1. Which of the following measures is the most important to decrease the risk of disease transmission in tissue transplantation?

- ☐ An appropriate medico-social history
- ☐ Performance of virus testing by NAT
- ☐ Performance of blood cultures
- ☐ Maintenance of a donor serum archive

2. What do you understand by risk?

- ☐ Potential damage caused by a current process or a future event
- ☐ The probability that an event of determined severity will occur in a specific place within a specific time frame
- ☐ A situation characterized by a serious interruption of the normal functioning conditions or processes
- ☐ Susceptibility and predisposition to suffer adverse events when impacted by a dangerous element

3. Which of the following combinations allows the evaluation of a defined risk with precision?

- ☐ Probability and detectability
- ☐ Probability and severity
- ☐ Severity and detectability
- ☐ Probability, severity and detectability

4. Which of the following is not a part of the risk management process?

- ☐ Risk identification
- ☐ Risk analysis
- ☐ Risk evaluation
- ☐ All are part of risk management

5. Which of the following measures is not suitable to reduce risks?

- ☐ Reduce severity
- ☐ Reduce probability

- ☐ Reduce detectability
- ☐ Reduce severity and probability

6. Within a system of risk management, the acceptance of the risk implies that there is a

- ☐ a. Residual Risk
- ☐ b. Theoretical risk
- ☐ c. Treatment
- ☐ d. Relative risk

7. Which of the following processes is being conducted in an inappropriate environment

- ☐ Dressing for entering a processing area in grade D or locker room in grade D
- ☐ Open sterile processing in Grade D
- ☐ Packaged product stored in a non-classified area
- ☐ Open sterile processing in Grade A

8. Which of the following actions can give rise to cross contamination?

- ☐ Use of gloves
- ☐ b. Inadequate maintenance of differential pressure
- ☐ Leaving the doors opened
- ☐ Daily cleaning

9. Which of the following statements regarding processing rooms is incorrect?

- ☐ The disinfectants used for cleaning should be periodically alternated
- ☐ The cleaning products need to be clearly specified in the cleaning procedure
- ☐ There is a need to keep cleaning records
- ☐ Processing rooms need to be cleaned only when dirty

10. Which one of the following controls is insufficient?

- ☐ Annual microbiological monitoring of grade A surfaces
- ☐ Annual air validation in grade D
- ☐ Daily control of non-viable particles in grade C

- ☐ Weekly microbiological sampling in changing rooms

11. A bio-vigilance system requires the notification, registration and communication of:

- ☐ Possible infectious disease that has been transmitted to the recipient through a tissue transplant.
- ☐ A failure in the tissue processing conditions within a Tissue Establishment
- ☐ A lack of documentation at the implantation centre regarding the final destination of the tissue
- ☐ All of the above

14. Quality control includes:

- ☐ Calibration of equipment with a critical measurement function
- ☐ Sampling and testing during the process
- ☐ Quality verification of the final product
- ☐ all of the above

16. According to DIRECTIVE 2004/23/EC the responsible person shall be responsible for:

- ☐ a. Ensuring that human tissues and cells are procured, tested, processed, stored and distributed in accordance with the current European Regulations and national laws
- ☐ b. Providing to the CA the required information related to accreditation, designation, authorisation or licensing of tissue establishments and tissue and cell preparation processes.
- ☐ c. Reporting any relevant information to establishments engaged in the donation, procurement, testing, processing, storage and distribution of human tissues and cells in order to facilitate traceability and ensure quality and safety control.
- ☐ d. Establishing a system to assure that any potential donor is detected in an adequate period of time to perform an effective donation

17. Which of the following conditions/qualifications is not compulsory for the TE responsible person?

- ☐ Possession of a diploma, certificate or other evidence of formal qualifications in the field of medical or biological sciences.
- ☐ At least two years practical experience in the relevant fields
- ☐ Knowledge in quality system, including training
- ☐ PhD in the field of field of medical or biological sciences

18. In which of the following BINOMIOS independency is needed?

- ☐ QC/Head of processing
- ☐ QA/Head of processing
- ☐ Qualified person/ QC
- ☐ Qualified person/ Head of processing

