THE DUTY OF CANDOUR
GUIDANCE FOR PROVIDERS AND INSPECTORS

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1 What is the Duty of Candour?

The Duty of Candour is laid out in Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. It requires Registered Providers and Registered Managers (known as “Registered Persons”) to act in an open and transparent way with anyone receiving care or treatment from them. The regulation also defines “notifiable safety incidents” and outlines the specific way registered persons must carry out the Duty of Candour if these incidents occur.

Essentially, the Duty of Candour is about people’s right to openness and transparency from their care provider. It applies to every health and social care provider regulated by the Care Quality Commission.

1.1 Background

“The way in which the Trust handled the matter can be viewed as an object lesson in how the tragedy of an avoidable death can be exacerbated by inappropriate handling of the case. It demonstrates the sad fact that, for all the fine words printed and spoken about candour, and willingness to remedy wrongs, there lurks within the system an institutional instinct which, under pressure, will prefer concealment, formulaic responses and avoidance of public criticism.”

Francis Inquiry into the failings at Mid-Staffordshire NHS Foundation Trust, 2013

The Duty of Candour was developed as a direct response to recommendation 181 of the Francis Inquiry report into failings at Mid Staffordshire NHS Foundation Trust. The Inquiry recommended that a statutory duty of candour be introduced for all health and care providers, and that it should be in addition to the requirement for candour in the NHS bodies’ standard contract and the professional duty of candour. The Duty has been referred to in subsequent inquiries into care failures (most recently the Paterson and Cumberlege reports) and is seen as a crucial, underpinning aspect of a safe, open and honest culture.

In fact, the Duty of Candour is so fundamentally linked to concepts of openness and honesty that often the policies and procedures related to it have come to be known by staff by other names (for example, “Being Open”, “Saying Sorry”, “Just Culture”), which can sometimes cause confusion. However, the activities required to meet the Duty of Candour regulation are specific, and it takes more than building a safe and open culture to deliver them.

1.2 What is the difference between the statutory and professional duties of candour?

Both the statutory and the professional duties of candour have similar aims - to ensure that those providing care are open and honest with the people using their services, particularly when something has gone wrong. However, the statutory Duty of Candour applies to organisations rather than individuals, and only in certain situations, known as ‘notifiable safety incidents’ (explained in detail later in this guidance).

This means that there will be cases where the professional duty applies but not the statutory one. Where the statutory duty does apply, it may well be carried out by the same person who carries out the professional duty, so it is important to remember that the statutory duty carries with it particular steps that must be covered and records that must be made. Carrying out the professional duty alone will not be enough to meet the requirements of the statutory duty.
While the responsibility for carrying out the professional duty is clearly located with the individual healthcare professional, the responsibility for the statutory duty is located with the provider of regulated activities, and in particular the ‘Registered Person’. In practice, however, notifiable safety incidents will occur at the point of care, so the Registered Person is more often responsible for ensuring that the Duty of Candour is being carried out appropriately by the professionals they employ, rather than actually carrying it out themselves. The two duties should mutually reinforce each other, creating a culture where it is in the providers’ interests to encourage their staff to be candid, and where professionals feel safe and supported to speak up and be honest when things go wrong.

The statutory duty is regulated by CQC, whilst the professional duty is overseen by regulators of specific healthcare professions – such as the General Medical Council and the Nursing and Midwifery Council. The following guidance is about the statutory Duty of Candour.

1.3 Does carrying out the duty mean the provider is at fault?

No. A crucial part of the Duty of Candour is the apology, and providers have sometimes been concerned that by apologising they are admitting liability. This is not the case and NHS Resolution (the litigation arm of the NHS) are at pains to make this clear:

“We have never, and will never, refuse cover on a claim because an apology has been given.” Helen Vernon, Chief Executive, NHS Resolution

In fact, in many cases, it is the lack of timely apology that pushes people to take legal action in the first place. To fulfil the Duty of Candour the provider must apologise for the harm caused, regardless of fault, as well as being open and honest about what has happened.

