

Pregnancy in Donation

This Management Process Description replaces  
MPD891/2

Copy Number

Effective 03/01/17

**Summary of Significant Changes**

Section 2.4: New information added in relation to other potential causes of an elevated  $\beta$ -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.

**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 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.**

To work to this MPD, in collaboration with the donating hospital staff and NORS retrieval teams (where appropriate).

To seek advice, where required, from the TMs/RMs/on call RMs for additional support and guidance.

**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.

**Duty Office staff**

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)

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

**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

National Patient Safety Agency – Patient Safety Guidance – ‘Checking Pregnancy Before Surgery’

<http://www.nrls.npsa.nhs.uk/resources/?EntryId45=73838>

[MPD881](#) – Findings Requiring Additional Action

[MPD882](#) – Communication with Families about Findings Requiring Additional Action

[MPD873](#) - Physical Assessment

[MPD875](#) – Patient Assessment (Family Conversation)

[FRM4211](#) – Patient Assessment Form (PA1)

[SOP3925](#) – Manual Organ Donation Process for a Potential Organ and/or Tissue Donor in the event of DonorPath/IT network unavailability

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### 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 family. This is important because the process of organ retrieval from a pregnant donor confirmed dead by neurological criteria – Donation after Brain Death (DBD), will cause the foetal heartbeat to cease and the foetus to subsequently die.
- 1.2. The act of Withdrawal of Life Sustaining Treatment (WLST) will cause the foetal heartbeat to cease and the foetus to die, where Donation after Circulatory Death (DCD) proceeds.
- 1.3. “Concealed” or “late diagnosis” pregnancy is not uncommon. In some patient groups the confirmation of pregnancy and compliance with antenatal care may be poor. For example:
  - over 50 per cent of women under the age of 18 do not receive ante-natal care until after 12-14 weeks gestation
  - an estimated 2 per cent receive no ante-natal care at all
  - it has been suggested that in UK antenatal clinics, up to 1 in 200 women will have a “late” presentation
- 1.4. Current practice in United Kingdom (UK) critical care units varies, and there are no national guidelines on routine pregnancy testing for female patients admitted to ICU.

### 2. Clinical Background To Pregnancy And Organ Donation

- 2.1. 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  $\beta$ -HCG (Human chorionic gonadotropin) will remain positive. Where a urine pregnancy test is positive a  $\beta$ -HCG blood tests must be performed to confirm pregnancy. If the result is positive, expert advice from a specialist practitioner in obstetric medicine must be sought in collaboration with the medical practitioner.
- 2.2. Trans-vaginal ultrasound should be able to diagnose pregnancy by 6-8 weeks gestation, although this requires an expert practitioner. Trans-abdominal ultrasound is reliable after approximately 10 weeks.
- 2.3. 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. For the purposes of this policy **female patients between 13 and 53** years of age should be considered as patients who could potentially be pregnant.
- 2.4.  $\beta$ -HCG is a hormone secreted by the early embryo and placenta. An elevated blood  $\beta$ -HCG level is usually indicative of pregnancy, with concentrations doubling every 2-3 days in the first weeks of pregnancy and levelling off thereafter. Other causes of an elevated  $\beta$ -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. A pelvic ultrasound scan will resolve diagnostic uncertainty on most occasions and it is important to engage the expert assistance of local obstetric services at an early stage. In circumstances where the patient has received clotting factor concentrate,  $\beta$ -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.

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- 2.5. In relation to deceased patients, to undertake a pregnancy test without the consent/authorisation of the patient's family/husband/partner is not appropriate.
- 2.6. A foetus is deemed to be viable after 24 weeks gestation. Ultrasound examination is the appropriate technique to establish gestational age.
- 2.7. If the foetus is thought to be viable (at or close to 24 weeks), the intention should be to deliver a live baby. This decision should be made in conjunction with the specialist practitioner in obstetric medicine and the patient's family member(s).
- 2.8. If there is no prospect that continued active treatment of the donor could allow the foetus to attain 24 weeks, then organ donation may continue with the agreement of the patient's family member(s). The foetus would inevitably die.
- 2.9. When a gestational age is thought to be above 20 weeks but below 24 weeks clinical decisions will have to be made by the medical practitioners in conjunction with specialist practitioners in obstetric medicine. Prolonged treatment of the donor following the diagnosis of death by neurological criteria may allow for a limited, but uncertain, time for further foetal development.
- 2.10. 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, and to provide information in relation organ and/or tissue donation.

