



WG23-09

The Duty of Candour Statutory Guidance 2023

The Health and Social Care (Quality and Engagement) (Wales) Act 2020

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GLOSSARY

Interpretation, in this guidance:

- the 2006 Act, means the National Health Service (Wales) Act 2006.
- the 2011 Regulations, means the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011.
- the Act means the Health and Social Care (Quality and Engagement) (Wales) Act 2020.
- apology, means an expression of sorrow or regret in respect of the notifiable adverse outcome.
- candour procedure means the procedure set out in the Candour Procedure Regulations that an NHS body must follow in relation to a notifiable adverse outcome.
- Candour Procedure Regulations means The Duty of Candour Procedure (Wales) Regulations 2023.
- Harm includes psychological harm, and in the case of a service user who is pregnant, loss of or harm to the unborn child.
- health care, means services provided in Wales under or by virtue of the 2006 Act for or in connection with—
 - (a) the prevention, diagnosis or treatment of illness.
 - (b) the promotion and protection of public health.
- illness, has the meaning given in section 206 of the 2006 Act.
- NHS body means—
 - (a) a Local Health Board.
 - (b) an NHS Trust.
 - (c) a Special Health Authority.
 - (d) a primary care provider.

- notifiable adverse outcome occurs when the duty of candour comes into effect in accordance with section 3 of the Act.
- service user, means a person, to whom health care is being or has been provided by an NHS body, who has suffered an adverse outcome.
- Special Health Authority means a body established under section 22 of the 2006 Act; but does not include any cross-border Special Health Authority (within the meaning of section 8A (5) of the 2006 Act) other than NHS Blood and Transplant.
- A person is a primary care provider in so far as (and only in so far as) the person provides health care on behalf of a Local Health Board by virtue of a contract, agreement or arrangement under Part 4, 5, 6 or 7 of the 2006 Act between the person and the Local Health Board.
- A service user is to be treated as having suffered an adverse outcome if the user experiences, or if the circumstances are such that the user could experience, any unexpected or unintended harm that is more than minimal.

- Review: a review is the clarification of the incident that has been reported and an assessment as to the level of harm that has occurred or could occur to the individual service user by a senior member of staff to assess whether the threshold for triggering the duty of candour has been met. This is sometimes referred to as approving the incident.
- Investigation: the in-depth examination (additional enquiries as listed in the Candour regulations) undertaken to understand what has occurred and any root causes and learning as outlined in the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011.
- For the purposes of this guidance and making the links with the Candour Procedure Regulations the term service user/person acting on their behalf is referred to in the Regulations as the 'relevant person.' NHS body is referred to in the Regulations as the 'responsible body.'
- Datix Cymru is a reporting and management digital platform for incidents and concerns and part of the Once for Wales Concerns Management System Programme, which includes Datix Cymru and CIVICA Experience Wales.

FOREWORD

The introduction of the duty of candour through the Health and Social Care (Quality and Engagement) (Wales) Act 2020¹ ('the Act'), highlights the Welsh Government's commitment to safe, effective and person-centred health services. The duty is placed on NHS Bodies (Health Boards, NHS Trusts, Welsh Special Health Authorities and NHS Blood and Transplant in relation to their Welsh functions) and on primary care providers in Wales in respect of services they provide under a contract or other arrangements with a Local Health Board.

The focus of the duty in the Act is ultimately to serve service users by ensuring that if the service user experiences, or if the circumstances are such that the service user could experience, any unexpected or unintended harm that is more than minimal, and the provision of health care was or may have been a factor, the service user, (or person acting on their behalf), is informed, provided with an apology and offered details of relevant services or support. The NHS body is also required to provide the service user/or person acting on their behalf with an explanation of the actions that the responsible body or the provider will take, and further enquiries that the responsible body or the provider will carry out, to investigate the circumstances of the notifiable adverse outcome, including any actions to be taken under the Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011².

Wales is not the only UK jurisdiction to have a duty of candour. In England, the duty is set out at Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities)

¹ Health and Social Care (Quality and Engagement) (Wales) Act 2020
<https://www.legislation.gov.uk/asc/2020/1/contents>

² The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011
<https://www.legislation.gov.uk/wsi/2011/704/contents/made>

Regulations 2014³. In Scotland, it is set out in Part 2 of the Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016⁴.

Our overarching policy objective, in line with our aspirations in a Healthier Wales⁵ for more integrated care, is to ensure that whether a person receives care from the NHS, or from a regulated provider of health care services, that person can be assured that they will be dealt with in an open and honest way by their care provider.

In social care, a duty of candour already exists for providers and responsible individuals of regulated services under the 2017 Regulations⁶.

Separate work is being taken forward to make Regulations to place a duty of candour on providers of independent health care in Wales, using powers under the Care Standards Act 2000⁷. We have enjoyed incredibly positive engagement with representatives of the independent health care sector in Wales and it is intended to collaborate with them to introduce a duty of candour that applies to the independent health care sector in Wales, with a projected coming into force date of April 2024.

We know the overwhelming majority of providers of health care services, want to deliver high quality, safe and compassionate care. However, equally, we know that despite these intentions, inevitably in complex and multi-faceted services, from time to time, people will suffer harm.

When they do, the way in which NHS Bodies, deal with these situations becomes especially important and can make an enormous difference to people's experience and to their ongoing relationship with their care provider. This is particularly important in health care settings where people often have long standing relationships with their care providers. Trust is hard to gain, but easy to lose. Being open and honest should be at the heart of every relationship between those providing, receiving and/or experiencing treatment and care.

³ The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (SI 2008/2936).
<https://www.legislation.gov.uk/ukdsi/2014/9780111117613/regulation/20>

⁴Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016
<https://www.legislation.gov.uk/asp/2016/14/contents>

⁴ Welsh Government 2018 A healthier Wales: long term plan for health and social care
<https://gov.wales/healthier-wales-long-term-plan-health-and-social-care>

⁶ Welsh Government the Regulated Services (Service Providers and Responsible Individuals) (Wales) Regulations 2017 <https://www.legislation.gov.uk/wsi/2017/1264/contents/made>

⁷ The Care Standards Act 2000 <https://www.legislation.gov.uk/ukpga/2000/14/contents>

1. Chapter 1 - Introduction and Purpose

Introduction

- 1.1 The Act will come into force on 1 April 2023. It is a lever for improving and protecting the health, care and well-being of the current and future population of Wales. It aims to ensure a stronger citizen voice and to improve the accountability of services to deliver a better experience and quality of care. Doing so contributes to a healthy and more prosperous country. In totality, the Act is intended to have a cumulative positive benefit for everyone in Wales, supporting a culture and the conditions that focus on driving improvements in health care.
- 1.2 This statutory guidance is aimed at helping the NHS Bodies to deliver the requirements of the duty of candour.
- 1.3 The legal basis for the duty is set out in Part 3 of the Act. Section 3 prescribes when the duty of candour applies. Section 4 requires the Welsh Ministers to make Regulations, which set out the procedure that NHS Bodies must follow when the duty of candour is triggered. Sections 5 to 8 prescribe the reporting requirements. These sections of the Act are considered in more detail further in the guidance.
- 1.4 Compliance with the duty of candour will also facilitate compliance by Local Health Boards, NHS Trusts and Special Health Authorities with:
- the duty of quality contained in section 2 of the Act, requiring Bodies to exercise their functions with a view to securing improvement in the quality of health services.
 - the socio-economic duty⁸ introduced by the Equality Act 2010⁹, requiring Bodies to have due regard to the desirability of exercising their functions in a way that is designed to reduce the inequalities of outcome which result from socio-economic disadvantage; and
 - the well-being duty within the Well-being of Future Generations Act (Wales) Act¹⁰ 2015 to conduct sustainable development.
- 1.5 The duty of candour supports all people in Wales, and information about it is accessible to them. It encourages better decision making and ultimately aims to deliver better outcomes for all people who access health services. It requires NHS Bodies to involve people in decisions that affect them and to facilitate preventative action, thereby improving the quality of services and looking to the long term.

⁸ Statutory Guidance: The Equality Act 2010 (Authorities subject to a duty regarding Socio-economic Inequalities) (Wales) Regulations 2021 <https://business.senedd.wales/documents/s113354/CLA5-07-21%20Paper%2023.pdf>

⁹ 2010 Equality Act <https://www.legislation.gov.uk/ukpga/2010/15/contents>

¹⁰ Well-being of future generations (Wales) Act 2015 <https://www.futuregenerations.wales/about-us/future-generations-act/>

- 1.6 The prevailing intention is therefore to build on the work that has already been achieved through better reporting and proportionate investigation of incidents, in line with the new National Patient Safety Incident Reporting Policy¹¹ and the introduction of the Putting Things Right¹² process for investigating Concerns and Complaints. The move to implement a more structured organisational duty of candour that is supported by statutory guidance and the Candour Procedure Regulations supports the further development of the culture of openness within the NHS in Wales.

