SoR 100 YEARS
THE SOCIETY OF RADIOGRAPHERS

Inclusive pregnancy status guidelines for ionising radiation: Diagnostic and therapeutic exposures

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Quartz House
207 Providence Square
Mill Street
London SE1 2EW

020 7740 7200
info@sor.org

www.sor.org

Transgender, non-binary, and intersex/variations in sex characteristics (VSC) inclusive practice begins with an active choice to change practice so that all are welcome and treated with dignity and compassion

Executive Summary

The Society of Radiographers (SoR) is the professional body and trade union for radiographers and the radiographic support workforce in the United Kingdom. We are committed to supporting radiographers to address healthcare inequalities in diagnostic imaging and radiotherapy, and ensure patients have a voice in the way our services are designed and delivered, by promoting co-production in the development of radiographic research, educational resources and professional body guidance. This guidance was co-produced by therapeutic and diagnostic radiographers, patients and people who are experts by experience.

Radiographers and other healthcare professionals, such as assistant practitioners, nuclear medicine technologists, sonographers, nurses, radiologists and clinical oncologists, all have a duty to reduce the risk of harm to patients in their care. It is a minimum requirement for registrants with healthcare regulators and is a common principle across the professions. When we refer to radiographers in this guidance, we include the radiographic workforce as a whole.

Inclusive practice, or behaving in a way that makes all people or groups of people feel included and valued, is integral to effective healthcare[1]. In 2020 Brighton and Sussex University Hospitals NHS Trust published Perinatal care for trans and non-binary people[2] which highlights the importance of recognising the preferred terminology individuals may have for their own anatomy. An example of this, used throughout this guidance, is breast/chest feeding. Radiographers should be led by the narrative chosen by the person with whom they are communicating.

It could be argued that the focus of risk management in diagnostic imaging (including nuclear medicine) and radiotherapy is primarily on ionising radiations, but patients might also be at risk of harm from our actions and inactions if we fail to practice in an inclusive way. The guidance provides the foundations for gender-inclusive practice in radiography. In particular it focuses on compliance with the pregnancy enquiry element of the requirement of Schedule 2 paragraph 1(c) of the Ionising Radiation (Medical Exposure) Regulations 2017[3] and the (Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018[4], hereafter referred to collectively as IR(ME)R. The underlying principles can be applied to existing breast/chest feeding enquiry procedures. Considerations when developing employer's written procedures are suggested for radiotherapy (appendix 1) and diagnostic imaging, including nuclear medicine (appendix 2).

There are overarching principles and valuable learning points throughout that apply equally to non-ionising radiation practices such as magnetic resonance imaging and ultrasound.

Understanding gender diversity and diversity in sex characteristics enhances safe practice. We present some of the considerations for healthcare professionals delivering care to transgender, non-binary and intersex (TNBI) individuals. People are all different and have personal health and care needs. It is the responsibility of all radiographers to develop competent skills to recognise and support those needs. Some people experience social exclusion due to their sexual orientation, gender identity or physical variations in sex characteristics (VSC). This may put them at increased risk during their pathway though diagnostic imaging, nuclear medicine or radiotherapy. Well-trained, informed and non-judgemental radiographers are advocates for the safe navigation of patients through their diagnostic and treatment journeys.

Using this guidance and the associated resources – the checklist, patient questionnaires, patient information leaflet and patient poster – will support services to comply with the legislation. It will improve understanding of the complexities associated with the health and care needs of two distinct groups: those with gender diversity and those with diversity in their physical sex characteristics. It describes the language and behaviours recognised as respectful and compassionate. It introduces the Inclusive Pregnancy Status (IPS) form for diagnostic imaging and radiotherapy; this is a questionnaire that enables patients and healthcare professionals to work together to sensitively build a picture of an individual patient's needs, gain informed consent and keep appropriate documented records. The guidance offers scenarios to illustrate some challenging situations radiographers might experience and provides options and solutions that respect individual choice and preserve dignity while achieving the most effective outcome for the patient.

The IPS forms have been piloted by the authors, and the results and associated learning from this are discussed. A key recommendation from the pilot studies is the need to educate the workforce and for radiology, nuclear medicine and radiotherapy service managers to prepare staff for a change in practice. Similarly, a patient information poster has been developed to explain to patients why these questions are asked.

It is considered pivotal to the successful implementation of the IPS forms for radiographers to work together with Medical Physics Experts (MPEs) and medical colleagues to develop consistent local procedures that comply with the requirement of IR(ME)R Schedule 2 paragraph 1(c) and are in line with the principles of this guidance. Suggestions for inclusion criteria for written procedures can be found in Appendices 1 and 2.

This guidance was produced in response to radiographers seeking advice from the Society of Radiographers about how to make their patient environments more inclusive and how to ensure their radiographic practice meets current legislative requirements. It supports employers to ensure their written procedures are fit for purpose and enables operators and practitioners to comply with IR(ME)R regulation 10(1).

The SoR would like to thank each member of the working party for their time, care and commitment in producing this guidance and to Lizzy Scott and Rachael Webster for their unfailing determination to improve the healthcare experiences of our gender-diverse population. Particular acknowledgement and the group's enormous gratitude must go to Stewart O'Callaghan, MSc, Founder and Executive Director of Live Through This for their wisdom, expertise, guidance and patience as we endeavoured to focus on our objectives and make this guidance current, relevant and safe. The group would like to acknowledge the time and expert advice freely offered by Valentino Vecchietti and Grace Murray of Intersex Equality Rights UK (IERUK) and thank them both for their valuable contribution to this document.

[1] Royal College of Nursing. (2020). Fair care for trans and non-binary people. Available at: https://www.rcn.org.uk/news-and-events/news/uk-updated-rcn-guidance-aims-to-ensure-fair-care-for-trans-patients-191120. Accessed: 15 October 2021.

[2] Green and Riddington. (2020). Perinatal Care for Trans and Non-Binary People. Available at: MP005-Perinatal-Care-for-Trans-and-Non-Binary-People.pdf (bsuh.nhs.uk). Accessed: 27 October 2021.

[3] UK Government. (2017). The Ionising Radiation (Medical Exposure) Regulations 2017. Available at: https://www.legislation.gov.uk/uksi/2017/1322/contents/made. Accessed: 15 October 2021.

[4] UK Government. (2018). The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018. Available at: https://www.legislation.gov.uk/nisr/2018/17/body/made. Accessed: 15 October 2021.

Glossary of Terms

These are terms used in the guidance. There are many terms that will be used by LGBTIQA+ communities that have not been listed; for more terms and definitions please visit the links provided in the further resources section.

Agender
A lived experience that does not relate to gender.

Assigned female at birth (AFAB)
Any person whose sex assignment at birth resulted in a declaration of 'female'.

Assigned male at birth (AMAB)
Any person whose sex assignment at birth resulted in a declaration of 'male'.

Chestfeeding
The act of feeding one's baby using one's chest or chest milk. Some people prefer to refer to their chest and chestfeeding rather than their breast and breastfeeding.

Cis/Cisgender
A person whose gender identity aligns with the sex they were assigned at birth. Pronounced 'sisgender' or 'sis'.

Cisnormative assumptions
A system of attitudes or beliefs that assumes people are cisgender or favours people who identify as such.

Deadname
A trans person's previous or birth name. It is considered offensive to use this name. 'Deadname' can be used as a noun and a verb.

Diverse sex development
A less commonly used umbrella term to refer to 40+ named naturally occurring variations in sex characteristics that a person can be born with. Diagnosis can occur in utero, in infancy, during childhood, as a teenager, or in adulthood. The abbreviation 'DSD' originally stood for the diagnostic umbrella term 'disorder of sex development,' which is broadly considered controversial by the intersex community because of its pathologising use of language. See also 'intersex', a commonly used cultural umbrella term, and 'variations in sex characteristics', a more recently coined umbrella term that is expected to become the legislative term for intersex. Also see 'sex characteristics'.

Endosex
A term used to describe a person whose innate sex characteristics and development typically conform to normative societal and medical expectations of either male or female. The antonym (opposite) is intersex.

Endosexism/Endonormative assumptions
The expectation, system or belief that assumes people will be endosex, and privileges/favours people with endosex bodies. Also see 'endosex' and 'intersex'.

Gender
A social construct informed by the norms, roles and behaviours that we attribute to being masculine, feminine or third gender.

Gender confirmation/affirmation
This replaces the term 'gender reassignment'. The process by which a person may undertake treatments to align their sex with their gender. Still referred to as gender reassignment in law and some other settings.

Gender dysphoria
The discomfort felt between one's gender and their sex assigned at birth. This may be mental, physical or social.

Gender expression
This is how an individual chooses to outwardly express their gender, which may or may not conform to societal 'norms'.

Gender fluid
A form of gender and expression that is not fixed.

Gender identity
An individual's personal sense of having a particular gender.

Gender Recognition Act (GRA) 2004
The Gender Recognition Act enables transgender people to apply to the Gender Recognition Panel to receive a Gender Recognition Certificate (GRC).

Gender Recognition Certificate (GRC)
People granted a GRC are, from the date of issue, considered in the eyes of the law to be of their acquired gender. This entitles a person to all the rights appropriate to a person of the acquired gender. This includes the right to retire and receive state pension at the age appropriate to the acquired gender and obtain a new birth certificate showing the recognised legal gender. A GRC is not retrospective and does not rewrite a person's gender history or affect things that occurred before it was issued.

Heteronormativity
A system of attitudes or beliefs that assumes or favours opposite-sex relationships and attraction.

Intersectionality
Theory introduced by Professor Kimberlé Crenshaw to describe how multiple facets of a person's identity can combine to make unique forms of oppression and discrimination. The theory was informed by Kimberlé's own experience of being both Black and a woman and the unique barriers she faces as a result.

Intersex
A commonly used umbrella term, which refers to 40+ named naturally occurring variations in sex characteristics that a person can be born with. Intersex is not an identity, it is a physical variation. Diagnosis can occur in utero, in infancy, during childhood, as a teenager, or in adulthood. Also see 'variations in sex characteristics' (VSC), 'diverse sex development' and 'sex characteristics'.

Interphobia
Prejudice, discrimination, fear or dislike towards someone who has a physical variation in their sex characteristics, commonly known as intersex. Intersex is not an identity; it is physical diversity that a person can be born with.

LGBTI
Initialisation of lesbian, gay, bisexual, transgender and intersex. Used to refer to three distinct marginalised community groups based on sexuality, gender identity and physical variations in sex characteristics. Although distinct, these three groups can also intersect. LGBTI (including the I after the T) has been used for many years throughout Europe, and the UK has now begun to update its usage too.

LGBTIQA+
A variant of LGBTI that includes lesbian, gay, bisexual, transgender, intersex, queer, asexual and others.

Misgendering
The act of accidentally or purposefully referring to or addressing a person by the incorrect gender and/or pronouns.

Non-binary
A term for people who do not identify with the discrete categories of male and female. This term includes a variety of gender expressions and identities.

Outing someone
Identifying someone as LGBTIQ+ without their consent. This is considered extremely harmful as there may be social factors or issues of safety involved in a person's choice to be discreet.

Pronoun
A word that takes the place of a noun in a sentence. The most common third-person pronouns we encounter are he, she and they. Correct pronoun use corresponding to a person's gender is important.

