# Open Disclosure

## NATIONAL POLICY

you & your health service

your service, your say

you said...we did

*people caring for people*

HSE

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Quality and Patient Safety Directorate

Tús Áite do
Shábháilteacht **1** Othar

Patient Safety **1** First

Gníomhaireacht Éileamh an Stáit

State Claims Agency

| Directorate | Quality and Patient Safety | Title: | Open Disclosure Policy |
|---|---|---|---|
| Document reference number: | QPSD-D-062-1 | Authors: | National Lead in Open Disclosure for the HSE and National Lead in Open Disclosure for the State Claims Agency |
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| Approval date: | 08/10/2013 | Responsibility for implementation | Managers of all health and social care services with support from Open Disclosure national leads, regional/local/group risk managers, risk managers forum and regional consumer affairs managers. |
| Revision date | 08/10/2015 | Responsibility for review and audit | The National Advocacy Unit |
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# Table of Contents

# 1. Glossary of Terms:

| Term/Abbreviation | Definition |
|---|---|
| Adverse event | An incident which results in harm to a person that may or may not be the result of an error. |
| Acknowledgement | An acceptance of the truth or existence of something. |
| Apology | An apology is a genuine expression of being sorry for what has happened.  It is an expression of regret. |
| Error | The failure of a planned action to be completed as intended or use of a wrong inappropriate or incorrect plan to achieve an aim. |
| Harm | Any physical or psychological injury or damage to the health of a person, including both temporary and permanent injury. |
| HSE | Health Service Executive |
| Incident | An event or circumstance which could have or did lead to unintended and/or unnecessary harm and/or a complaint loss or damage. |
| Near Miss event | An incident which could have resulted in harm but did not either by chance or timely intervention". |
| No harm event | An incident occurs which reaches the service user but results in no injury to the service user. Harm is avoided by chance or because of mitigating circumstances. |

| | |
|---|---|
| Open Disclosure | An open, consistent approach to communicating with service users when things go wrong in healthcare. This includes expressing regret for what has happened, keeping the service user informed, providing feedback on investigations and the steps taken to prevent a recurrence of the adverse event. |
| Service User | Please note that the term "service user" used throughout this policy includes patients and clients of the HSE and of services funded by the HSE. |
| SCA | State Claims Agency |
| Service | Please note that the term "service" as used throughout these guidelines refers to all HSE health and social care services including services funded by the HSE. |
| Staff | Please note that the term "staff" used throughout these guidelines includes all health and social care staff – all persons involved in the provision of care to service users across all of our health and social care services. |

## 2.    Policy

2.1:  Incident/Adverse Event: It is the policy of the Health Service Executive (HSE Incident Management Policy 2008) that incidents are identified, managed, _disclosed_ and reported and that learning is derived from them. The service user must be informed in a timely manner of the facts relating to the incident and an apology provided, where appropriate.

2.2:  Suspected Adverse Event: The service user should also be informed if an adverse event is suspected but not yet confirmed.

2.3:  No Harm Events: "No harm events" should generally be disclosed.

2.4:  Near Miss Events: Near miss events should be assessed on a case by case basis, depending on the potential impact it could have had on the service user e.g. wrong site procedure, which was noticed and corrected before surgery. If, after consideration of the near miss event, it is determined that there is a risk of/potential for future harm from the event then this should be discussed with the service user.

2.5:  The HSE will provide an environment in which staff feel supported in the identification and reporting of adverse events and also during the open disclosure and review process following an adverse event.

2.6:  The HSE will provide and facilitate training in open disclosure for health and social care staff.

2.7:  When a clinician makes a decision, based on his/her clinical judgement, not to disclose to the service user that an adverse event has occurred, the rationale for this decision must be clearly documented in the service user's healthcare record and this decision may need to be reviewed by the clinician at a later date, depending on the circumstances involved.

2.8:  The salient points discussed with service users during open disclosure meetings, including the details of any apology provided, should be documented in the service user's healthcare recorded in accordance with the National Guidelines on Open Disclosure 2013.

2.9:  All health and social care services must have the required governance processes in place to ensure that open disclosure occurs and to address situations where there is a difference of opinion as to whether open disclosure should occur or not.

2.10:  All health and social care staff have an obligation under the National Standards for Safer Better Healthcare 2012 to "fully and openly inform and support service users as soon as possible after an adverse event affecting them has occurred, or becomes known and continue to provide information and support as needed.

## 3.  Purpose

The purpose of this policy and the related Open Disclosure Guidelines is as follows:

3.1:  To ensure that communication with service users and their families/support persons following an adverse event is undertaken in an empathetic, informed and timely manner.

