

### Log of changes since last version

Section / Report sub heading	Page number	Detail of update
All	All	The whole framework has been reviewed and updated throughout to reflect the new single assessment framework for health.
S1 S2 S4 E2 C2 R1, R2 W4 W6	12 13 16 9 25 37 40 48 52	Link to MHRA <a href="http://www.hse.gov.uk/pUbns/priced/hsg107.pdf">http://www.hse.gov.uk/pUbns/priced/hsg107.pdf</a> November 2018/ Dec 2019: updated to reflect change in legislation about home TOP  Version 5
all		October 2019: Updated to take account of CQC generic changes.i.e. NICEQS15 updated throughout. Safeguarding prompts updated and also WRES prompts. In addition, RCoA references updated to 2019. DH list of licensed provider updated to May 2019. Ref to IHAS removed  December 2019 Fixing of multiple broken links



## Inspection framework: independent acute hospitals (and single specialty)

# Core service (or single specialty): Termination of pregnancy

This includes termination of pregnancy and incorporates ancillary activities that the provider carries out wholly or mainly in relation to termination of pregnancy. For example, sexual health screening, assessment and determining the legal grounds for abortion. Termination of pregnancy (TOP) refers to the treatment for termination of pregnancy, by surgical or medical methods, including feticide. Prescribing of abortifacient medicine is considered treatment for termination of pregnancy.

Where single specialty TOP services also provide male sterilisation, this will be considered within the inspection of the overall TOP service.

Regulation 20 of The Health and Social Care Act 2008 Care Quality Commission (Registration) Regulations 2009 applies to all non-NHS bodies that carry out TOP. Regulation 20 sets out specific legal requirements in relation to TOP that must be met. In addition to ensuring that providers meet requirements of the HSCA legislation, CQC must also be satisfied that providers meet and will continue to meet requirements of other relevant enactments; which in the case of TOP providers includes The Abortion Act 1967 (as amended) and The Abortion Regulations 1991. In addition, every independent place where treatment for TOP is carried out must be an \*Approved place and is required to follow the Department of Health's Required Standard Operating procedures (RSOPs') for Independent Sector Places.

\*Approved place is a place that has been approved by the Secretary of State for Health to provide treatment for TOP and as such holds a valid TOP licence issued by the Department of Health. (<u>List of DH licenced places as at May 2019</u>)
<a href="https://www.gov.uk/government/publications/clinics-authorised-to-carry-out-abortions">https://www.gov.uk/government/publications/clinics-authorised-to-carry-out-abortions</a>

### **Areas to inspect\***

The inspection team should carry out an initial visual inspection of each area. Your observations should be considered alongside data/surveillance to identify areas of risk or concern for further inspection.

- Clinic reception
- Screening rooms (where blood test and or ultrasound is carried out)
- Consultation rooms
- · Operating theatre and associated areas such as anaesthetic rooms and recovery
- Day care beds or where provided in-patient facilities

### Interviews/focus groups/observations

You should conduct interviews of the following people at every inspection:

- Clinical director/lead for TOP
- Nursing lead for TOP
- Registered Manager

#### You could gather information about the service from the following people, depending on the staffing structure:

- Midwife
- Senior nurse
- Counsellor
- Reception staff
- Healthcare support workers
- Women who are using the service (if appropriate)

- Safeguarding lead
- Ultrasonographers
- Anaesthetists, gynaecologists and other medical staff

# Safe

By safe, we mean people are protected from abuse\* and avoidable harm.

\*Abuse can be physical, sexual, mental or psychological, financial, neglect, institutional or discriminatory abuse.

# Key lines of enquiry: S1

S1. How do systems, processes and practices keep people safe and safeguarded from abuse?

### Report sub-heading: Mandatory training

Prompts	Professional standard	Sector specific guidance
<ul> <li>S1.1 How are safety and safeguarding systems, processes and practices developed, implemented and communicated to staff?</li> <li>S1.5 Do staff receive effective training in safety systems, processes and practices?</li> </ul>	<ul> <li>Skills for Health: Statutory/Mandatory         Core Skills Training Framework         <a href="https://www.skillsforhealth.org.uk/services/item/146-core-skills-training-framework">https://www.skillsforhealth.org.uk/services/item/146-core-skills-training-framework</a> </li> <li>RSOP 7 sets out providers should have regard to the statutory guidance 'Working Together to Safeguard Children'.</li> </ul>	<ul> <li>Does the service ensure that all staff are trained to appropriate level in safeguarding?</li> <li>If the service treats women under 18 years of age are staff supported to recognise potential cases of child sexual exploitation (CSE)</li> <li>Is there a policy for sepsis management and are staff aware of it?</li> <li>Have staff had training for screening and application of a sepsis protocol?</li> <li>Do they know of the providers sepsis policy?</li> </ul>

#### Report sub-heading: Safeguarding

- S1.1 How are safety and safeguarding systems, processes and practices developed, implemented and communicated to staff?
- S1.2 How do systems, processes and practices protect people from abuse, neglect, harassment and breaches of their dignity and respect? How are these monitored and improved?
- S1.3 How are people protected from discrimination, which might amount to abuse or cause psychological harm? This includes harassment and discrimination in relation to protected characteristics under the Equality Act.
- S1.4 How is safety promoted in recruitment practice staff support arrangements, disciplinary procedures, and ongoing checks? (For example Disclosure and Barring Service checks).
- S1.5 Do staff receive effective training in safety systems, processes and practices?
- S1.6 Are there arrangements to safeguard adults and children from abuse and neglect that reflect relevant legislation and local requirements? Do staff understand their responsibilities and adhere to safeguarding policies and procedures, including working in partnership with other agencies?

- Adult Safeguarding: Roles and Competencies for Health Care Staff: First edition: August 2018 <a href="https://www.rcn.org.uk/-/media/royal-college-of-nursing/documents/publications/2018/august/pdf-007069.pdf">https://www.rcn.org.uk/-/media/royal-college-of-nursing/documents/publications/2018/august/pdf-007069.pdf</a>
- Safeguarding Children and Young People: Roles and Competencies for Healthcare Staff (Intercollegiate document) Fourth edition: January 2019 https://www.rcn.org.uk/-/media/royalcollege-ofnursing/documents/publications/2019/j anuary/007-366.pdf
- Safeguard Children
   A guide to inter-agency working to safeguard and promote the welfare of children July 2018

   <a href="https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\_data/file/779401/Working\_Together\_to\_Safeguard-Children.pdf">https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\_data/file/779401/Working\_Together\_to\_Safeguard-Children.pdf</a>
- Female genital mutilation <u>multi-agency</u>
   <u>practice guidelines published in 2016</u>
   This multi-agency guidance on female
   genital mutilation (FGM) should be
   read and followed by all persons and

- How does the service ensure that the medical, psychological and social needs of children are met in an appropriate environment?
- What systems are in place to make sure the identity of women accessing the service remain confidential at all times? (Including for example systems to ensure staff do not announce full names at open reception areas).
- What systems does the service have in place for ensuring the safety and safeguarding of women, including specific guidance for young women less than 16 years of age?
- What arrangements are in place when (or if) a child under 13 years of age requests treatment, given the fact that a child under 13 years of age is not considered in law to be unable to consent to sexual activity?
- Do staff have an awareness of CSE and understand the law to detect and prevent maltreatment of children?

- S1.7 Do staff identify adults and children at risk of, or suffering, significant harm? How do they work in partnership with other agencies to ensure they are helped, supported and protected?
- bodies in England and Wales who are under statutory duties to safeguard and promote the welfare of children and vulnerable adults. It replaces female genital mutilation: guidelines to protect children and women (2014).
- DH Female Genital Mutilation and Safeguarding: Guidance for professionals March 2016
- Guidelines for physicians on the detection of child sexual exploitation (RCP, November 2015)
- NICE NG51 Sepsis: recognition, diagnosis and early management. <a href="https://www.nice.org.uk/guidance/ng51">https://www.nice.org.uk/guidance/ng51</a>
   /chapter/Recommendations
- Under Section 5 of the Sexual
   Offences Act 2003, a girl under 13
   years of age is not considered capable
   of giving her consent to sexual
   intercourse. Disclosure is not
   invariably required but it is usual in
   order that the interests of the child,
   which are paramount, may be
   protected. A doctor or clinician may be
   called upon to justify the action that he

- How do staff identify and respond to possible CSE offences? Are risk assessments used/in place?
- What safeguarding actions are taken to protect possible victims of CSE? Are timely referrals made? And is there individualised and effective multi-agency follow up?
- Are leaflets available about CSE with support contact details?
- If a child/young person is identified as being on a child protection plan, what systems are in place to ensure the correct information is shared and actions put in place
- Are young patients (i.e. children) who present for an abortion given the chance to disclose during a private moment when a parent or adult is not present?

or she has taken before the court or the statutory professional body. When such concerns arise in the context of abortion, whether during counselling or subsequently, the duty of the doctor or clinician is clear, and those who practise in this field should ensure that they are familiar with the procedures to be observed. Ref RGOC section 3.8 Refer to page 24 of the RCOG guidance for women under 16 years of age.

