Inspection guidance in Assisted Reproductive Technologies (ART)
Curriculum and Vademecum for inspectors

ARTHIQS – Deliverable 7
Work Package 4
# Deliverable No. 7: Inspection guidance in ART – Vademecum and curriculum for inspectors

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INTRODUCTION

Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 (EUTCD) set standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (T&C). The EUTCD considers the inspection as a major tool to ensure quality and safety of tissue establishment activities within the European Union (EU). Indeed, article 7 establishes the need for inspections and control measures and requires that tissue establishments are inspected within an interval not exceeding two years.

The EUTCD is now transposed in almost all member States (MS)\(^1\). However, EUTCD requirements are not fully implemented in the field of reproductive T&C\(^2\), particularly regarding inspections of ART Establishments (ARTE). This lack of implementation is leading to heterogeneous levels of regulation of ART practices within the EU.

Organisational systems in place are highly heterogeneous owing to the variety and complexity of legislations in the different MS. ART practices especially in the private sector - have swiftly and vastly expanded – in some countries, profiting from a lack of regulation and oversight by authorities. As a consequence, cross-border reproductive care has also been expanding, taking advantage of the principle of free circulation of patients, products and services within the EU.

Efficient and reliable inspection of ART centres represents a tool enabling protection and safety of donors and recipients from and within the EU. The EUTCD has specific requirements with the objective to harmonise inspection procedures everywhere in EU.

ARTHIQS WP4 aims to enhance ART expertise at authority level, and improve the capacity of the Competent Authority (CA) in each of the EU-28 Member States to implement the EUTCD and design national plans. WP4 therefore seeks to increase and harmonise the quality and safety of ART practices throughout the EU.

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\(^1\) 27 of 28 Member States have fully transposed the EUTCD 2004/23/EC and the 2006 technical directives (competent authorities for T&C meeting in Brussels, 2/2017)

\(^2\) Reports on implementation and voluntary and unpaid donation in T&C sector point out some gaps and difficulties in applying and enforcing the rules including the inspection framework (competent authorities for T&C meeting in Brussels, 9-10 June 2016)
The ARTHIQS survey on institutional practices in ART throughout the EU (Deliverable 5) has provided information on the organisations overseeing the ART sector in 11 countries. Different organisational models and mandates exist for CAs depending on the organisation of public health regulation and the existence of a law on ART prior to the EUTCD transposition:

- In all countries, one or several CAs are responsible for ART inspection,
- All CAs, except in the UK, have appointed inspectors who are not strictly dedicated to ART, mainly due to limited resources. The inspection team can be composed of health inspectors and ART experts,
- Most of the inspectors are medical doctors, pharmacists, biologists or nurses. In some countries, they can have an initial ART professional background,
- Inspectors receive a theoretical training on ART. The duration of the planned training (mainly theoretical) varies from 8 hours to 3 months. Practical training is mostly met through participation in inspections with a senior inspector,
- The operational manual for CAs “Inspection of tissue and cells procurement and tissue establishments” (version 1.1 April 2015) is officially used only in 3 countries, and is considered as not applicable to ART in other member states, where authorities have developed their own guidelines for inspection,
- Inspection should cover all clinical parts of ART activities (collection/procurement sites and application sites).

According to the survey results, inspectors should be trained in ART, have a basic knowledge in ART practices or at least be supported by an ART expert when conducting an inspection in that field.

This Deliverable 7 of ARTHIQS WP4 therefore aims to develop an inspection guidance in the form of a curriculum and a vade-mecum, short and operational documents available in electronic version, highlighting ART specificities in inspection.

- The curriculum aims to define the profile of inspectors in the field of ARTE inspections and emphasizes the need for a basic knowledge of ART activities in order to perform a relevant and undisputable inspection.
- The vademecum aims to support the inspectors in their mission regarding ARTE inspections, providing them with the basic knowledge in ART, focusing on key points to understand the complexity/specificity and the issues of the ART process and proposing some specific ways and means to conduct the inspection.

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**Deliverable No. 7: Inspection guidance in ART – Vademecum and curriculum for inspectors**
CURRICULUM

Qualification of inspectors

Inspectors should have a solid level of competence and performance in three domains: inspection process, quality management system in tissue establishments and ART-specific practices.

Who can inspect ART establishments? What is supposed to be known and applied for a relevant and unquestionable inspection in ART establishments?

Education

Inspectors shall possess a diploma or certificate or other evidence of formal qualification allowing them to perform an inspection in the field of healthcare and giving them an official status regarding their mission.

Depending on the MS law, inspectors usually belong to the healthcare inspectorate and have a medical or scientific background, awarded on completion of a university course or a course acknowledged as equivalent (MD, PhD, science, pharmacy, midwifery or nursing) or a non-health background (jurists or expert in quality management system...).

1. Irrespective of their initial background, in order to be efficient, inspectors should have a good knowledge on the inspection process of healthcare establishments. Tasks, responsibilities and principles of inspection in the field of national health system are supposed to be clearly defined at the national level and well known by inspectors.

2. Since quality management systems exist in all domains at the international level, the EUTCD has set standards for quality management that apply to the T&C sector. An operational manual for Competent Authorities “Inspection of tissue and cells procurement and tissue establishments" (April 2015) gives the basics to inspectors. Inspectors must also possess the knowledge of: a) the legal provisions transposing EUTCD, especially the rules for quality management in tissue and cells establishments b) the national regulation transposing the European technical directives that are in force in the MS. This second point is specific to T&C in the context of EUTCD requirements.