19. Who evaluates donor suitability?

- ☐ The director
- ☐ The MD responsible for retrieval
- ☐ The technician who performs the retrieval
- ☐ The biologist

20. TEs:

- ☐ Have to plan a warning system for serious events and adverse reactions but they're not forced to communicate them
- ☐ Decide to manage a serious event or adverse reaction on their own and they're not forced to communicate it
- ☐ Have to plan a warning system to communicate serious events and adverse reactions to the competent authority
- ☐

21. Tissue retrieval must be performed:

- ☐ Within 24h since cardiac arrest being the corpse cooled
- ☐ Within 12h since cardiac arrest being the corpse cooled
- ☐ Within 8h since cardiac arrest being the corpse not cooled
- ☐ Within 24h since cardiac arrest being the corpse not cooled

22. A donor is not suitable in case of:

- ☐ Positivity for HIV or HBV
- ☐ Risky social behaviour
- ☐ Risky social behaviour during the last 12 months
- ☐ All the answers are correct

23. Heart valves can be retrieved in:

- ☐ NHB donors
- ☐ HB donors
- ☐ Domino donors
- ☐ All the answers are correct

24. **How long should the donor record be kept?**

- ☐ 5 years
- ☐ 10 years
- ☐ 30 years

25. The tissue can be reported and distributed:

- ☐ By any pharmaceutical company
- ☐ After the competent authority permission
- ☐ In case of emergency without permission

26. Distribution's documentation must indicate:

- ☐ Possible antibiotic traces
- ☐ Storage temperature
- ☐ All substances used to preserve tissues
- ☐ All the answers are correct

27. All TEs must have:

- ☐ A certified quality system
- ☐ An accredited quality system
- ☐ A quality system

Vigilance

28 In the EU, who is responsible for reporting Serious Adverse Reactions or events?

- ☐ The tissue banks
- ☐ The transplant co-ordination centres
- ☐ Procurement organisations, tissue banks and transplant hospitals
- ☐ All the organisations involved from the selection of the donor to the follow up of the recipient

29. A serious adverse reactions is evaluated taking into account:

- ☐ The severity, the imputability and the potential impact
- ☐ The consequences for the recipient
- ☐ The severity, the imputability and the chance of recurrence
- ☐ All the above

30. Tissue Establishments

- ☐ Must have a system in place for the notification of serious adverse events and reactions and must communicate them to their hospital or other parent organisation
- ☐ Can decide how to manage any serious adverse event or reaction within the bank and are not obliged to communicate it to any other organisation.
- ☐ Must have a system in place for the notification of serious adverse events and reactions and are responsible for reporting them to the Competent Authority.
- ☐ Are not responsible for the notification of serious adverse events or reactions that occur in the facilities of third parties with whom they collaborate.

31. During transport of a heart valve from the bank to the user hospital in a distant city for immediate use, the package is stolen from the courier. Is this a serious adverse event that should be reported to the competent authority?

- ☐ Yes
- ☐ No if the surgeon can use an synthetic valve
- ☐ No, because there is no risk of adverse reaction in the recipient
- ☐ It should be reported to the police but not to the Competent Authority for tissues and cells.

Processing

32. Tissues must be processed in a grade A environment with at least a grade D background:

- ☐ To ensure adequate protection for the operator
- ☐ Because bacteria do not grow and proliferate in this environment
- ☐ To prevent environmental contamination and cross-contamination of the tissue
- ☐ To ensure maintenance of tissue viability

33. A processing environment should be classified using the following parameters:

- ☐ Particle counts and microbial counts
- ☐ Particle counts and, if the tissue is to be terminally sterilized, microbial counts
- ☐ Microbial counts only, if the environment is used for skin or cardiovascular tissue processing
- ☐ Temperature and humidity

34. If tissue is destined for terminal sterilization

- ☐ It can be processed in a grade A environment with an un classified background
- ☐ It can be processed in a grade D environment
- ☐ It can be processed in a grade C environment
- ☐ It should be processed in a grade A environment with a grade D background