PURPOSE OF THE GUIDANCE

- 1.7 Being open with service users and their representatives when things go wrong in their care is the right thing to do. The duty of candour is designed to create a safe environment that is supportive and empowering to those providing, receiving and/or experiencing NHS treatment and care.
- 1.8 In this guidance the word **must** refers to actions that are a legal requirement as set out in the Candour Procedure Regulations or in Part 3 of the Act. The remainder of the guidance is designed to provide a framework of best practice to assist NHS Bodies in the implementation and application of the duty.
- 1.9 In accordance with section 10 of the Act, NHS Bodies must have regard to the guidance when exercising functions related to the duty of candour. To 'have regard' means that those to whom the Duty applies will have to be familiar with it and demonstrably take its principles into account when making any relevant decisions with regard to incidents or concerns relating to service user health care. Should Bodies to whom the Duty applies decide to depart from the guidance set out here, any such departure should be properly reasoned and rational and balanced against their legal obligations under the Act.
- 1.10 The guidance contains illustrative examples and case studies to assist NHS Bodies to understand when the duty of candour is triggered and offers step by step procedure flow charts.
- 1.11 It also includes guidance for NHS Bodies' on compliance with the duties placed upon them with regard to reporting, which is a key element of the duty of candour.
- 1.12 The guidance provides the foundation for NHS Bodies to develop local policies and procedures, and training and support requirements that are tailored to the

¹¹ Welsh Government, May 2021 National Patient Safety Incident Reporting Policy
<https://du.nhs.wales/patient-safety-wales/patient-safety-incidents/>

¹² Welsh Government 2011 putting things right Guidance on dealing with concerns about the NHS from 1 April 2011 version 3. <https://nwssp.nhs.wales/ourservices/legal-risk-services/legal-risk-services-documents/general-medical-practice-indemnity-gmpi-docs/healthcare-quality-guidance-dealing-with-concerns-about-the-nhs/>

body and/or the particular services they provide and will help to achieve consistency of approach and equity of response in effect: an 'All-Wales model'.

- 1.13 The guidance will be complemented by an online training package to support NHS Bodies with the implementation of the duty. Building on the work that has already been started as part of the Putting Things Right process to embed candid behaviour, the Welsh Government training programme considers how to encourage the "cultural shift" by making openness and transparency a normal part of the culture across NHS Bodies in Wales.
- 1.14 The guidance is also intended as a reference for service users and their representatives. Leaflets are available to ensure that everyone in our community can access materials that will empower them to ask questions about the care and services they receive, to help them understand what the duty of candour means, and what they can expect from their care providers when it is triggered.
- 1.15 It is not intended to be a definitive interpretation of the legislation on duty of candour. The Act, Candour Procedure Regulations and the Duty of Candour guidance should be read together.
- 1.16 We also recognise the Act, Regulations and the framework around it, whilst important, is only one part of the process. It is also necessary to overcome the known barriers to an open and honest culture for the duty of candour to become truly embedded. The barriers include fear, a culture of secrecy and/or blame, lack of confidence in communication skills, fears that people will be upset and doubt that disclosure is effective in improving culture. Disclosure can also be inhibited by fear of blame, professional or institutional repercussions, legal liability, negative reactions and a lack of accountability.
- 1.17 A system without artificial barriers between NHS Bodies, where care and support are person centred, where staff are supported to improve care rather than just manage or deliver it, and where there is an emphasis on accountability, will help to overcome these barriers.

2 Chapter 2 – The Application of The Duty of Candour

Statutory duty of candour and existing professional duties of candour

- 2.1 There have been calls to place a duty of candour¹³¹⁴¹⁵¹⁶ on NHS Bodies in Wales, separate from, and complementing the non-statutory duties of candour that apply to a range of healthcare professionals as part of their professional regulation. Although, it should be acknowledged that professional Duty of candour guidance applies in more situations than the Welsh organisational Duty of Candour.
- 2.2 Healthcare professionals who are subject to a professional duty of candour have to be open and honest with service users, colleagues, their employers and relevant organisations, and must take part in reviews and investigations when requested. They must support and encourage each other to be open and honest¹⁷. They must also be open and honest with their regulators, raising concerns where appropriate. The fundamental principles of a duty of candour are therefore already embedded across a wide section of NHS Bodies through those professionals who work within them.
- 2.3 The statutory duty of candour and the professional duties of candour have the same aims – to be open and transparent with people receiving care and treatment. The strong links between the statutory and professional duties of candour will empower staff to speak openly about concerns, and seamlessly encourage learning to improve the quality-of-care provision.
- 2.4 The professional duty of candour relates to individual professional practice whereas the statutory organisational duty is placed on an organisation to ensure that when triggered service users have the same openness and transparency about what has occurred with their care applied by the organisation.

¹³ Kennedy, I, and others. The Bristol Royal infirmary inquiry. Learning from Bristol - The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995 [Internet]. Crown; 2001. Available from: https://webarchive.nationalarchives.gov.uk/20090811143822/http://www.bristol-inquiry.org.uk/final_report/the_report.pdf

¹⁴ Donaldson, L. Making Amends - A consultation paper setting out proposals for reforming the approach to clinical negligence in the NHS [Internet]. Department of Health Publications; 2003. Available from: https://webarchive.nationalarchives.gov.uk/20120809195448/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4060945.pdf

¹⁵ Francis, R, and others. Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry [Internet]. Staffordshire NHS Foundation Trust; 2013. Available from: <https://www.gov.uk/government/publications/report-of-the-mid-staffordshire-nhs-foundation-trust-public-inquiry>

¹⁶ Evans, K. "Using the Gift of Complaints" - a review of concerns (complaints) handling in NHS Wales. 2014. <https://gweddill.gov.wales/docs/dhss/publications/140702complaintsen.pdf>

¹⁷ Nursing and Midwifery Council and General Medical Council 2022 Openness and honesty when things go wrong: the professional duty of candour. https://www.nmc.org.uk/standards/guidance/the-professional-duty-of-candour/read-the-professional-duty-of-candour/#about_guidance

- 2.5 The statutory duty will promote a system wide culture of openness and honesty. It also places a requirement, at an organisational level for NHS Bodies, to follow a set procedure, underpinned by the Candour Procedure Regulations to evidence that a series of prescribed actions have been undertaken when the duty is triggered. These actions are described in Chapter 3 below, which is supported by a procedure flow chart found in **Annex C**. This infrastructure will help create the conditions for NHS Bodies to discharge the duty of candour with confidence when triggered. There are case studies in annex H which provide some clinical examples.
- 2.6 **Pharmacists and pharmacy technicians**
Registered pharmacists, pharmacy technicians and persons working under their supervision in a retail pharmacy should continue to be mindful of the provisions of the Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018 (“the Order”)¹⁸. Pharmacy professionals are at risk of prosecution under section 63 (adulteration of medicinal products) and section 64 (protection of purchasers of medicinal products) of the Medicines Act 1968¹⁹ in the event that they prepare or dispense medicines erroneously.
- 2.7 In order to benefit from the defences in section 67B (defence to offence of contravening section 63(a) or (b): product sold or supplied) and section 67C (defence to offence of contravening section 64) of the Medicines Act 1968, the conditions for benefitting from the defences must be satisfied, including the conditions relating to notification of the person to whom the product was intended to be administered.
- 2.8 Consequently, the requirements of the Order need to be considered alongside and in addition to the statutory duty of candour.

WHO DOES THE DUTY OF CANDOUR APPLY TO?

- 2.9 The duty of candour within Part 3 of the Act applies to the following NHS Bodies which are listed within section 11(3), and defined by reference to section 11(4) and (7):
- Local Health Boards.
 - Primary Care providers in Wales (i.e. General Practitioners, dentists, optometrists and pharmacists) in respect of the services they provide under a contract or arrangement with a Local Health Board (i.e. it applies to the NHS services provided by primary care providers).
 - NHS Trusts in Wales.
 - Welsh Special Health Authorities, and NHS Blood and Transplant in relation to the functions it exercises in relation to Wales.

¹⁸ The Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018.

<https://www.legislation.gov.uk/uksi/2018/181>

¹⁹ Medicines Act. <https://www.legislation.gov.uk/ukpga/1968/67/contents>

WHEN DOES THE DUTY OF CANDOUR PROCEDURE APPLY?

- 2.10 The duty comes into effect in relation to an NHS body if **both** of the following conditions are met:
- (1) The **first condition** is that a person (the “service user”) to whom health care is being or has been provided by the body has suffered an adverse outcome.
- 2.11 ‘Health care’ means services provided in Wales under or by virtue of the National Health Service (Wales) Act 2006 i.e. as part of any NHS service, for or in connection with:
- the prevention, diagnosis or treatment of illness; or
 - the promotion and protection of public health.
- 2.12 “Illness” includes any disorder or disability of the mind and any injury or disability requiring medical or dental treatment or nursing.
- 2.13 The meaning of health care is deliberately widely drawn to capture all of the NHS services provided in Wales.
- 2.14 A service user is to be treated as having suffered an adverse outcome if the user experiences, or if the circumstances are such that the user **could** experience, any unexpected or unintended harm that is more than minimal.
- 2.15 As set out in the Explanatory Notes to the Act, the duty may be triggered by an action taken by an NHS body during the provision of health care or by an omission to take action.
- 2.16 For the purpose of the duty of candour, harm includes psychological harm, and in the case of a service user who is pregnant, loss of or harm to the unborn child (section 11(7) of the Act).
- (2) The **second condition** is that the provision of the health care was or may have been a factor in the service user suffering that outcome.
- 2.17 The outcome must therefore relate to the provision of the care by the NHS body rather than being solely attributable to the person’s illness or underlying condition - see further in chapter 2.
- 2.18 It need not, however, be certain that the health care caused the harm. It is sufficient that the health care may have been a factor.
- 2.19 In the Candour Procedure Regulations when both of these conditions are satisfied and the duty is triggered, it is called a “notifiable adverse outcome.” **Annex A** sets out in flow chart form the trigger review process.