### 3. Determining Pregnancy Pre Consent/Authorisation

- 3.1. It is **not appropriate** for all female patients to be tested for pregnancy prior to approaching a family for consent/authorisation for organ and/or tissue donation. This would require additional consent from the family and could cause additional distress to a patient's family who are already in grief.
- 3.2. If a female potential donor is aged between 13 and 53 the SN-OD should, as part of the donor characterisation process, confirm with the relevant HCP whether a pregnancy 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.
- 3.3. If the patient is potentially brain stem dead (consider either DBD, or a patient who is brain stem dead and the family have requested DCD only) the SN-OD should also confirm whether the pregnancy test result was from a urine or blood sample and confirmed via a  $\beta$ -HCG blood test.
- 3.4. If the patient is not potentially brain stem dead (DCD), and the urine or blood test is negative, there is no requirement to request a  $\beta$ -HCG blood test.
- 3.5. The SN-OD must document their actions **on DonorPath**.

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#### 4. Determining Pregnancy Following Consent/Authorisation

- 4.1. As part of the Patient Assessment (Family Conversation) process, one of the questions on the DonorPath/[FRM4211](#) Patient Assessment (PA1) asks whether the patient could be pregnant. [MPD875](#) Patient Assessment (Family Conversation) should be utilised for further guidance on how to complete DonorPath/[FRM4211](#) Patient Assessment (PA1).
- 4.2. The SN-OD **must** ask the patient's family member(s) answering the questions on the [FRM4211](#) Patient Assessment (PA1) whether there is a possibility that the patient could be pregnant.
- 4.3. If the family member(s) answered that the patient could not be pregnant then no further action is required.
- 4.4. However, if 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.
- 4.5. If pregnancy is then also suspected by the medical practitioner, advice must be sought from a specialist practitioner in obstetric medicine. In addition, the family must be informed of the suspected pregnancy, and, where required, consent must be sought for a pregnancy test to be performed. This additional consent should be conducted by the medical practitioner and/or specialist practitioner in obstetric medicine.
- 4.6. If the family member(s) answered that the patient might be pregnant, or that they are unsure, then the SN-OD must seek consent/authorisation that a pregnancy test is performed in the following circumstances:
  - 4.6.1. **DBD** – If the patient is potentially brain stem dead (consider DBD or a brain stem dead patient in which the family have requested DCD only), the pregnancy test will be via a blood sample ( $\beta$ -HCG blood test), to ensure that a definite positive or negative results can be confirmed.
  - 4.6.2. **DCD** – If the patient does not fulfil the criteria for brain stem death (DCD) then the pregnancy test can be confirmed via a urine sample. If a urine pregnancy test is positive a  $\beta$ -HCG blood test must be performed to confirm pregnancy.
- 4.7. If the family do not give consent for a pregnancy test to be performed, but still give consent for organ and/or tissue donation to proceed, the organ and/or tissue donation process can still proceed.
- 4.8. The SN-OD must inform the medical practitioner of the results of the patient assessment conversation with the family. The SN-OD must also document the decision of the family in relation to consent for pregnancy testing in the patient's medical records, and ensure a copy of same is added to attachments in DonorPath. The SN-OD must record the date and time on DonorPath.

#### 5. Confirmed Pregnancy Prior To Organ Retrieval

- 5.1. If a donor is found to be pregnant prior to the organ retrieval, the SN-OD must postpone the organ donation process by contacting the Duty Office/RCPoCs and hold a discussion with the medical practitioner regarding the results.
- 5.2. The SN-OD must inform the TM/RM/on call RM for information, and request further advice and guidance, if required.

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- 5.3. A specialist practitioner in obstetric medicine must be contacted to provide specialist advice and perform an ultrasound examination to determine the gestational age. This request and referral is made by the medical practitioner.
- 5.4. The SN-OD must identify the clinical decision made by the medical practitioner and specialist medical practitioner in obstetric medicine on whether medical treatment of the patient will continue or not (to hold a discussion with family about the possibility of facilitating a live birth). This will be dependent upon the findings of the ultrasound examination.
- 5.5. The SN-OD must also confirm with the medical practitioner on how this information is to be communicated to the patient's family. 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). The SN-OD should provide support to the patient's family and answer any questions in relation to organ and/or tissue donation.
- 5.7. The SN-OD must document all their actions and communication with the patient's family and HCPs on DonorPath. The SN-OD must record the date and time on DonorPath.

