

Open Disclosure

NATIONAL GUIDELINES

Communicating with service users
and their families following adverse
events in healthcare



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

people caring for people



Directorate: Quality and Patient Safety	Title: Open Disclosure: Communicating with service users and their families following adverse events in healthcare
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A message from the WHO Patients for Patient Safety Network

Individual experience coupled with insights from patients/service users, family members and healthcare professionals, who have been involved in an adverse event, clearly point to across the spectrum benefits from open disclosure. In the immediate aftermath of an event, the window of opportunity which Dr Albert Wu calls the ‘Golden Moment’ is often lost because of defensiveness, efforts at damage limitation and fear of reputational damage both at individual and corporate level.


Accepting that harm is not intentional should help us to deal with events with honesty, openness and compassion for heartbroken people and those carrying the burden of responsibility.

Disclosure is not about blame, either apportioning blame or accepting blame. It is about integrity and being truly professional. Accepting responsibility and embracing accountability are part of that professionalism.

The best guidance is written in our own hearts. If such an incident happened to you or a member of your own family, how would you like to be treated, what would you want? You would want the occurrence to count for something, for you and your loved one to count, to matter. Defensiveness, lame excuses and denial will only compound the injury and the hurt.

Healing for all will come through acknowledgement that something happened which should not have happened, through demonstrating your own dismay and your regret that it happened. It is essential to really connect with the injured and resolve to examine the what, where, when, why and by whom with the purpose of preventing recurrence.

Disclosure is most importantly about learning. Consequently, it is not an event, it is a process. Having an opportunity to contribute to that process will often give meaning



to the tragedy for the patient and their family. ‘Sorry’ is the hardest word. It is also the word which shows that we care, that we wish things were otherwise.

It is important that healthcare professionals acknowledge their own hurt, anger and shame in the aftermath of an adverse event. Just as patients and family members need support in these situations, so do healthcare professionals. No one should find himself/herself abandoned at this important time.

Yes, we know what we should and must do. Guidelines serve to smooth the path in restoring and maintaining the trust of vulnerable patients in the professionals who often hold our lives in their hands and who we as patients want to be able to hold in high regard.

But it requires a combination of a supportive culture, system change and a demonstration of ethical behaviour coupled with professional and personal integrity to bring that to reality.

Margaret Murphy

External Lead Advisor

WHO Patients for Patient Safety Programme




Foreword

Florence Nightingale, in her Notes on Hospitals in 1859, stated “it may seem a strange principle to enunciate as the very first requirement in a hospital - that it should do the sick no harm”. The Health Service Executive (HSE) is dedicated and committed to providing safe and high quality health care to service users. However, as professionals working in health and social care services we are not infallible. Our desired outcome for patients/service users and their families is not always the final outcome. There are many variables in our work and sometimes, despite our best plans and efforts, things can go wrong. In some instances our actions may have impacted on the end result, but not always.

The healthcare provider/service user relationship is built on a foundation of trust, honesty and openness. When the service user does not trust or has little faith in the healthcare provider this can impact on their recovery in the long term. It is the policy of the HSE that incidents are identified, managed, disclosed and reported and that learning is derived from them.

Research has demonstrated that if we ignore or avoid communicating with service users when things go wrong they are more likely to pursue other routes such as the complaints process or the legislative route to get answers to their questions. These processes can often be perceived as being negative, time consuming or costly and they may, in turn, impact on the health and well-being of service users and health and social care staff. Communicating effectively with service users is therefore a vital part of the incident management process. It promotes person centred care and a just culture which encourages learning from adverse events and continuous improvement in the delivery of our health and social care services.

In addition to an event itself, how we personally manage it has a deep effect on all those involved – service users, their families, health and social care staff and services. The importance of staff support in the aftermath of an adverse event



cannot be under-estimated. There is significant evidence to demonstrate that the open disclosure process assists both service users and staff in the aftermath of an adverse event in relation to coping with the event and also in relation to achieving closure from the event.

These guidelines have been developed following and incorporating the learning from a two year open disclosure pilot programme. The key objectives of these guidelines are (a) to establish a standardised approach by healthcare professionals across all of our health and social care services in relation to how we communicate with service users following adverse events and (b) to ensure that communication with service users and staff members involved occurs in a supportive and timely manner.

The merits of open disclosure are endorsed by health service providers, indemnifying and professional bodies in the Republic of Ireland and throughout the world, and the benefits are significant for all those who provide and use our services.