Protected characteristic
As a result of the 2010 Equality Act, it is unlawful to discriminate against someone on the grounds of any of these protected characteristics: age, disability, gender reassignment, marriage or civil partnership, pregnancy and maternity, race, religion/belief, sex (gender) and sexual orientation.

Sex
The underlying biological profile of a person. It influences a range of bodily responses that are important in tackling infection or disease.

Sex registration at birth
In the UK everyone is assigned either male or female at birth and this is recorded on their birth certificate. In the case of a person who is born with a variation in their sex characteristics, they will still be assigned a sex of either male or female at birth. So, it is not effective to use 'sex assigned at birth' as an identifier of expected internal anatomy in the case of this population. Also see 'intersex', 'endosex' and 'sex characteristics'.

Sex characteristics
Refers to each person's physical features relating to sex, including genitalia and other sexual and reproductive anatomy, chromosomes, hormones, and secondary physical features emerging from puberty. Just as diversity and variation naturally exists in sexuality and gender identity, diversity and variation also naturally exist in sex characteristics. See also 'intersex', 'variations in sex characteristics', 'diverse sex development' and 'endosex'.

SOGI
Shorthand for sexual orientation and gender identity.

Stealth
Community term describing the ability to live as your gender without disclosing your transition.

Third gender
A distinct form of gender from that of male or female. Often culturally informed with a rich history such as the Hijra, Māhū, Fa'afafine, Two-Spirit and Muxe.

TNBI
Transgender, non-binary and intersex.

Trans(gender) man
A man who was assigned female at birth.

Trans(gender) woman
A woman who was assigned male at birth.

Transfeminine
A person who was assigned male at birth but whose gender identity is more female than male.

Transgender
An umbrella term for a person whose gender identity differs from the one they were assigned at birth.

Transition/Transitioning
The process by which an individual may make changes to their physical (eg. sex characteristics) and/or social (eg. behaviours, clothing, legal etc) presentation to live as the gender identity with which they identify.

Transmasculine
A person who was assigned female at birth but whose gender identity is more male than female.

Transphobia
Prejudice, discrimination, fear or dislike towards someone that is transgender based on their identity.

Variations in sex characteristics (VSC)
An umbrella term used to refer to 40+ named naturally occurring variations in sex characteristics that a person can be born with. Diagnosis can occur in utero, in infancy, during childhood, as a teenager or in adulthood. VSC is expected to become the legislative term for intersex. Also see 'intersex', a commonly used cultural umbrella term for VSC, and 'diverse sex development', another umbrella term, which is less common. Also see 'sex characteristics'.

Rationale

There are approximately 5–600,000 people who identify as transgender or non-binary in the UK. This is the best estimate based on 1% of the population [1,5]. Upper estimates of adults identifying as trans or non-binary are as high as 4.5% of the population when including full gender variance[6]. Publications use best estimates as some people might not want to disclose, some may be living in stealth and, until recently, gender monitoring questions only included binary options of 'male or female' or 'prefer not to say', resulting in a lack of accurate data.

It has been estimated that 1.7% of people are born with variations in sex characteristics (VSC)/intersex globally, and some of these individuals may have childbearing potential[7]. VSC/intersex occurs naturally and relates to physicality rather than gender identity. VSC/intersex are umbrella terms used to describe physical sex development that differs from what is generally expected of 'males' or 'females'[8]. These variations are congenital and can be chromosomal, gonadal, anatomical or hormonal. VSC/intersex individuals might identify as cisgender, transgender or non-binary[9]. It is important that healthcare professionals do not conflate transgender status with having an intersex variation.

This guidance was produced in response to radiographers seeking advice from the Society of Radiographers about how to make their patient environments more inclusive and how to ensure their radiographic practice meets current legislative requirements. A working party was formed and chaired by two SoR therapeutic radiographers with a vision for what was required by the workforce. Diagnostic and nuclear medicine radiographers were invited via a call out through the Diagnostic Advisory Group and the SoR Equalise forum.

The guidance may be applied to diagnostic imaging (including nuclear medicine) and radiotherapy. It is designed to help healthcare professionals in the UK comply with the Ionising Radiation (Medical Exposure) Regulations 2017[3] and the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018[4] (known collectively as IR(ME)R), specifically regarding checking the pregnancy status of individuals of all gender identities and diverse sex characteristics. Schedule 2 of IR(ME)R, Employer's Procedures paragraph 1(c) states that written procedures for exposures must include "making enquiries of individuals of childbearing potential to establish whether the individual is or may be pregnant or breastfeeding"[3,4]. It is always necessary to avoid accidental or unintended radiation exposure to a fetus. This guidance acknowledges that nuclear medicine procedures might be diagnostic or therapeutic, and while the general principles of inclusive practice apply to both, breastfeeding enquiries are not specifically included in this guidance.

When the wording of IR(ME)R changed, primarily to reflect the fact that those undergoing non-medical imaging exposures do not necessarily have a medical condition and therefore might not be patients, it also highlighted the need to recognise a more diverse gender spectrum and to include the needs of VSC/intersex individuals.

Guidance published in 2020 by the Royal College of Radiologists (RCR) in response to IR(ME)R explains that departments need to consider that a transgender (trans) male or non-binary individual could have the capacity to become pregnant[10,11]. It is important to note that a person born with an intersex variation may have the potential to become pregnant and that pregnancy enquiries should include this group[8]. An increasing number of trans men and non-binary individuals choose to become pregnant, and some have done so accidently while taking cross-sex hormones such as testosterone, often

mistakenly believed to be a contraceptive[12]. Radiographers therefore need to have the underpinning education and skills to effectively meet the needs of patients attending for appointments who present as male or non-binary and have a uterus and ovaries or are intersex women with the potential to become pregnant. The Care Quality Commission (CQC) IR(ME)R annual report for 2019/20 states that all departments need to "make sure that procedures in imaging and radiotherapy departments are inclusive of transgender and non-binary patients, including the procedure for making pregnancy enquiries"[13]. It is important to note that it is against the law to discriminate against anyone because of a protected characteristic. The four key protected characteristics associated with possibility of pregnancy or breastfeeding are: gender reassignment; being pregnant; sex; and sexual orientation[14].

The CQC IR(ME)R annual report 2019/20 highlighted the need for inclusive language in employers' policies and procedures. The report illustrates a notifiable incident involving a transgender male patient who underwent a Computed Tomography (CT) scan without the possibility of pregnancy being checked. He was found to be pregnant. With the correct checks in place, this was an avoidable incident. The learning from this event is documented in the report and includes the employer developing patient information posters and implementing a high-level transgender policy. The employer also shared the associated risks with clinical teams and local LGBTQ+ services.

Considering this incident, and enquiries to the SoR, it became apparent that the diagnostic imaging, nuclear medicine and radiotherapy workforce would benefit from further support to develop safe and effective policies and procedures to check pregnancy that include transgender, non-binary and intersex (TNBI) patients. A working party was created to address the issues that TNBI patients face when asked about pregnancy status for ionising radiation exposures. The guidance includes information on how to support TNBI patients, practice-based scenarios and resources for radiographers and patients to ensure pregnancy and breastfeeding enquiries are undertaken in a safe and dignified manner. This is to maintain patient safety and equality of care for TNBI service users. In diagnostic imaging and radiotherapy, it is important to include TNBI people in conversations about pregnancy, breastfeeding and ionising radiation to gain informed consent for every episode of care. All patients must be able to access equitable, personalised care that is safe and clinically appropriate. Radiographers using effective communication skills will enable TNBI patients to feel safe and comfortable about disclosing their gender history when appropriate, and to experience person-centred care.

There is currently a lack of gender identity and VSC/intersex monitoring for TNBI individuals, both through the Office of National Statistics/census data and in the NHS[15]. This presents a challenge to healthcare professionals trying to serve their specific needs and minimise the risk of incidents and misdiagnoses. There is extensive UK legislation outlined in the Equality Act 2010[16] and the Gender Recognition Act 2004[17] that prohibits discrimination and prejudice on the grounds of gender identity. However, discrimination is still frequently experienced by transgender, non-binary and intersex people across healthcare providers, including NHS services. This is reflected in the National LGBT Survey summary report 2018[18]. Healthcare professionals must work together to tackle discrimination, and ensure people feel welcomed, supported and safe using healthcare services.

The information and resources included in this guidance have been extensively assessed through the SoR consultation process in collaboration with TNBI organisations and taking into account lay person and patient feedback.

The primary objective for this guidance is delivering safe and equitable care for transgender, non-binary and VSC/intersex people alongside compassionate and respectful care for all patients.

Implementation of the recommendations in the guidance should reflect and address the best interests of the patient.

[1] Royal College of Nursing. (2020). Fair care for trans and non-binary people. Available at: https://www.rcn.org.uk/news-and-events/news/uk-updated-rcn-guidance-aims-to-ensure-fair-care-for-trans-patients-191120. Accessed: 15 October 2021.

[3] UK Government. (2017). Ionising Radiation (Medical Exposure) Regulations 2017. Available at: https://www.legislation.gov.uk/uksi/2017/1322/contents/made. Accessed: 15 October 2021.

[4] UK Government, 2018. The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018. Available at: https://www.legislation.gov.uk/nisr/2018/17/body/made. Accessed: 15 October 2021.

[5] Stonewall. (2017). The truth about trans. Available at: https://www.stonewall.org.uk/truth-about-trans. Accessed: 9 August 2021.

[6] Zhang, Q., Goodman, M., Adams, N., Corneil, T. and Hashemi, L. (2020). Epidemiological considerations in transgender health: A systematic review with focus on higher quality data. *International Journal of Transgender Health*. 21(2): 125–137. DOI: 10.1080/26895269.2020.1753136.

[7] Blackless, M., Charuvastra, A., Derryck, A., Fausto-Sterling, A., Lausanne, K. and Lee, E. (2000). How sexually dimorphic are we? Review and synthesis. *American Journal of Human Biology*. 12(20): 151–166. DOI: 10.1002/(SICI)1520-6300(200003/04)12:2<151::AID-AJHB1>3.0.CO;2-F.

[8] Government Equalities Office. (2019). Variations in sex characteristics: technical paper. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/771468/VSC_Technical_Paper_Web_Accessible.pdf. Accessed: 15 October 2021.

[9] Furtado, P., Moraes, F., Lago, R., Barros, L., Toralles, M. and Barroso, U. (2012). Gender dysphoria associated with disorders of sex development. *Nature Reviews Urology*. 9(11): 620–627. DOI: 10.1038/nrurol.2012.182.

[10] Royal College of Radiologists. (2020). Ionising Radiation (Medical Exposure) Regulations: Implications for clinical practice in radiotherapy. Guidance from the Radiotherapy Board. Available at: https://www.rcr.ac.uk/sites/default/files/guidance-on-irmer-implications-for-clinical-practice-in-radiotherapy.pdf. Accessed: 3 August 2020.

[11] Royal College of Radiologists. (2020). Ionising Radiation (Medical Exposure) Regulations: Implications for clinical practice in diagnostic imaging, interventional radiology and diagnostic nuclear medicine. Available at: https://www.rcr.ac.uk/publication/irmer-implications-diagnostic-imaging-interventional-radiology-diagnostic-nuclear-medicine. Accessed: 3 August 2020.

[12] Obedin-Maliver, J. and Makadon, H. J. (2016). Transgender men and pregnancy. *Obstetric Medicine*. 9(1): 4–8. DOI:10.1177/1753495X15612658.

