Annex A - Duty of Candour

Trigger Review Process

Is the NHS body providing care or has it provided care to the service user?

NB: An NHS body is responsible for complying with the Duty of Candour in relation to all health care, which it actually provides. Where a Health Board enters into arrangements with a primary care provider by virtue of contract, agreement or arrangement for the provision of NHS services, it is the primary care provider that is subject to the duty. Similarly, if a Health Board enters into arrangements with a NHS Trust for the provision of services it is the NHS Trust that is subject to the duty.

For commissioned services see Annex A1

YES

NO

Has the service user to whom healthcare is being or has been provided suffered an adverse outcome?

i.e. Did the service user suffer any unexpected or unintended harm that is more than minimal, or are the circumstances such that the service user could suffer any unexpected or unintended harm that is more than minimal in the future?

NO

Duty of Candour does not apply.

This decision should be appropriately ratified and clearly documented on the incident record.

YES

UNSURE

Refer to Annex B

Levels of harm framework

Was the health care provided a factor or may it have been a factor in the service user suffering the adverse outcome?

YES

NO

YES

NO

Duty of Candour does not apply.

This decision should be appropriately ratified and clearly documented on the incident record.

Duty of Candour applies.

The Duty of Candour procedure, as set out in Annex C, should be followed.

NB: Where the in-person notification is 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 this should be provided. This does not mean the NHS has 30 days to deliver the in-person notification as it should be delivered as soon as possible.

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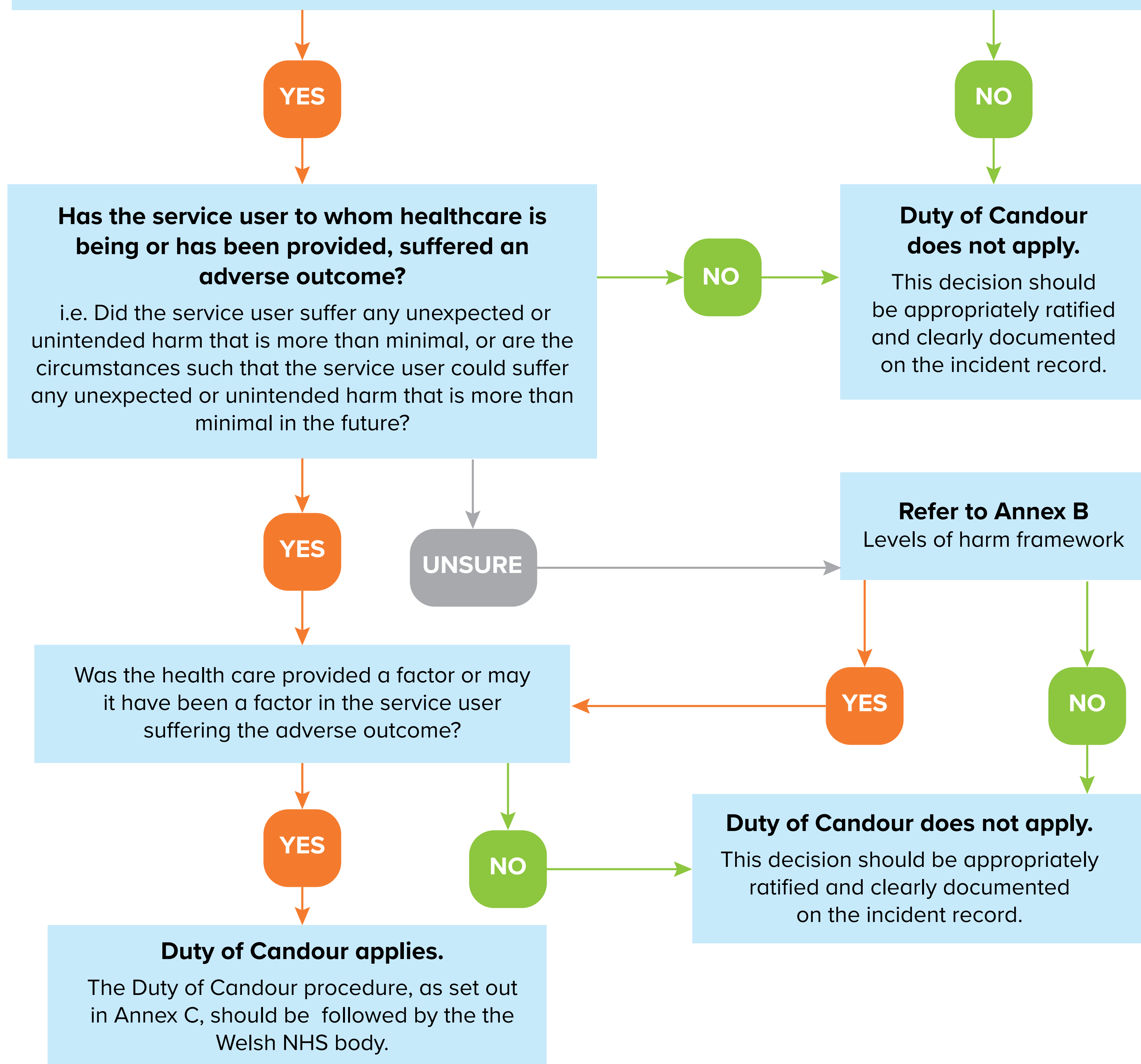
Annex A1 Trigger Review Process

Where services are commissioned

Has an NHS body entered into an arrangement for health care to be provided in Wales by someone other than another NHS body?

e.g Has a Health Board entered into an arrangement with an independent provider for the provision of health services in Wales?

NB: The Duty of Candour only applies where health care is delivered in Wales as part of the NHS in Wales. If for example a Health Board enters into arrangements with an English provider (whether that is an English NHS body or an independent provider in England) for the provision of health care services, it is the English Duty of Candour that will apply in relation to that care and the English provider will be responsible for complying with the English duty.



NB: Where the in-person notification is 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 this should be provided. This does not mean the NHS body has 30 days in which to deliver the in person notification as it should be delivered as soon as possible.

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Annex B - LEVELS OF HARM FRAMEWORK

The examples listed are meant only to be a guide and not an exhaustive list.

Level of harm	Incidents that would not trigger the duty of candour procedure
None	**Any patient safety incident that had the potential to cause harm, but impact resulted in no harm having arisen.** e.g: Appointment delayed, but no consequences in terms of health. e.g: Patient fall – where no harm was suffered or additional interventions required. eg: Near miss – where the potential for harm was noticed and action taken to avoid occurrence of harm.
Low harm/minimal harm	**Any patient safety incident that resulted in a minor increase in treatment and which caused minimal harm to one or more persons receiving NHS-funded care.** Minor increase in treatment could include**:** e.g: First aid, additional therapy, medication or rehabilitation e.g: Patient fall - requiring one off vital signs observation and/or minor treatment. e.g: Increase in length of stay by 1 - 3 days.
	When does the duty of candour apply? **IMPORTANT**- this section sets out the conditions that must be satisfied in order for the duty of candour to apply. These must be worked through when applying the harm framework.[1] The duty is triggered in relation to an NHS body if it appears to the body that **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) 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. 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

[1] For further guidance on determining whether the duty applies, please see Annex A and Annex H and Chapter 1 and 2 of the Statutory Guidance.

	could experience, any unexpected or unintended harm that is moderate or above. The duty may be triggered by an action taken by an NHS body during the provision of health care or by a failure to take action. **The duty is not triggered where harm is related to the natural course of the service user's illness or underlying condition.**
Unexpected or unintended moderate harm	**Examples of unexpected or unintended levels of moderate harm and types of incidents that would trigger the duty of candour procedure include:** **Moderate harm** – (a) **moderate increase in treatment** and (b) Significant but not permanent harm. **Moderate increase in treatment could include:** • An unplanned admission/re-admission, • An unplanned return to surgery, • Increase in length of stay by 4 -15 days, • Cancelling/postponement of treatment, • Transfer to another treatment/care area, such as secondary care or intensive care as a result of the incident. Examples of the type of incidents that would trigger the duty of candour procedure include: **Description of incident** – unplanned admission. Patient was seen by a member of the community MH team; who fails to recognise, or act on evidence of poor medication compliance/failure to adhere to treatment sessions/expression of suicidal thoughts. **Level of harm as a result** - the patient self-harms, causing moderate harm requiring admission to hospital. **Description of incident** - Operation cancelled. **Level of harm as a result** – Leading to deterioration and a longer stay in hospital > 4 days and recovery delayed. **Description of incident** - Patient receives opioids despite this being documented as an allergy. **Level of harm as a result** – Leading to the patient suffering a significant reaction and required emergency treatment. **Description of incident** - A mother had significant post-partum haemorrhage after a difficult delivery, and there was a delay in obtaining blood for transfusion.