Dr Philip Crowley
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and Patient Safety. HSE*

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Director of State Claims Agency

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The Medical Protection Society (MPS).
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A note on the development of these guidelines

These guidelines have been compiled by the HSE national lead in open disclosure and the State Claims Agency national lead in open disclosure to support the implementation of the HSE national policy on open disclosure across all health and social care services in the Republic of Ireland.

It should also be noted that open disclosure is a key component in the management of incidents as per the HSE Incident Management Policy 2008. This guideline has been developed to support a standardised approach to open disclosure in the context of incident management.


Please note that the term “service user” as used throughout these guidelines includes patients and clients of the HSE and of services funded by the HSE. The inclusion of family members/support persons in the disclosure process is at the discretion of the service user and it is important to comply with the requirements of patient confidentiality at all times.

Please note that the term “staff” as 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.

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.

These guidelines have been informed by:

- 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.

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- 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.
 - Feedback following wide consultation of the document nationally across health and social care departments and services, patient representatives, patient representative/advocacy groups, trade unions, regulatory bodies and indemnifying bodies.
 - Learning from the Irish Hospice Foundation's programme on "Breaking Bad News".

Please note that these guidelines are not incident management guidelines and should be used in conjunction with the HSE National Policy 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 and it is not intended to be prescriptive but to practically assist the implementation of the open disclosure policy across all health and social care services using best practice guidelines.

These guidelines support the National Healthcare Charter 2012 and the National Standards for Safer Better Healthcare 2012.

The open disclosure training module is a separate project and therefore separate to this guidance document.

The national open disclosure project in the Republic of Ireland is supported by the Medical Protection Society (MPS).

Accountability

The extent to which individuals are answerable to a higher authority.

Acknowledgement

An acceptance of the truth or existence of something.

Adverse event

An incident which results in harm to a person that may or may not be the result of an error.¹

Apology

An apology is a genuine expression of being sorry for what has happened.²

Clinician

A health professional, such as a physician, psychiatrist, psychologist, or nurse, involved in clinical practice, as distinguished from one specialising in research.³

Defamation

The Defamation Act 2009 Act defines defamation as the “publication, by any means, of a defamatory statement concerning a person to one or more than one person (other than the first-mentioned person), and “defamation” shall be construed accordingly.”⁴

An actionable defamatory statement has three ingredients:


- it must be published,
- it must refer to the complainant and
- it must be false.

¹ World Health Organisation The Conceptual Framework for the International Classification for Patient Safety: Version 1.1 Final Technical Report. Geneva, WHO World Alliance for Patient Safety, 2009 page 23.

² Canadian disclosure guidelines, Being Open with Patients and Families, Canadian Service User Safety Institute, 2011, page 19.

³ Farlex On-line medical dictionary accessed on the 19/07/2013.

⁴ Defamation Act 2009, Part 1 Preliminary and General.



Publication of the defamatory statement which may take the form of writing, spoken words, visual images, sounds or gestures and includes transmission through TV, radio and the internet.

Disclosure

In the context of this document disclosure refers to the process by which an adverse event is communicated to the service user.

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.⁵

Harm

Any physical or psychological injury or damage to the health of a person, including both temporary and permanent injury.⁶

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.⁷

Interpreter

A person who facilitates communication between users of different languages by use of oral translation or sign – language methods, either simultaneously or consecutively.

A just culture

An environment which seeks to balance the need to learn from mistakes and the need to take disciplinary action.⁸

Liability

Legal responsibility for an action or event.

⁵ World Health Organisation 2009 *Conceptual framework for the International Classification for Patient Safety, Version 1.1. Final Technical Report*, Geneva, page 22.

⁶ *Ibid*, page 116.

⁷ *Ibid*, page 120.

⁸ *Ibid*, page 122.

Near miss

An incident which could have resulted in harm but did not either by chance or timely intervention.⁹

MPS

Medical Protection Society: Society for medical indemnity protection.

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.¹⁰

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 patient informed, providing feedback on investigations and the steps taken to prevent a recurrence of the adverse event.¹¹

Patient

A person who is the recipient of healthcare.¹²

Patient safety incident

An event or circumstance which could have resulted, or did result, in unnecessary harm to a patient.¹³

Safety culture

The safety culture of a service is the product of individual and group values, attitudes, perceptions, competencies and patterns of behaviour that determine the commitment to and the style and proficiency of an organisation's health and safety management.¹⁴

⁹ World Health Organisation 2009 Conceptual framework for the International Classification for Patient Safety, Version 1.1. Final Technical Report, Geneva page 22.