[13] Care Quality Commission. (2020). IR(ME)R annual report 2019/20: CQC's enforcement of the Ionising Radiation (Medical Exposure) Regulations 2017. Available at: https://www.cqc.org.uk/sites/default/files/20201021-IR%28ME%29R-Annual-Report-2019-20-FINAL.pdf. Accessed: 15 October 2021.

[14] UK Government. (Undated). Discrimination: your rights. Available at: https://www.gov.uk/discrimination-your-rights. Accessed: 3 August 2021.

[15] Government Equalities Office. (2018). LGBT Action Plan: Improving the lives of lesbian, gay, bisexual and transgender people. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/721367/GEO-LGBT-Action-Plan.pdf. Accessed: 15 October 2021.

[16] UK Government. (2010). Equality Act 2010. Available at: https://www.legislation.gov.uk/ukpga/2010/15/contents. Accessed: 15 October 2021.

[17] UK Government. (2004). Gender Recognition Act 2004. Available at: https://www.legislation.gov.uk/ukpga/2004/7/contents. Accessed: 15 October 2021.

[18] Government Equalities Office. (2018). National LGBT Survey: Summary report. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/722314/GEO-LGBT-Survey-Report.pdf. Accessed: 15 October 2021.

Language and communication

The use of gender-neutral and inclusive language by healthcare professionals is important, not just for those who identify as trans or non-binary but also for VSC/intersex individuals as well as a wider audience. Society is shifting towards gender-neutral and inclusive language becoming normalised and not being seen as something that only addresses the needs of a minority of the population. The use of such language helps to educate staff and patients alike about the diversity of gender and physical sex characteristics.

While it is not possible to list all the terms and definitions currently in use, the glossary in this guidance seeks to include those that radiographers are most likely to come across in relation to radiography practice. The glossary contains content reproduced from resources provided by Live Through This, the UK's only LGBTIQ+ cancer charity, and Intersex Equality Rights UK.

The further resources section at the end of the guidance document contains links to a few short videos that might support an understanding of some of the terms and definitions covered in the glossary.

When talking with patients, it is important not to assume the pronouns they use. A patient should always be asked 'What pronouns would you like me to use for you?' and 'How would you like to be addressed?' Throughout the time a patient is in the care of a healthcare professional, the patient should always be referred to as they have indicated they would like to be addressed, including the use of their preferred name. For example, it is not uncommon for people to use a middle name as the name they are known by. The use of incorrect pronouns and/or referring to a patient's birth name when they have clearly stated how they wish to be addressed (known as 'deadnaming') is disrespectful and offensive, and could act as a trigger for their gender dysphoria.

Similarly, it is important not to assume someone is endosex (see glossary). As previously mentioned, a proportion of patients will have VSC/intersex variations, and so with this in mind, language should be respectful of this possibility. It is considered best practice to use the language used by the patient to describe their variation.

While mistakes may occur inadvertently, recognising and correcting such mistakes is an important part of learning. When a mistake is made, it is important to simply acknowledge the error and apologise. The patient could be asked for their pronouns or name to correctly address them, demonstrating changed behaviour. Healthcare professionals should provide a respectful apology, taking into account any discomfort this might cause. One way to limit the possibility of making a mistake would be to mirror the language the patient uses about themselves. This could either be when they are referring to themselves or when anyone who is attending an appointment with them does so. Do not assume the identity or relationship of the person/people that come with the patient. Use of the NHS Rainbow Badge scheme (see below) is one example of how radiology departments can show they are endeavouring to improve communication with their TNBI patients.

Mistakes may occur inadvertently but recognising and correcting such mistakes is an important part of learning.

NHS Rainbow Badge scheme

Not everyone finds it easy to talk about their gender or sexuality, and in a healthcare setting this may be even harder. The Government's National LGBT Survey in 2018 found that 40% of trans respondents who had tried to access public healthcare services in the previous year had experienced some form of negative reaction due to their gender identity. Furthermore, it was found that 18% of trans patients did not seek medical attention for fear of a negative reaction, while a further 18% had been on the receiving end of inappropriate curiosity[18].

Bolderston and Ralph (2016)[19] looked at the healthcare experiences of LGBT patients and highlighted the importance of healthcare professionals having an appropriate understanding of the specific issues facing this section of the population. Their paper sets out three main suggestions for healthcare providers to implement:

- Make positive changes to the healthcare environment by means of including literature/posters that make people feel welcome and let them know they are in a safe and welcoming space.
- Improve the form-filling aspect of many healthcare encounters to make it more inclusive.
- Eliminate barriers to care that often result from a lack of knowledge on behalf of healthcare professionals.

Adoption of the NHS Rainbow Badge scheme can help change the appearance of the environment[20]. The scheme was created by the Evelina London Children's Hospital as an initiative to promote inclusion for younger patients, helping to make it easier for them to approach staff and feel comfortable talking about issues around their sexuality or gender identity. The initiative proved so successful that it has now become a nationwide scheme for all age groups and is administered by charities such as the LGBT Foundation and Stonewall on behalf of NHS England. It aims to help promote inclusivity and make hospitals and other healthcare settings non-judgemental spaces for all LGBT+ patients, staff and visitors.

Why does it matter to have an awareness of gender and VSC/intersex?

As healthcare professionals it is important to have an awareness of gender identity and variations in sex characteristics and how they impact on the care provided for patients. It is not the job of a trans, non-binary or VSC/intersex patient to educate healthcare professionals on how this relates to their healthcare. Shepherd, Hanckel and Guise (2019) explored trans health and the risks of inappropriate curiosities, suggesting further appropriate resources for continued learning[21]. Educating yourself by accessing materials specifically produced to train and teach healthcare professionals is the most appropriate way to learn more and be able to better care for TNBI patients.

Sanders and Pedersen's 2018 guest editorial in *Radiography* suggested measures that could be introduced in imaging departments to improve communication with the gender-diverse community[22]. This included a template for the SIGE (Sex, Identity, Gender, and Expression) form on which the Inclusive Pregnancy Status (IPS) form is based.

> Some people registered female at birth will have an intersex variation and may not have a uterus. Therefore, it is important to identify this in early communications to avoid pursuing further unnecessary and potentially distressing enquiries.

Gender identity monitoring

In England, Wales and Northern Ireland, a patient wishing to change their name and/or gender marker on their medical records does so by contacting their GP. The GP initiates the process that ultimately results in the patient being issued a new NHS number. This update then filters down to hospital/radiology information systems. In Scotland, patients have a Community Health Index (CHI) number rather than an NHS number; however, the process for change remains broadly similar to that for patients in England, Wales and Northern Ireland.

A person does not require a Gender Recognition Certificate (GRC) or any other legal documentation to enable them to ask their GP to update their name and/or gender markers, and they need not have undergone any medical interventions related to their gender transition before they can request this. Keeping accurate records for TNBI patients ensures appropriate care is delivered across healthcare services. An example of this is whether a patient is invited to attend a national cancer screening programme, such as the NHS Cervical Screening Programme or NHS Breast Screening Programme.

The Gender Triangle

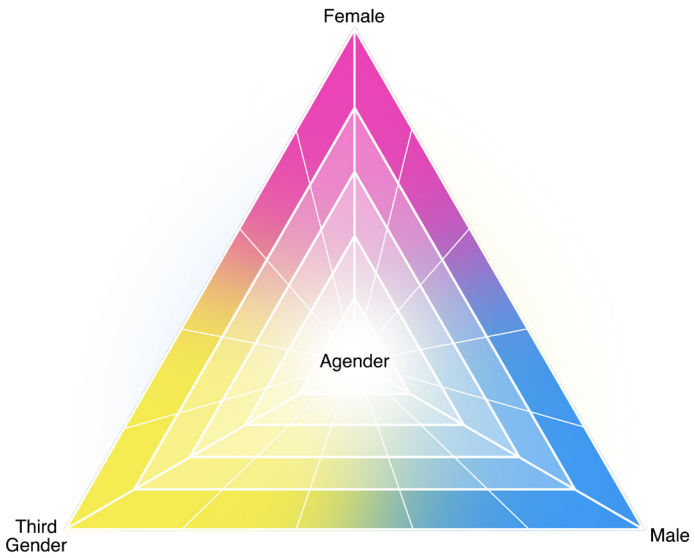

Image 1: Courtesy of O'Callaghan, S. (2021). Provider Pack: Breaking down barriers to LGBTIQ+ inclusive cancer care[23]

The Gender Triangle is a model that helps us to appreciate the spectrum of gender and where people might identify themselves within it.

Gender is a social construct informed by our views of which behaviours, social roles or relationships are considered masculine, feminine or outside these parameters. Currently, medical records only record sex in a binary format, and a person's gender tends to be inferred from this. This assumption can lead to interpersonal and system-based errors when it comes to caring for trans and non-binary patients. This model moves away from a binary understanding to a broader triangular approach where third genders, and other identities in between, are represented.

When we consider gender identity, it is important to appreciate that there is a broad scope for what is considered non-binary. Effectively, any point in the gender triangle that is not exclusively male or female might be considered in this way. For that reason, it is important to enable patients to self-identify and not to make assumptions.

A person might be agender, whereby they do not have a gender identity, or they might experience their gender in varying intensities, indicated by the levels radiating from the centre of the model. Another might be exclusively third gender, such as a two-spirit person. Others might feel somewhere in between these labels, and this is entirely okay. It might help to share this model with them to visually identify their gender identity if they lack the words to do so.

> For some, gender is a fixed part of their personhood. For others, this may be more fluid, and they may find themselves moving across the spectrum for a multitude of reasons or in different contexts. A person's gender identity may also shift over time, whereby a person transitions from one point on the model to another. They may choose to pursue gender transition-related healthcare, or they may not. Each person's transition is unique, and their gender identity should not be reduced to a medicalised view of their treatment history. You cannot assume a person's pronouns from their gender identity; it is always important to check.

Source: O'Callaghan, S. (2021). Provider Pack: Breaking down barriers to LGBTIQ+ inclusive cancer care[23].

Possible paths of transition

Transition is defined as the process by which a person brings their physical or social presentation into line with their gender identity. Transition is not a 'one size fits all' process. Each person's transition is unique and can be a combination of interventions that they feel are most appropriate to their transition goals. It should also be noted that some people might be in a position where other aspects of their health or pre-existing comorbidities might make routes of transition unfeasible. There are three main categories of transition:

- social – changing your gender expression to match your gender identity
- medical – taking hormones to affirm your gender identity
- surgical – having surgery to align your body with your gender identity.

A person may choose to undergo any combination of these actions to transition. It is important to note that surgery is not a de facto marker of transition 'success' or a 'completion' of transition, and we should not assume this in the people we meet.

Some surgical interventions, such as gender-affirming genital surgeries (also referred to as 'lower' or 'bottom' surgery), might have relevance in the application of radiation to the pelvis and for skin care following radiotherapy.

Transgender women and non-binary people assigned male at birth

Neovaginal surgery with bilateral orchiectomy may be undertaken by trans women and non-binary people assigned male at birth. The vaginal canal is most often achieved through penile inversion or sigmoid colon graft. During this process, the prostate remains in situ and is pushed slightly anterior by the space created for the vaginal canal. Externally, the vulva is often indistinguishable

from cisgender female anatomy. Some trans women or non-binary people may undertake a cosmetic vulvoplasty instead of neovaginal surgery. Again, the vulva is often indistinguishable from cisgender female anatomy, but there is no potential space for a vagina. It is therefore important to ensure which surgery a person has had, as it might not be obvious from external examination.