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3. Finally, with regards to ART specificities, inspectors must also have a basic knowledge related to the clinical and biological aspects of ART as well as the legal provisions and mandatory rules that apply in this field, in the MS concerned. Indeed:

- They will have to check the compliance with ethical principles, legal provisions and mandatory rules in force in the member state regarding ART activity,
- As they will have to perform a risk assessment during their inspection, they are supposed to identify critical steps of the clinical and laboratory processes, be able to understand what they noticed and anticipate potential risks and consequences for donors, patients, couples or children,
- They must know that inspecting ARTE is not only dedicated to ensure the quality and safety of the products (T&C) that will be used in clinical procedures, but to guarantee the quality and safety of practices for donors, patients, couples and children born after ART.

Knowing the limited availability of human resources, it is not required of inspectors to be exclusively dedicated to ART inspections.

**Personal qualities and behaviour**

Inspectors must have personal qualities such as:

- A good capacity to communicate and display a quick grasp of complicated issues. Be open-minded and able to build a positive relationship with the ARTE’s staff in order to reduce the anxiety surrounding the inspection process and promote an efficient collaboration,
- Reliability and punctuality. Inspectors must be available to respond to queries from the centre in a timely manner,
- High level of personal integrity and maturity,
- Without any conflict of interests in the ARTE to be inspected. Personal interest must be declared and updated in a transparent way and taken into account,
- According to the national legislation, ARTE can propose sensitive activities such as gamete donation, risk-reducing treatment as pre-implantation genetic diagnosis and fertility treatment of HIV and hepatitis-infected patients, fertility preserving treatment for patients, surrogacy or research on human embryos that might represent difficult moral or ethical issues for inspectors. Indeed inspectors must have an independent observation of the activities performed without any personal judgment or emotional reactions that could affect proceedings,
- Inspectors must comply with tasks and responsibilities defined in the MS. Inspectors must follow the reference sources. Inspectors must draw a detailed and factual report and assess the criticality of the statements on a risk analysis basis.

**Practical experience**

Inspectors should have a practical experience in at least one of the three domains described above: inspection of healthcare establishments, quality management system in tissue establishments and/or ART practices. They can have obtained a basic experience in such domains due to a previous position or post-graduate function or in working within a CA that manages inspections in tissue and cells establishments or medicinal products, quality management or expertise in ART.

Inspectors should have practical experience at the technical level in real time in inspection of healthcare establishments, blood banks, tissue establishments, and ARTE.
Initial training (and evaluation in theory and practice) should be provided, regardless of the qualification or previous experiences. Training must be built according to the initial background and experience of the candidate.

### Training

Training courses for inspectors aiming to cover all relevant topics should be organised in different versions differently and combined depending on the education and practical experience:

- **Initial training**, for newly designated inspectors when getting a position within an Inspectorate,
- **Continuous training**, in order to keep up with any technical and legal evolution in ART, or to maintain competencies and avoid deviation from appropriate proceedings,
- **Specialised training**, on national laws applying to ART and ART’s specific activities, such as donor evaluation, donor screening, fertility preservation, PGD… or to deal with concrete situations when inspectors have to face major risks,
- **Specific dedicated to cross-border training inspection**, in order to have a general knowledge on the different contexts and legal frameworks existing abroad to be able to join another MS inspection team if relevant. An inspector from abroad joining a cross-border inspection team should be aware of the eventually more stringent testing of the country of inspection.

Training should be organised at the National level with shared reference documents. The harmonisation of inspection process within a same National territory is worth considering even in case of MS composed of autonomous regions in charge of authorisations and inspections. National management of training courses leads to harmonised processes respecting the regional characteristics and plans.

Initial Training should propose:

- Theoretical courses, with the participation of ART experts, highlighting the specificities of ART practices
  - Conceived by people with different backgrounds,
  - Providing participants with relevant references that can include international guidelines (e.g. ESHRE guidelines, …)
- Practical exercises on concrete cases with round table meetings: "What would your reaction be if...?"
- Visit of an ARTE in order to enlighten/educate the candidates. So as to avoid any conflict of interest, it is recommended that the establishment to be visited should not be part of the territory the future inspector will have to inspect,
- Practical training on-site: a mentor-led training programme for inspectors should be in place in a progressive way:
  a. The trainee inspector first follows, as an observer, a senior inspector from the beginning of the process to the final report of several real inspections,
  b. The trainee then participates in inspections conducted by the mandated inspector,
c. And finally performs actual inspections under the supervision of a senior inspector. Some inspectors could have completed a training course led by the EU including the EUSTITE course.

Competences acquired by the trainees must be confirmed and documented by the CA prior to their authorisation/nomination to lead inspections.

An evaluation of the performance and competence of the inspectors should be periodically conducted (e.g. through crossed audits).

**Responsibilities**

Inspectors should be given an official written mandate by the CA, specifying their tasks in detail.

Inspectors have to declare their conflicts of interests and the CA should be able to provide the proof that this has been taken into account before mandating the inspector.

Inspectors are not supposed to make decisions on administrative penalties (e.g. authorisation’s revocation) that fall within CA mandate.

Inspectors are only responsible for what they observed and reported. Inspectors are not responsible for deficiencies that could not be detected during the inspection because of a limited time or a limited scope or any voluntary hidden defect on fact.