	Level of harm as a result – this led to the mother being transferred to the high dependency unit because of the post-partum haemorrhage and the delay in obtaining blood for the transfusion meant that her recovery was prolonged. The service user experiencing psychological harm: **Psychological harm** – means a psychiatric condition or the exacerbation of an existing psychiatric condition for a continuous period of at least 28 days. **For example,** **the non-concordance with antipsychotic medication by an informal admitted service user, where medication was secreted and hidden but not spotted by healthcare staff leading to increased auditory and sensory hallucinations and distress requiring intervention and treatment.** NB: The timeframe above should be used as a measure only. The focus must be on the level of unintended or unexpected harm. **Further detailed case study examples can be found in Annex H.**

Unexpected or unintended severe harm	**Examples of unexpected or unintended levels of severe harm and types of incidents that <u>would</u> trigger the duty of candour procedure include:** **Severe harm would include:** • Avoidable, permanent harm or impairment of health or damage leading to incapacity, disability, or the loss of recovery potential. • 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 stay by >15 days **Examples of the type of incidents that would trigger the duty of candour procedure include:** **Description of incident** - loss of recovery potential. Delays in thrombolysis or AHP treatment. **Level of harm as a result -** resulting in loss of recovery of walking or speech, which is permanent. **Description of incident** - Patient suffers an adverse reaction to medication that they are documented to be allergic to. **Level of harm as a result –** Leading to the patient suffering brain damage or other permanent organ damage. **Description of incident** - Patient suffer a perforation of the bowel during surgery. **Level of harm as a result –** Leading to patient requiring a colostomy and/or subsequent operations.
	Description of incident - Patient did not receive a planned follow up x-ray. **Level of harm as a result -** Patient was subsequently found to have lung cancer. The chances of survival had been significantly reduced by the 18 month delay in the follow up x-ray being performed. **Description of incident –** Female patient reports being sexually assaulted by another patient in a medium secure unit leading to severe escalation of symptoms, Chronic PTSD and self-harm incidents with attempts at suicide by hanging and cutting. **Level of harm as a result -** patient never recovers from the incident and suicide attempts requiring lifelong high levels of supervision. <u>**Further detailed case study examples can be found in Annex H.**</u>

Unexpected or unintended death	**Examples of unexpected or unintended death and types of incidents that <u>would</u> trigger the duty of candour procedure include:** **Examples of the type of incidents that would trigger the duty of candour procedure include:** **Description of incident** - Wrong blood transfused. **Level of harm as a result -** Leading to multi-organ failure and a fatal cardiac arrest. **Description of incident** - Patient suffers an adverse reaction to medication that they are documented to be allergic to. **Level of harm as a result** - Leading to severe anaphylaxis and subsequent death. **Description of incident -** Patient presents with chest pains and is asked to wait in clinic/practice/emergency department. **Level of harm as a result -** Patient suffers a fatal myocardial infarction in the waiting area, which they then die from. **Description of incident -** Patient presents acute distress and suicidal ideation in the emergency department but whilst waiting several hours to be seen absconds. **Level of harm as a result -** Patient falls from a local bridge and dies from their injuries. <u>**Further detailed case study examples can be found in Annex H.**</u>

Annex C - Duty of Candour Procedure

Incident has been reported and recorded via Datix Cymru and patient care record. A review of the incident is undertaken and an agreement is reached that, based on the information available at that time, the conditions set out in Annex A, have been met and the Duty of Candour applies.

Notification

On first becoming aware the duty has been triggered, (which is the start date for the Duty of Candour procedure), the NHS body must notify the service user/or person acting on their behalf.

NB: Where the in-person notification is later than 30 working days after the date on when the NHS body first became aware of the notifiable adverse outcome, an explanation of the reason for this should be provided and recorded. This does not mean that the NHS body has one month to make the notification.

The initial notification should be **'in-person'** (NHS bodies have discretion as to which method of in-person communication is most appropriate). However, the preference of the service user/person acting on their behalf should be considered and prioritised as well as factors such as the severity of the harm caused.

IN-PERSON CAN MEAN
By telephone, video call or face to face

Purpose of the in-person notification

- Acknowledge what has happened
- Offer an apology (see Annex E).
- Explain what information is known at that time about what has happened.
- Explain the next steps in relation what will happen next. (see Annex F).
- Offer support (see Annex D).
- Provide point of contact details.

Once in-person notification has been made, **written notification** must also be provided to the service user/person acting on their behalf within **five working days after the day of the in-person notification.**

Purpose of the written notification
(a written summary of what was said in the in-person notification)

- Reiterate the verbal apology (see Annex E).
- Detail any initial information on what is known about what has happened.
- Explain the intended actions to and further enquiries that the NHS body will undertake (see Annex F)
- Provide the details of the point of contact.
- Provide the details of any support required (see Annex D).

NB: Refer to chapter 4 of the Duty of Candour Guidance for all factors that must be covered.

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ANNEX D – Support for the service user/person acting on their behalf

It is important to recognise that there is often a psychological impact to the service user / person acting on their behalf that occurs in addition to the harm that has occurred from the healthcare involved in the notifiable adverse outcome or incident. How Service users are supported through this process has a critical impact on the ability of the service user/person acting on their behalf to process what has occurred.

Offering the details of support services to the service user/person acting on their behalf is part of the 'in person' notification process, both in relation to the incident itself and when communicating with them about the incident and throughout the duty of candour procedure process.

The type of support will vary with every situation, but could include:

- Allowing time and actively listening to the Service user or person acting on their behalf
- environmental adjustments for someone who has a physical or other disability.
- signposting to mental health services.
- utilising and organising local translation services.
- the support of an advocate, or other sources of independent help and advice such as AvMA (Action against Medical Accidents) or Cruse Bereavement Care.
- Health board or NHS Trust care after death or bereavement services
- The support of other family members.
- The support and involvement of the GP where appropriate and consented to be involved.

Useful contact details:

- Mental Health Advocates, MIND – www.mind.org.uk
- Llais (Citizen Voice Body for Health and Social Care) www.llaiswales.org
- AvMA - www.avma.org.uk
- Cruse Bereavement Support – www.cruse.org.uk
- Disability Wales - www.disablititywales.org.uk
- Welsh Language Commissioner www.welshlanguagecommissioner.wales
- Royal National Institute for the Blind, RNIB – www.rnib.org.uk
- Race Council Cymru – www.racecouncilcymru.org.uk
- Public Services Ombudsman for Wales – www.ombudsman-wales.or.uk
- Older People's Commissioner for Wales – www.olderpeoplewales.com
- NHS Centre for Equality and Human Rights - www.equalityhumanrights.wales.nhs.uk
- Learning Disability Wales - www.learningdisabilitywales.org.uk
- Information Commissioners Office – www.ico.org.uk/for-the-public
- Citizen Advice – www.citizenadvice.org.uk
- Children's Commissioner for Wales -www.childcomwales.org.uk
- Samaritans – www.samaritans.org

ANNEX D1 – Support for Staff involved in the Duty of Candour Procedure

The Candour Procedure Regulations set out that member of staff who engage in a notifiable adverse outcome must be provided with details of services or support

Those involved in the incident:

- It should be recognised that staff involved in a notifiable adverse outcome or incident will often, also need support.
- A range of emotions and reactions can be experienced by those staff whose actions or omissions may have been part of the healthcare being provided to the service user where harm has occurred or may yet occur.
- It is crucially important that consideration of the wellbeing of those members of the healthcare team is undertaken by local line managers and support is actively offered and provided early on in the procedure and throughout the investigation phase.
- The ethos of learning from incidents and the provision of psychologically safe environments to discuss how staff are feeling so that they can reflect on what has occurred and develop strategies to process and understand what occurred are of the upmost importance.

Those involved in the delivery of the Duty of Candour procedure:

- It is also essential to consider the need to support staff involved in the delivery of duty of candour procedure.
- Communicating difficult and emotionally upsetting news to service users or persons acting on their behalf is very challenging and requires adequate preparation and support.
- This support may be needed both before and after the in-person communication has occurred.
- It is the role of the clinical supervisor, senior clinician and line manager to ensure that staff are adequately prepared and supported through this process sharing their advice and experience.

Support to all staff involved:

- Local Line Managers, Clinical Supervisors, Workforce, Occupational health colleagues and Trade Union representatives can signpost staff to their Employee Wellbeing Service/Occupational Health/Employee Assistance Programmes.
- In addition there are several national support services available via the Health Education & Improvement Wales (HEIW) website [1], such as Health for Health Professionals (Canopi)[2], SilverCloud[3] and the Samaritans[4].

- 1]HEIW (2023) Workforce support. https://heiw.nhs.wales/support/
- [2] Canopi (formally Health for health professionals) https://hhpwales.nhs.wales/about-us/
- [3] SilvercloudWales. https://nhswales.silvercloudhealth.com/signup/
- [4] The Samaritans 2023 https://www.samaritans.org/

ANNEX E - MAKING A MEANINGFUL APOLOGY

It is of fundamental importance that the service user /person acting on their behalf receives a sincere apology in a timely manner that is clear and made in an empathetic way. The objective here is to address the need for information, clarify what has happened and to enable the recipient the opportunity to process what has happened in a supportive environment.

Preparation

It is essential to take the time to prepare for the communication with the service user/person acting on their behalf and any family members. Plan out what you are going to say and discuss this with a senior or peer. Ensure you have adequate time and are not distracted or likely to be interrupted. Being mentally 'present' and able to concentrate is very important part of your preparation. Also think about the needs of the service user/person acting on their behalf – what information do they need and how and what support may they need? (Refer to part 7 of the candour guidance document).

What has happened (be clear what is known and what is not yet known), **Who** is best to deliver this information, **When** is it best to deliver this and **How** you intend to deliver this. It is important to recognise that the '**Why** this has happened' is the purpose of the investigation process and not usually part of the apology at this early stage. Although it is common for Service Users/person acting on their behalf to ask this at this stage. It is acceptable to be honest and say that you are not certain of that at this point in time.

Delivery

You are imparting 'bad news' to a service user/person acting on their behalf, sometimes they are aware of an unexpected or unintended harm but not fully aware of the circumstances or they can be unaware of the unintended or unexpected harm outcome that has occurred. Be clear and factual and avoid jargon. Starting with an introduction of who you are and checking who it is you are talking to and who else is present.

Explain the reason why you are talking to them.

