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1. **Introduction**

The effects of harming a patient can be widespread and can have devastating emotional and physical consequences for patients, their families and carers as well as being distressing for the professionals involved.

*Being Open* about what happened and discussing events promptly, fully, openly, honestly, and compassionately can help patients, their families, carers and professionals cope better with the aftereffects.

Guiding Principles:

* Acknowledging, apologising, and explaining when things go wrong
* Conducting a thorough investigation into the event, be it an incident, complaint or claim and reassuring patients, their families and carers that lessons learned will help the event from recurring
* Providing support for those involved – patients, families, carers, or staff - to cope with the physical and psychological consequences of what happened.

It is a legal requirement to comply with the requirements of the Duty of Candour process where this is applicable.

The benefits of *Being Open* are widely recognised and supported by policy makers, professional bodies and litigation and indemnity bodies, including NHS England, the General Medical Council, the National Health Service Litigation Authority, the Medical Defence Union and the Medical Protection Society.

The NHS Constitution for England embeds the principles of *Being Open* as a pledge to patients in relation to complaints and redress. It states:

*‘The NHS also commits when mistakes happen to acknowledge them, apologise, explain what went wrong and put things right quickly and effectively’*

Remember: saying sorry is not an admission of liability and is the right thing to do.

1. **Purpose**

This policy aims to improve the quality and consistency of communication when service users are involved in a notifiable incident by ensuring that, if mistakes are made, service users and/or their carers receive the information they need promptly, in order to enable them to understand what has happened; that an apology is offered; and that service users and/or carers are informed of the action the Trust will take to try and ensure that a similar type of incident does not recur. An apology is not an admission of liability.

The ***Duty of Candour Policy and Being Open Policy*** should be read in conjunction with the ***Significant Event Policy and Procedure***, and the ***Complaints, Suggestions and Compliments Policy.*** It aims to create anenvironment where service users and/or their carers, clinical staff and managers all feel properly supported when things go wrong.

1. **Scope of this Document**

The policy is applicable to all clinical staff and non-clinical staff employed by Quay Primary Healthcare CIC.

Patients and their representatives must be informed as soon as reasonably practical of any notifiable incident.

A notifiable incident is defined as any unintended/unexpected incident in respect of the Patient during the provision of a regulated activity, which in the reasonable opinion of a health care professional could have or has resulted in:

The death of a Patient or:-

Severe harm, moderate harm or prolonged psychological harm.

**Severe harm** can be defined as a permanent reduction of bodily, sensory, motor, psychological or intellectual functions, including procedures carried out on the wrong person, or wrong area of the body of the right person.

**Moderate harm** can be defined as harm that requires a moderate increase in treatment, including re-admission, prolongation of care, admission to hospital, referral to hospital as an outpatient, cancelling of treatment that is otherwise needed, or transfer to another specialist facility or treatment area.

Moderate harm also includes significant but not permanent harm.

**Prolonged psychological harm** can be defined as psychological harm which a Patient has or is likely to experience for a continuous period of at least 28 days.

1. **Policy**
	1. **Acknowledge the incident**

Patient safety incidents should be acknowledged and reported as soon as they are identified (Appendix 1)

In cases where the patient, their family and carers inform healthcare staff that something untoward has happened, it must be taken seriously from the outset. Any concerns should be treated with compassion and understanding by all clinicians.

The recognition that a patient has suffered harm or has died as a result of a patient safety incident is a major event and rare in primary care. The incident may however arise elsewhere as a result of care in the practice. The Being Openprocess and the investigation and analysis of a patient safety incident should normally occur in the healthcare organisation where the incident took place, and inter-care cooperation may be required.

Take immediate action to prevent of further harm or recurrence. Where additional treatment is required, this should occur whenever reasonably practicable after a discussion with the patient and with appropriate consent.

**4.2 Investigate the incident**

Investigate in an open and non-threatening way. Encourage participation and document the findings (Appendix 2).

The multidisciplinary team, including the most senior health professional involved in the patient safety incident, should meet as soon as possible after the incident to:

• Establish the clinical and other facts.

• Assess the incident to determine the level of immediate response.

• Nominate who will be responsible for discussion with the patient, their family and carers.

• Consider the appropriateness of engaging patient support at this early stage. This includes the use of a facilitator, a patient advocate or a healthcare professional that will be responsible for identifying the patient’s needs and communicating them back to the clinical team.

• Identify immediate support needs for the staff involved.

• Ensure there is a consistent approach by all team members around discussions with the patient, their family and carers.