**Consulting expert**

The support by an ART professional or another expert could be necessary for the inspection team to assess risks in a relevant way.

Participation of expert(s) has to be organised by the CA complying with the rules in force in the MS concerned.

Tasks and responsibilities should be clearly defined at the national level, fully understood and respected during the whole process. The expert has to give expertise and should not interfere, comment or have any opinion. The expert role is only to support the inspection team, and acts as a consultant. This expert comments and final decision are at the discretion of the inspecting team.

Experts in ART can be gynaecologists, embryologists, nurses, midwives or any specialised expert who could not have the status of inspectors according to national laws.

Experts should not have any personal interest related to the establishment that is going to be inspected. A personal declaration must be filled out by the expert for transparency. The authority must take into consideration any conflict that would affect the provided expertise.

Experts could be asked to write an expertise report for the inspection team.

If needed, as it can be the case in smaller countries, a consulting expert (ART CA, Gynaecologist …) from abroad can be invited to participate to the inspection visit in order to share their experience of the field.
VADEMECUM

This short and practical document aims to support inspectors as an « aide-mémoire » in their mission of inspection of ARTEs. Reminding major information on ART specificities and key issues for quality and safety of practices, it provides inspectors with relevant tools for inspection.

- Practical glossary
- Summary sheets
  1. Basic knowledge for inspectors
  2. Pathway: an IVF cycle between partners with focus on...
  3. Inspection Procedure
     - General system-oriented inspection process
     - From tank to couple: backwards traceability
  4. Focus on critical issues through concrete examples
     - Risk assessment on mix-ups, what should be a “never event”
- Forms: inspection forms, dossier, inspection evaluation and report

PRACTICAL GLOSSARY

ART has been developing for more than 30 years now and practitioners adopted their own terminology.

The 2004/23/EC EUTCD uses general terminology for all T&C but are not cell-type specific and need to be adapted prior to transposition in the sector of ART, leading to a more complex implementation (table below).

Common definitions are essential for a clear understanding and a more standardised communication among regulators and ARTE representatives.

This glossary proposes correlations between EUTCD terms and specific ART wording when appropriate. It is intended for inspectors and aims to facilitate exchanges.

As a start...

Assisted reproductive technologies (ART)

ART cover all the treatments and procedures that include in vitro handling of sperm, oocytes and embryos for establishing a pregnancy. This includes - but is not limited to - intra-uterine insemination (IUI), in vitro fertilisation (IVF), with or without intracytoplasmic sperm injection (ICSI), embryo transfer, gamete, germinat tissue and embryo cryopreservation, gametes and embryo donation and gestational surrogacy.

Mostly - but not exclusively - ART attempts are dedicated to infertile couples with usage of their own gametes.

Fertility preservation in the context of ART

Fertility can be preserved through long-term cryopreservation of reproductive T&C. Fertility preservation is mainly performed before treatments that may be potentially deleterious for reproductive cells, like chemotherapy.

Fertility preservation that includes cryopreservation of sperm, oocytes and gonadic tissues is considered as part of ART activities, even if gonadal tissues can be cryopreserved with a purpose of transplantation.

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### Correlation between EUTCD and ART terminologies

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<th>ART</th>
<th>Specific ART features</th>
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<td><strong>Procurement site/organisation</strong></td>
<td>A healthcare establishment or a unit of a hospital or another body that undertakes the procurement of human T&amp;C</td>
<td>An establishment organising the collection of gametes for ART (tissue establishment/ART centre/Fertility clinic)</td>
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<td><strong>Tissue establishment (TE)</strong></td>
<td>A tissue bank or a unit of a hospital or another body where activities of processing, preservation, storage or distribution of human T&amp;C are undertaken</td>
<td>Establishments performing in vitro/lab ART activities: ART centres, ART laboratories, sperm banks, etc. (ARTE)</td>
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<tr>
<td><strong>Organisations responsible for application of human T&amp;C</strong></td>
<td>Healthcare establishment or a unit of a hospital or another body which carries out human application of human T&amp;C</td>
<td>Clinical unit where inseminations and embryo transfers are performed</td>
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<tr>
<td><strong>Human tissues and cells (T&amp;C)</strong></td>
<td>Material containing or consisting of human tissues and/or cells intended for implantation, transplantation, infusion, or transfer into a human recipient. Examples: musculoskeletal, bone, cartilage, meniscus, skin, cornea</td>
<td>All reproductive T&amp;C intended to be used/applied in a human recipient, for the purpose of ART or fertility preservation such as gametes (oocytes, sperm), zygotes, embryos (early embryos, blastocysts), ovarian tissue, testicular tissue</td>
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<td><strong>Authorisation/Licencing of activities and inspections</strong></td>
<td>Tissue establishments where activities of testing, processing, preservation, storage or distribution of human T&amp;C intended for human</td>
<td>ART activities include IUI, IVF/ICSI that represent a series of different processes.</td>
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## Donor evaluation/selection

The procedure of determining the suitability of a potential donor, living or deceased, to make a donation.

The term « selection » is not appropriate in the field of reproduction. ART between partners needs an evaluation of the quality of gametes and the risk of infectious diseases in order to adapt the technique to use. The evaluation is also performed in order to avoid as far as possible the transmission of genetic conditions to the offspring.