3.2: To provide an ethical framework for staff and health and social care services to fulfil their duty of care in relation to communicating with service users and their families/support persons following an adverse event. The principles of open disclosure form the basis of an ethical response and promote a fair and just culture within health care organisations and, when employed effectively, can lead to improved service user and staff acceptance of the event.

3.3:  To meet the requirements of the National Standards for Safer Better Healthcare 2012 and in particular Standard 3.5.

3.4:  To ensure that staff working in all of our health and social care services are consistent in their processes in relation to the application of the principles of Open Disclosure. (See Appendix A for The Principles of Open Disclosure)

3.5:  To ensure that staff involved in an adverse event are identified, monitored and provided with adequate support in the aftermath of the adverse event and also throughout the open disclosure and incident review process.

3.6:  To comply with the provisions of the National Healthcare Charter 2012.

## 4. Scope

This policy and the related Open Disclosure Guidelines apply to all staff working in the HSE health and social care services and in any services funded by the HSE.

Persons/agencies providing services or advice, directly or indirectly, to or on behalf of, including agencies and services funded by the HSE (refer to service level agreement) must have in place policies, procedures/guidelines which are compatible and consistent with this HSE policy and the related HSE and State Claims Agency (SCA) Open Disclosure Guidelines.

This policy and the related HSE and SCA Open Disclosure Guidelines have been designed to support the HSE Incident Management Policy in relation to the disclosure of incidents/adverse events to service users and their families/support persons.

## 5. Legislation, Regulation and related Polices, Procedures, Protocols and Guidelines (PPPG's).

### 5.1: Legislation:

A consultation paper by the Law Reform commission in 2008 recommended that
"*a statutory provision be considered which would allow medical practitioners to make an apology and explanation without these being construed as an admission of liability in a medical negligence claim*"

While Ireland currently has no protective legislation to assist the open disclosure process, it is envisaged that this status will change in the near future in the upcoming Health Information Bill in which it is anticipated there will be provisions affording some degree of protection in relation to open disclosure for healthcare staff.

## 5.2: Regulation:

5.2.1: The National Standards for Safer Better Healthcare 2012: Standard 3.5 states:

*"Service providers fully and openly inform and support service users as soon as possible after an adverse event affecting them has occurred, or becomes known and continue to provide information and support as needed."*

5.2.2: The Medical Council in their Guide to The Professional Conduct and Ethics for Registered Medical Practitioners 2009 state:

*"Service users and their families are entitled to honest, open and prompt communication with them about adverse events that may have caused them harm.".*

5.2.3: The Nursing and Midwifery Board of Ireland:

The Nursing and Midwifery Board of Ireland are currently revising the code of professional conduct and ethics for registered nurses and registered midwives and will be including the promotion of safe quality practice by nurses and midwives actively participating in incident reporting, adverse event reviews and open disclosure.

### 5.3: Related HSE PPPG's and National Standards.

5.3.1: The HSE and State Claims Agency National Guidelines: "*Open Disclosure: Communicating with Service Users and their Families following Adverse Events in Healthcare".* (Document reference number QPSD-GL-063-1)
This policy is to be used in conjunction with these guidelines.

5.3.2: The HSE Incident Management Policy 2008.

5.3.3: The HSE Complaints Policy and Procedures Manual "Your Service Your Say" 2009.

5.3.4: The National Standards for Safer Better Healthcare 2012.

5.3.5: The National Healthcare Charter 2012: "You and Your Health Service".

5.3.6: The HSE Policy for the Prevention and Management of Critical Incident Stress 2012.

## 6.   Roles and Responsibilities:

### 6.1: Roles

It is the role and duty of all health and social care managers to:

- Comply with this policy

- Ensure that employees are aware of this policy and the related Open Disclosure Guidelines which accompany this policy.
- Facilitate training for employees where necessary.
- Ensure that employees comply with this policy and the related Open Disclosure Guidelines which accompany this policy.
- Address incidents of non compliance with this policy.

It is the role and duty of all employees to comply with this policy and associated guidelines which accompany this policy and to co-operate in the open disclosure process, as required.

## 6.2: Responsibilities

As Open disclosure forms part of the incident management process, responsibilities at Local, Regional and National level are as per the HSE Incident Management Policy. Open Disclosure must be recognised as a necessary component in the management and review of incidents/adverse events.