2 How and when should the Duty of Candour be carried out?

2.1 When does the Duty of Candour apply and what is a Notifiable Safety Incident?

The Duty of Candour is a general duty to be open and transparent, and this applies at all times, in all cases. However, the regulation also specifies actions that must be carried out whenever something meets the specific criteria of a “Notifiable Safety Incident1”. This means that:

1) The incident must have been unintended or unexpected, and
2) Must be the result of the provision of a regulated activity, and
3) Already has, or might, result in death, or severe or moderate harm to the person receiving care.

The definitions of what constitutes severe or moderate harm vary slightly depending on whether or not the provider is a “health service body”2. For the purposes of this regulation, health service body means NHS Trust. The definitions vary because when the regulation was written, the harm

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1 “Notifiable Safety Incident” is a specific term that is defined within the Duty of Candour regulation and should not be confused with other types of safety incidents or notifications.
2 A “health service body” is defined in Section 9 of the National Health Service Act 2006 and includes all sorts of organisations, but the only one relevant for the Duty of Candour is NHS Trusts. Link to legislation: http://www.legislation.gov.uk/ukpga/2006/41/section/9
thresholds were aligned with existing notification systems in order to reduce the additional administrative burden for providers. So for NHS Trusts the thresholds are consistent with the National Reporting and Learning System (NRLS) (higher severity) definitions; whilst for all other providers they align with the CQC notification system for reporting deaths and serious injuries.

The following table shows how the regulation differs between the two:

<table>
<thead>
<tr>
<th>A “NOTIFIABLE SAFETY INCIDENT” IS:</th>
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<tbody>
<tr>
<td>Any unintended or unexpected incident...</td>
<td></td>
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<tr>
<td>That occurred in respect of a service user during the provision of a regulated activity...</td>
<td></td>
</tr>
<tr>
<td>And that, in the reasonable opinion of a health care professional...</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NHS Trusts (Covered in Section 8 of Regulation 20)</th>
<th>All other regulated services (Covered in Section 9 of Regulation 20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>...could result in, or appears to have resulted in:</td>
<td>...appears to have resulted in, or requires treatment to prevent:</td>
</tr>
<tr>
<td>The death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition</td>
<td>The death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition</td>
</tr>
<tr>
<td>Or: severe harm*, moderate harm*, or prolonged psychological harm* to the service user</td>
<td>Or: - an impairment of the sensory, motor or intellectual functions of the service user which has lasted, or is likely to last, for a continuous period of at least 28 days - changes to the structure of the service user’s body - the service user experiencing prolonged pain* or prolonged psychological harm*, or - the shortening of the life expectancy of the service user</td>
</tr>
</tbody>
</table>

*The terms underlined above have their own definitions specified in the regulation. These definitions are explained in the following table:

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3 https://www.cqc.org.uk/guidance-providers/notifications/notification-finder
DEFINITIONS OF HARM

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderate harm</td>
<td>harm that requires a moderate increase in treatment and significant, but not permanent, harm</td>
</tr>
<tr>
<td>Severe harm</td>
<td>means a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain damage, that is related directly to the incident and not related to the natural course of the service user’s illness or underlying condition</td>
</tr>
<tr>
<td>Moderate increase in treatment</td>
<td>an unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care)</td>
</tr>
<tr>
<td>Prolonged pain</td>
<td>pain which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days</td>
</tr>
<tr>
<td>Prolonged psychological harm</td>
<td>psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days</td>
</tr>
</tbody>
</table>

It is possible for an incident to trigger the harm threshold for NHS Trusts, but not for other service types, or vice versa. This may cause confusion where healthcare professionals work across sectors (for example, surgeons working in both NHS Trusts and independent hospitals. It is helpful to remember that it is the provider of the regulated activity that is responsible for carrying out the statutory duty (not the individual, as it would be for the professional duty), and so it is the notifiable safety incident definition relating to the type of provider which should be used.

If in doubt, it is always better to carry out the Duty. Remember that the purpose and spirit of the regulation is to ensure providers are open and honest with people whenever something goes wrong and that should be your priority.