Risk assessment

35. What is risk management as defined in the EU GTP?

- ☐ A financial investigation
- ☐ The overall quality management process by which risks are identified, evaluated, controlled, monitored and reviewed.
- ☐ A regulatory requirement for TE's
- ☐ Investigating and documenting that a process or system meets its pre-determined specifications and quality attributes

36. Which formula for Risk management is applicable according to the EU GTP?

- ☐ Risk = severity x probability (x detectability)
- ☐ Risk = severity x costs
- ☐ Risk = severity x demonstrability
- ☐ Risk = severity x solvability

37. Ideally, who should be involved in performing a risk assessment?

- ☐ The quality manager
- ☐ Process owner(s), possibly multidiscplinary
- ☐ One process owner
- ☐ Process owner(s) and quality manager

38. How often does a risk assessment should be done?

- ☐ One time, to establish the process the risk assessment is done to
- ☐ Every year
- ☐ Every three years
- ☐ Depends on the process changes and evaluation of the previous risk assessment

39. What can risk assessment provide for a TE? More answers possible

- ☐ A rationale for decisions on safety and quality of the primary processes
- ☐ Be compliant to the EU directive
- ☐ An evaluation of what still has to be validated
- ☐ Teambuilding

Agreements with OHRA

40. What items are necessary according to the EU GTP to have in agreements with OHRA or general conditions?

- ☐ Costprice of tissues
- ☐ Who to report SAE and/or SAR to = right answer
- ☐ Who is the Responsible Person
- ☐ Who arranges the transport of the tissues to the transplanting surgeon

41. Is it necessary according to the EU directive 2004/23 and both annexes to have agreements with third parties e.g. on storage conditions or transport?

- ☐ Yes, because responsibilities have to be established because of the costs

- ☐ Yes, because responsibilities have to be established in order to ensure the safety and quality of the tissues
- ☐ Depends, every TE can decide this for itself
- ☐ No, this is not at all necessary.

42. How long should donor data be recorded and kept on file?

- ☐ 15 years
- ☐ Forever
- ☐ 30 years after clinical use
- ☐ 30 years

43. Is it permitted for the clients to send the tissues on to other parties?

- ☐ No, this should be documented in the agreement or general conditions
- ☐ Yes, if the client pays for the tissue, it is his property and the client can do with it as he thinks right.
- ☐ Under certain circumstances if the client has permission from the contractor to do so.
- ☐ Yes, if there is a medical necessity.

Amniom

44. Past refractive surgeries of donor corneas are acceptable if donor corneas are planned for

- ☐ Penetrating keratoplasty (PKP)
- ☐ Deep anterior lamellar keratoplasty (DALK)
- ☐ Lamellar keratoplasty (LKP)
- ☐ Descemet's Stripping Automated Endothelial Keratoplasty (DSAEK)

45. After enucleation

- ☐ the bulbus should be immersed in organ culture solution

- ☐ the eye area and conjunctiva should be disinfected using a suitable disinfectant (e.g. PVD iodine)
- ☐ the donor appearance is to be restored
- ☐ the maximum recommended storage time of whole eye in moist chamber is 72 hours.

46. Corneas intended for organ culture should be preserved as soon as possible after death, however no later than

- ☐ 16 hours post mortem
- ☐ 24 hours post mortem
- ☐ 48 hours post mortem
- ☐ 72 hours post mortem.

47. Corneas intended for short-term hypothermic storage should be preserved as soon as possible after death, however no later than

- ☐ 16 hours post mortem
- ☐ 24 hours post mortem
- ☐ 48 hours post mortem
- ☐ 72 hours post mortem.

48. The excised corneoscleral discs that are to be transplanted as a viable living tissue may be stored

- ☐ in organ culture medium at temperatures from +10 to +40°C
- ☐ in hypothermic storage medium at temperatures below 0°C
- ☐ according to the instructions prescribed by the medium/solution manufacturer
- ☐ by freezing at sub-zero temperatures between -75ºC to - 196ºC for up to 2 years.

49. Microbiology testing

- ☐ is to be performed from the organ culture medium surrounding the donor cornea within 72 hours after cornea excision
- ☐ is not required during hypothermic storage of corneas
- ☐ is necessary from the organ culture medium only in the case of suspected contamination
- ☐ method should be chosen and validated by taking into account antimicrobial effects of antibiotics in the culture medium / preservation solution.

