

Annex B - LEVELS OF HARM FRAMEWORK

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

Level of harm	Incidents that <u>would not</u> trigger the duty of candour procedure
None	<p>Any patient safety incident that had the potential to cause harm but impact resulted in no harm having arisen.</p> <p>e.g: Appointment delayed, but no consequences in terms of health.</p> <p>e.g: Patient fall – where no harm was suffered or additional interventions required.</p> <p>eg: Near miss – where the potential for harm was noticed and action taken to avoid occurrence of harm.</p>
Low harm/minimal harm	<p>Any patient safety incident that resulted in a minor increase in treatment and which caused minimal harm to one or more persons receiving NHS-funded care.</p> <p>Minor increase in treatment could include:</p> <p>e.g: First aid, additional therapy, medication or rehabilitation</p> <p>e.g: Patient fall - requiring one off observations and/or minor treatment.</p> <p>e.g: Increase in length of stay by 1 - 3 days.</p>
	<p style="text-align: center;">When does the duty of candour apply?</p> <p>IMPORTANT- this section sets out the conditions that must be satisfied in order for the duty of candour to apply. These must be worked through when applying the harm framework.1</p> <p>The duty is triggered in relation to an NHS body if it appears to the body that both of the following conditions are met:</p> <ol style="list-style-type: none"> (1) The first condition is that a person (the “service user”) to whom health care is being or has been provided by the body has suffered an adverse outcome. (2) The second condition is that the provision of the health care was or may have been a factor in the service user suffering that outcome. <p>A service user is to be treated as having suffered an adverse outcome if the user experiences, or if the circumstances are such that the user</p>

[1](#) For further guidance on determining whether the duty applies, please see Annex A and Annex H and part 4, page 7 of the Guidance.

	<p>could experience, any unexpected or unintended harm that is moderate or above.</p> <p>The duty may be triggered by an action taken by a NHS body during the provision of health care or by a failure to take action.</p> <p>The duty is not triggered where harm is related to the natural course of the service user’s illness or underlying condition.</p>
<p>Unexpected or unintended moderate harm</p>	<p>Examples of unexpected or unintended levels of moderate harm and types of incidents that <u>would</u> trigger the duty of candour procedure include:</p> <p>Moderate harm –</p> <ul style="list-style-type: none"> (a) moderate increase in treatment and (b) Significant but not permanent harm. <p>Moderate increase in treatment could include:</p> <ul style="list-style-type: none"> • An unplanned admission/re-admission, • An unplanned return to surgery, • Increase in length of stay by 4 -15 days, • Cancelling/postponement of treatment, • Transfer to another treatment/care area, such as secondary care or intensive care as a result of the incident. <p>Examples of the type of incidents that would trigger the duty of candour procedure include:</p> <p>Description of incident – unplanned admission. Patient was seen by a member of the community MH team; who fails to recognise, or act on evidence of poor medication compliance/failure to adhere to treatment sessions/expression of suicidal thoughts. Level of harm as a result - the patient self-harms, causing moderate harm requiring admission to hospital.</p> <p>Description of incident - Operation cancelled. Level of harm as a result – Leading to deterioration and a longer stay in hospital > 4 days and recovery delayed.</p> <p>Description of incident - Patient receives opioids despite this being documented as an allergy. Level of harm as a result – Leading to the patient suffering a significant reaction and required emergency treatment.</p> <p>Description of incident - A mother had significant post-partum haemorrhage after a difficult delivery, and there was a delay in obtaining blood for transfusion.</p>

	<p>Level of harm as a result – Leading to mother being transferred to the high dependency unit as a result of the post-partum haemorrhage and the delay in obtaining blood for the transfusion meant that her recovery was prolonged.</p> <p>The service user experiencing psychological harm:</p> <p>Psychological harm – means a psychiatric condition or the exacerbation of an existing psychiatric condition for a continuous period of at least 28 days.</p> <p>NB: The timeframe above should be used as a measure only. The focus must be on the level of unintended or unexpected harm.</p> <p><u>Further detailed case study examples can be found in Annex H.</u></p>
<p>Unexpected or unintended severe harm</p>	<p>Examples of unexpected or unintended levels of severe harm and types of incidents that <u>would</u> trigger the duty of candour procedure include:</p> <p>Severe harm would include:</p> <ul style="list-style-type: none"> • Avoidable, permanent harm or impairment of health or damage leading to incapacity, disability or the loss of recovery potential. • Avoidable permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain damage. • Increased length of stay by >15 days <p>Examples of the type of incidents that would trigger the duty of candour procedure include:</p> <p>Description of incident - loss of recovery potential. Delays in thrombolysis or AHP treatment. Level of harm as a result - resulting in loss of recovery of walking or speech, which is permanent.</p> <p>Description of incident - Patient suffers an adverse reaction to medication that they are documented to be allergic to. Level of harm as a result – Leading to the patient suffering brain damage or other permanent organ damage.</p> <p>Description of incident - Patient suffer a perforation of the bowel during surgery. Level of harm as a result – Leading to patient requiring a colostomy and/or subsequent operations.</p>

	<p>Description of incident - Patient did not receive a planned follow up x-ray.</p> <p>Level of harm as a result - Patient was subsequently found to have lung cancer. The chances of survival had been significantly reduced by the 18 month delay in the follow up x-ray being performed.</p> <p><u>Further detailed case study examples can be found in Annex H.</u></p>
<p>Unexpected or unintended death</p>	<p>Examples of unexpected or unintended death and types of incidents that <u>would</u> trigger the duty of candour procedure include:</p> <p>Examples of the type of incidents that would trigger the duty of candour procedure include:</p> <p>Description of incident - Wrong blood transfused.</p> <p>Level of harm as a result - Leading to multi-organ failure and a fatal cardiac arrest.</p> <p>Description of incident - Patient suffers an adverse reaction to medication that they are documented to be allergic to.</p> <p>Level of harm as a result - Leading to severe anaphylaxis and subsequent death.</p> <p>Description of incident - Patient presents with chest pains and is asked to wait in clinic/practice/emergency department.</p> <p>Level of harm as a result - Patient suffers a fatal myocardial infarction in the waiting area, which they then die from.</p> <p><u>Further detailed case study examples can be found in Annex H.</u></p>