The use of fetuses and fetal material for research / report of the Advisory Group.

DEPARTMENT OF HEALTH AND SOCIAL SECURITY
SCOTTISH HOME AND HEALTH DEPARTMENT
WELSH OFFICE

THE USE OF FETUSES AND FETAL MATERIAL FOR RESEARCH

Report of the Advisory Group

LONDON
HER MAJESTY'S STATIONERY OFFICE
18½p net

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THE USE OF FETUSES AND FETAL MATERIAL FOR RESEARCH

Report of the Advisory Group

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1972

SBN 11 320478 7

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* Dr Clayson's term as President of the Royal College of Physicians of Edinburgh ended on 4 December 1970

† Appointed to the County Court Bench September 1970

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INTRODUCTION

1 We were appointed by the Secretary of State for Social Services and the Secretaries of State for Scotland and Wales on 19 May 1970, with the following terms of reference:

> "To consider the ethical, medical, social and legal implications of using fetuses and fetal material for research."

NUMBER OF MEETINGS

2 We held our first meeting on 30 July 1970 and we have met six times altogether.

EVIDENCE

3 Factual information on the use of human fetuses and fetal material for research was obtained from the Medical Research Council and the Public Health Laboratory Service. This is summarised in later sections of the report. In addition to this evidence a number of organisations were invited to comment on the matters within the terms of reference and we received some spontaneous representations.

4 While there were differences of opinion in the evidence we were impressed by the substantial measure of agreement in the views expressed. Our work has been greatly assisted by the evidence received, which we have studied and taken into account when reaching our conclusions, and we wish to record our thanks to all those who contributed. Their names are listed in Appendix 1.

5 The Chairman and members of the Advisory Group would like to put on record their appreciation of the help they have received from the Joint Secretaries, Dr Laycock and Mrs S E Reeve. Throughout they have facilitated communication with the large number of people involved in the whole investigation, and made an invaluable contribution to the repeated draftings that became necessary. Without their help the enquiry would have been a much more difficult task.

DEFINITIONS

6 The ethical problems which have arisen in recent years in relation to organ transplantation have emphasised the difficulties of defining terms such as "life" and "death". These difficulties have been encountered in the context of decisions relating to adults and children but in the case of the fetus in mid-pregnancy an additional difficulty arises in defining viability. In 1950 an Expert Committee of the World Health Organisation attempted to meet the problem of definition but since that time advances in medical knowledge have made their definitions unsatisfactory. We have decided to introduce our own definitions of some of the more important terms used in this report, as we consider these to reflect more accurately the current state of medical knowledge. Our definitions are set out below:

The Fetus: the human embryo from conception to delivery (and therefore including what is normally termed the embryonic state).

A Viable Fetus: one which has reached the stage of maintaining the co-ordinated operation of its component parts so that it is capable of functioning as a self-sustaining whole independently of any connection with the mother.

A Pre-Viable Fetus: one which, although it may show some but not all signs of life, has not yet reached the stage at which it is able, and is incapable of being made able, to function as a self-sustaining whole independently of any connection with the mother.

Fetal Death: the state in which the fetus shows none of the signs of life and is incapable of being made to function as a self-sustaining whole.

Fetal Tissue: a part or organ of the fetus, eg the lungs or liver.

Fetal Material: any or all of the contents of the uterus resulting from pregnancy excluding the fetus, ie placenta, fluids and membranes.

RESEARCH INVOLVING THE USE OF THE DEAD FETUS AND FETAL MATERIAL

7 Evidence was sought from a number of organisations known to use dead fetuses, fetal tissues and fetal material in the course of their work. Our enquiries showed that in most instances fetal tissues are used since tissues and cells may continue to live for a period after the fetus itself has died, even if they are separated from it. The use of the fetus as a whole is necessary only in a small number of investigations at present.

8 Fetal tissues may be used in various valuable ways, particularly in preventive medicine where there is generally no practical substitute for the fetal tissues used. This is especially the case in the field of virology. The enquiries we made showed that it is often difficult to distinguish between research uses and the diagnostic or therapeutic uses of the work which is being done. Some examples are described below and fuller details are given in Appendix 2.

