her presentation by dealing with options for doctors where laws were not developed. Abortion laws expressed both in basic and in developed forms permitted doctors to perform abortions when medical indications were indentified in good faith, she observed. Doctors who could provide suitable evidence of their good faith were thus in a secure position. To assist them to demonstrate good faith they could use a check-list of considerations which a doctor acting in the interest of a patient's health would apply. An adequate medical history, with diagnosis and prognosis properly recorded, as for any other conscientiously-proposed medical

procedure, would furnish convicing evidence. Furthermore, such evidence would be re-inforced if the fee charged for an abortion were moderate and in accordance with the reasonable means of the patient to pay, since if the procedure were medically necessary to preserve the patient's health, it could not conscientiously be priced beyond the patient's means.

88. A patient presenting an incomplete or a threatened abortion, impossible to identify as either spontaneous or induced in origin, exposed doctors to suspicions and risks against which legal protection was required. The conceptual transition of abortion law from criminal law to law focusing on health and welfare should permit immediate treatment to be given without regard to the production or preservation of forensic evidence.

Obligation and objection

89. Miss Cook pointed out that under both developed and basic law a doctor might have an obligation to peform an abortion. Where a woman's health was endangered in such a way that it was desirable to terminate her pregnancy, the practitioner's duty to the patient would necessitate the offer to her of the option to have an abortion. The doctor could not abandon the patient, but might have to refer her to someone else for the option to be taken up. Failure to offer the option, leading to the woman's death, might possibly incur prosecution for manslaughter by criminal negligence. If death, or injury to physical or mental health, resulted, a civil claim for malpractice might arise. Only a law expressly affording doctors, nurses and other personnel the right of conscientious objection to abortion would relieve them of their legal duty to a patient. A condition of such a law would be that it should state that performance of abortion was lawful upon specified indications.

Regulations

90. Where the drafting of an advanced law was proposed, legal regulation of abortion might be by means of the medical and other indications already outlined by Professor Dickens, Miss Cook continued. Alternative means existed, however, such as permitting persons of specified qualifications to make the decision that an abortion might be performed and to act accordingly. Some existing advanced laws specified that late-term procedures could be performed, except in emergency, only by doctors holding specialist qualifications. Conversely, it might follow that under a prospective advanced law paramedicals might be authorised to perform very early procedures.

91. An alternative to regulation by specifying professional qualifications was regulation by specifying the types of facilities required for the performance of abortions. Some advanced laws now in force specified the use of government or other specially-approved clinics or hospitals, where personnel could be expected to possess the requisite skills and conscientious judgement. The standard of facilities and the level of qualifications required could be related to the stages of the pregnancies to be terminated - early stages needing simpler facilities and lower qualifications, later stages needing more sophisticated facilities and higher qualifications.

92. Miss Cook suggested that this gestational criterion might also be applied to indications for the medical termination of pregnancy. Early abortion might be allowed on a broader range of indications than later abortion, which might be permitted, consistently with common child destruction laws, only to save life or prevent permanent serious injury to health.

93. She also stressed that, especially where abortion was permitted only on the grounds of preserving life or health, approval procedures required by advanced laws should not be such as to jeopardise the very services the laws were designed to make available. These procedures should not involve delay, or degrading difficulties for the pregnant woman, through the introduction of persons who were, in practice, unlikely to be accessible. Similarly, the introduction of a third party in the decision on treatment might give that party a right of veto over a medical initiative taken in good faith to preserve a woman's life or health.

94. Some advanced laws contained distinction and sometimes complex reporting requirements, presumably to prevent abuse of legal provisions. Evidence suggested, however, that in practise such reporting requirements served little purpose, except to differentiate the medical termination of pregnancy from other medical procedures. It was questionable whether requirements for abortion needed to be different from those relating to other comparable procedures.

