International Federation of Fertility Societies

Global Standards of Infertility Care

Standard 5.

Safety Monitoring for Assisted Reproduction Technology (IVF,ICSI) Recommendations for Practice

Name	Safety Monitoring
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Introduction:

The goal of IFFS Guidelines are to provide policy- and decision-makers and the clinical and scientific community with a set of recommendations that can be used as a basis for developing or revising institutional or national guidelines on selected practice recommendations for infertility practice.

The document addresses minimal standards of practice. It does not provide rigid guidelines but gives recommendations that provide the basis for rationalizing the provision of infertility services taking account of the most up-to-date information available.

The intent of IFFS practice standards is to help improve access to, quality of, and safety of infertility and assisted conception services. These improvements must be made within the context of users' informed choice and medical safety. Because national situations and programme environments vary so greatly, it is inappropriate to set firm international guidelines on infertility practice. However, it is expected that institutional and national programmes will use these clinical standards documents for updating or developing their own infertility guidelines in the light of their national health policies, regulatory framework, needs, priorities and resources. Adaptation is not always an easy task and is best done by those well-acquainted with prevailing health conditions, behaviours, and cultures.

This standard provides guidance on the reporting of the outcomes of IVF and related treatments including the common and serious adverse consequences. Adverse psychological and social sequelae may occur after these treatments but data collection is more problematic. Therefore whilst data collection is desirable it is not expected as part of this standard.

Rationale:

IVF treatments are increasingly practiced around the world and about 1 million treatment cycles are currently estimated to be performed annually. Some four and a half million children have been born after IVF treatments, yet so far there is no clear consensus on success in terms of safety[i]

An international 4-level system is currently operating (clinics – national registers – regional registers – World Reports) to monitor efficacy and access and, most importantly, to monitor and report on the safety of these procedures i.e. immediate treatment complications for women as well as obstetrical and peri-natal outcomes[ii]. The system is estimated to cover about 75% of all cycles performed, with large differences in different countries. A number of countries do have complete coverage but this is not the case everywhere. With cross border treatment increasingly commonplace the need for internationally agreed monitoring is further enhanced[iii]Long-term follow-up of psycho-social and medical outcomes is much more complicated and is usually not done routinely by the clinics but rather through either specific (often multi-centred) research projects or on a national basis[iv,v]

Knowledge about the safety of IVF is essential for all stakeholders in IVF: for patients (rational choices of treatments), for professionals (feedback on clinical policies)[vi], for industry (product developments)[vii] and for society (legal and economical considerations)[viii,ix] Safety data on IVF are needed to build and maintain confidence.

Recommendation for practice:

Clinics should collect and store individual safety data from all patients undergoing In Vitro Fertilisation and related technologies such as ICSI including those where donor eggs are used either

as egg share or full egg donation, in a traceable system (electronically and/or on paper), to be used for internal audit, review of clinical practices, patient information and for data export to national (or directly to international) IVF registers. It is recommended that data are also collected on cycles using thawed embryos and host surrogate arrangements.

Those centres who are the hub for satellite services should ensure that data collection is coordinated so as to avoid duplication of cycle information.

Data collection, storage and export should ensure patient confidentiality and comply with national and, where applicable, international, standards, regulations and legislation concerning data protection.

a. Reportable immediate ART treatment complications, include:

    1. Thrombo-embolic events
    2. Moderate or severe OHSS. (for the purposes of this standard moderate / severe OHSS is defined as that necessitating paracentesis or pleural drainage)
    3. Bleeding (defined as either from pelvic blood vessels requiring abdominal surgery or vaginal vessels requiring suture)
    4. Infection (defined as suspected post retrieval pelvic infection requiring therapeutic antibiotics).

       Serious anaesthetic complications should also be reported such as cardiac/ respiratory arrest and admission to intensive care.

b. Data to be collected from own clinical files and from reports back from referral hospitals

    1. Obstetrical outcomes (including live birth rates, serious pregnancy complications (defined as delivery before 37 weeks gestation; antepartum haemorrhage necessitating delivery; pre-eclampsia maternal death.

    2. Peri-natal outcomes (birth weight, gestational age, birth defects, morbidity and mortality), where - in both cases b. and c. - data should be collected by the clinics from

patients and from professionals in charge of the maternity and delivery care and the peri-natal care. The recommended standard of loss to follow-up at this level should not exceed 5 %.

National registers

National registers should be established in all countries undertaking infertility treatments to collect data from all clinics, cycle-by cycle or else as annual summary data, and report annually in a national report, in professional and also in lay language. Data should be exported annually to the regional register or else to the World Register directly.

Implementation: Recommendation for Practice 5.0 will be circulated in the following ways:

1. Publication in the IFFS newsletter
2. Inclusion in the IFFS World Assisted Conception Survey
3. Circulation to all member countries secretaries
4. To WHO and FIGO for inclusion in relevant publications

References:

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[iii] Principles of establishment of the First International Forum on Cross-Border Reproductive Care.Mainland L, Wilson E. Fertility and sterility, 2010, 1:

[iv]Safety of assisted reproduction, assessed by risk of abnormalities in children born after use of in vitro fertilization techniques. Alukal JP, Lipshultz LI. Nature clinical practice. Urology, 2008, 5: 140-50

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[vi] Mortimer D, Mortimer ST. Quality and Risk Management in the IVF Laboratory. Cambridge: Cambridge University Press, 2005, 232.

[vii] Safety of drugs used in assisted reproduction techniques. Al-Shawaf T, Zosmer A, Dirnfeld M, Grudzinskas G. Drug safety : an international journal of medical toxicology and drug experience, 2005, 28: 513-28

[viii] European Union. Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 'On setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage, and distribution of human tissue cells'. Official Journal of the European Union 2004:L102/48.

[ix] European Union. Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells. Official Journal of the European Union 2006:L294/32.