9 **Virology:** Fetal tissues are used in the routine diagnosis of and research on viruses pathogenic to man, notably those affecting the respiratory tract; the largest present user for this purpose is the Public Health Laboratory Service. Identification of different strains of the rhino viruses (the most common causes of colds) has been made possible on a large scale only by using cultures obtained

from fetal tissues since most of these organisms do not grow on cultures of non-human cells.

10 The properties of both established and new vaccines against viral infections are investigated in fetal tissue cultures, as these tissues provide excellent purity tests for the vaccines. For example, work is in progress on an influenza vaccine, and the vaccines for poliomyelitis and rubella (german measles) are manufactured from fetal tissue. Thus the use of fetal tissues has gone beyond basic research into the field of established practice in preventive medicine. For the future, it seems probable that the use of fetal tissues will offer the only chance for growing the viruses thought to cause hepatitis and infantile gastro-enteritis.

11 **Cancer Research:** Fetal tissues provide the best source of human cells that can be kept growing in tissue culture for the study of induction of disordered growth (analogous to cancerous growth) and of the effect of various agents on that disordered growth. Research in this field opens up future possibilities of diagnosis and treatment of cancer in children and adults.

12 **Arterial Degenerative Disease:** Fetal tissue cultures provide material for research on the development of connective tissues in the arterial wall and so may contribute to the knowledge of the origins of arterial degenerative disease.

13 **Immunology:** Fetal thymus cells and bone marrow grafts are used in research into the treatment of certain diseases of infants where the normal mechanism for resistance against infection is deficient (immuno-deficient conditions). Fetal cells are used to investigate renal and liver transplant rejection phenomena in adults and for tissue typing in transplant surgery.

14 **Congenital Deformities:** Research on the whole dead fetus is essential for the advancement of knowledge of fetal development and to investigate factors that might interfere with this so as to produce congenital deformities. It has already been found that the infection of the fetus with rubella virus can cause congenital heart disease, blindness and deafness, and that certain drugs can cause deformities of the limbs or internal organs; but many other structural deformities remain to be investigated.

RESEARCH ON THE FETUS IN UTERO

15 Observations have been made on the fetus in utero to estimate its growth, especially that of the head, to study its responses to sensory stimuli and to investigate the changes in heart rate. Special attention has been given to the variations in blood composition during labour and to the circulatory and respiratory changes which occur during and after birth.

RESEARCH ON THE WHOLE PRE-VIABLE FETUS

16 Research involving the whole pre-viable fetus has been carried out after delivery in certain countries to increase knowledge of perinatal physiology and pathology especially in regard to steroid metabolism. Stringent precautions have been taken to ensure that the fetuses used for such investigations are not viable.

SUPPLY OF FETUSES, FETAL TISSUE AND FETAL MATERIAL

17 Since 1958 the Medical Research Council has provided a grant to support the collection, preservation and distribution of fetuses, fetal tissues and fetal

material by the Royal Marsden Hospital, London. About 40 different establishments and individuals are supplied by this source. Inevitably costs for storage and transport are incurred and where appropriate these are met by the recipient. Outside the London area those requiring fetal tissues or material make similar arrangements with local hospitals.

THE PRESENT LEGAL BACKGROUND

18 The law governing the issues under discussion falls naturally into four parts: the criminal, the civil, the administrative (the statutes governing registration of births and deaths etc) and the disciplinary. In relation to both the criminal and civil law it is pertinent to note that the research under consideration is carried out in three separate legal jurisdictions (England and Wales, Scotland and Northern Ireland), in which the machinery of law enforcement is wholly, and the substantive law in part, different. An attempt to summarise the law in more than broad outline could therefore lead to confusion and no attempt is made to do so.

19 It is an important aspect of the law in all three jurisdictions that established practices over the whole range of medical and nursing treatment in the obstetric and paediatric field from the moment of conception until the fetus is firmly established as a live or dead child (in the normal colloquial sense) are subject to the strongest presumptions of legality.

