

Uterine transplantation surgical framework: How to progress beyond the experimental

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INTRODUCTION

Uterine transplantation (UTx) has been increasingly performed worldwide with over 100 UTx and 50 livebirths worldwide .

For UTx to be made more widely available to individuals with absolute uterine factor infertility (AUI), it needs to progress from an experimental research procedure to an established clinical treatment.

OBJECTIVES

- Examine how UTx fits within IDEAL framework for surgical innovation
- Test the hypothesis that UTx meets the criteria for an innovative treatment, as defined by Provost et al.'s framework for novel fertility interventions

METHODS

- Assessment of UTx using the IDEAL framework
- Evaluation of UTx according to the criteria outlined in Provost et al's framework for novel fertility interventions.
- Literature review comparing UTx outcomes with in-vitro fertilisation (IVF)

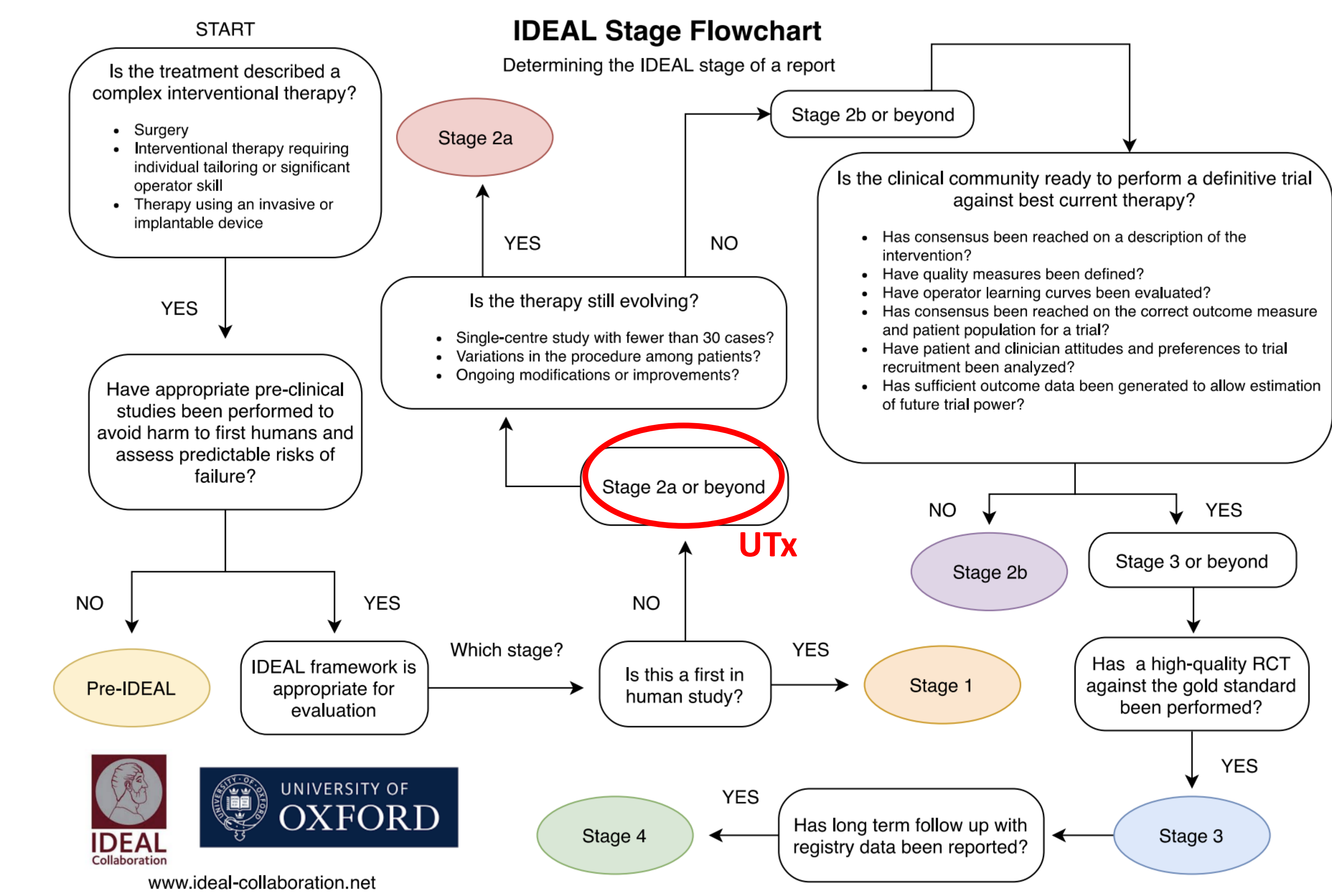
CONCLUSIONS

The results support the categorisation of UTx as an innovative treatment under Provost et al.'s framework. UTx offers a viable reproductive option for AUI, with a clear pathway toward becoming an established fertility treatment.

Ongoing research, clinical trials, and standardisation efforts will likely improve UTx outcomes, advancing its clinical adoption and benefiting those who wish to experience gestation and biological parenthood.

RESULTS

IDEAL FRAMEWORK



For UTx to move to stage 2b and beyond it requires involvement in randomised controlled trials.