Evaluation for a non-partner donation aims to determine the suitability of the donor regarding the risk of infectious diseases and genetic conditions and eventually reject him/her for donation.

## Donation

Donating human T&C intended for human application.

Two types of donation exist in ART:
- Partner donation of reproductive cells between a man and a woman who declare that they have an intimate physical relationship
- Non-partner donation of gametes or embryos created with gametes from another person apart from the recipient

Most ART are performed with gametes from partners that are infertile and wish to have a baby.

For single women, same sex couples or heterosexual couples with unavailable gametes, gametes from non-partner donors can be used.

## Donor

Every human source, whether living or deceased, of human cells or tissues.

Different type of “living donors” can exist:
- Partner donors
- Non-partner donors of gametes if the donor has no intimate relationship with the beneficiary
- Couples donor of embryos

Deceased donors are persons that already had their sperm cryopreserved while alive. Posthumous use depends on the National legislation.

The term “donor” can be confusing. In daily practices, it is used to designate non-partner donors.

In IVF between partners, oocytes and sperm from both partners are used.

## Procurement

A process by which T&C are made available for banking or

The term “procurement” is not used in ART
- For oocytes: pick up/recovery/retrieval/collection

The term “collection” is also used instead of procurement (rather more appropriate for the ART).
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<th>Storage</th>
<th>Distribution</th>
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<td>- For sperm: sperm collection when no surgical procedure is needed, or testicular sperm extraction when a surgical procedure is needed to obtain sperm from testis</td>
<td>All operations involved in the preparation, manipulation, preservation and packaging of T&amp;C intended for human application</td>
<td>The use of chemical means, alteration in environment conditions or other means during processing to prevent or retard biological or physical deterioration of T&amp;C</td>
<td>Maintaining the tissue or cells under appropriate controlled conditions until distribution</td>
<td>Transportation and delivery of T&amp;C to the site/organisation of human application</td>
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<td>Regardless of the evaluation/selection results, and the strategy applied, success cannot be guaranteed (pregnancy/birth/ “healthy child”)</td>
<td>In addition to the operations described for any tissue/cell, processing also applies to ART activities such as classical IVF, ICSI, sperm preparation, embryo culture, etc…</td>
<td>In ART, only cryopreservation is used as the mode of preservation of gametes, embryos or gonadic tissues (slow freezing or vitrification)</td>
<td>All reproductive T&amp;C can be cryopreserved in order to be used later in ART or transplantation</td>
<td>However gametes and/or embryos are mostly processed in the same ARTE where they are applied to the patients. Under these circumstances, the term “Distribution” is not appropriate.</td>
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This section contains general information on the basic knowledge expected for an ART inspector. These points are not exhaustive or detailed as this guide aims to point out the main fields of knowledge required. For more extensive information, please refer to “Guide to the Quality and Safety of T&C for Human Application, EDQM Council of Europe”.

Inspectors must have a basic knowledge in all ART aspects that they could face during the inspection of an ART establishment. Initial training should give them an ART specific background.

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**Reproductive Science & ART**

- Infertility (frequency, diagnosis, check-up...)
- Reproduction (Folliculogenesis, ovarian stimulation, oocyte pick-up...) and (Spermatogenesis, semen analysis, sperm preparation....)
- Environmental impact on gamete and embryo quality......
- ART techniques: Intrauterine insemination, IVF, ICSI, embryo transfer / embryo development and implantation, pregnancy / cryobiology of gametes, embryos and gonadal tissues...

**The ART laboratory**

- Identification and traceability (e.g. Donors, beneficiaries, embryo, material/consumable...)
- Facilities/premises (e.g. air quality, temperature, cryogenic room...)
- Specific equipment (e.g. ICSI...)
- Environment non-toxicity (e.g. floor covering...)
- Interaction with clinical procedures (e.g. embryo transfer...)
- Quality management system

**Evaluation**

- Registries: Donor registry, stored embryos/gametes registry...
- ART vigilance (adverse event reporting) / Risk Assessment Report (RAR)...
- Results of ART procedures: data collection, efficiency, multiple pregnancies...
- Follow-up for oocyte donors, offspring, genetic disease transmission after gamete donation...

**ART environment**

- Legislation in force in the MS (and EU), EUTCD implementation report
- Rapid Alert for T&C System / European Commission report
- Ethical and socioeconomic concerns about ART
- Innovative techniques already applied or still experimental
- ESHRE Guidelines & Reports
- Cross-border movements of donors, beneficiaries, reproductive T& Cells

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Ovarian stimulation

Ovarian stimulation is a hormonal treatment aiming to obtain several mature oocytes to be fertilised or cryopreserved to produce "good quality embryos".

Ovarian stimulation can be risky due to possible Ovarian Hyper Stimulation Syndrome (OHSS) and thrombosis. Severe OHSS is the most frequent complication encountered in IVF. In some cases OHSS can lead to severe metabolic disorders putting woman’s life in jeopardy. Thrombosis can also cause serious consequences.

OHSS and thrombosis represent well-known complications that must be anticipated in identifying at risk women:
- Medical history, blood testing...
- Cautious/low stimulation with anticoagulant drugs and attentive monitoring,
- Aspiration of all the follicles
- Freezing of all gametes / embryos
- Cancellation of the cycle if necessary

In vitro fertilisation (IVF/ICSI) and culture

Embryo transfer

Follow-up

Storage of remaining cryopreserved gametes and embryos
Embryo transfer

Embryo transfers can be performed at different stages: zygotes (D1), embryos with 4-8 cells (D2-3) or blastocysts (D5-6).