CRIMINAL LAW

20 The purpose behind the criminal law has always been the protection of the fetus at all stages. However, the law was developed and expounded before the great changes brought about by scientific advances and by the passing of the Abortion Act, with the result that the available authoritative statements of the law do not provide clear guidance in the present situation. Development of the law has also been limited by the rarity of cases in which the activities of the medical profession have given rise to prosecution.

21 The problem is essentially new and if, as we think, a measure of control is called for by both medical and lay opinion, the limited operation of the criminal law makes it an inadequate guide or instrument for this purpose. Having thus stated the limitations of criminal law, we have summarised what we understand to be its general effect. In all three jurisdictions the following acts may be taken to be criminal:

(a) deliberate or reckless injury to the fetus at any time between conception and delivery save under the provisions of the Abortion Act. (In this connexion it is worth observing that the protection afforded to the fetus is continuous and is not abrogated by the fact that it may be the intention at the time of the infliction of the injury that the fetus should be prevented by a subsequent abortion from attaining life.)

(b) deliberate or reckless injury to the fetus which has become a child born alive or capable of being born alive. (In England and Wales and Northern Ireland there is a statutory presumption that a fetus of 28 weeks development is capable of being born alive.)

CIVIL LAW

22 Civil law requires of a medical practitioner who undertakes the treatment of a patient the exercise of reasonable skill and care and treats failure in such care as negligence. Any negligence in diagnosis or treatment (whether experimental or not) which causes injury to a fetus will found a claim for damages notwithstanding that the conduct of the practitioner has been neither criminal nor unethical. Such a claim could also arise from harm caused to a fetus following negligent certification that it was not viable.

ADMINISTRATIVE LAW

23 The administrative law may be briefly summarised. In all three jurisdictions there are broadly similar statutory requirements for the registration of births, deaths and still-births, and for notification of births to the public health authority. These statutes have several purposes, statistical, administrative, and protective of life. For present purposes only the last is relevant. The requirement to register a birth applies only to live-births (irrespective of the duration of pregnancy) and to still-births, ie births not being live-births which take place after the 28th week of pregnancy. The delivery of a dead fetus before that stage is not registrable, nor is it notifiable to the public health authority.

DISCIPLINARY LAW

24 Much more material to the present problem is the disciplinary jurisdiction of the Disciplinary Committee of the General Medical Council and, on appeal, the Judicial Committee of the Privy Council. The Disciplinary Committee are empowered by statute to erase a doctor's name from the register of medical practitioners or to suspend his registration if they are satisfied that his behaviour constitutes "serious professional misconduct". They may also admonish a doctor on the same grounds. The limits of serious professional misconduct may extend far beyond those of criminal law. They reflect the high standard of ethical behaviour demanded of and accepted by the medical profession. The Disciplinary Committee see their primary duty as protection of the public. Their proceedings are public and their decisions are publicly reported.

THE IMPLICATIONS OF RESEARCH ON FETUSES AND FETAL MATERIAL

25 During our discussions we have been constantly aware of the public concern and of the ethical problems surrounding the use of fetuses, fetal tissues and fetal material for research. In reaching our conclusions, we have tried to maintain a balance between them and the contribution to medical science made by this form of research. In general, we feel that the contribution to the health and welfare of the entire population is of such importance that the development of research of this kind should continue subject to adequate and clearly defined safeguards. In the following paragraphs we consider the implications of undertaking research using the fetus, fetal tissue or fetal material and indicate the safeguards which we consider essential in the interests of both the public and the medical profession.

RESEARCH ON THE FETUS IN UTERO

26 We have given careful consideration to the question of carrying out

research involving the fetus during pregnancy. Investigations and tests may be carried out with the intention of benefiting the mother, her expected child or both, and in such instances ethical or legal objections do not arise. We understand that suggestions have been made that if it is the intention to terminate the pregnancy with the idea of preventing a live-birth, then it would be permissible to administer substances to the mother in order to see if these are harmful to the fetus. We cannot accept this. In our view it is unethical for a medical practitioner to administer drugs or carry out any procedures on the mother with the deliberate intent of ascertaining the harm that these might do to the fetus, notwithstanding that arrangements may have been made to terminate the pregnancy and even if the mother is willing to give her consent to such an experiment.

