GIG CYMRU NHS WALES | Iechyd Cyhoeddus Cymru Public Health Wales	**Reference Number:** PHW76/TP01 **Version Number:** 1 **Date of Next review:** May 2023

DUTY OF CANDOUR PROCEDURE

Introduction and Aim

Duty of Candour forms one of the requirements under the Health and Social Care (Quality and Engagement) (Wales) Act 2020. A formal procedure is required in Public Health Wales to support with the implementation of Duty of Candour which is due to come into force in Wales on 1 April 2023.

The document aims to provide a clear process for dealing with incidents where it is believed that the Duty of Candour may have or has been triggered and outlines the required steps to take once this has been identified. This procedure supports the Duty of Candour Policy.

Linked Policies, Procedures and Written Control Documents

All corporate policies and procedures are available on the Public Health Wales website

Related documents are:

Duty of Candour Statutory Guidance 2023

- Duty of Candour Policy
- Claims Management Policy
- Claims Management Procedure
- Complaints procedure
- Duty of Candour Procedure
- Health and Safety Policy & Procedure
- Incident Management Procedure
- Putting Things Right Policy
- Redress Procedure
- Risk Management Policy & Procedure

Scope This procedure has been produced for the management of incidents which has/may trigger the Duty of Candour.	
The scope of this procedure covers all staff employed by Public Health Wales.	
Equality and Health Impact Assessment	An Equality, Welsh Language and Health Impact Assessment has been completed and can be viewed on the policy webpages.
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Disclaimer
If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the Board Business Unit.

Summary of reviews/amendments				
Version number	**Date of Review**	**Date of Approval**	**Date published**	**Summary of Amendments**
V1	23/01/23	16/05/23	25/05/23	New policy introduced to support internal implementation of Duty of Candour

Contents

1 Introduction

This procedure details the process for dealing with incidents once it has been identified that the Duty of Candour may have or has been triggered.

It aims to ensure staff are supported with a concise point of reference when it is believed the Duty has been triggered, identify who will contact the service user, set out timescales and also provides links to precedent apology letters. The Procedure also encompasses how learning attained from Duty of Candour outcomes will be disseminated and monitored within Public Health Wales.

2 Background of the Duty of Candour

Duty of Candour will be implemented in Wales on 1 April 2023 through the Health and Social (Quality and Engagement) (Wales) Act 2020. The Duty has already been in place in Scotland and England for some time.

The purpose of the Duty is to build upon the current Putting Things Right legislation and promote a culture of openness and honesty to service users of health care in Wales. It is a lever for improving and protecting the health, care and well-being of the current and future population of Wales.

The Duty of Candour will complement the existing professional Duty of Candour required of individual healthcare professionals by the Nursing and Midwifery Council, the General Medical Council and many other professional regulatory bodies.

2.2 Who does the Duty of Candour apply to?

The Duty applies to the following NHS bodies:

- Local Health Boards;
- Primary Care providers in Wales (i.e. General Practitioners, dentists, optometrists, pharmacists) in respect of the services they provide under a contract or arrangements 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.

3 How is the Duty triggered

All of the following conditions must be met, for the Duty of Candour to be triggered and are set out in Annex A flow chart:

(1) A service user to whom **health care** should be offered; is being provided or has been provided has suffered an **adverse outcome**;

A service user is to be treated as having suffered an adverse outcome if the service user experiences, or if the circumstances are such that the user **could** experience any **unexpected or unintended harm** that is more than minimal.

(2) The **provision of the health care** was or may have been a factor in the service user suffering that outcome.

It need not be certain that the health care caused the harm. It is sufficient that it **could** have been a factor.

'Health care' is defined as services provided in Wales under or by virtue of the National Health Services (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**.

The Duty may be triggered by an **action taken** by an NHS body during the provision of the health care or by a **failure to take action**.

For the purpose of the Duty, harm also includes psychological harm, and in the case of a service user who is pregnant, loss of or harm to the unborn child.

The adverse 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.

Whether or not the Duty of Candour has been triggered will only be considered for those adverse outcomes which have been diagnosed or identified after 1st April 2023, it will not apply retrospectively. The error could however have occurred prior to 1st April 2023.

Please see the attached collection of examples of triggers for the Duty of Candour.

Please bear in mind that the adverse outcome for service users **must be unexpected** and therefore will not include the following:-

1. Known complications of diagnostic investigations which may result in re-admissions to hospital as this is not an unexpected adverse outcome.

