

HIGHLY CONFIDENTIAL

Addendum to Assessment Report prepared by the Peninsula Technology Assessment Group (PenTAG)

Tabled by Dr Rob Anderson, PenTAG, for inclusion in the papers for the:

NICE Appraisal Committee Meeting, 13th August, on alternative storage methods for donated kidneys.

ACADEMIC IN CONFIDENCE

Since submitting our Final Report to NICE, it has been brought to our attention that within the information (marked as *Academic in Confidence* within the Final Report dated 23rd June) we have unfairly overstated a weakness of the PPART study.

1. In section 5.3.1, where we appraise comparative studies that have evaluated the effectiveness of machine perfusion compared with cold storage, we wrongly stated that there was a “lapse in protocol” within the PPART study and that the storage of some kidneys was “outside the trial protocol” (p.57 of report).

Although [REDACTED] of the 45 transplant recipients in the machine perfusion trial arm were [REDACTED], we would like to correct the record that **this did not constitute a breach of the trial protocol**. It was stated in the PPART study protocol that [REDACTED]

2. Elsewhere, for example in the report’s Summary (p.5), we also refer to this issue as having “compromised” the data from the PPART study. Again, we would not want this to be taken as implying that the trial protocol had been breached, but merely that [REDACTED]

Stating that the PPART study results had been “compromised” in this way might also imply that in other studies of machine perfusion there would be no similar [REDACTED]. This is not the case. The report could have made it clearer that when using kidney perfusion machines there are inevitably [REDACTED].

[REDACTED] While this might lead to a potential reduction in the measured *efficacy* of machine perfusion, we recognise that this practice may also reflect the pragmatic realities of organ retrieval logistics, in which case this aspect of the PPART study might represent a better evaluation of the *effectiveness* of machine perfusion in routine NHS practice.

Rob Anderson, 11th August, Exeter.