Improving IVF Outcomes

Development of a simple blood test to predict the likelihood of a successful IVF embryo transfer.

HUDSON INSTITUTE OF MEDICAL RESEARCH

A recognised limitation of current clinical practice is our inability to effectively monitor a women's endometrium and its development into a 'receptive state' essential for successful embryo implantation.

Background

An estimated 121 million couples worldwide suffer infertility, with around half of these seeking medical assistance to start a family. There is increasing demand for assisted reproductive technologies, including in vitro fertilisation (IVF). Yet, despite advances in embryo quality testing and selection, IVF success rates worldwide are still below 30%. Up to 50% of women who undergo six embryo transfers will remain childless, with these repeat failures due to endometrial failure.

Endometrial receptivity is a crucial factor in determining whether IVF treatment will be successful or not. Embryo transfer needs to be carefully timed, to take place when the endometrium is receptive and capable of supporting a healthy pregnancy. Traditionally, it was thought that this timing – the 'window of implantation' – was the same for all women. However, it is now known that for one in four women the timing of this receptive stage is different, and the traditional timing of embryo transfer does not work.

The ability to test endometrial receptivity in real-time would aid clinical decision-making, reducing wastage of high-quality embryos as well as the emotional and financial costs associated with IVF.

The ideal test for endometrial receptivity

Currently, endometrial receptivity can only be tested in the cycle before embryo transfer takes place – not in the same cycle as transfer will actually happen.

Our team has developed a non-invasive serum-based multivariate diagnostic algorithm that can predict endometrial receptivity in the days prior to embryo transfer. It provides a real-time assessment of the endometrial quality, enabling informed decision-making by patients and clinicians as to whether to transfer in the same cycle as the test is performed, or to freeze the embryo for a better opportunity.

the ideal test is:	our assay	ERA - current standard
simple and non-invasive	Uses a serum sample, which can be easily collected in the clinic.	Uses endometrial tissue, which is invasive and damages the endometrium.
easy to perform	Protein assay using standard technology.	236 gene array.
available	Can be done on-site at a local pathology provider or fertility centre.	Samples are submitted to a single laboratory, with special requirements for shipment.
fast	Results in 12 hours.	Results in 10 days from sample receipt.
compatible	Non-invasive sample collection, and minimal likelihood sample is incompatible with test.	<5% chance of insufficient sample for test, leading to additional cycles and sample collection.
personalised	Multiple tests can be done in a single cycle to effectively monitor each woman's own window of implantation.	Multiple testing takes multiple cycles to determine the window of implantation.
real-time	Our test represents the endometrium in the cycle of transfer, so no additional costly cycles are needed.	Must be done the cycle prior to embryo transfer and presumes every cycle will be same.

Supporting Data

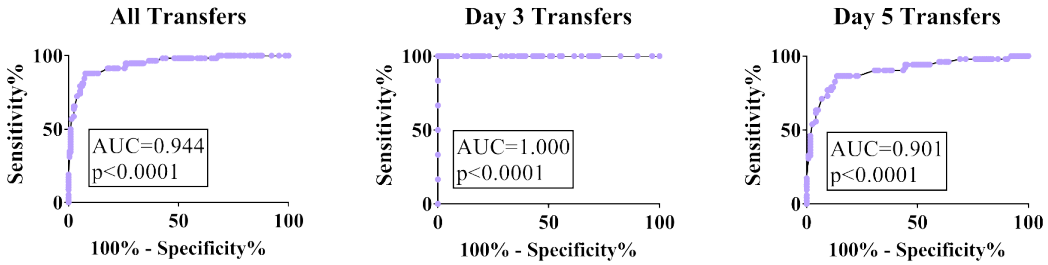

Figure 1. Receiver-operator-curve (ROC) analysis of the predictive algorithm performance of all transfers, day 3 and day 5 cohorts.

Development of an improved test

Hudson Institute is seeking a partner for further development and commercialisation of the assay.

Market

Infertility rates are increasing and currently 17% of couples in the developed world are seeking medical intervention for failure to conceive. There are over 1.2 million assisted reproductive therapy cycles performed annually, with only 20% resulting in a live birth. There is currently no test available in the marketplace that can tell if the endometrium will be friendly or hostile to an arriving embryo just a few days later.

IP position

Hudson Institute is sole owner of two patent applications currently progressing in National phase in USA, Europe, China, Canada and Australia:

1. WO/2015/149129 (priority date 2 April 2014)

2. WO/2017/054038 (priority date 30 Sept 2015)

Team

This program is led by Dr Tracey Edgell PhD, who has strong expertise in antibody and protein technologies, protein biomarker discovery and assay development having worked in the Australian biotechnology sector for more than a decade prior to joining Hudson Institute.

This team is complemented by expert clinician collaborators with experience in fertility and assisted reproductive technologies.

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Hudson Institute of Medical Research

Hudson Institute of Medical Research is a leading Australian medical research institute recognised internationally for research into reproductive health and pregnancy, infant and child health, hormones and health, inflammation and cancer. Our research programs span discovery science and translational research, and clinical trials.

Our worldwide scientific and medical collaborations provide a foundation for transformative healthcare programs across the globe, with our researchers leading developments in cell therapies, women's health, microbiome research, diagnostics, and cancer.

Partnership opportunities include:

- Therapeutics, including oncology and gene therapy
- Reproductive, women's and children's health
- Regenerative medicine
- Inflammation and immunology
- Diagnostics and biomarkers