MPD891/5 – Establishing Pregnancy Status and Pregnancy in Donation

Policy

There exists a possibility in cases of deceased organ donation from patients with reproductive capacity 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.

Objective

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.

Changes in this version

Total re-write of document – requires full training. Replaces process deviation **PVD722** Deviation to Pregnancy in Donation.

Roles

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.

ODT Hub Operations –

- To receive information communicated by the SN-OD.

1. Introduction

1.1. The possibility exists that 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/nearest relative/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 or the act of withdrawal of life sustaining treatment will cause the foetal heartbeat to cease and the foetus to die.

1.2. Beta 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 delivery, ectopic/molar pregnancy, 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 individuals whilst they were pregnant (usually unknowingly). In circumstances where the patient has received human derived clotting factor concentrate, β-HCG levels will likely 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 individuals with reproductive capacity (potential capacity to conceive +/- reproduce) should be screened for pregnancy pre-operatively.

2. Clinical background to pregnancy and organ donation

2.1 Organ donation has proceeded in circumstances of pregnancy. It is acknowledged that each case is rare, complex and a case by case approach is required with senior support and involvement in decision making.

2.2 In cases of pregnancy in potential organ donors, organ donation must NOT be raised until discussion with the Regional Manager/Regional Manager On Call.

3. Determining pregnancy status

3.1. For the purposes of this policy **patients with reproductive capacity** between 12 and 55 years of age **(prior to their 56th birthday)** must 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 must be confirmed via a β-HCG blood test not urine pregnancy test and it is **mandatory** to exclude pregnancy.

3.3. In all cases of organ donation, a β-HCG blood test must be performed to confirm pregnancy status, unless the individual 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 this 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/nearest relative/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/nearest relative/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 on DonorPath.

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

3.11. The local hospital is the default laboratory for performing the ß-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.

3.13. The only exception for not performing a β-HCG blood test is the known and/or documented total abdominal hysterectomy with bilateral salpingo-oopherectomy.

4. Physical assessment pregnancy suspected

4.1. If prior to confirmatory β-HCG blood tests, during the physical assessment process the SN-OD identifies or suspects 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 these circumstances 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. This needs to be escalated to the RM/RM On Call immediately, as per 5.1. 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. There have been reported cases of false positive results in paediatrics and young patients. In cases of an unexpected positive result seek expert advice regarding consideration of re-testing utilising heterophilic blocking tubes to confirm result.

6. Confirmed pregnancy status

6.1. 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.

6.2. 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/nearest relative/partner. Detailed guidance on how to facilitate conversations with patients' families can be found at **MPD882** – Findings Requiring Additional Action (Communication with Families).

6.3. 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).

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

England, Scotland and Wales:

- NHSBT has received communication from the Department of Health England, Scottish and Welsh Government, that clarifies in cases of pregnancy in potential organ donors, organ donation can be explored. However, ALL cases must be immediately escalated to RM/RM On Call.

- A multidisciplinary plan will be required (including SNOD, CLOD, RM, NHSBT senior Medical Team, Obstetrics, Intensive Care Consultant).
- Foetal viability and gestation must be established with the clinical team (including obstetrics) before further exploration of the organ donation process.
- The option of organ donation should NOT be raised with the family until it has been established that organ donation is an option and eligibility has been established.

Northern Ireland:

- NHSBT is still awaiting formal responses from Department of Health Northern Ireland regarding proceeding with organ donation in cases of pregnancy.
- In the case of a positive pregnancy test, known or suspected pregnancy, immediately escalate to a RM/RM On Call.
- Whilst NHSBT await a formal response advice may be sought by the RM/Senior NHSBT Medical colleagues from the relevant Department of Health to explore the possibility of proceeding with organ donation on a case by case basis.

7. Proceeding with retrieval post consent/authorisation in pregnant donors

Expert guidance has been sought from the BMA Ethics Committee.
The guidance is limited to cases where the foetus is not viable (not capable of being born alive).
In brief the guidance concludes that:

- Independent of any organ donation considerations there is agreement between the treating team and those close to the patient that the pregnant individual would not want treatment/ventilation continued.
- The best interests of the pregnant individual are the sole consideration when deciding whether life-prolonging treatment should be continued or withdrawn.
- The family of the patient must be in full support of organ donation proceeding.
- Donation in pregnancy should only occur after the withdrawal of life sustaining treatment (Maastricht 3 DCD) or after circulatory arrest in a brain-dead pregnant patient (Maastricht 4 DCD).
- In both scenarios organ recovery must only proceed after death of the foetus.

Senior clinical support and a multi-disciplinary approach is essential to plan retrieval and make decisions regarding maternal and foetal diagnosis of death, on a case by case basis.

Note:
DCD retrieval only in cases of pregnancy.

8. Unexpected pregnancy discovered during organ retrieval

8.1. 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.

8.2. The SN-OD must then postpone the organ donation process by contacting 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.

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

8.4. 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).

