Key Stakeholder Interviews - A Lay Summary

One component of the EVERREST Project is to ascertain the views of key stakeholders about the ethics of a clinical trial of growth factor therapy in pregnant women whose unborn babies are affected by fetal growth restriction (FGR). FGR is a serious condition and has a significant risk of stillbirth. Affected babies are small and may be born very early, which can cause them problems as a baby and later on in life. Until the trial is carried out it is not known whether this growth factor therapy will work for FGR and improve growth and whether it is safe in humans.

The key stakeholders interviewed were patient organisations and medical stakeholders in a number of European countries including the UK, Germany, Sweden and Spain. A series of ethical issues were raised but two main topics emerged from these interviews: the problem of obtaining informed consent from the pregnant woman whether or not to participate in the trial, and the psychological burden facing the woman making the decision when she has just been given the diagnosis of severe FGR.

A major ethical problem in a clinical trial is the need for accurate and adequate information in order for the trial participant to make an informed choice. Trial participants need to be informed of all known risks and benefits but also of the fact that they are free to withdraw from the trial at any stage. Many respondents were concerned about the pregnant woman being able to give valid informed consent because of the complexity of the growth factor therapy. They spoke of the need for transparent and jargon free information, the need for independent advice from, for example, psychologists, nurses, midwifes or parental organisations. There would also be need for the informed consent to be a continuing process rather than a single event with printed, clearly written information for the woman or couple to take away so that they could discuss the information without any possible pressure from the healthcare team.

The second major issue is the psychological stress of the woman making a decision when she has just been given the diagnosis of severe FGR. She essentially has three options: to wait and see and risk stillbirth or very early delivery, to terminate the pregnancy because of the disability she fears (although this only an option in the UK), or to expose the unborn baby to the risk of treatment which could lead to the possible survival of a severely disabled child who might otherwise have died. Women with a history of miscarriage, stillbirth and infant mortality may feel still greater pressure in participating in the trial. Many respondents were concerned about the psychological difficulty for the woman to make a decision in this situation. Clear and transparent information was advisable. Additional psychological support was necessary to help the woman make a decision. There appeared to be the risk in some countries that the decision becomes a medical one with the woman handing the responsibility over to the healthcare team.

The EVERREST Project anticipates a further interview stage with women who have experienced a pregnancy affected by severe FGR.