**RESPONSE OF THE UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND**

**TO THE CALL BY THE SPECIAL RAPPORTEUR ON THE RIGHTS OF PERSONS WITH DISABILITIES FOR CONTRIBUTIONS TO HER REPORT ON BIOETHICS AND DISABILITY**

In 1998, the Scotland Act, the Northern Ireland Act, and the Government of Wales Act established the three devolved legislatures and transferred to them some powers that were previously held at Westminster. Further powers have been devolved since these original acts, most recently through the Scotland Act 2016 and Wales Act 2017.  The UK’s devolution settlement means that the devolved administrations in Scotland, Wales and Northern Ireland are responsible for observing and implementing international obligations relating to devolved matters, which they do in consultation and agreement with the relevant UK Government Department, to ensure consistency. More generally, international relations, which include the negotiation of new international rights, is reserved to the UK.

* 1. **Please provide information on the legislative and policy framework in place in your country in relation to:**

*A) Pre-natal diagnosis*

The *2019/2020 National Genomic Test Directory for England* specifies which genomic tests are commissioned by the NHS in England, the technology by which they are available, and the patients who will be eligible to access a test.[[1]](#footnote-1) The Directory lists prenatal and carrier testing available as part of the *NHS National Genomics Service* announced in October 2018.

The *Human Fertilisation & Embryology Act 1990* (as amended), allows pre-implantation genetic diagnosis (PGD) in limited circumstances.[[2]](#footnote-2) Schedule 2, Section 1ZA of the act allows this, as follows:

*1) A licence under paragraph 1 cannot authorise the testing of an embryo, except for one or more of the following purposes—*

*(a) Establishing whether the embryo has a gene, chromosome or mitochondrion abnormality that may affect its capacity to result in a live birth,*

*(b) In a case where there is a particular risk that the embryo may have any gene, chromosome or mitochondrion abnormality, establishing whether it has that abnormality or any other gene, chromosome or mitochondrion abnormality,*

*(c) In a case where there is a particular risk that any resulting child will have or develop—*

*(i) a gender-related serious physical or mental disability,*

*(ii) a gender-related serious illness, or*

*(iii) any other gender-related serious medical condition,*

*establishing the sex of the embryo,*

*(d) In a case where a person (“the sibling”) who is the child of the persons whose gametes are used to bring about the creation of the embryo (or of either of those persons) suffers from a serious medical condition which could be treated by umbilical cord blood stem cells, bone marrow or other tissue of any resulting child, establishing whether the tissue of any resulting child would be compatible with that of the sibling, and*

*(e) In a case where uncertainty has arisen as to whether the embryo is one of those whose creation was brought about by using the gametes of particular persons, establishing whether it is.*

*2) A licence under paragraph 1 cannot authorise the testing of embryos for the purpose mentioned in sub-paragraph (1)(b) unless the Authority is satisfied—*

*(a) In relation to the abnormality of which there is a particular risk, and*

*(b) In relation to any other abnormality for which testing is to be authorised under sub-paragraph (1)(b),*

*that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition.*

*3) For the purposes of sub-paragraph (1)(c), a physical or mental disability, illness or other medical condition is gender-related if the Authority is satisfied that—*

*(a) It affects only one sex, or*

*(b) It affects one sex significantly more than the other.*

*4) In sub-paragraph (1)(d) the reference to “other tissue” of the resulting child does not include a reference to any whole organ of the child.*

In practical terms, the *Human Fertilisation & Embryology Authority* (HFEA) grants a licence after considering whether the clinical evidence meets the conditions of the Act, so that a rare condition is added to a list as being appropriate for testing by local genetic services.[[3]](#footnote-3) Pre-implementation genetic diagnosis is part of the NHS fertility service pathway, and so is commissioned Clinical Commissioning Groups (on their own or as part of local consortia).

The *NHS Fetal Anomaly Screening Programme* (FASP) is one of the 11 recommended screening programmes supported by the *UK National Screening Committee*. FASP offers screening for pregnant women to check the baby for fetal anomalies, Down’s, Edwards’ and Patau’s syndromes. A screening test is offered to pregnant women between 10+0 and 14+1 weeks of their pregnancy.[[4]](#footnote-4)

In Northern Ireland, population screening including antenatal screening and fetal anomaly screening, and associated diagnostic tests, are guided by the recommendations of the UK National Screening Committee. The Strategy for Maternity Care in Northern Ireland states that women should have appropriate access to prenatal scans and should, as necessary, be directed to appropriate support.

*B) Disability-related abortion*

In England, Scotland and Wales, the *Abortion Act 1967* permits termination of a pregnancy by a registered medical practitioner, subject to certain conditions.*[[5]](#footnote-5)*

Under the Act, abortion is legally available where two doctors agree that “there is a *substantial risk* that if the child were born it would suffer from *such physical or mental abnormalities to be seriously handicapped*”. These are commonly referred to as ‘Ground E’ abortions in reference to the applicable forms. There is no gestational term limit for abortions under this ground.

In each case, there should be a careful and sensitive enquiry as to the reason(s) for requesting an abortion. These reasons will be particularly complex in the case of abortions for fetal anomaly where the woman will need to be given time to understand the nature and severity of the condition so she is able to reach an informed decision about how to proceed and whether to continue with the pregnancy or seek a termination.

The decision to end what is usually a wanted pregnancy is extremely difficult and painful for most parents. The severity of the prognosis has a major bearing on their decision-making. Counselling is available at all stages of the screening pathway to support people as they come to terms with this extremely important decision.

