



NORTHERN
IRELAND
HUMAN
RIGHTS
COMMISSION

**Submission on policy proposals for a duty of
candour and being open**

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Summary of Recommendations

The Northern Ireland Human Rights Commission (NIHRC):

- 2.4 recommends that the term 'candour' is used to refer to the requirement to provide information in relevant circumstances.**
- 3.6 supports the introduction of a statutory individual Duty of Candour with a criminal sanction for breach.**
- 4.7 recommends that the statutory Duty of Candour applies to every healthcare organisation and everyone working for them.**
- 5.8 supports the routine requirements of the statutory organisational Duty of Candour, provided that detailed guidance is given to staff outlining how they can comply with these requirements.**
- 6.8 agrees with the proposed definition for the significant harm threshold for the Duty of Candour procedure.**
- 7.5 supports the proposed requirements under the organisational Duty of Candour when things go wrong.**
- 8.6 supports the proposed legislative requirement to provide an apology and the accompanying proposals outlined in the consultation document.**
- 9.3 supports the outlined proposals for support to health and social care professionals under the statutory organisational Duty of Candour and recommends that adequate resources are assigned to provide the necessary training and support for health and social care professionals to carry out their duties.**
- 10.6 supports the reporting and monitoring requirements as proposed in the consultation document.**
- 11.4 supports the proposed introduction of criminal sanctions for breach and an obstruction offence.**

1.0 Introduction

1.0 The Northern Ireland Human Rights Commission (the NIHRC), pursuant to Section 69(1) the Northern Ireland Act 1998, reviews the adequacy and effectiveness of law and practice relating to the protection of human rights. In accordance with these functions, this submission is made in response to the Department of Health's consultation on policy proposals for a duty of candour and being open.

1.1 The NIHRC bases its advice on the full range of internationally accepted human rights standards, including the European Convention on Human Rights, as incorporated by the Human Rights Act 1998, and the treaty obligations of the Council of Europe (CoE) and United Nations (UN). The relevant regional and international treaties in this context include:

- European Convention on Human Rights (ECHR);¹
- UN International Covenant on Civil and Political Rights (UN ICCPR);²
- UN International Covenant on Economic, Social and Cultural Rights (UN ICESCR);³

1.2 In addition to these treaty standards, there exists a body of 'soft law' developed by the human rights bodies of the CoE and UN. These declarations and principles are non-binding, but provide further guidance in respect of specific areas. A relevant standard in this context includes:

- UN Committee on the Economic, Social and Cultural Rights (UN CESCR Committee) General Comment No. 14 on the Right to the Highest Attainable Standard of Health Art. 12.

1.3 The NIHRC welcomes the opportunity to respond to the Department of Health's consultation policy proposals for a duty of candour and openness in Northern Ireland (NI). The structure of this response is broadly aligned to the structure of the consultation document, save where to avoid repetition, the issues have been grouped together.

¹ Ratified by the UK in 1951. Further guidance is also taken from the body of case law from the European Court of Human Rights (ECtHR).

² Ratified by the UK in 1966.

³ Ratified by the UK in 1966.

2.0 Use of terminology and definitions in respect of “openness” and “candour”

- 2.1 Article 12.1 of the UN International Covenant on Economic, Social and Cultural Rights (UN ICESCR) sets out “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health”.
- 2.2 The Committee on Economic, Social and Cultural Rights has elaborated on the obligations of states under the right to health, confirming that this is not to be understood as a right to be healthy, but as “a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health”.⁴ States are required to protect, respect and fulfil the right to health⁵, and are required by ‘progressive realisation’ to take steps towards the full realisation of Article 12 ICESCR.⁶
- 2.3 Under the obligation to protect, which requires the State to take measures that prevent third parties from interfering with article 12 guarantees, the Committee on Economic, Social and Cultural Rights has included as a specific example, the duty “to ensure that medical practitioners and other health professional meet appropriate standards of education, skill and ethical codes of conduct”.⁷ Further, under the obligation to fulfil, States are obliged:

to take positive measures that enable and assist individuals and communities to enjoy the right to health. States parties are also obliged to fulfil (provide) a specific right contained in the Covenant when individuals or a group are unable, for reasons beyond their control, to realize that right themselves by the means at their disposal. The obligation to fulfil (promote) the right to health requires States to undertake actions that create, maintain and

⁴ E/C.12/2000/4 Committee on Economic, Social and Cultural Rights ‘General Comment No. 14 (2000): The right to the highest attainable standard of health (article 12 of the International Covenant on Economic, Social and Cultural Rights)’, 11 August 2000, para 8

⁵ Ibid, para 33.