- RCOG section 4.19 page 32
- RSOP 6: Confidentiality
  Providers must have measures in place to safeguard patient confidentiality and all staff must be familiar with them. As a matter of law women seeking an abortion have the right to confidentiality from all clinical and ancillary staff. The Department of Health published "Confidentiality; NHS Code of Practice" in 2003. It is recommended that providers consider this document and any subsequent supplementary guidance, which sets out required practice for those who work within or under contract to NHS organisations in their policies.

# https://www.gov.uk/government/publications/confidentiality-nhs-code-of-practice

- RSOP 7: Service Provision for Children, Young People and Vulnerable Adults sets out explicit requirements regarding women aged 16 and 17 and also essential considerations that the medical, psychological and social needs of children under 13 years are met in an appropriate environment. Account should also be taken paragraph 67, 0 -18 Years: Guidance for all Doctors, General Medical Council, 2007 disclosing information without consent
- Mandatory reporting of FGM (girls under 18) DH pages updated 2017

### Report sub-heading: Cleanliness, infection control and hygiene

- S1.1 How are safety and safeguarding systems, processes and practices developed, implemented and communicated to staff?
- \$1.8 How are standards of cleanliness and hygiene maintained? Are there reliable systems in place to prevent and protect people from a healthcare-associated infection?
- NICE QS61 Statement 3: People receive healthcare from healthcare workers who decontaminate their hands immediately before and after every episode of direct contact or care.
- NICE QS61 Statement 4: People who need a urinary catheter have their risk of infection minimised by the completion of specified procedures necessary for the safe insertion and maintenance of the catheter and its
- Is the provider managing and decontaminating reusable medical devices in line with national guidance such as the DH Health Technical Memorandum on decontamination?

removal as soon as it is no longer needed.

- NICE QS61 Statement 5: People who need a vascular access device have their risk of infection minimised by the completion of specified procedures necessary for the safe insertion and maintenance of the device and its removal as soon as it is no longer needed.
- <u>Decontamination of surgical</u> <u>instruments (CFPP 01-01) (chapter 6)</u>
- DH Code of Practice on the prevention and control of infections

### Report sub-heading: Environment and equipment

- S1.1 How are safety and safeguarding systems, processes and practices developed, implemented and communicated to staff?
- S1.9 Do the design, maintenance and use of facilities and premises keep people safe?
- S1.10 Do the maintenance and use of equipment keep people safe?
- S1.11 Do the arrangements for managing waste and clinical specimens keep people safe? (This includes classification, segregation, storage, labelling, handling and,

- HSE Maintaining portable electrical equipment <a href="http://www.hse.gov.uk/pUbns/priced/hsg107.pdf">http://www.hse.gov.uk/pUbns/priced/hsg107.pdf</a>
- Managing Medical Devices Guidance for healthcare and social services organisations April 2015 <a href="https://assets.publishing.service.gov.uk/government/uploads/system/uploads/system/uploads/attachment\_data/file/421028/Managing\_medical\_devices\_- Apr\_2015.pdf">https://assets.publishing.service.gov.uk/government/uploads/system/uploads/s
- RSOP 22: Maintenance of Equipment

 Is equipment including surgical equipment, resuscitation and anaesthetic equipment available and fit for purpose and checked and tested in line with professional guidance?

where appropriate, treatment and disposal of	
waste.)	

Providers should minimise risks and emergencies through a programme of regular checking and servicing of equipment. This is particularly the case with anaesthetic and patient monitoring equipment.

(http://www.aagbi.org/sites/default/files/checking\_anaesthetic\_equipment\_20\_12.pdf

<a href="http://www.hse.gov.uk/pUbns/priced/hs">http://www.hse.gov.uk/pUbns/priced/hs</a>
 q107.pdf

### Key line of enquiry: **S2**

S2. How are risks to people assessed, and their safety monitored and managed so they are supported to stay safe?

#### Report sub-heading: Assessing and responding to patient risk

#### **Prompts**

- S2.5 Are comprehensive risk assessments carried out for people who use services and risk management plans developed in line with national guidance? Are risks managed positively?
- S2.6 How do staff identify and respond appropriately to changing risks to people who use services, including deteriorating health and wellbeing, medical emergencies or behaviour that challenges? Are staff able to seek support from senior staff in these situations?

#### **Professional standard**

- <u>Sepsis: recognition, diagnosis and early management</u> (NICE Guideline 51)
- Royal College of Physicians National Early Warning System <u>NEWS</u>
- RCOG guidance for women seeking abortion standard 6.0 sets out: All women undergoing an abortion should undergo a venous thromboembolism (VTE) risk assessment.
- NICE QS3 statement 1: All patients, on admission, receive an assessment

#### Sector specific guidance

- In cases where it is appropriate (for example if surgical abortion is carried out) has the service implemented a safe and effective escalation process e.g. Modified Early Warning System (MEWS), National Early Warning System (NEWS) and Paediatric Early Warning System (PEWS)?
- Are there agreed and documented protocols for the transfer of people using services to NHS care in the event of complications from surgery? Has the service established links with local NHS

- of VTE and bleeding risk using the clinical risk assessment criteria described in the national tool.
- RCoA Guidelines for the Provision of Anaesthesia Services for Preoperative Assessment and Preparation 2019 | The Royal College of Anaesthetists
- RCOG Best Practice Paper No. 2 published in June 2015

acute providers?

- How does the service ensure that risk based pre-operative assessment has been carried in out in line with guidance on pre-operative assessment (day cases/inpatient) from the Modernisation Agency? Including pre-operative assessment by the anaesthetist?
- How does the service ensure that assessment in respect of medical eligibility for abortion should is carried out to ensure that women who need specialist care (e.g. women with serious chronic medical conditions such as heart disease) are referred as soon as possible to an appropriate service?
- In case of surgical abortion being carried out, how does the service ensure compliance with the <u>5 steps to safer</u> <u>surgery</u>, World Health Organisation (WHO) surgical checklist?
- In cases where the service provides a male vasectomy service how does the service ensure compliance with the <u>5</u> steps to safer surgery?

For those patients that may be admitted and identified as having sepsis, is there evidence of continuation of monitoring and treatment? Is there evidence of the sepsis toolkit being used on the ward/clinic? If surgical TOP is undertaken what Clinical Guidelines for Early Medical Abortion at Home - England tested arrangements are in place in case https://bsacp.org.uk/approval-forof major or significant blood loss? In home-use-of-misoprostol-in-englandclinics without a dedicated blood fridge from-1-january-2019/ this includes an SLA where immediate availability of blood for transfusion may be required, effective tested communication systems, and access to emergency equipment, such as the appropriate sutures and packs. (The emergency arrangements will need to reflect the type of surgical termination undertaken and the degree of geographical isolation from other healthcare services). In services where early medical abortion is provided, and the service supply the second medication (misoprostol) to the woman to take away and administer at home; how does the service ensure that an appropriate assessment has been carried out that demonstrates that home abortion is appropriate of the individual concerned? Report sub-heading: Nurse staffing

- S2.1 How are staffing levels and skill mix planned and reviewed so that people receive safe care and treatment at all times and staff do not work excessive hours?
- S2.2 How do actual staffing levels and skill mix compare with the planned levels? Is cover provided for staff absence?
- S2.3 Do arrangements for using bank, agency and locum staff keep people safe at all times?
- S2.4 How do arrangements for handovers and shift changes ensure that people are safe?
- S2.7 How is the impact on safety assessed and monitored when carrying out changes to the service or the staff?

 RSOP 18: Staffing and Emergency Medical Cover:

Providers should ensure there is a sufficient number of staff with the right competencies, knowledge, qualifications, skills and experience to safeguard the health, safety and welfare of all who use the service and meet their routine and non-routine needs.

- NICE guidelines SG1 recommends a systematic approach to nurse staffing at ward level to ensure that patients receive the nursing care they need, regardless of the ward to which they are allocated, the time of the day, or the day of the week.
- RSOP 27: Abortions beyond 9 weeks gestation: Providers should ensure that staff performing abortions beyond nine
  - performing abortions beyond nine weeks gestation have the relevant skills and training.
- Chapter 7, page 61/62 of the Royal College of Obstetricians and Gynaecologists (RCOG) guidelines on the Care of Women Requesting an Induced Abortion (2011) sets out that when using manual vacuum aspiration (MVA) clinicians must be aware of their skill level when using this method at gestations higher than 9 weeks.

Is there an appropriate number of skilled staff for the services being provided and in particular the gestation and method of TOP being carried out?

Report sub-heading: Medical staffing

- S2.1 How are staffing levels and skill mix planned and reviewed so that people receive safe care and treatment at all times and staff do not work excessive hours?
- S2.2 How do actual staffing levels and skill mix compare with the planned levels? Is cover provided for staff absence?
- S2.3 Do arrangements for using bank, agency and locum staff keep people safe at all times?
- S2.4 How do arrangements for handovers and shift changes ensure that people are safe?
- S2.7 How is the impact on safety assessed and monitored when carrying out changes to the service or the staff?