3 Chapter 3 – Establishing the level of harm

More Than Minimal Harm

- 3.1 “More than minimal harm” is not defined in the Act. However, for the purposes of this guidance “more than minimal harm” is considered to constitute moderate harm, severe harm and death. This supports the existing processes for Putting Things Right and Being Open and also aligns with the national patient safety incident reporting policy and the Datix Cymru system, incident reporting module. Therefore, in practice, the duty of candour is triggered if the service user experiences, or the circumstances are such that the user could experience, unexpected or unintended harm that is of moderate degree or above and the provision of health care was (or may have been) a factor in the service user suffering that outcome.
- 3.2 Moderate Harm: is any significant but not permanent harm or harm that requires a ‘moderate increase in treatment’ relating to the incident. A moderate increase in treatment is defined as an unplanned return to surgery, an unplanned readmission, a prolonged episode of care, extra time in hospital or as an outpatient or transfer to another treatment area such as intensive care.
- 3.3 Severe Harm: is the permanent lessening of the bodily, sensory, motor, physiologic or intellectual functions, including the removal of the wrong limb or organ or brain damage, which is related directly to the incident and not related to a natural course of the service user’s illness or underlying condition.
- 3.4 Death: A death caused or contributed to by a patient safety incident, as opposed to a death which occurs as a direct result of the natural course of the patient’s illness or underlying condition
- 3.5 A level of harm framework, providing explanations of harm that are considered moderate and above, is included in **Annex B**.

Harm that is ‘unintended’ or ‘unexpected’

- 3.6 To be notifiable, the harm must be unintended or unexpected. It can be as a result of either an actual intervention/treatment, or an omission in care, for example, a missed cancer diagnosis.
- 3.7 Medical or surgical treatment and all care interventions may of course come with inherent risks or may in itself cause a temporary increase in symptoms.
- 3.8 Harm which is caused by the treatment itself (e.g. impairments in function as a result of surgery,) would not necessarily be notifiable. These may fall into the category of a known risk, which may have been explained to, and accepted by, the patient as part of the consenting process.

Side effects and complications

- 3.9 It is not the policy intention that all side effects to medication or treatment that have caused harm or yet may cause harm would necessarily trigger the duty of candour. Firstly the harm threshold has to be met and the harm must be unintended or unexpected as outlined above. In essence complications associated with care that was not discussed as a risk of the health care provided may meet the trigger threshold for the duty. There are well established mechanisms for reporting and monitoring the side effects and adverse reactions of medication which will still need to be followed and learned from whether the duty is triggered or not.
- 3.10 It is often unclear in the initial stages whether unintended or unexpected harm has or may occurred and discussion as part of a senior review is recommended where the situation is complex.

Harm caused deliberately

- 3.11 The majority of patient safety incidents that may lead to the triggering of the duty of candour often involve a conversation between managers and supervisors about whether a staff member involved in a patient safety incident requires specific individual support or intervention to continue to work safely. The implementation of action singling out an individual is rarely appropriate - most patient safety issues have deeper systemic causes and require wider action.
- 3.12 The Williams Report which reported on gross negligent manslaughter in the NHS highlights this approach²⁰ and recommended the establishment of a 'Just Culture' providing reassurance to healthcare professionals, patients and their families that gross negligence cases will be dealt with in a fair and compassionate manner and the subsequent just culture algorithm supports these discussions²¹.
- 3.13 However there are rare situations where it becomes clear that individual performance or actions or omissions may have breached professional codes of practice or criminal law and are not part of a wider patient safety organisational cause or action. It is imperative that the enactment of the duty of candour doesn't interfere with urgent police investigation or safeguarding multi agency strategy meetings and may be necessary that there is a consideration of a delay for the 'in-person' notification. Discussion with lead

²⁰ Williams N (2018) Gross negligence manslaughter in healthcare the report of a rapid policy review. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/717946/Williams_Report.pdf

²¹ NHSE and NHSI (2021) Just culture guide. https://www.england.nhs.uk/wp-content/uploads/2021/02/NHS_0932_JC_Poster_A3.pdf

investigators prior to any further disclosure is recommended. Regulation 12 of the Candour procedure regulations allows for this.

What does harm the service user ‘could experience’ mean?

- 3.14 It is important to note that the duty is triggered not only when harm is known to have occurred, but also in cases **where the circumstances are such that a person could experience harm that is more than minimal in the future from an incident that has already occurred.** For example, where an error in the administration of medication that was administered may cause harm that is more than minimal at a future point.
- 3.15 NHS Bodies will have to reach a judgment about whether the circumstances are such that the user could experience harm that is more than minimal. In the example of an error in the administration of medication, whether or not such an error may give rise to harm that is more than minimal may be dependent upon the nature of the medication that was given in error or the circumstances of the particular service user
- 3.16 To put this in context for practitioners, this has been explained by the GMC in their professional duty of candour guidance as, ‘in situations where a patient ‘may yet suffer harm’ as a result of an adverse outcome.
- 3.17 **Annex H** contains illustrative case studies that set out detailed examples of instances that would trigger the duty of candour and those that would not. It also contains examples of cases that demonstrate the duty being triggered where harm could occur in the future. (Case studies, 9, 10 & 11).

NEAR MISS INCIDENTS

- 3.18 These are any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to people receiving NHS-funded care in Wales. Near miss incidents are **not** considered a trigger for the duty of candour procedure. The duty is designed to capture more than minimal harm that is apparent at the time of the incident or may appear later. With a near miss incident, harm (or the potential for future harm) is averted. This is often as the action that would have induced the harm was stopped from occurring or avoided.
- 3.19 For example, the administration of the wrong medication was averted through an additional step or the intervention of another and so it did not occur. The difference between a near miss and an incident where harm could yet occur is that in an incident where harm could yet occur the action has occurred however the harm has yet to manifest.

- 3.20 However, due to their serious nature and the need to learn from such incidents and prevent their recurrence, near miss incidents should be managed following the normal reporting processes²².
- 3.21 Even though the statutory duty of candour under the Act is not triggered by a near miss, individual practitioners should familiarise themselves with the guidance on near misses provided by their professional regulatory Bodies. For example, both the Nursing and Midwifery Council²³ and the General Medical Council²⁴ provide guidance and support to practitioners on when and how to speak to service users about near miss incidents.

Harm that occurs to Service Users whilst waiting for diagnostics or care from the NHS

- 3.22 Since the Global SARS-CoV-2 Pandemic in 2020 there has been continued significant pressure on resources within the NHS and subsequently many more patients are awaiting diagnostics, procedures and care on NHS waiting lists. Care will need to be taken when considering harm that occurs while a service user is waiting for their treatment. Every step in a clinical pathway will entail a waiting time, which may be longer at times of significant service pressure.
- 3.23 Where a service user suffers harm whilst on a waiting list, this could **potentially** trigger the duty of candour.
- 3.24 For a Service User to be on a waiting list for a diagnosis or treatment there must usually be a referral which involves an assessment and clinical decision. In placing the Service user on the waiting list there will have been some consideration of the likely risk of waiting and the best interests of the service user in the prevailing service context. The service user is therefore considered to be under the care of a consultant or primary care physician and there is often active monitoring of the waiting list which involves an element of clinical input and judgment which also amounts to the provision of health care.
- 3.25 However, the other key components that must be satisfied before the duty is triggered is that the service user to whom health care is being or has been provided by the body has suffered an “adverse outcome,” and that the provision of the health care was or may have been a factor in the service user suffering that outcome. A service user is to be treated as having suffered an adverse

²² NHS Delivery Unit (2023) Patient Safety incidents. <https://du.nhs.wales/patient-safety-wales/patient-safety-incidents/>

²³ NMC and GMC (2019) Openness and honesty when things go wrong: the professional duty of candour <https://www.nmc.org.uk/globalassets/sitedocuments/nmc-publications/openness-and-honesty-professional-duty-of-candour.pdf>.

²⁴ GMC (2023) Being open and honest with patients in your care, and those close to them, when things go wrong <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/candour---openness-and-honesty-when-things-go-wrong/being-open-and-honest-with-patients-in-your-care-and-those-close-to-them-when-things-go-wrong#paragraph-21>

outcome if the user experiences, or if the circumstances are such that the user could experience, any “unexpected or unintended” harm that is more than minimal.

- 3.26 An example of this in practice is where a service user with angina is placed on a well-managed waiting list for a bypass procedure and suffers a heart attack while waiting. In this scenario the duty may not apply if the harm was as a result of the natural deterioration in their condition. This is because disease progression in itself would not necessarily trigger the duty of candour and the risk of that progression would normally be discussed with the service user. This doesn't mean that the service user shouldn't receive an apology and explanation of what has happened as a matter of best practice. However, if the service user had been mistakenly missed off the list or incorrectly prioritised, therefore creating an undue delay, which gave rise to the adverse outcome then the duty might apply.
- 3.27 Waiting lists should be actively managed, and new clinical decisions should be taken when the known risk changes to minimise harm to the service user. The materialisation of a risk that is known to the service user and clinician, in itself would not necessarily trigger the duty of candour.
- 3.28 The initiation of the duty of candour is designed to respond to a service user/ or person acting on their behalf, in an open and transparent way when things have or may have gone wrong in their care. These actions, as previously referenced, are not an admission of liability or breach of statutory duty.
- 3.29 It is strongly encouraged that, when more than one NHS body engages in the pathway of care, the NHS Bodies involved must work together in partnership to deliver the duty of candour procedure and are fully involved in the process. See chapter 6

4 Chapter 4 – The Candour Procedure

- 4.1 The Candour Procedure Regulations prescribe the actions that **must** be taken by an NHS body when the duty of candour is triggered.
- 4.2 This section of the guidance needs to be read in conjunction with those Regulations, and the procedure flow chart included in **Annex C**.