⁶ Ibid, para 30.

⁷ Ibid, para 35.

restore the health of the population. Such obligations include: (iv) supporting people in making informed choices about their health.⁸

- 2.4 The definition of candour set out in the consultation document denotes an element of proactivity on the part of the healthcare professional or organisation to volunteer relevant information where an individual has or may have been harmed by the provision of services, whether or not this information has been requested or a complaint has been made. It is distinguished from 'openness' which relates to the culture of enabling concerns or complaints to be raised without fear.⁹
- 2.5 Individuals may not be aware of the relevant questions they should ask of medical professionals, which may ultimately have a material impact on their treatment and their right to health. The requirement to proactively provide information to an individual relating to harm which has or may have occurred is more likely to enable an individual to make informed choices about their health. Thus, the definition of candour outlined in the consultation document would tend to be more aligned with the state duty to fulfil the right to health than 'openness'.
- 2.6 It should be noted that 'openness' is already one of the seven Nolan Principles of Public Life applying to all people appointed to work in positions of governance the health sector.¹⁰ Accordingly, a culture of openness should already be engrained within the health and social care system, where decisions and actions are undertaken in an open and transparent manner, and information is not withheld from the public unless there are clear and lawful reasons for doing so.
- 2.7 The Commission recommends that the term 'candour' is used to refer to the requirement to provide information in relevant circumstances.**

3.0 Statutory individual Duty of Candour

- 3.1 The consultation document sets out various policy proposals for a statutory individual Duty of Candour. In light of the information provided, the Commission recommends the introduction of a statutory individual Duty of

⁸ Ibid, para 35.

⁹ Department of Health 'Duty of Candour & Being Open – Policy Proposals for Consultation', 2021, at para 2.27.

¹⁰ [Seven Principles of Public Life](#)

Candour with criminal sanctions for breach.

- 3.2 In *Oyal v Turkey*, the ECtHR has made it clear that “knowledge of the facts and of possible errors committed in the course of medical care is essential to enable the institutions and medical staff concerned to remedy the potential deficiencies and prevent similar errors”.¹¹
- 3.3 The consultation document makes it clear that the proposed individual Duty of Candour would be accompanied by a number of safeguards, including a requirement that organisations protect and support health and social care professionals in fulfilling their statutory duty, and a proposed obstruction offence to prevent interferences with an individual performing their duty. The document also stresses that criminal liability would likely only attach “when investigation has found evidence of deliberate and intentional breach of the Duty”.
- 3.4 In the case of *Silih v Slovenia*, the ECtHR held that “even if the Convention does not as such guarantee a right to have criminal proceedings instituted against third parties, the Court has said many times that the effective judicial system required by Article 2 may, and under certain circumstances must, include recourse to the criminal law. However, if the infringement of the right to life or to personal integrity is not caused intentionally, the procedural obligation imposed by Article 2 to set up an effective judicial system does not necessarily require the provision of a criminal law remedy in every case. In the specific sphere of medical negligence the obligation may for instance also be satisfied if the legal system affords victims a remedy in the civil courts, either alone or in conjunction with a remedy in the criminal courts, enabling any responsibility of the doctors concerned to be established and any appropriate civil redress, such as an order for damages and/or for the publication of the decision, to be obtained. Disciplinary measures may also be envisaged”.¹²
- 3.5 Accordingly, to support an open culture, where possible mistakes or deficiencies may be earlier identified and addressed, it seems appropriate for the introduction of a statutory individual Duty of Candour with provision for criminal sanction. It is imperative that these obligations are accompanied by clear guidelines and training, so that health and social

¹¹ *Oyal v Turkey* (2010) ECHR 369, at para 76.

¹² *Silih v Slovenia* (2009) ECHR 571, at para 194.

care professionals are well informed of their duties and possible consequences for breach under the Duty of Candour legislation in ways designed not to impair clinicians and others going about their work in a normal way.

3.6 The Commission supports the introduction of a statutory individual Duty of Candour with a criminal sanction for breach.