27 Apart from these ethical considerations such experiments are undertaken at the risk of the investigator since, if the fetus is alive on termination of pregnancy but is handicapped or subsequently dies as a result of experiments conducted during pregnancy, the persons concerned would be liable to prosecution. Also, if the fetus is born alive but is handicapped as a result of such experiments it would be open to the parent to seek compensation through the courts. The existence of arrangements to terminate the pregnancy made before the experiments are conducted would not necessarily constitute a valid defence.

RESEARCH ON THE VIABLE FETUS

28 We consider it is important that there should be no ambiguity about the circumstances in which research can be carried out on a viable fetus. In our view when the fetus is viable after delivery the ethical obligation is to sustain its life so far as possible and it is both unethical and illegal to carry out any experiments on it which are inconsistent with treatment necessary to promote its life, although in many instances the techniques used to aid a distressed fetus are so new that they are in some degree experimental.

29 In England and Wales evidence of pregnancy for a period of 28 weeks or more is accepted as prima facie proof that the mother is at that time pregnant of a child capable of being born alive (Infant Life (Preservation) Act 1929). However in our view advances in medical knowledge have made it no longer acceptable to take the 28th week of pregnancy as indicating the time at which a fetus becomes capable of survival as fetuses delivered before that date, may, by modern techniques, be enabled to live.

30 We noted that in April 1970 the International Federation of Obstetrics and Gynaecology said that advances in neonatology had made parameters for definition of the period of viability based on 28 weeks' gestational age unrealistic. It recommended that the term "abortion" which implied that life could not be maintained in the fetus after expulsion from the mother should be restricted to terminations under 20 weeks (140 days). Similar views were expressed by a number of the organisations who submitted written evidence to us including the Royal College of Obstetricians and Gynaecologists and the Royal College of Midwives, although recommendations on the period of gestation which should be taken as prima facie evidence of viability varied from 18 to 24 weeks.

31 For ethical, medical and social reasons we recommend that for human fetuses evidence of a period of gestation of 20 weeks (140 days: this corresponds

to a weight of approximately 400–500 grammes) should be regarded as prima facie proof of viability at the present time. This date should be reviewed regularly to take account of the rapid changes taking place in medical knowledge. Accordingly consideration should be given to amendment of the Acts providing for registration and notification of births and deaths, the Infant Life (Preservation) Act 1929 and analogous legislation in Scotland and Northern Ireland.

RESEARCH ON THE PRE-VIABLE FETUS

32 We have given long and careful consideration to the position of a fetus which, although it shows signs of life in some of its organs, is pre-viable in that it is incapable of attaining a state in which it could exist as a self-sustaining whole independently of the mother. In our view, if it has been shown that a missing vital function in a fetus cannot be established, for example that the lungs are solid and therefore cannot be inflated, then the fetus has not developed to the stage of being recoverable.

33 We have had to weigh the benefits of research involving pre-viable fetuses against the objections which may be generated and the reasoned ethical and social arguments which are involved. In considering whether it is ethically justifiable to undertake such research we noted that society through Parliament, in permitting abortion in certain circumstances has accepted that where an abortion under the Act is carried out the pre-viable fetus is prevented from attaining life. Given this situation we have considered whether through research on such fetuses new knowledge may be gained which would ultimately benefit viable infants.

34 The medical evidence we received showed that the whole pre-viable fetus has offered an important opportunity that cannot be obtained in any other way for making observations of great value on the transfer of substances across the human placenta, the reaction of the immature fetus to drugs, and on the endocrinological development of the fetus and the development of the placenta. There is a particular need to determine the ability or otherwise of the fetus to deal with substances including drugs given therapeutically to benefit the mother, which may cross the placenta. Observations on the pre-viable fetus are necessarily limited to a period of two or three hours. They have, however, already contributed significantly to our understanding of vital physiological and biochemical processes before birth on which the development of a fetus into a normal child essentially depends. As yet our knowledge is not sufficient to enable us either to control or compensate for any deviation from the normal in such processes. Research on the pre-viable fetus promises, however, to be the most hopeful approach to understanding certain failures of the human brain to develop properly and the influence such factors as variants in sexual differentiation in utero may have on inherent behavioural patterns after birth.

