

27. Adverse incidents


This guidance note contains:

Mandatory requirements

- Extracts from the HFE Act 1990 (as amended)
- Extracts from licence conditions
- Reference to relevant HFEA Directions

HFEA guidance

- Definitions
- Reporting and timescales ■

 Refer to principle 11

■ Section includes interpretation of mandatory requirements



Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

17 The person responsible

(1) It shall be the duty of the individual under whose supervision the activities authorised by a licence are carried on (referred to in this Act as the “person responsible”) to secure–

- (g) that the Authority is notified and provided with a report analysing the cause and the ensuing outcome of any serious adverse event or serious adverse reaction.

24 Directions as to particular matters

(13) The Authority may give directions as to the information to be provided to it and any measures to be taken by the person responsible in the event of–

- (a) any occurrence which may adversely influence the quality or safety of gametes or embryos intended for human application
- (b) any adverse incident which may be linked to the quality or safety of gametes or embryos intended for human application, or
- (c) any misidentification or mix-up of gametes or embryos intended for human application.

Schedule 3A

Supplementary licence conditions: human application

Serious adverse events and serious adverse reactions

3 Licence conditions shall require such–

- (a) systems to report, investigate, register and transmit information about serious adverse events and serious adverse reactions, and
- (b) accurate, rapid and verifiable procedures for recalling from distribution any product which may be related to a serious adverse event or serious adverse reaction,

to be in place as are necessary to secure compliance with the requirements of Article 11 (notification of serious adverse events and reactions) of the first Directive and Article 5 (notification of serious adverse reactions) and Article 6 (notification of serious adverse events) of the third Directive.



Mandatory requirements (cont)

Licence conditions

- T118 The centre must establish, implement and comply with documented procedures to report, investigate, register and transmit information about serious adverse events and serious adverse reactions that occur on any premises to which a licence relates and any relevant third party premises.
- T119 The documented procedures referred to in licence condition T118 must enable the centre to communicate to the Authority, without delay:
- all relevant available information about suspected serious adverse events and reactions, and
 - the conclusion of the investigation to analyse the cause and ensuing outcome in relation to serious adverse events and reactions.
- T120 The person responsible must notify the Authority of any suspected serious adverse events and serious adverse reactions by providing the information set out below and such other information as the Authority may specify in Directions:
- identification of the centre
 - identification of the premises concerned
 - report identification
 - date of notification, and
 - date of serious adverse event/serious adverse reaction

In relation to serious adverse events the following information is also required:

- an evaluation of the event by activity, (procurement, testing, transport, processing, storage, distribution or other) and specification of the source of error, (defect in gametes or embryos, equipment or material failure or defect), human error or other (to identify preventable causes), to be followed by a conclusion report including items (a) to (e) above.

In relation to serious adverse reaction(s) the following additional information is also required:

- date and place of procurement of gametes or application of gametes or embryos
- unique donation identification number
- date of suspected serious adverse reaction
- details of gametes or embryos involved in the suspected serious adverse reaction, and
- type of suspected serious adverse reaction(s).

- T121 The centre must thereafter notify the Authority of the conclusion of the investigation into the serious adverse event/serious adverse reaction by providing at least the information set out below and any such other information as the Authority may specify in Directions:
- identification of the centre
 - identification of the premises concerned
 - report identification
 - date when the serious adverse event/serious adverse reaction was confirmed
 - date of the serious adverse event/serious adverse reaction, and
 - corrective measures taken.

In relation to serious adverse reaction(s) the following additional information is also required:

- date when the serious adverse reaction was confirmed
- unique donation identification number



Mandatory requirements (cont)

T121 (cont)

- i. confirmation of the type of reaction(s) or a change in the type of reaction(s),
- j. clinical outcome, if known:
 - i. complete recovery
 - ii. minor sequelae
 - iii. serious sequelae, or
 - iv. death
- k. root cause analysis
- l. outcome of investigation and final conclusions, and
- m. recommendations for preventive and corrective actions.