50. Microscopic evaluation for corneas intended for penetrating keratoplasty

- ☐ is performed with laser keratome
- ☐ is necessary only when macroscopic evaluation reveals induction of swelling of the intercellular space
- ☐ should include determination of endothelial cell density
- ☐ should be performed in uniform manner in accordance with the approved and validated standard operating procedures

51. The condition of the corneal endothelium is crucial for

- ☐ the maintenance of corneal hydration and transparency
- ☐ detection of congenital abnormalities of the anterior chamber, iris or lens
- ☐ evaluating the suitability of corneas intended for anterior lamellar procedures
- ☐ evaluating the suitability of corneas intended for penetrating keratoplasty

52. Slit lamp evaluation of cornea

- ☐ reveals epithelial defects
- ☐ should be performed only for enucleated eyes
- ☐ should include inspection of limbal area for signs of corneal pathology or post mortem artifacts
- ☐ can be used for endothelial cell count assessment

53. Donor corneas with an endothelial cell count of less than 2000 endothelial cells per mm2 in the final examination may be used for

- ☐ all corneal transplantations
- ☐ elective penetrating keratoplasty
- ☐ elective anterior lamellar keratoplasty
- ☐ all corneal transplantations when accepted by the transplanting surgeon

54. Amniotic membrane donors shall be screened at least for

- ☐ congenital or acquired disorders of the eye or previous ocular surgery
- ☐ significant local bacterial, viral, paracital or mycotic infection of the genital tract
- ☐ malignant tumours of the eye
- ☐ gestational diabetes of the donor

55. After retrieval until earliest processing of the tissue, the donor placentas are to be stored

- ☐ less than 1 hour at temperatures of 2-40°C
- ☐ at least 6 hours at temperatures of +2-10°C
- ☐ a maximum of 6 hours at temperatures of -75°C to -85°C
- ☐ a maximum of 6 months at temperatures of -75°C to -85°C

56. During preservation of placental tissue

- ☐ at least one sterility test of a placenta sample stored in preservative is to be performed
- ☐ the placenta shall be kept under laminar air flow
- ☐ the amniotic membrane shall be detached from nitrocellulose membrane
- ☐ the amniotic membrane may be decontaminated using antibiotics

57. Amniotic membrane shall be stored

- ☐ in sterile organ culture medium at room temperature for a maximum of 6 months
- ☐ in sterile glycerol in a freezer at -75°C to -85°C for a maximum of 12 months
- ☐ in liquid nitrogen, vapor phase
- ☐ as freeze dried in room temperature

IMPORT, EXPORT AND TRANSIT SECTION

58. To which requirements should TEs that import and export tissues comply?

- ☐ the relevant national laws, regulations and standards of the importing and exporting countries
- ☐ the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation
- ☐ the Declaration of Helsinki
- ☐ all the above

59. Does the valid import of tissue in one Member State imply that this tissue will automatically also be accepted in other Member States?

- ☐ yes, all EU Member States have transposed the EU Tissue and Cell Directives (EUTCD) to relevant national laws, regulations and standards

- ☐ no, in some Member States, (some parts of) the law, regulations and standards are more stringent than the EUTCD
- ☐ yes, the free movement of tissues within the EU lies at the heart of the EUTCD
- ☐ no, before entering the other EU Member State, special produce import taxes will be charged

60. In the EUTCD,the terms 'import' and 'export' apply for tissue exchanges between:

- ☐ a EU Member State and a non-EU country
- ☐ two non-EU countries
- ☐ EU Member States
- ☐ all the above

61. What are acceptable incentives for the import or export of tissues?

- ☐ accessibity, quality, and timeliness of tissue supply
- ☐ financial gain
- ☐ lower risk of infection
- ☐ higher quality of service

62. To which country's requirements must tissues in transit comply?

- ☐ the country from which the tissues originate
- ☐ the country in which they are temporarily stocked (in transit) and eventually processed
- ☐ the country to which they will eventually be transferred or exported
- ☐ all the above