¹⁰ Ibid, page 129.

¹¹ Australian Commission on Safety and Quality in Health Care: Open disclosure Healthcare Professionals Handbook, 2003 page 3.

¹² World Health Organisation 2009 Conceptual framework for the International Classification for Service user Safety, Version 1.1. Final Technical Report.

¹³ Ibid, page 131.

¹⁴ World Health Organisation 2009 Conceptual framework for the International Classification for Patient Safety, Version 1.1. Final Technical Report, Geneva page 139.



Service user

For the purpose of this document the term service user means a person who uses health and social care services.

SCA

State Claims Agency.

Systems Error

An error that is not the result of an individual's actions, but the predictable outcome of a series of actions and factors that comprise a diagnostic or treatment process.

1.1: Background

In January 2007, Mary Harney, Minister for Health & Children established the Commission on Patient Safety and Quality Assurance (“the Commission”) and instructed it, among other tasks, “to develop clear and practical recommendations which would ensure the safety of patients”.

In July 2008, the Commission completed its report entitled Building a Culture of Patient Safety. The report was published in August 2008 and approved by Government in January 2009.

In her foreword to the report, Chairperson Dr. Deirdre Madden states “... When such adverse events occur there must be a system in place that ensures that all those affected are informed and cared for, and that there is analysis and learning from the error to try and prevent the recurrence of such an event”.

Dr. Madden further records the objective of the Commission, namely, “to make recommendations for organisational, regulatory and educational reform which will create a culture of patient safety for our health system.”

On 27th January 2009, Government approved the Commission’s report and the Minister for Health & Children authorised the setting up of a Steering Group with a remit to drive the implementation of all the recommendations of the Commission’s report, as effectively and efficiently as possible.

One of the key recommendations of the report is the development and support of a culture of open disclosure to patients and their families following adverse events in healthcare resulting in harm to patients.

Open disclosure is defined by the Australian Commission on Safety and Quality in Health Care as “an open, consistent approach to communicating with patients when things go wrong in healthcare. This includes expressing regret for what has happened, keeping the patient informed, providing feedback on investigations and the steps taken to prevent a recurrence of the adverse event.”

1.2: Open Disclosure: Requirements as per the National Standards for Safer Better Healthcare 2012

In June 2012 the Health Information and Quality Authority (HIQA) launched the National Standards for Safer Better Healthcare.

Standard 3.5 under Theme 3 of these standards “Safe Care and Support” states a requirement that:

“Service providers fully and openly inform 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”.

1.3: Scope

The Commission recommended that the open disclosure standard apply anywhere healthcare is provided to service users.

These guidelines and the related open disclosure policy apply to all staff working in 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 these guidelines and the related HSE open disclosure policy. These guidelines have been developed to support the HSE Incident Management Policy in relation to the management of the open disclosure process following adverse events in healthcare.

1.4: When should Open Disclosure happen?

1.4.1: When a service user has experienced an “adverse event”

The patient outcomes that relate to adverse events are classified according to severity, using the World Health Organisation standardised taxonomy as follows:

- **Mild** – Patient outcome is symptomatic, symptoms are mild, loss of function or harm is minimal or intermediate but short term and no or minimal intervention (e.g. extra observation, investigation, review or minor treatment) is required. E.g. Wrong medication administered with short term mild effects.
- **Moderate** – Patient outcome is symptomatic requiring intervention. (e.g. additional operative intervention or additional therapeutic treatment), or causing permanent or long term harm or loss of function.
- **Severe** – Patient outcome is symptomatic requiring life-saving intervention or major surgical or medical intervention, shortening life expectancy or causing major permanent or long term harm or loss of function.
- **Death** – on the balance of probabilities death was caused or brought forward in the short term by the incident.

1.4.1.1: Understanding harm

The causes of adverse outcomes for service users vary from harm resulting from their underlying condition to harm resulting from the care/treatment provided to them. Harm associated with the care provided to them can be further categorised into harm caused by (a) the inherent risks of the treatment/investigation, (b) system failures and (c) provider performance or it may be due to a combination of all of these.

It is important to establish whether an adverse event has been caused by the performance of the provider or by an inherent risk/side effect/complication of the investigation/treatment provided. The inherent risks of some treatments/procedures can be misunderstood as provider error. This is one of the reasons why service user education and informed consent discussions prior to clinical interventions are so important.