Inform the Service User of the unintended or unexpected harm and what actually is known to have occurred. Show that the circumstances and the impact for the person affected are understood e.g. 'you were left not knowing what was happening'

Accept and acknowledge what should have happened 'We should have explained exactly what was going to occur to you'

ANNEX E – MAKING A MEANINGFUL APOLOGY

(**Continued)**

Apologise sincerely with empathy, using your body language and words carefully to reinforce the genuine nature of the apology. e.g. I am sorry that this has happened to you / I am deeply sorry for your experience / I apologise unreservedly for the distress and suffering this has caused you and your family.

Personalise the apology rather than a general expression of regret about the incident on the organisation's or another's behalf as this does not mean that you are taking personal responsibility.

Allow time for the service user and those present to process what you have said. Ask them if they understand what it is you have told them?

Ask them whether they have any questions. Show respect for and respond to questions sensitively.

Explain the next steps of the Duty of Candour Procedure – written letter in five working days confirming today's conversation and further information about the intended incident review process.

Making an apology is not accepting blame, culpability or legal liability. Refer to section 7e of the guidance for further detail.

People receiving this type of news can demonstrate the whole spectrum of responses and you must be prepared and planned how you are going to respond to these. Ensure you are safe and where possible it is always helpful to have a colleague with you.

Conclude the conversation sensitively bringing things to a natural close. e.g. I am truly sorry that this has happened to you and I am going to find out what happened and come back to you. In the meantime, my/your point of contact details are ……. Please do not hesitate to contact me if you have any questions during this time. I will also follow our conversation up with a letter setting out everything you need to know about the duty of candour procedure and the next steps we are going to be taking.

Document

In accordance with Regulation 9 of the Candour Procedure (Wales) Regulations 2022,

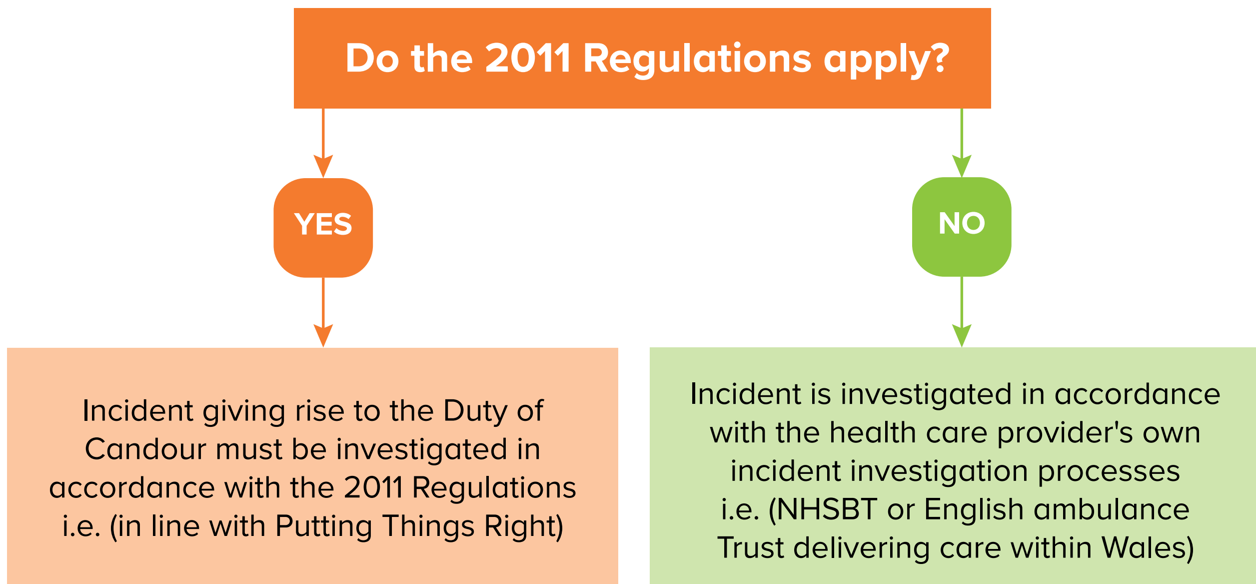
written records must be kept of the application of the duty of candour procedure including the apology. The conversation should also be carefully documented in the patient care record and on the incident record via Datix Cymru so that others involved in the clinical care or review of the incident can see that an apology has been given.

Resources:

1) https://resolution.nhs.uk/wp-content/uploads/2017/07/NHS-Resolution-Saying-Sorry-Final.pdf
2) https://mdujournal.themdu.com/issue-archive/issue-2/the-effective-apology
3) 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#saying-sorry
4) https://www.ombudsman.ie/guidance-for-service-providers/the-ombudsmans-guide-to-m/
5) https://www.spso.org.uk/sites/spso/files/csa/ApologyGuide.pdf
6) Bowie.P (2020) Safety and Improvement in Primary Care: The Essential Guide https://doi.org/10.1201/9780429165351

Annex F - Duty of Candour
Review process and record keeping

The primary purpose of the review is to determine what happened and why, determine what can done be done to prevent recurrence and to learn lessons.



In all instances, Regulation 9 of the Candour Procedure (Wales) Regulations 2023, regarding record keeping must be adhered to.
(Refer to chapter 3 of the candour guidance for further details).

NB: Consideration should also be given to whether the incident and the triggering of the Duty of Candour should be reported to a professional regulator

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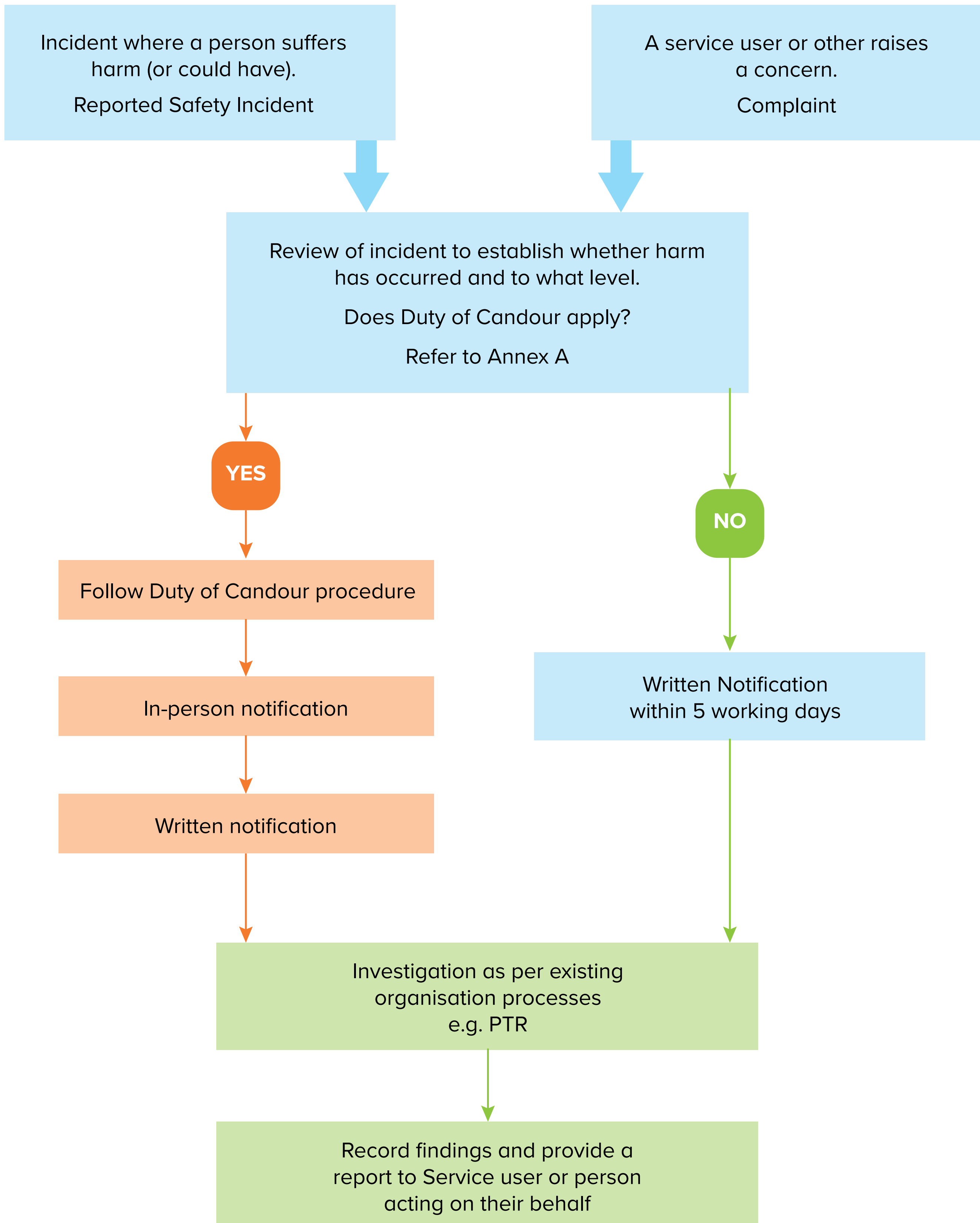
Annex F1 - Duty of Candour
Review Process and Record Keeping



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Annex G - Duty of Candour
Reporting, publication and monitoring

Primary Care Providers - duty to report

Primary Care Providers must prepare an annual report on whether the Duty of Candour has come into effect in relation to NHS health care they have provided.

The report must specify if the Duty of Candour has come into effect in the reporting year and if it has:

- Specify how often the Duty of Candour has come into effect during the reporting year.
- Give a brief description of the circumstances in which the duty came into effect.
- Specify any steps taken by the body with a view of preventing similar circumstances from arising in the future.