We have provided a number of worked examples in Appendix 1, but please note that it is impossible to cover all the possible incidents and permutations that may or may not qualify as Notifiable Safety Incidents. The regulation refers to the “reasonable opinion of a healthcare professional” and in the end it must be a matter for professional judgement.
FLOWCHART – Is this a Notifiable Safety Incident?

Has an incident resulted in the death of someone using your service?

Yes

No

Has an incident resulted in harm, or possible harm, to a person using your service?

Yes

No

Does that harm meet the thresholds in the “Definitions of Harm” table?

Yes or maybe

No

Was the incident unexpected or unintended?

Yes

No

Did it happen as a result of the care you delivered?

Yes or maybe

No

This is a Notifiable Safety Incident

This is not a Notifiable Safety Incident

Please note that whether or not something qualifies as a Notifiable Safety Incident, there is still an overarching duty to be open and transparent with people using services.
<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
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<tbody>
<tr>
<td>Does the Duty apply even if the patient gave consent for a procedure to be carried out?</td>
<td>Yes. If the incident meets the criteria for a notifiable safety incident, the Duty should be carried out even if the person gave consent for the procedure.</td>
</tr>
<tr>
<td>What should the provider do if they discover a notifiable safety incident that occurred in a different provider?</td>
<td>The Duty should be carried out by the registered person at the provider where the incident took place. The provider who has discovered the incident should inform the previous provider and must be open and honest with the person receiving care about whatever they have discovered, but they are not required to carry out the Duty on behalf of another provider.</td>
</tr>
<tr>
<td>If the incident occurred before the Duty came into force (before Regulation 20 commenced), but has only been discovered recently, should the Duty be carried out?</td>
<td>There is not a legal requirement to carry out the formal Duty for something that happened before the regulation existed. However, we would still expect providers to act within the spirit of the Duty and to apologise and be open and honest with people about whatever has been discovered.</td>
</tr>
<tr>
<td>The incident was not realised at the time but has been discovered through a retrospective case review. Does the Duty still apply?</td>
<td>Yes. (For incidents that occurred before the regulation came into force, see question and answer above.)</td>
</tr>
<tr>
<td>Does an apology constitute an admission of guilt?</td>
<td>No. (See section 1 of this guidance).</td>
</tr>
<tr>
<td>Does the Duty of Candour only apply if the provider was at fault?</td>
<td>No. The Duty of Candour applies whenever a notifiable safety incident occurs, and fault is not part of the definition of a notifiable safety incident.</td>
</tr>
<tr>
<td>What should the provider do if the health professional judges that it would not be in the person’s best interest to tell them what has happened?</td>
<td>We would expect this sort of situation to be extremely rare. However, if this is the case, the assessment and rationale behind the judgement must be clearly recorded and the incident must still be reported and investigated as usual.</td>
</tr>
<tr>
<td>If the incident happens when there are no staff actively caring for the person, does this still trigger the Duty of Candour? For example, what should happen if a person has an unwitnessed fall in a care home?</td>
<td>The care being delivered is the regulated activity – in this case “accommodation” for people who require nursing or personal care”. The person fell during the delivery of that regulated activity, so provided the harm thresholds are met, yes, the Duty of Candour should be carried out.</td>
</tr>
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4 The Duty of Candour regulation came into force in November 2014 for NHS bodies and April 2015 for all other organisations.
2.2 How is the Duty of Candour carried out?

Regulation 20 states that you must start the Duty of Candour process “as soon as reasonably practicable”. Unless there is good reason, CQC would therefore expect to see the process started within 10 working days of a notifiable safety incident being discovered.

The care provider’s Registered Person is responsible for carrying out or delegating the Duty, and they must liaise with the “Relevant Person”. The Relevant Person is defined as either the person who was harmed or someone acting lawfully on their behalf. Someone may act on the behalf of the person who was harmed if: the person has died; or is under 16 and not competent to make a decision; or is over 16 and lacking mental capacity\(^5\).

It is specified in the regulation that the care provider must:

1) Tell the relevant person, face to face, that a notifiable safety incident has taken place.
2) Apologise.
3) Provide a true account of what happened which covers everything the provider knows at that point.
4) Explain to the relevant person what further enquiries or investigations they will carry out.
5) Follow up by providing all the above information, and the apology, in writing, and providing an update on any enquiries.
6) Keep a written record of all communications with the relevant person.

