

Inspection framework: Independent single specialty providers of keepsake/ souvenir baby scans using diagnostic ultrasound equipment and if provided Non-invasive prenatal testing NIPTs

Log of changes since last version

Section / Report sub heading	Page number	Detail of update
All	All	This is a new inspection framework
various	Pages: 8,9,12,14,15,18,19,20,23,24,27,28	Updated to include new sector specific prompts and feedback from PHE screening removal of safety thermometer as a sub heading under safe
Environment and Equipment	Page 6 & 7	Removal of reference to PAT testing and inclusion of HSE guidance on portable electrical equipment and MHRA guidance on medical devices
Learning from complaints and concerns	Page 33	Additional prompt relating to ISCAS included
Various		Use of term 'concern' to replace anomaly (other than in reference to NIPTs)
Mandatory Training	Page 4	Core skills training framework referenced
Safeguarding	Page 4	Links to safeguarding updated
Records	Page 11	Updated link to NICE QS15

Section / Report sub heading	Page number	Detail of update
Evidence based treatment and care	Page 17	Reference to updated information on PHE screening programme and NIPTs training
Compassionate care	Page 26	Updated links to NICE QS15
Understanding the patient and those close to them	Page 28	Updated links to NICE QS15
Meeting individual needs	Page 31	Updated link to NICE QS15
Learning from complaints	Page 34	Prompt added in relation to complaints handling
Culture	Page 38	Link added to WRES IN IH providers
Whole Framework	-	Additional or strengthen prompts in relation to baby scanning services - areas included training and continuous development, information given to the woman, monitoring of frequent scanning, links to other healthcare professionals, policy and procedures

Inspection framework: Independent single specialty providers of keepsake/souvenir baby scans using diagnostic ultrasound equipment and if provided Non-invasive prenatal testing NIPTs

Single Specialty: Keep sake/souvenir Baby scans using diagnostic ultrasound equipment (and if provided Non-invasive prenatal testing – NIPTS)

This inspection framework should be used when inspecting the following types of service:

1. Single specialty services providing keep sake baby scans using diagnostic ultrasound equipment for the purposes of taking keep sake videos or images rather than for clinical diagnostic purposes or as part of maternity/pregnancy pathway of care.

If the service also offers non-invasive prenatal testing (NIPTs) as part of its services or as a discreet service, this should also be included in the inspection. There are specific additional prompts set out in the framework to use in gathering evidence for this type of testing.

Areas to inspect*

The inspection team should carry out an initial visual inspection of each area. Consider your observations alongside data and surveillance to identify areas of risk or concern for further inspection.

- The waiting area/room
- The room/premises in which the ultrasound takes place and/or where blood is taken for NIPTs
- Blood storage facilities for NIPTs
- Scanning equipment
- Any store room/facilities

Interviews, focus groups, observations

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

- People who use services and those close to them
- Administrative staff such as reception
- The person undertaking the ultrasound/ultrasound practitioner and the person taking the blood for NIPTs

Service specific things to consider

Some services may also be providing other diagnostic services including ultrasound scans of other organs such as kidneys. Therefore in addition you may need the diagnostic imaging core service framework.

This particular service is not part of the woman's maternity pathway, and it is important that women who receive this service are still advised to attend their NHS scans by the provider, as part of the usual maternity pathway.

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 style="list-style-type: none"> S1.1 How are safety and safeguarding systems, processes and practices developed, implemented and communicated to staff? S1.5 Do staff receive effective training in safety systems, processes and practices? 	<ul style="list-style-type: none"> Core skills training framework 	<ul style="list-style-type: none"> What mandatory training do staff undertake?

Report sub-heading: Safeguarding

<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Safeguarding intranet page and inspector handbook on safeguarding includes guidance on level of training required and CQC inspection of safeguarding. This includes the 2018 position statement on safeguarding children training. Adult safeguarding roles and competencies for healthcare staff August 2018 	<ul style="list-style-type: none"> Do staff receive appropriate safeguarding training, does this cover children and vulnerable adults? Does the provider have a safeguarding policy accessible to all staff? If the service provides ultrasound services to adolescents under the age of 18 years are there appropriate child safeguarding arrangements?
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<p>harassment and discrimination in relation to protected characteristics under the Equality Act.</p> <ul style="list-style-type: none"> • S1.4 How is safety promoted in recruitment practice, arrangements to support staff, 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? • 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? 	<ul style="list-style-type: none"> • Safeguarding children and young people roles and competencies for healthcare staff January 2019 • Working Together to Safeguard Children: Working together to safeguard children: A guide to inter-agency working to safeguard and promote the welfare of children. • FGM guidance: https://www.gov.uk/government/publications/multi-agency-statutory-guidance-on-female-genital-mutilation 	
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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?
- S1.8 How are standards of cleanliness and hygiene maintained? Are there reliable systems in place to prevent and protect people from a healthcare-associated infection?