Notification

- 4.3 The Act and Candour Procedure Regulations require NHS Bodies to notify on '**first becoming aware**' that the duty of candour has come into effect and not to wait for the findings of any initial investigation before notification.
- 4.4 It is important to note that regulation 4 of the Candour Procedure Regulations requires the NHS body to notify the **service user** who has suffered a notifiable

adverse outcome or a **person who is acting on their behalf** (in the Candour Procedure Regulations²⁵, this person is called the “relevant person”).

4.5 Notification may be made to a person who is acting lawfully on the service user’s behalf, where the service user:

- has died.
- is 16 or over and lacks capacity (within the meaning of the Mental Capacity Act 2005) in relation to the matter; or
- is under 16 and not competent to make a decision in relation to their care or treatment. (Also refer to Chapter 7)

4.6 The Candour Procedure Regulations also allow a service user with capacity to nominate a trusted person to act on their behalf in relation to the duty of candour, recognising that not everyone to whom the duty applies will want to engage personally with the process.

4.7 It is important to ensure that at all times the requirements of the UK General Data Protection Regulation (UK GDPR²⁶) are adhered to when accessing, processing and disclosing service user information. In cases where a representative is acting on behalf of a service user with capacity, consent for the representative to act should be obtained in writing and be kept under review throughout the process. This is also in line with the 2011 Regulations.

What does on ‘first becoming aware’ mean?

4.8 The requirement to notify the service user/person acting on their behalf on first becoming aware the duty has been triggered means that the NHS body should reflect and make a considered decision as to whether the conditions as set out in part 4 above have been met. Once determined by the NHS Body that the conditions as set out in part 4 above have been met, this would be considered to be the point at which the NHS body **‘first becomes aware’** that the duty has been triggered.

4.9 This is the start date for the duty of candour procedure (referred to in this Guidance and the appendices as “the procedure start date”), which **must** be followed, starting with the “in-person” notification to the service user/person acting on their behalf.

4.10 Each NHS body should have a robust and consistent process in place for determining whether reported adverse outcomes (incidents) trigger the duty or not. **This does not mean that NHS Bodies investigate the circumstances of the reported incident before making this decision.** There will need to be some reflection and decision making on the part of the NHS body before deciding if the duty has been triggered, but not a detailed investigation. It is important that

²⁵ National Health Service Wales (2023) The Duty of Candour Procedure (Wales) Regulations 2023.

²⁶ UK Government (2018) Data Protection Act 2018.

<https://www.legislation.gov.uk/ukpga/2018/12/contents>

arrangements are in place for organisations that provide services on behalf of NHS Bodies to ensure that the NHS body is notified of any trigger of the duty of candour (refer to chapter 6).

- 4.11 The use of the Datix Cymru system is not mandatory. However, its rollout and development has been designed to support the implementation of the duty of candour and it is available, to all NHS Bodies including all primary care providers.
- 4.12 Consequently, it is anticipated, and encouraged, that NHS Bodies report incidents through the Datix Cymru system. There is a prompt on the system to ask those completing/and or reviewing the incident report whether or not the duty of candour has been triggered and to record the level of harm and the system also facilitates the documentation of reasons that the duty wasn't triggered.
- 4.13 NHS Bodies will need to develop a system for locally undertaking the 'review' of those incidents that have initially been reported as meeting the criteria for triggering the duty of candour, i.e. where it is thought the conditions as set out in Chapter 2 above have been met. This could, for example, be as simple as recording that on review and after consideration, it was agreed that the threshold for more than minimal harm has been met or that it has not been met or that the harm was not unexpected or the harm that was suffered was not related to the provision of the health care.
- 4.14 **Therefore, the duty of candour procedure start date is the date on which an NHS body first becomes aware of a notifiable adverse outcome.**
- 4.15 Where the "in-person" notification is made later than 30 working days after the date the NHS body first becomes aware of a notifiable adverse outcome, which would be the candour procedure start date, an explanation should be provided and the reason for the delayed notification should be recorded on the incident report. This would be a rare occurrence but may happen where the duty of candour is triggered by a case review or a medical examiner review.
- 4.16 **This does not mean that the NHS body has routinely a 30-day period in which to deliver the 'in-person' notification.** The Act is clear that the NHS body must take all reasonable steps to deliver the "in-person" notification as soon as they become aware of the notifiable adverse incident.
- 4.17 Considering how this would apply in practice, the "sequence of events" would be as follows:
- a service user suffers harm related to (or potentially related to) treatment.
 - staff are free to apologise, explain what has happened to the service user/family as they should do to comply with their professional duties of candour.
 - they report the "incident" (in the majority of cases using Datix Cymru).
 - Datix Cymru prompts consideration of whether the duty of candour is triggered.
 - If, in the view of the person reporting the incident, it is felt that the duty is triggered by recording on the Datix Cymru incident module that moderate or

above harm has been caused or could be caused, an openness and transparency section will automatically open allowing the reporter to record further information in line with the duty of candour procedure requirement.

- If it is determined that the duty of candour has not been triggered, even though the moderate or above harm has been caused or could be caused, a note of the reasons for reaching such a decision must be recorded on the incident report in Datix Cymru.
- All incidents are reviewed internally by the NHS body (except where health care is provided by a commissioned or hosted partner).
- For those where it is agreed the conditions for meeting the duty of candour (set out at Chapter 2 above) are met, then notification of the service user is initiated.

How to notify

- 4.18 Notification to the service user or person acting on their behalf should be “in-person”²⁷ which means communication on the telephone, via audio-visual communication (such as a video call) or face to face. It is considered many service users would be surprised to receive a letter in the post advising them the duty had been triggered and may have questions/worries that will need to be answered/alleviated immediately. Leaving voice messages, is also not considered appropriate when making the “in-person” contact. Experience from recent stakeholder sessions also demonstrates that an “in-person” approach for the first contact is most appropriate.
- 4.19 However, NHS Bodies have a discretion as to which method of “in-person” communication is most appropriate. It may not be achievable in practical terms for there to be a face-to-face meeting with everyone in relation to whom the duty of candour has been triggered. The NHS body should consider each circumstance and identify the preferences of the service user/person acting on their behalf and make every effort to meet these where possible.
- 4.20 The factors that an NHS body must consider when determining which form of “in-person” notification is most appropriate are:
- a) severity of the harm.
 - b) nature and complexity of the notifiable adverse outcome.
personal circumstances of the service user (if known)
 - c) any communication already undertaken with the service user/person acting on their behalf
 - d) any known preferred method of communication of the service user/person acting on their behalf. This is particularly important where the service user may require support, for example where Welsh is the first language of the service user or their family or BSL or a foreign language interpreter may be needed.

²⁷ In accordance with regulation 4 of the Candour Procedure Regulations.

- 4.21 In some situations, the initial notification via the telephone or video call may suffice; in more complex cases it is likely to be more appropriate for a face-to-face meeting with the service user/person acting on their behalf to be arranged.
- 4.22 The NHS body must take reasonable steps to establish the preferred method of communication. They must also take reasonable steps to ensure that communication is in a manner that the service user/person acting on their behalf can understand²⁸. NHS Bodies are subject to Welsh Language Standards requirements as set out in the Welsh Language Standards (No. 7) Regulations 2018²⁹
- 4.23 It is recognised that in some instances, the preferred method of communication or service user contact preference, may not be known at the outset; establishing contact via the telephone may be necessary in the first instance to begin dialogue on what steps might need to be taken to allow the duty of candour procedure to be followed.

Who notifies and the purpose of the notification

- 4.24 The NHS body will need to determine the most appropriate person or persons to make the initial “in-person” notification to the service user/person acting on their behalf. The NHS body needs to consider whom is the most appropriate person or persons to make the initial “in-person” notification to the service user/person acting on their behalf.
- 4.25 Primarily, the initial contact with the service user/person acting on their behalf, is to acknowledge what has happened and offer a meaningful, personalised apology for the harm they have experienced or may yet experience and provide advice on what will happen next. (Refer to annexe E and other professional resources on communicating an apology).
- 4.26 The NHS body must nominate a person with sufficient knowledge, experience, training and understanding of the duty of candour procedure to be able to assist the service user/their representative with any questions that may arise as they go through the process, this is the “nominated point of contact”.
- 4.27 Regulation 4 of the Candour Procedure Regulations prescribes what **must** be covered in the initial “in-person” notification.
- 4.28 The person making the initial contact with the service user/person acting on their behalf must:
- clearly explain what information they know so far about what has happened.
 - outline why the NHS body is of the view the duty of candour has been triggered.

²⁸ See regulation 7 of the Candour Procedure Regulations.