The transfer of a single embryo is highly recommended in young women with "good quality embryos". For older women, more than one embryo, usually of lower quality, might be transferred (complying with the national regulation). The overall objective is to give significant chances of pregnancy and at the same time to avoid multiple pregnancies that are at risk for both maternal and foetal health.

Cryopreservation and storage

Storage in liquid nitrogen is the most common method used to store gametes, embryos and gonadal tissues. Cryopreservation and thawing are routine processes in ARTE. If kept under appropriate conditions, there is no evidence that cryopreserved T&C deteriorate after a certain time of storage. When kept for “autologous use”, there is no expiry date available.

Working in a cryogenic room and manipulating liquid nitrogen requires that personnel have been trained and are aware of the potential hazards. Specific protective equipment must be available and used.

Moreover, the safety of the cryopreserved products requires periodic controls of the performance of tanks. An untimely thawing deteriorates the products and leads to a loss of chances which can be definitive.

Non-partner donation evaluation/selection

Evaluation aims to exclude donors whose gametes might cause a health risk in the recipients or when donation process might cause harm to their own health.

Evaluation of donors includes an in-depth interview with different objectives such as a psychological assessment (motivations, consequences of the donation...) and search for risk factors of inheritable genetic conditions.

Non-partner gamete donation is strongly regulated in some countries while in other countries without such legal restraints, donation represents an increasing activity in the private sector.

Main issues:
- Need for protection of the welfare of oocyte donors and control of recruitment modes,
- Safety of donation as regards recipients’ and children’s health, including in the context of cross border reproductive care.
WHO ARE THE BENEFICIARIES OF ART?

- Infertile couples, after evaluation of their fertility, represent the major part of the beneficiaries,
- Couples at risk to transmit a genetic or viral disease to the child or to the partner can benefit from ART procedures in order to avoid transmission (non-partner donation, PGD (pre-implantation genetic diagnosis), ...),
- Patients undergoing oncologic treatment, with toxicity for their future fertility, can have access to cryopreservation of gametes or gonadal tissues,
- Single woman, lesbian couples and gay couples in the context of surrogacy can resort to non-partner donation,
- Woman wishing to cryopreserve oocytes in order to postpone pregnancy or for any other reason (social freezing).

Access to ART is highly different between MS depending on national legislations:

WHO ARE THE DONORS?

In the ART sector, for practitioners and public as well, a person designated as a “donor” is usually a non-partner donor. Nevertheless, the EUTCD requirements apply to partners and non-partner donors as well.

Non-partner gamete donation represents a minority of the global ART activities. In ART, most of the activities are dedicated to people having an intimate relationship and wishing to have a child with their own gametes.

National legal provisions are heterogeneous regarding the disclosure of the identity of non-partner donors to the beneficiaries or the children. Procedures in place must ensure that legal provisions are followed.

WHAT ARE THE PROCEDURES IN ART?

Different techniques exist, and are used according to the medical history, the needs, estimated likelihood of success and risks. They all involve handling of reproductive T&C:

- Intra-uterine insemination (IUI) with prepared sperm (either from partner or non-partner donor), that is limited to handling and processing sperm, and then introducing selected sperm into the woman’s uterus for in vivo fertilisation,
- IVF that involves handling of both oocytes and sperm. It can be divided into:
  ➢ classical IVF oocytes and sperm are mixed in culture media dishes for an in vitro fertilisation
  ➢ intracytoplasmic sperm injection procedure (ICSI) involves the injection of a single spermatozoon into each mature oocyte.
IVF usually lasts 2-3 days in order to obtain embryos with 4-8 embryonic cells, which are ready to transfer. It can extend to 6 days leading to blastocysts. This duration is chosen according to many factors (law in force, medical situation of the couple, biological conditions, team experience...)

- Cryopreservation and storage of gametes for later use (IUI or IVF)
- Cryopreservation and storage of embryos for later embryo transfer,
- Fertility preservation through cryopreservation and storage of reproductive T&C,
- Gamete donation and embryo donation.

**WHO ARE THE PROFESSIONALS?**

In the ART sector, embryologists and clinicians work closely together. Clinical and laboratory procedures are interlinked and interdependent, coordination is necessary.

Embryologists can be scientists, medical doctors, pharmacists, technicians or engineers, in accordance to national regulations. They are experienced and/or certified in embryology.

ESHRE proposes a programme aiming to certify competence of clinical embryologists working in IVF and to develop a formal recognition for embryologists.

Clinicians can be gynaecologists, obstetricians, urologists, midwives and nurses, specialists in reproductive endocrinology according to national regulations. They are experienced in reproductive medicine including ovarian stimulation and/or surgery.

ART team may include psychologists, geneticists, specialists in andrology and any other necessary specialist.
INSPECTION PROCEDURE

This section contains the common inspection procedure that is identical for the inspection in T&C sectors. For more extensive details, please refer to the operational manual on inspection available on http://ec.europa.eu/health/blood_tissues_organs/docs/manual_11_en.pdf.