(it can contain other information)

Primary Care Providers must send the annual report to the **Local Health Board** to which the report relates by 30 September each year.

The Local Health Board must prepare a summary of the reports received from the Primary Care Providers. The summary must –

- Specify how often, during the reporting year the Duty of Candour has come into effect in respect of health care provided on behalf of the Local Health Board by a Primary Care Provider.
- Give a brief description of the circumstances in which the duty came into effect.
- Describe any steps taken by the Primary Care Provider with a view to preventing similar circumstances from arising in future.

Local Health Boards will be responsible for publishing all information relevant to the Duty of Candour in respect of its own services and the services provided by Primary Care services for its area.

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Annex G1 - Duty of Candour Reporting, publication and monitoring

Local Health Boards, NHS Trusts and Special Health Authorities: reporting requirements

Local Health Boards, NHS Trusts and Special Health Authorities must prepare an annual report on the Duty of Candour.

The report must specify whether, during the reporting year, the Duty of Candour has come into effect in respect of the provision of health care by the body. The report must -

- Specify how often the Duty of Candour has come into effect during the reporting year.
- Give a brief description of the circumstances in which the duty came into effect.
- Specify any steps taken by the body with a view to preventing similar circumstances from arising in the future.

(it can contain other information)

NHS bodies must publish their candour reports by 31 October each year.

Confidentiality

The report published must not name –

- Any person to whom health care is being or has been provided by or on behalf of the body, or
- Any person acting on such a person's behalf.

In addition, regard must be given to the need to avoid including any information which, even though it does not actually give an individual's name, is in the circumstances likely to enable the identification of that individual.

Monitoring

Local ownership and accountability with regular compliance reviews should be integrated into existing governance frameworks.

Compliance with the duty will form part of the matters considered by Health Inspectorate Wales when inspecting and reviewing the NHS.

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.

NB: Refer to chapter 8 of the Duty of Candour Guidance for further details.

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ANNEX H – CASE STUDY EXAMPLES

The examples listed are for illustrative purposes only and are not intended to be an exhaustive list or taken as directives. It is the responsibility for each NHS body to have local decision making processes that consider, on a case-by-case basis, the individual circumstances of each case and this includes the individual circumstances and experiences of each service user involved.

The following case studies are examples of how the duty of candour checklist questions are used to consider whether or not the duty of candour is triggered.

For the duty of candour to be triggered, the answer to all three checklist questions must be yes.

Case study 1: Community Pharmacy

The description of the incident is the same throughout, but the outcomes are different.

A pharmacy received a prescription for 28 Loratadine 10mg (Antihistamine (non-drowsy) tablets, one to be taken each morning. The pharmacy inadvertently supplied 28 Lorazepam tablets 1mg tablets, one to be taken each morning. The medication received is used for anxiety disorders and could have a sedative effect. The service user was unaware that the tablets were not the prescribed tablets.

Outcome 1: The service user fell asleep at home and missed a shopping trip with friends.

Checklist to see if the duty of candour is triggered?

- **Has the service user experienced, or are the circumstances such that they could experience, harm that was unintended or unexpected?**
  Yes. The service user was inadvertently supplied with the wrong medication, which was unintended.

- **Is that harm more than minimal**
  No. The service user fell asleep at home and missed a shopping trip with friends. This would not meet the criteria for more than minimal harm.

- **Was the provision of health care a factor, or may have been a factor, in the service user suffering more than minimal harm?**
  Yes. The provision of health care was a factor but the service user did not suffer more than minimal harm.

Conclusion: Duty of candour was not triggered in this case as the service user did not suffer more than minimal harm. An investigation into how the service user was inadvertently supplied with the wrong medication should still be carried out.

Outcome 2: The service user fell asleep at work and was spoken to by her manager.

Checklist to see if the duty of candour is triggered?

- **Has the service user experienced, or are the circumstances such that they could experience, harm that was unintended or unexpected?**
  Yes. The service user was inadvertently supplied with the wrong medication, which was unintended.

- **Is that harm more than minimal?**
  No. The service user fell asleep at work and was subject to a disciplinary interview. This would not meet the criteria for more than minimal harm.

- **Was the provision of health care a factor, or may have been a factor, in the service user suffering more than minimal harm?**
  Yes. The provision of health care was a factor but the service user did not suffer more than minimal harm.

Conclusion: Duty of candour was not triggered in this case as the service user did not suffer more than minimal harm. An investigation into how the service user was inadvertently supplied with the wrong medication should still be carried out.

Outcome 3: The service user fell asleep while driving resulting in a whiplash injury and damage to her and another vehicle.

Checklist to see if the duty of candour is triggered?

- **Has the service user experienced, or are the circumstances such that they could experience, harm that was unintended or unexpected?**
  Yes. The service user was inadvertently supplied with the wrong medication, which was unintended.

- **Is that harm more than minimal**
  Yes. As a result of taking the wrongly supplied medication, the service user experienced a sedative side effect, which led her to fall asleep while driving and being involved in a road traffic accident, resulting in a whiplash injury. This meets the criteria for harm that is more than minimal.

- **Was the provision of health care a factor, or may have been a factor, in the service user suffering more than minimal harm?**
  Yes. The provision of health care was a factor as the pharmacy inadvertently supplied the wrong medication.

Conclusion: The answers to all three questions are "yes", so this triggers the duty of candour process, and the duty of candour procedure should be followed to completion.

Case study 2: Acute Speech & Language Therapy

The description of the incident is the same throughout, but the outcomes are different.

A speech and language therapist (SaLT) undertook an assessment of a service user on a trauma and orthopaedic ward who had been referred by the team due to signs of worsening dysphagia since his recent fractured neck of femur surgery. His chest x-ray showed right basal consolidation. He was being treated for an emerging aspiration pneumonia. The therapist observed that the service user was distractible and struggled to coordinate thin fluids in his mouth - tending to enter his airway prematurely and cause coughing fits. He was better able to swallow and coordinate more viscous fluids and smoother dietary textures. The SaLT recommended a short term trial of Level 2 thickened fluids and a Level 4 smooth pureed diet whilst he made a full recovery. The SaLT discussed her recommendations with the staff nurse and wrote in the medical notes but forgot to place a SaLT recommendation bed sign above the service user's bed, which is usual practise in this health board.

Outcome 1: The service was given thin fluids and a normal diet for their next meal until the SaLT Associate Practitioner noticed the omission on visiting the ward and placed a bedside notice prior to their evening meal. The service user remained chesty but there was no significant change in his health presentation.

Checklist to see if the duty of candour is triggered?

- **Has the service user experienced, or are the circumstances such that they could experience, harm that was unintended or unexpected?**
  Yes. The service user was inadvertently supplied with the texture fluids and diet, which was unintended.

- **Is that harm more than minimal?**
  No. The service user remained symptomatic of the aspiration pneumonia but didn't require oxygen and any other support and remained stable with no significant deterioration in his health. This would not meet the criteria for more than minimal harm.

- **Was the provision of health care a factor, or may have been a factor, in the service user suffering more than minimal harm?**
  Yes. The provision of health care was a factor but the service user did not suffer more than minimal harm.

Conclusion: Duty of candour was not triggered in this case as the service user did not suffer more than minimal harm. An investigation into how the service user was inadvertently supplied with the wrong diet and fluids should still be carried out.

Outcome 2: The service user continued to be given thin fluids and a normal diet for the next 2 days and suffered a serious choking incident. He suffered a respiratory arrest, was resuscitated but incurred hypoxia of the brain, leading to worsening cognitive deficits, a prolonged hospital stay and a change in health needs leading to a conversion from a residential to a nursing home placement.

Checklist to see if the duty of candour is triggered?

- **Has the service user experienced, or are the circumstances such that they could experience, harm that was unintended or unexpected?**
  Yes. The service user was inadvertently supplied with the wrong texture diet and fluids, which was unintended.

- **Is that harm more than minimal**
  Yes. As a result of taking the wrongly supplied diet and fluids, the service user experienced a significant choking episode, which led to a hypoxic brain injury. This meets the criteria for harm that is more than minimal.

- **Was the provision of health care a factor, or may have been a factor, in the service user suffering more than minimal harm?**
  Yes. The provision of health care was a factor as the SaLT did not display the correct swallow recommendations above the bedside, which led to other staff on shift not realising that the service user should be taking modified diet and fluid textures. In addition, staff on the ward did not communicate the instructions given verbally and staff did not read the instructions written in the medical notes.

Conclusion: The answers to all three questions are "yes", so this triggers the duty of candour process, and the duty of candour procedure should be followed to completion.

To avoid duplication, the checklist questions to consider whether or not the duty of candour procedure is triggered have been removed from the following case studies.

By way of reminder -

For the duty of candour to be triggered, the answer to all three checklist questions must be yes:

- Has the service user experienced, or are the circumstances such that they could experience, harm that was unintended or unexpected?
- Is that harm more than minimal?
- Was the provision of health care a factor, or may have been a factor, in the service user suffering more than minimal harm?

The following case studies are examples of when the duty of candour would be triggered and the same case study with a different outcome

Case study 3: Bowel Screening

A service user is recommended for a colonoscopy under general anaesthetic. The service user did not undergo the colonoscopy within the policy time limits due to systemic delays.

When the colonoscopy did eventually take place (some 70 weeks after the initial recommendation), a biopsy was taken which indicated a suspicion of invasive malignancy.

When the colonoscopy was performed, staff became aware that the service user had been delayed in receiving the recommended colonoscopy.

The Consultant and MDT reached a consensus based on symptoms, history and histology that the delay in diagnosis impacted upon the development and stage of cancer and therefore the treatment options available to the patient.