It is important that there is a discussion with the service user regardless of the reason harm has occurred. It is recommended that in all incidents where harm has occurred and where it is attributed to the inherent risks of a treatment/procedure the incident are reviewed to establish all of the contributory factors. An analysis of the incident may indicate that there was a combination of factors which contributed to the harm experienced by the service user.

Service users expect to be informed about any harm they have experienced whatever the reason for it and including an explanation in relation to harm resulting from their disease process.

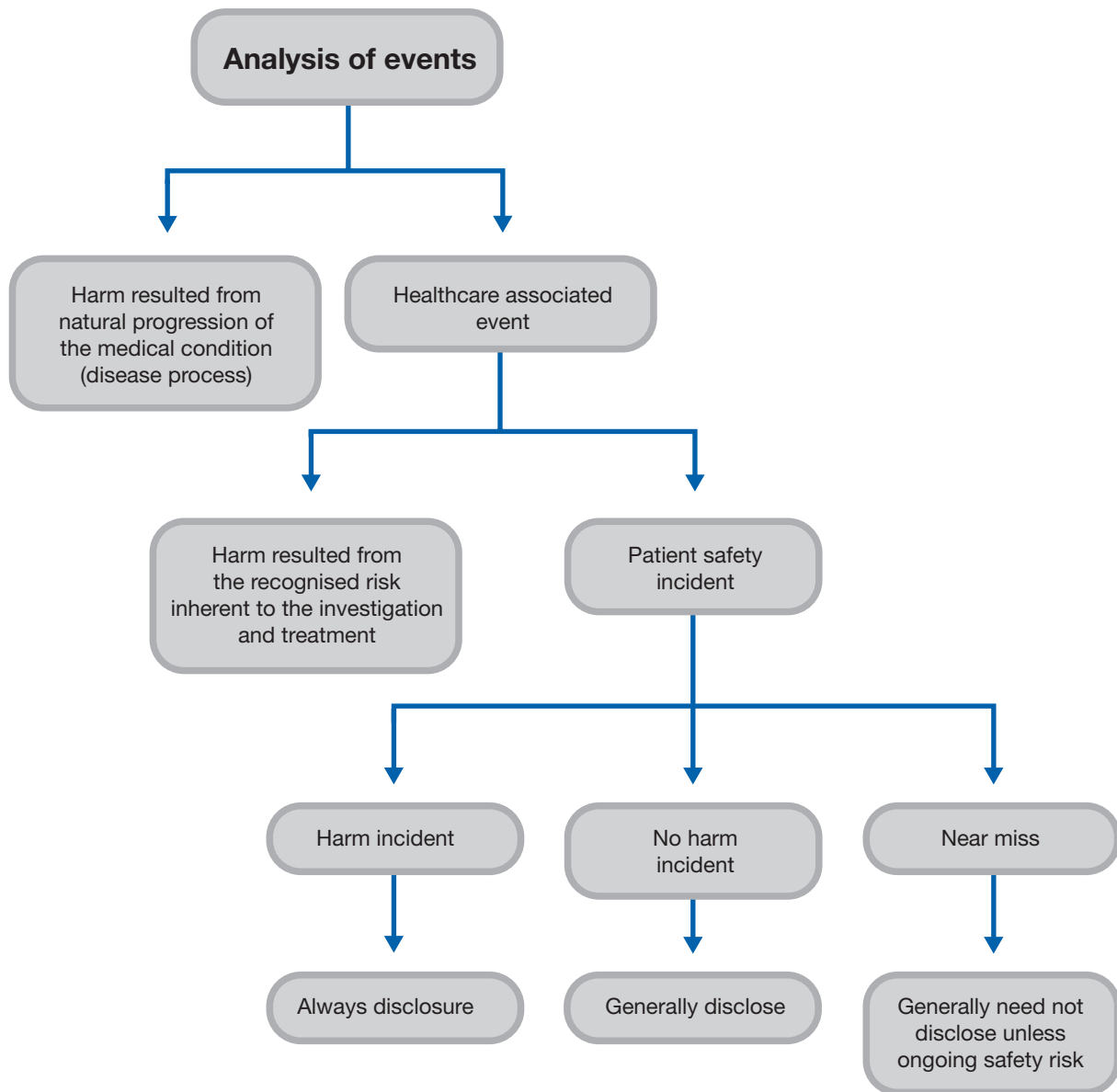
1.4.2: *When a service user experiences a “no harm event”*

“No harm events” should generally be disclosed e.g. a simple medication error resulting in no harm to the patient.