At no stage should there be a bias towards abortion. Diagnosis or prognosis does not always tell the whole picture of each individual case. In 1990, when the grounds for abortion where amended, Parliament agreed that doctors were best placed to make these decisions with the woman and her family. All staff involved in the care of a woman, or couple, facing a possible termination of pregnancy must adopt a nondirective, non-judgmental and supportive approach.

The Royal College of Obstetricians and Gynaecologists has published guidance to help doctors and other health professionals support women and their families when a fetal abnormality is diagnosed and to help women to decide, within the bounds of the law, whether or not to have an abortion.[[6]](#footnote-6)

The Scottish Government also believes that patients should have access to safe abortion services, within the limits of the law. Therefore, patients should be free to choose whether to have an abortion or not where one of the grounds for the lawful termination of pregnancy under the Abortion Act 1967 is met. This includes allowing women the freedom to decide whether or not to terminate their pregnancy if a serious fetal abnormality is diagnosed.

The law in Northern Ireland is different. Currently, abortion is only lawful in Northern Ireland where the continuance of the pregnancy threatens the life of the woman, or would adversely affect her physical or mental health in a manner that is real and serious and permanent or long term. At present, fetal anomaly is not in itself grounds for a legal termination of pregnancy. However, the *Northern Ireland (Executive Formation etc) Act 2019* gained Royal Assent on 24 July 2019.[[7]](#footnote-7) Following amendments tabled in both houses, the Government is under a duty to bring forward regulations to introduce a new legal framework for abortion in Northern Ireland by 31 March 2020 if the Northern Ireland Executive is not reformed by 21 October 2019.

The Government will take this obligation very seriously if it comes into effect.

*C) Informed consent to medical treatment and scientific research*

It is a general legal and ethical principle that valid consent *must* be obtained from an individual before starting a treatment or physical intervention. For consent to be valid, it must be given voluntarily by an appropriately informed person who has the capacity to consent to the intervention in question and it must be given freely, without undue pressure or coercion. The *Health and Social Care Act 2008 (Regulated Activities) Regulations 2014* set out the principle that care and treatment must only be provided with the consent of the relevant person.[[8]](#footnote-8) For treatment, consent is usually verbal, i.e. a person will be asked to say whether they agree to any examination or treatment. If the examination or treatment is complicated, for example an operation, they may be asked to sign a form showing that they agree to it. Consent must be given before any aspect of the project starts. The *Medicines for Human Use (Clinical Trials) Regulations, Statutory Instrument No. 1031 (2004)* states in Schedule 1 Part 5 (‘Conditions and Principles which Apply in Relation to an Incapacitated Adult’) that informed consent given by a legal representative to an incapacitated adult in a clinical trial shall represent that adult’s presumed will.[[9]](#footnote-9) The *Mental Capacity Act 2005* also states that, where an individual does not have the relevant capacity to consent, any decision made for or on behalf of the person must be in their best interests.[[10]](#footnote-10) When determining the best interests of an individual, other relevant agencies and individuals involved in the care and support of the individual must be consulted.

The Mental Capacity Act 2005

The Mental Capacity Act also requires that all practical and appropriate steps be taken to enable a person to make the decision themselves. Sections 30-33 of the Act provide lawful authority for intrusive research to be carried out involving people without capacity, provided that the research has been approved by an appropriate body. An appropriate body is a Research Ethics Committee (REC) recognised by the Secretary of State or Welsh Ministers. All National Health Service (NHS)[[11]](#footnote-11) RECs in England and Wales are recognised. RECs in Scotland and Northern Ireland are not recognised for the purposes of the Mental Capacity Act.

The Act provides a comprehensive framework for decision making on behalf of adults aged 16 and over who are unable to make decisions for themselves. It applies to all decisions taken on behalf of people who permanently or temporarily lack capacity to make such decisions themselves, including decisions to include such people in research. All researchers working with research participants who lack, or may lack, capacity need to be aware of its underlying principles and the provisions relating to research.

The Act’s rules for research that includes people who lack capacity to consent to their involvement cover:

• When research can be carried out

• The ethical approval process

• Respecting the wishes and feelings of people who lack capacity

• Other safeguards to protect people who lack capacity

• How to engage with a person who lacks capacity

• How to engage with carers and other relevant people.

It also explains:

• The specific rules that apply to research involving human tissue and

• What to do if research projects have already been given the go-ahead.

The Act applies to all research that is intrusive. ‘Intrusive’ means research that would be unlawful if it involved a person who had the capacity to consent, but had not consented to take part. The Act does not apply to research involving clinical trials testing new drugs.

The Act is accompanied by a statutory *Code of Practice* providing guidance on how it should be used.[[12]](#footnote-12) Researchers and others making decisions involving people lacking capacity have a legal duty to abide by the guidance in the Code of Practice. Chapter 11 of the Code (‘How does the Act affect research projects involving a person who lacks capacity?’) gives guidance on involving adults who lack capacity to consent to take part in research. It sets out:

• What the Act means by ‘research’

• The requirements that people must meet if their research project involves

somebody who lacks capacity

• The specific responsibilities of researchers, and

• How the Act applies to research that started before the Act came into force.

All participants entering into a clinical study/research project must have given informed consent before any aspect of the project starts (interventional or non-interventional) and a copy filed in their medical records, unless a properly constituted ethics committee has decided otherwise. In exceptional circumstances, enrolment may take place prior to informed consent where urgent treatment needs to be provided. The Medicines for Human Use (Clinical Trials) regulations specifically require that potential subjects be informed of the right to withdraw from the trial at any time without being subject to any resulting detriment, and require subjects to be given a contact point where further information about the trial can be obtained. Compliance with and suitability of standard operating procedures is verified through audit and external inspection.