Neither adoption nor surrogacy present a comparable alternative for those with AUI.

UTx therefore lacks a suitable control group, rendering the IDEAL framework unsuitable for guiding UTx's clinical transition.

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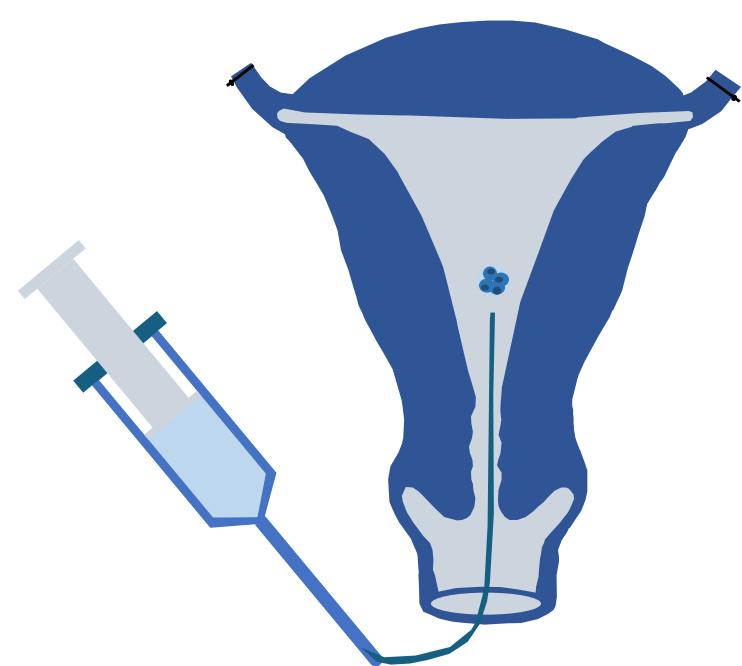
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PROVOST FRAMEWORK

	Criteria	Fulfilled by UTx
1.	Data collected during experimental phase must have shown proof of efficacy.	Yes
2.	The data collected regarding safety and effectiveness must be reassuring when compared to data from children conceived by standard fertility treatment (e.g. IVF)	Yes
3.	The data collected must be based on a procedure that has been described in sufficient detail and with limited variability between studies.	Yes
4.	The data must have been obtained by reliable studies published in peer-reviewed journals	Yes

UTx meets the Provost framework criteria to qualify as an innovative fertility treatment

IVF OUTCOMES: NATIVE UTERUS vs. UTX



	Native uterus	UTx
Pregnancy rates/ET	31%	43%
Miscarriage rates/ET	5%	10%
Live birth/ET	26%	35%

ET: embryo transfer

UTx outcomes appear to be better than native uterine IVF.

While UTx is more invasive and carries higher risks than traditional fertility treatments, these risks are deemed acceptable due to the lack of alternative reproductive options for people with AUI.

The safety profile of UTx is expected to improve as the procedure evolves and more data becomes available.