Human Reproduction Open, pp. 1–4, 2019
doi:10.1093/hropen/hoz005

human reproduction open

OPINION

Standard terminology for reproductive tissue and cell products for use in ART

P. Ashford [1,*], K. Rydman[2], A. Sparks[3], K. Tilleman[4], and M. Freire[1]

[1]ICCBBA, Redlands, CA, USA [2]IVFCryo, LLC, Los Angeles, CA 90043, USA [3]Department of Ob/GYN, University of Iowa Hospitals and Clinics, Iowa City, IA 52242, USA [4]Department for Reproductive Medicine, Ghent University Hospital, 9000 Ghent, Belgium

*Correspondence address: ICCBBA, P.O. Box 11309, San Bernardino, CA 92423-1309, USA. E-mail: paul.ashford@iccbba.org
orcid.org/0000-0002-9256-8239

Submitted on December 12, 2018; resubmitted on January 18, 2019; editorial decision on February 8, 2019; accepted on February 11, 2019

ABSTRACT: Medical products of human origin (MPHO) distributed for use in assisted reproduction are currently labelled and identified using national or local systems. Products may be distributed internationally with potentially confusing identification labelling due to inconsistent terminology and definitions. In other fields of MPHO activity terminology has previously been standardized through professional collaboration as a precursor to adoption of a global standard for identification, coding and labelling. The International Council for Commonality in Blood Bank Automation (ICCBBA), an international nongovernmental organization in official relations with the World Health Organization, brought together representatives from professional societies to develop a terminology using a well-established methodology. The terminology was reviewed by professional associations and released for public comment. Further refinements were made following the comment period. Representatives of the American Society for Reproductive Medicine (ASRM), ESHRE, the Reproductive Tissue Council of the American Association of Tissue Banks (AATB) and ICCBBA met by international conference call and interacted by email. The terminology was developed using a standard model previously used across many areas of MPHO. A terminology comprising six classes, and six attribute groups has been developed. The terminology design is such that additional classes, attribute groups and attribute values can be added to meet the developing needs of the ART community. The level of detail incorporated into the terminology is based on the consensus view of the experts. The objective has been to provide sufficient detail to satisfy clinical need in product identification but there is the possibility that the level of detail may need to be adjusted in the future. The terminology is designed in a way that can readily accommodate such adjustments. Adoption of a standard terminology provides the basis for standardization of identification, coding and labelling and the use of internationally standardized barcoding to improve the accuracy and efficiency of information transfer and to reduce the risks of harm due to manual transcriptions errors.

Key words: standardization / terminology / coding / classification / products / tissue banking / ART / ISBT 128

Introduction

Tissues and cells for use in ART are distributed widely and may cross international borders. Local or national systems of identification are unlikely to be adequate to support cross-border traceability and information transfer. In the European Union (EU), Directives have addressed this concern by introducing a Single European Code (Commission Directive (EU), 2015/565) to be used on tissues distributed in EU Member States.

There is, however, an increasing need to develop an international approach to traceability and the analysis of outcome data (De Geyer *et al.*, 2016). The need for a globally consistent terminology and a supporting coding system to ensure unique identification of medical products of human origin (MPHO) is widely recognized (World Health Assembly, 2010; Warwick *et al.*, 2013).

The International Committee Monitoring Assisted Reproductive Technologies (ICMART) International Glossary on Infertility and Fertility Care, 2017 (Zegers-Hochschild *et al.*, 2017) provides important standard terminology for use in the ART field, but does not address the specific topic of terminology of tissue and cell products distributed for ART.

The International Council for Commonality in Blood Bank Automation (ICCBBA), a nongovernmental organization in official relations with the World Health Organization, manages the ISBT 128 international information standard widely used for the coding and labelling of MPHO. The organization has prior experience of developing consensus terminology having previously worked with the cellular therapy and ocular tissue communities.

