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Ethical and governance challenges in human fetal tissue research

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Abstract

Genetics holds the key to understanding normal human biology and possibly many of the major causes of human disease and impairment. Research into human developmental genetics seems, therefore, to be both necessary and justified. However, such research requires the use of embryonic and fetal tissue obtained from spontaneous abortions and elective termination of pregnancy. This paper examines the arguments in favour of using tissue from elective terminations and the evolution of regulatory frameworks for this research. The paper argues that the recent statutory and regulatory reforms in the UK have not properly addressed the issue of ethically obtaining postimplantation human embryos for research. It is argued that the recent reforms have left the Polkinghorne guidelines untouched but that these are now unequal to the task. A practical suggestion for reform of the approach to the informing and consent of potential donors is offered.

Introduction

In this paper, we argue that women facing termination of pregnancy are capable of considering the donation of aborted tissues for research, a capacity not recognized by the current guidelines. We contend that women in this position are no more vulnerable to undue influence than in other research contexts and that they are capable of reflecting upon the detail of the research. Moreover, we argue that the provision of information and seeking consent are means of demonstrating respect for the women concerned. We shall defend this position while criticizing the existing approach informed by the Polkinghorne guidelines.¹

Pfeffer and Kent have previously discussed some of the ethical challenges in the use of human fetal tissue for research where the tissue is obtained from legal terminations of pregnancy.² They particularly focus upon the specific issues of the type of donor consent required by regulation and the general level of transparency adopted regarding the use of this form of human tissue. The starting point for their analysis is also the Polkinghorne guidelines drawn up to address this specific subject at a time when the existing legal and regulatory

framework was feared to be inadequate for a sensitive issue and a potentially controversial use of human tissue. Since that time human tissue research has become a fast-moving tidal zone. Scandals regarding the retention of human tissue in the UK and France have caused public outcry and increased public sensitivity to the uses and potential abuses of human tissue in research.³ The burgeoning development of human embryonic stem cell research and human gamete research related to both stem cells and fertility treatment have shown the capacity science has to outpace regulation and legislation.

Our argument arises from our research into the ethical and governance challenges facing a pan-European research network, which uses human fetal tissue to study gene expression in early human development. In this paper, we re-visit the issues of consent and transparency, examine the status of fetal tissue in relation to the debates about other forms of embryonic tissue and discuss the arguments and justification for this form of research.

Background

The Developmental Gene Expression Map project is a design study that will generate the tools and framework for a research infrastructure dedicated to gene expression mapping in early human development.⁴ The project developed out of pre-existing research within the Institute of Human Genetics at Newcastle University, which is one of the two sites of the Medical Research Council– Wellcome Trust Human Developmental Biology Resource (HDBR)⁵ and our work contributes to the design of the governance framework for the proposed research infrastructure.

Developmental gene expression studies seek to identify the genes that are active in particular locations at particular stages of human development. Such studies cannot be conducted without access to the developing embryo and this is only possible by using model animals, particularly the mouse, or by using donated tissue from women who have undergone elective termination of pregnancy or suffered a spontaneous abortion. Although there are many terminations in the UK and some tissue is collected for research on an ad hoc basis, only the HDBR systematically collects and maintains this tissue for

distribution to researchers on request. The human embryo or fetus is thus considered a scarce resource for scientists to work with, often described as ‘precious’.^{6–8}

The case for using human fetal tissue rests upon arguments that this form of research will have a number of important benefits, expanding the knowledge of normal human development with potential health benefits for human disease. Burn and Strachan⁶ argue that the 1:30 incidence of major birth defects makes a strong case for studying the action of genes

in normal human development to provide a baseline from which understanding of abnormal development can be derived. Lindsay and Copp⁸ note the discovery that some late onset disorders may have their origins in fetal development and that mapping normal development is a crucial step in revealing gene function and role in disease. Fougerousse et al.⁹ also argue that research on human developmental samples is justified on purely scientific grounds, since it is known that there are differences in expression patterns between genes in human and mouse and the resulting phenotypes, with an example being the genes implicated in limb girdle muscular dystrophy. We must also bear in mind that human embryos held in existing anatomical collections are inadequate for gene expression studies as preservation methods are such that gene products such as RNA are lost. There is thus a requirement for new collections to be made, and in the UK this must be done in a manner conforming to the Polkinghorne guidelines.