1.4.3: *When a service user is exposed to a “near miss event”*

Near miss events generally do not require disclosure but all 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 the service user should be appraised of the situation and supported going forward.

Algorithm 1: Circumstances when disclosure should take place, as demonstrated below:



1.5: Legal considerations

In its report *Building a Culture of Service user Safety* the Commission states:

“The system of compensation for medical negligence in existence in Ireland is not conducive to an open and honest communication process... Clinicians and risk managers are fearful of the consequences if they inform patients of an adverse event and often the event remains undisclosed and therefore the lessons from the event

are never learned or shared with others who may be in similar situations in the future”¹⁵.

At the same time, the Commission acknowledged, as a general principle:

...” that every patient is entitled to open and honest communication regarding his/her healthcare... If something happens to a patient in the course of treatment and care which impacts or could impact on the person’s health or quality of life, the patient should be informed of this event, given an adequate explanation of the event and reassured that measures have been taken to prevent such an event occurring again in the future to him/her or to anyone else”.

The Commission acknowledged the difficulties such a legal environment presents and made recommendations with regard to providing legal protection/privilege for open disclosure and clinical audit, in the belief that patient safety was best served by healthcare facilities and clinicians being free to participate fully in open disclosure and clinical audit. Some of the key recommendations include:

Recommendation 4:17

Legislation should be enacted to provide legal protection/privilege for open disclosure. Such legislation should ensure that open disclosure, which is undertaken in good faith in compliance with national standards developed in accordance with the recommendation above, cannot be used in litigation against the person making the disclosure.

Recommendation 7:11

Legislation should be enacted to give exemption from Freedom of Information legislation and to grant legal protection from disclosure to data related to patient safety and quality improvement that are collected and analysed by healthcare organisations for internal use or shared with others solely for purposes of improving safety and quality.

The Republic of Ireland currently has no protective legislation to assist the open disclosure process. It is envisaged that this status will change in the near future. A consultation paper by the Law Reform Commission in 2008 recommended that

¹⁵ Department of Health and Children. “Building a Culture of Service user Safety”—Report of the Commission on Patient Safety and Quality Assurance, Dublin Stationary Office 2008, Page 4.

“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.”¹⁶

It is anticipated that the upcoming Health Information Bill will contain provisions in it affording some degree of protection for healthcare personnel in relation to the open disclosure process.

Healthcare facilities and clinicians can consult with their relevant professional indemnity service in advance of participating in an open disclosure process, if required.

¹⁶ Law Reform Commission “Consultation Paper on Alternative Dispute Resolution” (LRC CP 50 2008).

The Principles of Open Disclosure

2

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 Agency¹⁷. 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/or 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 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

¹⁷ National Patient Safety Agency. *National Reporting and Learning Service Saying Sorry When Things Go Wrong Being Open-Communicating Patient Safety Incidents with Patients, their Families and Carers*, Maple Street, London 2009, page. 14.

also expect to be supported by the service following an adverse event and throughout the open disclosure and incident management and 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.

(See Appendix G of this document for further information on Clinical Governance Processes.)

9. **Confidentiality:** The information collated following an adverse event is often of a sensitive nature and therefore service user 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.

(See section 6.3.17 for further guidance on confidentiality)

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.

Open Disclosure: The service users' perspective

3

3.1: Introduction

The HSE National Healthcare Charter 2012 states that “Patients can expect open and appropriate communication throughout their care, especially when plans change or if something goes wrong.” When things go wrong service users and their families need to be provided with a factual explanation in relation to what has happened.

3.1.2: Health and social care providers need to understand:

- (a) The importance of informing service users of the potential for an adverse event to occur and the documentation of the salient points in relation to the same i.e. informing the service user of and explaining the possible side effects/complications associated with their condition/treatment/procedure.
- (b) The impact of adverse events on service users and what their needs are in the aftermath of an adverse event.
- (c) The importance of the open disclosure process in assisting service users when they are coping with an adverse event and enabling them to reach a stage of closure after the event.
- (d) The importance of open disclosure in relation to the safety culture within health and social care services and how service users can contribute to (i) the learning from adverse events and (ii) improving the quality of care delivered by health and social care services.
- (e) The importance of including the service user's perspective in relation to the event.