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

9. Tissue Donation

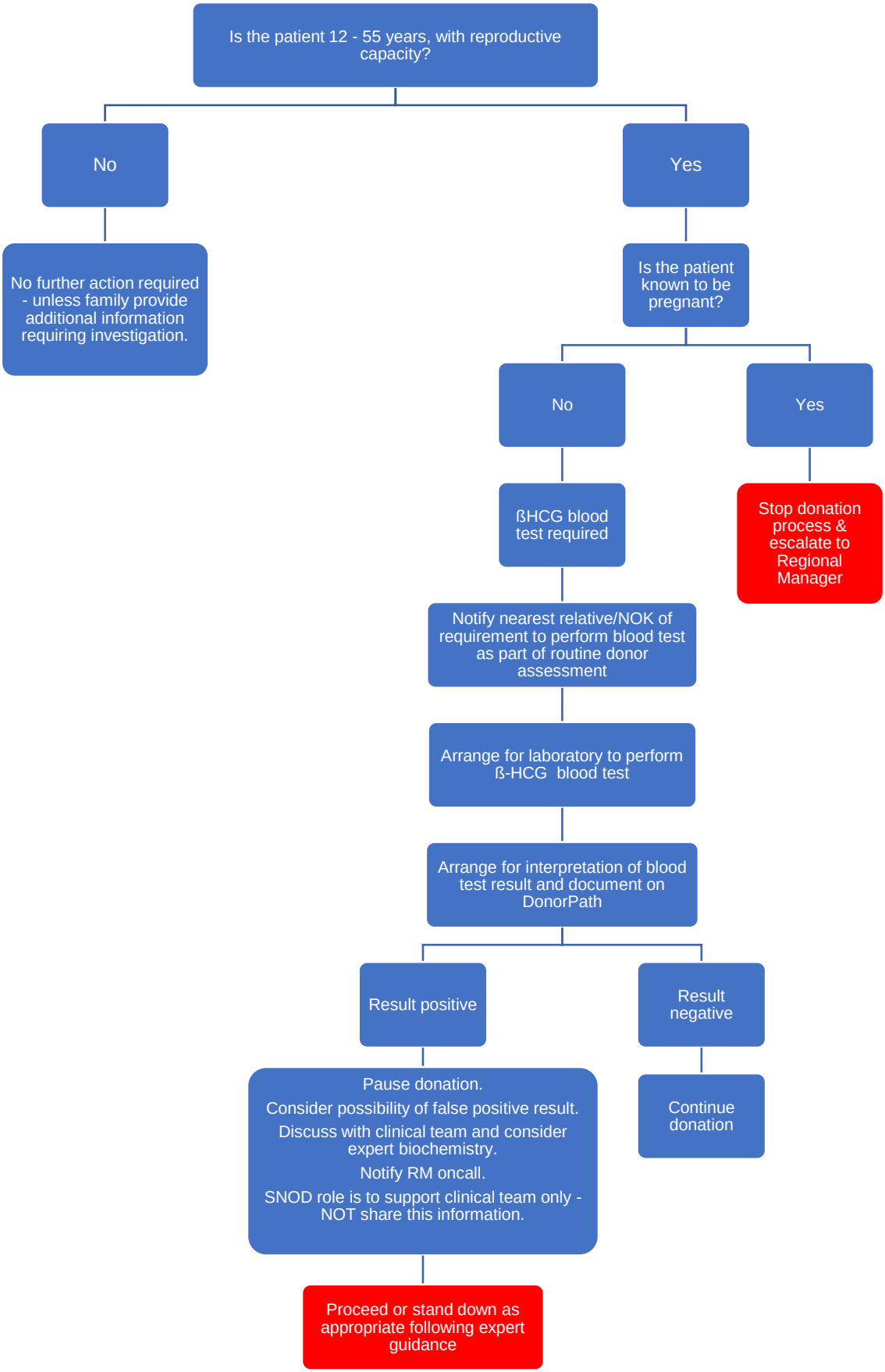
9.1. If a positive pregnancy status is confirmed, organ donation will be explored on a case by case basis. In these cases, it may be appropriate to continue with tissue donation. Seek guidance from National Referral Centre (Tissue Services) or SNBTS in Scotland.

10. Clinical Governance

10.1. If advised or deemed appropriate the SN-OD must record the case on-line via NHSBT Clinical Governance reporting system at the earliest opportunity post process to enable the analysis of case and identification of learning. The SN-OD should inform their regional team manager.

11. Recording of information

11.1. 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. All documented entries must be signed and dated. Guidance on good documentation can be found in **MPD385** and examples of good documentation in **INF135**.


Is the patient 12 - 55 years, with reproductive capacity?
No
Yes
No further action required - unless family provide additional information requiring investigation.
Is the patient known to be pregnant?
No
Yes
ßHCG blood test required
Stop donation process & escalate to Regional Manager
Notify nearest relative/NOK of requirement to perform blood test as part of routine donor assessment
Arrange for laboratory to perform ß-HCG blood test
Arrange for interpretation of blood test result and document on DonorPath
Result positive
Result negative
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.
Continue donation
Proceed or stand down as appropriate following expert guidance

Definitions

- **SN-OD** – Specialist Nurse – Organ Donation for the purposes of this document the terminology 'SN-OD' will apply to either Specialist Nurse/Requestor or Specialist Practitioner with the relevant knowledge, skills and training in organ donation, working within NHSBT Organ Donation Services Teams (ODST).
- **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 who can perform detailed examinations to determine the gestational age of the foetus and give specialist advice on treatment decision in relation to foetal viability.
- **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.
- **Reproductive Capacity** – a person who has the potential capacity to conceive +/- reproduce.
- **Child bearing age** – 12 to 55 years.
- **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).
- **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** – Beta Human chorionic gonadotropin.
- **Total abdominal hysterectomy** – removal of womb, cervix, fallopian tubes and ovaries.
- **BMA** – British Medical Association.

Related Documents / References

- **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'
- https://webarchive.nationalarchives.gov.uk/20171030140119/http://www.nrls.npsa.nhs.uk/resources/clinical-specialty/womens-health/?entryid45=73838&p=1
- **MPD385 –** Good documentation practice
- **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)
- **INF947** – Rationale Document for Medical and Social History Questionnaire

- **SOP3925** – Manual Organ Donation Process for a Potential Organ and/or Tissue Donor in the event of DonorPath/IT network unavailability
- **INF135** – Examples of GOOD Documentation Practice