- RSOP 18: Staffing and Emergency Medical Cover: Providers should ensure there is a sufficient number of staff with the right competencies, knowledge, qualifications, skills and experience to safeguard the health, safety and welfare of all who use the service and meet their routine and non-routine needs.
- Royal College of Anaesthetists'
   Guidelines for the Provision of
   Anaesthetic Services (GPAS) 2019
   <a href="https://www.rcoa.ac.uk/gpas2019">https://www.rcoa.ac.uk/gpas2019</a>
   These documents make a number of recommendations. Refer to full RCOA guidance for full details.
- Refer also to <u>Academy of Medical</u> <u>Royal Colleges Safe Sedation</u> <u>Practice for Healthcare Procedures:</u> <u>2013</u>
- RCOG Guidelines 'Care of Women Requesting Induced Abortion (2011)
   9.6 includes the following recommendation: Services should regularly audit the number of staff competent to provide all methods of contraception, including contraceptive implants and intrauterine methods, and the availability of such staff during the working week.

- Is appropriate anaesthetic cover provided during and following the procedure?
- What arrangements are in place to ensure that if conscious sedation is used during surgical abortion, it is only undertaken only by trained practitioners and in line with DH guidance?

### Key line of enquiry: S3

**Prompts** 

S3. Do staff have all the information they need to deliver safe care and treatment to people?

Report sub-heading: Records

### S3.1 Are people's individual care records, including clinical data, written and managed in a way that keeps people safe?

- S3.2 Is all the information needed to deliver safe care and treatment available to relevant staff in a timely and accessible way? (This may include test and imaging results, care and risk assessments, care plans and case notes.)
- S3.3 When people move between teams, services and organisations (which may include at referral, discharge, transfer and transition), is all the information needed for their ongoing care shared appropriately, in a timely way and in line with relevant protocols?
- S3.4 How well do the systems that manage information about people who use services support staff, carers and partner agencies to deliver safe care and treatment? (This includes coordination between different electronic and paper-based systems and appropriate access for staff to records.)

### **Professional standard**

- NICE QS15 statement 3; People using adult NHS services experience coordinated care with clear and accurate information exchange between relevant health and social care professionals
- RSOP 23: Notification of Death of a Patient

Arrangements must be in place to immediately notify the CQC and the Department of Health in the event of the death of a patient.

A record must be kept of the date, time, cause and place of death. If the notification has been provided verbally over the telephone, information should be confirmed in writing to the Department of Health within 24 hours.

 Records management code of practice for health and social care.
 (This code sets out standards required for the management of records for organisations who work within, or under contract to the NHS in England)

### Sector specific guidance

- If the service carries out surgical abortion, how does the service ensure that appropriate pre-op assessment is recorded?
- How does the service ensure that wherever possible, the woman's GP is informed about any treatment for abortion?

- RCOG guidance 'the care of women requesting induced abortion' sets out in recommendation 8.2
   On discharge, all women should be given a letter providing sufficient information about the procedure to allow another practitioner elsewhere to manage any complications.
- RSOP3 sets out:

It is recommended that, wherever possible, the woman's GP should be informed about any treatment for abortion. Then, in the event of a woman requiring post-abortion emergency care or related care in the longer term, the GP would be aware of all treatments provided and be in a better position to determine the appropriate therapy. All women should be told of their right to confidentiality and their decision must be respected if they do not want their GP to be informed.

### Key line of enquiry: **S4**

S4. How does the provider ensure the proper and safe use of medicines, where the service is responsible?

Prompts	Professional standard	Sector specific guidance
Report sub-heading: <b>Medicines</b>		
S4.1 How are medicines and medicines- related stationery managed (that is, ordered, transported, stored and disposed of safely	NICE QS61 Statement 1: People are prescribed antibiotics in accordance with local antibiotic formularies.	<ul> <li>Are allergies clearly documented in the prescribing document used?</li> </ul>

- and securely)? (This includes medical gases and emergency medicines and equipment.)
- S4.2 Are medicines appropriately prescribed, administered and/or supplied to people in line with the relevant legislation, current national guidance or best available evidence?
- S4.3 Do people receive specific advice about their medicines in line with current national guidance or evidence?
- S4.4 How does the service make sure that people receive their medicines as intended, and is this recorded appropriately?
- S4.5 Are people's medicines reconciled in line with current national guidance on transfer between locations or changes in levels of care?
- S4.6 Are people receiving appropriate therapeutic drug and physical health monitoring with appropriate follow-up in accordance with current national guidance or evidence?
- S4.7 Are people's medicines regularly reviewed including the use of 'when required' medicines?
- S4.8 How does the service make sure that people's behaviour is not controlled by excessive or inappropriate use of medicines?

- Are nursing staff aware of policies on administration of controlled drugs
- Are there local microbiology protocols for the administration of antibiotics and are prescribers using them?
- What SLAs exist (if required) for the provision of pharmacy support?
- In services where early medical abortion is provided and the service supply the second medication (misoprostol) to the woman to take away and administer at home; how does the service ensure that the medication supplied is appropriately prescribed and dispensed in accordance with medicines requirements?

### Key line of enquiry: **S5 & S6**

- S5. What is the track record on safety?
- S6. Are lessons learned and improvement made when things go wrong?

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**Prompts** 

- S5.1 What is the safety performance over time?
- S5.2 How does safety performance compare with other similar services?
- S5.3 How well safety is monitored using information from a range of sources (including performance against safety goals where appropriate)?
- S6.1 Do staff understand their responsibilities to raise concerns, to record safety incidents, concerns and near misses, and to report them internally and externally, where appropriate?
- S6.2 What are the arrangements for reviewing and investigating safety and safeguarding incidents and events when things go wrong? Are all relevant staff, services, partner organisations and people who use services involved in reviews and investigations

- Professional standard
- A never event is a serious incident that is wholly preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all providers. The event has the potential to cause serious patient harm or death, has occurred in the past and is easily recognisable and clearly defined.
  - Revised never events policy and framework (2015)
  - o Never events list 2015/16
  - Never Events List 2015/15 -FAQ
- Serious Incidents (SIs) should be investigated using the <u>Serious</u> <u>Incident Framework 2015.</u>
- RSOP 21: Risk Management
   All providers should have in place a formal risk management system and keep a risk register to identify and

 Evidence of adherence to duty of candour regulation, including process and evidence for written apologies

Sector specific guidance

- S6.3 How are lessons learned, and themes identified and is action taken as a result of investigations when things go wrong?
- S6.4 How well is the learning from lessons shared to make sure that action is taken to improve safety? Do staff participate in and learn from reviews and investigations by other services and organisations?
- S6.5 How effective are the arrangements to respond to relevant external safety alerts, recalls, inquiries, investigations or reviews?

- minimise any risks to women and staff within their premises. Protocols should exist on action to be taken should incidents occur.
- (NICE QS66 Statement 4): For adults who receive intravenous (IV) fluid therapy in hospital, clear incidents of fluid mismanagement are reported as critical incidents.
- Duty of Candour: As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred a health service body must notify the relevant person that the incident has occurred, provide reasonable support to the relevant person in relation to the incident and offer an apology.

#### Report sub-heading: Safety Thermometer

- S5.1 What is the safety performance over time?
- S5.2 How does safety performance compare with other similar services?
- S5.3 How well safety is monitored using information from a range of sources (including performance against safety goals where appropriate)?
- NICE QS3 Statement 1: All patients, on admission, receive an assessment of VTE and bleeding risk using the clinical risk assessment criteria described in the national tool.
- NICE QS3 Statement 4: Patients are re-assessed within 24 hours of admission for risk of VTE and bleeding.
- Safety Thermometer

### **Effective**

By effective, we mean that people's care, treatment and support achieves good outcomes, promotes a good quality of life and is based on the best available evidence.

### Key line of enquiry: **E1**

E1. Are people's care, treatment and support achieves good outcomes, promotes a good quality of life and is based on the best available evidence.

Prompts Professional standard Sector specific guidance

#### Report sub-heading: Evidence-based care and treatment

- E1.1 Are people's physical, mental health and social needs holistically assessed, and is their care, treatment and support delivered in line with legislation, standards and evidence-based guidance, including NICE and other expert professional bodies, to achieve effective outcomes?
- E1.2 What processes are in place to ensure there is no discrimination, including on the grounds of protected characteristics under the Equality Act, when making care and treatment decisions?
- E1.3 How is technology and equipment used to enhance the delivery of effective care and treatment and to support people's independence?

- RCOG guidance <u>'the care of women requesting induced abortion'</u> sets out the following recommendations:
  - 6.19 services should make available information about the prevention of STIs and offer condoms for STI prevention to women undergoing abortion.
  - 6.20 all methods of contraception should be discussed with women at the initial assessment and a plan agreed for contraception after the abortion'.
  - 8.6 effort should be made to ensure that women leave the abortion facility with effective

- How does the service ensure that
  - > AAGBI guidelines

the principles in the following?