4.0 Scope of a statutory organisational Duty of Candour and a statutory individual Duty of Candour

- 4.1 In General Comment No. 14 on the Right to the Highest Attainable Standard of Health, the Committee on Economic, Social and Cultural Rights, sets out that the State's obligations to protect include, "the duties of States to adopt legislation or to take other measures ensuring equal access to health care and health-related services provided by third parties;" and "to ensure that privatization of the health sector does not constitute a threat to the availability, accessibility, acceptability and quality of health facilities, goods and services".¹³
- 4.2 Limiting a statutory organisational Duty of Candour only to regulated organisations that directly provide health and social care services and limiting a statutory individual Duty of Candour to registered professionals directly providing health and social care services could create a distinction in the services provided by different healthcare organisations. This distinction could run counter to the state's obligations to protect, as outlined above.
- 4.3 Article 2 of the European Convention on Human Rights (ECHR) guarantees the right to life, which the European Court of Human Rights (ECtHR) has confirmed includes positive and procedural obligations.¹⁴ The procedural obligation requires the State to undertake an effective, official investigation where there have been alleged breaches of this right. Such an investigation must be capable of identifying those responsible, be prompt, independent, be subject to public scrutiny and involve the next of

¹³ E/C.12/2000/4 Committee on Economic, Social and Cultural Rights 'General Comment No. 14 (2000): The right to the highest attainable standard of health (article 12 of the International Covenant on Economic, Social and Cultural Rights)', 11 August 2000, para 35.

¹⁴ *Centre for Legal Resources on behalf of Valentin Cămpăneanu v Romania* (2014) ECHR 972, at para 130.

kin.¹⁵ The State is also required to act on their own motion and “cannot leave it to the initiative of the next of kin either to lodge a formal complaint or to take responsibility for the conduct of any investigative procedures”.¹⁶

- 4.4 In fulfilling this procedural obligation, the ECtHR has clarified that the State is under an obligation to investigate in situations where individuals have sustained life-threatening injuries or loss of life in suspicious circumstances. In *Lopes de Sousa Fernandes v Portugal*, the judgment referred to earlier jurisprudence and held that the ECtHR “has interpreted the procedural obligation of Article 2 in the context of health care as requiring States to set up an effective and independent judicial system so that the cause of death of patients in the care of the medical profession, whether in the public or the private sector, can be determined and those responsible made accountable”.¹⁷ In such cases, the ECtHR has held that Article 2 ECHR must also be considered to require the State to have in place an effective independent judicial system to secure the legal means capable of establishing the facts, holding accountable those at fault and providing appropriate redress to the victim.¹⁸
- 4.5 If a healthcare organisation was involved in a situation where Article 2 ECHR was engaged, this would require an investigation into the course of events requiring detailed disclosure, regardless of whether the organisation and/or staff were regulated or registered to directly provide health and social care services.
- 4.6 Accordingly, the Commission recommends that the scope of the statutory Duty of Candour applies to every healthcare organisation and everyone working for them, as set out in Justice O’Hara’s recommendations.
- 4.7 The Commission recommends that the statutory Duty of Candour applies to every healthcare organisation and everyone working for them.**

¹⁵ *Jordan v the United Kingdom* (2001) ECHR 327 at para 105.

¹⁶ *Ibid.*

¹⁷ *Lopes de Sousa Fernandes v Portugal* (2017) ECHR 1107, at para 214.

¹⁸ *Sinim v Turkey* (2017) ECHR 524, at para 59.

5.0 Routine requirements of statutory organisational and individual Duties of Candour

- 5.1 The consultation document proposes that the statutory organisational Duty of Candour entail routine requirements where staff will be required and supported to give full and honest answers to any question reasonably asked by a patient about their treatment. Under a statutory individual Duty of Candour, staff will be expected to be open in all circumstances, from routine interaction with patients on a day-to-day basis, to openness to improve performance, as well as evincing candour when things have gone wrong¹⁹.
- 5.2 Article 21 of the UN International Covenant on Civil and Political Rights (UN ICCPR) recognises that everyone has the right to “seek, receive and impart information of all kinds.” The UN Committee on Economic, Social and Cultural Rights has recognised that access to accurate information is essential to realising the right to the highest attainable standard of health. According to the Committee, accessibility of healthcare, entails “the right to seek, receive and impart information and ideas concerning health issues”.²⁰
- 5.3 Article 8 ECHR encompasses the right to respect for private and family life, home and correspondence. Although the object of Article 8 is essentially that of protecting an individual from arbitrary interference by public authorities, it does not merely compel the State to abstain from such interference: in addition to this primarily negative undertaking, there may be positive obligations inherent in an effective respect for private life.²¹ The right to effective access to information concerning health and reproductive rights falls within the scope of private and family life within the meaning of Article 8.²² There may be positive obligations inherent in effective respect for private or family life which require the State to provide essential information about risks to one’s health in a timely manner.²³

¹⁹ Department of Health ‘Duty of Candour & Being Open – Policy Proposals for Consultation’, 2021, at para 4.39.