95. In conclusion, Miss Cook suggested that governments which were unable to back up an advanced law with the resources needed to make it operate properly might better serve the interests of their people by having a developed law. Furthermore, where available resources were limited these might be used more beneficially by being concentrated on preventive care, through programmes providing contraceptives and information about contraception.

Discussion

The cost of illegal abortion

96. The workshop recognised that costs associated with illegal abortion were a sizeable charge upon the limited resources of personnel and facilities in all countries. Individual and family costs were expressed in women's deaths and morbidity, in infertility caused by unskilled interference, and also, for instance, in premature school-leaving. It was not possible in many cases to identify whether the abortions were spontaneous or induced. Frequent cases occurred, however, where abortion induced by such means as the use of herbs or crude instruments had grave results. Virtually all abortion-related deaths in major hospitals were known to have followed illegal interference. For survivors of such interference there was a high risk of secondary infertility, which could have unfortunate personal consequences, particularly in African cultures.

97. It was noted that medical developments in recent years had greatly reduced the risks relating to medically-performed

terminations of pregnancy. Such risks were now less than those connected with childbirth. In the first few weeks of a missed menstrual period vacuum aspiration techniques could be employed, and safe operating-room techniques were available for the termination of pregnancies of up to 12 weeks. Such means as vaginal prostaglandin tablets offered promise for the future. Later terminations carried greater risks; in the interests of health care it was best to perform terminations at the earliest possible stage, preferably in the first trimester - i.e. within the first 12 weeks after conception.

98. It was also noted that modern thinking on abortion, as reflected in recent legal developments in many parts of the world, had turned from concentration on criminality to consider actions of health and welfare. New laws enacted in recent years thus tended to focus on the health and well-being of women and children as indications for the lawful termination of pregnancy.

99. Participants pointed out, however, that to liberalise the law on abortion might place existing health services under even greater pressure than that at present caused by the need to treat complications arising from illegal abortions. It was thought desirable, therefore, also to give attention to preventive medical intervention, notably through making the means of contraception more easily available and encouraging their use.

100. The lack of sufficient data, systematically gathered, on the consequences of illegal abortion, was thought to conceal the extent of the problem, particularly from government agencies. Information could be obtained from hospitals, schools and other sources on the social cost of maintaining legal prohibition in appearance, if not in practice - of the medical termination of pregnancy.

The law and its shortcomings

101. The workshop noted that abortion laws tended to be expressed in three different ways. Basic law prohibited abortion when done "unlawfully", but was silent on the circumstances in which abortion might be performed lawfully. Developed law recognised the legality of abortion carried out in order to save a woman's life, or to preserve her physical or mental health. Advanced law prescribed a range of medical, and sometimes non-medical, indications for lawful abortion and procedures for establishing legality before the event. Developed law interpreted basic law in accordance with the Bourne case of 1938, so that developed law could be seen as implicit in basic law, as understood by lawyers and as interpreted by Commonwealth judges after the event. It was considered, however, that the law was better understood by doctors and the public at large when its meaning was explicit.

102. The disadvantages fo the law appearing to doctors and the public to be prohibitive were seen to include the following:

(a) Women turned to illegal means of procuring abortion, even when legally entitled to the procedure, and might delay going to hospital when illegal interference had resulted in injury or infection.

(b) Pre-abortion and post-abortion counselling (for instance, the provision of advice on methods of contraception) was inhibited by the potentially criminal setting of abortion.

(c) The unreliability of available services might deny a woman the opportunity calmly to consider and discuss whether to end a legally termirable pregnancy.

(d) Lack of time might deny a person authorised to perform a termination the opportunity to decide whether the applicant for abortion was genuinely seeking it or was acting under pressure from someone else, such as her partner or her family.

103. The workshop recognised that, while there were instances of manslaughter charges against illegal practitioners being laid, prosecutions for unlawful abortion as such were rare. In a number of jurisdictions they were unknown. It thus appeared that a law with identified harmful effects was being neither enforced nor amended. In such circumstnaces, particularly where change to an advanced law was found impracticable, it was thought that the law might at least be clarified, for the guidance of doctors and women, by an authoritative statement of the life and health indications on which abortion was permissible.