Checklist to see if the duty of candour is triggered?

Yes - The duty of candour would be triggered in this case and the duty of candour procedure should be followed to completion as the delay in diagnosis impacted upon the development and stage of cancer and therefore the treatment options available to the patient. The service user may have been able to have less invasive treatment, had the colonoscopy investigations been carried out within the prescribed time limits.

The provision of health care was a factor as there was a delay in the diagnostic test being undertaken.

Same case study – different outcome

A service user is recommended for a colonoscopy under general anaesthetic.

The service user should have undergone a colonoscopy within the desired nationally agreed timescales.

The service user called their GP when they had not heard anything for a few weeks and the GP chased this up with the screening programme. An appointment was scheduled for a colonoscopy soon after and the cancer was detected and the cancer was amenable to less invasive treatment which may not have been the case if there had been further delays.

Checklist to see if the duty of candour is triggered?

No – The duty of candour would not be triggered in this case as the service user did not suffer more than minimal harm as a result of the service user and GP's actions to chase up the appointment. The procedure was carried out within the prescribed time scales.

A review into why the service user was not followed up routinely should still be carried out.

Case study 4: Service provision

57 year old male presented to a hospital at 17:45 with sudden onset of slurred speech and arm weakness secondary to a suspected stroke. CT

Same case study: different outcome

57 year old male's wife called 999 at 13:00 as the patient had developed a sudden onset of slurred speech and arm weakness secondary to

scanning identified an anomaly amenable to thrombectomy. The thrombectomy service operates between 08:00 and 20:00. The thrombectomy service was contacted at 18.30. The patient was not accepted for transfer as he would not have arrived in time. The patient suffered permanent neurological deficit.

Checklist to see if the duty of candour is triggered?

Yes - The duty of candour would be triggered in this case and the duty of candour procedure should be followed to completion as the service user did not receive the necessary treatment to prevent permanent neurological deficit, which was unintended and would meet the criteria for harm that is more than minimal.

The provision of health care was factor as the service that could potentially have prevented the permanent neurological deficit was not available 24hrs.

a suspected stroke. The Ambulance Service was contacted at 13:00 and responded to the patient conveying the patient to the hospital by 13:45. Due to capacity issues within the emergency department the CT scan was undertaken 2 hours later identifying an anomaly amenable to thrombectomy.

The thrombectomy service operates between 08:00 and 20:00. The thrombectomy service was contacted at 15:45 and the patient was accepted for transfer at 16.00. There was a further delay in the transfer of the patient and was subsequently transferred for treatment at 18.45, which was successful. The treatment was within the therapeutic window and successful despite the delay. **Checklist to see if the duty of candour is triggered?**

No – The duty of candour would not be triggered in this case as the service user did not suffer more than minimal harm.

A review into the provision of services to meet service user needs should still be carried out.

Case study 5: Inpatient head injury

A service user was due to be discharged from hospital following a successful hernia operation. Prior to his discharge he was found on the floor by side of bed in the bay by a member of the nursing team. A bony injury was evident to the head. Observations were recorded and neurological observations were noted to be abnormal. The service user was transferred for a CT scan, the results of which showed a subdural haemorrhage. The service user remained in hospital for 3 months recovering from the subdural haemorrhage. He required substantial rehabilitation from a number of professions, including occupational therapy, speech and language therapy and physiotherapy for a further six months, which continued at home.

Checklist to see if the duty of candour is triggered?

Yes - The duty of candour would be triggered in this case and the duty of candour procedure should be followed to completion as the service user sustained a head injury after being found on the floor by the side of his bed in hospital, which was unintended and unexpected.

The service user sustained a subdural haemorrhage, which led to an additional 3 months in hospital and requiring, substantial rehabilitation from a number of professions, including occupational therapy, speech and language therapy and physiotherapy for a further six months at home, which would meet the criteria of more than minimal harm.

The provision of health care was a factor as the service user was an inpatient at the time of the harm being sustained.

Same case study: different outcome

A service user was due to be discharged from hospital following a successful hernia operation. Prior to his discharge he was found on the floor by side of bed in the bay by a member of the nursing team. Observations were recorded and neurological observations were noted to be abnormal. The service user was transferred for a CT scan, the results of which were normal. The service user remained on regular observations, which after 24 hours returned to normal. The service user remained in hospital for a further 24 hours to be monitored and was subsequently successfully discharged home.

Checklist to see if the duty of candour is triggered?

No – The duty of candour would not be triggered in this case as the service user did not suffer more than minimal harm.

A review into how the service user ended up on the floor by the side of the bed with a head injury should still be carried out.

Case study 6: Nurse management

A service user is admitted with a myocardial infarction and is judged eligible for an infusion of a thrombolytic (clot busting) agent, which must be started immediately if she is to have any

Same case study – different outcome

A service user is admitted with a myocardial infarction and is judged eligible for an infusion of a thrombolytic (clot busting) agent, which must

benefit. The medication is prescribed, and the infusion is drawn up into a syringe driver. A nurse connects an intravenous line to the syringe driver and starts the infusion to run over one hour.

The nurse is distracted by a call from another staff member just before completing the setting up of the infusion.

One hour later the service user is reviewed to see if the infusion has been effective. Unfortunately the service user is feeling worse and the nurse notices a pool of fluid under the service user's bed. On further investigation the line running from the syringe driver has never been attached to the patient and the infusion has dripped on to the floor under the patient. It was too late to administer further treatment within the window of time from the onset of symptoms to gain maximum benefit.

Checklist to see if the duty of candour is triggered?

Yes - The duty of candour would be triggered in this case and the duty of candour procedure should be followed to completion as there was a failure to complete the connection of intravenous therapy, which resulted in moderate harm of an untreated myocardial infarction, leading to permanent cardiac impairment and a reduced life expectancy, which was unintended. This would meet the criteria for more than minimal harm.

The provision of health care was a factor as the intravenous therapy was part of the service users care plan.

be started immediately if she is to have any benefit. The medication is prescribed, and the infusion is drawn up into a syringe driver. A nurse connects an intravenous line to the syringe driver and starts the infusion to run over one hour.

The nurse is distracted by a call from another staff member just before completing the setting up of the infusion.

A Health Care Assistant, who was attending to the service user's care needs at that time, noticed that the line running from the syringe driver had not been attached to the service user within the first 15 mins. A senior member of staff was alerted and the infusion was re-drawn up and started.

Checklist to see if the duty of candour is triggered?

No - The duty of candour would not be triggered in this case as harm was avoided as the Health Care Support worker had identified that the line to the syringe driver had not been connected and took the appropriate action to ensure the infusion was commenced by the senior member of staff.

A review into why the line running from the syringe driver had not been attached to the patient should still be carried out.

Case study 7: NHS Blood & Transplant

A Welsh kidney transplant patient received the offer of a kidney from an English solid organ donor. Organ Donor Characterisation occurred which included routine microbiological test results. The kidney offer was accepted, and the service user subsequently received the transplant.

Two weeks later it was identified that one of the microbiology results was entered incorrectly on the donor record, meaning the transplant centre transplanted based on the incorrect result. The centre was informed of the error. Based on the new information the service user was commenced on IV anti-virals and required an increased inpatient stay of over 14 days.

Checklist to see if the duty of candour is triggered?

Yes - The duty of candour would be triggered in this case and the duty of candour procedure should be followed to completion as the service user's kidney offer was accepted with incorrect information and therefore appropriate prophylactic treatment was not commenced timely.

The service user required anti-virals and an increased inpatient stay of over 14 days, which meets the criteria for more than minimal harm.

The provision of health care was a factor as it was identified that one of the microbiology results had been entered incorrectly on the donor record.

Same case study: different outcome

A Welsh kidney transplant patient received the offer of a kidney from an English solid organ donor. Organ Donor Characterisation occurred which included routine microbiological test results. The kidney offer was accepted.

Prior to the transplant, it was identified that one of the microbiology results was entered incorrectly on the donor record, meaning the transplant centre accepted based on the incorrect result. The centre was informed of the error. Based on the new information and the fact that the error was identified prior to transplantation, the centre could make an informed decision around acceptance and plan any prophylactic treatment as appropriate.

Checklist to see if the duty of candour is triggered?

No - The duty of candour would not be triggered in this case as the error was identified prior to transplantation, the centre was able to make an informed decision around acceptance and plan any prophylactic treatment as appropriate. Therefore, harm was not more than minimal.

A review into why the incorrect results had been entered incorrectly on to the donor card should be carried out.

Case study 8: Laterality error

A service user's right ankle is x-rayed instead of the left. The images were reported as normal with no injury identified. The service user continued to experience pain and sought further advice from his GP, who, on reviewing the x-ray report, identified the error and contacted the Radiology department. A further x-ray confirmed an injury to the left ankle. The delay in diagnosis led to the service user requiring a different care plan, which included the

Same case study: different outcome

A service user's right ankle is x-rayed instead of the left. The images were reported as normal, no injury identified. Prior to the service user leaving the Radiology Department the referral and x-ray report were checked and the error was identified. A further x-ray was undertaken on the left ankle, which confirmed an injury. The service user was referred to Fracture Clinic and received the appropriate treatment.

need for surgery and intensive physiotherapy treatment.

Checklist to see if the duty of candour is triggered?

Yes - The duty of candour would be triggered in this case and the duty of candour procedure should be followed to completion as a result of the wrong ankle being x-rayed, the service user's injury was not identified, which was unintended.

The delay in diagnosis resulted in the need for a moderate increase in treatment, prolonged pain and the appropriate treatment options not being identified in a timely manner. All of which meets the criteria for more than minimal harm.

