

Proposal for joint project between NHS Blood and Transplant (RINTAG) and the NIHR Innovation Observatory to generate a pipeline analysis in organ transplantation.

The responsibilities of RINTAG include identifying and assessing the potential for new treatments and technologies to positively impact on the clinical organ transplantation pathway and providing expert guidance to NHS BT on the risks and benefits of adoption of these new approaches into clinical practice.

To date this has been based predominantly on the personal experience of RINTAG members about what new technologies are in development or close to reaching the clinic. This risks missing important technologies or treatments that might be at an earlier stage in the development pathway and also introduces the risk of perceived bias towards certain technologies with which RINTAG members have personal experience or interests.

The **NIHR Innovation Observatory (NIHRIO)** is a national resource funded by the National Institute for Health Research that performs assessments that are relevant to researchers, the NHS and industry. One of their major functions is in producing “Horizon scanning” reviews in different therapeutic and disease areas. NIHRIO uses cloud based computing technology and have developed software that can extract information from a wide range of databases, registries, conference proceedings, publications, industry forums etc.

A short video of the techniques being used by NIHRIO can be seen at this link <http://www.io.nihr.ac.uk/>

There are several different models of review that NIHRIO perform but the one that would provide really valuable information to RINTAG, funding bodies and policy makers is a **full pipeline review**. This review would provide an unbiased deep dive into the therapeutic and technology pipeline in Organ Transplantation and would be done as a partnership between NIHRIO and discipline experts as a small expert writing group on behalf of RINTAG. The aim is that the review would generate a report containing all the factual information but with expert interpretation to produce a publishable review that would be valuable to the organ transplant community.

The proposed scope of the pipeline review would be to identify new therapeutics, devices or technologies which could broadly increase the number and quality of donor organs for transplantation and can improve the number and longevity of donor organs used in transplantation. The scope would be limited to whole organ transplantation (which includes islet cell transplant) but would not include haemopoetic stem cell transplantation.

Potential Search terms:

Organ transplantation (Heart / Lung / Liver / Kidney or Renal / Pancreas / Small bowel and Islet cells)
 Donor organs / donor organ quality
 Extended criteria organs / marginal organs / donation after circulatory death
 Organ preservation / organ flushing
 Preservation solutions
 Organ transportation
 Organ perfusion to include Ex-vivo perfusion, Machine perfusion, Normothermic perfusion, hypothermic perfusion, regional perfusion.
 Ex-vivo lung perfusion / ex-vivo heart perfusion/ ex-vivo normothermic perfusion
 Organ reconditioning
 Trade names in the space: Transmedics, OrganOx, Organ Assist, Cradle of Life, XVIVO.
 Donor organ allocation
 “Organ” can be replaced with any of the types of organ listed above.
 Advanced therapeutics/ cell therapies / biological therapies and organ transplantation
 Rejection and organ transplantation

Infection and organ transplantation
Hand transplantation
Limb transplantation
Uterine transplantation
Olfactory bulb transplantation
Transplant biobanking

Proposal and Costs:

Support is sought from NHS Blood and Transplant for the following:

To formally engage with NIHR innovation observatory to perform a full pipeline review of organ transplantation.

To establish a small key opinion leader writing group on behalf of RINTAG to work with NIHRIO to deliver the finished review.

Proposed expert writing group membership:

Andrew Fisher – Lung (Chair)
XX - Heart
XX – Liver
XX - Kidney
XX – Pancreas, small bowel and Islets
Nick Watkins – NHS BT R&D representative
James Woltmann – NIHRIO Market analyst
Mike Trenell – NIHRIO Director
Maria McGee – NHS BT administrative support

It is anticipated that most of the work of the group will be achieved via email communication and video conferencing although one face to face meeting in Newcastle at NIHRIO might be required in the later stages.

The usual cost for NIHRIO production of a full pipeline report is approximately £10,000. However for an NHS/academic collaboration where the time of the expert writing group is given freely to support the project in a timely manner then this can be negotiated. There may be publication costs depending on which journal is chosen for final submission. Some very modest travel costs might be required for the one face to face meeting in Newcastle.

Timeline

Evidence from NIHRIO from completing other pipeline reviews is that the rate limiting step is securing the necessary input and work from the key opinion leader writing group.

The aim would be to develop a firm timeline starting end May 2018 once group members appointed which can deliver the finished publication ready report by end November 2018.

Andrew Fisher
Nick Watkins
26th April 2018