2. Waiting lists for the screening programmes i.e. due to delays from lack of resources/ pandemic. It is recognised in the Statutory Guidance that people do have to wait for diagnosis and treatment and, in many cases, their condition will deteriorate whilst they wait for treatment. This deterioration is not **unexpected** for the purposes of the triggering of the Duty of Candour.

3. Interval cancer reviews in the Breast Test Wales Programme which are classified as Minimal Signs (equivalent to satisfactory, with learning points) do not amount to Duty of Candour Triggers but are subject instead to Disclosure of Audit procedures.

4. Interval cancer reviews in the Breast Test Wales Programme where the outcome is unclassifiable, will not amount to Duty of Candour triggers.

5. Interval cancer reviews in the Cervical Screening Wales Programme which are classified as satisfactory with learning points, will not amount to Duty of Candour triggers.

3.1 Categorisations of levels of harm

More than minimal harm is defined as *moderate harm, severe harm or death*. Levels of harm are included in a framework at Annex B.

3.1.2. Moderate harm is defined as:-

(a) Moderate increase in treatment and
(b) Significant but not permanent harm.

3.1.2. Moderate increase in treatment could include:-

- An unplanned admission/ re-admission
- An unplanned return to surgery
- Increase in length of stay in hospital by 4-15 days
- Cancelling/ postponement of treatment – please bear in mind that the Duty will only be triggered if the cancellation/ postponement has resulted in an adverse outcome for the service user which is more than minimal
- Transfer to another treatment/ care area, such as secondary care or intensive care as a result of the incident

3.1.3. Psychological harm could include:-

- A psychiatric condition or the exacerbation of an existing psychiatric condition for a continuous period of a least 28 days.

N.B. We are unlikely to come across standalone psychological harm where there has been no impact upon a service user's diagnosis. It would likely require the review of medical records by an independent medico-legal Consultant to establish if a delay of any kind has resulted in psychological impact.

3.1.4. Severe harm would include:-

- Avoidable, permanent harm or impairment of health or damage leading to incapacity, disability or the loss of potential recovery.

- Avoidable permanent lessening of bodily, sensory, motor, physiologic or intellectual functions including removal of the wrong limb or organ or brain damage.

- Increased length of hospital stay by more than 15 days.

Examples of severe harm would include the following:-

- Hysterectomies, mastectomies, requirement for chemotherapy.
- Requirement for stoma bag.
- Infertility.
- Future requirement for colostomy bag.
- Psychological treatment requiring Cognitive Behaviour Therapy ("CBT") for an extended period.
- Future care and assistance needs, inability to work.
- Mental incapacity.
- Future requirement for surgery
- Neuro-rehabilitation therapy

4 Determining if Duty of Candour has been triggered.

Public Health Wales are required to notify a service user that the duty of candour has come into effect on 'first becoming aware'. The Statutory Guidance advises that this means that we must not wait for the findings of any initial investigation before notification to the person affected or the person who is acting on their behalf.

However, for most Public Health Wales' services, we will not be able to determine whether a service user has experienced an adverse outcome as a result of **unexpected harm** that is more than minimal without an investigation. For example we will not be able to determine if there has been

an error or if Duty of Candour has been triggered for those service users who present with an interval cancer, until an investigation has been carried out.

The investigation will be different for each service to arrive at a conclusion as to whether an error could have resulted in harm. For screening, this includes considering the initial error (for pathway errors), examining the service users' pathway, considering their diagnosis and assessing whether the error has adversely impacted the development of for example a cancer, treatment pathways and life expectancy.
The investigation may not be complete until all areas of the pathway/ service have been examined before we consider approaching the service user for a meeting. It will not be appropriate to notify a service user without having all of the information concerning their whole experience with our service to hand.

Please see the attached Cervical Screening Wales investigation flowchart as an example of what may be required in the investigation.

Whether unexpected harm has been caused will be different for each service Public Health Wales provides and whilst there may be an error that could amount to a breach of our duty of care, in order to apply the Duty of Candour, this must have caused or could have caused moderate or severe harm. This may be dependent on the length of delay it took to carry out a second set of test results or how long a service user has been on the wrong pathway.

In microbiology, if test results have been incorrectly categorised as negative, we potentially will not know if there is an adverse outcome for a patient, unless deterioration is identified by a treating Clinician and we are made aware.

The Investigation lead will be the person who identifies the error and carries out the investigation and an Investigation Report must be completed to document the investigation.

4.1.1 Cohort Investigations

Where it is identified that a cohort of people could have been adversely impacted by an error in a PHW service, this must need to be logged as one Nationally Reportable Incident on Datix. All service users will need to be followed up to assess if harm could have been caused by the error. For those where harm is identified that could have been caused or contributed to by a PHW service error, an individual Datix incident record should be opened for Duty of Candour to be considered on an individual basis.