62. Who is responsible for the approval of imported tissues and the approval for exportation of tissues?

- ☐ the competent authorities of the importing or exporting countries
- ☐ the Qualified Person of the importing or exporting TE
- ☐ the Responsible Person of the importing or exporting TE
- ☐ all the above

63. What should the import/export register include?

- ☐ details of the reason why the decision was made to import or export the tissues
- ☐ when the tissues were imported or exported and where from or to
- ☐ the uses to which they were put, when the tissues were transferred elsewhere
- ☐ all the above

64. Why would one favour the implementation of a global coding system over a European coding system?

- ☐ with the growing global circulation of transplantable material, a global coding system would allow for a better traceability
- ☐ a global coding system would facilitate the import and export of tissues
- ☐ the use of a global coding system could offer benefits in combating commercial trade
- ☐ the annual import/export balance

CONTINUITY PLAN

65. What will be the fate of tissues when the activities of TE are terminated and the TE did not manage to set up an appropriate continuity plan?

- ☐ the CA will determine the fate of the tissues
- ☐ the tissues will be destroyed
- ☐ the tissues will be sold by a court bailiff to recover the debt
- ☐ the donor family will determine the faith of the tissues

66. Which terms and conditions should be described in a tissue transfer agreement?

- ☐ the responsibilities and commitments of each party
- ☐ the type, the anticipated quantities and the transport conditions of the tissues, documentation and material that will eventually be transferred
- ☐ directions for handling commercialised tissues, including sharing of any royalties
- ☐ all the above

SPECIFIC SKIN REQUIREMENTS

67. What is the maximum age limit for skin donors?

- ☐ 65 years

- ☐ there is no maximum age limit
- ☐ 75 years
- ☐ 85 years for men, 95 years for women

68. Would you recommend allograft skin of a parent for resurfacing large burn areas in children? Why (not)?

- ☐ yes, it can overcome skin allograft shortage when the use of cadaver skin is avoided for cultural reasons
- ☐ yes, it can overcome skin allograft shortage when the use of cadaver skin is avoided for alleged safety reasons (e.g. HIV transmission)
- ☐ no, the skin of a parent is not necessarily compatible with his child
- ☐ no, this practice is not recommended since it does not necessarily increase the biosecurity and results in an unnecessary medical risk with regard to the donor as well as an unnecessary cost to society

69. Tick the skin specific donor exclusion criteria

- ☐ implantation of dura mater allograft
- ☐ auto-immune dermatoses
- ☐ malignant tumors of the anterior segment
- ☐ dermal mucinosis

70. Is human skin (or it's derived products) used in vanity and cosmetic procedures?

- ☐ no, it is illegal to use skin in vanity and cosmetic procedures
- ☐ no, the use of human skin products in vanity or cosmetic procedures offers no advantages over the use of animal (e.g. porcine) skin products
- ☐ yes, some skin-based products are used, off-label and without explicit donor consent, in vanity procedures such as lip and –penis widening
- ☐ yes, the use of human skin products in vanity and cosmetic procedures is common and widely accepted today

71. What is the maximum post mortem time for skin procurement?

- ☐ 48 h, provided that the donor was refrigerated within 12 h after death and the blood samples for donor screening were collected and processed within 24 h after death
- ☐ 48 h, provided that the donor was refrigerated within 12 h after death and the blood samples for donor screening were collected and processed within 24 h after death
- ☐ 24 h, provided that the donor was refrigerated within 6 h after death and the blood samples for donor screening were collected and processed within 12 h after death
- ☐ 48 h, provided that the donor was refrigerated within 6 h after death and the blood samples for donor screening were collected and processed within 24 h after death

72. What is an appropriate thickness for partial thickness skin allografts?

- ☐ 0.5 – 1.0 nm
- ☐ 200 – 1000 µm
- ☐ 0.2 – 1.0 mm
- ☐ 0.5 – 1.0 cm

73. Why are skin donor sites treated with anti-bacterials prior to recovery of skin allografts and why are the recovered skin allografts often incubated in an antibiotic cocktail prior to processing?