²⁹ The Welsh Language Standards (No. 7) Regulations 2018 [The Welsh Language Standards \(No. 7\) Regulations 2018 \(legislation.gov.uk\)](https://legislation.gov.uk)

- provide an apology. Guidance on how to make a meaningful, personalised apology is set out below and in Annex E.
- provide the contact details of whom is the nominated point of contact for the NHS body. The nominated point of contact is the person the service user/person acting on their behalf will contact if they have any questions about the duty of candour process.
- provide an explanation of the actions and further enquiries the NHS body will undertake to investigate the circumstances of the notifiable adverse outcome. This includes any actions the NHS body (or where services have been commissioned from an independent provider in Wales, the provider) will take under the 2011 Regulations. The investigation of the notifiable adverse outcome is considered further at Chapter 5.
- communicate to the service user/person acting on their behalf details of any services or sources of support which the NHS body reasonably thinks may be of assistance to them, taking account of their needs. **Annex D** sets out useful contacts for support options.
- Document this in the service users care record and on datix Cymru.

4.29 Regulation 4 also requires the person making the ‘in-person’ notification to provide an explanation to the service user/person acting on their behalf if the date on which the ‘in-person’ notification is made by the NHS body is more than 30 working days after the date on which the NHS body first became aware of the notifiable adverse outcome. This is to explain any delay in notification that could arise, for example, following a retrospective case review. The law requires that the NHS body makes the “in-person” notification on first becoming aware of the notifiable adverse outcome and therefore it does not mean that NHS Bodies routinely have 30 working days from the date the notifiable adverse outcome occurred to make the “in-person” notification.

4.30 It is also good practice to establish what the service user/person acting on their behalf understands about what has happened. The person making the notification on behalf of the NHS body should also demonstrate they understand the circumstances and the impact for the person affected. They should not question the extent of harm suffered by the person affected or the circumstances of the ‘incident’ as the service user has experienced it.

4.31 This may be the starting point for longer conversations with the service user/person acting on their behalf and it will be important for all involved that this initial contact is carried out in the true spirit of the duty, with openness, empathy and sincerity.

4.32 *Things to consider – **Before the “in-person” notification takes place:***

- has someone from the NHS body already been in contact with the service user/person acting on their behalf? This may be related to this incident or other aspects of their healthcare.
- what discussions or information exchange have already taken place (if any)?
- what is known about what has happened and the level of harm sustained or could be sustained?

- is the preferred method of notification known? e.g. verbal, written, electronic; it is recommended to check any previous datix, Welsh clinical portal, Welsh PAS or care records.
- who will be the nominated point of contact within the NHS body following the initial notification?
- what support is available to the service user/person acting on their behalf, to assist them during the notification process and afterwards?
- ensure that communication is in a manner that the service user or the person acting on their behalf, can understand including Welsh if that is their first language.
- Consider the location of the conversation if it is to be face to face or via video call to ensure privacy and confidentiality are maintained.
- It should also be recognised that a service user may have a number of questions relating to their care and the presence of a member of the clinical team may be prudent

Follow up in writing

4.33 Following the “in-person” notification, regulation 5 of the Candour Procedure Regulations requires the NHS body to take all reasonable steps to write to the service user/person acting on their behalf (unless they have indicated they do not wish to engage in the candour process) within five working days after the day of the ‘in-person’ notification. Notification in writing includes notification via email.

4.34 The aim of the written notification is to confirm in writing what has been discussed at the “in-person” notification. This is to aid the understanding of the service user/person acting on their behalf, and also to provide the NHS body with a record of what has been discussed.

4.35 Therefore the written must include:

- a description that explains clearly what information is known so far about what has happened
- a reiteration of the verbal apology,
- the information provided in the ‘in-person’ notification, which for completeness is as follows:
 - the reason that the NHS body considers that the duty of candour has been triggered.
 - the name and contact details of the person at the NHS body nominated as the point of contact for the service user/person acting on their behalf in respect of the duty of candour procedure,
 - an explanation of the actions that the responsible body or the provider will take, and further enquiries that the responsible body or the provider will carry out, to investigate the circumstances of the notifiable adverse outcome, including any actions to be taken under the 2011 Regulations
 - a reiteration of the offer of details of relevant services or support, and
 - where the “in-person” notification is made later than 30 working days after the date on which the NHS body first became aware of the notifiable adverse outcome, an explanation of the reason for the delay.

- Document this on Datix Cymru

- 4.36 Consideration should be given to personalising the notification letter with a handwritten signature. It has been suggested during focus sessions with members of the public that a handwritten signature has a positive impact when an apology of this nature is being conveyed.
- 4.37 The NHS body **must** take all reasonable steps to send the written notification to the service user/person acting on their behalf within **five working days** following the date of the “in-person” notification.
- 4.38 It is important to acknowledge that delayed or poor communication makes it more likely that the service user/person acting on their behalf, will seek information in a different way, for example, by making a complaint or taking legal action. It may also mean that they will not feel that there has been openness and honesty in the process from the outset.

The Apology

- 4.39 Making a meaningful, personalised apology is a key part of the “in-person” notification process. **Annex E** provides further information on making an apology as part of the duty of candour procedure.
- 4.40 A meaningful, personalised apology can be a practical way of maintaining or restoring trust. When conveyed with empathy, sincerity and understanding, an apology can be effective and powerful and it is crucial for everyone involved when the duty of candour is triggered, including the service user/person acting on their behalf, and the staff who care for them. The impact on everyone involved when the duty of candour is triggered cannot be underestimated. For the service user/person acting on their behalf, an apology is usually the most important action that any one individual and organisation can take, and it is important that a timely apology is given in accordance with the regulations.
- 4.41 People who feel that they have not been listened to or informed openly and honestly from the outset are more likely to feel that the harm they have suffered has been compounded and can lead to the loss of trust in their health care provider. This can result in feelings of anger and cause a break down in the relationship. It may also mean that escalated action is taken.
- 4.42 It is recognised that there may be misconceptions and misunderstanding that the provision of an apology equates to an acceptance of blame, culpability or even legal liability³⁰.
- 4.43 This is not the case, and it should not give rise to any such assumption or hinder or delay the offer of an apology.
- 4.44 “Apology” is defined within regulation 2 of the Candour Procedure Regulations as:

³⁰ Compensation Act 2006 section 2. <https://www.legislation.gov.uk/ukpga/2006/29/contents>

apology means an expression of sorrow or regret in respect of the notifiable adverse outcome.

- 4.45 Regulation 13 specifically provides that an apology or any other step taken in accordance with the candour procedure does not amount to an admission of negligence or to a breach of statutory duty.
- 4.46 The giving of an apology acknowledges what has happened or at this stage what is known to have happened and provides assurance, the matter is being taken seriously and opportunities for learning will be taken to prevent similar circumstances from arising in the future. It is important to ensure the apology covers what is known at that point without speculating or including assumptions on what may have happened or caused the incident to occur. It is helpful to admit at this early stage that a lot may be unknown but that more detail is likely to become clearer during the investigation that follows.
- 4.47 We recognise that sometimes staff can find it difficult to say sorry when harm has occurred or may occur at some point in the future. They may be unclear if they can say sorry and worry that the timing for doing this will not be right, or that they will make things worse, especially as the service user/person acting on their behalf, may be understandably angry and upset. **Annex E** aims to provide guidance to support staff in this regard.
- 4.48 It is best practice to document the verbal apology in the patient care record. This means that the entire care team will know when an apology has been given and can avoid duplication.

Notification of results of further enquiries

- 4.49 Regulation 6 of the Candour Procedure Regulations requires NHS Bodies to notify the service user/person acting on their behalf of the results of any further enquiries (investigations) carried out by the NHS body that may have been referred to in the “in-person” notification. These enquiries are understood to be the investigation that is to be undertaken by the NHS body.
- 4.50 In practice, in the vast majority of cases once the service user/person acting on their behalf has been notified, the NHS body will undertake further enquiries and investigate the circumstances in which the duty of candour came into effect in accordance with the provisions of the 2011 Regulations. NHS Bodies will be familiar with this process as it governs the way in which incidents are currently investigated.
- 4.51 Communication with the service user/person acting on their behalf under the provisions of the 2011 Regulations, which includes a requirement to outline in writing the outcome of investigations, will also satisfy the requirements of regulation 6 of the Candour Procedure Regulations, so avoiding duplication in the event that the 2011 Regulations apply.
- 4.52 As set out below in Chapter 5, the 2011 Regulations do not apply to all NHS Bodies – for example, they do not apply to NHS Blood and Transplant.

Additionally, there may be exceptional circumstances where the 2011 Regulations do not apply. In these circumstances, NHS Bodies should ensure that they have arrangements in place to enable them to comply with the notification requirements in regulations 4, 5 and 6.

Communication with service user/person acting on their behalf

4.53 Regulation 7 prescribes what an NHS body must do if it is unable to make contact with the service user or a person acting on their behalf to:

- (i) make the “in-person” notification (regulation 4),
- (ii) the written notification (regulation 5),
- (iii) to notify of results of further enquiries (regulation 6),

or if the service user or person acting on their behalf declines to participate in communication with the NHS body.

4.54 If the NHS body, having taken reasonable steps, is unable to make contact, the attempts to make contact must be recorded as part of the information that is required to be kept by virtue of regulation 9 (Records), see guidance on record keeping below. Ideally the information should be recorded on the incident record, which in most circumstances will be datix Cymru.

4.55 If the service user/person acting on their behalf, indicates that they do not wish to communicate with, or receive information from the NHS body, this must also be clearly recorded in accordance with regulation 9 and the person’s wishes respected. Again, good practice would be to record this on the incident record (datix Cymru), and also on the service user’s care records.