The provision of health care was a factor as the Radiologist x-rayed the wrong body part.

Checklist to see if the duty of candour is triggered?

No - The duty of candour would not be triggered in this case as the error was identified and corrected and more than minimal harm was avoided.

A review into why the wrong ankle was x-rayed should still be carried out.

EXAMPLES OF HARM THAT <u>COULD</u> OCCUR

Case study 9: Optometric practice, clinical care.

A service user presents with intermittently painful and red eyes but all the results from the eye examination are within normal limits, including intra-ocular pressures of 11mmHg right and left. The optometrist suspects dry eye as the cause of the discomfort and recommends ocular lubricants. Later that day the optometrist discovers that the tonometer used is inaccurate: The optometrist checks the calibration of the tonometer and discovers that it is damaged, incorrectly calibrated and needed repair.

Due to an escalation of symptoms, the service user sought emergency treatment the following day. They were diagnosed with angle closure and intra-ocular pressures of 41 and 45 mmHg. The service user required systemic drugs to prevent permanent vision loss. The outcome would not be known for a number weeks.

Checklist to see if the duty of candour is triggered?

Yes - The duty of candour would be triggered in this case and the duty of candour procedure should be followed to completion as the service user could experience permanent vision loss, which was unintended.

On assessment the service user's condition was found to have deteriorated significantly. The service user required systemic drugs to prevent permanent vision loss. The outcome would not be known for a number weeks. This would meet the criteria for harm that is more than minimal that could occur.

The provision of health care was a factor. If the instrumentation had been regularly calibrated, the misdiagnosis is unlikely to have occurred.

Case study 10: NHS Blood & Transplant

A Welsh resident was referred to an English Transplant Centre for assessment for liver transplantation. The referral was made and the service user was assessed as suitable for liver transplantation and their registration form was submitted to NHS Blood and Transplant for entering onto the transplant waiting list.

On entering the registration onto the national transplant database an error was made which meant that the service user details did not appear correctly. This error was not identified and the service user subsequently did not receive a number of suitable liver offers; on review at least one of these offers would have been accepted and the service user would have received a transplant.

Checklist to see if the duty of candour is triggered?

Yes - The duty of candour would be triggered in this case and the duty of candour procedure should be followed to completion as the service user missed a number of offers that led to a delay in receiving a liver transplant, which could lead to more than minimal harm in the future.

The provision of health care was a factor as the service user details were entered incorrectly in the national transplant database.

Same case study: different outcome

A Welsh resident was referred to an English Transplant Centre for assessment for liver transplantation. The referral was made and the service user was assessed as suitable for liver transplantation and their registration form was submitted to NHS Blood and Transplant for entering onto the transplant waiting list.

On entering the registration onto the national transplant database an error was made which meant that the service user details did not appear correctly. This error was identified shortly afterwards and corrected; during this time no suitable offers had been made and therefore there was no impact for the service user.

Checklist to see if the duty of candour is triggered?

No - The duty of candour would not be triggered in this case as the error was identified and corrected and harm was avoided.

A review into why the incorrect service user details were added to the data base should still be carried out.

Case study 11: NHS Blood & Transplant

A Welsh resident was referred to a Welsh Transplant Centre for assessment for kidney transplantation. The referral was made and the patient was assessed as suitable for kidney transplantation and their registration form was submitted to NHS Blood and Transplant.

A suitable kidney offer became available for the service user, however at the time an error was made by NHSBT and the offer was made to a

Same case study: different outcome

A Welsh resident was referred to a Welsh Transplant Centre for assessment for kidney transplantation. The referral was made and the patient was assessed as suitable for kidney transplantation and their registration form was submitted to NHS Blood and Transplant.

A suitable kidney offer became available for this service user, however at the time an error was made by NHSBT and the offer was made to a

different service user. This error was not identified and meant the correct service user missed an offer of a kidney that was suitable.

Checklist to see if the duty of candour is triggered?

Yes - The duty of candour would be triggered in this case and the duty of candour procedure should be followed to completion as the service user missed the opportunity to receive a suitable kidney, which could lead to more than minimal harm in the future.

The provision of health care was a factor as the error occurred in the processes managed by NHSBT.

different service user. This error was identified after the offer had been made to the incorrect service user. The offer was immediately withdrawn and offered to the correct service user. The kidney was subsequently successfully transplanted to the correct service user.

Checklist to see if the duty of candour is triggered?

No - The duty of candour would not be triggered in this case as the error was identified and corrected and more than minimal harm was avoided.

A review into why the incorrect service user details were added to the data base should still be carried out.

AN EXAMPLE INVOLVING RECOGNISED AND CONSENTED FOR COMPLICATIONS OF A PROCEDURE

Case study 12: Optometry

A service user attends an optometry practice for her routine sight test. The service user explains to the optometrist that she has had symptoms of flashing lights and floaters. The optometrist advises a dilated assessment is required and is given consent from the service user to proceed and administers the drops for dilation. The optometrist diagnosis a posterior vitreous detachment and provides the service user with written information about the condition and explains what the service user needs to do should there be an increase in his symptoms.

The service user contacted the practice four hours later complaining of an extremely painful red eye and blurred vision. It was arranged for him to be seen as an ocular emergency as a primary angle-closure suspect. The service user received a Peripheral Laser Iridotomy, as he was affected by a primary angle closure suspect secondary to the dilation.

Checklist to see if the duty of candour is triggered?

Yes - The duty of candour would be triggered in this case and the duty of candour procedure should be followed to completion as the service user required emergency intervention by way of a Peripheral Laser Iridotomy, which was unintended. This would also be considered as a moderate increase in treatment and would therefore meet the criteria for more than minimal harm.

The provision of health care was a factor as the dilated assessment and prescribed treatment was undertaken at the Optometric practice.

NB: A primary angle-closure suspect is a known risk, albeit rare, this risk would have been discussed as part of the consent procedure. The risk of the adverse event occurring is part of the balance of risk to ascertain whether the investigation is in the patients' interest and ensure valid informed consent.

Whether or not consent is appropriately obtained does not affect the duty of candour procedure being triggered. This includes recognised and consented for complications of a procedure. The recording and investigating of the incident are important processes that needs to be triggered, even if it is subsequently found the optometrist acted correctly throughout.

EXAMPLES INVOLVING MORE THAN ONE NHS BODY

Case study 13: Optometry and Ophthalmology

A service user attends the Optometric practice for his routine sight test in September. He mentions that he was due to be seen by the Ophthalmology team in the Hospital under the specialist Wet AMD clinic in March but hasn't been seen and his vision has significantly deteriorated. On reviewing the records, it appears that the referral was sent to the Ophthalmology Department at the Hospital in March as planned. On contacting the Ophthalmology Department in the Hospital, it was established that the referral had been received in March but there were no further records to say what action had been taken and it was confirmed that no appointment had been arranged for the service user.

Checklist to see if the duty of candour is triggered?

Yes – The duty of candour would be triggered in this case and the duty of candour procedure should be followed to completion as a result of no action being taken by the Ophthalmology Department in the Hospital the service user has not been assessed by the specialists in the field of Ophthalmology and his vision has significantly deteriorated, which was unintended.

It is not known whether the deterioration is reversible or whether this could lead to irreversible sight loss. This meets the criteria for more than minimal harm.

The provision of health care was a factor, however not in relation to the Optometric practice.

NB: In this scenario, the Ophthalmology Department in the Hospital, are considered to be the 'providing body' in terms of the legislation (i.e. their provision of health care did or does have the potential to trigger the duty of candour) and would therefore be responsible for the duty of candour process, and should follow the duty of candour procedure to completion.

Although the Optometric practice is involved in the episode of care, they are not the 'providing body'. They may however, 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 are expected to co-operate fully in an open and facilitative manner throughout the duty of candour procedure and share any learning identified as a result of the review, including any actions to be taken with a view to preventing similar circumstances from arising in the future.

Case study 14: General Practice and Secondary Care

Baby B was born at term, and feeds well. Two weeks later, mum takes him to see the GP as he is no longer feeding well, he is not gaining weight and he seems jaundiced.

The GP examines him and says the jaundice is mild and common with breastfeeding babies. the GP tells mum to come back in a few days if his colour doesn't improve.

Two days later, mum brings baby B in. He's floppy and won't feed. The GP realises that the baby B is far more jaundiced than was first thought and on reflection feels that the GP should have referred him to the local paediatric team. He sends the mother and baby B to children's A&E for an urgent evaluation.

In the hospital they find that baby B has a dangerous concentration of bilirubin in his blood and needs a prolonged admission to hospital. Exposure to this high concentration may have caused long-term damage to baby B's brain.

Checklist to see if the duty of candour is triggered?

Yes – The duty of candour would be triggered in this case as a result of baby B's severity of condition not being fully recognised. Baby B was found to have a dangerous concentration of bilirubin in his blood and needed a prolonged admission to hospital. Exposure to this high concentration may have caused long-term damage to baby B's brain. This is considered harm that it more than minimal.

The provision of health care was a factor, as baby B was under the care of the GP, who undertook an examination and provided advice to mum.

NB: In this scenario, the lead paediatrician contacted the GP and informed him of the findings following baby B's admission to the children's A&E. The GP reported the incident via the Datix Cymru system and this triggered the duty of candour procedure. The GP was responsible for following the duty of candour procedure to completion.

Due to the circumstances, the GP agreed that someone needed to explain to mum straightaway that the bilirubin test should have been done earlier, apologise, and tell her what could happen next. While either of them could do this, they decided that the paediatrician should speak to mum, as she is more able to explain what the likely outcomes will be for baby B, and what will happen next in Baby B's care.