²⁰ E/C.12/2000/4 Committee on Economic, Social and Cultural Rights ‘General Comment No. 14 (2000): The right to the highest attainable standard of health (article 12 of the International Covenant on Economic, Social and Cultural Rights)’, 11 August 2000, at para 12.

²¹ *X and Y v the Netherlands* (1985) ECHR 4, at para 23.

²² *K.H. and Others v Slovakia* (2009) ECHR 709, at para 44.

²³ *Guerra and Others v Italy* (1998) ECHR 7, at paras 58 and 60.

- 5.4 The ECtHR has underlined the importance of giving access to information regarding risks to health: “it is well established that the High Contracting Parties also have a positive obligation under Article 8 of the Convention to have in place regulations ensuring that medical practitioners consider the foreseeable consequences of planned medical procedures on their patients’ physical integrity and inform patients of these beforehand in such a way that they are able to give informed consent.” If a foreseeable risk materialises without the patient having been duly informed in advance, the State may be found in breach of Article 8.²⁴
- 5.5 Notably, the ECtHR has also recognised the need to strike a balance under Article 8, stipulating that “it should further be borne in mind that in discharging their positive obligations towards the alleged victims of medical malpractice, the authorities must also have regard to counter-considerations, such as the risk of unjustifiably exposing medical practitioners to liability, which can compromise their professional morale and induce them to practise, often to the detriment of their patients, what has come to be known as “defensive medicine”.”²⁵
- 5.6 During a course of ongoing treatment, where new information has come to light about potentially adverse health issues, healthcare professionals should provide this new information to individuals to ensure that treatment is consistently being provided with their informed consent. This would be in line with the state’s obligations under Article 8 ECHR and the proposed routine requirements incumbent on organisations and health and social care professionals to provide full and honest answers to patients about their treatment.
- 5.7 Given the need to strike a balance between the rights of individuals to relevant information in order to provide their informed consent to medical procedures and treatment, and the avoidance of placing too onerous obligations on medical practitioners, it is important that health and social care professionals are supplied with detailed guidance on how they can comply with the routine requirements.

5.8 The Commission supports the routine requirements of the statutory organisational Duty of Candour, provided that detailed

²⁴ *Trocellier v France* (dec.) 75725/01 Decision 5.10.2006, at para 4.

²⁵ *Vasileva v Bulgaria* (2016) ECHR 273, at para 70.

guidance is given to staff outlining how they can comply with these requirements.

6.0 Significant harm threshold

- 6.1 The ECtHR has held that Article 8 ECHR imposes a positive obligation on States to secure to their citizens the right to effective respect for their physical and psychological integrity.²⁶ This obligation may involve the adoption of specific measures, including the provision of an effective and accessible means of protecting the right to respect for private life.²⁷ Such measures may include both the provision of a regulatory framework of adjudicatory and enforcement machinery protecting individuals' rights and the implementation, where appropriate, of these measures in different contexts.²⁸
- 6.2 Article 8 is a qualified right, which means that restrictions may be permissible in certain limited circumstances. The conditions upon which a State may interfere with the enjoyment of the right to private and family life are set out in Article 8(2) ECHR. Limitations are allowed if they are "in accordance with the law" or "prescribed by law" and are "necessary in a democratic society" for the protection of one of the objectives set out in Article 8(2) ECHR.
- 6.3 Not every act or measure which adversely affects moral or physical integrity will interfere with the right to respect to private life guaranteed by Article 8. However, the ECtHR has held "that even a minor interference with the physical integrity of an individual must be regarded as an interference with the right to respect for private life under Article 8 if it is carried out against the individual's will".²⁹
- 6.4 The consultation document proposes a definition of the various forms of 'harm' arising from an unintended or unexpected incident that would trigger a 'notifiable incident' and require compliance with the statutory Duty of Candour procedure.³⁰

²⁶ *Glass v the United Kingdom* (2004) ECHR 103, at paras 74-83; *Milićević v Montenegro* (2018) ECHR 908, at para 54.