- [Ultrasound transducer decontamination - best practice summary](#)
- [Decontamination poster](#)
- [Health and Safety Executive BBV](#)

- What training do staff received in relation to infection control?
- Are appropriate cleaning procedures in place for ultrasound probes, following an abdominal examination?
- Are there suitable handwashing facilities?
- Who carries out the cleaning of the premises and equipment?
- Is there a cleaning schedule in place?
- Is cleaning equipment available and stored correctly?

For NIPTs

- Are appropriate arrangements in place to reduce risk of exposure to blood-borne viruses(BBV)? What are the arrangements?

Report sub-heading: **Environment and equipment**

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| <ul style="list-style-type: none"> • 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, where appropriate, treatment and disposal of waste.) | <ul style="list-style-type: none"> • HSE guidance on portable electrical equipment • MHRA managing medical devices • https://www.gov.uk/government/publications/ultrasound-what-it-is-how-it-works-and-the-impact-of-exposure/ultrasound-what-it-is-how-it-works-and-impact-of-exposure • BMUS Safety statements • Sonography ergonomics poster • Work related musculoskeletal disorders sonographers | <ul style="list-style-type: none"> • Is emergency/ first aid equipment readily available and appropriate for example, available in the examination room? • Is the emergency/first aid equipment regularly checked and what is the process for checking it? • Do the staff receive training in emergency/ first aid equipment? • Is appropriate equipment available for the procedures provided at the premises? • How are staff trained to use the equipment? • How is equipment maintained and serviced? How frequently is this done and is it in line with manufactures guidance? • What are the arrangements for disposal of any clinical waste? • Is appropriate Personal Protective Equipment available? |
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		<ul style="list-style-type: none"> • Is there adequate storage for consumables? • Does the environment promote the privacy and dignity of the woman? • How does the provider ensure that the scanning environment is set up to avoid work related musculoskeletal disorders (WRMSD)? <p>For NIPTs</p> <ul style="list-style-type: none"> • Is the environment appropriate for taking blood, how is this done? <p>How are sharps disposed of?</p> <ul style="list-style-type: none"> • How is the blood labelled, stored and sent away for processing , is there a system for tracking samples to the recipient laboratory ?
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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	Professional standard	Sector specific guidance
<ul style="list-style-type: none"> 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? 	<ul style="list-style-type: none"> https://www.gov.uk/government/publications/ultrasound-what-it-is-how-it-works-and-the-impact-of-exposure/ultrasound-what-it-is-how-it-works-and-impact-of-exposure 	<ul style="list-style-type: none"> How do they make sure people receive care quickly if an emergency situation arises on the premises? Are there clear processes to escalate unexpected or significant findings at the examination? How is this done and to whom? Are women still advised to attend their NHS scans as part of their maternity pathway? How is this done? Are women who undertake these scans given information about the risks of frequent scanning? How frequently are women scanned are there limits on the number of scans an individual woman can have? Are re-scanning rates monitored? How would the provider respond if they had a concern, did not detect the baby's heart beat or suspected a multiple pregnancy?

Report sub-heading: **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?

- What are the staffing arrangements, how many staff are there and what are their roles?
- What is the local induction policy for staff?
- If working alone, does the provider carry out risk assessments to minimise risks associated with lone working?
- Is there access to an appropriate healthcare professional if required e.g. the women's GP or is the woman directed to contact her midwife e.g. if there is a concern?

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?

Key line of enquiry: **S3**

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

Prompts

Professional standard

Sector specific guidance

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

- <https://www.nice.org.uk/guidance/qs15/chapter/Quality-statement-3-Information-exchange>

- Is sufficient information obtained from the woman prior to their scan e.g. allergies, number of weeks pregnant?