The purpose of these meetings and communications is to share whatever is known about the incident truthfully, openly and with compassion and support. The person who was harmed has a right to understand what has happened to them. The meeting is not about trying to apportion blame, and in any case, it is likely that investigations will still be underway at this point.

Throughout the process the provider must give “reasonable support” to the relevant person, both in relation to the incident itself and when communicating with them about the incident. “Reasonable support” will vary with every situation, but could include, for example, environmental adjustments for someone who has a physical disability; an interpreter for someone who does not speak English well; information in accessible formats; the support of an advocate; or signposting to mental health services. We would expect to see that providers have involved family members and carers in any discussion with the relevant person if that is what the relevant person wishes. It is about taking reasonable steps to ensure that the Duty of Candour is carried out in a way which is as accessible and supportive as possible.

Providers must keep their own clear records of cases where they have carried out the Duty. These incidents will also qualify as notifiable incidents and as such should be reported through the STEIS and NRLS/PSIMS systems or the CQC Notifications system. For more information see https://www.cqc.org.uk/guidance-providers/notifications/notification-finder

If the relevant person cannot be, or refuses to be, contacted, the provider will not be able to carry out the Duty of Candour, but must keep a written record of all attempts to make contact. They must still report the incident through the relevant notifications system and investigate it in order to prevent harm occurring to others.

\(^5\) In accordance with the Mental Capacity Act 2005
3 How does CQC regulate the Duty of Candour?

The Care Quality Commission has been responsible for regulating the Duty of Candour since November 2014 for NHS Trusts and April 2015 for other health and social care providers. It is one of the fundamental standards – below which care should never fall – and as such is an area of regulation we pay special attention to.

There are important limits to CQC’s role, in that we do not investigate individual notifiable safety incidents in relation to what caused the harm, or individual health practitioners in relation to their part in the incident – these responsibilities reside with the provider and professional bodies. CQC’s role is to regulate the provider and ensure it is fulfilling its responsibility to carry out the Duty of Candour.

Every provider should be creating an environment that encourages candour, openness and honesty at all levels. Candour is a critical underpinning factor in a culture of safety, as it is only when organisations are open and honest that they can effectively learn from their mistakes and improve the care that people receive.

During our public consultation in 2018, people shared examples of both poor and good practice that they had experienced. When things went wrong...

“In my experience, the only aim by the service provider was to hide the truth of a serious incident”

“The Trust has still not been open and honest or told us the truth about the circumstances of my daughter’s death. They have consistently adopted the “deny, delay, defend, deceive” approach directly in contradiction to the Duty of Candour”

“At no point did anyone say sorry or talk us through how this mistake had happened”

People told us that cover ups and a lack of apology compounded the level of harm they had experienced following the initial incident.

When the Duty of Candour had been carried out well, people talked about how they had received a “heartfelt apology”, that the care provider has been “honest from the outset”, that “it was not a tick-box exercise”, and that assurance was given that things were being put in place to prevent the incident happening to others – that mistakes had been acknowledged and learned from.

3.1 Registration

The Duty of Candour applies to every provider registered with CQC. Therefore we will expect to see evidence during the registration process that the provider and registered person understand their obligations under Regulation 20. They should understand when and how to carry out the Duty of Candour and have training, policies and systems in place to ensure their employees are able to implement it. Providers should also be able to explain how they will support their staff to be open and honest when something goes wrong and how this sits within a broader culture of safety.
3.2 Monitoring, assessment and inspection

We approach the monitoring of the Duty of Candour through the lens of the service...
- being well-led
- having an open and safe culture
- meeting the regulatory requirements of the Duty of Candour

When we hold monitoring calls, assess the data and information we receive, or visit the location on inspection, we will be looking for evidence that all three factors are met.