The Polkinghorne Guidelines

The first relevant regulatory framework in the UK was Sir John Peel's published in 1972.¹⁰ Peel's Code of Practice on the use of fetal tissue in research recognized the need to protect a viable fetus outside the womb, but created a category of 'non-viable fetus' defined as being less than 20 weeks gestation. The use of the whole pre-viable fetus was permitted 'where 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' and there was no discussion of any requirement that only the dead fetus may be so used. By the mid-1980s, attempts to treat conditions such as Parkinson's disease by the transplantation of neural tissue obtained from aborted fetuses led to concerns that the Peel Report was outdated and a committee was convened under the chairmanship of John Polkinghorne to reconsider the issues of the use of fetuses in research and therapy. It was thought that successful neural transplantation techniques would lead to an increased demand for tissue and could influence a woman's decision to terminate a pregnancy.¹ There was also a tension to be addressed between the view that Peel had on the availability of embryos for research and the views expressed about the status of the embryo by the Warnock committee in 1984.¹ While Warnock recommended that no research should be performed on living embryos older than 14 days postfertilization, the Polkinghorne Committee recognized that Rule 4 of Peel's Code of Practice permits the use of the whole pre-viable fetus in research. This was thus open to the interpretation that living embryos beyond 14 days could be used in research, provided they were recovered from terminations. The Polkinghorne Committee subsequently produced a new set of guidelines and despite changes to other relevant areas of law such as the Human Fertility and Embryology Act 1990 (HFE Act) and the Human Tissue Act 2004 (HT Act) these have remained the main

regulatory guidance for the use of fetal tissue in research.

The Polkinghorne Guidelines are structured around the following key principles:

- † Consent to donate embryonic tissue for research must be obtained after a decision has been reached by the woman to terminate her pregnancy;
- † The woman should be informed only of the general purpose to which her tissue may be put;
- † The woman cannot specify the use to which the donated tissue is put;
- † The medical team caring for the woman must not have any connection with the research team who may use the tissue;
- † Tissue samples should be held by an intermediary and must be anonymous.

A pivotal principle within the guidelines is the principle of ‘separation’, that is the separation of the decision to abort from the decision to donate tissue for research, and the separation of the researchers from the source of the tissue.¹ Separation is further achieved by providing the potential donor with only general information regarding the nature of the research. There are a number of concerns which underpin this strategy but, on our reading, the single most serious concern for the Polkinghorne committee was that all measures ought to be taken to avoid any form of pressure or coercion in the decision to terminate. We contend that the Polkinghorne guidelines are now in need of review, to accord with the evolution of practice relating to consent for research. The Royal College of Obstetricians and Gynaecologists¹¹ have expressed the view that the guidance on consent in Polkinghorne is probably illegal and that the separation of researchers from the source of tissue is hampering research. While this latter point is no reason to change matters, the former needs to be considered. Anderson et al.¹² used their findings from empirical research conducted with women in Edinburgh to raise questions regarding the need for such strong principles of separation as Polkinghorne requires. Finally, the Polkinghorne Committee itself recognized that the guidelines were the product of the legislative, administrative and medical practice of the day and would require revision and as we shall argue, that time is now.

We now turn to consider and challenge a number of the intuitions underpinning the Polkinghorne Guidelines. One issue we wish to contest is Polkinghorne’s concern that women considering a termination are vulnerable to coercion or influence in their decision and that a detailed invitation to donate to research may ‘contaminate’ the will of a woman with a

motivation related to the research rather than her own health and wellbeing. We find this questionable because there is no evidence to suggest that this is a reasonable concern since consent for research is obtained only after the decision to terminate has already been made. In the case of transplantation of fetal tissues, where it was speculated that women may attempt to conceive in order to donate to a specific person, this had already been ruled out by the regulations governing transplantation.

So, although we accept that there is a good reason to separate the decision to terminate pregnancy from the decision to donate tissue for research, we find that the other mechanisms of separation are not defensible when compared with the approaches adopted in other morally analogous and equally complex research contexts. It is of course true that in many research contexts a 'gatekeeper', a person not involved in the research but known to the patient, is often used to make the first approach to potential research subjects to allow them the opportunity to refuse involvement at the earliest and easiest opportunity. However, this is not analogous to the Polkinghorne principle of separation since the gatekeeper does inform the potential subject in some detail of the nature of the research about to be undertaken. There are of course many instances when clinicians are of necessity directly involved in the recruitment of research subjects. However in both the gatekeeper and the direct approach to recruitment, it is the research ethics committee who judges that the quality and detail of the information is sufficient to allow the participant to make an informed decision.