5 Commissioned Services

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 boards/Trusts enter 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.

Similarly, if a Health Board enters into arrangements with Public Health Wales for the provision of services, the duty rests with Public Health Wales.

6 Procedure once Duty of Candour is believed to be triggered

After the investigation has taken place, when it is suspected that the Duty may have been triggered, a meeting should be arranged as soon as reasonably practicable with the following to determine if the Duty has been triggered:-

- Director of Screening/ Consultant in Public Health;
- Head of Programme/ Clinical Lead/ Lead Scientist/ Lead Nurse; and - Claims Manager/ Head of Putting Things Right.

In readiness for the meeting, the following information should be available:-

- An overview of the issue that has potentially triggered the Duty of Candour, details of what has happened, why this may have happened and the impact of the issue on the service user.

- An update on the service user's condition and prognosis.

- Remedial action for the error, what action needs to be taken to correct the error and ensure this does not happen again? Has this been corrected and is the service user now receiving the correct service/ treatment?

- What lessons have been learned and how have these been shared to date.

- Establish whether we have the service user's telephone contact details.

Once it has been determined at this meeting that the Duty of Candour has been triggered, the Claims Manager will confer with the Putting Things Right Team for the decision to be reviewed by Assistant Director of Nursing, Head of Putting Things Right and the Claims Manager to sign off the Duty of Candour trigger decision. This meeting must be held within 24 hours of the Duty of Candour decision meeting as the in person notification must take place within **as soon as reasonably practicable after this** meeting but will be subject to the convenience and circumstances of the service user.

Once it is agreed that Duty of Candour is triggered, the Claims Manager will notify the designated lead who triggered the Duty of Candour meeting for a Datix record to be opened as an incident.

An in person notification (face to face or over the phone) must take place with the service user either by telephone or face to face and must take place within **30 working days** of determining that the Duty has been triggered.

6.1 Purpose of Duty of Candour Decision Meeting:-

Please be aware that there may be some overlap for Nationally Reportable Incidents and Duty of Candour. Nationally Reportable Incidents ("NRIs") are categorised as follows:-

"A patient safety incident which caused or contributed to the unexpected or avoidable death, or severe harm, or one or more patients, staff members or members of the public, during NHS funded healthcare."

1. Determine if the Duty of Candour and NRI has been triggered.

2. Agree how best to notify the service user, i.e. with an initial telephone call to notify and apologise or sent a notification letter, inviting a telephone/ face to face discussion. This will be contingent upon the following and will also apply to consideration of whether the in-person notification takes place over the phone or in person:-

(a) Severity of the adverse outcome;

(b) How physically or mentally well the person is to meet face to face and if they are under the care of the symptomatic services;

(c) Complexity of the notifiable adverse outcome;

(d) Any communication which has already taken place e.g. with radiology, colposcopy, colonoscopy services;

(e) Preferred method of communication of the service user and whether they wish to be kept updated during the course of the investigation.

3. A designated lead professional must be agreed from the attendees at the Duty of Candour Decision Meeting.

4. Discuss whether it is appropriate to offer to the service user an investigation under the Putting Things Right ("Redress") Regulations. This will be dependent upon the severity of harm as Redress

investigations are for those cases which compensation will not exceed £25,000.

5. For the purpose of the Breast Test Wales Programme, the Duty of Candour disclosure meeting with the service user must always take place in person at a screening venue, so that the mammograms can be presented and discussed with the service user at the time of the meeting.

6. It must be agreed at the Duty of Candour decision meeting who will update the Datix Cloud record following the meeting. The outcome of the meeting discussion must be recorded on the Datix Cloud record in the relevant sections relating to Duty of Candour with rationale if Duty of Candour is considered not to apply. A record of the discussion must be recorded within the progress notes of the record.

6.2 Making contact with the Service User

Contact should be made with the service user as follows:-

1. Telephone call to discuss that we have reviewed the screening/ treatment pathway/outbreak control outcome/ test results and explain that we are calling to make them aware of our findings and apologise. Offer the opportunity to explain in more detail either over the phone now or put in writing and then allow the service user the opportunity to decide if they would like a face to face or over the phone meeting and provide key contact details.

N.B If the circumstances are such that the service user is very unwell or we do not have telephone contact details, it may be appropriate to send an initial notification apology letter first, offering to meet. This can be agreed at the Duty of Candour Decision Meeting.

2. Depending on the outcome of the telephone call with the service user, either send initial notification apology letter or discuss arranging a face to face meeting or second telephone call.