4.56 In accordance with regulation 7(3)(b) of the Candour Regulations NHS Bodies are not required to provide information to or communicate with the service user/person acting on their behalf in these circumstances where they have indicated that they do not wish to communicate with or receive information from the NHS body. However, the investigation of the incident giving rise to the triggering of the duty must continue so that lessons can be learned, and quality improvements made.

4.57 The NHS body should inform the service user/person acting on their behalf that they can contact the NHS body should they change their mind about their involvement in the process.

4.58 The NHS body must take reasonable steps to ascertain the service user/person acting on their behalf’s preferred method of communication and, where reasonably practicable, communicate with them by this method.

4.59 The NHS body must take all reasonable steps to ensure that any communication with the service user/person acting on their behalf is in a manner they can understand this is especially important where disability is present or where the service user is a vulnerable adult or child or young person.

Support and Training

- 4.60 it is important to recognise that the service user or person acting on their behalf may be very affected by the information contained within the 'in-person' notification and will need ongoing support as they come to terms with the impact on them of the harm that has occurred or may occur as highlighted in chapter 4.
- 4.61 NHS staff go to work to provide high quality care to those in need of care and treatment. When a service user suffers an adverse outcome and the duty of candour is triggered, it is important to recognise that staff involved in the care of the service user will also be impacted and may require support.
- 4.62 Regulation 8 of The Candour Procedure Regulations sets out the requirements in relation to training and support.
- 4.63 The requirements are for relevant training and guidance to be given to all staff involved in:
- the provision of health care; and
 - investigating or managing notifiable adverse outcomes, and
 - any other relevant members of staff who engage in performing or exercising functions in connection with the duty of candour procedure.
- 4.64 As well as all clinical staff, in practice this would include senior staff (including Board level staff) responsible for overseeing the management of adverse outcomes in their organisations, those directly involved with the investigation, management and/or notification of notifiable adverse outcomes and any other staff who deal with complaints and concerns. At primary care level this would for example include practice managers.
- 4.65 Training modules will be developed nationally in liaison and are available via digital platforms to all NHS staff including primary care providers. This guidance document and annexes provide all the relevant support documents to assist NHS Bodies in discharging their duty in respect of ensuring staff awareness of the duty of candour.
- 4.66 The Candour Procedure Regulations also set out that the NHS body must provide a member of staff who engages in a notifiable adverse outcome with details of services or support available, taking into account:
- the circumstances relating to the notifiable adverse outcome; and
 - the staff member's needs.
- 4.67 NHS Bodies will have mechanisms in place and local support services available to pro-actively offer the appropriate provision of support and assistance to staff members through their Employee Wellbeing Service/Occupational Health/Employee Assistance Programmes.

- 4.68 In addition there are several national support services available via the Health Education & Improvement Wales (HEIW) website³¹, such as Health for Health Professionals (Canopi)³², SilverCloud³³ and Samaritans³⁴.
- 4.69 Local Line Managers, Clinical Supervisors, Workforce and OD professionals (including employee wellbeing and occupational health colleagues) and Trade Union representatives will also be able to signpost staff to appropriate support services.

Record keeping

- 4.70 Section 4(3)(c) of the Act requires the Candour Procedure Regulations to prescribe the records that NHS Bodies must keep in relation to the discharge of the duty.
- 4.71 Regulation 9 of the Candour Procedure Regulations requires NHS Bodies to keep an accurate written record for each notifiable adverse outcome in respect of which the candour procedure is followed.
- 4.72 The written record must include every document and piece of correspondence relating to the notifiable adverse outcome, not limited to:
- the notification of the duty.
 - attempts to contact the service user/person acting on their behalf.
 - any decision by the service user/person acting on their behalf not to be contacted in relation to the duty of candour; and
 - all documentation relating to the review to establish whether the duty has been triggered and the subsequent investigation of the notifiable adverse outcome, that is undertaken by the NHS body, including the response or interim report issued under regulations 24, 26 or 31 of the 2011 Regulations.
- 4.73 It is considered good practice to record any decision not to trigger the duty (where triggering was contemplated). It is important that accurate records are kept supporting quality assurance mechanisms needed to identify areas for learning and improvement and also to enable NHS Bodies to comply with their reporting requirements under the Act which are considered in part 11 below.
- 4.74 It is envisaged that the Datix Cymru system will be used for the purposes of reporting and recording keeping.

³¹ HEIW (2023) Workforce support. <https://heiw.nhs.wales/support/>

³² Canopi (formally Health for health professionals) <https://hhpwales.nhs.wales/about-us/>

³³ SilvercloudWales. <https://nhs.wales.silvercloudhealth.com/signup/>

³⁴ The Samaritans 2023 <https://www.samaritans.org/>

5 Chapter 5 - The Investigation

- 5.1 When notifying the service user or person acting on their behalf that the duty of candour has been triggered, an NHS body must (in accordance with regulations 4(3)(e) and 5(3)(c) of the Candour Procedure Regulations) also give an explanation of the actions and further enquiries it will take to investigate the circumstances of the notifiable adverse outcome.
- 5.2 In the vast majority of cases, this means following the 2011 Regulations procedure for investigating concerns. “Concerns” as defined in the 2011 Regulations includes all patient safety incidents.
- 5.3 However, there will be instances where, even though the duty of candour applies, an investigation under the 2011 Regulations will not be required. For instance, the 2011 Regulations do not apply to NHS Blood and Transplant, they will follow their internal procedures for investigating patient safety incidents.
- 5.4 In relation to an investigation under the 2011 Regulations, as is currently the case, the investigation must be proportionate, conducted openly and efficiently and the focus should be on improving quality, safety and sharing learning.
- 5.5 The service user/person acting on their behalf should be invited to contribute to the terms of reference of the investigation and contact should be maintained throughout the investigation, if this is what has been agreed. The preference of the service user/person acting on their behalf should be considered as not everyone will want to be involved to this extent.
- 5.6 The outcome of the investigation will be communicated to the service user or their representative in accordance with regulation 24 of those Regulations or, in the case of care provided by Health Boards, NHS Trusts or Welsh Special Health Authorities, in line with regulations 26 and 31 where the redress arrangements have been applied.
- 5.7 Consideration should be given to whether the incident should be reported to other Bodies e.g. an employer or professional regulator, the Medical Examiner service or HM Coroner. Additionally the incident may meet the National Reportable Incident threshold and be reported to Welsh Government.
- 5.8 Staff involved in the treatment or care that resulted in the duty being triggered should, where appropriate, be involved in the investigation process and also be advised of the final outcome. Further information in relation to the investigation and record keeping can be found in **Annex F**.
- 5.9 There have been some amendments to the 2011 Regulations to make them compatible with the duty of candour. The principal amendments are set out in regulation 14 of the Duty of Candour Procedure Regulations. Their effect is to ensure that both the duty of candour and the PTR procedures work in harmony and to ensure that there is not any duplication of processes.

6 Chapter 6 - Complex Arrangements and The Duty of Candour

Where more than one NHS body may be involved in the Duty of Candour procedure

- 6.1 It is often the case that a range of NHS Bodies engage in an episode of care where the duty of candour is triggered. **Annex H** has case study examples for reference.
- 6.2 Although not all of the Bodies involved in the provision of an episode of care will necessarily be the 'providing body' in terms of the legislation (i.e. their provision of health care did not or does not have the potential to trigger the duty of candour) they may need to become involved in providing information as part of a review or providing support for the service user/person acting on their behalf. All parties must co-operate fully in an open and facilitative manner throughout the duty of candour procedure and share with each NHS body any learning identified as a result of the subsequent investigation/ review, including any actions to be taken with a view to preventing similar circumstances from arising in the future.
- 6.3 There may also be occasions where several NHS Bodies each are providing health care to a single service user and each trigger the duty of candour procedure for multiple 'notifiable adverse outcomes' in relation to a single course of treatment. **Annex H** has case study examples for reference.
- 6.4 In such circumstances, it would be best practice for the NHS Bodies to seek to communicate with the service user/person acting on their behalf to gain the appropriate consent, in line with UK GDPR, to undertake a co-ordinated approach to notification. Otherwise, there is a risk the service user or person acting on their behalf will feel overwhelmed or confused by the process if they get multiple notifications. This is particularly important where the harm is Severe, or a death has occurred.
- 6.5 The aim should be to make the process as easy as possible for those involved and, in particular, for the service user or person acting on their behalf.
- 6.6 However, each NHS body (providing body) still has its own responsibility under the Candour Procedure Regulations and must ensure and be able to evidence that, as individual organisations, they have complied with the requirements of those Regulations.
- 6.7 Where there are multiple NHS Bodies involved in the duty of candour, the subsequent investigation is undertaken as detailed in regulation 17 of the 2011 Regulations. Regulation 17 deals with concerns involving more than one responsible body. It places a duty on responsible Bodies (subject to obtaining the relevant consents from the service user or person acting on their behalf) to cooperate for the purposes of coordinating the handling and investigation of concerns and the provision of a coordinated response.

- 6.8 If an NHS body discovers that an incident that would trigger the duty of candour procedure has occurred in a different NHS body, the NHS body that discovers the 'incident' should inform the NHS body where the 'incident' occurred so that the latter can then implement the duty of candour procedure. The NHS body that discovers the 'incident' must also be open and transparent with the service user about what they have discovered. However, they are not required to perform the specific duty of candour procedure; this should be conducted by the responsible NHS body, i.e. the 'providing body' where the duty of candour was triggered.