Uterine transplantation has resulted in live births in cisgender women and non-binary people assigned female at birth, but at the time of writing this guidance, has not yet been applied to transgender women and non-binary people assigned male at birth. However, there is discussion of its future viability and healthcare professionals should be aware of this as a potential for pregnancy.

Transgender men and non-binary people assigned female at birth

Phalloplasty or metoidioplasty may be undertaken by trans men and non-binary people assigned female at birth. Phalloplasty is the surgical creation of a penis, whereby a surgeon harvests one or more 'flaps' of skin and other tissues from a donor site on the body (usually the forearm but sometimes from the lower abdomen or buttocks) and uses it to form a penis.

Metoidioplasty is the surgical creation of a penis using existing genital tissue. It is considered a less extensive procedure than phalloplasty and is performed after the clitoris has been enlarged through testosterone therapy.

Not all trans men and non-binary people assigned female at birth will undergo a hysterectomy and/or vaginectomy. For this reason, it is important to check with all patients for any potential possibility of pregnancy.

Considerations for VSC/intersex individuals

VSC/intersex relates to physicality and is not included in the gender triangle. Medical records classify VSC/intersex infants as either male or female. This does not always concur with their primary or secondary sex characteristics. For example, some VSC/intersex women assigned female at birth will have XY chromosomes and will not have a uterus or ovaries and some VSC/intersex women will have XX chromosomes and will not have fallopian tubes.

Transition pathways for VSCs/intersex individuals can differ from pathways for trans endosex individuals. For example, a transgender man who has an intersex variation might not have ovaries or a uterus, but have XY chromosomes and been registered female at birth. Although in some cases the internal organs might correspond to the sex category assigned at birth, in other cases they might not.

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Respect and dignity

"*Everyone has the right to the highest attainable standard of physical and mental health, without discrimination on the basis of sexual orientation or gender identity*."[24,25]

It is important to note that healthcare professionals do not need to change their religious or personal beliefs to provide good care, and to treat each individual with respect and dignity. Healthcare professionals have a professional and moral duty to maintain patient dignity and treat people with equality and respect. These principles are reflected in the Society and College of Radiographers (SCoR) *Patient public and practitioner partnerships within imaging and radiotherapy: Guiding principles*[26].

Patient-centred care means understanding personal needs and involving patients in decisions about them. By doing so, healthcare professionals can deliver appropriate and tailored care. Every individual who accesses health and care services deserves the same high-quality compassionate care.

The Health and Care Professions Council (HCPC) is the regulator with which all radiographers must be registered. It is a requirement of the HCPC's standards of conduct, performance and ethics that registrants challenge discrimination[27]:

The HCPC code of conduct states:

"1.5 You must not discriminate against service users, carers or colleagues by allowing your personal views to affect your professional relationships or the care, treatment or other services that you provide."

"1.6 You must challenge colleagues if you think that they have discriminated against, or are discriminating against, service users, carers and colleagues."

Every effort must be made to challenge transphobia (prejudice or discrimination towards someone who is transgender based on their identity), interphobia (prejudice, discrimination, fear or dislike towards someone who has a physical variation in their sex characteristics), and harmful assumptions within services and wider society. Radiographers should show commitment and pay careful attention to using inclusive language and practices that reflect and celebrate an increasingly diverse society. TNBI people might go on to experience fear and anxiety accessing future healthcare services if they have had a poor experience in diagnostic imaging or radiotherapy, whether due to ignorance or intolerance. TNBI people might have already experienced distress due to previous negative experiences in healthcare settings, and radiographers have the opportunity to positively impact on this by preventing further inequalities in care.

It is essential to evidence and showcase open and inclusive environments in which TNBI people feel safe to ask and answer questions relating to pregnancy and breastfeeding. The IPS form demonstrates an inclusive approach, and the patient information posters begin to promote safe environments within which this sensitive information can be discussed. All healthcare providers should strive to create a psychologically safe environment that allows everyone to express their identity and be their authentic selves, without fear of negative repercussions.

According to *The NHS Patient Safety Strategy: Safer culture, safer systems, safer patients*[28], the key contributory factors to achieving this are:

- staff who feel psychologically safe themselves
- a strong culture of valuing and respecting diversity
- a compelling vision and commitment at director level
- determined leadership at all levels
- evidenced teamwork – non-judgemental attitudes, promoting equity, challenging discriminatory behaviour
- a focus on change – appropriate and continuous educational and learning support rather than punishment.

As discussed previously, language is key when creating a safe environment. Using gender-neutral language, such as 'partner', they/them pronouns and 'person', instead of gendered language minimises cisnormative and endornormative/endosexist assumptions (see Glossary). However, there is more that can be done to ensure people feel safe entering healthcare. Body language plays an important role in communication with patients. Radiographers should be adequately trained to be aware of, and avoid, their own negative facial expressions and judgemental or inappropriate tone of voice or body language.

Gender identity and sex characteristics are an important part of who we are; people should feel free to express themselves authentically. The NHS is working towards a culture of 'personalised care' that aims to treat the individual by considering a person's whole identity and physicality. This is essential in holistic care and has a direct impact on patient experience and outcomes. By recognising the needs of TNBI people within healthcare services, whether this is through avoiding misgendering (the act of accidentally or purposefully referring to or addressing a person by the incorrect gender and/or pronouns) or providing trans-inclusive and VSC/intersex-inclusive resources, healthcare professionals can treat everyone with the respect and dignity they deserve.

Using inclusive pregnancy-checking procedures demonstrates:

- an informed understanding of TNBI health
- appropriate knowledge and skills to provide best care
- compassionate and person-centred care.

It has been found that healthcare professionals lack knowledge and understanding of trans, non-binary and VSC/intersex healthcare. Webster and Drury-Smith (2021) summarised that transphobia and trans-exclusionary resources are still present throughout oncology, leading to harmful assumptions and the patient being afraid to disclose gender identity to healthcare professionals[29]. If patients feel uncomfortable, unsafe or anticipate a negative reaction, they might be less likely to disclose gender identity or variations in sex characteristics and pregnancy status.

Informed consent

The act of gaining informed consent is necessary for any procedure and should be undertaken for each and every episode of care.

The Yogyakarta Principles state that "all persons [should be] informed and empowered to make their own decisions regarding medical treatment and care, on the basis of genuinely informed consent, without discrimination on the basis of sexual orientation or gender identity", and sex characteristics are included in

the additional guidance of the Yogyakarta Principles plus 10[24,25]. TNBI people should be active participants in the healthcare processes that concern them. They must have full autonomy and responsibility over their own bodies, and therefore they must be able to decide on the treatments and interventions that affect them. To do so, they must be informed about all available options, their medical requirements and consequences[30].

Seeking patient consent prior to undertaking an examination or treatment procedure is not only a fundamental, ethical and legal requirement of all healthcare professionals, it is also a common courtesy as part of the process of creating a relationship of trust between healthcare professionals and the patient or service user. When carrying out any procedure, the healthcare professional is ultimately responsible for ensuring that the patient or service user is legitimately consenting to the procedure being undertaken. It is the healthcare professional who will be held responsible in law if this is later challenged[31]. Particular consideration should be given to obtaining consent from paediatric patients. More information can be found in the section of this report on additional considerations.

When considering consent for ionising radiation exposures, the requirement of IR(ME)R Schedule 2 paragraph 1(i) also applies.

> For radiation exposures, this means ensuring the person understands the benefits and risks to themselves and an unborn baby, as well as how we store information relating to their gender history, so that a TNBI person can make an informed decision.

Best practice points

'Practice pointers' for developing a more inclusive service – adapted from Education to improve cancer care for LGBTQ+ patients in the UK[32].

Area	Behaviour	Examples of good practice
Direct patient care	• Ask a patient's preferred name	'What name would you like me to use?'
	• Ask a patient's pronouns	'I need to make notes about our discussion, what pronouns should I use for you?'
	• Ask open questions about support networks	'Who are the people in your life that provide you with support?'
	• Explain why we are asking about sex registered at birth and pregnancy	'This procedure/treatment uses ionising radiation, which could be harmful to a fetus. Therefore, we need to ask if there is any possibility of pregnancy.'
	• Only ask about gender-affirming procedures and variations in sex characteristics if relevant to current management. In the case of pregnancy status enquiries, check if the patient is sure whether they could be pregnant	Use the IPS form with follow-up discussion with patient
	• Ensure patient is consistently addressed appropriately on letters and across all software systems throughout their management	

Area	Behaviour	Examples of good practice
Healthcare environment	• Train non-clinical staff in appropriate terminology in relation to sexual orientation, gender identity and variations in sex characteristics	The option to have staff badges that include pronouns with name and profession
	• Display gender-neutral posters that clearly depict pregnancy checking (please see SoR associated resources)	Posters, leaflets and videos that have TNBI-inclusive imagery, patient support groups/other resources
	• Wear the NHS Rainbow Badge or lanyard	
	• Ensure gender-neutral toilets are available and are clearly signposted	
	• Display posters with diverse imagery and TNBI-specific resources in clinic spaces	eg. the SoR/Fujifilm pregnancy check poster (see Further resources)
	• Include a gender-neutral patient information leaflet explaining pregnancy-checking procedures and what staff are doing to ensure a safe environment for patients living in stealth (please see SoR associated resources)	
	• Ensure your written procedures consider the needs of gender-diverse people across all patient pathways	Invite a TNBI patient representative to join patients and lay people in co- production initiatives for service design and delivery, 'no decision about me without me' Develop trust/board/organisational TNBI committees or networks
Improving the healthcare evidence base	• Encourage patient participation in research and address patient concerns about use of their data	See Further resources: LGBT Foundation. (2021). Good practice guide to monitoring sexual orientation and trans status 2021: If we're not counted, we don't count[33]
	• Encourage institutions to adopt sexual orientation and gender identity monitoring	
	• Encourage sexual orientation and gender identity to be included/ recorded in research studies	See: Studying trans: recommendations for ethical recruitment and collaboration with transgender participants in academic research[34]
Education	• Familiarise yourself with existing charity resources for TNBI patients	Royal College of General Practitioners (RCGP) LGBT Health Hub
	• Access existing TNBI healthcare educational resources	
	• Attend LGBTQ+ education events run by local organisations, charities and NHS trusts	SoR webinar on how to implement the IPS form and guidance Live Through This: healthcare training sessions and resources

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[34] Vincent, B. W. (2018). Studying trans: recommendations for ethical recruitment and collaboration with transgender participants in academic research. *Psychology & Sexuality*. 9(2): 102–106. DOI: 10.1080/19419899.2018.1434558. Available at: Studying trans: recommendations for ethical recruitment and collaboration with transgender participants in academic research: Psychology & Sexuality: Vol 9, No 2 (tandfonline.com). Accessed: 27 October 2021.

Privacy and legislation

Radiographers must work within the law. They must be aware of how the different aspects of legislation apply to each element of their clinical practice. For the purpose of this guidance, we will examine the implications under IR(ME)R, GRA 2004 and Equality Act 2010. For further information about legislation related to radiographic practice please take a look at the SoR website[35].

Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R)

Preventing unintentional exposure of a fetus is a basic and long-standing tenet in radiation safety practices. There has been a requirement for employers to have a written procedure in place for how this should be done since IR(ME)R legislation was first introduced in 2000. The regulations also make specific reference to considerations for individuals who could be pregnant or breastfeeding with regards to the justification (Regulation 11) and optimisation of exposures (Regulation 12).