The Mental Capacity Act does not currently apply to Northern Ireland, and matters relating to capacity and incapacity are determined by common law and the Clinical Trial Regulations. From 1 October 2019, the Mental Capacity Act will provide a statutory framework for people who lack capacity to consent to research, where this research is intrusive but does not constitute a clinical trial. The Act provides that the research must meet certain criteria, must be approved by an appropriate body and that there must be a person appointed to be consulted with in relation to the research. In Northern Ireland, the default position is that consent is required for participation in research unless a properly constituted research ethics committee has decided otherwise.

In Scotland, the legal framework for making non-emergency treatment decisions concerning patients who do not have the capacity to make the decision on their own is contained in the *Adults with Incapacity (Scotland) Act 2000*[[13]](#footnote-13) and the *Mental Health (Care & Treatment) (Scotland) Act 2003.*[[14]](#footnote-14) The Age of Legal Capacity (Scotland) Act 1991[[15]](#footnote-15) provides, in section 2, the circumstances in which a person under the age of 16 may consent to medical treatment on their own. Where this Act does not apply, the Children (Scotland) Act 1995[[16]](#footnote-16) provides the legal framework for a decision to be made on the child’s behalf by either the parent(s), legal guardians, or a court.

Situations such as Emergencies

There are however extremely rare exceptions when treatment can proceed without consent from the patient. For example, in an emergency, if a patient cannot give their consent and there is no time for anyone else to make a decision for the individual, doctors can treat them. However, they can only do so if this is necessary to save the person’s life or stop the person from suffering more serious harm. The legal framework that supports this position is primarily founded in the common law.

Additional guidance regarding cases where research does not need consent to be lawful under the Mental Capacity Act is available here: <https://gov.wales/sites/default/files/publications/2019-06/mental-capacity-act-2005-and-consent-for-research.pdf>

This guidance includes what to do when consent has been obtained prior to loss of capacity, what exactly constitutes ‘intrusive’ research, and where various provisions of the act do and do not apply.

Guidance and Standards

A UK Supreme Court decision requires healthcare professionals to take into account the person’s individual circumstances and preferences when explaining a treatment to them. The judgment made clear what is expected when discussing risk with a patient and brings the law more closely in line with *General Medical Council* (GMC) guidance.[[17]](#footnote-17) The GMC’s guidance is being reviewed to reflect changes in the legal, policy and workplace environments since its publication. Publication of final guidance is expected in late 2019.

The GMC’s draft guidance on decision-making and consent sets out what doctors should consider when discussing treatment and care with their patients. It reflects the law, policy and healthcare settings in England, Northern Ireland, Scotland and Wales. The GMC will use the guidance as a benchmark to assess whether a doctor’s actions or decisions have fallen seriously or persistently below the standards expected. All doctors are expected to comply with this guidance and the Government will work with the GMC to help ensure that any additional training or support that doctors might need is made available. To support publication, the GMC is in the process of developing an implementation plan.

The *UK Policy Framework for Health and Social Care Research*[[18]](#footnote-18) sets out principles of good practice in the management and conduct of research and the responsibilities for satisfying them. These principles protect and promote the interests of patients, service users and the public in health and social care research, by describing ethical conduct and proportionate, assurance-based management of health and social care research, in order to support and facilitate high-quality research in the UK that has the confidence of patients, service users and the public. The framework states that Research participants are afforded respect and autonomy, taking account of their capacity to understand. Where there is a difference between the research and the standard practice that they might otherwise experience, research participants are given information to understand the distinction and make a choice, unless a research ethics committee agrees otherwise. It also states that before the research project is started, any anticipated benefit for the individual participant and other present and future recipients of the health or social care in question must be weighed against the foreseeable risks and inconveniences once they have been mitigated.

The aforementioned extreme cases aside, performing medical treatment without a person’s consent is both a criminal assault, which can be prosecuted under the criminal law, and a civil assault, for which an action for damages can be pursued under the civil law. Failing to obtain proper consent is also a matter of professional misconduct which can be punished by a healthcare professional’s regulatory body. The *Medical Act 1983* sets the legal framework under which the GMC may discipline doctors. It is imperative under UK law that an individual has received sufficient information to enable them to understand the nature of what is proposed (including around the presence of observers) to ensure valid consent.

*D) Protection of persons with disabilities undergoing research*

The *Health Research Authority* is a body of the UK Government’s Department of Health and Social Care. Its core purpose is to protect and promote the interests of patients and the public in health and social care research. The *Research Ethics Service* (RES) is one of the Health Research Authority's core functions, committed to enabling and supporting ethical research in the NHS. It protects the rights, safety, dignity and wellbeing of research participants.[[19]](#footnote-19)

An REC is a group of people appointed to review research proposals to assess formally if the research is ethical. This means the research must conform to recognised ethical standards, which includes respecting the dignity, rights, safety and well-being of the people who take part. The Devolved Administrations and the Health Research Authority provide a Research Ethics Service so that research proposals relating to their areas of responsibility can be reviewed by an REC. The Research Ethics Service consists of RECs, as well as head offices that co-ordinate the development and management of their operations.

The *Governance Arrangements for Research Ethics Committees* (GAfREC) is a UK policy document outlining what is expected from RECs when reviewing research proposals, how RECs should operate and when their review is required.[[20]](#footnote-20)

Section 3 of the document states that RECs must be assured that there are proportionate safeguards to protect people taking part in research. The benefits and risks of taking part in research, and the benefits of research evidence for improved health and social care, should also be distributed fairly among all social groups and classes. Selection criteria in research protocols should not unjustifiably exclude potential participants, for instance on the basis of economic status, culture, age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex or sexual orientation. RECs should take these considerations into account in reviewing the ethics of research proposals, particularly those involving under-researched groups. Section 4.2 states that the Research Ethics Service as a whole should reflect the diversity of the adult population of society, taking account of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex and sexual orientation. This applies to both the lay and expert membership. Appointing authorities should take steps, with support from the relevant head office, to publicise the work of RECs and encourage applications for membership from groups which are under-represented.