General system-oriented inspection process

- Should be conducted on-site and cover all processes and activities including organizational structure, policies, responsibilities, quality management, personnel, facilities, equipment, ART procedures, audits, etc.
- Could be necessary for any significant variation from the initial/accreditation/authorization/... or in cases of major deficiencies (e.g. serious adverse events [SAE] or reactions [SAR])
- Other types of inspection can be carried out depending on the activities of the ART establishment (ARTE): thematic inspections, desk-based reviews (not on site), re-inspections as a follow-up or to assess corrective actions, joint inspections (with another EU competent authority) in specific circumstances.

Prior to inspection

Initiating the inspection (CA level)

- Appoint the inspection team leader (inspections by a single inspector should be avoided)
- Define the objectives, scopes and criteria for the inspection
- Select the inspection team and, when appropriate, consultant experts in specific domains (ART or others domains)
- Notify the establishment to be inspected (except in unannounced inspection), request all relevant documents

Conducting the document review (CA level/ Inspection team level)

- Review the ARTE dossier, the reports from previous inspections (if any) and follow-up actions
- Determine adequacy with respect to the inspection criteria

Preparing the on-site inspection (CA level/ Inspection team level)

- Prepare the inspection plan according to the ARTE characteristics: dossier, previous inspections...
- Inform the ARTE to be inspected: objectives, what units and people will be required and when, what documentation should be available for review during the inspection or sent in advance...
- Prepare working documents
During inspection

**Conducting the on-site inspection**
- Conduct the opening meeting, review the organization chart and all documents required and verify information, inspect facilities and equipment
- Create a constructive and communicative atmosphere, accompany any findings with instructive and motivating comments
- Respect routine daily ART work, patient confidentiality and proceed in a systematic way
- Prepare the conclusions of the inspection and conduct the closing meeting

After inspection

**The inspection report**
- Approval and distribution of the inspection report with listed deficiencies
- Evaluation of the action plan proposed by the ARTE inspected
- Issue recommendations to the CA responsible for authorization, accreditation and licensing

Follow-up the inspection

WARNING: ART specificities!!!

- Provision of information regarding risks and outcomes to donors and beneficiaries
- Medical file and specific informed consents of donors and beneficiaries
- Different testing requirements apply for partner, compared to a non-partner procedure
- SOPs/ a formal communication pathway should be drafted for each important step
- Specific identification and traceability to reduce risks of mix-up in complex processes (*e.g.* ART between partners needs identification of the 2 partners during the whole process until embryo transfer or storage)
- Specific requirements (air quality, environment, devices and media should be devoid of any toxicity towards reproductive tissues, gametes and embryos)
- Registries/data base of stored embryos and donor gametes
- Follow-up of female donors and children born after ART including the surveillance of inherited genetic conditions through non-partner donation.

*Deliverable No. 7: Inspection guidance in ART – Vademecum and curriculum for inspectors*
At all the critical steps of an IVF cycle, inspectors should control procedures and means implemented to ensure (at least):

- Traceability of identity checking (both first names and full names or codes)
- Traceability of dates and operators
- Traceability of medical devices used (straws, dishes, culture media...)

Inspectors could compare the number and identification of straws in the container to data recorded in the couple’s medical file and in the Registry/Data base of stored embryos.

Inspectors could check that traceability of dates, operators, and medical devices used (straws, media...) is ensured.

Inspectors should have access to the written procedures/SOPs and the official report on the dedicated ART attempt.

Regarding cryopreservation, they should easily obtain the information on:
- Technique used, date, operator and medical devices used (consumables, media...).
- Number of cryopreserved embryos and number of straws

They should be able to compare all information with those recorded (e.g. Registry/Data base of stored embryos) as regards localisation of straws in the tank, number of straws/embryos...

The number of transferred embryos during the fresh embryo transfer, operator, dates, identity checking should be available.

IVF technique must be recorded (classical IVF or ICSI). The number of mature oocytes, zygotes, embryos and blastocysts obtained recorded, and the embryo assessment must also be traced.

Dates, operator, technique, equipment (incubators) and medical devices used (consumables, media...) must be traced as well.

Oocyte collection - All the following data must be available:
- Identity checking procedure
- Date, operator
- Anaesthesia mode
- Number of collected and mature oocytes
- Number of follicular fluids specimen

Sperm collection - All the following data must be available:
- Identity checking procedure
- Date
- Characteristics of the semen’s specimen
- Declaration when collection out of site

Inspectors should request to see validated written procedures/ SOPs on information to be shared between clinicians and embryologists.

Inspectors should control that the procedure is applied to the case being controlled.

Informed and signed consents should be available in the medical file of the couple.

Dates and results of testing for both members of the couple as required by the EUTCD / National regulation should be controlled.
RISK ASSESSMENT ON MIX-UP – What should be a “never event”

Mix-up is the term used to name misidentification, an error in the allocation of gametes or embryos or a contamination of the material used with the wrong gamete. Mix-ups can occur at any stage of the laboratory or clinical process of IVF.

Mix-up represents the most shared fear among ART actors. Mix-ups may have many serious consequences including a loss of chances through a loss of gametes/embryos and worse, they might sometimes result in a live birth.

Mix-ups do not represent exceptional events. Mix-up should be a “never event”.

A patient presenting knowingly false identification documents is considered a fraudulent activity.

Any misidentification or mix-up must be reported as a serious adverse event, regardless of whether they result in a live birth or not.

In a well-organised ART centre with appropriate procedures of identity checking, the risk should be extremely low.