<p>may include test and imaging results, care and risk assessments, care plans and case notes.)</p> <ul style="list-style-type: none"> • 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.) 		<ul style="list-style-type: none"> • How does the person carrying out the scan/ sonographers access previous reports or images when a women attends multiple times? • Does the provider communicate with GPs or other healthcare professionals if required - for example if there is a possible concern? <p>For NIPTs</p> <ul style="list-style-type: none"> • How are test results communicated with the GP or other healthcare professionals if required e.g. if there is a possible concern or anomaly?
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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: Medicines		
<ul style="list-style-type: none"> • S4.1 How are medicines and medicines-related stationery managed (that is, ordered, transported, stored and disposed of safely and securely)? (This includes medical gases and emergency medicines and equipment.) • S4.2 Are medicines appropriately prescribed, administered and/or supplied to people in 		Not applicable in this service

<p>line with the relevant legislation, current national guidance or best available evidence?</p> <ul style="list-style-type: none"> • 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? 		
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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?

Prompts	Professional standard	Sector specific guidance
Report sub-heading: Incidents		
<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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. Never Events Policy and Revised Framework 2018 Never Events List 2018 Serious Incidents (SIs) should be investigated using the Serious Incident Framework 2015. Duty of Candour: As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred a registered provider must notify the relevant person that 	<ul style="list-style-type: none"> How is learning from incidents managed and disseminated? If something goes wrong with the scan how is it communicated to the woman? <p>NIPTs</p> <ul style="list-style-type: none"> If something goes wrong with the NIPTs how is it communicated to the woman?

<ul style="list-style-type: none"> • 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? 	<p>the incident has occurred, provide reasonable support to the relevant person in relation to the incident and offer an apology.</p>	
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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		
<ul style="list-style-type: none">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?	<ul style="list-style-type: none">guidelines for professional ultrasound-practiceWhat is ultrasound how does it work and what is the impact of exposure?https://phescreening.blog.gov.uk/2018/12/10/a-new-home-for-nipt-training-resource/	<ul style="list-style-type: none">How is national guidance taken into account when writing policies and procedures?How often are policies reviewed?

<ul style="list-style-type: none"> • 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? 		
<p>Report sub-heading: Nutrition and hydration</p>		
<ul style="list-style-type: none"> • 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? 		<ul style="list-style-type: none"> • Are any refreshments such as water made available at the premises?
<p>Report sub-heading: Pain relief</p>		
<ul style="list-style-type: none"> • E1.6 How is a person's pain assessed and managed, particularly for those people where there are difficulties in communicating? 		<p>Not applicable in this service</p>

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		
<ul style="list-style-type: none"> • E2.1 Is information about the outcomes of people's care and treatment (both physical and mental where appropriate) routinely collected and monitored? • 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? 		<ul style="list-style-type: none"> • How is the quality of the service monitored e.g. audit or peer review of images? <p>Scan & NIPTs</p> <ul style="list-style-type: none"> • If they identify a suspected anomaly on a scan or the woman receives a higher chance result for NIPTs, how do they confirm their suspected findings, and how do they review that and apply learning to practice?

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
Report sub heading: Competent staff		
<ul style="list-style-type: none"> • E3.1 Do people have their assessed needs, preferences and choices met by staff with the right skills and knowledge? • 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? 	<p>What is ultrasound how does it work and what is the impact of exposure?</p>	<ul style="list-style-type: none"> • Are staff who conduct the scan appropriately trained, how is this kept up to date? Who does the scan and how are results communicated to the woman? • Do staff undertake continuous professional development and is the training staff undertake monitored in any way by the provider? • Are equipment training records available for any staff who operate the equipment • Are staff trained on a) using the equipment and b) interpreting the images (to include sexing)? • What training do staff have to perform transvaginal scans, how are they assessed and what assurance does the provider have regarding this?

