



Patient Safety
Patient Safety Incident Response Framework

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Incidents and Duty of Candour

Patient Safety Team
February 2024

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Aims:

- Incidents and PSIRF
- What is Duty of Candour?
- Understanding and identifying what is and isn't a DoC case
- What do we need to do to meet the requirements
- Types of harm and how this relates to the duty
- Saying 'Sorry'

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- Triage all Datix incidents
- Investigate patient safety incidents
- Support the inquest process from a trust perspective
- Facilitate embedded learning events to share the learning
- Oversee the Patient Safety workstreams, which include reducing falls, reducing harm from pressure ulcers, reducing violence and aggression, deteriorating patient, reducing restrictive practice, suicide prevention
- Duty of Candour
- Medical Devices

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Patient Safety Incident Response Framework (PSIRF)

PSIRF replaces the Serious Incident Framework – no more RCA investigations

Investigations now focus on systems with an emphasis on learning

Learning from Patient Safety Events (LfPSE)

LfPSE now features on Datix

The aim is to get more qualitative data on incidents to promote learning


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What is candour?

Honesty, open, transparent


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The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

- The Regulation was a response to the Francis Report in 2013 that reviewed the care at Mid Staffordshire NHS Foundation Trust
- Regulation 20: *a health service body must act in an open and transparent way with relevant persons in relation to care and treatment provided*
- We have a legal duty to inform patients and/or families when there has been an *unintended or unexpected* incident that caused *harm*


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Outside of the legal duty, you have a **general duty of candour** to act in an open and transparent way to your service users. There is no threshold for the general duty.


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Regulation 20 duty – triggered when a Notifiable Safety Incident occurs

NSI: an *unintended or unexpected* incident that must have caused *harm*

An unintended or unexpected incident that does not result in harm is not a NSI and the statutory DoC does not apply (but don't forget your general duty)

e.g. a patient falls but is not injured – it was unexpected but there was no harm so still needs to be reported as there was a fall BUT the regulation 20 duty is not triggered

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Types of harm:

1. Death
2. Severe Harm
3. Moderate Harm
4. Prolonged Psychological Harm


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Death

Expected death	Unexpected death
97 year old palliative patient with DNAR in place dies in hospice	32 year old female jumps in front of a train
Expected – so although an incident internally, not for DoC purposes	Unexpected – DoC applies


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Severe harm


A permanent lessening of bodily, sensory, motor, physiological or intellectual function that is directly related to the incident, e.g maiming, brain damage


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Moderate harm

- a. harm that requires an increase in treatment AND;
- b. is significant but not permanent

Increase in treatment such as: unplanned return to surgery, unplanned re-admission, a prolonged episode of care

e.g. medication error resulting in A&E treatment and the patient makes a good recovery

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When incidents occur staff often feel personally affected

Fear of saying sorry – fear of litigation or disciplinary action and the fear that it will have a negative impact on professional careers

May lead to under reporting or not reporting incidents at all

Saying sorry does NOT equal negligence nor is it an admission of guilt – it is acknowledgement that something happened

Candour has nothing to do with fault – once this is understood, saying sorry becomes easier

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Why is saying sorry important?

Firstly, it's the right thing to do – patients and/or their families have a right to know what happened and why

Professional duty to be open and honest


Maintains trust

Prevents claims – majority of claims result from lack of explanation, not being offered an apology or feeling the apology was insincere


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When to say sorry

Say sorry as soon as possible

You don't have to have all the answers straight away but reassure the patient and/or their family that it will be looked into


The apology can come from anyone at any level

Make sure you ask someone senior to provide you with support


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What to say

What happened?

Why did it happen? (if known)

What was the impact?

What happens next?

What will be done to prevent it happening again? (if you don't know then simply giving reassurance that the incident will be looked into is enough at this stage)

Document your conversation in the patient's clinical record

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Do's	Do NOT's
'I am sorry that this happened'	'We are sorry you feel that something happened to you'
'I am truly sorry for the distress we caused'	'I was told to offer you an apology'
'We have learned that...'	'The Trust apologise for...'
Use simple language, you may be speaking to a distressed person	
Consider the environment and ensure you have enough time to have a conversation	

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- Remember your **general duty** to be open and honest
- Saying sorry does not mean you are accepting liability
- Report incidents via DatixWeb – any queries contact the Serious Incidents Team
- Be sincere, compassionate and speak plainly when having DoC discussions
- Ensure good documentation
- Seek support from your seniors
- If you are concerned that DoC regulations are not being adhered to in your workplace contact the Serious Incidents Team

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