- > RCOG guidelines
- How does the service ensure that appropriate evidence-based advice and treatment is provided in respect of sexually transmitted infection and family planning/contraception advice to women using the service?

surgery is managed in accordance with

 How does the service ensure that when termination takes place, it is performed as early as possible after having

- E1.4 Are the rights of people subject to the Mental Health Act 1983 (MHA) protected and do staff have regard to the MHA Code of Practice?
- E1.7 Are people told when they need to seek further help and advised what to do if their condition deteriorates?
- contraception and with information about where to go for further advice or treatment of symptoms, emotional problems or for contraception if it was declined at the time of the procedure
- 6.21 Feticide should be performed before medical abortion after 21 weeks and 6 days of gestation to ensure that there is no risk of a live birth.
- Refer to all of section 7 setting out about specific guidance for surgical vacuum aspiration and also surgical dilation and evacuation.
- 7.14 Services should be able to provide surgical abortions without resort to general anaesthesia.
- RSOP 9 Gestational limits: All registered providers should indicate which gestations and methods they intend to offer as part of the application process to both the CQC, to carry out a regulated activity, and to DH, to be an approved place.
- Chapter 7, page 61 of the Royal College of Obstetricians and Gynaecologists (RCOG) guidelines on the Care of Women Requesting an

- received the woman's informed consent to the procedure being performed?
- How does the service ensure that methods of termination of pregnancy, including feticide and methods of surgical termination are carried out in accordance with the RCOG guidelines?
- What arrangements are in place so that surgical abortions may be carried out without resorting to general anaesthetic? (If the woman prefers this method)
- Does the service ensure that clear advice is provided to patients about what to do if problems are experienced following discharge? (for example, excessive bleeding)
- Has the service adapted guidance on quality standards for sepsis screening and management?
- Once transferred from the acute area of the hospital to a ward, are patients reviewed on their sepsis management?

- Induced Abortion (2011) summarises the methods considered to be appropriate for women presenting at different gestations.
- RSOP10: Professional Guidelines:

  Providers should have regard to relevant clinical and professional guidance.
- RSOP 13: Contraception and Sexually Transmitted Infections (STI) Screening: Providers should be able to supply all reversible methods of contraception, including Long Acting Reversible methods (LARC) which are the most effective and offer testing for STIs as appropriate.
- RCOG Guidelines 'Care of Women Requesting Induced Abortion (2011) https://www.rcog.org.uk/globalassets/doc uments/guidelines/abortionguideline\_web\_1.pdf
- Long Acting Reversible Contraception, NICE
- NICE guidelines PH51 Contraceptive services for under 25's https://www.nice.org.uk/guidance/ph5
   1
- RCA Guidance on the Provision of Anaesthesia Services for Day Surgery

### 2019 NICE NG51 Sepsis: recognition, diagnosis and early management. https://www.nice.org.uk/quidance/ng5 1/chapter/Recommendations NICE QS66 Statement 2: Adults receiving intravenous (IV) fluid therapy in hospital are cared for by healthcare professionals competent in assessing patients' fluid and electrolyte needs, prescribing and administering IV fluids, and monitoring patient experience. (NICE QS3 Statement 5): Patients assessed to be at risk of VTE are offered VTE prophylaxis in accordance with NICE guidance. NICE QS90 (2015) UTI in adults Report sub-heading: Nutrition and hydration E1.5 How are people's nutrition and hydration needs (including those related to culture and religion) identified, monitored and met? Where relevant, what access is there to dietary and nutritional specialists to assist in this? Report sub-heading: Pain relief

•	E1.6 How is a person's pain assessed and
	managed, particularly for those people
	where there are difficulties in
	communicating?

- RCOG Guidelines 'Care of Women Requesting Induced Abortion (2011)
  - 7.16 Women should routinely be offered pain relief such as nonsteroidal anti-inflammatory drugs (NSAIDs) during surgical abortion.
  - 7.17 Prophylactic paracetamol (oral or rectal) is ineffective in reducing pain after surgical abortion and is **not** recommended.
  - 7.25 Women should routinely be offered pain relief (for example NSAIDs) during medical abortion
  - 2.26 Oral paracetamol has not been shown to reduce pain more than placebo during medical abortion and is **not** recommended.
- Core Standards for Pain Management Services in the UK Refer to standard 6.4

 How does the service ensure that during and following termination of pregnancy people using services receive effective pain relief? (including women going home following treatment for EMA)

### Key line of enquiry: **E2**

E2. How are people's care and treatment outcomes monitored and how do they compare with other similar services?

Prompts	Professional standard Sector specific guidance	
Report sub heading: Patient outcomes		
E2.1 Is information about the outcomes of people's care and treatment (both physical and mental where appropriate) routinely collected and monitored?	Audits in respect of termination of pregnancy services recommended by the RCOG include care and treatment under the following headings:	Does the service audit outcomes of treatments being provided for termination of pregnancy? Including waiting times? And early medical abortion where the service supplies the

- E2.2 Does this information show that the intended outcomes for people are being achieved?
- E2.3 How do outcomes for people in this service compare with other similar services and how have they changed over time?
- E2.4 Is there participation in relevant quality improvement initiatives, such as local and national clinical audits, benchmarking, (approved) accreditation schemes, peer review, research, trials and other quality improvement initiatives? Are all relevant staff involved in activities to monitor and use information to improve outcomes?

- o 9.1 Pathways of care
- o 9.2 Information provision
- 9.3 Women's choice
- 9.4 Pre-abortion assessment
- 9.5 Abortion procedures
- o 9.6 Care after the abortion
- RSOP16: Performance Standards and Audit: All providers should have in place clear locally agreed standards against which performance can be audited, with specific focus on outcomes and processes.

Subjects which providers and commissioners should audit include:

- Waiting times.
- The outcome of consultations; the number of women who do not proceed to a termination.
- The use and availability of pathways to specialist services for women with significant medical conditions and to antenatal care for women deciding to continue their pregnancy.
- The availability of a female doctor for women who wish to consult a woman especially those from certain cultural backgrounds and ethnic minorities, with arrangements for non-English speaking women.

- second medication (misoprostol) to the woman to take away and administer at home?
- In cases where feticide and or surgical termination of pregnancy is carried out is there participation in sepsis audit?
- What evidence is there that management has changed in response to their audits?

0	The number of staff competent to
	provide all methods of reversible
	contraception.

- Patient choice across the range of service provision to include follow-ups, contraception and abortion methods.
   Patient experience for those who have returned home after taking the 2nd drug for a medical abortion.
- Rates of complications. The prevention of infective complications.
- o Failure rates.
- The number of women who have had repeat abortions and whether they left the service with suitable contraception including uptake of LARC.
- o Patient experience.
- o Complaints/critical incidents.
- Number of patients who return for follow-up appointments.

### Key line of enquiry: **E3**

E3. How does the service make sure that staff have the skills, knowledge and experience to deliver effective care, support and treatment?

Prompts		Professional standard	Sector specific guidance
Re	port sub heading: Competent staff		
•	E3.1 Do people have their assessed needs, preferences and choices met by staff with the right skills and knowledge?	<ul> <li>RCN Termination of Pregnancy: An RCN Nursing Framework June 2017</li> <li>Faculty of Sexual and Reproductive Health training e.g.</li> </ul>	In cases where surgical termination or late medical termination of pregnancy takes place does the service ensure that all relevant staff complete an

- E3.2 How are the learning needs of all staff identified? Do staff have appropriate training to meet their learning needs to cover the scope of their work and is there protected time for this training?
- E3.3 Are staff encouraged and given opportunities to develop?
- E3.4 What are the arrangements for supporting and managing staff to deliver effective care and treatment? (This includes one-to-one meetings, appraisals, coaching and mentoring, clinical supervision and revalidation.)
- E3.5 How is poor or variable staff performance identified and managed? How are staff supported to improve?
- E3.7 Are volunteers recruited where required, and are they trained and supported for the role they undertake?

- http://www.fsrh.org/pdfs/SpecialtyModule3.pdf
- RCOG guidance 'the care of women requesting induced abortion' sets out in recommendation 6.4 'For the minority of women who require formal, therapeutic counselling, services should have referral pathways in place with access to trained counsellors with appropriate expertise"
- Chapter 7, page 61 of the Royal College of Obstetricians and Gynaecologists (RCOG) guidelines on the Care of Women Requesting an Induced Abortion (2011) summarises the methods considered to be appropriate for women presenting at different gestations. The purpose of the requirement to specify gestation and methods is to ensure that what is being proposed is in keeping with the physical environment and clinical expertise available.
- Reference:
  - o RSOP3: Post Procedure
  - o RSOP14: Counselling
  - RSOP27 Abortions beyond nine weeks gestation.
- Reference: Royal College of Anaesthetists' Guidelines for the

- appropriate level of resuscitation training, including ALS training as necessary? And is the whole multidisciplinary team competent in resuscitation response and procedure?
- How does the service ensure that all staff complete safeguarding training? Including professional healthcare staff completing level 3 safeguarding training?
- How does the service ensure the 24hrs dedicated post abortion procedure support line is staffed by individuals trained in offering support in this speciality?
- How does the service ensure that therapeutic support being offered to women is provided by appropriately trained and experienced staff?
- How does the service ensure that in particular where abortions are carried out beyond nine weeks gestation, that healthcare professionals have received additional training and maintain competency? Are there arrangements in place to make sure that local healthcare providers are informed in cases where a

Provision of Anaesthetic Services (GPAS) 2019

<u>Guidelines for the Provision of</u> <u>Anaesthetic Services (GPAS) 2019 | The</u> <u>Royal College of Anaesthetists</u>

 NICE NG51 Sepsis: recognition, diagnosis and early management. <a href="https://www.nice.org.uk/guidance/ng51/chapter/Recommendations">https://www.nice.org.uk/guidance/ng51/chapter/Recommendations</a> staff member is suspended from duty?