		<p>For NIPTs</p> <ul style="list-style-type: none">• What training do the staff who take the blood receive, and how is this kept up to date?• Are staff trained in any way to be able to explain and discuss the associated benefits and limitations of the NIPTs screening with women?
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Key line of enquiry: E4

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

Prompts	Professional standard	Sector specific guidance
Report sub-heading: Multidisciplinary working		
<ul style="list-style-type: none"> • 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, person-centred care and support when they use, or move between different services? • E4.4 Are all relevant teams, services and organisations informed when people are 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? 		<ul style="list-style-type: none"> • Does the provider communicate with GPs or other healthcare professionals if required for example if there is a possible anomaly or concern? • Does the provider have appropriate links with local safeguarding specialists/professionals if required? • For NIPTs • How is the woman referred to fetal medicine services if necessary, does this include any processes for confirming the woman has attended and entered care? • Does the provider seek feedback from the fetal medicines following a referral? • Does the provider communicate with GPs or other healthcare professionals if required?

		<ul style="list-style-type: none"> • What working arrangements are in place between the provider and the laboratory that does the test? Including detailed plans for tracking of sample, through receipt in lab, analysis, and receipt of result by the provider?
<p>Report sub-heading: Seven-day services</p>		
<ul style="list-style-type: none"> • 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: **Health promotion**

- E5.1 Are people identified who may need extra support? This includes:
 - people in the last 12 months of their lives
 - people at risk of developing a long-term condition
 - carers
- E5.2 How are people involved in regularly monitoring their health, including health assessments and checks, where appropriate and necessary
- E5.3 Are people who use services empowered and supported to manage their own health, care and wellbeing and to maximise their independence?
- 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?
- 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.)

Key line of enquiry: E6

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

Prompts	Professional standard	Sector specific guidance
Report sub-heading: Consent, Mental Capacity Act and DOLs		
<ul style="list-style-type: none"> 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 guidance? 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 ensure that it is used in a safe, 	<ul style="list-style-type: none"> 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 BMA Children and young people tool kit Gillick competence MHA 1983 Code of Practice (including children and young people – chapter 19) PHE: Ultrasound: what it is, how it works and impact of exposure. Section 5 of this guidance is of particular relevance to baby souvenir scans' https://www.gov.uk/government/public 	<ul style="list-style-type: none"> Is the woman's consent to care and treatment always sought in line with legislation and guidance? How does the service ensure that women using it are informed of the limitations and risks associated with the scan, so they can make an informed decision on proceeding with the scan? Are Parents-to-be seeking baby keep sake or souvenir scans' memorabilia scans provided with information published by Public Health England (PHE)? Is consent obtained to share information with the woman's GP and is the reason why this might be necessary, clearly explained to the woman? Does the service have a referral pathway for women experiencing acute anxiety or mental health crises during pregnancy? Are there any red flag indicators they look for e.g. repeat attendance?

<p>proportionate, and monitored way as part of a wider person centred support plan?</p> <ul style="list-style-type: none"> • 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? 	<p>ations/ultrasound-what-it-is-how-it-works-and-the-impact-of-exposure/ultrasound-what-it-is-how-it-works-and-impact-of-exposure</p> <ul style="list-style-type: none"> • http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp) or http://www.medicalprotection.org/uk/england-factsheets/consent-basics • https://www.gov.uk/government/publications/fetal-anomaly-screening-programme-standards 	<p>For NIPTs</p> <ul style="list-style-type: none"> • How does the service ensure that the woman fully understands the procedure and potential results of the test before consenting? • Is the woman's consent always sought in line with current legislation and guidance? • Is the woman's consent obtained to share information and results with their GP if necessary, is it documented and is the reason why this might be necessary clearly explained to the woman?
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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?

Prompts	Professional Standard	Sector specific guidance
Report sub-heading: Compassionate care		
<ul style="list-style-type: none"> • 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 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? 	<ul style="list-style-type: none"> • https://www.nice.org.uk/guidance/qs15/chapter/Quality-statement-1-Empathy-dignity-and-respect • https://www.nice.org.uk/guidance/qs15/chapter/Quality-statement-2-Contacts-for-ongoing-care 	<ul style="list-style-type: none"> • Are women who have the scan able to speak to the staff without being overheard?

