

Title Assessment of oocyte/embryo vitrification and warming procedures

Agency HAS, French National Authority for Health (Haute Autorité de santé)

5 avenue du Stade de France – F 93218 La Plaine Cedex, France

Tel: +33 (0)1 55 93 70 00, contact.seap@has-santé.fr, www.has-sante.fr

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Aim

The Haute Autorité de santé (HAS [French National Authority for Health]) has decided to assess oocyte and embryo vitrification and warming procedures in order to be able to rule on the appropriateness of including them in the NABM (Nomenclature of Procedures in Laboratory Medicine).

Conclusions and results

Analysis of the available data leads us to conclude that:

- the principal and most relevant outcome for assessing the effectiveness and safety of vitrification - the livebirth rate - has not been assessed in the studies involved in the synthetic literature;
- compared to slow-freezing, oocyte and embryo vitrification has yielded better results in terms of clinical pregnancy and oocyte and embryo survival rates;
- no statistically significant difference was observed in the results obtained with vitrification and fresh oocytes;
- there are no data indicating that there is any increased risk connected with vitrification compared to slowfreezing, although the available data do not allow any precise conclusions to be drawn as to safety;
- the conditions of implementation are described in the decree relating to the rules of good clinical and laboratory practice in medically assisted procreation (MAP);
- oocyte and embryo vitrifications are widely used in France;
- owing to the poorer performance obtained with slowfreezing of oocytes, it would be advisable to consider

replacing this technique completely by oocyte vitrification;

- given that embryo vitrification offers better results compared to those obtained with slow-freezing, it would be advisable to consider replacing this technique completely by embryo vitrification;
- currently, there are embryos that have been cryopreserved by both slow-freezing and by vitrification which will at some stage be "thawed" or "devitrified". However, and in order to take account of these two types of technique, it would be appropriate to create a single procedure called "embryo warming", a term recommended, moreover, by the BLEFCO association (French association of medical pathologists researching the fertilisation and conservation of eggs) and ABM (the French Biomedicine Agency) in place of "thawing" or "devitrification", irrespective of the cryopreservation technique used.

Methods

The method of assessment used by HAS in this discussion paper is based on a critical analysis of the synthetic scientific literature data (systematic review of the literature with or without meta-analysis, health technology assessment (HTA), professional recommendations regarding the technique), a study of the regulatory framework with a review of the legislation currently in place, the opinion and data provided by the ABM along with a sounding, as a stakeholder, of BLEFCO.

Written by

Chantal ANDRIAMANGA HAS (French National Authority for Health - Haute Autorité de santé), France.