The GP practice subsequently arranged to see the mother the GP apologised personally to the mother. The duty of candour procedure was carried out to completion by the GP practice.

Case study 15: Dental and Pharmacy

A regular attender at a dental practice attends for a routine six-month check-up. The service users wears a full upper denture and has retained teeth in the lower arch. At the examination, the palate has a white coating which can scrape off and it is obvious that the patient's denture hygiene needs to be improved. A diagnosis of oral candidiasis is

Same case study: different outcome

A regular attender at a dental practice attends for a routine six-month check-up. The service user wears a full upper denture and has retained teeth in the lower arch. At the examination, the palate has a white coating which can scrape off and it is obvious that the service user's denture hygiene needs to be improved. A diagnosis of

made, and a prescription issued for 50mg Fluconazole for 14 days.

Two weeks after this appointment the service user's wife comes into the dental practice very concerned. Four days ago, the service user had severe pain in the stomach and was taken to A&E. Following investigations, it was discovered that the service user was suffering from a gastric bleed and when blood tests were taken his INR (International Normalised Ratio) was found to read 5.2.

The service user's wife informed the dentist that four months ago the service user had suffered a DVT (Deep Vein Thrombosis) after returning from holiday and had been placed on Warfarin with a target range of 1.5-2.5. The hospital discovered that the service user had been prescribed Fluconazole which increases the anticoagulant effect of Warfarin and was likely to be the cause of the increase in his INR to 5.2 which is dangerously high. On looking at the clinical notes, no medical history had been taken from the service user so the fact he was taking Warfarin was missed.

Checklist to see if the duty of candour is triggered?

Yes - The duty of candour would be triggered in this case and the duty of candour procedure should be followed to completion as the service user suffered a gastric bleed after being prescribed medication by the dentist, which was unintended.

The gastric bleed put the service user's life at risk. He required additional emergency treatment further interventions, which would meet the criteria for more than minimal harm.

The provision of health care was a factor as the medication was prescribed by the dentist and issued by the pharmacist.

NB: In this scenario the Dentist would report the incident that triggers the duty of candour procedure. The Dentist would be required to follow the procedure to completion. The Dentist would also be required to inform the Pharmacist,
who would also be required to report an incident

oral candidiasis is made, and a prescription issued for 50mg Fluconazole for 14 days.

That afternoon a phone call is received at the practice from the local pharmacy. When issuing the prescription for Fluconazole the pharmacist cross checked the other medications that the service user was prescribed. It was discovered that the service user was prescribed Warfarin due to a DVT diagnosis four months ago. There is a known interaction between Fluconazole and Warfarin which increases the anticoagulant effect of Warfarin. The pharmacist did not dispense the prescription to the service user.

Checklist to see if the duty of candour is triggered?

No - The duty of candour would not be triggered in this case as the error was identified and corrected and more than minimal harm was avoided. This would still be reported on Datix Cymru and investigated as a no harm incident.

NB: In this scenario the Pharmacist would inform the Dentist of the incident. The Dentist would be responsible for establishing why an inadequate medical history had been taken.

that triggers the duty of candour procedure. The Pharmacist would be required to follow the procedure to completion.

Case study 16: Optometry

A service user contacted an Optometry Practice (1), for an appointment, with symptoms of flashing lights and floaters in their right eye for 24 hours. The service user had a history of retinal tear in their left eye several years ago. No triage was undertaken and no further advice was given by Optometry Practice (1). The service user then contacted their GP who advised them to attend another Optometry Practice. The service user was seen the by the 2nd Optometry Practice the following day and was urgently referred to the hospital for a retinal tear.

Checklist to see if the duty of candour is triggered?

Yes - The duty of candour would be triggered in this case and the duty of candour procedure should be followed to completion as the service user did not receive the appropriate advice and treatment from the Optometry Practice (1), which was unexpected. The service user required urgent treatment for a retinal tear, which would meet the criteria for more than minimal harm.

The provision of health care was a factor as the service user did not receive the appropriate advice and treatment from the Optometry Practice (1).

NB: In this scenario either the 2nd Optometry Practice, GP or service user could alert the 1st Optometry Practice to the incident. The 1st Optometry Practice would be responsible for reporting the incident that triggers the duty of candour procedure which should be followed to completion.

Case study 17: Three Health Boards and a Trust

A service user was seen by a Health Board, following an urgent suspected cancer referral. He was subsequently referred for a specialist opinion, and seen by the 2nd Health Board. A further specialist opinion was sought from a 3rd Health Board. The service user received cancer treatment from the NHS Trust. All NHS bodies were responsible for the multidisciplinary management of the service user's care.

When the service user was reviewed by the NHS Trust, it was clear that the disease progression between referrals had worsened. It was agreed that the cancer would have been amenable to treatment earlier in the service user's journey between the 1st Health Board and the 3rd Health Board. The service user subsequently died.

Checklist to see if the duty of candour is triggered?

Yes - The duty of candour would be triggered in this case and the duty of candour procedure should be followed to completion as there were delays in the service user's pathway that led to the service user experiencing extensive disease progression within the liver and lungs and subsequently died, which would meet the criteria of more than minimal harm.

The provision of health care was a factor as there was a delay in the service user pathway.

NB: In this scenario, each NHS body involved with the service user's pathway would be required to trigger the duty of candour procedure and follow this to completion.

In such circumstances, it would be good 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 with their reviews, as they would for any other 'concern'. The aim should be to make the process as easy as possible for those involved and, in particular, would be less burdensome for the service user/their representative.

However, each NHS body (providing body) still has its own responsibility under the duty of candour requirements and must ensure and be able to evidence themselves that these have been met.

GENERAL CASES WHERE DUTY OF CANDOUR IS TRIGGERED

Case study 18: Optometry and Ophthalmology

A diabetic service user had developed a painful right eye. He was seen in and Optometric practice where he was found to have high intra-ocular pressure in both eyes. The service user was referred to the hospital. Within the referral it was noted that the service user's right eye pressure was 40mmHg and 20mmHg in the left eye.

The service user was subsequently examined at the hospital and during this appointment it was noted that the pressure in the right eye was 44 and the left eye was 24. The service user was prescribed eye drops and Acetazolamide tablets however, the tablets were not available in the pharmacy.

The service user attended an appointment a couple of weeks later at the hospital where he was re-prescribed Acetazolamide and the intention was for the patient to be urgently referred to a cross border hospital. However the referral was not made until 10 days later in error.

When the patient subsequently attended the appointment at the cross-border hospital, the right eye pressure was 34 and the left eye pressure was 19. The right eye was subsequently found to be irreversibly blind.

Checklist to see if the duty of candour is triggered?

Yes - The duty of candour would be triggered in this case and the duty of candour procedure should be followed to completion as there was a delay in the service user receiving the appropriate treatment and medication, which was unintended and unexpected.

The service user was found to be irreversibly blind in the right eye, which would meet the criteria of more than minimal harm.

The provision of health care was a factor as there was an error causing a delay in the service user receiving the appropriate treatment and medication.

Case study 19: Radiology

A service user complains of neck pain after a fall. His GP refers him for x-rays. The radiologist reports back that the x-ray showed no fracture or dislocation.

Six months later, the service users returns to the GP with a persistent cough and he's been coughing up flecks of blood. His GP refers him for an urgent chest x-ray. A consultant radiologist identifies a large mass at the apex of the right lung.

The consultant radiologist views the service user's earlier x-ray. She notes that the mass is clearly visible, though smaller, at the edge of the film. The mass is confirmed as a primary lung tumour that has metastasised. It is not amendable to surgical or immune/chemo therapy.

Checklist to see if the duty of candour is triggered?

Yes – The duty of candour would be triggered in this case and the duty of candour procedure should be followed to completion as a mass was identified as being clearly visible on an x-ray that had been undertaken six months previous but this had not been reported on at the time, which was unintended.

The size of the mass had grown in the six months from the previous x-ray. The mass was confirmed as a primary lung tumour that had metastasised and was not amendable to curative treatment. This would meet the criteria for more than minimal harm.

The provision of health care was a factor as the service user had been referred for x-rays, which could have identified the mass 6 months earlier but this had not been referred to in the report and appears to have been missed.

NB: In this scenario, the consultant radiologist reports the incident that triggers the duty of candour procedure and is responsible for following the duty of candour procedure to completion.

Case study 20: Catheter insertion

A service user had a urinary catheter inserted for acute urinary retention. Staff observed that since insertion the service user was agitated and was going back and forth to bathroom, which was out of character for the service user. The service user explained to staff that he had a dragging feeling from the urinary catheter.

The service user allowed staff to examine him. The staff found the area was bloody and red. On checking service user's notes to ensure the correct urinary catheter had been inserted, it was discovered that the male patient had a female only urinary catheter in situ. The female catheters are shorter in length meaning the retaining balloon inflated in the urethra.

The service user suffered severe urethral trauma, pain and haemorrhage. There was also a concern of longer-term effects, which included urethral strictures, retention and incontinence.

Checklist to see if the duty of candour is triggered?

Yes - The duty of candour would be triggered in this case and the duty of candour procedure should be followed to completion as the service user suffered severe urethral trauma, pain and haemorrhage. There was also a concern of longer-term effects, which included urethral strictures, retention and incontinence, all of which would meet the criteria for more than minimal harm.

The provision of health care was a factor as the insertion of the catheter caused harm.