- Have staff in the department received training on sepsis
  - Screening
  - Management
  - Provider policy
- Where failure in the sepsis protocol has been identified have staff been given support and education

### Key line of enquiry: **E4**

**Prompts** 

E4. How well do staff, teams and services within and across organisations work together to deliver effective care and treatment?

Professional standard

### Report sub-heading: Multidisciplinary working

- E4.1 Are all necessary staff, including those in different teams, services and organisations, involved in assessing, planning and delivering care and treatment?
- E4.2 How is care delivered and reviewed in a coordinated way when different teams, services or organisations are involved?
- E4.3 How are people assured that they will receive consistent coordinated, personcentred care and support when they use, or move between different services?
- E4.4 Are all relevant teams, services and organisations informed when people are

- Transition between inpatient hospital settings and community or care home settings for adults with social care needs (NICE guideline 27)
- RCOG guidance 'the care of women requesting induced abortion' sets out in recommendation
   8.15 Before she is discharged, future contraception should have been discussed with each woman and contraceptive supplies should have been offered

- Sector specific guidance
- How does the service work with other health and social care services to meet the needs of women? for example in relation to:
  - Continuity of care with GPs, communication between GPs in respect of termination of pregnancy.
  - Team working between theatre/ward staff e.g. sharing information on never events
- How does the service ensure that following an abortion procedure taking

discharged from a service? Where relevant, is discharge undertaken at an appropriate time of day and only done when any necessary ongoing care is in place?	8.2 On discharge, all women should be given a letter providing sufficient information about the procedure to allow another practitioner elsewhere to manage any complications.	<ul> <li>place women are discharged of necessary requirements for one post procedural care are in place.</li> <li>How does the service ensure the objectives of The Academy of Incomposition of I</li></ul>	going ce? hat the Royal inicians n f who has r patient liate screening
Report sub-heading: Seven-day services			
E4.5 How are high-quality services made available that support care to be delivered seven days a week and how is their effect on improving patient outcomes monitored?			

# Key line of enquiry: **E5**

E5. How are people supported to live healthier lives and where the service is responsible, how does it improve the health of its population?

Prompts	Professional standard	Sector specific guidance			
Report sub-heading: <b>Health promotion</b>	eport sub-heading: <b>Health promotion</b>				
<ul> <li>E5.1 Are people identified who may need extra support? This includes:</li> <li>people in the last 12 months of their lives</li> <li>people at risk of developing a long-term condition</li> <li>carers</li> <li>E5.2 How are people involved in regularly monitoring their health, including health assessments and checks, where appropriate and necessary</li> <li>E5.3 Are people who use services empowered and supported to manage their own health, care and wellbeing and to maximise their independence?</li> <li>E5.4 Where abnormalities or risk factors are identified that may require additional support or intervention, are changes to people's care or treatment discussed and followed up between staff, people and their carers where necessary?</li> <li>E5.5 How are national priorities to improve the population's health supported? (For example, smoking cessation, obesity, drug and alcohol dependency, dementia and cancer.)</li> </ul>	<ul> <li>RSOP12: sets out that information provided should include strategies for prevention of infection (E.G. of HIV and sexually transmitted infections)</li> <li>RSOP13</li> </ul>	<ul> <li>Are women provided with information regarding promotion of their sexual health?</li> <li>Are women who choose not to start a contraception method immediately given information about local contraception providers in addition to their General Practitioner?</li> </ul>			

### Key line of enquiry: **E6**

**Prompts** 

E6. Is consent to care and treatment always sought in line with legislation and guidance?

### Report sub-heading: Consent, Mental Capacity Act and DOLs

- E6.1 Do staff understand the relevant consent and decision making requirements of legislation and guidance, including the Mental Capacity Act 2005 and the Children's Acts 1989 and 2004 and other relevant national standards and guidance?
- E6.2 How are people supported to make decisions in line with relevant legislation and quidance?
- E6.3 How and when is possible lack of mental capacity to make a particular decision assessed and recorded?
- E6.4 How is the process for seeking consent monitored and reviewed to ensure it meets legal requirements and follows relevant national guidance?
- E6.5 When people lack the mental capacity to make a decision, do staff ensure that best interests decisions are made in accordance with legislation?
- E6.6 How does the service promote supportive practice that avoids the need for physical restraint? Where physical restraint may be necessary, how does the service

- Consent: patients and doctors making decisions together (GMC)
- Consent The basics (Medical Protection)
- Department of Health reference guide to consent for examination or treatment
- BMA Consent Toolkit

Professional standard

- BMA Children and young people tool kit
- Gillick competence
- RSOP 14 and RCOG Guidelines ' Care of Women Requesting Induced Abortion (2011) highlights that:

"all women attending an abortion service will require a discussion to determine the degree of certainty of their decision and their understanding of its implications as part of the process of gaining consent. Careful and sensitive enquiry as to the reasons for requesting an abortion should

- Sector specific guidance
- As part of the consent process, how does the service ensure that women attending for abortion are certain of their decision and understand its implications?
- How does the service ensure that all women and young persons is seeking abortion voluntarily?
- In areas where ethnic minority groups form a significant proportion of the local population, are processes in place to aide translation during the consent process?

ensure that it is used in a safe, proportionate, and monitored way as part of a wider person centred support plan?

 E6.7 Do staff recognise when people aged 16 and over and who lack mental capacity are being deprived of their liberty, and do they seek authorisation to do so when they consider it necessary and proportionate? be made, with the opportunity for further discussion, especially where women express any doubts or suggestion of pressure or coercion"

Note: It should be noted that with respect to termination of pregnancy services while women may choose to use family or friends as interpreters, in gaining consent to a procedure the provider needs to be absolutely certain that the woman is fully consenting. This can be guaranteed only if an independent professional interpretation service is used.

• RCOG 2011 recommendation 4.10

#### Also see:

- RCOG Best Practice Paper No. 2

  June 2015 section about assessment.
- RSOP 8: Consent
- GMC publications: `0-18 Years: Guidance for all doctors'

http://www.gmc-

<u>uk.org/guidance/ethical\_guidance/children\_g</u> uidance 70 71 contraception.asp

#### http://www.gmc-

uk.org/guidance/ethical guidance/children g uidance 64 69 sexual activity.asp

#### http://www.gmc-

uk.org/guidance/ethical guidance/children g uidance 24 26 assessing capacity.asp

 Additional reference: BMA guidance on "Law and Ethics of Abortion" (November 2007) and the Department of Health's comprehensive reference guide to consent for examination or treatment (2009) also set out good practice in this area.

http://bma.org.uk/search?query=law%20a
nd%20ethics%20on%20abortion

# Caring

By caring, we mean that the service involves and treats people with compassion, kindness, dignity and respect.

### Key line of enquiry: C1, C2 & C3

- C1. How does the service ensure that people are treated with kindness, dignity, respect and compassion, and that they are given emotional support when needed?
- C2. How does the service support people to express their views and be actively involved in making decisions about their care, support and treatment as far as possible?
- C3. How is people's privacy and dignity respected and promoted?

Generic prompts	Professional Standard	Sector specific guidance		
Report sub-heading: Compassionate care				
C1.1 Do staff understand and respect the personal, cultural, social and religious needs of people and how these may relate to care needs, and do they take these into account in the way they deliver services? Is this	<ul> <li>NICE QS15 statement 1 People using adult NHS services are treated with empathy, dignity and respect.</li> <li>NICE QS15 statement 2 People using adult NHS services understand the</li> </ul>	Is appropriate help and support provided for women by the staff before and after TOP?		

- information recorded and shared with other services or providers?
- C1.2 Do staff take the time to interact with people who use the service and those close to them in a respectful and considerate way?
- C1.3 Do staff show an encouraging, sensitive and supportive attitude to people who use services and those close to them?
- C1.4 Do staff raise concerns about disrespectful, discriminatory or abusive behaviour or attitudes?
- C3.1 How does the service and staff make sure that people's privacy and dignity needs are understood and always respected, including during physical or intimate care and examinations?
- C3.2 Do staff respond in a compassionate, timely and appropriate way when people experience physical pain, discomfort or emotional distress?

roles of healthcare professionals involved in their care and know how to contact them about their ongoing healthcare needs.

 Do all staff adopt a non-directive, nonjudgemental and supportive approach to women receiving treatment for abortion?

#### Report sub-heading: Emotional support

- C1.5 Do staff understand the impact that a person's care, treatment or condition will have on their wellbeing and on those close to them, both emotionally and socially?
- C1.6 Are people given appropriate and timely support and information to cope emotionally with their care, treatment or condition? Are
- RSOP28 sets out:
   All staff caring for the mother must adopt a non-directive, non-judgemental and supportive approach.
- RSOP 14 sets out:
   All women requesting an abortion should be offered the opportunity to discuss their options and choices with, and receive therapeutic support from, a trained pregnancy counsellor and
- How is emotional support provided during and after TOP? In particular where 20 to 24-week gestation terminations are being undertaken?
- How do staff ensure appropriate assessment for anxiety and depression is provided?