Mixed Care Delivery Between NHS Bodies and Social Care Organisations

- 6.9 Where a service user is receiving care from an NHS body and a provider of social care (whether in a mixed model of delivery or separately), it is possible that multiple providers may have contributed to the harm that has been caused to the service user. In such cases each provider will have its own responsibilities under the duty of candour (or its equivalent for providers of social care).

- 6.10 The providers of both health and social care should liaise and work together to notify and investigate the incident in order to minimise any distress and to avoid multiple communications to the service user. For example it would not normally be appropriate for a family to receive two separate 'in-person' notifications about the death of a family member because of a lack of communication between providers.

However, each provider will retain their individual responsibilities under their respective duty of candour and must satisfy themselves that they have been met.

Application of the Duty of Candour procedure to commissioned and hosted services

- 6.11 Section 11 of the Act clarifies which organisation will be responsible for complying with the duty of candour in situations where services are provided by one body on behalf of another. The position, in relation to different arrangements is set out below:

Services Commissioned by an NHS Body from Another NHS Body in Wales

- 6.12 An NHS body in Wales is responsible for complying with the duty of candour in relation to all care which it actually provides. Therefore, for example, where a Health Board enters into arrangements with a primary care provider for the provision of NHS services, it is the primary care provider who is subject to the duty.

- 6.13 Similarly, if a Health Board enters into arrangements with an NHS Trust in Wales for the provision of services, the duty rests with the NHS Trust.

Services Commissioned from Non-NHS Bodies in Wales

- 6.14 If an NHS body enters into an arrangement for the provision of services with someone other than another NHS body, the duty to comply with the duty of candour rests with the NHS body. Therefore, for example, if a local Health Board enters into an arrangement with an independent provider for the provision of services, the duty will apply to the local Health Board.
- 6.15 In these circumstances, it would be for the NHS body to notify the service user or person acting on their behalf for both the “in-person” notification in accordance with regulation 4, and the written notification in accordance with regulation 5.
- 6.16 The provisions of the 2011 Regulations apply to persons who provide services under arrangements with an NHS body. Therefore, as is the case currently, it would be for the independent provider to investigate the circumstances of the notifiable adverse outcome and communicate the result of that investigation to the service user/person acting on their behalf.
- 6.17 NHS Bodies should ensure that their commissioning arrangements with non-NHS independent providers in Wales require the independent provider to notify them when they are of the view that the duty of candour has been triggered, so that the NHS body can comply with its obligations in relation to notification under the Act. The commissioning arrangements will also need to require the independent provider to provide sufficient information to the NHS body to enable them to comply with their reporting obligations under section 7 of the Act.

Application of the Duty of Candour to Care Commissioned Outside of Wales

- 6.18 The duty of candour under the Act only applies where health care is delivered in Wales as part of an NHS service. If, for example, a local Health Board enters into arrangements with an English provider, whether that provider is an NHS body or an independent provider, for the provision of health care services in England, it is the English duty of candour, under the Health and Social Care Act 2008 that may apply in relation to that care.
- 6.19 Part 7 of the National Health Services (Concerns, Complaints and Redress arrangements) (Wales) Regulations 2011 outlines the approach to be taken in terms of services carried out by England, Scotland and Northern Ireland NHS Bodies when patient safety incidents and concerns have been raised.

Annex A1 sets out the procedure flow chart for services that are commissioned.

Hosted Services:

- 6.20 Where healthcare is delivered by an organisation or service that is hosted by an NHS body (for example a clinical network), the Duty of Candour applies to the NHS body as the legal entity that hosts the service or organisation.

7 Chapter 7 – Special Considerations

Children And Young People

- 7.1 The duty of candour applies in respect of health care that is provided in Wales to children and young people. The welfare of children and young people, and their rights to be fully involved in decisions about their care and treatment, are essential principles to the approach to be taken when things go wrong with a child's or young person's care³⁵.
- 7.2 Under the UNCRC (article 12), children and young people - where they are able and wish to be - should be involved in discussions about adverse outcomes that directly affect them. This is in conjunction with the child's or young person's right to the highest attainable levels of health (article 24) and the right to receive and impart information (article 13).
- 7.3 Honesty, transparency and openness are the guiding ethical principles to be adopted and discussions must be conducted in a sensitive manner that take age, the child or young person's experience of health care, their mental capacity and the wishes of the individual child or young person and, where appropriate, those with parental responsibility into consideration.
- 7.4 In discharging the duty of candour in circumstances involving health care that has been provided to a child or young person, the NHS body must notify the "relevant person" of the notifiable adverse outcome (see regulation 3 of the duty of candour regulations). This might be the child or young person themselves, unless they are:³⁶
- 16 or over and lack capacity (within the meaning of the Mental Capacity Act 2005) in relation to the matter, or
 - under 16 and not competent to make a decision in relation to their care or treatment,
- in which case the "relevant person" is a person legally acting on the child or young person's behalf.

³⁵ UN Convention on the Rights of the Child - United Nations. https://www.unicef.org.uk/wp-content/uploads/2019/10/UNCRC_summary-1_1.pdf

³⁶ Regulation 3 of The Duty of Candour Procedure (Wales) Regulations also provide that the "relevant person" is someone acting on the service user's behalf if the service user has died or has informed the responsible body that they have nominated a person to act on their behalf.

- 7.5 Where the matter concerns a child who is under the age of 16, it is important that consideration is given as to whether the child is “Gillick competent”³⁷ i.e., whether the child has the requisite legal capacity and sufficient maturity and intelligence to understand the information provided and to make decisions about their own health and medical treatment. The health care professional seeking the child or young person’s consent should undertake the Gillick competency assessment if they have been adequately trained to do so.
- 7.6 However, even where the child is “Gillick competent,” or where a young person is considered to have the requisite mental capacity, children and young people should be encouraged to involve their parents or guardians in these discussions where that is advisable and beneficial. Alternatively an advocate may be of use in this circumstance. Parents and Guardians are often best placed to understand and advise the health care team and, in many circumstances, an important source of support for the child and young person coming to terms when harm has occurred with their care.
- 7.7 The use of appropriate language and explanation needs to be thought through carefully and, where appropriate, conducted in a timely manner and in partnership with parents or guardians. The use of appropriate professionals with experience in communicating with children can be of immense value in these circumstances. This is important in order to mitigate against the risk of causing further harm or distress in notifying the child or young person of the notifiable adverse outcome, whilst also remaining open and honest with the child or young person about what has happened in accordance with the duty of candour, and the broader rights of children and young people to be kept fully informed.
- 7.8 Where a child is not considered to be “Gillick competent” then notification must be given to a person acting on the child’s behalf (e.g., their parents or legal guardian).
- 7.9 In this circumstance, it is important to take in to account the parents’ or guardians’ views as to how a child or young person can be informed about what has happened in their care or treatment and consideration should be given as to how the health care team can support that discussion. As part of that discussion, consideration should be given as to the best interests of the child or young person in terms of the manner within which the discussion is undertaken, taking care not to cause further harm or distress.
- 7.10 Consideration must always be given to safeguarding principles and guidance and the need, at times, to report concerns around a child or young person’s safety discovered through these discussions where this is mandated legally or professionally.
- 7.11 Good documentation of decision-making and the assessment of competency to understand and participate in decisions about their care is imperative. It is also important that any decisions made not to share information are regularly reviewed.

³⁷ Gillick v West Norfolk and Wisbech AHA [1986] A.C. 112

- 7.12 It must be recognised that children and young people are often aware of incidents and changes in their care, and it can be extremely helpful to a young person to understand why it has happened.
- 7.13 Often children and young people may fear unclear outcomes. These fears can be generated when issues and incidents are not discussed, and children and young people are left uncertain about why things have occurred and what the next steps are in their care. This leads to increasing anxiety, worry and mental stress.
- 7.14 Ensuring children and young people are afforded the opportunity to be partners in the decision-making process about their care, with their parents or guardians and their health care team is imperative, where this is appropriate and possible. It is important to always have the child, young person and their family unit at the centre of good honest and open communication and the decisions about their care and this is especially important when unintended or unexpected harm has occurred.

Retrospective application of the Duty

Retrospective Case Reviews

- 7.15 Adverse outcomes may become known following retrospective serious case reviews, a large number of patients recalled or following a decision made by the medical examiner service or a coroner's inquest, where the cause of death attributed was not known at the time of the incident. Additionally, further detail, not known during the initial review, may become known during the investigation of the incident. In these cases, the duty may still apply.
- 7.16 At the point of such a case review, and if the requisite conditions for the duty of candour have been met, the organisation therefore becomes 'aware' of the notifiable adverse outcome. It is at this point that the DOC procedure should be initiated, if not previously initiated.
- 7.17 In the event that the 'in-person' notification is made later than 30 working days after the responsible body first became aware of the notifiable adverse outcome, the responsible body must provide an explanation of the reason for the delay.

Adverse Outcome Incidents Which Occur Before the Duty of Candour Came into Force

- 7.18 The Duty of Candour legislation is not intended to operate in respect of adverse outcomes which occurred before the date that the legislation came into force. In practical terms, this means that the conditions triggering the duty of candour (i.e. the provision of health care and the harm which occurred), must have taken place after 1 April 2023. However, we would still expect you to apologise and to be open

and transparent with people about whatever has been discovered **in line with the ethos of putting things right**³⁸.