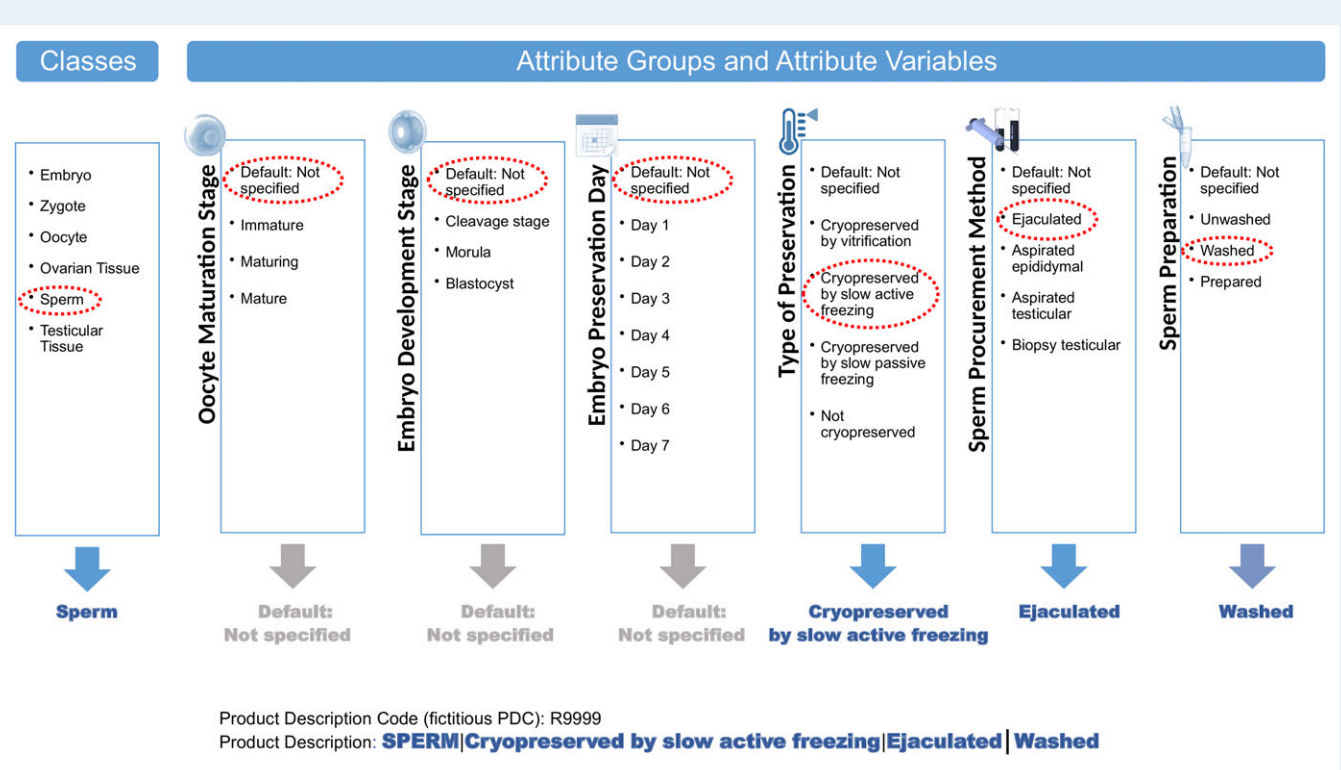

Figure 1 **Diagram showing how terminology elements are combined to create a product description.**

Table I **Classes of ART product with definitions.**

Class	Definition
EMBRYO	The biological organism resulting from the development of the zygote, until eight completed weeks after fertilization, equivalent to 10 weeks of gestational age.
ZYGOTE	A single cell resulting from fertilization of a mature oocyte by a spermatozoon and before completion of the first mitotic division.
OOCYTE	The female gamete.
OVARIAN TISSUE	Fragment of the ovary.
SPERM	The male gamete.
TESTICULAR TISSUE	Fragment of testicular tissue.