RECs act primarily in the interests of research participants. The interests of researchers and research are always secondary to the dignity, rights, safety and well-being of people taking part in research. RECs take into account the interests and safety of the researchers, as well as the public interest in reliable evidence affecting health and social care, and enable ethical and worthwhile research of benefit to participants or to science and society.

Section 1 Part 5 (‘Conditions and Principles which Apply in Relation to an Incapacitated Adult’) of the *Medicines for Human Use (Clinical Trials) Regulations, Statutory Instrument No. 1031 (2004)* also serves to protect persons with disabilities undergoing research. Notably in its requirements that:

* Informed consent given by a legal representative to an incapacitated adult in a clinical trial shall represent that adult’s presumed will.
* The clinical trial must be designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and the cognitive abilities of the patient.
* The risk threshold and the degree of distress have to be specially defined and constantly monitored.
* The interests of the patient always prevail over those of science and society.

Section 51 of the Adults with Incapacity (Scotland) Act 2000 lays down strict conditions under which surgical, medical, nursing, dental or psychological research involving them is permissible in Scotland. These conditions include that:

* research of a similar nature cannot be carried out on an adult who is capable of deciding whether or not to participate
* the research must be in order to obtain knowledge of the causes, diagnosis or treatment or care of the individual’s incapacity, or the effect of any care or treatment relating to it
* Ethics Committee approval for the research has been obtained
* the research is likely to produce real and direct benefit to the individual
* the individual does not indicate unwillingness to participate in the research

*E) Euthanasia and assisted suicide*

Under section 2(1) of the *Suicide Act 1961* it is an offence to perform an act capable of encouraging or assisting the suicide or attempted suicide of another person with the intention to so encourage or assist.[[21]](#footnote-21) The maximum penalty for an offence under section 2(1) is 14 years’ imprisonment. Encouragement or assistance is a crime even if the person ends their life overseas in a country where assisted dying is legal. Both euthanasia and assisted suicide are illegal‎ throughout the UK.

The Director of Public Prosecutions’ (DPP) *Policy for Prosecutors in Respect of Cases of Encouraging or Assisting Suicide* (published in February 2010 and updated in October 2014) sets out the factors that prosecutors will consider when deciding whether or not it is in the public interest to prosecute in cases of encouraging or assisting suicide.[[22]](#footnote-22) The DPP’s policy does not apply in cases of euthanasia.

Parliament has debated this issue on several occasions, the most recent being a debate in the House of Commons on 11 September 2015, when the Assisted Dying (No.2) Bill had its Second Reading[[23]](#footnote-23). (The Bill was rejected by 330 votes to 118.)

* 1. **Information and statistical data in relation to:**

*A) The availability, accessibility and use of prenatal diagnosis*

The *NHS Genomic Medicine Service* will provide equitable access to genomic testing to patients across the NHS from 2019.

In 2016, the UK National Screening Committee (NSC) made a recommendation to offer non-invasive prenatal test (NIPT) as a contingent test in NHS fetal anomaly screening programme (FASP). The UK NSC conducted a full review of the published scientific and cost evidence relating to NIPT.[[24]](#footnote-24) The key objective of NHS FASP is to enable prospective parents to make informed choices, at each step along the screening pathway.

The intention is to offer NIPT to women who are identified as having a higher chance of a trisomy (1 in 150 or more) so they have access to a better test that will provide a much better estimate of how likely their baby is to have a trisomy. If the fetus has a high chance of having a trisomy, the woman and her partner will wish to discuss the implications of this result with their medical team, which may involve further tests. They may decide to terminate the pregnancy.

The national introduction of the evaluative roll out of NIPT as a contingent screening test is yet to be implemented into the NHS FASP. Once NIPT is rolled out, data on the choices women make regarding screening and/or diagnosis will be collected. Data will also be collected on the pregnancy outcomes of women who choose to have screening and about babies born with Down’s syndrome.

In Northern Ireland, antenatal screening, fetal anomaly screening, and associated diagnostic tests are offered to all pregnant women and are provided free of charge by the Health and Social Care system. Uptake of these screening programmes is over 90%. The Strategy for Maternity Care in Northern Ireland states that women should have appropriate access to prenatal scans and should, as necessary, be directed to appropriate support.

*B) The availability, accessibility and use of disability-related abortion*

Registered Medical Practitioners are legally required, under the Abortion Act 1967, as amended, to notify the Chief Medical Officer (CMO) of every abortion performed in England and Wales - whether carried out in the NHS or an approved facility in the independent sector and whether or not the woman is a UK resident.

The UK Government’s Department of Health and Social Care provides form *HSA4* for this purpose. The HSA4 form asks the Medical practitioner to provide details about the grounds under which the abortion was performed.[[25]](#footnote-25) Data from the HSA4 forms are used to produce Abortion statistics for England and Wales.[[26]](#footnote-26)

The UK NSC recognises concerns that there may be an increase in the number of possible terminations following a diagnosis of Down’s syndrome after an NIPT result.

The 1967 Abortion Act allows for abortion without time limit in some circumstances including when "there is a substantial risk that if the child were born it would suffer from such physical or mental abnormalities as to be seriously handicapped."