3.2: *The impact of adverse events on service users*

Service users may experience the following:

- Anxiety in relation to what has happened and the possible consequences for them and their family.
- Uncertainty in relation to their on-going care and the management of their condition.
- Fear of what lies ahead for them.
- Feelings of being “let down” or betrayed by the service.
- Anger/bitterness towards the service/staff involved and towards life i.e. why me?
- Humiliation.
- Disappointment.
- Confusion as to how the adverse event could have happened.
- Feelings of denial in relation to what has happened.
- Minor stress related symptoms or the more significant symptoms of Post-Traumatic Stress Disorder.
- Secondary problems e.g. social and economical factors associated with a longer stay in hospital or the impact of the adverse event.
- Concerns regarding the same thing happening to other service users
- Feeling of panic, flight or fight.

3.3: *Service user expectations*

Several studies have demonstrated that service users expect the following:

- At least 98% of service users want to be told the truth about what happened.
- Openness, transparency, respect, accountability and compassion.
- An acknowledgement of the adverse event.
- To know and understand what has happened to them.
- An apology/expression of regret regarding their condition and for what has happened.
- To have their story/concerns heard and staff to listen to them and understand things from their perspective.
- To have their questions answered and concerns addressed.
- To be involved in decisions about their care and to be aware of all of the options available to them.
- To be included as contributors to the investigation process.
- **To be provided with factual information which they can understand in relation to:**
 - (a) The adverse event.

- (b) Actions taken by the service following the event.
- (c) Actions taken or planned by the service to try to prevent a recurrence of the event.
- (d) Reviews which are happening in relation to the event and the outcome of the same.
- (e) Steps taken by the health and social care service in relation to any recommendations made by the review team.
- (f) What support services are available to them, if required, and how to access these support services.
- On-going communication with the healthcare team.
- An agreed plan and reassurance in relation to their on-going care and follow up.

3.4: Benefits of disclosure for service users

Research undertaken as part of the evaluation of the pilot of the National Open Disclosure Standard in Australia¹⁸ demonstrates the benefits of the open disclosure process to service users. They include the following:

- Open disclosure may assist in providing closure for the service user.
- It can assist in healing the relationship between the service user and the healthcare provider.
- It will help to rebuild trust and confidence that is vital for the service user/ healthcare partnership.
- It encourages a culture of honesty and openness.
- It can lead to enhanced relations with service users and healthcare providers.

3.5: Ethical considerations

The relationship between healthcare providers and their service users is based on the principles of trust, openness, honesty, transparency and respect. Health and social care providers are obligated to facilitate the disclosure of information to service users following an adverse event and to do so in a way which respects the service user's situation, feelings and autonomy and which puts the welfare of the service user first. If the service user has been provided with all of the factual information in relation to the adverse event he/she can make informed decisions in relation to their ongoing care.¹⁹ This fosters a relationship of trust between the service user and both the healthcare team and the health and social care service.

¹⁸ Final Report for the Australian Commission on Safety and Quality in Healthcare "Evaluation of the Pilot of the National Open Disclosure Standard" University of technology, Sydney (2007). Page 116-118.

¹⁹ Medical Council's "Guide to the Professional Conduct and Ethics for Registered Medical Practitioners" Dublin 2009, page 19

3.5.1: *The Medical Council’s “Guide to the Professional Conduct and Ethics for Registered Medical Practitioners”²⁰ obliges doctors to disclose adverse events to service users:*

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

3.5.2: The Nursing and Midwifery Board of Ireland also promote that nurses and midwives actively participate in the open disclosure process and will be including this in their Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives which is currently being revised.

3.5.3: It is important that all health and social care services have the required governance processes in place to ensure that open disclosure occurs and to address/manage situations when there is a difference of opinion as to whether open disclosure should occur or not.

²⁰ Australian Commission on Safety and Quality in Healthcare 2003: *Open disclosure Manager’s Handbook, A Handbook for Hospital Managers to assist with the Implementation of the Open Disclosure Standard*, Canberra p 3.

Staff Support: Caring for the “second victims” of an adverse event

4.1: Introduction

These guidelines demonstrate how open disclosure plays an important role in relation to how well service users cope following an adverse event.

Existing literature also demonstrates how the open disclosure process plays an equally important role in how well staff who are involved in the adverse event i.e. the Second Victims, cope following the event. Disclosure and apology can help staff to heal and recover from the event and it also helps to preserve the relationship between staff and service users.²¹

Research has demonstrated that the under-reporting of clinical incidents/adverse events by staff results mainly from their fear of litigation and disciplinary action and from working in a culture of infallibility which does not encourage honesty and transparency, both of which are required in the open disclosure process.