²⁷ *Airey v Ireland* (1979) ECHR 3, at para 33; *McGinley and Egan v the United Kingdom* (1998) ECHR 51, at para 101; *Roche v the United Kingdom* (2005) ECHR 956, at para 162.

²⁸ *A, B and C v Ireland* (2010) ECHR 2032, at para 245.

²⁹ *Storck v Germany* (2005) ECHR 406, at para 143.

³⁰ Department of Health 'Duty of Candour & Being Open – Policy Proposals for Consultation', 2021, at paras 3.15-3.16.

6.5 In the case of *Csoma v Romania*, the applicant went to hospital for a planned abortion. After expelling the foetus, she suffered profuse bleeding and ultimately had a total hysterectomy and bilateral adnexectomy to save her life, which left her permanently unable to bear children. One of her claims was that she had not been informed of the nature and possible consequences of the procedure. In upholding her claim, the ECtHR outlined the general principles it has established concerning the State's responsibility for medical negligence under Articles 2 and 8 ECHR.:

“Contracting States are under an obligation to introduce regulations compelling both public and private hospitals to adopt appropriate measures for the protection of their patients’ lives. Moreover, the Court has underlined that it is important for individuals facing risks to their health to have access to information enabling them to assess those risks. It has considered it reasonable to infer from this that the Contracting States are bound, by virtue of this obligation, to adopt the necessary regulatory measures to ensure that doctors consider the foreseeable consequences of a planned medical procedure on their patients’ physical integrity and to inform patients of these consequences beforehand, in such a way that the latter are able to give informed consent. In particular, as a corollary to this, if a foreseeable risk of this nature materialises without the patient having been duly informed in advance by doctors, the State Party concerned may be directly liable under Article 8 for this lack of information.”³¹

6.6 In reaching its decision, the ECtHR further clarified that it “attaches weight to the existence of prior consent in the context of a patient’s right to respect for his or her physical integrity. Any disregard by the medical personnel of a patient’s right to be duly informed can trigger the State’s responsibility in the matter.”³²

6.7 Following the ECtHR’s case law, the State’s obligations under Articles 2 or 8 ECHR may be engaged if a patient suffers ‘harm’ as defined in the consultation document from an unintended or unexpected incident if the patient was not properly informed of the risks involved in the medical procedure beforehand.

³¹ *Csoma v Romania* (2013) ECHR 2013, at paras 41–42.

³² *Ibid*, at para 48.

6.8 The Commission agrees with the proposed definition for the significant harm threshold for the Duty of Candour procedure.

7.0 Requirements when things go wrong

- 7.1 The consultation document sets out procedural requirements that organisations and members of staff will be required to follow when a “notifiable incident” occurs.³³ With respect to the statutory organisational duty, this includes procedures such as notifying the patient, while providing reasonable support, as soon as reasonably practicable that a notifiable incident has occurred, a written summary of the notifiable event which includes an apology, and information on further action taken by the organisation in respect of the incident. The statutory individual duty is proposed to require members of staff to report notifiable incidents, and participate openly and honestly in any subsequent investigation.³⁴
- 7.2 The positive obligations under Article 2 ECHR require an effective independent judicial system to be put in place so that the cause of death of patients in medical care can be determined and those responsible held accountable. Parallel to the obligations under Article 2 ECHR, States have a duty under Article 8 ECHR to establish an effective regulatory framework, providing victims of medical negligence with access to proceedings under which they can, in appropriate cases, obtain compensation for damage.³⁵
- 7.3 In *Lopes de Sousa Fernandes v Portugal*, the applicant’s husband died following a series of complications after a nasal polypectomy.³⁶ The applicant alleged that her husband’s death was the result of negligence by the medical staff caring for him. Following her husband’s death, the applicant made a number of attempts requesting an explanation for the sudden deterioration in her husband’s health and subsequent death.
- 7.4 The ECtHR held that there had been a violation of the procedural limb of Article 2 ECHR on the grounds that the subsequent investigations and court actions had lacked promptness and effectiveness. An investigation

³³ Department of Health ‘Duty of Candour & Being Open – Policy Proposals for Consultation’, 2021, at paras 3.19 and 4.41.