35 We accept that in the case of single births any fetus of less than 20 weeks gestational age (400–500 grammes) is pre-viable and as such has not yet reached the stage at which it can exist as a living entity. We noted the evidence that in the pre-viable fetus of 300 grammes or less as distinct from the fetus approaching full term those parts of the brain on which consciousness depends are, as yet, very poorly developed structurally and show no signs of electrical activity. After

exhaustive consideration we have reached a unanimous view that it would be wrong to exclude the use of the pre-viable fetus for research, provided the following conditions are observed:

(1) Only fetuses weighing less than 300 grammes should be used.

(2) The responsibility for deciding that the fetus is in a category which may be used for this type of research must rest with the medical attendants at its birth and never with the intending research worker.

(3) Such research should only be carried out in departments directly related to a hospital and with the direct sanction of the ethical committee to which reference is made later in this report (paragraph 47).

(4) Before permitting such research the ethical committee should satisfy itself: (a) on the validity of the research; (b) that the required information cannot be obtained in any other way; and (c) that the investigators have the necessary facilities and skill.

RESEARCH ON THE DEAD FETUS

36 When considering the implications of research on the whole dead fetus the difference in the Acts governing the use of human tissue for research makes it necessary to distinguish between the fetus which dies after birth and the fetus which is dead because separation from the mother involves the termination of its life.

37 Where a fetus dies after birth the provisions of the Anatomy Acts 1832 and 1871 and the Human Tissue Act 1961 apply as they would to any other deceased person. Subject to the proper implementation of these provisions there are no legal restrictions on the use of the whole fetus or parts thereof for research. Where a fetus is born dead the Anatomy Act and the Human Tissue Act do not apply and consequently there are no statutory restrictions on the use of the whole fetus or parts thereof for research.

38 After a thorough examination of the evidence, we are satisfied that the benefits to be derived from the use of the whole dead fetus in the prevention and treatment of disease and deformity are such that it would be a retrogressive step to prevent it. In our view it should be allowed to continue, provided it is carried out within the context of the general recommendations which we make later in this report on the control to be exercised whenever fetuses, fetal tissues or fetal material are used for research.

RESEARCH ON FETAL TISSUES AND FETAL MATERIAL OTHER THAN THE FETUS

39 Having regard to the essential contribution that is made by this research to preventive medicine there is, in our view, no reason to object to the use of fetal tissues and fetal material for these purposes subject to our general recommendations for control over research referred to later in the report.

40 Since 1968 commercial use of the placenta and retroplacental blood, not otherwise used by the National Health Service, has been accepted practice provided that the products to be derived from them are intended for therapeutic use. We see no ethical or legal objections to this practice.

CONSENT TO RESEARCH

41 Where a fetus is viable the overriding responsibility of the doctor is to

promote and preserve its life and the parent's consent can normally be inferred for procedures consistent with this aim. There are also areas of research which whilst not jeopardising the health and welfare of the fetus are not of direct benefit to that particular fetus. In such cases we consider that express consent should be obtained from the parent. As stated in paragraph 37, where the fetus is born alive and later dies the provisions of the Human Tissue Act and the Acts concerned with certification of causes of death and investigation by coroners (in Scotland, Procurators Fiscal and Sheriffs) apply and enquiry must be made as to whether there is objection on the part of the parent before the body can be used for research.

42 Where the separation of the fetus from the mother leads to the termination of its life there is no statutory requirement to obtain the parent's consent for research, but equally there is no statutory power to ignore the parent's wishes. A number of organisations who discussed this question in their evidence expressed the view that to seek consent could be an unnecessary source of distress to parents. We share this view but believe the parent must be offered the opportunity to declare any special directions about the disposal of the fetus. In our view this opportunity could be provided by adding an appropriate clause to the form giving the patient's consent to the operation thus minimising any possible distress.

