

Directions given under the Human Fertilisation and Embryology Act 1990 as amended

Reporting adverse incidents and near misses

Ref: 0011
Version: 2

These Directions are:	GENERAL DIRECTIONS
Sections of the Act providing for these Directions:	Section 12 (1) (d) and (g); and 24 (13)
These Directions come into force on:	1 October 2009
These Directions remain in force:	Until revoked
This version issued on:	1 October 2011

1. Licensed centres must report to the HFEA all adverse incidents (serious adverse events, serious adverse reactions, breaches of confidentiality and severe ovarian hyperstimulation syndrome (OHSS)) and near misses.
2. The person responsible (PR) or, in the PR's absence, a senior colleague must notify the Director of Compliance or nominated representative at the HFEA that an adverse incident or near miss has occurred or has been identified as having occurred within 12 working hours of the identification of the incident.
3. The person responsible (PR) or, in the PR's absence, a senior colleague must submit an HFEA adverse incident report form to the Authority within 24 hours of discovery. A copy of the report form is available from the HFEA website.

Definitions

4. The terms listed in these Directions are explained below:
 - (i) An 'adverse incident' is any event, circumstance, activity or action which has caused, or has been identified as potentially causing harm, loss or damage to patients, their embryos and/or gametes, or to staff or a licensed centre. This includes serious adverse events, serious adverse reactions, breaches of confidentiality and ovarian hyperstimulation syndrome (OHSS) which requires a hospital admission and has a severity grading of severe or critical.
 - (ii) A 'serious adverse event' is:
 - (a) any untoward occurrence which may be associated with the procurement, testing, processing, storage or distribution of gametes or embryos intended for human application and which, in relation to a donor of gametes or a person who receives treatment services or non-medical fertility services,

(i) might lead to the transmission of a communicable disease, to death, or life-threatening, disabling or incapacitating conditions, or

(ii) might result in, or prolong, hospitalisation or illness, or

(b) any type of gamete or embryo misidentification or mix-up.

(iii) A 'serious adverse reaction' is an unintended response, including a communicable disease, in a donor of gametes intended for human application or a person who receives treatment services or non-medical fertility services, which may be associated with the procurement or human application of gametes or embryos and which is fatal, life-threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or illness.

(iv) 'Severe ovarian hyperstimulation syndrome' (OHSS) is when a patient is diagnosed with OHSS which requires a hospital admission and has a severity grading of severe or critical (as defined in the Royal College of Obstetricians and Gynaecologists guideline).

(v) A 'near miss' is an occurrence that, but for luck, skill or judgment, might have become an adverse incident.

Ruth Fasht

Ruth Fasht OBE

20 July 2011

Chair of the Compliance Committee in accordance with delegated powers granted by the Human Fertilisation and Embryology Authority on 17 December 2008.

Version control	
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