- they advised how to find other support services?
- C2.7 What emotional support and information is provided to those close to people who use services, including carers, family and dependants?
- this offer should be repeated at every stage of the care pathway.
- RCOG Guidelines 'Care of Women Requesting Induced Abortion (2011)
  paragraph 4.14 sets out:
  Clinicians caring for women requesting abortion should be able to identify those who require more support than can be provided in the routine abortion service setting, for example young women, those with a pre-existing mental health condition, those who are subject to sexual violence or poor social support, or where there is evidence of coercion.
- How do staff ensure that appropriate support provided following TOP that take place due to congenital abnormality?
- How is appropriate specialist bereavement support provided that meets the individual circumstances of the women?

### Report sub-heading: Understanding and involvement of patients and those close to them

- C2.1 Do staff communicate with people so that they understand their care, treatment and condition and any advice given?
- C2.2 Do staff seek accessible ways to communicate with people when their protected equality or other characteristics make this necessary?
- C2.3 How do staff make sure that people who use services and those close to them are able to find further information, including community and advocacy services, or ask questions about their care and treatment? How are they supported to access these?
- C2.4 Are people empowered and supported, where necessary, to use and link with support networks and advocacy, so that it will

• RSOP 12: Information for Women

Women must be given impartial, accurate and evidence-based information (verbal and written) **delivered neutrally** and covering the following:

- Alternatives to abortions (for instance adoption and motherhood)
- Abortion methods appropriate to gestation
- The range of emotional responses that may be experienced during and following an abortion
- What to expect during and after the abortion (to include potential side effects,

- How do staff ensure women (including those under 18 years) are given the opportunity of making an informed choice about all available TOP methods that are appropriate and safe for their clinical need and risk?
- How do staff ensure women are given the opportunity to take information away with them if they wish to inform their decision making?
- How do staff make sure that women are informed about postoperative care and possible complications and

- have a positive impact on their health, care and wellbeing?
- C2.5 Do staff routinely involve people who use services and those close to them (including carers and dependants) in planning and making shared decisions about their care and treatment? Do people feel listened to, respected and have their views considered?
- C2.6 Are people's carers, advocates and representatives including family members and friends, identified, welcomed, and treated as important partners in the delivery of their care?
- C3.3 How are people assured that information about them is treated confidentially in a way that complies with the Data Protection Act and that staff support people to make and review choices about sharing their information?

- complications and any clinical implications)
- Full discussion of contraception options and the supply of chosen method
- Testing for sexually transmitted infections including HIV and strategies in place for infection prevention
- RSOP3: Post procedure
- NHS contraception guide about vasectomy.
   <a href="http://www.nhs.uk/conditions/contrace">http://www.nhs.uk/conditions/contrace</a>
   <a href="ption-guide/pages/vasectomy-male-sterilisation.aspx">ption-guide/pages/vasectomy-male-sterilisation.aspx</a>
- NICE QS15 statements 5 People using adult NHS services have their preferences for sharing information with their family members and carers established, respected and reviewed throughout their care
- NICE QS15 statement 6, People using adult NHS services are supported in shared decision making

- advised how to access 24hr advice and support following termination of pregnancy?
- In services where early medical abortion is provided, and the service supply the second medication (misoprostol) to the woman to take away and administer at home; How does the service ensure that:
  - that the woman understands how to administer the medication?
  - that the woman knows who to contact in case she changes her mind and continues the pregnancy, or if her circumstances significantly alter or should unexpected difficulties arise?
- How do staff ensure that women are made aware that contents of the statutory HSA4 form used to inform the CMO of abortions will be used for statistical purposes by the Department of Health and that the data published is anonymised?
- How does the service make sure that there is appropriate and sensitive discussion about cost involved in

responsi	nere the women will be ble for full or partial cost of reatment?
vasector patients they und	rvice is providing male ny, how do staff involve in discussions to ensure that erstand and have access to on about vasectomy?

# Responsive

By responsive, we mean that services meet people's needs

## Key line of enquiry: R1 & R2

- R1. How do people receive personalised care that is responsive to their needs?
- R2. Do services take account of the particular needs and choices of different people?

·				
F	Prompts	Professional standard	Sector specific guidance	
F	Report sub-heading: Service delivery to meet the needs of local people			
•	R1.1 Do the services provided reflect the needs of the population served and do they	RSOP 25: Referrals from Bureaux  Premises approved for the termination of pregnancy should not accept women from		
	ensure flexibility, choice and continuity of care?	any bureau that is not on the register of		
•	R1.2 Where people's needs and choices are not being met, is this identified and used to	approved Pregnancy Advisory Bureaux held by the Department of Health.		
	not being met, is this identified and used to	Approved premised may accept referrals		

- inform how services are improved and developed?
- R1.3 Are the facilities and premises appropriate for the services that are delivered?

from a GP or medical consultant. NHSfunded women can access services through routes agreed via local commissioning arrangements.

#### Report sub-heading: Meeting people's individual needs

- R1.4 How does the service identify and meet the information and communication needs of people with a disability or sensory loss. How does it record, highlight and share this information with others when required, and gain people's consent to do so?
- R2.1 How are services delivered, made accessible and coordinated to take account of the needs of different people, including those with protected characteristics under the Equality Act and those in vulnerable circumstances?
- R2.2 How are services delivered and coordinated to be accessible and responsive to people with complex needs?<sup>1</sup>
- R2.3 How are people, supported during referral, transfer between services and discharge?
- R2.4 Are reasonable adjustments made so that people with a disability can access and use services on an equal basis to others?

- NICE QS15 statement 4 People using adult NHS services experience care and treatment that is tailored to their needs and preferences
- Accessible Information Standard
- RSOP 14:Counselling
- RCOG Guidelines 'Care of Women Requesting Induced Abortion (2011)
- RSOP 15: Disposal of Fetal Tissue

All providers should have policies on disposal of fetal tissue which take account of relevant guidance detailed below. Information about disposal should be available for women setting out their choices.

Please refer to HTA guidance published March 2015 regarding disposal of pregnancy remains following pregnancy loss or termination.

- What arrangements are in place to ensure that where women have a preexisting physical or mental health condition that clinical pathways are in place for access to appropriate medical back up services if required?
- What arrangements are in place, tailored to age, comprehension and social circumstances to identify those who may require additional support and counselling. These may include young women, women with mental health problems, women with learning disability, women with poor social support and where there is evidence of coercion?
- Does the provider comply with Accessible Information standards?
- What arrangements are in place to manage specific needs of women seeking abortion for fetal abnormality

<sup>&</sup>lt;sup>1</sup>. For example, people living with dementia or people with a learning disability or autism.

- R2.5 Do key staff work across services to coordinate people's involvement with families and carers, particularly for those with multiple long-term conditions?
- HTA Code of practice about Disposal of Pregnancy Remains Following Pregnancy Loss or Termination
- RCOG has produced the good practice guidance Disposal Following Pregnancy Loss Before 24 Weeks Gestation (2005) (Good Practice No 5) which provides a further source of information if required.
- RCN guidance about <u>managing</u> <u>disposal of pregnancy remains</u>.
   Published October 2015
- The Stillbirths and Neonatal Society (SANDS (2007)) guidelines for professionals also highlight the need for sensitive disposal.

http://www.uk-sands.org/Home.html

 RSOP 28: Fetal Awareness and Abnormality

The Royal College of Obstetricians and Gynaecologists (RCOG) released two working party reports in March 2010:

- Fetal Awareness
- <u>Termination of pregnancy for fetal</u> abnormality
- Accessible Information standards NHS England
- RCOG guidance: Care of Women Requesting Induced Abortion (2011

- which reflect guidance from the RCOG?
- How do staff ensure that women are given the opportunity of making informed choice about disposal of pregnancy remains or burial of the fetus or pregnancy remains?
- What steps have been taken to ensure areas where children under 18 years are treated are safe and suitable for the age group?
- What reasonable adjustments are made for a person under 18 years that might struggle with the hospital environment?
- Are arrangements in place so that women receiving treatment for early medical abortion are given the opportunity (if assessed as appropriate) to be supplied with the second medication (misoprostol) to take away and administer at home?

recommendation 8.5 sets out that A 24-hour telephone helpline number should be available for women to use after abortion if they have any concerns.

## Key line of enquiry: **R3**

**Prompts** 

R3. Can people access care and treatment in a timely way?

### Report sub-heading: Access and flow

- R3.1 Do people have timely access to initial assessment, test results, diagnosis, or treatment?
- R3.2 Can people access care and treatment at a time to suit them?
- R3.3 What action is taken to minimise the length of time people have to wait for care, treatment, or advice?
- R3.4 Do people with the most urgent needs have their care and treatment prioritised?
- R3.5 Are appointment systems easy to use and do they support people to access appointments?
- R3.6 Are appointments care and treatment only cancelled or delayed when absolutely necessary? Are delays or cancellations explained to people, and are people

#### **Professional standard**

- RSOP 11: Access to Timely Abortion Services
   Providers should have arrangements in place to minimise delays in women accessing services and a choice of method should be provided at all gestations
- RCOG Guidelines 'Care of Women Requesting Induced Abortion (2011)

Recommendation 4.24 and 4.25:
Women who need more time to reach a decision should be free to delay the procedure and be provided with further counselling if requested. It is essential to ascertain that a woman is sure of her choice to proceed with abortion; however, when that is confirmed, there is no advantage in further delay since the risks associated with abortion increase with

#### Sector specific guidance

- How does the provider ensure that women are offered an appointment within five working days of referral or self-referral?
- How does the provider ensure that women are offered the abortion procedure within five working days of the decision to proceed, and that the total time from access to procedure does not exceed ten working days?
- How does the provider ensure that women who present beyond 12 completed weeks or require abortion for urgent medical reasons, receive care promptly to minimise further risk to health?
- How does the provider ensure that women can choose to delay appointments/booked procedures and

- supported to access care and treatment again as soon as possible?
- R3.7 Do services run on time, and are people kept informed about any disruption?
- R3.8 How is technology used to support timely access to care and treatment? Is the technology (including telephone systems and online/digital services) easy to use?

increasing gestation. Women should also be informed that they can change their mind at any time before the procedure and cancel the abortion.