An opportunity missed?

The process leading up to the new legislation covering the use of human tissue was the opportune moment for a revision of the Polkinghorne Guidelines. The Department of Health consultation document of July 2002, *Human Bodies, Human Choices*,¹³ contained a specific discussion of fetal tissue and while some aspects of the Polkinghorne Guidelines were thought to be questionable by the authors, others were not. The areas that were implicitly accepted by the authors were:

- † The use of fetal tissue in research is ethically acceptable;
- † There is a requirement for review of research using fetal tissue by a research ethics committee;
- † That no form of inducement should be offered to donate;
- † That consent for the termination should be given before any approach to consent to donate to research

is made;

† That provision for conscientious objection to participation by medical staff be retained;

† The idea of an intermediary between clinicians and researchers is still valid, but there are legitimate reasons why this may not be a requirement, provided REC approval is granted, as at present;

† That the body of the fetus and fetal tissue should not be the subject of property rights.

Some aspects of the Polkinghorne Guidelines were considered for modification and these will be discussed below, however, the HT Act¹⁴ that emerged does not address these or any other issues relating to fetal tissue. Searching the text of the Act electronically reveals no instances of the term ‘fetus’ or its synonyms.¹⁵ Since the HT Act has not revoked or revised the Polkinghorne Guidelines, we believe this leaves the legal position regarding the procedures to be followed when collecting postimplantation fetal tissue to be unchanged and as we shall argue inadequate.

The HT Act provided for the creation of the Human Tissue Authority (HTA) and gave this body the responsibility to provide information and guidance to those working under its authority. However at some point between the consultation of 2002 and the drafting of the code of practice on consent, the issue of fetal tissue was either forgotten or for some reason removed. The code of practice on consent published by the Authority in January 2006¹⁶ only goes so far as to acknowledge the ethical sensitivity of using fetal material for research and suggests a requirement for consent to use this tissue. However, without directly addressing the use of hEFT in research, it implies that Polkinghorne remains in force.

Consent or no consent?

As noted above, some aspects of the Polkinghorne Guidelines were considered for change in the consultation phase for the HT Act and among them was the question of consent.¹³ This can be summarized as:

† If fetal tissue is being gathered for a specific project, then informed consent should be sought in line with standard practice in other areas;

† If the tissue is to be used for therapy then the woman should not be able to identify where or when it was

used, or specify its use;

† If tissue is to be banked then the woman should be given a choice regarding whether the tissue is identifiable or anonymous;

† The potential donor should be asked whether or not she wishes to be contacted about future use of stored tissue, if it was identifiable, or told that no further contact will be made, if the tissue is anonymous.

The department published a summary of the responses to the consultation,¹⁷ and although as with all such secondary data sources we see the results through the interpretation and (perhaps unconscious) prejudices of the writer, the results state that there was a consensus on many points, including the acceptance of the proposed revised approach to consent as outlined above. Furthermore, with regard to the principle of separation, the consultation responses indicated that there was no need for an independent intermediary, although the reasons behind this view were not published.

The consultation in 2002 found that, against the expectations of those who set the questions, the respondents saw no need for separation and this supports the findings of Anderson et al.,¹² so far the only published empirical research of women in the UK. In this only 8% of women seeking an abortion felt that the doctor should have nothing to do with the research while 25% of women not (then) seeking an abortion who were surveyed thought that the clinician and researcher should be separate. This study did not explore the reasons underlying the women's responses and so, as with many other aspects of this subject, we believe there is a need for further qualitative empirical research.

While the government consultation sought views on seeking a form of informed consent, Anderson et al. asked only whether consent should be sought. Although 63% of all women surveyed in the 1994 study agreed that consent should be sought, less than half the women asked wanted details of the research to be undertaken. Women who had never had a termination were more likely to say they would want information than those who had previously had a termination, in the ratio of 38% against 23%.¹² This appears to contradict the finding of the 2002 consultation where informed consent was favoured. In a further finding that contradicts Polkinghorne's vision of the need for the separation of researchers from the source of tissue, Anderson et al. found that 54% of women who had never had a termination and 33% of women who had had a termination wanted to be able to ask questions of the researcher. With these comments in mind we now turn to consider the issues of consent and the quality of information that should be made available to donors.