8 Chapter 8 - Oversight arrangements.

- 8.1 Regulation 10 requires NHS Bodies to designate a person to be responsible for maintaining a strategic oversight of the operation of the candour procedure set out in the Candour Procedure Regulations. Where the NHS body is a local Health Board, a Trust, or a Special Health Authority (including NHS Blood and Transplant in relation to its Welsh functions) the person must be one of its non-officer or non-executive directors, as appropriate.
- 8.2 Primary care providers have discretion in relation to whom to assign such roles.
- 8.3 Regulation 11 requires NHS Bodies to designate a person who has overall responsibility for the effective day to day operation of the procedure under the Candour Procedure Regulations (the “responsible officer”). Where the NHS body is a local Health Board, a Trust, or a Special Health Authority (including NHS Blood and Transplant in relation to its Welsh functions) the responsible officer must be one of its officer members or executive directors, as appropriate.
- 8.4 For primary care providers, it must be the person who acts as the Chief Executive of the body. If there is no Chief Executive, it is:
- the person who is the sole proprietor.
 - in cases of a partnership, a partner; or
 - in any other case a director or person responsible for management.
- 8.5 The Candour Procedure Regulations allow for the functions of the responsible officer to be delegated to another person, provided that person is under the direct control and supervision of the responsible officer. However, accountability will rest with the responsible officer themselves.
- 8.6 It is considered good practice for the persons designated in accordance with regulations 10 and 11 of the Candour Procedure Regulations to be the same persons nominated, respectively, under regulations 6 and 7 of the 2011 Regulations³⁹ due to the close linkages between the candour procedure and the procedure for investigating concerns in the 2011 Regulations.

³⁸ Putting Things Right – Guidance on dealing with concerns about the NHS from 1 April 2011 Version 3 – November 2013 <https://nwssp.nhs.wales/ourservices/legal-risk-services/legal-risk-services-documents/general-medical-practice-indemnity-gmpi-docs/healthcare-quality-guidance-dealing-with-concerns-about-the-nhs/>

³⁹ Reg 6 of the 2011 Regulations requires a person to be appointed to maintain a strategic oversight of the arrangements for dealing with concerns under those Regulations and regulation 7 requires a person to be appointed to have responsibility for ensuring effective day to day operation of the arrangements for dealing with concerns in an integrated manner.

REPORTING REQUIREMENTS

- 8.7 Under the duty, NHS Bodies will be required to report annually on compliance with the duty and publish their reports. Local Health Boards will be required to collate this information from those primary care providers with whom they enter into a contract or arrangements for services and publish a combined report. **Annex G** includes a flow chart setting out the reporting, publication and monitoring requirements.
- 8.8 When reporting, NHS Bodies will be required to specify if the duty of candour has been triggered in the reporting year (defined as each period of 12 months ending on 31st March, (each financial year), and if it has:
1. state how often the duty of candour has been triggered during the reporting year.
 2. give a brief description of the circumstances in which the duty was triggered; and
 3. specify any steps taken by the body with a view to preventing similar circumstances from arising in the future.
- 8.9 The report must be prepared as soon as practicable after the end of each financial year.
- 8.10 To streamline annual reporting in Wales and reduce duplication of content whilst ensuring all regulatory requirements are met, Health Boards, Trusts and SHAs should include their candour reports in the Putting Things Right Report which should be published pursuant to regulation 51 of the 2011 Regulations⁴⁰ by **31st October** each year.
- 8.11 Regulation 51 of the 2011 Regulations requires NHS Bodies to prepare an annual report on information regarding concerns, (where concerns is taken to include complaints, patient safety incidents and claims). For primary care providers, this includes sending their report to the Local Health Board with whom they have entered into arrangements with, allowing for collation and publication within a Local Health Board's Annual Putting Things Right report⁴¹, and considered within each organisation's Annual Quality Statement.

Primary Care providers: duty to report

⁴⁰ The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 (SI 2011/704). Available from: <http://www.legislation.gov.uk/wsi/2011/704/contents/made>

⁴¹ Welsh Government. Putting things right - Guidance on dealing with concerns about the NHS from 1 April 2011 [Internet]. Welsh Government; 2013. Available from: <http://www.wales.nhs.uk/sites3/Documents/932/Healthcare%20Quality%20-%20Guidance%20-%20Dealing%20with%20concerns%20about%20the%20NHS%20-%20Version%203%20-%20CLEAN%20VERSION%20-%2020140122.pdf>

- 8.12 Primary Care providers must prepare a report in respect of the health care they provide under a contract or other arrangement with their Health Board. The report must state whether during the reporting year (defined as each period of 12 months ending on 31st March, (each financial year)), the duty of candour has been triggered in respect of the provision of health care by the primary care provider.
- 8.13 If it has, the report must:
1. specify how often this has happened during the reporting year,
 2. give a brief description of the circumstances in which the duty was triggered,
 3. describe any steps taken by the provider with a view to preventing similar circumstances from arising in future.
- 8.14 The prepared report must be supplied to the Local Health Board on completion.
- 8.15 If the Primary Care provider has provided health care on behalf of two or more Local Health Boards, a separate report is to be prepared and supplied to each Local Health Board on completion.
- 8.16 Local Health Boards receiving the report must prepare a summary of the reports received from the Primary Care providers in the candour report that they publish.
- 8.17 Consequently, in order to give Local Health Boards time to compile the summary, such reports must be provided to the relevant Local Health Board by no later than **30th September** each year.
- 8.18 Although the use of the Datix system is not mandated, functionality on Datix will facilitate the collation of information necessary to satisfy the reporting requirements that need to be submitted to local Health Boards.

Publication of Reports

- 8.19 The annual reports on the duty of candour must be published as soon as practicable after the end of the financial year. In the case of Local Health Boards, their report must include the summary of the reports provided by primary care providers providing services on the Local Health Board's behalf.
- 8.20 The Local Health Board will therefore be responsible for publishing information relevant to the duty of candour in respect of its own services and the services provided by primary care providers in its area. This will mean that all the information about the duty of candour in respect of the Local Health Board area will be published together.
- 8.21 As set out above, such reports should be published by **31st October** each year.

BOARD ASSURANCE AND MONITORING ARRANGEMENTS

- 8.22 Breach of the duty of candour is not a criminal offence. The focus of the duty to be on learning and improving, not on punitive sanctions when NHS Bodies fall short in their application of the duty.
- 8.23 However, NHS Bodies should consider how monitoring of the effective implementation of the actions required by the duty of candour can be integrated into existing corporate governance frameworks, processes and procedures. Assurance should be sought to confirm that all elements of the procedure are being implemented when they should be, and that there are ways of supporting continuous improvements and refinements in the way that the NHS body discharges its legal responsibilities.
- 8.24 Leaders and managers within the NHS body should ensure that the implementation of the duty of candour forms a key part of the learning systems within their service areas, and that the necessary integration and alignment with processes and procedures has taken place and reinforces the values expected in their service area.
- 8.25 In respect of Health Boards, Trusts and Special Health Authorities, the expectation is that there will be local ownership and accountability with regular updates being provided via Quality and Safety Committee (or equivalent) meetings, where Independent Members can seek assurance, the duty is being discharged and learning is being taken forward and concerns are escalated to the Board if appropriate.
- 8.26 Implementation of, and compliance with the duty will also be scheduled for discussion at quality and delivery group meetings between Welsh Government and individual NHS Bodies, the national quality and delivery group and will inform the Joint Executive Team (JET) meetings and the Minister for Health and Social Service's appraisals with the Chairs of Health Boards, Trusts and Special Health Authorities.
- 8.27 The Welsh Government will monitor the content of the annual reports alongside other sources of information which will help triangulate the application of the duty with, for example, consideration of serious incidents reported in line with the new National Patient Safety Incident Reporting policy.
- 8.28 Compliance with the duty will also form part of the matters considered by Healthcare Inspectorate Wales (HIW) when inspecting and reviewing the NHS.
- 8.29 The annual reporting requirements will also provide information to the public and the Welsh Government about the duty, which will help to make the process transparent and accessible to the public and Bodies such as the Citizen Voice Body for Health and Social Care, Wales.

CONFIDENTIALITY

- 8.30 It is important to ensure that at all times the requirements of GDPR are adhered to when accessing, processing and disclosing service user information. Reports and publications must not identify any person to whom health care is being or has been provided by or on behalf of the NHS body, or any person acting on behalf of a service user.
- 8.31 Care must also be taken not to unwittingly enable a person to be identified from the information provided within a report. It is not necessary to name a person in order for them to be identifiable if, for example, a case has received media attention or, to cite another example, where a person has a rare medical condition and simply naming the condition could render the person identifiable.
- 8.32 The sharing of any information needs to also consider whether there is a conflicting need that may delay such sharing of information such as a criminal investigation or safeguarding process as set out in regulation 12 of the candour procedure regulations.
- 8.33 When completing records under duty of candour staff should remember that any records made in relation to the incident may be disclosable to the individual under UK GDPR (if their personal data) or to the general public under the Freedom of Information Act (if not personal data). Staff should also involve their organisation Data Protection Officer (DPO) when a notifiable adverse outcome appears to involve a personal data breach as there may also be reporting requirements to the Information Commissioners Office under UK GDPR.