Both IR(ME)R 2017 and the Northern Ireland regulations[3][4] came into force on 6 February 2018. One notable change in the updated legislation was in the wording of the requirements, which changed from "females of childbearing age" in IR(ME)R 2000, to "individuals of childbearing potential" in IR(ME)R. The revision is considered to address deficiencies in the historic models of gender used in UK law, when the historic model had always considered gender to be a binary and unchanging option. This model of gender is outdated and at odds with current knowledge and understanding of gender and its application in modern society. The change in wording of this requirement facilitates the provision of safe and equitable care to all service users, including cisgender, transgender, non-binary, endosex and intersex individuals.

While IR(ME)R might not stipulate that there must be formal written documentation of this pregnancy enquiry process, nor that such records must be retained, there are aspects of the regulations where it may be difficult to demonstrate legal compliance in the absence of any formal documentation. Part of the employer's legal responsibility is to ensure duty holders are compliant with written procedures provided by the employer (Regulation 6 (2)), as well as to establish a formal quality assurance programme for all written employer's procedures (Regulation 6 (5) (b)). There is also a legal responsibility on both practitioners and operators to comply with the employer's procedures, for which individual duty holders may wish to have a mechanism for demonstrating and evidencing their own legal compliance (Regulation 10 (1)). Furthermore, IR(ME)R stipulates that where relevant, an operator may not initiate an exposure unless they have made an enquiry of individuals of childbearing potential to ascertain if they may be pregnant or breastfeeding (Regulation 11(1) (f)). Under Regulation 19, any person being prosecuted for failing to comply with the requirements of IR(ME)R may offer in defence, evidence that they took all reasonable steps and showed due diligence to try and avoid committing the offence. The absence of documentation that a pregnancy status enquiry has taken place could harm a defendant's ability to demonstrate that they had shown due diligence to comply with Regulation 11(1) (f).

The preference for best practice models to include formal documentation and confirmation of pregnancy enquiries is also relevant with regards to the employer's responsibilities under Regulation 8 of IR(ME)R. Regulation 8 places a responsibility on employers to investigate, record the findings, and potentially notify the enforcing authorities when there is suspicion that a significant accidental or unintended exposure (SAUE), or a clinically significant accidental or unintended exposure (CSAUE) has occurred. Both the enforcing authorities and professional bodies have provided guidance around the definitions and criteria for an incident to be classed as an SAUE or a CSAUE[36,37].

As incident investigations always involve a retrospective review of events, clear procedures and good documentation practices are essential. Regulation 8 (4) requires the employer to notify the enforcing authority of an incident unless the preliminary investigation demonstrates "beyond reasonable doubt" that no incident has occurred. Formal documentation of enquiries to establish whether the individual is, or may be, pregnant or breast/chest feeding might be one method of providing reasonable doubt.

Schedule 2 and Regulation 6 require employers to have a written procedure for making pregnancy and breast/chest feeding enquiries, and best practice should include formal documentation of the questions asked and the individual's responses. This is likely to be strengthened, when appropriate, by a signature from both parties to acknowledge the enquiries were made and accurate responses provided. A record of this enquiry should be retained to facilitate retrospective review. This would then be available when required as part of an incident investigation, a procedure compliance audit, or as part of a quality assurance review of the adequacy of written procedures.

It is acknowledged that there is potential for the employer's responsibility for compliance with health and safety legislation to be at odds with their obligations to comply with equality and diversity legislation, in particular the Gender Recognition Act 2004 (GRA) and Equality Act 2010. The SoR believes providing adequate information in line with Schedule 2 paragraph 1(i) is key to ensuring actions are undertaken with the valid informed consent of each individual.

The Gender Recognition Act (GRA) 2004

The Gender Recognition Act 2004 (GRA)[17] was widely considered to be a ground-breaking piece of legislation that acknowledged and supported the rights of trans people living in the UK. One of its key functions was to provide people with a process to obtain a Gender Recognition Certificate (GRC) that would allow individuals to change the sex registered on their birth certificate and be legally recognised as their chosen gender. This process affects how marriage, criminal justice and pension laws apply to a person and is intended as a method to protect gender history. To apply for a GRC, a person must be over 18, have a formal diagnosis of gender dysphoria, have lived as their acquired gender continuously for at least 24 months, and declare that they intend to live as this gender for the rest of their lives. Not all trans people will apply for a GRC, and many in the trans community are petitioning for it to be updated due to its medicalised approach, associated costs and use of a strict binary gender model[38]. Between 2004 and 2020, 6,929 GRC applications were submitted, with a total of 6,010 certificates issued[39].

Holders of a GRC have legal protection. It is a criminal offence for someone acting in a professional capacity to disclose a person's trans status without their consent, with some minor and specific exceptions. It should be noted that in a healthcare setting disclosing a patient's gender history to another healthcare professional can only be done when it is directly related to their care or treatment and must be with the patient's consent. In TNBI-inclusive healthcare, this protection of privacy is considered best practice for all patients, regardless of GRC status.[1]

There is a process for re-registering gender on NHS records in England. There are very few instances when a person would be required to provide evidence that they hold a GRC (see Gender identity monitoring).

A trans person can legally change their name, title and gender on their patient record and does not need to have undergone gender reassignment treatment to do so. They will be given a new NHS number and must be registered as a new patient. All previous medical information will be transferred to the new NHS record but information relating to their previous identity should not be included.

The Equality Act 2010

The Equality Act 2010 (EA)[16] came into force on 1 October 2010, with some specific provisions that delayed enactment between April 2011 and October 2012. The Equality Act sought to replace several separate anti-discrimination laws with a single act to provide clarity and consistency of provisions. The Act defines nine separate groups of individuals as having a 'protected characteristic'. The Equality Act does not acknowledge VSC/intersex people.

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[1]Note: at the time of writing there has been public consultation around proposed changes to the legislation but no indication as to when an amendment of the GRA 2004 or new gender recognition legislation might be expected in the UK.

The EA defines gender reassignment as a protected characteristic. It is unlawful for a person to be treated less favourably because of a protected characteristic. Transgender people are protected by the EA when they access healthcare regardless of whether they are in possession of a GRC. A transgender person does not have to have undergone surgery for this protected characteristic to apply to them.

The legislation establishes a legal duty and responsibility for public sector service providers to consider all individuals when carrying out their day-to-day work, in shaping policies and delivering services. More explicitly, these service providers must seek to eliminate discrimination, harassment and victimisation. NHS providers are public service providers, and, as such, all NHS trusts must seek to meet the needs of, and minimise disadvantages experienced by, people and service users due to their protected characteristics. Furthermore, they should seek to encourage people with protected characteristics to participate in public life or other activities where participation is low. This aspect may be particularly pertinent with regards to the trans community, given the negative experience and avoidance of healthcare services that is reported in this patient group[40].

The Equality Act is intended to be proportionate and consider the potential for policies or services to have a substantial effect on, or discriminate against, all service users. Where it is well established that radiation services should routinely make pregnancy enquiries of individuals when there is risk of a fetal exposure to radiation, it would then seem appropriate that consideration for such enquiries should be made equitably to all service users where there is potential for this risk to exist.

Legal considerations when creating an IR(ME)R compliant procedure

When there is sufficient risk to justify the creation of a safety check for one group of individuals, to omit this safety check in another cohort with the same potential for harm is potentially discriminatory and could be considered grounds for prosecution under the Equality Act 2010 where the group being disadvantaged share a protected characteristic such as gender reassignment. To knowingly ignore the risk of harm to a group of patients sharing a protected characteristic does not fulfil the public service provider's obligations to promote equality within its service.

Consideration must also be given to which IR(ME)R duty holder the responsibility for making pregnancy enquiries is delegated to. While there might be a legal requirement for entitled referrers to provide sufficient and relevant medical history to inform and enable the practitioner to justify an exposure, it should be remembered that there is no explicit legal requirement within IR(ME)R for a referrer to undertake a pregnancy or breastfeeding enquiry. The responsibility for making pregnancy enquiries is an operator task. Where there is more than one operator, the employer's written procedure should clarify to which operator this task is delegated. IR(ME)R Regulation 11(1)(f)) requires that "a person must not carry out an exposure unless in the case of an individual of childbearing potential, the person has enquired whether that individual is pregnant or breastfeeding, if relevant".

If a patient is in possession of a Gender Recognition Certificate and does not consent to the referrer sharing information about their gender history, it could be a criminal offence to do so. The referring clinician's interaction with the patient might occur weeks in advance of the exposure taking place, which could call into question the validity of any enquiries made or consent obtained at that time. For this reason, the operator should always check that the referral information matches the information provided by the patient.

It is best practice for employer's procedures to require a formal record of pregnancy enquiries to be made, demonstrating IR(ME)R compliance by all relevant duty holders. Both the GRA and EA provide protections to preserve the privacy and dignity of individuals who are undergoing or have undergone gender reassignment, and allow that there should be no reference to an individual's sex registered at birth documented in the medical notes without their consent. It is therefore necessary to provide service users with a sufficient explanation as to why this information is recorded, as well as how and where it will be stored, and who may have access to that information, so that they can give informed consent for this information to be stored as part of their medical record.

Patients should be assured that their personal information will be stored in line with the General Data Protection Regulation (GDPR) and the Caldicott Principles[41,42]. As consent is required to store this information, it also means that an individual has the right to refuse to consent to this information being stored. If an individual does not consent to have this information stored and recorded in their medical records it creates a challenge for the service provider to fulfil their legal obligations to health and safety yet maintain their responsibilities for equality and diversity.

It is suggested that, due to the potential risk of harm, an employer's first legal obligation could be considered to be upholding the health and safety of the individual, creating a theoretical hierarchy of legal responsibility. At the time of writing, the authors are unable to find any evidence of UK case law where this theory has been tested.

Where an employer's written procedure requires enquiries to be made of all patients irrespective of their gender, it is considered appropriate for patients to be informed, before they complete a questionnaire relating to pregnancy, that this may also facilitate a more accurate clinical evaluation of the images by informing the reporting clinician of sex registered at birth. This might help a person decide what is in their best interests.

If a patient does not consent to the documentation of an enquiry regarding their gender history, it is recommended that a pragmatic solution is sought; one that is in line with the patient's wishes and satisfies the employer's legal responsibilities under IR(ME)R. In this case, the clinical urgency of the examination should be considered by the referrer and practitioner. The practitioner should re-evaluate the benefits and risks of continuing and rejustify the exposure when appropriate.

Given the potential for conflict between legal requirements in this instance, it is suggested that local employer's procedures are sufficiently robust to enable duty holders to meet their legal requirements under the IR(ME)R, GRA 2004 and EA 2010. Local procedures should be in place that detail how these reasoned decisions are documented. This should be supported by adequate training so healthcare professionals understand the various legal obligations. Recommendations for inclusion criteria in written procedures can be found in Appendices 1 and 2.

Summary

Complying with the IR(ME)R, GRA and EA can raise some challenges. A patient's gender history is protected by law, yet operators, as duty holders under IR(ME)R, must make enquiries about possible pregnancy to prevent harm to a fetus.