The thorny issue of consent

In fairness to the Polkinghorne Guidelines there is a definite acknowledgement of the need for explicit consent as stated in Chapter 6 and elsewhere in the report. This position is a marked improvement on that of the Peel Report, which adopted the view that tissue could be used where there is 'no known objection on the part of the parents'.¹

The Peel position can be seen as a well meaning but paternalistic attempt to avoid distressing discussions with donors. However, although Polkinghorne insists on explicit consent it also requires that consent should be general in nature, without full disclosure of the nature of the research. We consider this position to be inadequate but acknowledge that there are a number of potential alternatives. We will now explore three positions and argue in favour of one solution.

In the post-Bristol, post-Alder Hey era there has been a move towards a form of consent that is, if not fully, then adequately informed.¹⁸ In the context of research, there has been a long consensus since the Declaration of Geneva (1948) that the quality of the information provided to research participants ought to involve full or very detailed disclosure.¹⁹ It could therefore be regarded as a foundational principle that participation in research should be on the basis of voluntary and adequately informed consent, a principle echoed within the numerous local, national and international guidelines on participation in research.²⁰ The General Medical Council²⁰ in their guidance to doctors on research, not only insist upon sufficiently detailed information but disclosure in a form that is likely to be understood by the research subject. However, it must also be acknowledged that even under the HT Act it remains a lawful option to use waste tissue for research without the requirement for consent.

The HTA are yet to issue specific guidance on the use of fetal tissue except that in acknowledging the sensitivity of using aborted fetal tissue they suggest that consent is required.¹⁶ The code of practice for consent issued by the HTA in July 2006 notes that while consent lies at the heart of the HT Act there are exceptions to this, one of which is the use of tissue in research. No consent from the patient is required for the storage and use of their tissues providing that the research has ethical approval and that the tissue is anonymized. In recognizing the fetus as the woman's tissue, and thus involving a living donor, a legal argument could be made for the nonconsensual use of tissue recovered from abortion. It is acknowledged, however, that obtaining consent represents best practice in acquiring tissue and is preferable to anonymization and non-consensual use.

Since the HT Act and the HTA codes of practice have left the Polkinghorne Guidelines as the regulatory framework for obtaining embryonic and fetal tissue for research, there is clearly a

disjunction between the principles of appropriate consent on which the Act was founded and actual practices permitted by the HTA regarding fetal tissue. How can consent be informed if the Polkinghorne Guidelines prevent the woman from knowing what research, if any, is proposed? The possibility that fetal tissue may be used in genetic research or in the creation of cell lines makes the case for informed and possible conditional consent more pressing because of the acknowledged complexities of research involving genetic information and which has potential health implications for the donor and other family members.²¹

There are three possible positions with regard to consent.

No consent required

The idea that no consent is required for the use of fetal tissue following legal termination is premised on a number of established practices and intuitions. For example, the practice of utilizing tissue normally disposed of following a surgical intervention. The idea that some human tissue can be rightfully described as ‘waste’ or ‘surplus’ fits with a number of moral arguments, which have been developed as ways of dissolving if not resolving several complex moral problems. These range from pro-abortion arguments to the arguments used to defend embryonic research of all kinds by showing that embryos and similar ‘tissues’ lack moral significance.^{22–24} From these perspectives, it is concluded that ‘no moral significance’ means ‘no moral problem’.

General consent

The model advocated by the Polkinghorne Guidelines is an approach to consent that is one of the strategies of separation, which Polkinghorne sees as essential to prevent any form of coercion or undue influence on the woman’s decision to have a termination. In principle, this approach is compatible with English common law approaches to consent in which the quality and nature of the information to be disclosed is a matter of professional judgement rather than based on what the patient wishes to know.²⁵ However, the legal position has only been defined in relation to consent to treatment whereas the thrust of ethical guidance on research insist upon a high standard of disclosure and information as discussed above. Polkinghorne’s insistence on the separation principle as necessary is confusing, since if consent to donate to research is always post a valid consent to terminate the pregnancy then in what way could the second decision be said to influence the first? We suggest that the Polkinghorne Guidelines are a symptom of traditional paternalistic attitudes, which display bad faith towards the women facing this decision.