3. Due regard must be given to Welsh Language Standard requirements when contacting a service user.

4. Consideration must be given to a service user's language and sign language requirements. Please consult the Trust Accessible Information AIS Policy for further guidance. If the service user's first language is not English or preferred language is something other than English, steps

must be taken to ensure that an appropriate translator is available and can attend the in person notification meeting.

5. Consideration must be given to a service user's accessibility requirements when meeting anywhere other than at a service user's home. Provision must be made so that the service user can attend a venue which accommodates their accessibility requirements.

6. Agree who will be contacting the service user for the in person notification and if over the phone it will always be one of the following:-

(1) Director of Screening/ Consultant in Public Health Lead/ Professional Lead;

(2) Head of Programme;

(3) Clinical Lead;

(4) Lead Nurse;

(5) Lead Scientist.

If the in person notification will take place face to face, two members of staff are required to attend. The service user must also be offered the opportunity to bring someone of their choosing with them for support. Please ensure that it is recorded on Datix within the progress notes, who attends the in person meeting.

7. The apology letter should be prepared immediately, so that it can be sent to the service user by recorded delivery within **five working days** of the in person notification. Precedent apology letters and a Duty of Candour leaflet have been prepared and are accessible on the PHW Sharepoint as a guide however these should be tailored to the incident concerned and the handler should provide a meaningful apology.

8. A Relevant Person may be notified of our Duty of Candour obligations on behalf of a service user 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.
- Has nominated a trusted person to act on their behalf as a Relevant Person. Not all service users will want to engage personally with the process.

7 In person and written notification

The in person notification whether face to face or by telephone must express reflection, regret, reason for the error and the remedy, to include the following (Annex E):-

- A clear explanation of what has happened and why the Duty of Candour has been triggered.

- A meaningful and personalised apology.
- Contact details for a nominated point of contact following the in person notification. Please provide details of the Duty of Candour mailbox, this will be monitored to the Claims Manager and forwarded to the appropriate person.

- Provide details of next steps if there is any further investigation or further enquiries to be made and times and dates if and when we will be in touch again.

- Provide an offer for the service user to be kept involved and updated of any ongoing investigations.

- If screening/ further testing is still required, provide details as to how this has been rectified and any follow up appointments.

- Ensure that the service user understands what is being explained to them and offer to answer any questions they may have. Explanations should be provided in clear and plain language as far as possible.

- Provide a copy of the NHS Duty of Candour leaflet at the in person meeting and if this takes place over the phone, include a copy with the apology letter.

7.1 Written Notification

A follow up letter must be sent by recorded delivery to the service user within **five working days** of the in person meeting and must reflect the in person meeting and ongoing arrangements. The follow up letter must include the following:-

(a) Description of any initial consideration of the notifiable adverse outcome;

(b) A reiteration of the verbal apology. An apology means an expression of sorrow or regret in respect of the notifiable adverse outcome and should not amount to an admission of liability;

(c) A record of the information provided in the in-person notification;

(d) The reason we consider that the duty of candour has been triggered;

(e) The contact details for the Duty of Candour inbox which will be monitored by the Claims Manager and further requests from service users will be forwarded to the appropriate person within the relevant Programme for an appropriate response;

(f) An explanation of any further investigations to be carried out;

(g) A reiteration of the offer of details of relevant services or support, and;

(h) Where the 'in-person' notification is made later than 30 working days after the date on which we first became aware of the notifiable adverse outcome, an explanation of the reason for the delay;

(i) Ideally a hand written signature on the letter of apology and the letter or e-mail enclosing the letter must be uploaded to the document section on Datix on the day it is sent.

It is recommended that the apology is included within the service user's clinical records by forwarding it to their GP, so that all staff are aware that an apology has been made and all documentation must be uploaded to the Datix incident record.

7.2 Unable to contact the Service User

If having taken all reasonable steps, Public Health Wales is unable to contact the service user, the attempts to make contact must be recorded on the Datix incident record. Please update the progress notes that they are contemporaneous with the dates of telephone contact and ensure all letters, documents and e-mails are logged in the document section of the module and all required Datix fields completed in full.

If the service user indicates that they do not wish to communicate with, or receive information from Public Health Wales, please clearly record this on the Datix incident record. You are not required to provide information to or communicate with the service user/ Relevant Person where they indicate they do not wish to communicate or receive information. Make them aware that

they can contact Public Health Wales in the future, should they change their mind about their involvement in the process.

However, the review of the incident triggering the Duty of Candour must continue to ensure any identified learning leads to quality improvements being made to prevent a reoccurrence and recorded in the Investigation which is to be uploaded to the documents section of the Datix incident and also recorded in the progress notes.