4.2: The impact of adverse events on staff

A significant proportion of healthcare workers will experience varying degrees of stress as a result of exposure to an adverse event. It is important to be aware that staff can suffer from traumatic stress which is associated with minor incidents and near misses as well as major and catastrophic incidents where a service user has died or has been left with a major disability. Individual responses range from common uncomplicated stress-related reactions to the more complex post-traumatic stress disorder.²² Connecting with their vulnerability enhances insight and helps staff to be more compassionate towards each other and towards their patients.

²¹ Canadian Disclosure Guidelines: Being Open with Patients and Families, Canadian Patient Safety Institute, Edmonton 2011

²² Ibid

4.2.1: Staff may experience the following:

- Feelings of incompetence and isolation.
- Denial and avoidance of responsibility – discounting of the importance of the event.
- Emotional distancing.
- Overwhelming guilt in relation to the event itself and the impact on the service user.
- Guilt if open disclosure has not occurred.
- Poor insight.
- Panic resulting in a fight or flight reaction.
- Feelings of abandonment.
- A desire to disclose to the service user but with uncertainty in relation to how to proceed with this.
- **Symptoms of Post-Traumatic Stress Disorder (PTSD): While everyone experiences PTSD differently, there are three main types of symptoms:**
 - (a) Re-experiencing the traumatic event;
 - (b) Avoiding reminders of the trauma;
 - (c) Increased anxiety and emotional arousal.

(See Appendix 'B' of this document for a detailed list of symptoms associated with PTSD)

- Improved recovery following the open disclosure process.

4.3: Stages associated with staff reaction following an adverse event:

There are six recognised stages associated with staff reaction in the aftermath of an adverse event/traumatic event as follows: ²³

²³ Scott SD, Hirschinger LE, Cox KR, McCoig M, Brandt J, Hall LW. The natural history of recovery for the healthcare provider "second victim" after adverse service users. *Qual Saf Health Care*. 2009; 18(5):325-330.

Table A: Stages associated with staff reaction following an adverse event

STAGE NAME	FEATURES OF THIS STAGE
1 Chaos	<ul style="list-style-type: none"> • Error realised and recognised • Questioning how and why did it happen? • Care for the patient
2 Intrusive reflections	<ul style="list-style-type: none"> • Re-evaluation of the event • Haunted re-enactments of the event • Self isolation
3 Restoring personal integrity	<ul style="list-style-type: none"> • Managing gossip • Questioning trust • Fear
4 Enduring the inquisition	<ul style="list-style-type: none"> • Realisation of seriousness • Wonder about repercussions • Who can I talk to?
5 Obtaining emotional first aid	<ul style="list-style-type: none"> • Seeking personal and professional support • Where can I turn to for help?
6 Moving on:	
(a) Dropping out	<ul style="list-style-type: none"> • Changing professional role • Leaving profession, or • Going to a new practice location
(b) Surviving	<ul style="list-style-type: none"> • Coping • Continue to be plagued by the event but performing at the expected level
(c) Thriving	<ul style="list-style-type: none"> • Gains insight and perspective into error • Learns from the event • Not focused solely on the error

4.4: Barriers to disclosure

The following are some of the significant barriers/concerns identified by healthcare providers in relation to conducting the disclosure process following an adverse event:

- Fear of litigation: There is currently no legislation to provide legal protection for health and social care staff in the Republic of Ireland when disclosing an adverse event. This can be a major inhibiting factor.
- There is a lack of knowledge as to how to disclose an adverse event.
- There is a lack of knowledge as to what to disclose. For example, whether to disclose an error if the harm was trivial or if the service user was unaware that harm had occurred.²⁴
- Lack of training to assist healthcare staff when disclosing adverse events to service users.
- Fear concerning an adverse effect on professional advancement and reputation.²⁵
- Uncertainty with regard to the extent of the information to be disclosed. A survey of American and Canadian physicians found a wide variation regarding the information physicians would disclose: 56% mentioned the adverse effect but not the error while 42% disclosed that an error did in fact occur.²⁶
- Lack of peer support and support from management staff.