• Accessible Information standards NHS England

(From 31 July 2016, all organisations that provide NHS care or adult social care are legally required to follow the Accessible Information Standard.)

this choice always overrides issues of timeliness?

 Does the provider comply with Accessible Information standard by identifying, recording, flagging, sharing and meeting the information and communication needs of people with a disability / sensory loss?

### Key line of enquiry: R4

R4. How are people's concerns and complaints listened and responded to and used to improve the quality of care?

Prompts Professional standard Sector specific guidance

#### Report sub-heading: Learning from complaints and concerns

- R4.1 How well do people who use the service know how to make a complaint or raise concerns and how comfortable do they feel doing so in their own way? How are people encouraged to make a complaint, and how confident are they to speak up?
- R4.2 How easy is it for people to use the system to make a complaint or raise concerns? Are people treated compassionately and given the help and support, through use of accessible

- The <u>NHS constitution</u> gives people the right to
  - Have complaints dealt with efficiently and be investigated.
  - Know the outcome of the investigation.
  - Take their complaint to an independent Parliamentary and Health Service Ombudsman.

- information or protection measures if they need to make a complaint?
- R4.3 How effectively are complaints handled, including to ensure openness and transparency, confidentially, regular updates for the complainant, a timely response and explanation of the outcome, and a formal record?
- R4.4 How are people who raise concerns or complaints protected from discrimination, harassment or disadvantage?
- R4.5 To what extent are concerns and complaints used as an opportunity to learn and drive improvement?

Receive compensation if they have been harmed.

RSOP 17 complaints and feedback

All approved places should have systems in place to undertake post-care patient satisfaction surveys and feedback aimed at identifying women's experiences and views on the treatment they have received.

#### Well-led

By well-led, we mean that the leadership, management and governance of the organisation assures the delivery of high-quality person-centred care, supports learning and innovation, and promotes an open and fair culture.

### Key line of enquiry: W1

W1. Is there the leadership capacity and capability to deliver high-quality, sustainable care?

Prompts	Professional standard	Sector specific guidance	
Report sub-heading: Leadership			
W1.1 Do leaders have the skills, knowledge, experience and integrity that they need – both	Note the Department of Health consider that prominent display of the	Does the service display the certificate of approval (issued by the Department)	

when they are appointed and on an ongoing basis?

- W1.2 Do leaders understand the challenges to quality and sustainability, and can they identify the actions needed to address them?
- W1.3 Are leaders visible and approachable?
- W1.4 Are there clear priorities for ensuring sustainable, compassionate, inclusive and effective leadership, and is there a leadership strategy or development programme, which includes succession planning?

certificate is a matter of good practice.

 Refer to to Regulation 20 (6) of the CQC Registration Regulation 2009 which sets out requirement of a register in respect of TOP.

National Safety Standards for Invasive
Procedures (NatSSIPs) Version number:
1 published: 7 September 2015. Applies
to those providing NHS funded care

of Health) within the clinic/hospital?

- Does the service maintain a register of people undergoing a TOP, which is completed in respect of each person at the time the TOP is undertaken and is retained for a period of not less than 3 years beginning on the date of the last entry?
- Does the service ensure that a record is maintained of the total numbers of TOPs undertaken? This record can be in paper or electronic form.
- How do leaders ensure that employees who are involved in the performance of invasive procedures develop shared understanding be educated in good safety practice, as set out in the national standards?

### Key line of enquiry: W2

W2. Is there a clear vision and credible strategy to deliver high-quality sustainable care to people who use services, and robust plans to deliver?

Prompts Professional standard Sector specific guidance

Report sub-heading: Vision and strategy

- W2.1 Is there a clear vision and a set of values, with quality and sustainability as the top priorities?
- W2.2 Is there a robust, realistic strategy for achieving the priorities and delivering good quality sustainable care?
- W2.3 Have the vision, values and strategy been developed using a structured planning process in collaboration with staff, people who use services, and external partners?
- W2.4 Do staff know and understand what the vision, values and strategy are, and their role in achieving them?
- W2.5 Is the strategy aligned to local plans in the wider health and social care economy, and how have services been planned to meet the needs of the relevant population?
- W2.6 Is progress against delivery of the strategy and local plans monitored and reviewed, and is there evidence to show this?

#### • <u>RSOP26</u>

It is the responsibility of providers, in consultation with commissioners, to develop good clinical practice within their local setting, reflecting evidence-based guidelines from relevant professional bodies.

• Fit and Proper Persons Guidance

 How does the service make sure that staff provide TOP care and treatment in accordance with the professional guidance published by the RCOG and other professional bodies?

## Key line of enquiry: W3

W3. Is there a culture of high-quality, sustainable care?

Generic prompts	Professional Standard	Sector specific guidance
Report sub-heading: Culture		
W3.1 Do staff feel supported, respected and valued?	<u>NMC Openness and honesty when</u> <u>things go wrong</u> : the professional duty of candour	How is the provider meeting the requirements related to Duty of Candour? (for example, training,

- W3.2 Is the culture centred on the needs and experience of people who use services?
- W3.3 Do staff feel positive and proud to work in the organisation?
- W3.4 Is action taken to address behaviour and performance that is inconsistent with the vison and values, regardless of seniority?
- W3.5 Does the culture encourage, openness and honesty at all levels within the organisation, including with people who use services, in response to incidents? Do leaders and staff understand the importance of staff being able to raise concerns without fear of retribution, and is appropriate learning and action taken as a result of concerns raised?
- W3.6 Are there mechanisms for providing all staff at every level with the development they need, including high-quality appraisal and career development conversations?
- W3.7 Is there a strong emphasis on the safety and well-being of staff?
- W3.8 Are equality and diversity promoted within and beyond the organisation? Do all staff, including those with particular protected characteristics under the Equality Act, feel they are treated equitably?
- W3.9 Are there cooperative, supportive and appreciative relationships among staff? Do staff and teams work collaboratively, share

- NRLS Being Open Communicating patient safety incidents with patients, their families and carers
- <u>Duty of Candour</u> CQC guidance
- RSOP24: Providers must not request fees are paid for an abortion either directly or indirectly until two certificates of opinion necessary for a legal abortion under the Act have been provided.

This requirement ensures that women are free of any fear of exploitation when accessing termination of pregnancy services. Where the abortion provider has a contract to provide abortion services on behalf of the NHS the woman should be informed and should therefore not be charged a fee.

 https://www.england.nhs. uk/about/equality/equalityhub/equality-standard/

- support for staff, audits and monitoring)
- How does the service ensure that women are free of any fear of financial exploitation when accessing termination of pregnancy services and that where services are provided on behalf of the NHS the woman are informed not charged a fee?
- Where the provider has an NHS Standard Contract to provide treatment:
  - What work is being undertaken to address workforce equality at a provider level?
  - How have you implemented any organisation-wide strategy or priorities on workforce race equality in your location?
  - How are you ensuring at a location level that there is an inclusive workplace for staff, which welcomes diversity?
  - What work has been undertaken to ensure that staff from different equality groups feel able to speak up about their experiences at work – either as

responsibility and resolve conflict quickly and constructively?

- an employee or in relation to patient care?
- Are there mechanisms for providing all staff at every level with the development they need, including high-quality appraisal and career development conversations?

#### Key line of enquiry: W4

**Generic prompts** 

W4. Are there clear responsibilities, roles and systems of accountability to support good governance and management?

**Professional Standard** 

#### Report sub-heading: Governance

- W4.1 Are there effective structures. processes and systems of accountability to support the delivery of the strategy and good quality, sustainable services? Are these regularly reviewed and improved?
- W4.2 Do all levels of governance and management function effectively and interact with each other appropriately?
- W4.3 Are staff at all levels clear about their roles and do they understand what they are accountable for, and to whom?
- W4.4 Are arrangements with partners and third-party providers governed and managed effectively to encourage appropriate interaction and promote coordinated, personcentred care?

## RSOP23

Arrangements must be in place to immediately notify the CQC and the Department of Health in the event of the death of a patient.

A record must be kept of the date, time, cause and place of death. If the notification has been provided verbally over the telephone, information should be confirmed in writing to the Department of Health within 24 hours

- Refer also to Regulation 20 (10) of the **CQC** Registration Regulation 2009
- RSOP2: All providers should have protocols and procedures in place covering the

What mechanism is in place to ensure that the registered person informs CQC in writing about death of a woman within 12 months of using the TOP service?