To comply with all aspects of legislation and to treat individuals with respect and dignity, radiographers making pregnancy and breastfeeding enquiries should:

- not rely on assumptions about a person's gender identity or sex characteristics
- be aware that the referrer may not have been able to share information about the transition or pregnancy status of a person, or been aware that the person had a VSC/intersex variation
- be aware that if a person consents to share their trans status, they might not be consenting to share it further, and so careful consideration must be made with regard to documentation for each episode of care
- know what is meant by informed consent
- ensure no one is disadvantaged because of their sex or gender
- ensure the same processes and procedures are applied to everyone
- know the procedure in the event that information on the possibility of pregnancy cannot be obtained or is unclear
- ensure all reasoned decisions are documented in line with local procedures.

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[42] Department of Health. (2013). Information: To share or not to share: Government response to the Caldicott Review. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/251750/9731-2901141-TSO-Caldicott-Government_Response_ACCESSIBLE.PDF. Accessed: 5 October 2021.

Inclusive Pregnancy Status (IPS) form: Putting guidance into practice

The Royal College of Radiologists[10,11] suggests using the SIGE (Sex, Identity, Gender, Expression) form created by Sanders and Pederson (2018), the first published recommendation for an inclusive pregnancy form for radiology[22]. There has been no pilot study or comprehensive study in the UK using the SIGE form, apart from a small study in a nuclear medicine department that asked for patient feedback[43,44]. The anatomical language on the form was described in the feedback as "harsh", and a simpler, more straightforward question was suggested. The working party has built on the work of Sanders and Pederson and consulted with UK trans charities and individuals to adapt the way pregnancy status questions are asked to suit all genders. Inclusive Pregnancy Status (IPS) forms for radiotherapy (appendix 3) and diagnostic imaging and nuclear medicine (appendix 4) were created to ascertain childbearing potential by firstly asking all patients aged 12–55 (this age range can vary slightly to reflect the defined local risk range) for sex registration at birth, and acknowledges VSC/intersex patients. The patient is directed to the second section on pregnancy status if it is relevant to them.

Why do we recommend asking about sex registration at birth?

It could be argued that it is better to ask every patient the question, 'do you have the potential to become pregnant?' rather than enquiring about their sex registration at birth first. This might avoid an individual feeling forced into outing themselves or disclosing a transition.

However, this could also lead to assumptions being made during the pregnancy enquiry that it is safe to proceed when in fact there is a risk of pregnancy (see scenario below). The IPS form is well positioned to not only protect pregnancy but also to give patients the opportunity to disclose sex registered at birth and/or their VSC/intersex status to avoid accidental or unintended radiation exposure. There is no obligation to disclose gender history as per the GRA (see Privacy and legislation), but healthcare professionals need to be consistent and clear in the information they give and the questions they ask patients. Patients might be more likely to benefit from disclosure when it is supportive of their health and is relevant to their care.

Scenario – Enquiry without the Inclusive Pregnancy Status form

An accidental or unintended exposure could be made on a pregnant individual when, for example, a trans male patient answers 'no' to the pregnancy enquiry because they mistakenly believe they cannot become pregnant while taking hormone therapy. The enquiry form does not have prompts for the radiographer to ask additional appropriate questions to ensure it is safe to proceed with the exposure. There is no further safety barrier to prevent unintended exposure of a fetus.

It is recommended that NHS services ask for a patient's sex registered at birth in addition to the sex/gender marker on their NHS record as an inclusive model of gender identity monitoring[33]. This two-step process is how a patient's trans status is identified (see Language and communication). By being consistent, greater continuity of care is achieved throughout health services. Healthcare providers should aim to provide clear opportunities for trans patients to safely disclose their gender history, such as during introductions or history taking. Staff need training and support to carry out these tasks sensitively and effectively.

Without an enquiry of sex registration at birth there is a possibility of a potential misdiagnosis due to assumptions about physical sex characteristics. Knowing the sex registered at birth can help with image interpretation and clinical evaluation. Assumptions can fail to appreciate the sex-based differences that can inform health, anatomy and diagnosis in radiology. As gender identity monitoring is not mandatory yet, asking those between the ages of 12 and 55 years ensures radiographers are asking sex registered at birth when it is relevant to that episode of care.

Scenario – Misdiagnosis with subsequent radiation incident

A trans female patient attends for an ultrasound scan of the abdomen. Identity checks were confirmed with the patient in accordance with local employer's procedures.

The patient was not given the opportunity to disclose their gender history. The ultrasound images showed a mass in the lower abdomen. The patient was referred for further investigation of the mass using CT and the exposure was justified by the practitioner.

Upon arrival in the CT department and having received information about the benefits and risks of having the CT scan, including the need to exclude pregnancy, the patient is asked to complete a form and confirms there is no possibility of pregnancy. The abdominal CT scan revealed the mass to be the prostate gland.

There are contributory factors to this incident. The failure to provide sufficient information to the patient or to ask sex registered at birth resulted in an avoidable radiation exposure. The patient had been given some information to enable them to consent to the procedure and it was their decision to continue. However, if they had been asked about their sex registered at birth, the ultrasound scan could have been interpreted differently. The exposure was justified in this case as the benefit of excluding a suspicious abdominal mass outweighed the risk of the exposure. However, it might not have been justified had all the information been available to the IR(ME)R practitioner.

Why are there two different forms?

There are significant differences in radiation risk, and therefore in practice, between diagnostic and therapeutic radiography. This is reflected in the two forms that have been designed.

Diagnostic imaging and nuclear medicine

In diagnostic imaging and nuclear medicine there is often very limited information about the patient on the referral and there may be no previous imaging history available. The risk of irradiating a fetus varies from negligible or very low in extremity limb radiography to higher in some CT, nuclear medicine and interventional procedures. Risk, anatomy being exposed, and population age demographics are some of the factors that should be considered in the appropriate use of the IPS form in diagnostic imaging.

Radiotherapy (including radionuclide therapy/molecular radiotherapy/nuclear medicine therapy)

In radiotherapy the patient has already been through an extensive diagnostic pathway and might have embarked on treatments such as surgery, chemotherapy, immunotherapy or hormone treatment. Consequently, asking about the patient's last menstrual period (LMP) can be unreliable as different cancer treatments can cause irregular menstruation or perimenopause.

The IPS form includes two statements that patients must acknowledge: understanding not to become pregnant during radiotherapy and understanding the possibility of pregnancy after hormone therapy or chemotherapy. Patients must also be advised that radiotherapy treatment can vary between one visit and seven weeks. The IPS form is valid for the episode of care; in this instance the episode of care equates to the current radiotherapy prescription. Therefore, any prolonged interval of care in radiotherapy would require pregnancy status to be checked again. An example could be the gap between external beam radiotherapy and the start of brachytherapy, which would be an interval in care requiring a further pregnancy check.

Due to the number of visits, patients should be asked about preferred names and pronouns at the first appointment or 'first day chat' rather than on the IPS form. With the patient's consent, this can then be recorded on the radiotherapy treatment system for radiographers to use throughout the patient's treatment.

Statement on the use of IPS form

The SoR and collaborating organisations support and recommend the use of the Inclusive Pregnancy Status form in diagnostic imaging, nuclear medicine and radiotherapy departments, as printed in these guidelines. These forms have been thoroughly assessed by the working party, TransActual, Live Through This, Teenage Cancer Trust, Intersex Equality Rights UK and, importantly, by TNBI patient representatives, patients with lived experience of cancer and patient partnership groups.

Both forms have been trialled in UK departments and patient and staff feedback analysed. See the section on UK pilot studies for a summary of the results. Any amendments to the questions should be assessed and discussed appropriately with patient involvement, including TNBI people.

> It is important to note that the form should be used in conjunction with the posters and leaflets provided in this guidance. Patients should be given the relevant information in a psychologically safe environment, meaning one in which they feel comfortable sharing personal details with healthcare professionals. This is especially important for TNBI patients who choose not to disclose their gender history or VSC/intersex status. Providing the right information and environment ensures patients are fully informed and supported to make the decision to consent to the use and storage of their personal information (see Respect and dignity).

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Practice-based scenarios

Potential scenario 1 – A patient is unwilling to complete the IPS form

- A patient attends an imaging appointment.
- They are given the information leaflet and the IPS form to fill in, but when called in for the examination, the patient explains they don't want to disclose which sex they were registered as at birth.
- The radiographer is empathetic and arranges more privacy to discuss this further. The radiographer explains why the information is required and how that information is stored, including who has access to it.
- The patient still does not wish to disclose. The radiographer asks if they are happy to answer the 'possibility of pregnancy' question only.
- The patient agrees, confirms there is no possibility of pregnancy and signs the IPS form.
- This is then added to their records as evidence that pregnancy status was checked, but no gender history is recorded.

Potential scenario 2 – A patient explains their VSC/intersex status

- A patient attends a CT scan of her pelvis and begins to complete the IPS form.
- The patient explains to the radiographer that she has an intersex variation and, despite being registered female at birth, was born without a uterus or ovaries.
- The radiographer asks permission to annotate this on the referral or IPS form so that the reporting radiographer or radiologist is aware when they report the CT scan.
- The patient agrees and signs the IPS form.

Possible scenario 3 – A patient is taking cross-sex hormones

- A patient attends radiotherapy CT planning, answers 'female' to the registered at birth question and answers 'no' to the possibility of pregnancy.
- Before the CT planning scan, they let the radiographer know they are now concerned that they might be pregnant as they have read the statement on testosterone on the form but thought the testosterone they had recently started taking would prevent pregnancy due to the very infrequent menstruation it had caused.
- Due to the uncertainty around ovulation timing, the radiographer follows local procedures to ascertain the possibility of pregnancy and discusses the outcome with the referring clinician and practitioner.
- The exposure is rejustified and the planning scan proceeds.
- The radiographer discusses future pregnancy prevention during radiotherapy treatment by using barrier contraception such as condoms.

UK pilot studies

Changes to clinical practice are best introduced in collaboration with those expected to undertake the change (eg. radiographers) and those impacted by the change (eg. patients).

Pilot studies tested the use of a version of the SIGE form that was later termed the IPS form.

Radiographers have been aware of the need to comply with the requirements of IR(ME)R to make enquiries of individuals of childbearing potential since February 2018. It has been the focus of guidance, organisational policies and procedures, and study events since this date. The UK IR(ME)R regulators (appendix 5) expect services to demonstrate how they meet this requirement, and so it is important that all IR(ME)R duty holders (nurses, assistant practitioners, radiographers, radiologists, clinical oncologists and other healthcare professionals) understand how they can do this sensitively and appropriately with all individuals in their care.

It is acknowledged that during the pilot studies, no VSC/intersex organisations or patients were included. However, Intersex Equality Rights UK was invited to collaborate during the development of this guidance, with subsequent amendments being made to all resources. Although these changes are significant in acknowledging VSC/intersex individuals, the overall rationale of the piloted IPS forms is unchanged.

Liverpool University Hospitals NHS Foundation Trust: Radiology pilot study

Initial groundwork to test the use of the IPS form was undertaken at the Royal Liverpool University Hospital (when it was part of Royal Liverpool and Broadgreen University Hospitals NHS Trust) in consultation with Cheshire and Merseyside Adult Gender Identity Collaborative (CMAGIC), Liverpool Transgender Best Practice Group and the NHS Liverpool Clinical Commissioning Group (CCG) Transgender Task and Finish Group to see how to improve practices in radiology. Further development into a pilot study to introduce the IPS form into clinical practice was completed at the then newly merged Liverpool University Hospitals NHS Foundation Trust. This included staff compliance and staff and patient feedback. Phase one of the pilot study was undertaken to determine the challenges associated with introducing this change in practice.