During an inspection, inspectors can also opt for a risk assessment on mix-ups.

*What are the procedures and means in place to avoid mix-up in this centre? Did everyone validate and sign written procedures? Is there a training programme, evaluation of staff abilities and audit regarding the risk of mix-up? Are allocated resources relevant to the activity (personal, facilities, equipment)? How is identification verification traced?*

**Risk factors to be known**

ART involve many operators taking part in many successive steps which lead to a non-exceptional risk of mix-up.

Deteriorated work conditions can increase the risk of mix-up such as:

- Work overload of the staff combined with an inadequate organisation of the ART centre,
- Lack of/or a poor quality management system, lack of an audit system and/or poorly trained staff,
- Lack of written procedures, which are validated and signed by all the actors, check lists, double checking at critical steps, identification verification and traceability...

**Critical steps to be defined**

Misidentification and/or mismatching of gametes and embryos may occur at any stage of ART. However some steps are critical:

- Oocyte retrieval that involves clinicians, anaesthetist and embryologist, needs a strictly regulated interface between all the personnel involved,
- Sperm collection with the appropriate identification of the container used,
- *In vitro* fertilisation, matching the right patient’s oocytes to the correct sperm prior to fertilisation,
- At embryo transfer, matching the right embryos to the correct patient,
- Cryopreservation, needing to identify straws.

**Basic rules to apply**

- Procedures must be written, validated and well-known by all actors involved,
- Personnel must be trained, familiarised and periodically evaluated as regards identito-vigilance. Concentration should not be in danger due to phone calls ....
- Activity must be in balance with the available resources and laboratory equipment/premises,
- Identity checking must be traced (date, operator, and means).

**Identification means to be controlled**

- Copying identity paper in the medical file
- Asking patient to tell his/her first and full names
- Labelling (names, codes, bar code) on
  - Sticky labelling
  - Wristband
  - Writing on dishes/tubes with indelible pen
- Witnessing.
# FORM FOR AN ARTE INSPECTION FINDINGS

*The content should be based on the national reference sources*

<table>
<thead>
<tr>
<th>Inspection team</th>
<th>Name</th>
<th>Attached Unit/Department</th>
</tr>
</thead>
<tbody>
<tr>
<td>Competent Authority</td>
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<tr>
<td>Lead inspector</td>
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<td>Inspectors</td>
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<tr>
<td>Consulting ART Expert (if relevant)</td>
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<table>
<thead>
<tr>
<th>Inspected ARTE</th>
<th>Name</th>
<th>Phone and email</th>
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</thead>
<tbody>
<tr>
<td>ARTE</td>
<td></td>
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<tr>
<td>Responsible person</td>
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<tr>
<td>Attendees from direction</td>
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<td>Tissue establishment number (set out in the EU Tissue Establishment Compendium)</td>
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<tbody>
<tr>
<td>Dates</td>
<td>_ _ / _ _ / _ _ / _ _</td>
</tr>
<tr>
<td>Type of inspection</td>
<td>General on site  On specific topics  On documentation  Routine periodic inspection  Authorisation process  After adverse event  Low success rate  Complaints  Other </td>
</tr>
<tr>
<td>Inspected activities</td>
<td>IUI  IVF/ICSI  Donation  Fertility preservation  PGD/PGS </td>
</tr>
<tr>
<td>Reference sources</td>
<td></td>
</tr>
<tr>
<td>Last inspection (if relevant)</td>
<td>_ _ / _ _ / _ _ / _ _</td>
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<td>Authorisation/accreditation dates (if relevant)</td>
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</tbody>
</table>

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**Deliverable No. 7: Inspection guidance in ART – Vademecum and curriculum for inspectors**
<table>
<thead>
<tr>
<th>Topics</th>
<th>Should be available</th>
<th>Observation</th>
<th>Comments</th>
</tr>
</thead>
</table>
| Quality management system in general | • Quality policy  
• Quality manual  
• A person in charge of quality management… |             |          |
| Management review process     | • Quality indicators  
• Internal audits  
• Satisfaction questionnaires  
• Complaints procedure… |             |          |
| Documentation                 | • Documented policies  
• SOPs… |             |          |
| Records management            | • Management of records  
• Registries  
• Medical records  
• Consent  
• Data protection/confidentiality  
• Back-up/recovery system… |             |          |
| Traceability                  | • Identity check  
• Labelling  
• Coding … |             |          |
| Vigilance                     | • Non conformity reporting  
• Notification of adverse event and reaction… |             |          |
| Personal                      | • Adaptation to activities  
• Organisational chart  
• Responsible person  
• Plan for continuous professional development … |             |          |
<p>| Job description               | |             |          |</p>
<table>
<thead>
<tr>
<th><strong>Facilities/Premises and environment</strong></th>
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<tbody>
<tr>
<td>Diploma/experience/s/background</td>
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<tr>
<td>Continuous training</td>
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<td>Evaluation</td>
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<tr>
<td><strong>Hygiene/waste management</strong></td>
<td>SOPs…</td>
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<tr>
<td><strong>Air quality</strong></td>
<td>SOPs…</td>
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<tr>
<td><strong>Cryogenic room</strong></td>
<td>Specific with appropriate security features…</td>
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<tr>
<td>Temperature control</td>
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<tr>
<td>Environment toxicity</td>
<td>Environment control</td>
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<tr>
<td><strong>Equipment and medical devices</strong></td>
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<tr>
<td>CE marked as available</td>
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<tr>
<td>Critical equipment identification</td>
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<tr>
<td>New equipment</td>
<td>Validation before use…</td>
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<td>Control and record of temperatures</td>
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<tr>
<td>Extra available in case of failure of any critical material</td>
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<td>Agreement with third party</td>
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<tr>
<td><strong>More specific… based on risk analysis</strong></td>
<td>Identification means</td>
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<td>Double check…</td>
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<td>Interaction with clinicians</td>
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<tr>
<td>Embryo transfer (procedures, number of transferred embryos, …)</td>
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</table>
Did the ARTE decide any action plan with corrective measures for the near future?

