Key Stakeholder Interviews - An updated 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). This summary provides a complete account of the views of all stakeholders interviewed, updating the account published in December 2013. In total 34 interviews were conducted with representatives form patient organisations/advocacy groups, midwifery associations, representatives in the disability movement and medical stakeholders, in the UK, Germany, Sweden and Spain and amongst European-level stakeholder groups.

The overall conclusion drawn from the interviews was that respondents had a generally favourable view of the ethics and social acceptability of the trial. To a large extent the trial was not seen to raise any different ethical concerns from other trials in pregnancy where women would have to make similar difficult decisions under emotional stress and where very similar problems regarding the informed consent considerations might arise. As long as the treatment was effective in reducing the number of stillbirths and very premature births, the main concern remained whether there was any likelihood of harm from the treatment to either the woman or the fetus. Disability groups interviewed had no fundamental objections to the EVERREST therapy.

The need for accurate and adequate information to allow for informed choice regarding trial participation is a major issue in any clinical trial. 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 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 and for printed, transparent, jargon-free information for the woman or couple to take away so they could discuss it without any possible pressure from the healthcare team.

A 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, 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. Many respondents were concerned about the psychological difficulty for the woman to make a decision in this situation. Clear and unbiased information about the possible risks and benefits of the treatment were considered important. Additional psychological support was necessary to help the woman make a decision. There appeared to be the concern that in some countries the decision about whether to accept treatment becomes a medical one with the woman handing the responsibility of that decision over to the healthcare team.