Sector specific guidance

- What arrangements are in place to ensure that there are locally agreed standards against which performance can be audited, with specific focus on outcomes and processes?
- How does the service ensure that protocols regarding delegation of duties in relation to medical abortions

services they deliver (covering both methods of abortion and gestation bands). In particular, policies should be in place covering the delegation of duties in relation to medical abortions, the follow up of women who go home after an EMA, and the management of conscientious objections.

RSOP1: (RSOP1 reflects the law for all TOP provision)
 The Abortion Act 1967 regulates the provision of abortion services in England, Wales and Scotland. If an abortion is performed which does not comply with the terms of the Act, then an offence will have been committed under the Offences Against the Person Act 1861 and /or the Infant Life (Preservation) Act 1929.

**HSA1** – **Must** be completed and signed by two doctors before an abortion is performed. The HSA1 form **must** be kept for 3 years from the date of termination.

**HSA2** – Completed before an abortion is performed or, if that is not reasonably practicable, within 24 hours of an emergency abortion and kept for 3 years from the date of termination.

are being followed?

- How does the service ensure that conscientious objection (set out as a clause in the Abortion Act) is the managed appropriately and in line with professional guidelines?
- If the service does not provide the 24hr helpline themselves, how do they know that the helpline is meetings women's needs and also meets requirements of RSOP 3?
- How does the service make sure that staff provide TOP care and treatment in accordance with the Abortion Act 1967?
- How does the service make sure that necessary documentation and records required under the Abortion Act 1967 are being properly maintained?
- How has the service made sure that staff are informed about the changes to the abortion legislation that came into effect on 1 January 2019?
- What arrangements are in place to make sure that the certificate(s) of opinion HSA1 are signed by two

As a matter of best practice we expect forms HSA1 and HAS2 to be kept with the patient's notes.

See DH Guidance note for completing the HSA1 and HSA2 abortion forms

 RSOP 16: Performance Standards and Audit

All providers should have in place clear locally agreed standards against which performance can be audited, with specific focus on outcomes and processes.

- RSOP21 Risk Management
   All providers should have in place a formal risk management system and keep a risk register to identify and minimise any risks to patients and staff within their premises. Protocols should exist on action to be taken should incidents occur.
- RSOP 20:
   Confirmation of Professional Status
   A named senior manager or director must be responsible for ensuring that qualifications, experience, GMC registration / NMC PIN reference are confirmed for all medical, midwifery, nursing staff and counsellors.
- RSOP 4
   All providers must undertake to inform the Department of Health of any change in the ownership of the

- medical practitioners in line with the requirements of the Abortion Act 1967 and Abortion Regulations 1991?
- Can the service 'describe' the arrangements for obtaining these opinions?
- What arrangements are in place to make sure that in cases of an emergency HSA2 form is completed by the medical practitioner within 24 hrs.' and retained for 3 years?
- How does the service monitor and ensure that Regulation 20 of the Health and Social Care Act 2008 Care Quality Commission (Registration) Regulations 2009 and the Department of Health Independent Sector RSOP's are fully complied with?
- What are the arrangements to ensure those staff working under practising privileges hold appropriate indemnity insurance in accordance with <u>The</u> <u>Health Care and Associated</u> <u>Professions (Indemnity Arrangements)</u> Order 2014

Key line of enquiry: <b>W5</b>	controlling business or in the premises.	<ul> <li>How does the service ensure that people managing the service comply with the legal requirements of the Abortion Act 1967 (as amended) and the Abortion Regulations 1991 and support those staff by ensuring appropriate protocols and procedures are in place with respect to fulfilling legal requirements?</li> <li>What are the governance procedures for managing and monitoring any SLAs the provider has with third parties?</li> </ul>	
W5. Are there clear and effective processes for managing risks, issues and performance?			
Generic prompts	Professional Standard	Sector specific guidance	
Report sub-heading: Managing risks, issues and	performance		
W5.1 Are there comprehensive assurance systems, and are performance issues escalated appropriately through clear structures and processes? Are these regularly reviewed and improved?	RSOP 18: Staffing and Emergency Medical Cover: Protocols should also cover transfer to specialist services including intensive care and dealing with anaesthetic emergencies	Does the service have tested back up emergency generators in place in case of failure of essential services?	
W5.2 Are there processes to manage current and future performance? Are these regularly reviewed and improved?	NICE QS61 Statement 2:     Organisations that provide healthcare have a strategy for continuous improvement in infection prevention and control, including accountable		

- W5.3 Is there a systematic programme of clinical and internal audit to monitor quality, operational and financial processes, and systems to identify where action should be taken?
- W5.4 Are there robust arrangements for identifying, recording and managing risks, issues and mitigating actions? Is there alignment between the recorded risks and what staff say is 'on their worry list'?
- W5.5 Are potential risks taken into account when planning services, for example seasonal or other expected or unexpected fluctuations in demand, or disruption to staffing or facilities?
- W5.6 When considering developments to services or efficiency changes, how is the impact on quality and sustainability assessed and monitored? Are there examples of where financial pressures have compromised care?

leadership, multi-agency working and the use of surveillance systems.

### Key line of enquiry: W6

W6. Is appropriate and accurate information being effectively processed, challenged and acted upon?

Generic prompts	Professional Standard	Sector specific guidance
Report sub-heading: Managing information		
W6.1 Is there a holistic understanding of performance, which sufficiently covers and integrates people's views with information on quality, operations and finances? Is	HSA4 – Must be sent to the CMO within 14 days (by post or electronically). DH strongly encourage the use of electronic reporting as this is a more secure system and reduces the risk of lost or	How does the service ensure that HSA4 forms are always completed in accordance with the Abortion Regulations 1991 and submitted in a timely manner to the Chief Medical

- information used to measure for improvement, not just assurance?
- W6.2 Do quality and sustainability both receive sufficient coverage in relevant meetings at all levels? Do all staff have sufficient access to information, and do they challenge it appropriately?
- W6.3 Are there clear and robust service performance measures, which are reported and monitored?
- W6.4 Are there effective arrangements to ensure that the information used to monitor, manage and report on quality and performance is accurate, valid, reliable, timely and relevant? What action is taken when issues are identified?
- W6.5 Are information technology systems used effectively to monitor and improve the quality of care?
- W6.6 Are there effective arrangements to ensure that data or notifications are submitted to external bodies as required?
- W6.7 Are there robust arrangements (including internal and external validation) to ensure the availability, integrity and confidentiality of identifiable data, records and data management systems, in line with data security standards? Are lessons learned when there are data security breaches?

misplaced forms or missing data.

NB: advice is that In cases where early medical abortion involves home abortion: When completing the Abortion Notification (HSA4) form, in section 4d ("name and address of treatment with prostaglandin") it is sufficient to record the address as "home" or "residence" as long as this is the same as that entered in section 3c ("patients details" -"postcode or complete address"), otherwise enter full details here. Section 4dii ("date of treatment with prostaglandin") should be recorded as the date on which you advise the patient self-administers misoprostol Refer to page 6 of https://bsacp.org.uk/approval-forhome-use-of-misoprostol-in-englandfrom-1-ianuary-2019/

#### Officer?

 In services where early medical abortion is provided, and the service supply the second medication (misoprostol) to the woman to take away and administer at home; How does the service know that the HSA4 form is completed appropriately to indicate that treatment was provided at home?

# Key line of enquiry: W7

Are the people who use services, the public, staff and external partners engaged and involved to support high-quality sustainable services?

5	Sustainable services?		
G	eneric prompts	Professional Standard	Sector specific guidance
R	eport sub-heading: <b>Engagement</b>		
•	W7.1 Are people's views and experiences gathered and acted on to shape and improve the services and culture? Does this include people in a range of equality groups?	RSOP 17: Patient Feedback and Complaints:     All approved places should have systems in place to undertake postcare patient satisfaction surveys and	How does the service review feedback from people who have used the service?
•	W7.2 Are people who use services, those close to them and their representatives actively engaged and involved in decision-making to shape services and culture? Does this include people in a range of equality groups?	feedback aimed at identifying women's experiences and views on the treatment they have received.	
•	W7.3 Are staff actively engaged so that their views are reflected in the planning and delivery of services and in shaping the culture? Does this include those with a protected characteristic?		
•	W7.4 Are there positive and collaborative relationships with external partners to build a shared understanding of challenges within the system and the needs of the relevant population, and to deliver services to meet those needs?		
•	W7.5 Is there transparency and openness with all stakeholders about performance?		

# Key line of enquiry: ${\it W8}$

W8. Are there robust systems and processes for learning, continuous improvement and innovation? Sector specific guidance **Prompts Professional standard** Report sub-heading: Learning, continuous improvement and innovation W8.1 In what ways do leaders and staff strive How has the service considered and for continuous learning, improvement and acted on serious incident innovation? Does this include participating in investigations and action plans? appropriate research projects and recognised accreditation schemes? W8.2 Are there standardised improvement tools and methods, and do staff have the skills to use them? W8.3 How effective is participation in and learning from internal and external reviews, including those related to mortality or the death of a person using the service? Is learning shared effectively and used to make improvements? W8.4 Do all staff regularly take time out to work together to resolve problems and to review individual and team objectives, processes and performance? Does this lead to improvements and innovation? W8.5 Are there systems to support improvement and innovation work, including objectives and rewards for staff, data systems, and processes for evaluating and sharing the results of improvement work?