This is a sensitive issue, however; equality and disability legislation only covers the rights of living persons; under English law a fetus is not recognised as a legal person in its own right. The European Court of Human Rights has said that the issue of when the right to life begins comes within the states’ margin of appreciation because of the lack of consensus among member states on the question.

The screening programme is also compliant with its obligations under the *UN Convention on the Rights of Persons with Disabilities[[27]](#footnote-27)* and any obligations under the *Equality Act.[[28]](#footnote-28)*

The *Abortion (Scotland) Regulations 1991*[[29]](#footnote-29) require any medical practitioner who terminates a pregnancy in Scotland to notify the Scottish Government’s Chief Medical Officer within seven days of the termination. Information Services Division (ISD) uses anonymised data from these notifications for its publication on terminations of pregnancy. ISD’s most recent report is for the year ending December 2018[[30]](#footnote-30). In 2018, 159 abortions were carried out in Scotland under Ground E, accounting for 1.2% of the total number of terminations.

In Northern Ireland, annual statistics are published on termination of pregnancy, but these do not identify terminations that are disability-related. During 2017/18 there were 8 terminations of pregnancy carried out on women aged 30 years and over, 4 terminations of pregnancy carried out on a woman aged 25 to 29, and none on women aged 24 and under – all of these were carried out on women normally resident in Northern Ireland.[[31]](#footnote-31) As regards disability-related abortion, currently[[32]](#footnote-32) the law on termination of pregnancy is different in Northern Ireland from the rest of the UK. At present in Northern Ireland, foetal anomaly is not in itself grounds for a legal termination of pregnancy. A termination will only take place where a doctor has assessed that there is a real and serious, long term or permanent, risk to the physical or mental health of the woman. As referred to earlier, under the *Northern Ireland (Executive Formation etc) Act 2019*, the UK Government is under a duty to bring forward regulations to introduce a new legal framework for abortion in Northern Ireland by 31 March 2020 if the Northern Ireland Executive is not in place by 21 October 2019. This would include provision of abortions in cases of severe fetal impairment.

Abortion statistics for England and Wales are published yearly. The figures for 2018[[33]](#footnote-33) show that 3,269 Ground E abortions were performed, amounting to approximately 2% of total abortions. 75% of these were performed medically compared to 71% of all abortions, whilst the over-35 age group had the highest proportion of Ground E proportions (3.7%) and the under-20 age group had the lowest (0.3%).

It is very rare for an abortion treatment to require a stay in hospital of one or more nights. In 2018, 320 women (0.2%) were reported as having duration of stay of one or more nights in a hospital or clinic after their abortion. 134 of these stays (3.7%) were for abortions performed at later gestations of 20 weeks and over. Of all abortions in England and Wales, 98% were funded by the NHS – an increase of 7 percentage points from 2008. 72% of abortions took place in the independent sector - an increase of 19 percentage points from 2008.

*C) The practice of informed consent to medical treatment and scientific research*

It is a general legal and ethical principle that valid consent *must* be obtained from an individual before starting a treatment or physical intervention. For consent to be valid, it must be given voluntarily by an appropriately informed person who has the capacity to consent to the intervention in question. See answers above for more detail.

*D) The existence of measurements of quality of life which affect both clinical decision-making and health policy*

The measurements of Patient-Reported Outcome Measures(PROMs) is a programme of evaluation of surgical outcomes based on questionnaires completed by patients before and after their surgery. Eligible patients are those treated by or on behalf of the English NHS for the following procedures: hip replacements, knee replacements, varicose vein surgery and groin hernia surgery.

PROMs data and analyses, including from Hospital Episode Statistics PROMs (HES-PROMs) linked data, are published each month by NHS Digital. Publications include:

* + Monthly summary statistics;
  + Quarterly detailed statistics, including extensive reusable datasets and either an analysis of a topic of interest from the datasets or, once a year, a detailed annual report of the latest finalised annual data.

The latest provisional data covering the year leading up to April 2019 was published in August 2019.[[34]](#footnote-34) In 2015, the NHS published a case study illustrating how this data informs clinical practice.[[35]](#footnote-35) The case study details how PROMs data led to a change in the implant brand used in knee and hip replacements, a move away from resurfacing patella during surgery, and the routine preservation of the infra-patella fat pad during total knee replacement (all at the Northumbria NHS Healthcare Foundation Trust).

The UK’s National Institute for Health and Care Excellence (NICE) produces evidence-based guidance and advice for health, public health and social care practitioners and develops quality standards and performance metrics for those providing and commissioning health, public health and social care services.

NICE has historically used the ‘Quality Adjusted Life Year’ (QALY) to incorporate a patient’s health-related quality of life into its guidance regarding the selection and prioritisation of healthcare interventions. The QALY is used to quantify the benefit of a given healthcare intervention – with one year of perfect health equalling one QALY and one year of less than perfect health having a QALY value between 0–1. The health benefits of an intervention are expressed as QALYs gained.