It is important to realise that it is possible for the provider to be open and transparent but still not meeting the Duty of Candour. This is because Regulation 20 is very specific about exactly how the duty must be carried out in terms of:
- the types of incidents which trigger the duty
- the various process steps, meetings and records that must take place
- what those meetings and records should cover
- that the process should be carried out in a timely manner
- that appropriate support should be provided to the person harmed or their representative

There are a range of ways CQC assesses compliance with the Duty. We may:
- Follow up incidents reported through STEIS or CQC Notifications that have been marked as triggering the Duty of Candour to ensure the process was followed through appropriately
- Follow up incidents reported through STEIS or CQC Notifications that were NOT marked as triggering the Duty of Candour, but which appear from the descriptions to have required it
- Ask providers to tell us about recent incidents
- Follow up on reports of incidents from the public or people using services that appear to have triggered the Duty of Candour to ensure it took place
- Ask people who have received the Duty of Candour what their experience was like
- Question frontline staff about their understanding of the Duty of Candour and how they would go about implementing it
- Question the registered person about their policies and processes for recording and carrying out the Duty, and for training staff
- Investigate senior staff and board members’ level of understanding of the Duty and how they ensure staff feel supported to speak up and be open and honest about incidents

Not all forms of monitoring and assessment will result in a formal report written by CQC, but whenever such a report is written it **must** contain information about our findings in relation to the Duty of Candour.

3.3 Enforcement

The ultimate responsibility for ensuring the provider is carrying out the Duty of Candour rests with the Registered Person. Where CQC believes this is not happening, we can use our powers of enforcement, and can prosecute breaches of parts 20(2)(a) and 20(3) of the regulation.

Regulation 20 also allows us to move directly to criminal enforcement action if we wish. In 2019 we issued 14 Fixed Penalty Notices in respect of 8 incidents occurring at 2 NHS Trusts, and in 2020 we undertook a criminal prosecution for breach of the regulation.

Where an inspector considers a breach may have taken place, they must follow CQC’s Enforcement Policy and Decision Tree [https://www.cqc.org.uk/guidance-providers/regulations-enforcement/enforcement-policy](https://www.cqc.org.uk/guidance-providers/regulations-enforcement/enforcement-policy)
3.4 Frequently asked questions about CQC’s role

<table>
<thead>
<tr>
<th>FREQUENTLY ASKED QUESTIONS</th>
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</thead>
<tbody>
<tr>
<td>Question</td>
</tr>
<tr>
<td>Does CQC investigate individual notifiable safety incidents?</td>
</tr>
<tr>
<td>Does CQC make judgements about the performance of individual healthcare professionals?</td>
</tr>
<tr>
<td>What enforcement action can CQC take?</td>
</tr>
<tr>
<td>Does CQC have any flexibility in the application of the Duty of Candour regulation?</td>
</tr>
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</table>
APPENDIX 1

Worked examples of the criteria for notifiable safety incidents

Remember – to qualify as a notifiable safety incident, the following criteria must be met:

1) The incident must have been unintended or unexpected, and
2) Must be the result of the provision of a regulated activity, and
3) Already has, or might, result in death, or severe or moderate harm to the person receiving care.

If any of the 3 criteria are not met, it is not a notifiable safety incident.

The following are examples of how to apply these criteria...

CASE STUDY 1

A patient in an NHS hospital experienced pain during an elective Caesarean section due to incomplete anaesthesia from an epidural line. The patient found this experience traumatic and subsequently had an acute episode of severe anxiety and depression which lasted more than 28 days.

Assessment:

The incident we are concerned with is the partial failure of the epidural line.

1) Was the incident unexpected or unintended? YES
2) Was it the result of a regulated activity? YES
3) Has it resulted in death or severe or moderate harm? YES.

The patient is receiving care in an NHS hospital so the definitions in Regulation 20(8) apply (to note: if the care had been delivered in an independent hospital Regulation 20(9) would apply instead). The incident has resulted “prolonged psychological harm” (psychological harm lasting more than 28 days).

Conclusion:

This is a notifiable safety incident, and all steps outlined in the Duty of Candour regulation should be carried out.

