Summary of Significant Changes

Total re-write requires full training. Replaces process deviation (PVD503 - Deviation to Pregnancy in Donation). Donor Characterisation and Organ Retrieval must not proceed from a pregnant donor irrespective of the week of gestation. Requirement to perform a blood test for β-HCG (Human chorionic gonadotropin) in all female patients 12 – 55 years.

Policy

There exists a possibility in cases of deceased organ donation from female patients where pregnancy may be evident or detected. It is vital that the SN-OD is aware of this possibility and is able to work closely with the medical team in facilitating the correct course of action in relation to organ donation, whilst minimising any additional distress to the patient’s family.

Purpose

To guide and support the SN-OD in facilitating the actions to take to establish pregnancy status, when pregnancy is suspected and/or when pregnancy is confirmed.

Responsibilities

Specialist Nurse – Organ Donation (SN-OD)

Note: This MPD is to be utilised by a qualified and trained SN-OD. If the SN-OD is in training, this MPD is to be utilised under supervision.

Team Manager

To provide appropriate support and guidance to the SN-OD, as required.

Regional Manager

To provide appropriate support and guidance to the SN-OD and TM, as required.

ODT Hub Operations

To receive information communicated by the SN-OD.

Definitions

SN-OD – Specialist Nurse – Organ Donation for the purposes of this document the terminology "SN-OD" will apply to either Specialist Nurse or Specialist Practitioner with the relevant knowledge, skills and training in organ donation, working within NHSBT Organ Donation Services Teams (ODST).

RM – Regional Manager – line manager of the Team Manager

TM – Team Manager -line manager of the SN-ODs

NTLC – National Transplant Liaison Coordinators (formerly NHSBT Duty Officer)
Pregnancy in Donation

**HCP** - Health Care Professional – a nursing or medical professional who is responsible for the patient’s care.

**NODC** – National Organ Donation Committee

**Specialist Practitioner in Obstetric Medicine** – a specialist medical professional trained in obstetric medicine that can perform detailed examinations to determine the gestational age of the foetus and give specialist advice on treatment decision in relation to facilitating a live birth.

**Lead Retrieval Surgeon** – Refers to the Lead Surgeon for Abdominal and/or Cardiothoracic retrieval. Confirms pregnancy during the organ retrieval procedure.

**DonorPath** - Secure electronic system that SNODs utilise to register potential organ donors and upload donor characteristics prior to organ offering using an iPad or PC. DonorPath also creates and stores an electronic donor record of the donation process.

**EOS** – Electronic Offering Service

**DBD** – Donation following Brain Death – a patient in whom death has been certified/pronounced life extinct using neurological criteria and organ and/or tissue donation proceeds.

**DCD** – Donation following Circulatory Death – a patient in whom death has been certified/pronounced life extinct using cardiorespiratory criteria and organ and/or tissue donation proceeds.

**RCPoC** – Recipient Centre Point of Contact – receives information from the SN-OD/NORS team in relation to suspected and/or confirmed pregnancy

**Medical Practitioner** – medically trained healthcare professional responsible for the patient’s care.

**Patient family** – for the purposes of this document “patient family” refers to the family, friends and significant others of the patient.

**β-HCG** – Human chorionic gonadotropin

### Applicable Documents

- **MPD867** – Patient Information to be Communicated to Recipient Centre Points of Contact
- **POL162** – Donor Characterisation
  
- **MPD881** – Findings Requiring Additional Action
- **MPD882** – Findings Requiring Additional Action (Communication with Families)
- **MPD873** - Physical Assessment
- **MPD875** – Patient Assessment (Family Conversation)
- **FRM4211** – Medical and Social History Questionnaire (MaSH)
- **SOP3925** – Manual Organ Donation Process for a Potential Organ and/or Tissue Donor in the event of DonorPath/IT network unavailability
1. Introduction

1.1. The possibility exists that female patients who could be considered as potential organ and/or tissue donors may be pregnant. It is imperative therefore that during the patient assessment process, the possibility of the patient being pregnant is explored with the next of kin/husband/partner and a confirmatory blood test performed.

**Note:**
This is important because the process of organ retrieval from a pregnant donor confirmed deceased by neurological criteria – Donation after Brain Death (DBD), will cause the foetal heartbeat to cease and the foetus to subsequently die. The act of Withdrawal of Life Sustaining Treatment (WLST) will cause the foetal heartbeat to cease and the foetus to die, if Donation after Circulatory Death (DCD) was to proceed.