QALYs are calculated by multiplying years of life x quality of life value. NICE defines health-related quality of life as: “A combination of a person’s overall physical, mental and social wellbeing; not merely the absence of disease.” A patient’s quality of life is assessed via a questionnaire (typically based on values such as ability to carry out activities of daily life, impact of pain and mental distress), and the questionnaire answers are translated into a quality of life value from 0–1. The person with the condition is usually asked to complete the questions but in certain cases their carer can answer for them.[[36]](#footnote-36) NICE’s preferred quality of life measurement scale is the EQ-5D, although they will make decisions based on tools used in the available evidence for the subject under scrutiny. The EQ-5D is a questionnaire that has five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/ depression, each of which can be at one of three levels of severity, for example: no problems, some/moderate problems and extreme problems (although a new five-level version is now coming into use). This health state measure can describe 243 unique combinations. A score can be assigned to each of these states based on the analysis of preference data revealed in a survey of approximately 3000 members of the public in the UK by researchers at the University of York Centre for Health Economics.[[37]](#footnote-37)

In 2017, NICE began engagement in a two and a half year project ‘Extending the QALY’ led by the School of Health and Related Research (ScHARR) at the University of Sheffield, with collaborators from the University of Kent, the Office of Health Economics and the EuroQuality of life Research Foundation. The project is being co-funded by a grant from the Medical Research Council (MRC) and the EuroQuality of life Research Foundation.[[38]](#footnote-38)

*E) The practice of experimental, controversial and/or irreversible treatments*

There are several ways in which patients can access experimental treatments if other treatments have not worked or are not available. GMC guidance states that healthcare professionals must provide effective treatments based on the best available evidence, and that patients must be told whether a proposed treatment is experimental and about any additional risks or uncertainties.[[39]](#footnote-39) Beyond this, and within the constraints of available funding, it is up to healthcare professionals to judge what treatment to offer based on their knowledge of the patient. This can involve administering or prescribing unlicensed treatments, or prescribing licensed medicines or CE-marked medical devices ‘off-label’, which means for a use or purpose different to that for which they have been licensed.[[40]](#footnote-40) This could include use for a different dosage, a different duration of treatment, or in a different patient group, such as a drug that has only been licensed for adults being prescribed to a child, or a different disease.[[41]](#footnote-41)

In a rapidly spreading epidemic or other emergency situation with high mortality rates, it might not be possible to initiate clinical trials immediately. As a result, national authorities can allow experimental treatments as part of the emergency response as per Article 5 of the Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use.[[42]](#footnote-42) According to NHS commissioning policy, it is standard practice not to fund treatments that are considered experimental, but exceptions can be made.[[43]](#footnote-43) The NHS Cancer Drugs Fund can be used to fund access to promising, newly licensed cancer drugs while further evidence is collected.[[44]](#footnote-44) As part of compassionate use schemes, manufacturers may offer experimental medicines free-of-charge to eligible NHS patients until sufficient evidence is available to decide whether its use should be publicly funded.[[45]](#footnote-45) When patients (or those caring for them) seek treatments outside the NHS or abroad, they will usually have to source their own funding.

In Northern Ireland, the Department of Health only endorse NICE approved Technology Appraisals, Clinical Guidelines (CGs) and Public Health Guidelines. These are evidence-based and would not be of an experimental nature.

Please also refer to response to Question 4 related to clinical trials and ethics committees.

*F)\_The practice of euthanasia and assisted suicide on persons with disabilities*

As of 31 July 2019, there have been 152 cases referred to the Crown Prosecution Service (CPS) by the police that have been recorded as assisted suicide since 1st April 2009. Of these 152 cases, 104 were not proceeded with by the CPS and 29 cases were withdrawn by the police.

There are currently three ongoing cases. Three cases of encouraging or assisting suicide have been successfully prosecuted. One case of assisted suicide was charged and acquitted after trial in May 2015 and eight cases were referred onwards for prosecution for homicide or other serious crime.

The CPS collects data to assist in the effective management of its prosecution functions. The CPS does not collect data that constitute official statistics as defined in the Statistics and Registration Service Act 2007. Official statistics relating to sentencing, criminal court proceedings, offenders brought to justice, the courts and the judiciary are maintained by the UK Government’s Ministry of Justice (MOJ).[[46]](#footnote-46)

Although both euthanasia and assisted suicide are illegal, those who require palliative care or who are facing the end of their life may – on occasion –ask healthcare professionals caring for them for assistance to die. The Royal College of Nursing recognises this and has issued comprehensive guidance to help staff deal with such cases.[[47]](#footnote-47) It sets out the law on assisted suicide and the law on advance decisions, and explores why patients might express a wish to die and how healthcare staff might respond.

The GMC issued guidance in January 2013, which combines key principles from *Good Medical Practice* and *Treatment and Care towards the End of Life.*[[48]](#footnote-48) It aims to support doctors in acting within the law should someone ask for their help to die.

The *British Medical Association* (BMA) has also issued guidance for members.[[49]](#footnote-49) This also sets out the legal position and advises doctors to avoid all actions that might be interpreted as assisting, facilitating or encouraging a suicide attempt.

The BMA itself recognises that the views of its members may vary widely but it believes that the ongoing improvement in palliative care allows patients to die with dignity. The BMA insists that physician-assisted suicide should not be made legal in the UK; that neither voluntary nor non-voluntary euthanasia should be made legal in the UK; and that if euthanasia were legalised, there should be a clear demarcation between those doctors who would be involved in it and those who would not.

Patients have a right to good palliative care – to control pain and other symptoms – as well as psychological, social and spiritual support. The NHS also provides extensive guidance to patients on:

* Where patients can receive care
* Coping with (and discussing) a terminal diagnosis
* Managing pain and other symptoms
* Coping financially and benefits entitlement
* Making a legally binding advance decision to refuse treatment
* Creating a lasting power of attorney so someone a patient trusts can make decisions if thatpatient loses capacity.[[50]](#footnote-50)
  1. **Information on discrimination against persons with disabilities on research involving humans**

We make great efforts to support active public involvement, including people with disabilities, in health and social care research through INVOLVE which was established in 1996 and is part of, and funded by, the National Institute for Health Research.[[51]](#footnote-51) It is one of the few government-funded programmes of its kind in the world.

The requirements of the Equality Act 2010[[52]](#footnote-52) are embedded within the training of members of Research Ethics Committees. Completion of diversity training within 12 months of appointment is a condition of membership. Members would not approve research proposals where they considered the design of a study or trial that would discriminate.