³⁴ *Ibid*, at para 4.41.

³⁵ *Vasileva v Bulgaria* (2016) ECHR 273, at para 63; *Mehmet Ulusoy and Others v Turkey* (2019) ECHR 485, at para 82.

³⁶ *Lopes de Sousa Fernandes v Portugal* (2017) ECHR 1174.

took two years to open, a further one year to appoint an inspector to head the investigation, and after seven years and ten months, the investigation was stayed pending the outcome of criminal proceedings. Proceedings before the Medical Association took approximately four years and five months, which the ECtHR held to be an unreasonable length of time, considering they had merely consisted of examining the patient's medical records and the opinions of the specialist panels, without any evidence being heard. Finally, criminal proceedings against one of the doctors in the medical team lasted six years and eight months, and the ECtHR considered the proceedings to have been ineffective and not conducted promptly.³⁷

7.5 In light of the foregoing reasons, the Commission supports the proposed requirements under the organisational Duty of Candour when things go wrong.

8.0 Apologies

- 8.1 The Consultation document proposes introducing a legislative requirement to provide an apology as part of the Duty of Candour procedure. It further notes the risk that legislating for an apology in Duty of Candour legislation may lead to apologies that become standardised or formulaic in nature.
- 8.2 Genuine apologies, as statements that acknowledge an error and its consequences, which take responsibility, and communicate regret for having caused harm, can decrease blame, reduce anger, increase trust, and improve relationships.³⁸ A genuine apology can allow healing for both parties to a dispute.
- 8.3 Genuine apologies may also constitute an important form of access to justice. In 1994, Lord Woolf was appointed to review the rules of civil procedure, with a view to improving access to justice, reducing the cost of litigation and removing unnecessary complexity. With respect to his review of medical negligence litigation, Lord Woolf found that "some victims want an explanation or apology rather than financial compensation, but are forced into protracted litigation because there is no other way of resolving the issues".³⁹ Accordingly, an apology with sincerity and proper form may

³⁷ Ibid, paras 229-234.

³⁸ Robbennolt, Jennifer "Apologies and Medical Error", *Clinical Orthopaedics and Related Research* (2009) 467(2), at 376.

³⁹ Lord Woolf, *Access to Justice Interim Report*, HMSO (1995), at para 14.

provide elements of closure to a victim, following a notifiable incident.

8.4 The Commission supports the proposed legislative requirement to provide an apology as part of the Duty of Candour procedure and the proposals under the statutory organisational Duty of Candour.

8.5 The Commission stresses the importance that any apologies provided under the Duty of Candour procedure are sincere and genuine, and focus on the needs of the person who suffered harm.

8.6 The Commission supports the proposed legislative requirement to provide an apology and the accompanying proposals outlined in the consultation document.

9.0 Proposals for support for staff

9.1 The proposed Duty of Candour legislation entails the introduction of a number of new statutory initiatives that health and social care professionals that will have to adopt or comply with in addition to their existing health and social care duties.

9.2 The Commission supports the initiatives introduced in the consultation document, however, these initiatives will need to be introduced alongside sufficient resources for training and supporting staff in order to allow staff to carry out these additional duties. In this respect, the Commission supports the consultation document's recognition that "any successful organisational Duty of Candour will depend on each organisation providing adequate support and protection for staff to enable them to work within an open and honest culture".⁴⁰ Given it is proposed that the Duty of Candour legislation will entail the introduction of a number of statutory obligations, it is imperative that adequate resources are set aside to enable health and social care professionals to comply with these duties.

9.3 The Commission supports the outlined proposals for support to health and social care professionals under the statutory organisational Duty of Candour and recommends that adequate resources are assigned to provide the necessary training and

⁴⁰ Department of Health 'Duty of Candour & Being Open – Policy Proposals for Consultation' (2021) at para 4.39.

support for health and social care professionals to carry out their duties.