CASE STUDY 2

An Occupational Therapist completed an assessment with a care home resident whose mobility was deteriorating. They advised that grab rails were needed in a person’s bathroom before it was safe for them to use the bath and that in the meantime staff should assist the person to have a strip wash each morning. The manager failed to update the person’s care plan or inform the care staff of this change, so staff supported the person to take a bath the following morning as usual. The person slipped when getting out of the bath and broke their arm. The arm was put in a plaster cast and the person needed full assistance for all aspects of their care for 6 weeks until the cast was removed. The person made a full recovery.
Assessment:

The incident we are concerned with is the failure to up-date the person’s care plan and advise their carers of the Occupational Therapist’s advice before the grab rails were installed.

1) Was the incident unexpected or unintended? YES
2) Was it the result of a regulated activity? YES
3) Has it resulted in death or severe or moderate harm? YES.
   The patient is receiving care in a care home so the definitions in Regulation 20(9). The injury in this case is a broken arm and would fall under Regulation 20(9)(b)(ii) as if the injury was left untreated the service user could experience any of the scenarios referred to in Regulation 20(9)(a)(i) to (v).

Conclusion:

This is a notifiable safety incident, and all steps outlined in the Duty of Candour regulation should be carried out.

CASE STUDY 3

A prescribing error on a mental health ward resulted in a patient being given double her normal dose of Lithium for several days. She became symptomatic for Lithium toxicity which required inpatient admission. She made a full recovery.

Assessment:

The incident we are concerned with is the overdose of Lithium.

1) Was the incident unexpected or unintended? YES
2) Was it the result of a regulated activity? YES
3) Has it resulted in death or severe or moderate harm? YES.
   The patient is receiving care in an NHS Trust so the definitions in Regulation 20(8) apply. The incident resulted in moderate harm as defined in 20 (7) (significant, but not permanent, harm, and a moderate increase in treatment).

Conclusion:

This is a notifiable safety incident, and all steps outlined in the Duty of Candour regulation should be carried out.

CASE STUDY 4

A patient with a severe allergy to latex went for a dental procedure. The nature of the allergy had been stated in the medical history questionnaire. The dentist did not check this history before starting the procedure and was wearing latex gloves. The patient developed an anaphylactic reaction which required hospitalisation. The patient made a full recovery.

Assessment:

The incident we are concerned with is the failure to check the patient’s allergies.
1) Was the incident unexpected or unintended? YES
2) Was it the result of a regulated activity? YES
3) Has it resulted in death or severe or moderate harm? YES.  
   The patient is receiving care in a dentist surgery so the definitions in Regulation 20(9) apply. 
   The incident meant that the service user required further treatment to prevent death from 
   anaphylaxis (Regulation 20 (9)(b)(i)).

Conclusion:

This is a notifiable safety incident, and all steps outlined in the Duty of Candour regulation should be 
carried out.

CASE STUDY 5

A young man falls over whilst playing badminton and presents to his GP the next day with a swollen 
and painful foot and ankle. His GP decides not to order an x-ray and sends him home with advice to 
rest, ice, compress and elevate the leg. He tells the man he can weight bear fully. Over the following 
week, the pain and swelling does not improve and then man re-presents at the GP surgery and sees 
a different doctor who sends him for an x-ray. He is found to have a fracture of the base of 5th 
metatarsal which should have been managed in a plaster cast and non-weight bearing. Due to this 
mismanagement, the patient develops a non-union over the following 6 weeks which causes him 
ongoing pain and eventually requires surgical intervention in hospital.

Assessment:

The incident we are concerned with is the mismanagement of the fracture.

1) Was the incident unexpected or unintended? YES
2) Was it the result of a regulated activity? YES
3) Has it resulted in death or severe or moderate harm? YES.  
The patient is receiving care in a GP surgery so the definitions in Regulation 20(9) apply. The 
incident has resulted in prolonged pain; impairment of motor functions and the need for 
surgical intervention.

Conclusion:

This is a notifiable safety incident, and all steps outlined in the Duty of Candour regulation should be 
carried out.
Further examples relating to harm thresholds

The Royal College of Surgeons uses the following example as part of their statutory Duty of Candour training, to demonstrate how different levels of harm can be the result of the same initial incident:

A patient’s bowel has been accidentally perforated during surgery. What happens next?