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Do the corrective measures relate to the finding deficiencies?

Yes ☐
No ☐
## Form for an ARTE Inspection Report

### Inspection Team

<table>
<thead>
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### Inspection

#### Dates

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#### Type of inspection

- General on site ☐
- On specific topics ☐
- On documentation ☐

- Routine periodic inspection ☐
- Authorisation process ☐
- After adverse event ☐
- Low success rate ☐
- Complaints ☐
- Other ☐

#### Inspected activities

- IUI ☐
- IVF/ICSI ☐
- Donation ☐
- Fertility preservation ☐
- PGD/PGS ☐

#### Reference sources

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<th>_ _ / _ _/ _ _ _ _</th>
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### Findings

**Short description**

- Describe :
  - Conduction of inspection

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Deliverable No. 7: Inspection guidance in ART – Vademecum and curriculum for inspectors

<table>
<thead>
<tr>
<th>Topics</th>
<th>Deficiencies Technical or regulatory (Critical, Major or other)</th>
<th>Correction measures already planned in short term</th>
<th>Recommendations from the inspection team</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality management system</td>
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<td>Documentation</td>
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<td>Records management</td>
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<td>Vigilance</td>
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<td>Personal</td>
<td>Staff management</td>
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<td></td>
<td>Control and record of temperatures</td>
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</tbody>
</table>

Inspected activities

Provide a list of inspected activities and non-inspected activities.

Personal met/interviewed on this occasion

Overview of findings

Give an overview of findings
With reference to previous inspections (if relevant) and corrective measures taken since last inspection
## Distribution/transport

<table>
<thead>
<tr>
<th>Category</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extra available in case of</td>
<td>Extra available in case of failure of any</td>
</tr>
<tr>
<td>failure of any critical material</td>
<td>critical material</td>
</tr>
<tr>
<td>Medical device</td>
<td>Medical device</td>
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<tr>
<td>Temperature control</td>
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<tr>
<td>Agreement with third party</td>
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<tr>
<td>Traceability</td>
<td>Traceability</td>
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<tr>
<td>Vigilance</td>
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</tbody>
</table>

## More specific... based on risk analysis

<table>
<thead>
<tr>
<th>Category</th>
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<tr>
<td>Identity vigilance</td>
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<td>Selection and evaluation</td>
<td>Selection and evaluation donors/laboratory</td>
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<tr>
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<td>tests</td>
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</tr>
<tr>
<td>Embryo transfer</td>
<td>Embryo transfer</td>
</tr>
</tbody>
</table>

## In total

**Regulatory issues**

- Critical deficiencies [x]
- Major deficiencies [x]
- Other deficiencies [x]

**Technical issues**

- Critical deficiencies [x]
- Major deficiencies [x]
- Other deficiencies [x]

## Conclusion

The inspector(s) should state whether, in the course of the inspection, the ARTE was operating in accordance with the National regulatory references, provided, where relevant, appropriate corrective action and should mention any other item to draw to the attention of the requesting authority.

Attention should be paid to the wording used. It would be better to use conditional tenses when the TE needs to fulfil critical requirements before receiving final approval from the Inspectorate.

Reference may be made to conclusions recorded in other documents, such as the close-out letter, depending on National procedures.

## Recommendations for the ARTE

New inspection on site to plan in short term
Revocation or suspension of authorisation, …

## Recommendations to the CA/enforcement authority regarding the inspected ARTE

New inspection on site to plan in short term
Revocation or suspension of authorisation, …

## Name(s):

---

*Deliverable No. 7: Inspection guidance in ART – Vademecum and curriculum for inspectors*
CONCLUSION

The inspection team of an ARTE has to be composed of trained and evaluated inspectors according to their education and experiences in ART activities. Inspectors must have fully understood that ART practices have to be controlled as regards to the quality and safety for donors, patients, couples and children.

An accurate training of inspectors in ART is essential to provide for legitimacy, relevance and efficiency, even if they are not exclusively dedicated to ART inspection.

If ART consultants join the inspection team in order to provide inspectors with ART in-depth expertise, their role and tasks must be clearly defined in formal documents and respected during the whole process.

Competent Authorities have to manage resources in order to:

- Plan and implement periodic routine inspections in all ART centres complying with National regulation/EUTCD requirements,
- Promote harmonisation during inspections in ART practices through continuous training of inspectors and provide inspectorates with shared reference documentation and tools in ART,
- Provide their Ministry of Health with all relevant useful information and an overview of National ART practices (e.g. through an annual summarised report of inspections),
- Reassure the European Commission on the correct implementation of the EUTCD,
- Reassure Member States on the quality and safety of practices and their harmlessness for the cross-border donors and beneficiaries.