**4.3. Ensure truthfulness, timeliness and clarity of communication**

Information about a patient safety incident must be given to patients, their families and carers in a truthful and open manner by an appropriately nominated person with appropriate skills. Patients should be provided with a clear explanation of what happened, delivered in a timely, open, and honest way. Patients and their families/carers should be provided with information about what happened as soon as practicable.

Any information given should be factual as known at the time and should be updated as new information may emerge as the matter is investigated. Establish one point of contact – a staff member who will communicate with them on all aspects.

**4.4 Apologise where you need to**

Provide a face-to-face apology delivered by the most appropriate member of staff to patients, their families, and carers as soon as possible. Consider both seniority and the relationship to the patient, and experience and expertise in the type of patient safety incident that has occurred when nominating an individual.

This should be the most senior person responsible for the patient’s care and/or someone with experience and expertise in the type of incident that has occurred.

They should be:

• Known to, and trusted by, the patient, their family, and carers.

• Have a sound knowledge of the incident.

• Be senior.

• Be able to offer an apology and an explanation of the facts.

• Be able to maintain a relationship with the patient or their family where possible.

The initial discussion is the first part of an ongoing communication process.

The patient, their family and carers should be advised of the identity and role of all people attending any opendiscussion beforehand, allowing them to state their own preferences about which staff they would prefer to be present, or omitted. The meeting may:

• Offer genuine sympathy and an apology.

• State the facts that are known as agreed by the multidisciplinary team. Where there is disagreement this may be deferred until further investigations have taken place.

• Take the patient’s or family’s views into account.

• Ensure that communication and terminology are appropriate to the needs of the family, with jargon avoided.

• Give an explanation about what will happen next in the short through to long-term treatment plan and investigation.

• Give information on likely short and long-term effects of the incident. The long-term effects may have to be considered later.

• Offer support for the patient, their family, and carers. This may involve getting help from third parties such as charities and voluntary organisations, as well as offering more direct assistance.

Follow-up discussions with the patient, their family and carers will be required as part of the Being Openprocess. A written record of each discussion should be maintained, and a copy provided to the patient’s representatives.

A written apology can follow, which clearly states the healthcare organisation is sorry for the suffering and distress resulting from the incident, and what the next steps are, and should be issued quickly.

**4.5 Recognise patient/family expectations**

Patients, their families and carers can reasonably expect to be fully informed of the issues surrounding a patient safety incident in a face-to-face meeting with a representative from the practice, and this should be facilitated. Determine what expectations they have in the resolution process.

They should be treated sympathetically, with respect and consideration, and be offered support appropriate to their needs.

**5. Professional support**

Quay Primary Healthcare CIC encourages a culture where members of staff feel able to report patient safety incidents without worry. Staff should also feel supported throughout the incident investigation process as they may be suffering or stressed by the events.

Staff should not be unfairly exposed to punitive disciplinary action, increased medico-legal risk, or any threat to their registration, however where there is potentially a reason to believe a member of staff has committed a punitive or criminal act, they should be advised at an early stage to enable them to obtain separate legal advice and/or representation, perhaps from a defence organisation. This may be done in a supportive and sensitive way and should not be accusative.

**6. Risk Management and Systems Improvement**

The practice Significant Event Procedure should be used to examine the underlying causes of a patient safety incident. These investigations should focus on improving systems of care and the discussion of learning points. Document the discussions and formalise changes to procedure. Communicate changes to the patient as part of the Openness policy.

**7. Multidisciplinary Responsibility**

All staff involved in patient care should be aware of the incident and the issues or changes arising. Major incidents often arise from a systems failure over a period of time or a culmination of minor lapses rather than from the single action of an individual.

Investigate and correct any deficiencies in operational systems or risk control measures that may have contributed to the error.

**8. Clinical governance**

Being openrequires the support of clinical governance frameworks, through which patient safety incidents can be investigated and analysed to find out what can be done to prevent their recurrence. These findings should be treated as learning points and discussed. Incorporate the risk and the resultant actions in the Quay Primary Healthcare CIC

Risk Management Framework.

**9. Confidentiality**

Policies should comply with the patient’s, their families, and carers’ rights, and also staff rights to privacy and confidentiality. Details of a patient safety incident should be considered as confidential. The consent of the individual concerned should be sought prior to disclosing information beyond the clinicians involved in treating the patient. Rules of confidentiality apply.

**10. Continuity of care**

Patients are entitled to expect that they will continue to receive all usual treatment and continue to be treated with dignity, respect, and compassion. If a patient expresses a reference for their healthcare needs to be taken over by another team, the appropriate arrangements should be made for them to receive treatment elsewhere.

**11. An Open Culture**

A culture of openness is where:

• Staff are open about incidents they have been involved in.