104. It was also recognised that some societies were unable to accept, or even to consider, an advanced law, which might include such indications for legal abortion as threatened damage to fetus, social or socio-medical grounds, and the juridical grounds of rape or incest. Further, participants considered that it would be unwise for a government to contemplate the introduction of such a law unless it was able to provide the personnel and facilities which the operation of an advanced law might require. It might be more beneficial to devote scarce resources to family planning programmes.

Protection and liability

105. The workshop accepted that doctors acting under a developed law could be protected by a clear statement of its provisions, by providing evidence that they were acting in good faith, and by charging moderate fees. They should be able to treat cases of incomplete or threatened abortion without fear of criminal involvement. At the same time, they should be made aware that wrongful refusal to treat a patient, who would suffer injury if her pregnancy continued, might expose them to civil legal liability, or even to criminal liability should the patient die.

Special requirements

106. It was noted that under advanced law the availability of abortion services was regulated not only by indications concerning the patient but also by specifying the qualifications

of practitioners authorised to terminate pregnancies, the types of equipment and facilities required for the procedure, and the gestational limits. Such requirements could be framed so as to make abortion more accessible in the early stages of pregnancy, but harder to obtain in the later stages. Participants considered that approval procedures should be governed by medical need and should not involve undue delay; nor should they be subject to veto by a third party, although discussion with parents might be desirable because of cultural sensitivities. An advanced law allowing non-medical indications might accommodate the views or interests of third parties.

Conscientious objection

107. The workshop agreed that the right of an authorised person conscientiously to object to abortion per se should be properly recognised, but it was considered that this should apply only when the patient's health needs would be properly met if the authorised person were to withdraw from the case. A law stating that abortion was lawful in given circumstances should include provision for conscientious objection. The suggestion that a conscientious objector should be placed under the obligation to secure the services to another authorised person who was willing to perform the procedure did not meet with agreement.

Acceptability

108. On the question of the general acceptability of abortion, the workshop recognised that it was for each country to decide how the difference between preserving a prohibitive law for public purposes, at a cost of health care, and using the law pragmatically to reduce harmful acts and their consequences (and perhaps leaving the protection of moral values to non-legal institutions) should be resolved. Disapproval of abortion might remain, but it might be made legally acceptable as the best of several sad options available.

109. There was some discussion of the rape indication for abortion, which was found to raise issues of a technical legal nature, and in particular the issue of whether it was open to unacceptable abuse. It was noted that a woman's sincere claim that she had been raped and a doctor's acceptance that her mental health was consequently threatened might justify abortion under the mental health indication contained in a developed law. Evidence of the doctor's good faith should protect from criminal liability the doctor deciding to terminate a pregnancy. It was also noted, however, that there was in some countries wide public acceptance of the rape indication for abortion.

110. Participants observed that the approval procedures for abortion should be realistic and appropriate to local circumstances, and should not make excessive demands on medical personnel or on women who applied. It was suggested that, in principle, as for any other legitimate procedure, only a single doctor's clinical judgement should be required for abortion on medical grounds. For non-medical indications, however, other special opinions might be required.

111. It was noted that the abortion indication of contraceptive failure presented problems of evidence. It was suggested that this indication might be considered acceptable if narrowly construed as a fail-safe or safety-net means to encourage the practice of contraception. Again, evidence of the doctor's good faith in deciding to terminate a pregnancy on these grounds would be required. It was also suggested that an indication allowing termination of a pregnancy occurring soon after childbirth might be justified, as constructively assisting the spacing of childbirth where this was culturally acceptable.