<ul style="list-style-type: none"> • 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? 		
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Report sub-heading: Emotional support

<ul style="list-style-type: none"> • 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 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? 	<ul style="list-style-type: none"> • https://www.gov.uk/government/publications/ultrasound-what-it-is-how-it-works-and-the-impact-of-exposure/ultrasound-what-it-is-how-it-works-and-impact-of-exposure • Improving news delivery in ultrasound 	<ul style="list-style-type: none"> • Do staff provide women who use the service with information leaflets / written information to explain the procedure? Does the information reflect PHE advice on the potential risks associated with scans of this type? • If a potential concern is detected during the scan how is this communicated to the woman and what support is made available to them? • Do staff receive any training on how to communicate with the woman if something is wrong? • Are women provided with information and advice upon leaving? For
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		<p>example, do patients know who to contact if there is a concern or issue?</p> <p>For NIPTs</p> <ul style="list-style-type: none"> • Are women given appropriate information about the procedure and is it clearly explained? • What support is made available to the women when they receive their test results? • Are women given any additional information or signposted to other services which can offer support and counselling, or parent support groups?
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Report sub-heading: Understanding and involvement of patients and those close to them

<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • https://www.nice.org.uk/guidance/qs15/chapter/Quality-statement-5-Preferences-for-sharing-information • https://www.nice.org.uk/guidance/qs15/chapter/Quality-statement-6-Decision-making 	<ul style="list-style-type: none"> • Are women fully involved in the service they receive? • Do women who use the service fully understand the service and what they will receive as a result? • Do women describe knowing who to contact if they were worried about their condition or treatment after they have had their scan, or when they get home?
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<p>questions about their care and treatment? How are they supported to access these?</p> <ul style="list-style-type: none"> • C2.4 Are people empowered and supported, where necessary, to use and link with support networks and advocacy, so that it will 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? 		<ul style="list-style-type: none"> • Is information regarding safeguarding from abuse displayed where service users will see it? • In cases where the woman will be responsible for full or partial cost of care or treatment, are there appropriate discussions about cost? • Is information and support provided in a child friendly format to help adolescents under 18 years of age to make decisions about or agree to care and treatment (including consent/assessment). <p>For NIPTs</p> <ul style="list-style-type: none"> • Is it made clear what type of NIPTs is being undertaken in the laboratory and what it will report? • Do women describe knowing who to contact if they are worried about their condition or treatment after they receive their results, or when they get home?
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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?

Prompts

Professional standard

Sector specific guidance

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 ensure flexibility, choice and continuity of care?
- R1.2 Where people's needs and choices are not being met, is this identified and used to inform how services are improved and developed?
- R1.3 Are the facilities and premises appropriate for the services that are delivered?

- Is the environment appropriate (comfortable / sufficient seating, toilets and magazines, drinks machine?)?
- Is information provided (to women) in accessible formats?
- Is the service flexible e.g. are appointments available during the evening and at weekends?

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 co-ordinated to be accessible and responsive to people with complex needs?¹
- 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?

- <https://www.nice.org.uk/guidance/qs15/chapter/Quality-statement-4-Individualised-care>

- How does the service ensure that appointments allow women sufficient time to ask questions?
- Is appropriate information made available in languages other than English? Is the information accessible and easy to read?

¹. For example, people living with dementia or people with a learning disability or autism.

<ul style="list-style-type: none">• 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?		
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Key line of enquiry: R3

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

Prompts	Professional standard	Sector specific guidance
Report sub-heading: Access and flow		
<ul style="list-style-type: none"> • 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 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 		<ul style="list-style-type: none"> • Are women offered a choice of appointments? • How long are women kept waiting once they arrive for their scan or NIPTs? • What is the waiting times for results?

technology (including telephone systems and online/digital services) easy to use?

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		
<ul style="list-style-type: none"> • 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 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? 	<ul style="list-style-type: none"> • The NHS constitution gives people the right to <ul style="list-style-type: none"> ➢ 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. ➢ Receive compensation if they have been harmed. <p>The Independent Sector Complaints Adjudication Service (ISCAS) is the patient complaints adjudication service for independent healthcare Only applicable though if the provider subscribes to ISCAS</p> <p>(please note that you may need to open this link in a non-IE browser)</p>	<ul style="list-style-type: none"> • How are complaints managed and what learning has been adopted from complaints, how was the learning applied? • Where the internal complaints process has been exhausted, what arrangements are in place for the independent review of complaints where the patient is receiving non-NHS funded care (e.g. is the service a member of the Independent Services Complaint Advisory Services (ISCAS) of which membership is voluntary, and if not, does the provider have an alternative arrangement?). This includes NHS Private Patient Units, whose patients do not have access to the PHSO if their care is not NHS funded.