Adequately informed consent – the Helsinki model

The third approach is that of adequately informed consent where the quality and detail of the

information is specific and in a form likely to be understood by the person who is to give their consent. At a bare minimum this should include the risks involved and some material detail of the potential research or clinical use of the tissue and the reasons why such research is justified. The implications for the woman that may result from any genetic analysis on the embryo should also be made clear, although this will be dependant on the approach to anonymization taken by the researchers. The current collection of material in the Hopital Necker in Paris, for example, uses a link-anonymized approach while the HDBR in the UK holds anonymous tissue.²⁶ Another aspect of the contemporary approach to research ethics is the right of the individual to withdraw from a study. For example, this is the case in the UK for embryo donation to stem cell research where there is a right to withdraw up to the point at which the embryo is in the possession of the researcher in the laboratory.²⁷ The requirement for the anonymous donation of tissue under the Polkinghorne Guidelines means that once donated, samples can never be withdrawn. Again, there is an incongruity with the code of practice on consent issued by the HTA where paragraph 66 notes that consent should be sought for donation of fetal tissue but paragraph 107 states that ‘a competent person is entitled to withdraw consent at any time’.¹⁶

A contemporary approach

In considering a contemporary approach to regulating the donation of fetal tissue to research then one solution might lie in the adoption of a ‘no requirement for consent’ model. This would be one way in which the woman’s decision to terminate could be perfectly insulated from potential inducement. Such an approach would also be consistent with the HT Act, which allows the anonymous use of surplus tissue in research and research tissue banks. To deny this solution requires a careful unpicking of the sensitivities presumed to attach to these specific tissues obtained in this specific way. Such explanations are not forthcoming, either within the Act or within the Polkinghorne Guidelines.

The alternative is to adopt a standard that requires adequately informed consent at the level usually required for participation in other forms of research. Indeed the HTA uses the term ‘appropriate consent’ throughout the codes of practice issued to date.²⁸

As discussed earlier, there is scant empirical evidence on which to base any firm suggestion for an approach to the reform of the Polkinghorne Guidelines. However, revision of consent was considered in the consultation leading to the HT Act and it is a matter for future research to uncover the reasons why not only was this suggestion not taken forward when it was supported by the majority of respondents, but also why the whole issue of fetal tissue was omitted from the Act.

The other aspect of the principle of separation apparent in the Polkinghorne Guidelines is that of the clear lack of connection between the clinicians and the researchers. Anderson et al. found that the women they surveyed saw no need for this separation with at most 25% of women thinking this desirable and this finding was supported by the consultation before the drafting of the Human Tissue Bill.¹⁷ In considering the practicalities of the separation of clinician from researcher, it is clear that there must be some form of contact, for agreeing the processes for taking consent and the methods of collection of the tissue and its storage and transport. It is thus unrealistic, and perhaps counter-productive, to continue to insist upon a separation of researchers from those providing care for a woman who requests a termination.

Conclusion

This is a complex and changing field in which we have demonstrated the need to re-think and reform the current guidelines. In our view, the 'no consent' approach to fetal tissue should not be adopted. We believe that the adequately informed consent model ought to be adopted in the context of a specific set of guidelines issued by the appropriate authority. This may include a change to the primary legislation by reform of the HT Act, or perhaps more straightforwardly by the issuing of specific guidance from the HT Authority.

The model of adequately informed consent not only reflects an ethic of respect for persons it also coheres with the general presumption in favour of informed consent, considered to be the basic premise of contemporary research ethics. We do not claim to have successfully unpicked the thorny issue of the moral status of the fetus, there is clearly a need for further empirical and conceptual research in this area. Conceptual research may go some way to developing an account of the status of the fetus vis-a-vis the mother's tissues useful for regulation and guidance. However, the moral status of the embryo and fetus is likely to remain ambiguous since it is characterized by multivalency between the different contexts in which issues arise. This observation alone suggests the need for caution rather than bold stances when formulating regulation. Empirical research in this field may also contribute to exploring the effectiveness and acceptability of practice.

Finally, the possibility that fetal tissue may be used in transplantation, genetic and cell-line research, each with its attendant moral complexity, again suggests that women asked to donate should have enough information to be able to consider the implications of their decision and be offered the possibility of conditional consent and future withdrawal.

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