Table II **Attribute Groups with definitions.**

Group Name	Definition
Oocyte Maturation Stage	Describes the stage of maturation of the oocyte.
Embryo Development Stage	Describes the stage of development of the embryo.
Embryo Preservation Day	Indicates the number of days following insemination on which the embryo was preserved (calendar days).
Type of Preservation	Describes the technique used to preserve the tissue or cells.
Sperm Procurement Method	Describes the method used to procure sperm.
Sperm Preparation	Provides information about the preparation of sperm.

ICCBBA working with the American Society for Reproductive Medicine (ASRM), ESHRE and the Reproductive Tissue Council of the American Association of Tissue Banks (AATB) has developed an international terminology for the classification of ART products distributed by tissue establishments.

Materials and Methods

ICCBBA established a working group during 2016 to review ART product terminology. In early 2017, representatives from ASRM, ESHRE and the Reproductive Tissue Council of AATB were added to the group to form an ICCBBA ART Technical Advisory Group (ARTTAG). ARTTAG met by regular conference calls (seven calls over 24 months) and supporting email communications to develop an international terminology for use in the labelling of ART products.

Terminology was developed following the standard ICCBBA approach that uses Classes as a high-level description of the product combined with attribute groups and values to provide additional detail (Rice, 2018).

The draft terminology was released for public consultation in August 2017. Comments were received from several sources and these were

Table III Attribute variables permitted in each Attribute Group with definitions.

Attribute Group	Attribute Variables	Definition
Oocyte Maturation Stage	Default: Not specified	No information about the oocyte maturation stage is provided OR not applicable (i.e. product is not an oocyte).
	Immature	An oocyte at prophase of meiosis I (i.e. an oocyte at the germinal vesicle (GV) stage).
	Maturing	An oocyte that has progressed from prophase I but has not completed telophase I, thus does not exhibit the first polar body.
	Mature	An oocyte at metaphase of meiosis II, exhibiting the first polar body and with the ability to become fertilized.
Embryo Development Stage	Default: Not specified	No information about the embryo development stage is provided OR not applicable (i.e. product is not an embryo).
	Cleavage stage	Embryo beginning at the two cell stage and up to, but not including, the morula stage.
	Morula	Embryo after completion of compaction, typically 4 days after insemination or ICSI.
	Blastocyst	Embryo at the blastocyst stage, containing a fluid filled central cavity, an outer layer of cells and an inner group of cells. Typically occurs at day 5–6 after insemination.
Embryo Preservation Day	Default: Not specified	No information about the embryo preservation day is provided OR not applicable (i.e. product is not an embryo).
	Day 1	Embryo preserved on day 1 after insemination.
	Day 2	Embryo preserved on day 2 after insemination.
	Day 3	Embryo preserved on day 3 after insemination.
	Day 4	Embryo preserved on day 4 after insemination.
	Day 5	Embryo preserved on day 5 after insemination.
	Day 6	Embryo preserved on day 6 after insemination.
	Day 7	Embryo preserved on day 7 after insemination.
Type of Preservation	Default: Not specified	No coded information is provided about the type of preservation. Details about the type of preservation may appear as text on the tissue or cells container label or in accompanying documentation.
	Cryopreserved by vitrification	Product cryopreserved using a technique that leads to a glass-like solidification.
	Cryopreserved by slow active freezing	Product cryopreserved using a computerized controlled-rate freezer.
	Cryopreserved by slow passive freezing	Product cryopreserved without using a computerized controlled-rate freezer.
	Not Cryopreserved	Fresh or refrigerated product.
Sperm Procurement Method	Default: Not specified	Collection or recovery method is not specified, or not applicable (i.e. product is not sperm).
	Ejaculated	Sperm procured from ejaculate.
	Aspirated epididymal	Sperm procured by aspiration from epididymis.
	Aspirated testicular	Sperm procured by percutaneous aspiration from testis.
	Biopsy testicular	Sperm procured by biopsy of testis.
Sperm Preparation	Default: Not specified	No information about the preparation of sperm is provided, or not applicable (i.e. product is not sperm).
	Unwashed	Raw ejaculate.
	Washed	The ejaculate has been washed by centrifugation in a buffer solution.
	Prepared	Viable sperm cells have been isolated from other contents of the seminal fluid.

used to further refine the terminology. In particular, modifications were made to align the terminology with the 2017 ICMART International Glossary.