# 7. Guideline:

## *Open Disclosure Process Algorithm*

**ADVERSE EVENT OCCURS**
*Severe? Moderate? Mild?*
*Minimise risk of further harm. Provide appropriate clinical care. Document clinical facts in service user's healthcare record.*

→ *Manager/Consultant to alert Risk Management*

*Consider if debriefing is required for staff?*

**CLINICAL INCIDENT MANAGEMENT AND REPORTING PROCESS**
*Statutory reporting requirements*

→ *Identify under what process the incident will be investigated.*

**INFORM SERVICE USER/SUPPORT PERSON OF THE ADVERSE EVENT**
*Service users should be informed of the occurrence of an adverse event that has resulted in or is expected to result in harm to the patient.*
*This includes all sentinel events.*
*Consider if there is a reason to defer disclosure at this time/can disclosure cause additional harm?*

**INITIATE THE OPEN DISCLOSURE PROCESS**
*Initial disclosure to the service user should occur as soon as possible (within 24-48 hours of the incident, if practicable).*
*. First, identify a key contact person to support communication between the service and the service user/support person. Then identify who will undertake the Open Disclosure Discussion and how the meeting(s) will be conducted. Refer to Open Disclosure Team Example for role descriptions.*

→ *Refer to "before, during and after disclosure" checklist.*

**NOTIFY THE SERVICE USER**

*Inform the service user of the facts available in relation to the incident. Avoid speculation.*

→ **WHEN IT IS ESTABLISHED THAT AN ERROR HAS OCCURRED APOLOGISE TO THE SERVICE USER**
*Note: An expression of regret or apology should not include any admission of fault until the facts are known*

→ **. PROVIDE SUPPORT**
*Agree a plan for the service user's on-going care, to include the identification of any on-going supports required.*

**Agreed feedback and support for patients/next-of-kin/support person and staff**

Please refer to the HSE and State Claims Agency Open Disclosure National Guidelines document: "*Open Disclosure: Communicating with Service Users and their Families following Adverse Events in Healthcare*" (Document reference number QPSD-GL-063-1) accompanying this policy which supports the implementation of an effective open disclosure process in health and social care services.

## 8. Revision and Audit:

Revision and audit of this document, in conjunction with the related HSE and SCA Open Disclosure Guidelines, is necessary to ensure its success.

The National Advocacy Unit will be responsible for the revision of this document on a 2 yearly basis, or sooner if appropriate.

The review of the document and the guidelines will include feedback from healthcare staff and service users in relation to the effectiveness of the policy.

An audit of implementation and compliance at service level is also necessary. Suggested areas to audit are as follows:

- ❖ The inclusion of open disclosure in the incident management process.
- ❖ The service user experience of the open disclosure process.
- ❖ Staff experience of the open disclosure process.
- ❖ Management of open disclosure as per the principles of open disclosure.

## 9. Implementation Plan:

9.1. An email will be sent by the Communications Department to all users in the system to notify them of this policy and the accompanying open disclosure guideline document. Both documents will be placed on the HSE and HSEland website and staff will be directed to read them and if it pertains to their work, to sign off that they have read, understood and agree to adhere to the provisions as outlined in the documents.

9.2: Regional QPS offices and QPS forum to assist in the implementation of this policy and the accompanying guideline.

9.3: As part of the national implementation plan for Open Disclosure the Open Disclosure Policy and Guidelines documents will be provided to healthcare services as part of the on-line Open Disclosure resource pack.

9.4: The implementation plan at local/service level should provide for the following:

- The assignment of responsibility for the implementation of the policy and guidelines i.e.(named person(s)/job title(s).
- The identification of what training needs are required, if any.
- The identification of the realistic resources required to implement the policy and guidelines.
- The identification of the most effective method to communicate the policy and guidelines to all relevant staff, including the provision of awareness sessions on Open Disclosure for all staff and the utilisation of e-learning programmes when available.
- The provision for feedback.

9.5:  This policy and the accompanying open disclosure guidelines form part of the national strategy for the implementation of open disclosure across all health and social care services.

9.6: There will be a formal launch at national level of the HSE National Policy on Open Disclosure Policy and of the HSE and SCA National Guidelines on Open Disclosure.

## 10.   A note on the development of this policy:

This policy has been informed by :

- o An evidenced based research of best practice in open disclosure in other countries that have had open disclosure standards in place for some time and in particular Australia, Canada, America and the UK.

- o The learning from the 2 year open disclosure pilot programme in 2 hospitals in the Republic of Ireland (The Mater Misericordiae University Hospital, Dublin and Cork University Hospital, Cork City) which finished in October 2012.

- o Learning from the Irish Hospice Foundation's programme on "Breaking Bad News".