1.2. Human chorionic gonadotropin (β-HCG) is a hormone secreted by the early embryo and placenta. An elevated blood β-HCG level is usually indicative of pregnancy, with concentrations doubling every 2-3 days in the first weeks of pregnancy and levelling off thereafter.

1.3. Under normal circumstances, blood and urine pregnancy tests are reliable by 6 weeks gestation and, although the urine test may subsequently become negative after approximately 16 weeks, blood tests for β-HCG will remain positive.

1.4. Other causes of an elevated β-HCG include a recent miscarriage, hormone-secreting tumours such as choriocarcinoma and administration of clotting factor concentrates such as Octaplex and Beriplex that have been prepared from plasma donated by women whilst they were pregnant (usually unknowingly). In circumstances where the patient has received clotting factor concentrate, β-HCG levels are likely to be relatively low and will not rise with time; retrospective analysis of blood samples taken before its administration may also aid diagnosis.

1.5. Ultrasound scanning will resolve diagnostic uncertainty on most occasions, indicate gestational age and assist the specialist clinicians with establishing viability. It is important to engage the expert assistance of local obstetric services at an early stage.

1.6. Clinical decisions made by the medical practitioners and specialist practitioners in obstetric medicine will be determined in the light of individual circumstances and will involve the patient’s family member(s). The SN-OD’s function in this is to support the patient’s family, where required and it is appropriate to do so.

1.7. The National Patient Safety Agency (NPSA) state that best practice indicates that all female patients of childbearing age should be screened for pregnancy pre-operatively. Whilst there are no clear guidelines on the age ranges, the NPSA have documented organisations that routinely screen female patients between the ages of 12 and 55 years.

2. Clinical background to pregnancy and organ donation

2.1. Whilst we await new guidance from the respective Departments of Health donor characterisation and organ retrieval **must not proceed** from a pregnant donor irrespective of the week of gestation.
3. Determining pregnancy status

3.1. For the purposes of this policy female patients between 12 and 55 years of age should be considered as patients who could potentially be pregnant and therefore there is a requirement to establish pregnancy status in this group.

3.2. The recommendation from the National Organ Donation Committee (NODC) is that the pregnancy test result should be confirmed via a β-HCG blood test not urine pregnancy test and it is mandatory to exclude pregnancy.

3.3. In cases of organ donation a β-HCG blood test must be performed to confirm pregnancy status in both DBD and DCD potential donors, unless the woman is already known to be pregnant.

3.4. The SN-OD should, as part of the donor characterisation process, confirm with the relevant HCP whether a β-HCG blood test has already been performed on the patient during their admission to hospital. POL162 Donor Characterisation and associated documents should be utilised for detailed guidance, where required.

3.5. If a β-HCG blood test has been performed during the current hospital admission and results interpreted there is no requirement to repeat the test.

3.6. If a β-HCG blood test has not been performed during current admission the SNOD must inform the next of kin/husband/partner that for donation to proceed and as part of routine donor assessment a blood test will be required to exclude pregnancy.

3.7. The SN-OD must ask the patient’s family member(s) answering the questions on the FRM4211 Medical and Social Questionnaire (MaSH) whether there is a possibility that the patient could be pregnant. MPD875 Patient Assessment (Family Conversation) should be utilised for further guidance on how to complete DonorPath/FRM4211 Medical and Social Questionnaire (MaSH).

3.8. It is important that the SNOD communicate that this blood test is required to be performed, even if the next of kin/husband/partner answered that it’s not possible that the patient could be pregnant and, in the event, that a urine pregnancy test has already been performed during admission. It is recommended that this is similar to the conversations advising families of the requirement to perform virology screening.

3.9. The SN-OD must document the conversation with the family in relation to requirement for pregnancy testing in the patient’s medical records and DonorPath.

3.10. If next of kin/husband/partner object to β-HCG blood test donation cannot proceed.

3.11. The local hospital is the default laboratory for performing the β-HCG blood test. If there are difficulties accessing a β-HCG blood test, escalate to RM/On call RM.

3.12. Interpretation of result must be performed by a competent clinician and documented in the medical notes and uploaded to DonorPath.
4. **Physical assessment pregnancy suspected**

4.1. If prior to confirmatory β-HCG blood tests, during the physical assessment process the SN-OD identifies a possibility that the patient may be pregnant; this must be discussed with the medical practitioner. Please refer to [MPD873](#) Physical Assessment for detailed guidance on how to undertake the physical assessment process.