Version A

The bowel perforation is repaired at the time of surgery; the area is appropriately washed out and the patient requires only antibiotic therapy.

This would be classified as a LOW HARM incident. It would therefore not meet the criteria for a Notifiable Safety Incident and would not require the formal steps of the statutory Duty of Candour. (However, the surgeon would still disclose the incident to the patient as part of the professional duty of candour and through the usual hospital reporting processes).

Version B

The bowel perforation was not picked up at the time of the surgery. It resulted in septicaemia and the patient had to return to theatre to have the perforation repaired.

This would be classified as a MODERATE HARM incident. It therefore meets the criteria for a Notifiable Safety Incident and all steps outlined in the Duty of Candour regulation should be carried out.

Version C

The bowel perforation required the patient to have a temporary colostomy and then a major operation.

This would be classified as a SEVERE HARM incident. It therefore meets the criteria for a Notifiable Safety Incident and all steps outlined in the Duty of Candour regulation should be carried out.
APPENDIX 2

The Duty of Candour regulation in full

Taken from Regulation 20, Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (with subsequent amendments added below).

20.—

(1) Registered persons must act in an open and transparent way with relevant persons in relation to care and treatment provided to service users in carrying on a regulated activity.

(2) As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred a registered person must—
(a) notify the relevant person that the incident has occurred in accordance with paragraph (3), and
(b) provide reasonable support to the relevant person in relation to the incident, including when giving such notification.

(3) The notification to be given under paragraph (2)(a) must—
(a) be given in person by one or more representatives of the registered person,
(b) provide an account, which to the best of the registered person's knowledge is true, of all the facts the registered person knows about the incident as at the date of the notification,
(c) advise the relevant person what further enquiries into the incident the registered person believes are appropriate,
(d) include an apology, and
(e) be recorded in a written record which is kept securely by the registered person.

(4) The notification given under paragraph (2)(a) must be followed by a written notification given or sent to the relevant person containing—
(a) the information provided under paragraph (3)(b),
(b) details of any enquiries to be undertaken in accordance with paragraph (3)(c),
(c) the results of any further enquiries into the incident, and
(d) an apology.

(5) But if the relevant person cannot be contacted in person or declines to speak to the representative of the registered person —
(a) paragraphs (2) to (4) are not to apply, and
(b) a written record is to be kept of attempts to contact or to speak to the relevant person.

(6) The registered provider must keep a copy of all correspondence with the relevant person under paragraph (4).

(7) In this regulation—

"apology" means an expression of sorrow or regret in respect of a notifiable safety incident;
"moderate harm" means—
(a) harm that requires a moderate increase in treatment, and
(b) significant, but not permanent, harm;

"moderate increase in treatment" means an unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care);

"notifiable safety incident" has the meaning given in paragraphs (8) and (9);

"prolonged pain" means pain which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days;

"prolonged psychological harm" means psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days;

"relevant person" means the service user or, in the following circumstances, a person lawfully acting on their behalf—
(a) on the death of the service user,
(b) where the service user is under 16 and not competent to make a decision in relation to their care or treatment, or
(c) where the service user is 16 or over and lacks capacity in relation to the matter;

"severe harm" means a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain damage, that is related directly to the incident and not related to the natural course of the service user's illness or underlying condition.

(8) In relation to a health service body, "notifiable safety incident" means any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in—
(a) the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition, or
(b) severe harm, moderate harm or prolonged psychological harm to the service user.

(9) In relation to any other registered person, "notifiable safety incident" means any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional—
(a) appears to have resulted in—
(i) the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition,
(ii) an impairment of the sensory, motor or intellectual functions of the service user which has lasted, or is likely to last, for a continuous period of at least 28 days,

(iii) changes to the structure of the service user's body,

(iv) the service user experiencing prolonged pain or prolonged psychological harm, or

(v) the shortening of the life expectancy of the service user; or

(b) requires treatment by a health care professional in order to prevent—

(i) the death of the service user, or

(ii) any injury to the service user which, if left untreated, would lead to one or more of the outcomes mentioned in sub-paragraph (a).