CONSCIENTIOUS OBJECTIONS

43 The evidence we received strongly suggested that some members of staff may have conscientious objections to the use of fetuses or fetal tissues for research. We recommend that no member of staff should be under any duty to participate in research on the fetus, fetal tissue or fetal material if he or she has a conscientious objection. We also received representations that experiments on the fetus or dissections for fetal tissues should not be carried out within the operating theatre or place of delivery. We have no reason to believe that this has ever occurred, but we agree that it should not happen.

FINANCE

44 The public disquiet voiced about the use of fetuses, fetal tissue and fetal material for research has been influenced in part by the suggestion that financial transactions are involved. In our view any charges made are acceptable only if they do no more than meet the necessary costs incurred in administering these services, such as those provided by the Royal Marsden Hospital. In no other circumstances should there be monetary exchange for fetuses, fetal tissue or fetal material.

RECORD OF FETUSES, FETAL TISSUE AND FETAL MATERIAL

45 We recommend that wherever fetuses, fetal tissue or fetal material are used for research the relevant institutions should ensure that a record is kept of all such material supplied or received and of its source and destination. In our view this record would be a valuable safeguard and should be available to the central advisory body to which we refer later in the report.

FUTURE CONTROL OF RESEARCH

46 Because of the concern expressed generally over this form of research we have given particular attention to its future control. We note that a report

published in 1967 by the Committee on the Supervision of the Ethics of Clinical Investigations in Institutions set up by the Royal College of Physicians of London recommended that:

> "The competent authority (eg Board of Governors, Medical Schools Council, Hospital Management Committee, or equivalent body in non-medical institutions) has a responsibility to ensure that all clinical investigations carried out within its hospital or institution are ethical and conducted with the optimum technical skill and precautions for safety. This responsibility would be discharged if, in *medical institutions* where clinical investigation is carried out, it were ensured that all projects were approved by a group of doctors including those experienced in clinical investigation. This group should satisfy itself of the ethics of all proposed investigations. In *non-medical institutions* or wherever clinical investigation (ie any form of experiment on man) is conducted by investigators with qualifications other than medical the supervisory group should always include at least *one* medically qualified person with experience in clinical investigation."

This was accepted by the Ministry of Health and Hospital Memorandum (68) 33 asked hospital authorities in England and Wales to arrange with the medical staff of their hospitals for it to be put into effect.

47 We recommend that all research using the fetus, fetal tissue or fetal material should be approved by such a committee whatever the institution in which the research is undertaken; research involving the pre-viable fetus should only be carried out in departments directly related to hospitals. The committee should accept responsibility for ensuring that such investigations are ethical. In approving research projects using the fetus, fetal tissue or fetal material the committee should use as a guideline the principles which we set out in the suggested Code of Practice at the end of this report.

48 We considered whether this type of research justified any safeguards additional to those mentioned already, in particular whether a lay member should be appointed to the ethical committee. Our conclusion was that clinical decisions are the responsibility of the clinician, and that ethical questions are for the profession to consider. Given a change in the minimum limit of viability (see paragraph 31), and guidance to the profession in a code of practice, together with the overall safeguards of the law, particularly the disciplinary control referred to in paragraph 24, we consider that the interests of all concerned would be sufficiently protected.

49 Some of the evidence received suggested that there should be legislation to provide for the licensing of those who wished to undertake research using fetuses, fetal tissue or fetal material similar to the licences issued to those undertaking research on animals. In our view a system of licensing would be unnecessarily cumbersome and a code of ethical practice would be an adequate safeguard as it is in the case of research involving all patients. A code would have the advantage of flexibility in that it could be modified in the light of future experience without recourse to amending legislation, and it would not entail the establishment of permanent machinery for the issue of licences and an inspectorate.