Paramedicals

112. While it was recognised that in some circumstances it might be permissible, as was the case of other comparable medical procedures, for paramedicals to perform terminations of pregnancy under a doctor's supervision, there was disagreement about the desirability of paramedicals doing this independently, on their own decision. The distinction was also drawn between the position of a paramedical acting where a doctor was available, and that of a paramedical acting where the only alternative might be non-treatment. Some participants thought that it might be appropriate for paramedicals to perform terminations during the earlier stages of pregnancy, but others insisted that the person carrying out terminations should possess the skill required to deal with possible complications.

Resources

113. On the subject of resources, it was pointed out that an applicant refused an abortion by a hospital on the ground of inadequate resources might seek illegal means and then return to the hospital shortly afterwards as an emergency case. The initial refusal would thus have saved nothing in hospital services. Alternatively, the unwanted child, when born, might be abandoned and might then have to be maintained at public expense. On the other hand, it was also pointed out that patients needing other than abortion procedures whose treatment was delayed by the admission of abortion patients might themselves become emergency cases. Competition for scarce hospital resources was unavoidable and could not invariably be resolved in favour of abortion patients.

Legal provisions

114. The suggestion was made that laws prohibiting abortion might possibly be so construed as to restrict evolving methods of contraception. It was considered that legal provisions dealing with contraceptive methods (e.g. in drug laws) should be kept separate from abortion law.

115. Although sympathy was expressed, there was not complete agreement on the principle of decriminalising termination of pregnancy during the first trimester on the grounds that this would permit prompt treatment when it was safest and when there was least psychological trauma.

116. The question was raised of why legislation on abortion needed to be different from that on other medical procedures, in being governed by criminal law whereas the other procedures were not. It was felt that justification of the distinction

Appendix C

Regular Review

Prostaglandins in human reproduction

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Prostaglandins undoubtedly play a major part in reproduction, including the control of parturition, and are now believed also to be concerned in many other vital processes, but their precise functions are not fully understood. Nevertheless, much is known; and the prostaglandins are now widely used. Current clinical applications include prelabour cervical priming as well as induction of labour, termination of first and second trimester pregnancy, and management of abnormal pregnancy.

The prostaglandins are hormone-like compounds. They differ from classical hormones in being synthesised and released locally on demand from precursor fatty acids and are rapidly inactivated and metabolised in the blood stream. Within cells they are thought to exert their effects by changes in cyclic AMP; release of calcium ions may be important in some target tissues, including the myometrium.

The naturally occurring prostaglandins are a group of at least 14 related compounds, each a 20-carbon hydroxyfatty acid possessing a five-carbon ring and two side chains. Prostaglandin chemistry and nomenclature are complex, but of the naturally occurring prostaglandins only two, prostaglandin E_2 (PGE_2) and prostaglandin $F_{2\alpha}$ ($PGF_{2\alpha}$), are clinically important in reproduction. Biosynthetic and metabolic pathways need not be considered here except to observe that some of the endoperoxide precursors are physiologically active and that two recently discovered related compounds, prostacyclin (PGI_2) and thromboxane A_2, are powerful regulators of blood clotting. The activity of prostaglandins may be modified by substitution of artificial groups in the molecule (for example 15-methyl- or 16:16-dimethyl-groups), resulting in analogues resistant to degradation or more specific in action; some already show promise in clinical use.

The therapeutic uses of the prostaglandins in labour and abortion depend on three properties. Firstly, they are strikingly uterotonic, stimulating or augmenting uterine contractions. Despite contradictions in very early work, both PGE_2 and $PGF_{2\alpha}$ stimulate contractions, PGE_2 being some five times more potent than $PGF_{2\alpha}$. Secondly, the prostaglandins are responsible for the structural alterations in its connective tissue which soften and "ripen" the uterine cervix. A third possible role as a luteolytic agent, inhibiting the corpus luteum and preventing production of progesterone, has been substantiated in animals but remains unproved in man.