Please also refer to information regarding the Health Research Authority and Northern Irish national ethics committees in response to question 5 below.

* 1. **How national ethics committees address the rights of persons with disabilities**

Ethics committees actively consider whether research studies take account of the rights of persons with disabilities. For example, the delivery of participant information may be in various formats, including those tailored to people with visual impairment.

For the purpose of research ethics review in Northern Ireland, disability is defined in a wide sense and includes any person involved as a research participant in a study with any type of impairment or illness, mental or physical which has a substantial and long-term adverse effect on that person’s ability to carry out normal day-to-day activities. By this definition, a high proportion of research participants may be considered to have a disability.

Researchers who plan to include people as research participants in their research projects must apply to the *Health and Social Care Research Ethics Committees* in Northern Ireland using an application form.[[53]](#footnote-53) Researchers are required to provide information regarding a range of different aspects of their planned research. This includes:

* Justification of inclusion or exclusion of vulnerable groups
* Patient and public involvement in the design of the research study
* Potential risks and burdens to research participants
* Benefits to the research participant
* Identification of potential research participants, and how they are to be approached
* Taking informed consent including the voluntariness of the consent taken from vulnerable participants.

The *Adults with Incapacity (Ethics Committee) (Scotland) Regulations 2002*[[54]](#footnote-54) also outline that, before approving any research under section 51 of the Adults with Incapacity (Scotland) Act, the Committee must take into account:

* The objectives, design, methodology, statistical considerations and organisation of the research;
* The relevance of the research and the study design;
* The justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and future participants;
* The suitability of the lead researcher;
* The adequacy of the written information to be given and the procedure for obtaining consent; and
* The arrangements for the recruitment of research participants.
  1. **The extent and nature of involvement of persons with disabilities in the work of national ethics committees**

The Health Research Authority (HRA) places a strong emphasis on patient involvement. A key reason for this is so that the needs of patients (including those with disabilities) are taken into account in the design, conduct and dissemination of research. The HRA also places a strong emphasis on information for participants being appropriate to allow for those with learning disabilities. The HRA also publishes information about equality and diversity in relation to its volunteer members.[[55]](#footnote-55)

Disability data held by Scottish Health Boards relating to staff who support RECs and volunteers who serve on the Committees are incomplete. However, according to data reported by the Health Boards, in September 2019 no REC staff members and 2.4% of REC members who responded to surveys declared a disability.

In Northern Ireland, persons with disabilities are involved in the work of nation ethics committees in the appointment of Health and Social Care Research Ethics Committee members,[[56]](#footnote-56) in the appointment of staff to service the committees,[[57]](#footnote-57) and researchers in attendance at the committee meetings.[[58]](#footnote-58)

1. **Innovative initiatives that have been taken at the local, regional or national level to promote and ensure the rights of persons with disabilities in bioethical discussions**

The UK has many innovative initiatives taken at the local, regional or national level to promote and ensure the rights of persons with disabilities in bioethical discussions. These are mentioned throughout this response.