Analysis of the data highlighted:

- Radiographers – lack of understanding of the need for change, fear of change and lack of confidence around having the benefit/risk conversation with patients, fear of using the wrong language
- Patients – lack of understanding of the need to be asked about possibility of pregnancy, fear of disclosing pregnancy, embarrassment related to questions about gender identity.

Patient experience: Initial use of IPS form

Negative feedback was reported by a patient in the IPS form's early roll-out, which was found to be due to miscommunication and a lack of understanding by the radiographers completing the procedure. The patient had a transgender son, and she felt the attitude of the radiographer was derogatory and lacking in compassion and understanding.

This identified a need for effective staff engagement to ensure successful operational roll-out of the IPS questionnaire. It highlighted a need to educate and train staff and to provide adequate patient information to facilitate appropriate benefit–risk conversations. This was undertaken using staff meetings, where group discussions were encouraged to raise queries and address any concerns before the new procedure was implemented. Scenarios were used to demonstrate the importance of understanding gender-specific needs and language, including the impact on clinical evaluation of images in trans gender people. Posters were used to alert patients to the importance of disclosing a potential pregnancy.

Patient experience: Post staff training

Feedback from a patient with a transgender son was reported. This patient was positive about the inclusive nature of the department and the consideration radiographers gave to the potential unborn child in a transgender patient.

Phase two of the pilot study included staff and patient feedback questionnaires being implemented alongside the new Inclusive Pregnancy Status form. The questionnaires covered:

- measuring understanding of why the questions were asked in the IPS form
- how the questions were asked (eg. if privacy was maintained)
- whether any improvement could be made.

The findings from phase two are summarised as follows:

- Radiographers showed an understanding of the IPS form and the rationale for changing practice.
- Patient questionnaires resulted in positive feedback; however, understanding of the rationale was low until this was explained by the radiographer completing the procedure.
- Staff reported concerns that they might have ‘confrontational situations’ when asking the pregnancy status of those who are cis-male. However, 80% of cis-male patients completing the questionnaire said they were ‘OK’ with the IPS form and understood why this change in questioning was necessary.

Following educational engagement sessions exploring the wider implications of this practice change, staff reported higher levels of confidence and improved use of appropriate language when communicating benefit and risk information with TNBI individuals. Guidance around how to complete the IPS questionnaire together with the patient was found to be helpful to staff. Some reported preferring to leave a patient to complete the document alone and answer any questions later, and others preferred to complete it together with the patient to give guidance as required. If left alone to complete the form, the patient must first be given adequate information about the benefits and risk of radiation exposure to a fetus and then be given the opportunity, time and suitable environment to ask questions. As stated before, informed consent for each episode of care is required.

The aim in the UK is 100% compliance in the use of the new form and procedure. Radiographers should be supported to move away from the long-standing practice of only enquiring about pregnancy with those that present as female.

The SoR considers that missed opportunities to safeguard TNBI people due to ineffective procedures or inadequate IT systems are not acceptable.

Leeds Cancer Centre: Radiotherapy pilot study

A radiotherapy IPS pilot study was run during April 2021 at Leeds Cancer Centre. All patients aged 12–55 years were asked to answer an IPS questionnaire alongside the new IPS form on attendance at their radiotherapy planning scan appointment. This questionnaire asked patients for their understanding of the sex registration at birth question and the acknowledgement of the pregnancy status declaration. There was a comment box for suggested improvements to the form.

Results included the following:

- 37 patients completed the form.
- 30 identified as female and seven as male.
- None identified as transgender or non-binary.
- 34 out of 37 respondents (92%) answered 'very clear' or 'clear' in terms of the statements and wording of the form. There were no suggestions for improvement.
- Comments included "form straightforward" and "perfect!"

Radiographer compliance with the procedure was audited for April and May 2021, with a result of 96% compliance for patients aged 12–55 years completing the IPS. It is noted that there are a low number of cis men referred for radiotherapy in this age group, compared with cis women. This is assumed to be due to a lower rate of cancer incidence in those registered male at birth aged 12–55 years in the wider Yorkshire area. Radiographer experience was not audited, but anecdotal feedback has raised no issues and some positive responses from patients, including cis men (from whom radiographers were apprehensive of receiving a negative response) and a parent of a transgender child, who was very pleased to see evidence of inclusivity in a hospital setting.

The process is as follows:

- The IPS form is completed at CT planning and scanned into the patient's electronic notes in the trust computer system.
- During the introductory phone call, the day before treatment starts, patients who identify as registered female at birth on the IPS form are asked the pregnancy question again and verbally agree to the following statements.
  - "I understand that radiation can be harmful to an unborn child and confirm that there is no possibility I am or might be pregnant, or that I am currently or intending to breastfeed."
  - "I will inform staff if this situation changes at any point during the course of my radiotherapy treatment."
- This is part of an assessment form completed by the radiographer in the radiotherapy information system.
- The treatment radiographers performing their first day checks confirm that this assessment form was completed.

In concordance with the diagnostic study, staff education is key to ensuring compliance with this new protocol. Staff at Leeds Cancer Centre are also due to receive general education on LGBTIQA+ issues in radiotherapy and cancer care.

Cambridge University Hospitals NHS Foundation Trust: Radiotherapy pilot study

Compliance was assessed in May 2021 according to how many patients were asked about their pregnancy status in the age range required (12–55 years) during their radiotherapy CT planning appointment (the first appointment in radiotherapy when a CT scan is performed). It was found that only 50% of patients were asked about pregnancy status. The IPS form was rolled out during July 2021 alongside a patient feedback questionnaire.

The process of recording is as follows:

- The IPS form is given to the patient at their CT planning appointment; this is then checked by a radiographer in the CT room to ensure the patient has privacy for any follow-up discussion.
- The IPS form is signed by a radiographer and uploaded to the online radiotherapy system. It is stored in the 'documents' section where the consent form and radiotherapy planning documents are stored.
- On the first treatment appointment, the radiographer must check all documents as part of a '1st fraction check'. Included is the IPS form, which is checked and approved by the radiographer completing this task. This information will also allow the radiographer to make the decision regarding whether pregnancy status needs to be checked at the 'first day chat' (a meeting between patient and radiographer to discuss treatment process and side effects and answer any questions). An example would be if the patient has not completed an IPS form previously, or if they have ticked 'female registered at birth'.
- The check is then done during the first day chat and signed as per standard practice in the patient notes.

Results from July 2021 for CT planning appointments included an increase in compliance to 88.5%. Improvements can still be made, with 75% of forms filled correctly and 83% signed correctly by a radiographer. At the time of publication, data was still being collected for all the treatment units, as many patients had not yet started radiotherapy. The aim was to be 100% compliant in CT planning by the end of August and in treatment units by September 2021.

Patient feedback

A total of 41 completed feedback questionnaires were collected from patients during July 2021. Feedback was collected on their understanding of the form, their understanding of 'sex registered at birth', how clear the information was to them and if the environment was acceptable for being asked pregnancy status.

Results are as follows:

- 98% understood why they were being asked to fill in the IPS form.
- 95% understood what was meant by 'sex registered at birth'.
- 100% responded that the form was clear about avoiding pregnancy during radiotherapy planning and treatment.
- 93% agreed that the environment was acceptable
- Two patients commented that asking about the pregnancy of those who believe they are 'infertile' as a result of treatments for cancer is insensitive and can be very distressing to answer at every [radiology/radiotherapy] appointment. Further discussions with these patients were aimed at trying to explain the rationale and that the chance of infertility from cancer treatment (such as chemotherapy, and pelvic radiotherapy) is never 100% certain. Patients understood but said that radiographers should be mindful of this when asking these questions.

Based on the results, the department continue to use the IPS form and monitor patient feedback. Staff engagement and understanding has been key to its success in the radiotherapy department. Compliance data was being collected through to September 2021 and audited as per standard practice.

Recommendations for training and education

Based on the results of the pilot studies, it is recommended that a staff engagement exercise is undertaken to identify any knowledge and skills gaps in those acting as IR(ME)R operators (undertaking exposures, authorising under guidelines issued by the IR(ME)R practitioner, and making clinical evaluations) and those acting as IR(ME)R practitioners (justifying exposures). Particular attention should be given to communication skills for those undertaking the benefit and risk conversation with patients and carers.

Training considerations should include:

- Adequate understanding of the requirements of IR(ME)R and its application to individuals
- Adequate understanding of the requirements of the GRA and its application to individuals
- The Health and Care Professions Council (HCPC) standards of conduct, performance and ethics and standards of proficiency for radiographers, in particular the requirements to "not discriminate against service users, carers or colleagues by allowing your personal views to affect your professional relationships or the care, treatment or other services that you provide" and to "be aware of the impact of culture, equality and diversity on practice"
- Language – appropriate terminology and what is considered inappropriate/ what to avoid saying and doing
- The need for collaboration with the local Medical Physics Experts (MPEs) to identify 'at risk' groups, for example everyone undergoing radiotherapy or higher dose nuclear medicine examinations such as positron emission tomography (PET), anyone between the age of 12 and 55 where the pelvic region is exposed to ionising radiation in diagnostic imaging, and anyone administered a radioactive substance who is breast/chest feeding
- The importance of consistently applying procedures to everyone in 'at risk' groups
- The importance of not making assumptions about sex registered at birth based on how an individual presents themselves
- The importance of respecting an individual's right to consent (or not)
- The legal requirements for processing data and the implications of this regarding consent for a single episode of care.

Explaining the wider implications to staff and using real-life scenarios helps to ensure a better understanding of the essential changes required for modern inclusive practice. The primary objective for implementation of the guidance and documents must be to ensure the best interests of the patient.

Additional considerations

Children and adolescents

It is a requirement of IR(ME)R (Regulation 12 (8)(a)) that the practitioner and operator must pay particular attention in relation to medical exposures of children. It is important that all duty holders involved in the patient pathway recognise the additional considerations for children when considering benefit, risk, and potential for pregnancy[3],[4]. The number of children identifying as trans or non-binary is increasing[38]. In addition to this, United Nations Free & Equal campaign for intersex awareness notes that up to 1.7% of babies are born with sex characteristics that do not fit typical definitions of male and female.

Intersex is an umbrella term for over 40 different variations in sex characteristics. Some are recognised prenatally, and others become apparent in either childhood, adolescence or adulthood. It is therefore important that employer's procedures reflect these considerations.

Children are individuals aged under 16 in Scotland and under 18 in the rest of the UK. Unless established otherwise, young people aged 16 or 17 are generally considered to have sufficient capacity to consent to their own treatment[45] but children younger than this might be competent to give consent for themselves. For more information, please see *Obtaining consent: a clinical guideline for the diagnostic imaging and radiotherapy workforce*[31].

If a child is able to consent, pregnancy status can be discussed in private with them and the IPS form can be used in the same way as it would for an adult patient. For those who are not able to consent, the setting of the conversation will depend on the individual's circumstances and the presence of a parent or guardian who is authorised to consent on their behalf. The needs of each child should be assessed individually. Some children, potentially those who are younger, might not understand what is meant by 'sex registered at birth' and radiographers could rephrase using simpler language, such as 'were you born a boy or a girl?' or direct the question to a parent or guardian. Intersex children might also be uncertain about their potential to become pregnant. Navigating these conversations with appropriate communication is important to ensuring young people feel comfortable to disclose.