<ul style="list-style-type: none"> • R4.5 To what extent are concerns and complaints used as an opportunity to learn and drive improvement? 		
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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
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Report sub-heading: **Leadership**

<ul style="list-style-type: none"> • W1.1 Do leaders have the skills, knowledge, experience and integrity that they need – both 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 		
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strategy or development programme, which includes succession planning?		
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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
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Report sub-heading: Vision and strategy

<ul style="list-style-type: none"> • 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? 		
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<ul style="list-style-type: none">• W2.6 Is progress against delivery of the strategy and local plans monitored and reviewed, and is there evidence to show this?		
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Key line of enquiry: **W3**

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

Prompts	Professional Standard	Sector specific guidance
Report sub-heading: Culture		
<ul style="list-style-type: none"> W3.1 Do staff feel supported, respected and valued? 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 vision 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? 	<ul style="list-style-type: none"> NMC Openness and honesty when things go wrong: the professional duty of candour NRLS - Being Open Communicating patient safety incidents with patients, their families and carers Duty of Candour – CQC guidance WRES in Independent health care providers 	<ul style="list-style-type: none"> What processes and procedures does the provider have to ensure they meet the duty of candour? For example, training, support for staff, policy and audits.

<ul style="list-style-type: none"> • 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 responsibility and resolve conflict quickly and constructively? 		
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Key line of enquiry: W4

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

Prompts	Professional Standard	Sector specific guidance
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Report sub-heading: **Governance**

<ul style="list-style-type: none"> • 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? 	<ul style="list-style-type: none"> • The Health Care and Associated Professions (Indemnity Arrangements) Order 2014 	<ul style="list-style-type: none"> • What are the governance procedures for managing the service? • How does the provider ensure that all staff undergo appropriate checks as required by Schedule 3 of the HSCA 2008 (Regulated Activities) Regulations 2014?
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<ul style="list-style-type: none"> W4.4 Are arrangements with partners and third-party providers governed and managed effectively to encourage appropriate interaction and promote coordinated, person-centred care? 		
<p>Key line of enquiry: W5</p>		
<p>W5. Are there clear and effective processes for managing risks, issues and performance?</p>		
<p>Prompts</p>	<p>Professional Standard</p>	<p>Sector specific guidance</p>
<p>Report sub-heading: Managing risks, issues and performance</p>		
<ul style="list-style-type: none"> W5.1 Are there comprehensive assurance systems, and are performance issues escalated appropriately through clear structures and processes? Are these regularly reviewed and improved? W5.2 Are there processes to manage current and future performance? Are these regularly reviewed and improved? 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'? 		<ul style="list-style-type: none"> How are the staff made aware of the provider's policies and procedures?

<ul style="list-style-type: none"> 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? 		
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Key line of enquiry: W6

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

Prompts	Professional Standard	Sector specific guidance
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Report sub-heading: **Managing information**

<ul style="list-style-type: none"> 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 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? 	<p>https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/</p> <p>CAP: Healthcare: Overview</p>	<ul style="list-style-type: none"> Is there a system in place to ensure women using the service are provided with a statement that includes terms and conditions of the services being provided to them and the amount and method of payment of fees? Are arrangements for advertising or promotional events in accordance with advertising legislation and professional guidance? What happens to videos or scans that are performed, how are they stored and for how long?
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<ul style="list-style-type: none"> • 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? 		
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Key line of enquiry: **W7**

W.7 Are the people who use services, the public, staff and external partners engaged and involved to support high-quality sustainable services?

Prompts	Professional Standard	Sector specific guidance
Report sub-heading: Engagement		
<ul style="list-style-type: none"> • 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? • 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? • 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? 		<ul style="list-style-type: none"> • Are customer surveys in use and are the questions sufficiently open ended to allow people to express themselves? • Is there evidence of change where appropriate from comments/complaints raised through customer surveys and the complaints process?

Key line of enquiry: **W8**

W8. Are there robust systems and processes for learning, continuous improvement and innovation?

Prompts	Professional standard	Sector specific guidance
Report sub-heading: Learning, continuous improvement and innovation		
<ul style="list-style-type: none"> • W8.1 In what ways do leaders and staff strive for continuous learning, improvement and innovation? Does this include participating in 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? 		