The prostaglandins are also concerned in other reproductive functions including ovulation and the control of menstruation, so that their clinical uses seem likely to be extended. In other instances (for example, dysmenorrhoea, thought to be due to accumulation of endometrial prostaglandins) there is a place for non-steroidal, anti-inflammatory drugs which are "prostaglandin synthesis inhibitors." The use of prostaglandin inhibitors in premature labour is more controversial; there is a potential risk that the fetus could be compromised since patency of the ductus arteriosus is believed to be maintained by endogenous prostaglandins.

The prostaglandins were first used clinically by intravenous infusion to induce labour in 1968[1 2] and to induce abortion in 1970.[3 4] As it became apparent that intravenous administration, especially in the high concentration needed for abortion, caused unpleasant side effects (notably vomiting and diarrhoea), this route has since been largely superseded, with varying degrees of success, by alternatives including oral, intramuscular, intrauterine (extra-amniotic or intra-amniotic), and vaginal administration.

Induction of labour and cervical ripening

The early studies of induction of labour using intravenous prostaglandins showed the effectiveness of the method and established dose ranges. Initial comparisons with orthodox oxytocin infusion produced conflicting views,[5] but continuing experience showed that generally prostaglandins were no more effective than oxytocin—except in patients in whom the cervix was unripe[6] (see later). Early fears that prostaglandins would produce hypertonus and fetal distress more often than oxytocin have not been clearly substantiated.[7] The chief disadvantage of the method is the frequency of gastrointestinal side effects, and as a result oral, vaginal, and intrauterine (extra-amniotic) routes of administration have been explored in recent research studies.

The convenience of oral treatment makes it attractive, but it is generally less effective than other routes of administration. The necessary systemic absorption produces troublesome side effects, which with $PGF_{2\alpha}$ are severe. Oral tablets of PGE_2 are available and are usually prescribed at a dose of 0·5 mg hourly (increasing step-wise to 2 mg) and combined with amniotomy. Gastrointestinal side effects occur in about one-fifth of patients, and vomiting reduces the likelihood of successful induction (especially in primigravidae, who require higher doses). The usefulness of the method is chiefly in multiparae with favourable induction prospects.[8]

The most recently identified obstetric use of the prostaglandins is that of "priming" or "ripening" (that is, softening and effacing) the cervix—in practical terms an important development. Though the ripening effect was commented on in some early clinical studies,[2] many assumed that it was the indirect result of induced uterine contractions. Now there is increasing evidence that prostaglandins, especially PGE_2, bring about the structural alterations in the connective tissue of the cervix accompanying ripening which are a necessary prelude to progressive labour and delivery.[9 10]

The prognosis in induced labour is governed primarily by the degree of ripeness of the cervix, best expressed in a Bishop score or "inducibility" score.[11] When the cervix is unripe (long, tightly shut, and rigid) labour is difficult to establish and it may "fail to progress" or be prolonged, often resulting in a high caesarean section rate and a poor outcome for mother and fetus.[12]

Prospects can be much improved by ripening of the cervix with prostaglandins before induction. Latent-phase cervical effacement and dilatation are achieved with little or no distress to the patient, with intact fetal membranes, and without jeopardy to the fetus. Local administration is best; the technique first used (in 1976) was extra-amniotic administration through a transcervical catheter of PGE_2 in a methyl cellulose gel the night before planned induction.[12] Assessment of this method in 121 primigravidae with unripe cervices (inducibility score 0-3) showed that one-fifth laboured without further intervention, while in the remainder labour was shorter, the caesarean section rate was halved, and fetal well-being improved compared with a control group.