Case study 21: Medical management

A service user, with a moderate right sided pleural effusion is short of breath due to the accumulated fluid preventing full expansion of the lung on that side. The consultant asks the junior doctor to drain the fluid by inserting a chest drain. The pre-procedure chest radiograph clearly shows a large effusion on the right side, but the doctor fails to recheck the radiograph before starting the procedure.

The service user is wrongly prepared for a drain insertion on the left side, which involves cleaning the skin, instilling local anaesthetic and attempting to confirm the presence of fluid by using a small calibre needle. Ultrasound guidance isn't used and no fluid is obtained from the left side of the chest. Despite this the doctor then proceeds to insert a large bore tube into the left side of the chest, and again no fluid is obtained. The doctor then removes the drain.

The incident was discovered after a repeat chest X-ray was undertaken to check for any air accumulation. The patient was informed, and the correct procedure was then performed.

Checklist to see if the duty of candour is triggered?

Yes - The duty of candour would be triggered in this case and the duty of candour procedure should be followed to completion as the drain was inserted into the wrong side, which was unexpected and unintended.

The service user had undergone a wrong procedure, which required a moderate increase in treatment for the procedure to be undertaken on the correct side. This would be considered harm that is more than minimal.

The provision of health care was a factor as the procedure to drain the chest fluid was part of the service users care plan.

Case study 22: Prescribing

A woman was prescribed the combined oral contraceptive after previous confirmed DVT/PE. After taking the oral contraception for 4 weeks, the woman went on to develop severe pain in her calf and breathing difficulties. On seeking medical attention and following an ultrasound scan, she was diagnosed with a DVT, which required a care plan including the commencement of anticoagulation medication, which she was to take for at least three months.

Checklist to see if the duty of candour is triggered?

Yes - The duty of candour would be triggered in this case and the duty of candour procedure should be followed to completion as the service was prescribed the combined oral contraceptive after previous confirmed DVT/PE, which was unintended.

She developed a DVT and breathing difficulties after being taking the combined oral contraception for 4 weeks. She required additional treatment by way of anticoagulation medication, all of which meets the criteria for harm that is more than minimal.

The provision of health care was a factor as the service user was prescribed (and took) the combined oral contraceptive on the advice of her GP who missed the entry in her notes that she had a previous confirmed DVT/PE.

Case Study 23: Child and Adolescent Mental Health Service

A 15-year-old girl attended the Emergency Department with a history of Deliberate Self-Harm and depression at 2.30 am. There was a 12-hour delay in finding a suitable bed for the individual within a young person's mental health ward. She was being cared for in the Emergency Department assessment area by paediatric Emergency Department nursing staff and supervised with one agency

Registered Mental Health Nurse, with a risk assessed supervision plan that stated that she required a 2:1 ratio of supervision. During this delay, where she was being cared for in the Emergency Department, she manages to abscond from the hospital grounds and has a further episode of deliberate self- harm using glass to cut her wrists.

This has occurred due to the delay in finding an appropriate bed and being adequately supervised in the correct environment.

Checklist to see if the duty of candour is triggered?

Yes - The duty of candour would be triggered in this case and the duty of candour procedure should be followed to completion as the delay in finding the bed in the young person's mental health unit meant that the service user was being cared for in the Emergency Department instead of the correct environment where treatment could be undertaken. Additionally, the level of supervision needed was not met. The service user absconded and cut her wrists which, would be considered harm that is more than minimal. The service user also sustained further psychological harm of an attempted suicide which impacted on the risk assessment undertaken and meant the service user was unable to be returned to the foster home she had been living in for many years.

The provision of health care was a factor as the service user was to be admitted under the mental health act for assessment as part of the care plan.

Case Study 24: Adult Mental Health

A Service User was discharged from an acute ward, following an admission for worsening mania and psychosis with the premise of prescribed follow up of a home visit within 7 days from the Crisis Response team. There was a breakdown of communication of what this follow up would be. The service user received a morning telephone call from a member of the Crisis Response Team instead of a face to face follow up visit however the service user didn't answer the phone. This was repeated the next day which again ended without contact. At the next review, which was a face-to-face visit, some 8 days after discharge there was evidence of a deterioration in the service user's Mental Health. The service user had been delaying their evening medications due to staying up and taking them late which meant they were sleeping through to the afternoon. There was increasingly missing medication times and periods of sleeplessness and agitation were evident. It was acknowledged that had a face to face visit occurred the first time, it would have provided a more robust assessment of the individual's mental health, which included physical appearance, non-verbal interaction, cues within the environment, all of which would have contributed to a more holistic assessment that would not have been possible over the telephone.it was also acknowledged that there was learning in terms of the escalation of a service user who isn't responding on the telephone which may have allowed intervention to occur earlier.

Checklist to see if the duty of candour is triggered?

No - The duty of candour would not be triggered in this case as the unintended harm was deterioration in concordance with treatment plan leading to harm but not harm that would be considered more than minimal.

The provision of health care was a factor as the service user refers to the Care and Treatment Plan lacked the detail to say a face to face assessment was needed and they placed a routine review in place for this service user, instead of an urgent assessment when the service user didn't answer the phone.

Case Study 25: Adult Mental Health

A service user on an acute admissions area in mental health is deteriorating rapidly and risk to others is increasing and therefore requiring assessment and transfer to a Psychiatric Intensive Care Unit bed. The outcome of the referral and telephone assessment by the Psychiatric Intensive Care Unit team was that whilst there is a bed available the team felt that the individual does not require a Psychiatric Intensive Care Unit bed. This results in a disagreement between the 2 Multi-Disciplinary Teams.

There is a further deterioration in the service user's mental health, and he becomes physically aggressive towards others, violent attacking and injuring another patient, requiring seclusion. At this point the Psychiatric Intensive Care Unit team then agreed to the transfer. The subsequent admission lasted 6 months.

Checklist to see if the duty of candour is triggered?

Yes - The duty of candour would be triggered in this case and the duty of candour procedure should be followed to completion as the delay in accepting the patient meant he remained in an unsuitable placement, the service user's mental health deteriorated and was violent to others. Restrictive practices had to be used in the form of restraint and chemical sedation, which may have been avoided if transferred to PICU sooner. Additionally psychological harm that is moderate was triggered as his deterioration lasted for more than 28 days.

The provision of health care was a factor as the service user was admitted under the mental health act section 3 for treatment and his condition deteriorated requiring transfer to higher level of care which didn't happen before harm could occur.

Case Study 26: Learning Disabilities

An individual living in the community family home, who has been prescribed a different type of manual handling equipment by the manual handling advisor based on a risk assessment they completed. This equipment was not ordered within a timely manner and followed by a further delay in follow up due to staff sickness. At the next review there was evidence of deterioration in the person's physical condition with numerous falls and a wrist fracture as a result of using the outdated care planned manual handling equipment during this period.

Checklist to see if the duty of candour is triggered?

Yes - The duty of candour would be triggered in this case and the duty of candour procedure should be followed to completion as the delay in ordering the recommended equipment put the service user at harm which was more than minimal.

The provision of health care was a factor as the Care coordinator acknowledges a failure in providing the right resources which has led to the person coming to harm.

Case Study 27: Learning Disabilities

An individual from a community family home was administered their long-acting antipsychotic medication by injection. The patient was admitted to a general hospital with vomiting. The following day the medication was administered again despite the service user repeatedly attempting to communicate that they had received it the previous day. The staff didn't believe her when she said she'd already 'had the jab', and records hadn't been properly consulted. Additionally, there was an inadequate handover and no attempt was made to verify the service user's accounts with the community home. This led to toxic levels 3-5 weeks later and the service user died.

Checklist to see if the duty of candour is triggered?

Yes - The duty of candour would be triggered in this case and the duty of candour procedure should

be followed to completion as the administration of a second long-acting anti-psychotic medication led to toxic levels occurring and harm more than minimal.

The provision of health care was a factor as the care coordinator and the hospital acknowledges a failure in providing the right handover, and the hospital not verifying documentation and not listening to the service user or checking with the care coordinator which has led to the person coming to harm.

Case study 28: o n c o l o g y

65 year old man with advanced bowel cancer treated with three chemotherapy agents (capecitabine or agent containing 5FU, trifluridine and tipiracil) is consented for side effects carefully covering common, less common and rare side effects with effective monitoring for hematological toxicity he was then admitted to the Emergency Department following admitted with bradycardia, with follow up arranged by GP with the cardiology team. He was treated initially with fluids and he was screened for sepsis. 12 lead ECG showed signs of heart block. His condition stablises and he is discharged home and told to continue his chemotherapy. The patient returned to the emergency department in complete heart block requiring emergency pacing.

Checklist to see if the duty of candour is triggered?

Yes - The duty of candour would be triggered in this case and the duty of candour procedure should be followed to completion as the service user required emergency pacing for complete heart block as a side effect that was present but treatment was continued instead of being suspended and cardiotoxicity occurred. The provision of health care was a factor as it was identified that cardiotoxicity had occurred and treatment was continued.

Same case study: different outcome

65 year old man with advanced bowel cancer treated with three chemotherapy agents (capecitabine or agent containing 5FU, trifluridine and tipiracil) is consented for side effects carefully covering common, less common and rare side effects with effective monitoring for hematological toxicity he was then admitted to the Emergency Department following admitted with bradycardia, with follow up arranged by GP with the cardiology team. He was treated initially with fluids and screened for sepsis. 12 lead ECG shows signs of heart block. After discussion with the patient a decision to stop his capecitabine or agent containing 5FU due to the rare side effect of heart block being present.

Checklist to see if the duty of candour is triggered?

No - The duty of candour would not be triggered in this case as the side effect that manifested was expected consented for and explained and monitored. Treatment was discontinued on the discovery of the side effect.