

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.

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

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.

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.

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 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.

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.

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 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.

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 COULD 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 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 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.

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 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 the service user, however at the time an error was made by NHSBT and the offer was made to a

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. He 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 he thought and he should have referred him to Paediatrics. He sends mum 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 and the duty of candour procedure should be followed to completion as a result of baby B's condition not being fully appreciated. 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 is 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 he 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 mum, the GP apologised personally to mum. 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 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 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.

NB: In this scenario the Pharmacist would inform the Dentist of the incident. The Dentist would be responsible for establishing why no 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 (2). The service user was seen by the Optometry Practice (2) 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 Optometry Practice (2), GP or service user could alert the Optometry Practice (1) to the incident. The Optometry Practice (1), 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 Board and a Trust

A service user was seen by Health Board 1, following an urgent suspected cancer referral. He was subsequently referred for a specialist opinion, and seen by Health Board 2. A further specialist opinion was sought from Health Board 3. 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 Health Board 1 and Health Board 3. 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 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 an 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 Diamox tablets however, the Diamox 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 Diamox and the intention was for the patient to be referred to a cross border hospital. However the referral was not made until 10 days later.

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 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 user 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 inoperable.

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 inoperable. 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 identified a mass but this had not been referred to in the report.

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. 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 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 incorrect urinary catheter had been fitted.

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 look at 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. 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 and informs the service user that the fluid has obviously disappeared since the radiograph was taken.

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 performed later that day.

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 despite it being recorded 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 is while the delay has occurred in finding an appropriate bed and being 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 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 admission ward, 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 telephone call from a member of the Crisis Response Team instead of a face to face follow up visit. At the next review, which was a face to face visit, there was evidence of a deterioration in the service user's Mental Health. 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.

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 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.

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.

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 practice had to be used in the form of restraint and chemical sedation, which may have been avoided if transferred to PICU sooner.

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.