T122 The centre must ensure that an accurate, rapid and verifiable procedure is in place, which will enable it to recall from distribution any product that may be related to a serious adverse event or reaction.

Directions

0011 – Reporting adverse incidents and near misses

For a copy of the relevant Directions visit www.hfea.gov.uk



HFEA guidance

Definitions

27.1 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.

27.2 A serious adverse event is defined in the HFE Act 1990 (as amended) as:

'(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 gametes or embryo misidentification or mix-up'.

27.3 A serious adverse reaction is defined in the HFE Act 1990 (as amended) as:

'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'.



- 27.4** A 'near miss' is an occurrence that, but for luck, skill or judgment, would in all probability have become an adverse incident.

Reporting and timescales



Interpretation of mandatory requirements

27A

HFEA Directions require centres to report all adverse incidents and near misses to the HFEA. This includes adverse incidents occurring at third party premises, where there is a third party agreement in force between the centre and that third party.

Centres must report all adverse incidents or near misses to the HFEA by telephone within 12 working hours of their identification. This verbal notification must include the:

- (a) centre's name
- (b) HFEA centre identification number
- (c) contact details of the person responsible
- (d) date of the initial notification or report
- (e) name of any individual affected
- (f) date and time of the adverse incidents and near misses
- (g) details of gametes or embryos involved in the incident, and
- (h) type of incident, including any transmission of infectious agents.

In addition, the centre must inform the HFEA in writing of all adverse incidents or near misses occurring at that centre (or, if the event relates to treatment that involves a third party, at a centre with which it has a third party agreement) by completing an adverse incident form.

The centre must email the completed form to incident.reporting@hfea.gov.uk within 24 working hours of discovering the incident.

- 27.5** The centre's documented procedures should ensure that any adverse incident or near miss that may result in harm to the patient, patient's partner or donor is recorded and reviewed.

- 27.6** If an adverse incident or near miss occurs, centres are expected to:

- (a) review relevant procedures to minimise the risk of the incident happening again, and
- (b) inform the HFEA of the revised procedures.

- 27.7** When investigating serious adverse events and reactions, the centre should evaluate all assisted-conception processes directly related to the adverse event, and all relevant processes involving the:

- (a) management of resources
- (b) training and competence of staff
- (c) equipment
- (d) materials
- (e) information systems, and
- (f) control of environment.

A copy of the investigation report should be submitted to the HFEA.



HFEA guidance (cont)

27.8 The HFEA also expects centres to report adverse incidents that arise from the use of equipment and materials. Reports of this nature should be sent to the Medicines and Healthcare products Regulatory Agency (MHRA), as the relevant 'competent authority'. An 'adverse incident' in this context is an incident that produces, or has the potential to produce, unwanted effects involving the safety of patients, users and others. This reporting is distinct from, but complementary to, that required by the HFEA.

See also guidance note:

- [26 – Equipment and materials](#)
- [32 – Obligations and reporting requirements of centres](#)

27.9 The centre should, in line with professional body guidance, inform patients/donors of any adverse incidents that may have resulted in harm to them, their gametes or their embryos.



Other legislation, professional guidelines and information

- National Patient Safety Agency – Being open: communicating patient safety incidents with patients, their families and carers – www.nrls.npsa.nhs.uk/resources/?entryid45=65077
- NHS Litigation Authority – Apologies and Explanations – www.nhs.uk/NR/rdonlyres/00F14BA6-0621-4A23-B885-FA18326FF745/0/ApologiesandExplanationsMay1st2009.pdf
- General Medical Council – Good Medical Practice – www.gmc-uk.org/guidance/good_medical_practice.asp
- Nursing and Midwifery Council – The code: standards of conduct, performance and ethics for nurses and midwives – www.nmc-uk.org/Nurses-and-midwives/The-code/The-code-in-full/