Soon, however, essentially similar benefits were being obtained by the simpler non-invasive technique of vaginal administration of PGE_2 gel.[13] In a group of 168 primigravidae the instillation of PGE_2 gel resulted within half to 2 hours in backache and uterine contractions of mild intensity (recurring at one to three minute intervals and not exceeding 40 mm Hg pressure), persisting for four to five hours and then waning or else progressing to established labour. With PGE_2 5 mg the cervical score improved in 88% while 49% began labour before planned induction. There were no maternal or fetal side effects.[13]

As the method was extended to primigravidae and multigravidae with Bishop's scores in all ranges the results showed that as the pretreatment cervical score increased so did the proportion of patients labouring during priming, while the average duration of labour decreased, the frequency of spontaneous vaginal delivery increased, analgesic requirements diminished, and caesarean section was less often required. These benefits were greatest when labour followed priming without the need for formal induction—which occurred in about 40% of primigravidae with an unripe cervix rising to 90% in multigravidae with a favourable cervix.[14]

The value of preinduction ripening of the cervix with vaginal PGE_2 has since been confirmed in a much wider experience; an alternative to the gel is the use of glyceride-based or other simple pessaries prepared in hospital pharmacies.[15 16]

Differences in patient selection, treatment protocols, and criteria for success make comparisons of induction studies difficult. Nevertheless, in one representative study using 3 mg pessaries of PGE_2 43% of the 110 primigravidae with Bishop scores of 0-4 laboured after a single priming pessary without formal induction while the remainder received a second pessary. There were six failed inductions. In multigravidae when the cervix was ripe (Bishop score ≥ 4) 90% laboured without additional measures.[16] In another trial, when inducibility scores were favourable, pretreatment with PGE_2 pessaries (5 mg in primigravidae, 2·5 mg in multigravidae) was followed by amniotomy in three hours. Successful labour and delivery ensued in about 80% of multigravidae and 60% of primigravidae without the need for oxytocin infusion; further, there was a reduced requirement of epidural analgesia and the incidence of postpartum haemorrhage was lowered.[16]

While there have been no control studies, the cervical ripening method has been used successfully in many patients previously delivered by caesarean section and in those with breech presentation, in whom the promotion of the effacement and dilatation of the latent phase of labour with intact membranes may have merit.[15] Most authors have not considered it necessary to monitor "low risk" and uncomplicated cases, but continuous monitoring (at least for the first four to five hours) would seem prudent for patients in whom insufficiency is suspected.[14 15]

The evidence from all these published data points to the relative safety of the method and its freedom from adverse effects. Because priming doses are low, gastrointestinal symptoms are very uncommon (less than 1%), as is any thermogenic effect. Uterine hypertonus is likewise rare, while if it occurs fetal distress is not always evident.

Nevertheless, while the value of vaginal prostaglandins in ripening the unfavourable cervix when labour needs to be induced may be considered well established, their use for routine induction of labour is perhaps more controversial. The method is gaining in popularity, for it offers important benefits in patient acceptability and ease of management for medical personnel. Labour tends to be more natural than after formal induction, analgesic requirements are reduced, and both women in labour and nursing staff appreciate the likely avoidance of intravenous oxytocin infusion and the immobility it entails, while permitting patients to walk about during early labour may actually hasten delivery.

The prostaglandin cervical priming method would be still more widely used were a conveniently packaged product available. Unfortunately, in the current simple formulations PGE_2 does not possess adequate long-term stability and this has prevented development of a commercial product. This lack has prompted the use in some units of oral tablets of PGE_2 by the intravaginal route.[17] An additional practical problem is that dissolution and absorption of the available products are rapid (within two to four hours), with the possible risk in some multiparae of unduly rapid labour. A recent report of induction of labour using a novel polymer vaginal device suggests that these drawbacks can be resolved to provide a stable delivery vehicle giving controlled sustained release of PGE_2.[18] Such a development would be welcome, for on grounds of efficacy, safety, and acceptability vaginal PGE_2 seems likely to be used increasingly for cervical ripening as a prelude to formal induction or as an alternative procedure which may make induction unnecessary.

Other obstetric uses

The management of fetal death in utero has been much simplified by the prostaglandins, which now provide safe and effective means of emptying the uterus in missed abortion or intrauterine death near term and also in cases of hydatidiform mole and anencephaly. Intravenous infusion or extra-amniotic injection may be used, but equally good results follow simple vaginal administration of PGE_2 in gels or pessaries.[19] High dosage, as in one series,[20] provokes gastrointestinal irritation, but if dosage is related to gestation and the size of the uterus, side effects are not troublesome.