### 6. Confirmed Pregnancy In Donation During The Organ Retrieval Process

- 6.1. If a donor is found to be pregnant during the organ retrieval, the Lead Retrieval Surgeon will inform the SN-OD. The SN-OD must then postpone the organ donation process by contacting the Duty Office/RCPoCs and hold a discussion with the medical practitioner 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.
- 6.2. The SN-OD must also ask the NORS retrieval team to "stand down" from the organ retrieval process until further clinical decisions can be made. The NORS team's lead retrieval surgeon may have concerns in proceeding with the organ retrieval process in view of a suspected pregnancy. The lead retrieval surgeon should seek advice from their lead consultant at the NORS centre. The final decision of the lead retrieval surgeon must be documented by the lead retrieval surgeon in the patient's medical records. The SN-OD must ensure that a copy of this medical entry is added to attachments in DonorPath.
- 6.3. If the advice given to the NORS team is not to proceed with the organ retrieval process, the SN-OD must inform the TM/RM/on call RM for information, so that this decision can be escalated to senior management for further advice and guidance, where required.
- 6.4. The SN-OD must confirm with the medical practitioner if the clinical decision is to return with the patient to the critical care area so that a specialist practitioner in obstetric medicine can undertake a specific examinations, or whether a specialist practitioner in obstetric medicine is to attend the theatre to undertake specific examinations to determine the gestational age and viability of the foetus.
- 6.5. Once the results of the specific examinations have been confirmed, the SN-OD must identify the clinical decision made by the medical practitioner and specialist practitioner in obstetric medicine. This decision will be whether medical treatment of the patient will continue to facilitate a live birth.
- 6.6. In addition, the SN-OD must also clarify how the patient's family member(s) are to be informed. In regard to Pregnancy in Donation, the specialist practitioner in obstetric medicine must be involved in the decision making process. Detailed guidance on how to facilitate conversations with patients' families can be found at [MPD882](#) – Findings Requiring Additional Action (Communication with Families)

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- 6.7. The medical practitioner, in conjunction with the specialist practitioner in obstetric medicine (where appropriate), must lead the conversation when discussing the pregnancy test results with the patient's family member(s). The SN-OD should provide support to the patient's family and answer any questions in relation to organ and/or tissue donation.
- 6.8. The SN-OD must document all their actions and communications with the patient's family, and HCPs for the patient's medical record and the SN-OD must ensure that a copy of this medical entry is added to attachments in DonorPath. The SN-OD must record the date and time on DonorPath.

### 7. Patients Where Pregnancy Is Known And At 24 Weeks Or Over In Gestation Where The Decision Not To Deliver Or Support The Foetus In Utero Has Been Made

- 7.1. If the donor has presented as a potential DBD donor, BSD tests can be completed to ascertain a diagnosis. However, the donor **must not** proceed to theatre as a DBD donor. It is considered that the clamping of the aorta would directly result in the death of the foetus and as such maybe an offence in accordance with the Infant Life (Preservation) Act 1929.
- 7.2. **These donors must only proceed as DCD donors.**
- 7.3. Before WLST, the SNOD should facilitate a conversation between the Lead NORS surgeons (Abdominal and Cardio Thoracic if appropriate) and the obstetrician to establish a plan for the retrieval process. Consideration should be given to how the uterus is moved to ensure no obstruction during the retrieval process (retractor or held by a member of the team); and should spontaneous miscarriage be a risk, a plan in place.
- 7.4. For these donors to proceed as a DCD, an additional stage is required during the declaration of death. Before the retrieval operation can commence, both maternal and foetal death **must** be established; declaration of maternal death should be completed by the clinicians in charge of the patients care and the foetal death by the obstetrician.
- 7.5. Heparin and steroids maybe considered in these patients if they have been declared brain stem dead.

### 8. Non Proceeding/Suspended Organ And/Or Tissue Donation

- 8.1. There are a variety of reasons why organ and/or tissue donation cannot proceed, or that the donation process is postponed, due to a positive pregnancy result. These include, but are not limited to:
  - Family withdrawal of consent/authorisation
  - Coroner/Procurator Fiscal object to donation/withdrawal of consent
  - Clinical decision to continue treatment to facilitate a live birth
  - Lack of resources (for example, no specialist practitioner in obstetric medicine available to perform examination)
- 8.2. If organ and/or tissue donation can no longer proceed, then the SN-OD should support the family, where requested and appropriate to do so.
- 8.3. The SN-OD must inform:
  - the TM/RM/on call RM that organ and/or tissue donation will no longer proceed.
  - the NTLC/RCPoC(s)/Tissue Establishment(s)/Eye Bank that organ and/or tissue donation will no longer proceed.

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- 8.4. If organ and/or tissue donation is postponed until a more appropriate time the SN-OD should support the family, where requested and appropriate to do so.
- 8.5. The SN-OD should also determine a future course of action with the medical practitioner, to facilitate organ and/or tissue donation at the appropriate time (for example, following the live birth from the patient).
- 8.6. The SN-OD must inform:
- the TM/RM/on call RM that organ and/or tissue donation has been postponed.
  - the **NTLC/RCPoC(s)/Tissue Establishment(s)/Eye Bank** that organ and/or tissue donation has been suspended.
- 8.7. Clear clinical decisions must be communicated to all stakeholders involved in the donation process.
- 8.8. **If advised** by the ODT team manager/regional manager/on call regional manager, 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.
- 8.9. The SN-OD must also document clearly the sequence of events on **DonorPath and EOS**, via the referral forms, giving clear details as to the reasons why donation could not proceed or was postponed.

### 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](#).