   This policy should be used in conjunction with the HSE and SCA National Guidelines on open disclosure, the HSE Incident Management Policy and the HSE Policy for Preventing and Managing Critical Incident Stress.

This is an evidenced based document designed to practically assist the implementation of open disclosure across all health and social care services.

## 11. References:

The Australian Commission on Safety and Quality in Health Care: 'Open Disclosure Healthcare Professionals Handbook, 2003.

The HSE Incident Management Policy 2012

The HSE and SCA Open Disclosure Guidelines 2012.

The NSW Health Open Disclosure Policy Directive 2007 – Revised 2012

The World Health Organisation Conceptual Framework for the International Classification for Service user Safety Technical Report (January 2009).

The MPS Members Handbook.

The Medical Council's Guide to The Professional Conduct and Ethics for Registered Medical Practitioners 2009)

The National Healthcare Charter 2012: You and Your Health Service.

The HSE Procedure for developing Policies, Procedures, Protocols and Guidelines.

The National Standards for Safer Better Healthcare 2012.

The HSE Complaints Policy and Procedures Manual "Your Service Your Say" 2009.

The UK National Patient Safety Agency Principles of Open Disclosure.

The HSE Policy for the Prevention and Management of Critical Incident Stress 2012.

## 12: Revision History Sheet:

| Document Control No.   -                     | (Revision No.    Version 1        ) |
|----------------------------------------------|-------------------------------------|
| **Section**                                  | **Changes Made**                    |
|                                              |                                     |
|                                              |                                     |
|                                              |                                     |

**Appendix A**
**The Principles of Open Disclosure**

There are ten principles designed to assist health and social care services to create and embed a culture of open disclosure. These have been adopted from the UK National Patient Safety Agency.[1] The disclosure process should encompass these principles.

1. Acknowledgement: Health and social care services should acknowledge to the service user that an adverse event has occurred and initiate the open disclosure process, in line with national policy.

2. Truthfulness, timeliness and clarity of communication: The service user should be provided with information in a timely manner - focusing on the factual information available at the time. Ideally the open disclosure process should commence within 48 hours of the event occurring or the event becoming known and as soon as the service user is physically and emotionally available to receive the information.

3. Apology/ expression of regret: An apology/expression of regret, regarding the condition of the service user and for what has

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[1] National Service user Safety Agency, National Reporting and Learning Service: saying sorry when things go wrong Being Open- communicating service user safety incidents with service users, their families and carers. 2009, p.14.

happened as a result of an adverse event, is important and should be forthcoming. When it is clear, following a review of the adverse event, that the healthcare provider is responsible for the harm to the service user (e.g. wrong site surgery) it is imperative that there is an acknowledgment of responsibility and an apology provided as soon as possible after the event.

4. Recognising the expectations of service users: The service user may reasonably expect to be fully informed of the facts and consequences in relation to the adverse event and to be treated with empathy and respect.

5. Professional Support: Health and social care services should promote the development of a "just culture" as staff will then feel more encouraged and willing to report incidents/adverse events/near miss events. Staff can also expect to be supported by the service following an adverse event and throughout the open disclosure and incident review process.

6. Risk management and systems improvement: The investigation of adverse events should be undertaken in line with the HSE incident management policy and be inclusive of the review of recommendations to ensure that any recommendations/actions

taken are effective and that they will reduce the likelihood of a recurrence of the event.

7. Multidisciplinary responsibility: Open disclosure involves multidisciplinary accountability and response. Clinical, senior professional and managerial staff should be identified to lead in and support the process.

8. Clinical governance: The open disclosure process is one of the key elements of the HSE clinical governance system. Health and social care services are required to have appropriate accountability structures in place which ensure that open disclosure occurs and that it is integrated with other clinical governance systems and processes including clinical incident reporting and management procedures, systems analysis reviews, complaints management and privacy and confidentiality procedures.

9. Confidentiality: The information collated following an adverse event is often of a sensitive nature and therefore patient confidentiality is paramount. Service user information is generally held under legal and ethical obligations of confidentiality. All health and social care policies, procedures,

and guidelines in relation to privacy and confidentiality for service users and staff should be consulted with and adhered to.

10. Continuity of care: Steps need to be taken to reassure the service user in relation to the management of their immediate care needs and to also reassure them that their care will not be compromised going forward. Transfer of care to another facility may be requested by the service user and should be facilitated when it is possible to do so. A member of staff should be identified who will act as a contact person for the service user to keep them informed of the situation and to maintain open channels of communication between the service user and the health and social care service.