4.2. In this circumstance confirmatory β-HCG blood tests are required, as per the process above.

5. **Pregnancy test result positive**

5.1. On identification of a positive pregnancy test result or suspected pregnancy with a potential organ donor, organ donation must be halted and there is a requirement to escalate this information to the RM/on call RM.

5.2. **False positives** in β-HCG blood tests are possible. An unexpected positive result should be discussed with the treating medical practitioner in charge of the patient’s care and expert biochemistry opinion may be required.

5.3. There have been reported cases of false positive results in paediatrics and young female patient; in cases of an unexpected positive result in these circumstances seek expert advice regarding consideration of re-testing utilising heterophilic blocking tubes.

**Confirmed pregnancy status**

5.4. If the result is positive or pregnancy confirmed, regardless of foetal viability, the medical practitioner will seek expert advice from a specialist practitioner in obstetric medicine to guide any decisions regarding pregnancy. Organ donation must not proceed in cases of confirmed pregnancy.

5.5. The SN-OD must confirm with the medical practitioner how the information relating to pregnancy status is to be communicated to the patient’s next of kin/husband/partner. Detailed guidance on how to facilitate conversations with patients’ families can be found at [MPD882](#) —Findings Requiring Additional Action (Communication with Families).

5.6. The medical practitioner, in conjunction with the specialist practitioner in obstetric medicine (where appropriate), should lead the conversation when discussing the pregnancy test results with the patient’s family member(s).

5.7. The SN-OD should provide support to the patient’s family and answer any questions in relation to organ and/or tissue donation only.

6. **Confirmed pregnancy during organ retrieval**

6.1. In the exceptionally unlikely event that pregnancy is discovered during organ retrieval – organ retrieval **must** immediately stop and urgent advice sought from RM/on call RM.
Pregnancy in Donation

6.2. The SN-OD must then postpone the organ donation process by contacting the Hub Operations/RCPoCs and hold a discussion with the medical practitioner in charge of the patient’s clinical care on how to proceed. Please refer to MPD881 Findings Requiring Additional Action – Section 4 on the SN-OD’s responsibilities during the organ retrieval process.

6.3. The SN-OD must confirm with the medical practitioner the clinical decisions relating to patient care.

6.4. The medical practitioner, in conjunction with the specialist practitioner in obstetric medicine (where appropriate), must lead the conversation when discussing the pregnancy status with the patient’s family member(s).

6.5. The SN-OD should provide support to the patient’s family and answer any questions in relation to organ and/or tissue donation. Detailed guidance on how to facilitate conversations with patients’ families can be found at MPD882 – Findings Requiring Additional Action (Communication with Families).

7. Tissue Donation

7.1. If a positive pregnancy status is confirmed, organ donation must not proceed. However, in these cases it may be appropriate to continue with tissue donation.

8. Clinical Governance

8.1. If advised by the TM/RM/on call RM, the SN-OD must record the case on-line via NHSBT Clinical Governance reporting system at the earliest opportunity post process. So that the management team can analyse the sequence of events, and reasons for non-donation. The SN-OD should also inform their regional team manager, for information.

9. Recording of information

9.1. The SN-OD must record details of all conversations with the patient’s family, all HCPs involved in the donation process, HM Coroner/Procurator Fiscal, and any other relevant parties. These details must be located in the patient’s medical records and a copy of same added to attachments in Donor Path. All documented entries must be signed and dated. Guidance on good documentation can be found in MPD385 and examples of good documentation in INF135.
**Pregnancy in Donation**

1. **Is the female patient 12 - 55 years?**
   - **No**
     - No further action required - unless family provide additional information requiring investigation.
   - **Yes**
     - **Is the patient known to be pregnant?**
       - **Yes**
         - Stop donation process & escalate to Regional Manager
       - **No**
         - βHCG blood test required
           - Notify family/NOK of requirement to perform blood test as part of routine donor assessment
           - Arrange for default laboratory to perform βHCG blood test
           - Arrange for interpretation of blood test result and documentation in medical notes and DonorPath
           - **Result negative**
             - Continue donation
           - **Result positive**
             - Pause donation.
               - Consider possibility of false positive result.
               - Discuss with clinical team and consider expert biochemistry.
               - Notify RM oncall.
               - SNOD role is to support clinical team only - NOT share this information.
             - Stop donation process

This copy is uncontrolled unless printed on ‘Controlled’ paper