7.3 Reasonable Steps to Contact Programme Participants

The following will be considered as reasonable steps to contact the service user/ relevant person/ next of kin:-

1. Contact via telephone in the first instance and leave a voicemail (just to request a call back). The voicemail must only include the name and contact number of the person leaving the voicemail. No information regarding the reason for contact should be left in the voicemail, in the event of an incorrect or out of date contact number.

2. If we receive no response from the service user to telephone contact that day, send a letter to their current address on system.

3. If there is no response, from the service user, two further letters are to be sent at 4 week intervals and the second to last letter must indicate that we will not be making further contact after our third and last letter. However, the service user is welcome to get in touch in the future should they wish to.

8 Staff support

All staff involved in the Duty of Candour process must be supported. There is a responsibility on Line Managers to support staff throughout the process and support a no blame culture.

Wellbeing support is available to staff and line Managers and resources can be found here on the People & Organisational Development webpages.

9 National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2022 (Putting Things Right)

Putting Things Right ("PTR") ordinarily initiates an internal investigation by Public Health Wales when a service user raises a complaint or concern externally. If following an investigation a breach of duty is identified, the Redress process may then be offered to a service user, to establish if the breach has caused any harm for which the service user may be eligible for a remedy under PTR (Redress).

For Duty of Candour, the investigation process is initiated by the NHS Body who identified the error. Redress as a remedy to a service user following the outcome of the Duty of Candour investigation.

Where the Duty of Candour is triggered, the time period for responding to a concern runs from the date Public Health Wales makes the 'in person' notification to the service user or relevant person.
Both the in person notification and written notification must offer to take the investigation forward in accordance with Redress. Please make the Claims Manager aware as soon as possible if the service user wishes to take up the offer of Redress and the Claims Manager will take this process forward and open a record on Datix.

Any Putting Things Right investigation to whom a concern relates, or the relevant person, should be notified of whether the outcome of the investigation grades the harm as moderate or severe. If this has already been included in the Duty of Candour letter and meeting, there is no need to repeat this in the PTR investigation.

The PTR process involves obtaining an external report from an independent expert to consider causation and the extent of the harm. The Trust will therefore require the consent of the service user to take the investigation under Redress forward as consent will be required for the release of medical records to the independent expert.

Under the Redress Scheme, investigation will be made into whether a qualifying liability has arisen as a result of:-

(1) the missed opportunity in care/ pathway error/ service error, i.e. does this amount to a breach of our duty of care owed to the service user and;

(2) has this resulted in harm to the service user (causation).

A Regulation 24 or a Regulation 26 response should be issued within 30 days of receipt of the notification of the concern or, where the Duty comes into

effect, the day on which the 'in-person' notification takes place whichever is the later.

The offer of Redress or decision not to make an offer must be communicated to the person raising the concern, or their representative within 12 months of receipt of the notification of the concern or, where the Duty come into effect, the day on which the 'in-person' notification takes place whichever is the later.

10 Monitoring Learning

A centralised record will be maintained by the Claims Manager for all Duty of Candour Triggers and the learning which has been identified for oversight and assurance of actions by the Putting Things Right Team. All Programmes will be required to forward details of the learning and how rectifications have been implemented to the Claims Manager once an investigation is complete.

Programme learning will be shared as it currently is for concerns, Nationally Reportable Incidents and claims. This includes seeking to understand what happened by speaking with the individual colleague involved in the incident and involving them in any ongoing investigation and formulation of any remedial actions. Clinical supervision or ongoing support should also be offered to any staff involved in any Duty of Candour incident.

Feedback will be provided by managers and the learning shared nationally across services in educational sessions to demonstrate any clinical interpretations of decisions and feedback to those colleagues who input administratively into the different systems.

Learning will continue to be shared across all services at Senior Management Team Meetings to benefit all parts of the organisation, particularly for those areas of learning which would be relevant to Screening Programmes, Health Protection and Microbiology.

Appendix - Links

Please find below, helpful links to various resources to support this procedure.

Resource Title	Externally available	Internally available
Annex A – How the Duty is Triggered		✓
Annex B – Levels of Harm		✓
Annex C – Duty of Candour Trigger Procedure		✓
Annex E – Making a Meaningful Apology		✓
All Wales NHS Duty of Candour Leaflet	✓	
Southern Health NHS Leaflet	✓	
Duty of Candour PHE Screening Programme Guidance	✓	
Duty of Candour Example Triggers		✓
Letter of Notification and Apology Letters		✓
Statutory Guidance on Waiting Lists	✓	
BTW DoC Disclosure Process		✓