Results

The terminology comprises six classes and six attribute groups. Each product is described by a Class and is further classified by selecting appropriate attribute variables. Only one attribute variable can be selected from each attribute group, and the default value applies if the attribute variable is not explicitly stated. Figure I shows how the terminology elements are combined to create a product classification.

The Classes with their definitions are shown in Table I. The six attribute groups are shown in Table II. Each attribute group has a default value (applies if no other variable is selected), and a number of mutually exclusive variables. The attribute variables for each attribute group together with their definitions are shown in Table III.

Discussion

It has been possible to develop a consensus terminology for the description of ART products distributed by tissue establishments. This terminology covers the majority of product types currently distributed, and has the flexibility to expand to incorporate new product types as these are developed.

Standardization of the terminology used to describe and label ART products is an essential first step towards the development of internationally standardized coding. Such standardization is essential to support the increasingly complex distribution paths that products follow and to facilitate the use of computers and automated identification systems to improve safety and traceability.

The terminology developed provides a dictionary of terms with associated definitions that can be combined to provide globally consistent product descriptions. It is designed to allow distinction between products where such is required on safety or inventory management grounds. Use of the terminology will help to ensure a common understanding of product definitions.

The ongoing maintenance of the terminology will be managed by the ARTTAG administered by ICCBBA and with representation from leading scientific and professional societies in the field of ART. The tables will be extended as new products are developed. Proposed additions will be reviewed by the advisory group to ensure an appropriate level of definition and coding detail is maintained. The most up-to-date version of the terminology will be maintained on the ICCBBA website (www.iccbba.org) and will be publicly available

The terminology developed is compatible with the ISBT 128 coding system for MPHO (Cabana, 2018). ISBT 128 is widely used for the coding and labelling of MPHO and provides a globally unique identifier for the donation as well as providing a standardized machine readable format that facilitates the use of barcode readers for rapid and accurate capture and transmission of information.

Acknowledgements

The authors wish to acknowledge the contributions of A. Saniewska-Kilim and S. Timshel who participated in the early stages of the terminology development.

Authors' roles

P Ashford led the development process and provided expertise on structured terminology; K Rydman, A Sparks, and K Tilleman provided subject matter expertise to ensure the terminology meets the needs of the user community, M Freire co-ordinated the consultations and ensured that the developed terminology was compatible with the ICCBBA framework.

Funding

There was no funding agency for this work.

Conflict of interest

None declared.

References

Cabana E (ed). *ISBT 128 Standard: Technical Specification*. Redlands, CA: ICCBBA, 2018. www.iccbba.org. ISBN 978-1-933243-78-8. 2018. Accessed 16 August.

Commission Directive (EU) 2015/565 amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells. OJ 2015;L93:43–55

De Geyer CH, Wyns C, Mocanu E, de Mouzon J, Calhaz-Jorge C. Data Collection Systems in ART must follow the pace of change in clinical practice. *Hum Reprod* 2016;**31**:2160–2163.

Rice B (ed). *ISBT 128 Standard: Standard Terminology for Medical Products of Human Origin*. Redlands, CA: ICCBBA, 2018. www.iccbba.org.

Warwick R, Chapman J, Pruett T, Wang H. Globally Consistent Coding Systems for Medical Products of Human Origin. *Bull World Health Organ* 2013;**91**:314–314A.

World Health Assembly. Human Tissue and Organ Transplantation. WHA Resolution 63.22. 2010. Available at http://www.who.int/transplantation/. Accessed 14 August 2018

Zegers-Hochschild F, Adamson G, Dyer S, Racowsky C, de Mouzon J, Sokol R, Rienzi L, Sunde A, Schmidt L, Cooke I *et al.* The International Glossary on Infertility and Fertility Care, 2017. *Human Reprod* 2017;**32**:1786–1801.