- ☐ the dermatome used for skin retrieval is not sterile
- ☐ superficial decontamination of the skin donor sites is not indefectible
- ☐ skin is often retrieved from non-heart-beating donors
- ☐ in contrast to most harvested tissues (e.g. musculoskeletal tissue and heart valves), skin is inherently colonised by microorganisms and thus non-sterile at harvesting

74. Where should one look for when choosing a skin decontamination or preservation process?

- ☐ the efficiency of the decontamination or preservation process
- ☐ maintaining clinically relevant properties (e.g. viabilty) of the skin
- ☐ maintaining the immunogenicity of the skin
- ☐ all the above

75. From which donor sites is it inappropriate to procure skin?

- ☐ the inner thighs
- ☐ the neck, face and other places which could be visible when people pay their last respects to the donor
- ☐ the lower back
- ☐ all the above

76. Where should one pay specific attention to when 'reconstructing' a skin donor?

- ☐ the donor sites should be decontaminated

- ☐ measures should be taken to prevent fluid loss from the donor sites
- ☐ the donor sites should be covered with artificial skin
- ☐ all the above

78. What are the objectives of the microbial evaluation of cryopreserved skin?

- ☐ ensure a total absence of pathogens
- ☐ provide proof of sterility
- ☐ ensure the absence of substantial bioburdens of inherent skin commensals
- ☐ prove the efficiency of the cryopreservation procedure

79. Which glycerol concentrations are normally used in the glycerolisation of skin?

- ☐ 5%
- ☐ 20-30%
- ☐ 45%
- ☐ 85-98%

80. Which statements regarding skin cryopreservation are true?

- ☐ cryopreservation ensures a certain skin integrity and viability
- ☐ cryopreservation significantly reduces immunogenicity
- ☐ cryopreservation supports a certain viral, bacterial and fungal survival
- ☐ cryopreservation eliminates skin viruses

81. Why would one remove the cells from donor skin?

- ☐ it ensures a better preservation
- ☐ it lowers the antigenicity of skin, which can be an advantage in certain clinical applications
- ☐ it allows the skin to be processed in a grade C environment, instead of grade A
- ☐ It allows the skin to be used in cosmetic procedures

.

81. The exclusion criteria for musculoskeletal tissue donors is not:

- ☐ osteoporosis
- ☐ osteopetrosis
- ☐ diabetes
- ☐ Paget's disease

82. Musculoskeletal tissue retrieval from deceased donors shall occur no later than:

- ☐ always 12 hours after death
- ☐ 24 hours after death if body was cooled 12 hours after death
- ☐ 48 hours after death if body was cooled 12 hours after death
- ☐ always 48 hours after death

83. Musculoskeletal tissue retrieval from deceased donors shall occur no later than:

- ☐ 15-65 years for both sexes
- ☐ 15-45 years for women
- ☐ 25-45 years for both sexes
- ☐ 25- 45 years for women

84. For reconstruction of the donor's body after procurement of musculoskeletal tissues could be used:

- ☐ wooden stick
- ☐ animal bone that match the size
- ☐ cotton
- ☐ paper towels

85. A storage time of cartilage for chondrocyte culture should not exceed:

- ☐ 1 day
- ☐ 2 days
- ☐ 3 days

- ☐ 4 days

86. Cancellous bone grafts cannot be prepared from:

- ☐ epiphysis of distal femur
- ☐ diaphysis of femur
- ☐ vertebral body
- ☐ iliac crest

87. The defeating procedure of bone tissue can be done by:

- ☐ shaking machine with water
- ☐ cHCl solution
- ☐ lyophilisation
- ☐ alcohol

88. Sterilisation of musculoskeletal grafts can be done by:

- ☐ irradiation
- ☐ autoclaving
- ☐ demineralization
- ☐ lyophilisation

89. Musculoskeletal grafts can be stored at room temperature after:

- ☐ demineralization
- ☐ DMSO conservation
- ☐ lyophilisation
- ☐ three layers vacuum packaging

90. Cultured chondrocytes should be transported at temperatures:

- ☐ 2-8°C
- ☐ 10-15°C
- ☐ 20-25°C
- ☐ -20°C