50 We also considered whether any central body should be set up to advise in cases where the local committee is uncertain of the ethics of particular

investigations. We concluded that it would not be necessary to have a permanent body to handle the limited number of enquiries which are likely to arise. Instead we recommend that arrangements should be made for a small informal advisory body with legal representation and including members drawn from the Medical Research Council, the Royal College of Obstetricians and Gynaecologists, the General Medical Council and the British Paediatric Association to be convened when the need for central advice arises. It might be considered appropriate for this advisory body to cover the United Kingdom.

RECOMMENDED CODE OF PRACTICE

This code has no binding legal force but is the result of a careful consideration of all relevant factors in the light of the available evidence. It is hoped that it will prove acceptable to the bodies statutorily responsible for disciplinary matters in the medical and nursing professions.

1 Where a fetus is viable after separation from the mother it is unethical to carry out any experiments on it which are inconsistent with treatment necessary to promote its life.

2 The minimal limit of viability for human fetuses should be regarded as 20 weeks' gestational age. This corresponds to a weight of approximately 400–500 grammes.

3 The use of the whole dead fetus or tissues from dead fetuses for medical research is permissible subject to the following conditions:

(i) The provisions of the Human Tissue Act are observed where applicable;
(ii) Where the provisions of the Human Tissue Act do not apply there is no known objection on the part of the parent who has had an opportunity to declare any wishes about the disposal of the fetus;
(iii) Dissection of the dead fetus or experiments on the fetus or fetal material do not occur in the operating theatre or place of delivery;
(iv) There is no monetary exchange for fetuses or fetal material;
(v) Full records are kept by the relevant institution.

4 The use of the whole pre-viable fetus is permissible provided that:

(i) The conditions in paragraph 3 above are observed;
(ii) Only fetuses weighing less than 300 grammes are used;
(iii) The responsibility for deciding that the fetus is in a category which may be used for this type of research rests with the medical attendants at its birth and never with the intending research worker;
(iv) Such research is only carried out in departments directly related to a hospital and with the direct sanction of its ethical committee;
(v) Before permitting such research the ethical committee satisfies itself: (a) on the validity of the research; (b) that the required information cannot be obtained in any other way; and (c) that the investigators have the necessary facilities and skill.

5 It is unethical to administer drugs or carry out any procedures during pregnancy with the deliberate intent of ascertaining the harm that they might do to the fetus.

APPENDIX 1

Organisations and individuals who submitted evidence to the Advisory Group

(i) The following organisations submitted evidence to the Group:

Blair Bell Research Society
Board for Social Responsibility of the National Assembly of the Church of England
British Council of Churches
British Medical Association
British Paediatric Association
Karolinska Institute—Department of Obstetrics and Gynaecology (Stockholm)
Medical Research Council [evidence was also submitted by the Reproduction and Growth Research Unit of the MRC]
Medical Women's Federation
National Association of Theatre Nurses
National Institute of Health, Bethesda, United States
Office of the Chief Rabbi
Patients Association
Public Health Laboratory Service
Roman Catholic Church
Royal College of Midwives
Royal College of Nursing and National Council of Nurses in the United Kingdom
Royal College of Obstetricians and Gynaecologists
Society for the Protection of Unborn Children
Swedish Committee on International Health Relations
Swedish Medical Research Council—Reproductive Endocrinology Unit
Union of Liberal and Progressive Synagogues
Universities of Aberdeen, Dundee and Edinburgh

(ii) The following individuals submitted evidence to the Group:

Mr Michael Wilkinson, FRCS
Mr R Wilson, MSc

APPENDIX 2

Projects utilizing human fetuses fetal tissue and fetal material

The work reported has been loosely grouped into physiological and anatomical categories. Items mentioned here include some of those already referred to in the text.

General Fetal Metabolism

1 Fetal head measurements to confirm the accuracy of ultrasonic cephalometry.
2 Fetal size in relation to amniotic fluid production.
3 Fetal size in relation to maternal smoking habits in and before pregnancy.
4 Water exchange between maternal, fetal and amniotic fluid environments.