Termination of pregnancy

Despite their potential as fertility-regulating agents, the prostaglandins have not yet fulfilled all their promise. Experience has so far fallen well short of expectations in relation to termination of early pregnancy. Prostaglandins have,

however, established a place in the termination of second trimester pregnancy, and in many units they are used to the exclusion of alternative methods.

Second trimester terminations—The shortcomings of the natural prostaglandins (PGE_2 and $PGF_{2\alpha}$) as abortifacients are related to their rapid inactivation and the degree of gastrointestinal irritation caused by systemic absorption. Early studies showed that intravenous treatment for abortion requires high dosage (five times that required for induction of labour) and causes unacceptably severe vomiting and diarrhoea, while oral treatment is ineffective. Vaginal administration also results in prominent side effects and is not consistently successful.

Fortunately, however, the prostaglandins act locally and are effective when given by the intrauterine route. This was first achieved by the simple technique of extra-amniotic instillation using a catheter introduced just through the cervix, and later by intra-amniotic injection through the abdominal wall. The latter was promoted as a "one shot" method, but a large experience of treatment with intra-amniotic $PGF_{2\alpha}$ has shown that, for an acceptable level of efficacy (90% or more abortions within 48 hours; mean abortion time less than 24 hours), an injection of 25 mg frequently needs to be repeated, while if the initial dose is increased to 40-50 mg gastrointestinal side effects are severe.[5 21] Because of its limited availability intra-amniotic PGE_2 has been used less widely, but several studies have shown its effectiveness, the administration of 20 mg, or 10 mg repeated in six hours, giving a high success rate with relatively few side effects.[5 21]

The extra-amniotic method is comparable in efficacy with the intra-amniotic route. Two hourly instillations of PGE_2 200 μg (or $PGF_{2\alpha}$ 750 μg) or equivalent amounts by continuous infusion results in abortion within 48 hours in some 90% of patients.[22 23] In 1975 it was shown that the extra-amniotic administration of PGE_2 1·5-3 mg in a viscous methyl cellulose gel provides a more prolonged effect, limiting or eliminating the need for frequent or continuous injection and gives equivalent results.[24] Nowadays this is the method commonly used. Because the dosage is low the incidence of gastrointestinal effects is lower with extra-amniotic than with other routes of administration, while the theoretical risk of infection has in practice not proved a hazard.

To shorten abortion times prostaglandins may be used in conjunction with other methods such as the intra-amniotic injection of hyperosmolar saline or urea solutions,[25] or laminaria tents (advocated particularly in the United States). Alternatively, abortion can be accelerated by using the enhancement effect of intravenous oxytocin (100 mU/min).[26] Intra-amniotic hypertonic solutions carry a risk of serious adverse effects—for example, hypernatraemia or consumptive coagulopathy—and are probably best reserved for ensuring lack of fetal viability in gestations of 20 weeks or over.

Though prostaglandin analogues are not available in Britain except for investigations, several have been evaluated clinically and the $PGF_{2\alpha}$ analogue 15-methyl $PGF_{2\alpha}$ has been widely tested in other countries. Longer acting than the parent compound (because the 15-methyl-group inactivates the dehydrogenase enzyme responsible for the first and most rapid step in prostaglandin metabolism), it has the merit that a single intra-amniotic injection of 2·5 mg[27 28] or a single extra-amniotic administration of 1 mg[28 29] usually suffices, but side effects are unfortunately troublesome. While repeated intramuscular injection is effective, the accompanying severe gastrointestinal side effects are generally unacceptable.[30] The analogue has also been administered per vaginam (1-1·5 mg three hourly) in glyceride-based pessaries.[31] Its high efficacy (resulting in about 90% abortions in 30 hours) is again marred by the high level of gastrointestinal symptoms. Moreover, these success rates were not substantiated when a single "longer acting" Witepsol pessary was used,[32] while incorporation of the agent in a silastic vaginal device did not provide the expected controlled, sustained release and gave disappointing results.[33 34] Equally or more effective, yet causing many fewer side effects, the 16:16-dimethyl-PGE_2 analogue and its semicarbazone ester would have great potential were it not for their lack of stability.[35] Improved products may be forthcoming. Meantime, the vaginal route remains an attractive goal because of its non-invasive nature, though in mid-pregnancy a considerable proportion of incomplete abortions occur (40-70%) requiring evacuation.