1. <https://www.england.nhs.uk/publication/national-genomic-test-directories/> [↑](#footnote-ref-1)
2. <https://www.legislation.gov.uk/ukpga/1990/37/contents> [↑](#footnote-ref-2)
3. More information can be accessed at: <https://www.hfea.gov.uk/treatments/embryo-testing-and-treatments-for-disease/pre-implantation-genetic-diagnosis-pgd/>. [↑](#footnote-ref-3)
4. Information on the national screening standards for NHS FASP and how the programme is commissioned and provided can be accessed at: <https://www.gov.uk/topic/population-screening-programmes/fetal-anomaly> [↑](#footnote-ref-4)
5. <https://www.legislation.gov.uk/ukpga/1967/87/contents> [↑](#footnote-ref-5)
6. <https://www.rcog.org.uk/en/guidelines-research-services/guidelines/termination-of-pregnancy-for-fetal-abnormality-in-england-scotland-and-wales/>. [↑](#footnote-ref-6)
7. <http://www.legislation.gov.uk/ukpga/2019/22/contents/enacted/data.htm> [↑](#footnote-ref-7)
8. <http://www.legislation.gov.uk/ukdsi/2014/9780111117613/contents> [↑](#footnote-ref-8)
9. <http://www.legislation.gov.uk/uksi/2004/1031/pdfs/uksi_20041031_en.pdf> [↑](#footnote-ref-9)
10. <http://www.legislation.gov.uk/ukpga/2005/9/contents> [↑](#footnote-ref-10)
11. The National Health Service (NHS) is the publicly funded national healthcare system in the United Kingdom. [↑](#footnote-ref-11)
12. <https://www.gov.uk/government/publications/mental-capacity-act-code-of-practice> [↑](#footnote-ref-12)
13. <http://www.legislation.gov.uk/asp/2000/4/contents> [↑](#footnote-ref-13)
14. <http://www.legislation.gov.uk/asp/2003/13/introduction> [↑](#footnote-ref-14)
15. <http://www.legislation.gov.uk/ukpga/1991/50/introduction> [↑](#footnote-ref-15)
16. <http://www.legislation.gov.uk/ukpga/1995/36/introduction> [↑](#footnote-ref-16)
17. <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/consent> [↑](#footnote-ref-17)
18. <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/> [↑](#footnote-ref-18)
19. More information available here: <https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/> [↑](#footnote-ref-19)
20. [www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/governance-arrangement-research-ethics-committees/](http://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/governance-arrangement-research-ethics-committees/) [↑](#footnote-ref-20)
21. <http://www.legislation.gov.uk/ukpga/Eliz2/9-10/60> [↑](#footnote-ref-21)
22. <https://www.cps.gov.uk/sites/default/files/documents/legal_guidance/assisted-suicide-policy.pdf> [↑](#footnote-ref-22)
23. <https://services.parliament.uk/bills/2015-16/assisteddyingno2.html> [↑](#footnote-ref-23)
24. <https://legacyscreening.phe.org.uk/fetalanomalies>. [↑](#footnote-ref-24)
25. See an example here: <https://www.gov.uk/government/publications/abortion-notification-forms-for-england-and-wales>. [↑](#footnote-ref-25)
26. Most recent statistics available here: <https://www.gov.uk/government/statistics/abortion-statistics-for-england-and-wales-2018>. [↑](#footnote-ref-26)
27. <https://www.un.org/development/desa/disabilities/convention-on-the-rights-of-persons-with-disabilities.html> [↑](#footnote-ref-27)
28. <http://www.legislation.gov.uk/ukpga/2010/15/contents> [↑](#footnote-ref-28)
29. <http://www.legislation.gov.uk/uksi/1991/460/contents/made> [↑](#footnote-ref-29)
30. <https://www.isdscotland.org/Health-Topics/Sexual-Health/Abortions/> [↑](#footnote-ref-30)
31. <https://www.health-ni.gov.uk/news/northern-ireland-termination-pregnancy-statistics-201718> [↑](#footnote-ref-31)
32. Legislation on termination of pregnancy in Northern Ireland may change under the terms of the Northern Ireland (Executive Formation etc.) Act 2019, which requires the Secretary of State for Northern Ireland to ensure that the recommendations in paragraphs 85 and 86 of the most recent CEDAW report (as they relate to Northern Ireland) are implemented in respect of Northern Ireland if the Ministerial offices in the Northern Ireland Executive have not been filled by 21 October 2019. [↑](#footnote-ref-32)
33. <https://www.gov.uk/government/statistics/abortion-statistics-for-england-and-wales-2018> [↑](#footnote-ref-33)
34. <https://digital.nhs.uk/data-and-information/publications/statistical/patient-reported-outcome-measures-proms/for-hip-and-knee-replacement-procedures-april-2018-to-march-2019> [↑](#footnote-ref-34)
35. <https://digital.nhs.uk/data-and-information/data-tools-and-services/data-services/patient-reported-outcome-measures-proms/proms-clinical-case-study-data-informs-clinical-practice> [↑](#footnote-ref-35)
36. <https://onlinelibrary.wiley.com/doi/pdf/10.1002/psb.1562> [↑](#footnote-ref-36)
37. https://www.york. ac.uk/che/pdf/DP138.pdf [↑](#footnote-ref-37)
38. <https://www.nice.org.uk/news/article/nice-to-work-with-partners-on-developing-new-ways-to-measure-quality-of-life-across-health-and-social-care> see also: <https://scharr.dept.shef.ac.uk/e-qaly/> [↑](#footnote-ref-38)
39. <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/consent> [↑](#footnote-ref-39)
40. <https://www.gov.uk/government/publications/medical-devices-off-label-use/off-label-use-of-a-medical-device> [↑](#footnote-ref-40)
41. <http://nuffieldbioethics.org/project/children-research> [↑](#footnote-ref-41)
42. <https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2001_83_cons2009/2001_83_cons2009_en.pdf> [↑](#footnote-ref-42)
43. <https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/08/cp-03.pdf> [↑](#footnote-ref-43)
44. <https://www.england.nhs.uk/cancer/cdf/> [↑](#footnote-ref-44)
45. <https://www.gov.uk/guidance/apply-for-the-early-access-to-medicines-scheme-eams> [↑](#footnote-ref-45)
46. <https://www.cps.gov.uk/publication/assisted-suicide> [↑](#footnote-ref-46)
47. <https://www.rcn.org.uk/professional-development/publications/pub-005822> [↑](#footnote-ref-47)
48. <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/when-a-patient-seeks-advice-or-information-about-assistance-to-die> [↑](#footnote-ref-48)
49. <https://www.sheffield-lmc.org.uk/website/IGP217/files/8%2020150153%20BMA%20Guidance%20on%20Assisted%20Suicide%20Update%202015.pdf> [↑](#footnote-ref-49)
50. <https://www.nhs.uk/conditions/euthanasia-and-assisted-suicide/> [↑](#footnote-ref-50)
51. More information available here: <https://www.invo.org.uk/> [↑](#footnote-ref-51)
52. <http://www.legislation.gov.uk/ukpga/2010/15/contents> [↑](#footnote-ref-52)
53. [www.myresearchproject.org.uk](http://www.myresearchproject.org.uk) see also: <https://www.myresearchproject.org.uk/help/hlpcollatedqsg-nhsrec.aspx> [↑](#footnote-ref-53)
54. <http://www.legislation.gov.uk/ssi/2002/190/contents/made> [↑](#footnote-ref-54)
55. <https://www.hra.nhs.uk/about-us/governance/equality-and-diversity/> [↑](#footnote-ref-55)
56. Members of the ethics committees are volunteers who are appointed by an open and transparent public appointment process to attract members from diverse backgrounds. [↑](#footnote-ref-56)
57. The recruitment process for staff also complies with the public duty to comply with Section 75. There are staff members with declared disabilities both visible and non-visible who support the committees and work directly with researchers who submit research ethics applications. [↑](#footnote-ref-57)
58. Researchers are invited to attend committee meetings in person or by teleconference or videoconference. The venues in which the ethics committees meet are complaint with the Disability Discrimination (Northern Ireland) Order 2006 . [↑](#footnote-ref-58)