Patients under 18 might have socially transitioned with family, friends and at school, but are unlikely to have undergone gender affirmation surgery and/or hormone treatment, though patients over 16 with a history of puberty blockers can start cross-sex hormones[46]. Puberty blockers pause puberty until a child can be sure what interventions they might want as an adult. It is important that children in this position understand whether they could become pregnant or not.

Safeguarding

A child disclosing that they identify as transgender or non-binary is not a safeguarding issue. However, if a child, as part of the pregnancy discussion, discloses that they may be sexually active and they are under 13 years of age, this is a safeguarding risk that needs to be escalated to the appropriate paediatric safeguarding team. Under UK law, this is statutory rape (Sexual Offences Act 2003)[47] and the safety of the child is of paramount priority.

Nuclear medicine

For information relating to pregnancy and/or breastfeeding, please see the Administration of Radioactive Substances Advisory Committee (ARSAC) notes for guidance[48]. Anyone involved in the administration of radiopharmaceuticals should consult this document before revising written procedures relating to the requirement of IR(ME)R Schedule 2 paragraph 1(c). Particular attention should be given to Section 7: Pregnancy, conception, and breastfeeding. While the whole section is relevant to those administering radiopharmaceuticals, the key principles in relation to this guidance are noted.

Section 7.3 states the need for any individual of childbearing potential to be asked whether they are or might be pregnant, and that the employer's procedure should describe when and how enquires are made as well as specifying the age range of individuals who should be asked. Furthermore, Section 7.7 stipulates the need for documented evidence in relation to any enquiries made of pregnancy status.

With regard to individuals who are breast/chest feeding, or lactating, Section 7.18 states the need to give specific written instructions and to record these in the medical records. Sections 7.2 and 7.22 describe advice on potential dose to the infant from ingestion of breast/chest milk and precautions to take during administration of specific radioactive substances.

[45] NHS. (Undated). Children and young people: Consent to treatment. Available at: https://www.nhs.uk/conditions/consent-to-treatment/children/. Accessed: 9 August 2021.

[46] NHS. (Undated). Treatment: Gender dysphoria. Available at: https://www.nhs.uk/conditions/gender-dysphoria/treatment/. Accessed: 9 August 2021.

[47] UK Government. (2003). Sexual Offences Act 2003. Available at: https://www.legislation.gov.uk/ukpga/2003/42/contents. Accessed: 15 October 2021.

[48] Administration of Radioactive Substances Advisory Committee. (2014). Notes for guidance on the clinical administration of radiopharmaceuticals and use of sealed radioactive sources. Available at: https://www.gov.uk/government/publications/arsac-notes-for-guidance. Accessed: 15 October 2021.

Further resources

Websites

Gender Identity Research & Education Society (GIRES). Gender diversity training for primary care teams. Available at: https://www.gires.org.uk/e-learning/

Royal College of General Practitioners (RCGP) LGBT Health Hub

UN Free & Equal | INTERSEX AWARENESS (unfe.org)

Videos

Defining LGBTQ. Available at: https://www.youtube.com/watch?v=tRvFj3ugdWU

How to talk (and listen) to transgender people. Available at: https://www.ted.com/talks/jackson_bird_how_to_talk_and_listen_to_transgender_people#t-106857

A guide to pronouns and gender inclusive language. Available at: https://www.youtube.com/watch?v=cSENAfrv3TU

What are the symptoms of gender dysphoria? Transgender man explains. Available at: https://www.youtube.com/watch?v=rgrSSlqUukA

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LGBT Foundation. (2020). Hidden Figures: LGBT health inequalities in the UK. Available at: https://s3-eu-west-1.amazonaws.com/lgbt-website-media/Files/b9398153-0cca-40ea-abeb-f7d7c54d43af/Hidden%2520Figures%2520FULL%2520REPORT%2520Web%2520Version%2520Smaller.pdf

Sanders, V. and Pederson, S. (2018). Improving communication with the gender diverse community in diagnostic imaging departments. *Radiography*. 24: S3–S6. DOI: doi.org/10.1016/j.radi.2018.04.011.

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Appendix 1

Radiotherapy

Considerations for IR(ME)R employer's procedure for making enquiries of individuals of childbearing potential to establish whether the individual is or might be pregnant

- Define the individuals to whom the procedure applies (local risk group, including age range).
- Define when the procedure applies – prior to planning, verification and treatment.
- Consider the steps required for making the enquiry and recording the response (using the IPS form). Are there different outcomes for different responses? Perhaps illustrate with a flowchart.
- Consider where the information is recorded and for how long. Be mindful of who has access to this.
- Describe how to manage challenging situations, including when to seek further advice and from whom.
- If a pregnancy test is required, ensure a local procedure for this is referenced. The procedure should include:
  - the type of test required eg urine, blood
  - who undertakes the pregnancy test
  - the training and assessment of competency required to undertake the test and, where appropriate, deliver the results to the patient
  - how the result is delivered to the patient and by whom
  - where the result is documented.
- Define the actions to be taken:
  - when the pregnancy test is negative
  - when the pregnancy test is positive. Consider rejustification of the exposure, taking into account the use of alternative non-ionising imaging, the impact of delaying the procedure, obtaining patient consent to continue and involvement of an MPE for fetal dose assessment.
  - when pregnancy cannot be excluded (patient is unsure or does not consent to a pregnancy test).
- Consider how to proceed if the patient lacks capacity to answer the question or is unconscious or anaesthetised.
- Consider how to proceed if the patient consents to answering the questions but does not consent to the information being recorded.
- Consider who should sign and date the IPS form (usually the patient and the radiographer).
- Where there are multiple operators for an exposure, ensure the procedure makes it clear that the radiographer making the exposure is responsible for ensuring there is no possibility of pregnancy.

Appendix 2

Diagnostic Imaging (including nuclear medicine)

Considerations for IR(ME)R employer's procedure for making enquiries of individuals of childbearing potential to establish whether the individual is or might be pregnant

- Define the individuals to whom the procedure applies (local risk group, including age range).
- Define the exposures to which the procedure applies (or range of exposures, where appropriate).
- Consider the steps required for making the enquiry prior to the exposure and recording the response (using the IPS form). Are there different outcomes for different responses? Perhaps illustrate with a flowchart.
- Consider where the information is recorded and for how long. Be mindful of who has access to this.
- Where it is known that the patient is pregnant, consider the need for consultant-to-consultant discussion prior to making referrals.
- Describe how to manage challenging situations, including when to seek further advice and from whom.
- If a pregnancy test is required, ensure a local procedure for this is referenced. The procedure should include:
  - the type of test required eg urine, blood
  - who undertakes the pregnancy test
  - the training and assessment of competency required to undertake the test and, where appropriate, deliver the results to the patient
  - how the result is delivered to the patient and by whom
  - where the result is documented.
- Define the actions to be taken:
  - when the pregnancy test is negative
  - when the pregnancy test is positive. Consider rejustification of the exposure, taking into account the use of alternative non-ionising imaging, the impact of delaying the procedure, obtaining patient consent to continue and involvement of an MPE for fetal dose assessment.
  - when pregnancy cannot be excluded (patient is unsure or does not consent to a pregnancy test).
- Consider how to proceed if the patient lacks capacity to answer the question or is unconscious.
- For exposures in theatre when the patient is already anaesthetised, consider checking pregnancy status against the World Health Organization (WHO) Surgical Safety Checklist completed prior to anaesthesia administration.
- Consider how to proceed if the patient consents to answering the questions but does not consent to the information being recorded.
- Consider who should sign and date the IPS form (usually the patient and the radiographer).
- Where there are multiple operators for an exposure, ensure the procedure makes it clear that the radiographer making the exposure is responsible for ensuring there is no possibility of pregnancy.

Appendix 3

Radiotherapy Inclusive Pregnancy Status (IPS) form

(Embedded link to form)

The Inclusive Pregnancy Status (IPS) form was created to ascertain childbearing potential by firstly asking all patients aged 12–55 (this age range can vary slightly to reflect the defined local risk range) for sex registration at birth, and acknowledges VSC/intersex patients. The patient is directed to the second section on pregnancy status if it is relevant to them.

Appendix 4

Diagnostic Imaging and Nuclear Medicine Inclusive Pregnancy Status (IPS) form

(Embedded link to form)

The Inclusive Pregnancy Status (IPS) form was created to ascertain childbearing potential by firstly asking all patients aged 12–55 (this age range can vary slightly to reflect the defined local risk range) for sex registration at birth and acknowledges VSC/intersex patients. The patient is directed to the second section on pregnancy status if it is relevant to them.

Appendix 5

The IR(ME)R regulators in the United Kingdom

England: The Care Quality Commission
www.cqc.org.uk/irmer-notification

Wales: Healthcare Inspectorate Wales
IRMERIncidents@Wales.GSI.Gov.UK

Northern Ireland: The Regulation and Quality Improvement Authority
www.rqia.org.uk

Scotland: Healthcare Improvement Scotland
hcis.irmer@nhs.net

Appendix 6

Breastfeeding in individuals without childbearing potential

Although IR(ME)R requires a written procedure to ask 'individuals of childbearing potential' if they are breastfeeding, it should be noted that breastfeeding is possible in individuals without childbearing potential. The literature on cisgender women undergoing a hormonal/physical regimen to induce lactation outside of pregnancy (e.g. when adopting a baby) is somewhat established[1–5]. In recent years, this same regimen has been used to induce lactation in several trans women, who have been successful in feeding their babies[6–10]. Therefore, these individuals should also be given information about whether it is safe for them to continue breastfeeding after a nuclear medicine procedure.

Nuclear medicine

Following feedback, specific nuclear medicine considerations have been added to the guidelines. Inclusive pregnancy and breast/chest feeding enquiries should be considered alongside existing radiopharmaceutical administration procedures.

- After nuclear medicine therapy, patients will be advised not to become pregnant for a set period after the administration.
- After nuclear medicine therapy, individuals will be advised not to make somebody else pregnant for a set period after the administration. The original guidance focussed on people assigned female at birth (AFAB), but people assigned male at birth (AMAB) also need information regarding conception.
- Breastfeeding should be discussed when using the nuclear medicine therapy form as people must refrain from breastfeeding for a set period after nuclear medicine therapy administration.

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Dr Alison Berner
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Authors

Elizabeth Scott, Senior Therapeutic Radiographer. Leeds Cancer Centre **(joint chair)**

Rachael Webster, Senior Therapeutic Radiographer and Cancer Research UK (CRUK) RadNet Translational Research Radiographer. Cambridge University Hospital NHS Foundation Trust (**joint chair**)

Stewart O'Callaghan MSc, Founder and Executive Director. Live Through This

Ben Stuttard, Diagnostic Radiographer, Nuclear Medicine. Liverpool University Hospitals NHS Foundation Trust. Representative of SoR equalities group Equalise

Matthew Noonan, Radiology Research Manager and Lead Radiation Protection Supervisor (Royal Liverpool University Hospital). Liverpool University Hospitals NHS Foundation Trust

Kate Harrington, Advanced Radiographic Practitioner(trauma) and Main X-ray Area Lead. Liverpool University Hospitals NHS Foundation Trust

Andrea Bangay, OP, Mobiles and Paediatric Lead Radiographer. University College London Hospitals NHS Foundation Trust.

Lynda Johnson, Professional Officer for Clinical Imaging. Society of Radiographers

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