First-trimester termination—Most first trimester abortions are dealt with surgically by vacuum aspiration and generally complications are few, but potential risks from injury and haemorrhage are associated with rapid mechanical dilatation of the cervix. With the aim of reducing these problems and—possibly—the risk of premature delivery from cervical incompetence in a subsequent pregnancy, prostaglandins may be administered not to induce abortion but for their cervical "priming" effect before surgery. Endocervical administration of PGE_2 gel and intravaginal PGE_2 in a pessary[36] have both been used, but the most promising results have come from one of the newer PGE analogues either in a vaginal suppository[37] or intramuscularly.[38] Such methods are likely to be used more frequently as these newer preparations become available.

Early investigators prophesied an important place in fertility regulation for the prostaglandins when used to induce menstruation or prevent or interrupt early pregnancy through luteolysis or interference with implantation by effects on uterotubal contractility. At this early stage of pregnancy abortion may be almost indistinguishable from normal menstruation, and, provided bleeding is not unduly prolonged and pain and side effects are kept to a minimum, the method has great potential.

To date, however, the luteolytic effect in women has not been substantiated and the attainment of the expected objectives has proved elusive. Yet the prospect of a simple, safe, non-invasive, chemical method for early abortion remains a major goal, and recent research has concentrated on the development of vaginal pessaries containing newer prostaglandin analogues.

Though the natural prostaglandins are effective by transcervical intrauterine injection the results have been disappointing when they are given vaginally. Nevertheless, vaginal treatment became practicable with the synthesis of prostaglandin analogues which, by resisting metabolic degradation, have enhanced potency and longer action or show greater specificity of action, so causing fewer side effects. The new compounds have been administered in cellulose derived gels or simple lipid-based pessaries (usually three to four hourly) with a degree of success, though clinical trials have shown that not all the problems have been resolved. For example, while the uterotonic potency of the $PGF_{2\alpha}$ analogue 15-methyl-$PGF_{2\alpha}$ (the most widely tested analogue) is high, the severity of gastrointestinal side effects limits its clinical applicability.[39 40]

More selective in action, the 16-16-di-methyl-PGE_2 analogue and its semicarbazone ester are, at least, equally effective and cause fewer adverse effects when given in repeated vaginal pessaries[35 40] and would have considerable clinical impact were it not that problems of chemical instability have hampered commercial development. The same lack

of stability affects other recent PGE derivatives which have shown clinical promise. One of these, 16-phenoxy-ω-tetranor-PGE_2, has given encouraging results by the intramuscular route,[41] the other 16:16-di-methyl-trans-Δ_2-PGE_1 when administered vaginally.[42]

Current research is seeking to overcome the disadvantages of the products available. The instability of PGE_2 and PGE analogues may be resolved by the employment of improved gels[43] or by new sustained-release vaginal delivery systems.[18] The development of such devices would undoubtedly promote the use of vaginal PGE_2 in the induction of labour on a much wider scale and might be expected to result in better prostaglandin products for use in the termination of early pregnancy and menstrual induction. A prostaglandin analogue with an appreciable luteolytic effect in women remains an actively pursued research goal, while other derivatives exhibiting greater specificity of action and therefore fewer side effects are being sought in pharmaceutical laboratories. These and other related research developments may be expected to extend to the range of the clinical uses of these remarkable compounds in obstetrics and gynaecology.

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