5 The changes in oxygen partial pressures and acid base balance in hypoxia at various stages of pregnancy.
6 Carbohydrate metabolism in hypoxic fetuses and the effects of maternal dextrose infusions.
7 Glycoprotein synthesis in fetal liver.
8 Study of glucoronide metabolism for future treatment of neonatal jaundice or steroid imbalance.

Endocrinology

1 Detection of hormones that are solely fetal in origin and could possibly be measured in maternal tissues to enable the degree of fetal well-being to be determined.
2 Adrenal steroid metabolism in the fetal gland and the excretion of such steroids into the amniotic fluid at various stages.
3 Investigation of prolactin using fetal pituitary glands.
4 Cholesterol metabolism in relation to plasma protein levels.
5 Insulin secretion in the fetal pancreas and the effects on carbohydrate metabolism.
6 Gonadotrophin assay in fetal pituitary glands and stimulation of fetal pituitary activity in vitro.
7 Fetal intracellular binding site of progesterone with reference to possible blocking of histocompatible antigens.
8 Parathyroid metabolism in early pregnancy.

Haematology

1 Blood volume studies at different maturities.
2 Changes in fetal blood composition and development of plasma proteins.
3 Bone marrow maturation in relation to peripheral fetal blood.
4 Folate metabolism in the fetus and its accumulation in various tissues—notably liver and pancreas.
5 Studies of rhesus incompatibility using fresh suspensions of fetal liver cells.
6 Structure and properties of fetal haemoglobin and its variants.

Cardiology

Fetal electrocardiography performed directly on hysterotomy specimens and correlation with records made whilst the fetus was in utero.

Alimentary Tract

1 Fetal swallowing mechanisms in mid-trimester and the effects of anencephaly.
2 The pharmacology and innervation of small gut of the fetus.
3 The activity of some liver enzymes and their alteration with maturity.
4 Vitamin A content and activity of liver (and brain).

Renal and Urinary Tracts

1 Urine excretion and the production of amniotic fluid.
2 Changes in constitution of fetal urine in relation to renal maturity.
3 Culture of renal tissues to elucidate the development of fetal renal malignancies.

Skin

1 The origin and shedding of skin cells into the liquor.
2 Permeability of fetal skin and its variations with maturity.
3 The growth of fetal oral squamous epithelium in tissue culture.
4 Steroid metabolism in various skin sites of the body.
5 Biochemical assay of glycogen in fetal skin as a means of glycogen storage.

Amniotic Fluid Physiology

1 The circulation of fluid in relation to fetal and placental weight.
2 Composition of fluid in relation to fetal blood.
3 The origin and development of cells in the amniotic fluid.
4 Electrical conductivity of fluid and its effects in fetal electro-cardiographic studies.
5 Secretion of steroid hormones from the vessels of the umbilical cord into the liquor.
6 Alterations in trace metal metabolism in relation to proteins and electrolytes levels in amniotic fluid.

Placental Metabolism

Much work is proceeding in the transfer of various drugs and macro-molecules, while other research is investigating glucose, amino-acid and steriod transfers.

Immunology

1 Fetal antibody production in hosts of other species with subcellular fractions from homogenates of the fetal tissues.
2 Carcinoma embryonic antigens present in adult tumours and fetal tissue only. Developments in their use in diagnosis of cancer in the adult and possibly their use for cancer therapy.
3 Fetal thymus cells are used in the investigation of human anti-lymphocyte globulin and other immunosuppressive agents.
4 Research on auto-immune conditions and immunopathological states using fetal tissue.

Chromosome Studies

1 Abnormalities in therapeutic abortions (providing background figures to those produced after spontaneous abortions).
2 Y chromosome detection by fluorescent techniques.
3 Effects of X irradiation on chromosomes in ovarian tissue culture and total numbers of ova.

Anatomy

1 Fetuses are used at all stages of development for teaching of medical and nursing students.
2 Studies of neuro-anatomy using fetal brain tissue.

Printed in England for Her Majesty's Stationery Office
by Ebenezer Baylis & Son Ltd., The Trinity Press, Worcester, and London

Dd 502409 K120 5/ 72

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