• Staff are accountable for their actions.

• Staff feel able to talk to their colleagues about an incident.

• Organisations are open with patients, the public and staff when things have gone wrong and explain what lessons will be learned.

• Staff are treated fairly and are supported when an incident happens.

**12. Resulting Death**

It is important to consider the emotions of bereaved relatives. The patient’s family and carers will probably need information on the processes that will be followed to identify the cause(s) of death. Establishing open channels of communication may also allow the family and/or carers to indicate whether they need bereavement counselling or assistance at any stage.

The Being Opendiscussion and any investigation may occur a coroner’s inquest but consider whether it may be better to wait until after the coroner’s report, to help focus on the facts of the incident.

**13. Disagreement**

Relationships with the family may break down as a result of a perceived error. They may not accept information and may refuse to be involved in any discussion. In this case:

• Attempt to deal with this as soon as possible.

• Involve family where you can.

• Provide details of support services.

• Use an alternative clinician to mediate, e.g. another partner or external PCO or PALS liaison.

• Provide details of the formal NHS complaints procedure.

**14. References**

* National Patient Safety Agency, 2004 *Seven Steps to Patient Safety*
* National Patient Safety Agency 2009. *Being Open: Patient Safety Alert NPSA/2009/PSA/003.* [www.npsa.nhs.uk](http://www.npsa.nhs.uk)
* National Patient Safety Agency, 2009 *Root Cause Analysis Investigation Tools*
* Department of Health 2009. *The NHS Constitution* [www.dh.gov.uk](http://www.dh.gov.uk)
* National Patient Safety Agency, *Building a Memory: preventing harm, reducing risks and improving patient safety* [*www.npsa.nhs.uk*](http://www.npsa.nhs.uk)
	+ CQC Regulations Guidance for NHS Bodies 2014 [www.cqc.org.uk](http://www.cqc.org.uk)

**15. Equality Impact Assessment**

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | YES/NO | COMMENTS |
| 1 | Does the policy/guidance affect one group less or more favourably than another on the basis of; |  |  |
|  | * Race/ethnic or national origin/colour/nationality
 | No |  |
|  | * Disability
 | No |  |
|  | * Gender
 | No |  |
|  | * Religion / belief culture
 | No |  |
|  | * Sexual orientation
 | No |  |
|  | * Age
 | No |  |
|  | * Marital status
 | No |  |
|  | * Pregnancy or maternity
 | No |  |
| 2 | Is there any evidence that some groups are affected differently? | No |  |
| 3 | If you have identified potential discrimination, are any exceptions valid, legal and/ or justifiable? | No |  |
| 4 | Is the impact of the policy/ guidance likely to be negative? | No |  |
| 5 | If so can the impact be avoided? | Yes |  |
| 6 | What alternatives are there to achieving the policy/ guidance without the impact? | N/A |  |
| 7 | Can we reduce the impact by taking different action? | N/A |  |

**Duty of Candour Letter Template Appendix 1**

**Quay Primary Healthcare CIC**

**The Outset**

**Suite 08**

**Sankey Street**

**Warrington**

**WA1 1NN**

**Tel: 01925 363009**

**PRIVATE AND CONFIDENTIAL**

*(Insert date)*

*(Insert name and address)*

**Letter to be sent to the patient affected by the incident**

(Remove prior to sending)

Dear **[name the person likes to be known as]**

You were recently receiving care from our Quay Primary Healthcare CIC Clinician and as he/she **[name and designation]** explained to you, **[brief description of the incident and what has previously been discussed]** whilst you were a patient at **[name the practice or care home]**.

I would like to take this opportunity to express my sincere apologies that this event has occurred while you were under our care and to assure you that Quay Primary Healthcare CIC aims to provide a quality service to all patients. We are therefore, undertaking a full investigation into the incident in an effort to understand exactly what happened and to find out whether there is something that we could do differently in future to stop this happening to anyone else.

We would like the opportunity to discuss and share our findings with you and therefore, I would like to invite you to come to a meeting, once the investigation has been completed, this can be arranged at a mutually convenient time. I am more than happy for you to bring a relative or friend with you if this would help. Alternatively, it may be that you do not feel a meeting would be of any help, either now or in the future and that is, of course, your decision: there is absolutely no pressure for you to come and talk to us. We just wanted to give you the opportunity, should you wish to do so.

The investigation process can take up to 60 working days to complete. I will be your lead contact during this time and, whether you wish to attend a meeting or not, I should be grateful if you would ringme on the number at the top of this letter. We can then make any necessary arrangements. If you feel that you do not wish to telephone, I am more than happy to hear from you by letter.