10.0 Reporting and monitoring

- 10.1 The consultation document proposes introducing an obligation under Duty of Candour legislation that organisations report on their operational application of the Duty of Candour.⁴¹ It also proposes a requirement that any public statements on its performance, or statements made to regulators regarding its application of the Duty of Candour be truthful and not misleading by omission.⁴²
- 10.2 Article 2 ECHR imposes a duty on the State to secure the right to life by putting in place effective criminal law provisions to deter the commission of offences against an individual, backed up by law enforcement machinery for the prevention, suppression and punishment of breaches of such provisions. This obligation requires by implication that there should be some form of effective official investigation when there is reason to believe that an individual has sustained life threatening injuries or loss of life in suspicious circumstances, or circumstances potentially engaging the responsibility of the State due to alleged negligence.⁴³
- 10.3 In *Oyal v Turkey*, the applicants' son had been infected with HIV through a blood transfusion following his premature birth. In connection with its finding that there had been a breach of Article 2 ECHR, the ECtHR held that "apart from the concern for the respect of the rights inherent in Article 2 of the Convention in each individual case, more general considerations also call for a prompt examination of cases concerning medical negligence in a hospital setting. Knowledge of the facts and of possible errors committed in the course of medical care is essential to enable the institutions and medical staff concerned to remedy the potential deficiencies and prevent similar errors. The prompt examination of such cases is therefore important for the safety of users of all health services."⁴⁴

10.4 Where the event of injury falls short of threatening the right to life as

⁴¹ Ibid, at para 3.29.

⁴² Ibid.

⁴³ *Mustafa Tunç and Fecire Tunç v Turkey* (2013) ECHR 587, at para 171; *Lopes de Sousa Fernandes v Portugal* (2017) ECHR 1174.

⁴⁴ *Oyal v Turkey* (2010) ECHR 369, at para 76.

secured under Article 2 ECHR, the ECtHR has held that the State may be under the same obligations to impose regulations requiring public and private hospitals to adopt appropriate measures to protect the physical integrity of their patients, and secondly, make available to victims of medical negligence a procedure capable of providing them, if need be, with compensation for damage, under Article 8 ECHR.⁴⁵

10.5 The monitoring and reporting requirements may enable organisations and regulators to identify systemic issues, providing them with an opportunity to rectify and ultimately better protect patients. Through the use of disaggregated data, the monitoring and reporting requirements could help illuminate patterns, leading to the identification of potential issues such as for example, institutional racism, which regulators could draw upon and address accordingly. As the ECtHR has pointed out, timely identification of breaches and deficiencies is essential to enable organisations to address issues and avoid repeating similar incidents.

10.6 The Commission supports the reporting and monitoring requirements as proposed in the consultation document.

11.0 Criminal sanctions for breach and obstruction offence

11.1 The consultation document proposes the introduction of criminal sanctions for a number of specified breaches under the proposed Duty of Candour.⁴⁶ Further, it is proposed that a director, manager, secretary or similar officer of the organisation responsible for the breach, may be subject to proceedings if it is proved that the breach was committed with their consent, connivance, or as a result of their neglect.⁴⁷

11.2 In *Lopes de Sousa Fernandes v Portugal*, the ECtHR clarified that “the Court has interpreted the procedural obligation of Article 2 in the context of health care as requiring States to set up an effective and independent judicial system so that the cause of death of patients in the care of the medical profession, whether in the public or the private sector, can be determined and those responsible made accountable. While, in some

⁴⁵ *Vasileva v Bulgaria* (2016) ECHR 273, at paras 63-69.

⁴⁶ Department of Health ‘Duty of Candour & Being Open – Policy Proposals for Consultation’ (2021) at para 3.36.

⁴⁷ *Ibid*, at para 3.40.

exceptional situations, where the fault attributable to the health care providers went beyond a mere error or medical negligence, the Court has considered that compliance with the procedural obligation must include recourse to criminal law, in all other cases where the infringement of the right to life or to personal integrity is not caused intentionally, the procedural obligation imposed by Article 2 to set up an effective and independent judicial system does not necessarily require the provision of a criminal law remedy".⁴⁸

11.3 The criminal sanctions for breach and obstruction are proposed to apply following the wilful breach by an organisation and / or its officers. Following *Lopes*, it is clear that the ECtHR has envisaged that the procedural limb of Article 2 ECHR may, in exceptional cases require recourse to criminal law. Clear guidance must be provided to organisations and health and social care professionals regarding when criminal sanctions for breach may arise.

11.4 The Commission supports the proposed introduction of criminal sanctions for breach and the obstruction offence.

⁴⁸ *Lopes de Sousa Fernandes v Portugal* (2017) ECHR 1174, at paras 214–215.

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