Yours Sincerely,

Record of Implementation of Being Open Policy Appendix 2

|  |
| --- |
| 1. Patient Name …………………………………………………….… Date of Incident …………………………. Incident Number …………………..NHS Number ………………………............................. Nominated staff lead on *Being Open* for this incident …………………………………………………………………………..……………………………………………………………………………………………….………….Person responsible for communications with the patient …………………………………………………………………….…………………………………………………………………………………………………..…………… |
| 1. Brief overview of the incident ……………………………………………………………………………………………….…………………………………

……………………………………………………………………………………………….…………………………………………………………………………………………………………………………………………………………………..……………………………………………………………………………………………….………….…………………………………………………………………………..……………………………………………………………………………………………….………….…………………………………………………………………………..……………………………………………………………………………………………….………….…………………………………………………………………………..……………………………………………………………………………………………….…………. |
| 1. Additional people/organisations informed e.g. Coroner, Police, Safeguarding Team (please specify)

…………………………………………………………………………..……………………………………………………………………………………………….………….…………………………………………………………………………..……………………………………………………………………………………………….…………. |
| 1. Record of initial discussion with patient /carer

Date ……………………………................... Time ………………………………….. Full apology given ………………………... Yes …………………………………………………………………………..……………………………………………………………………………………………….………….…………………………………………………………………………..……………………………………………………………………………………………….………….…………………………………………………………………………..……………………………………………………………………………………………….………….…………………………………………………………………………..……………………………………………………………………………………………….………….…………………………………………………………………………..……………………………………………………………………………………………….………….…………………………………………………………………………..……………………………………………………………………………………………….………….…………………………………………………………………………..……………………………………………………………………………………………….………….…………………………………………………………………………..……………………………………………………………………………………………….…………. |
| 1. Record of 1st meeting with patient / relative / carer – detailed record of discussion

Date …………………………………….. Time …………………………….. Venue ……………………………………………………………………………………Those present :Name ……………………………………………………………………………………….. Involvement …………………………………………………………………Name ……………………………………………………………………………………….. Involvement …………………………………………………………………Name ……………………………………………………………………………………….. Involvement …………………………………………………………………Name ……………………………………………………………………………………….. Involvement …………………………………………………………………Name ……………………………………………………………………………………….. Involvement ………………………………………………………………...Name ……………………………………………………………………………………….. Involvement …………………………………………………………………Establish concerns of patient/relative/carer…………………………………………………………………………..……………………………………………………………………………………………….………….…………………………………………………………………………..……………………………………………………………………………………………….………….…………………………………………………………………………..……………………………………………………………………………………………….………….Record of meeting…………………………………………………………………………..……………………………………………………………………………………………….………….…………………………………………………………………………..……………………………………………………………………………………………….………….…………………………………………………………………………..……………………………………………………………………………………………….………….…………………………………………………………………………..……………………………………………………………………………………………….………….…………………………………………………………………………..……………………………………………………………………………………………….………….…………………………………………………………………………..……………………………………………………………………………………………….………….…………………………………………………………………………..……………………………………………………………………………………………….………….…………………………………………………………………………..……………………………………………………………………………………………….………….…………………………………………………………………………..……………………………………………………………………………………………….………….Patient informed of investigation outcome and action plan progress to date Yes Plan of next stage in process agreed with patient/relative/carer …………………………………………………………………………………………………………………………………………………………………………………………. …………………………………………………………………………………………………………………………………………………………………………………………. |
| 1. Record of subsequent communications

Date …………………………………………………………. Time ……………………………………………………………………………...Communication typeTelephone …………………………………. Face to Face ……………………………… Letter ……………………… Other ………………………………..By/with whom …………………………….…………………………………………………………………………………………………………………………………..Content of communication (in brief) …………………………………………………………………………………………………………………………………………………………………….………………..………………………………………………………………………………………………………………………………………………………………………………………….………………………………………………………………………………………………………………………………………………………………………………………….………………………………………………………………………………………………………………………………………………………………………………………….………………………………………………………………………………………………………………………………………………………………………………………….………………………………………………………………………………………………………………………………………………………………………………………….…………………………………………………………………………………………………………………………………………………………………………………………. |
| 1. Completion of Process

Feedback on completion of process………………………………………………………………………………………………………………………………………………………………………………………….………………………………………………………………………………………………………………………………………………………………………………………….………………………………………………………………………………………………………………………………………………………………………………………….………………………………………………………………………………………………………………………………………………………………………………………….………………………………………………………………………………………………………………………………………………………………………………………….…………………………………………………………………………………………………………………………………………………………………………………………. |