4.5: Benefits for staff

Open disclosure:

- Encourages a culture of honesty and openness.
- Helps to foster an environment where staff are more willing to learn from adverse outcomes.
- Enhances the professional relationship between health and social care services management staff and clinicians.
- Enhances how professionals communicate with each other with regard to clinical outcomes.
- Leads to better relations with service users.
- Leads to improved staff recovery and closure.

²⁴ Gallagher, T.H., Garbutt, J. M., Kapp, J.M., et al "Choosing your words carefully: How physicians would disclose harmful medical errors to service users. *Arch Intern Med*, 2006 Vol.166, pp. 1585-1593.

²⁵ Finkelstein, D., Wu, A. W., Holtzman, N. A et al "When a physician harms a service user by a medical error: Ethical, Legal and Risk Management Considerations" *J Clin Ethics*, 1997, Vol. 8, No. 4, pp. 330-335.

²⁶ Gallagher, T.H., Waterman, A.D., Garbutt, J.M., et al "US and Canadian physicians" attitudes and experiences regarding disclosing errors to service users. *Arch Intern Med*, Vol 166, pp. 1605-1611.

- Allows the staff member's personal and professional integrity to remain intact.
- Lightens the burden of guilt.
- Provides an opportunity for staff to engage in reflective learning and to be more effective in the future.

4.6: Responsibility of the service to staff

4.6.1: Cultural change/promoting a “just” culture

Staff support does not begin following an adverse event. It begins with the development and support of a ‘just’ culture within the service. A just culture supports a disclosure culture. A just culture seeks to balance the need to learn from mistakes and the need to take disciplinary action.²⁷ It is important that health and social care services foster a positive, supportive work environment where good communication, support and mutual respect is the norm.²⁸ Where a true just culture exists “no one is ever hesitant to speak up on behalf of a patient and everyone has a high degree of confidence that their concerns will be heard respectfully and acted upon.”²⁹

Where a just culture exists staff will feel more encouraged and willing to report incidents/adverse events/near miss events, including their own, in the knowledge that there is fair minded treatment of this information and that there are structures in place within the service to promote learning from events and to ensure that steps are taken to prevent/reduce the likelihood of a recurrence of the event. It is important that staff involved in the adverse event can participate in the review of the event and that they are also involved in helping to bring the event to closure/resolution.

A just culture offers a climate which fosters trust and in which staff are not held accountable for systems failings over which they have no control. There needs to be a general acknowledgement within the multidisciplinary healthcare team and the general public that errors

²⁷ WHO Conceptual Framework for the International Classification for Patient Safety, Version Final Technical Report, Geneva 1.1, 2009

²⁸ HSE Policy for the Prevention and Management of Stress in the Workplace 2012

²⁹ Leonard MI, Physician Leader, Kaiser Permanente, Respectful Management of Serious Clinical Adverse Events, Cambridge, Massachusetts: Institute for Healthcare Improvement; 2011

are inevitable. A “just” culture however is not “non accountable”. Investigations should identify where reckless/negligent conduct and known violations of policy/procedure exist and ensure that the appropriate action is taken as per the service’s internal policies, procedures, protocols and/or guidelines.

4.6.2: Support frameworks

4.6.2.1: Significant commitment is required from health and social care services to:

- Have quality assured open disclosure frameworks in place;
- Help staff to overcome any initial reluctance they are experiencing in relation to seeking support;
- Support staff during the open disclosure process; and
- Identify and address the practical, professional, psychological, emotional and social needs of staff in the aftermath of an adverse event.

4.6.2.2: Professor Albert Wu has published many works on medical error and the ‘second victim’ and he makes the following recommendations in relation to staff support following an adverse event:

- There should be a humanistic approach to investigations that explicitly acknowledges the inevitability of second victims.
- When risk management is notified about a significant adverse event, in addition to the root cause analysis investigation that is initiated, there needs to be a parallel investigation to determine if there are second victims.
- The emotional health of caregivers needs to be a consideration in incident investigation and resulting action plans.
- There needs to be increased awareness institution wide, delivery of emotional first aid, utilisation of existing resources for counselling when necessary and the necessity of treatment in some cases.
- Services should acknowledge the potential need for formal psychological intervention for particularly profound reactions.
- In conducting the investigation, care should be taken to avoid treating the physician like he or she is on “trial” for a crime.

- Why not begin every investigation by saying to the involved staff member “This must be very difficult for you. How are you doing?”

4.6.2.3: The HSE Policy for Preventing and Managing Critical Incident Stress 2012 developed by the National Health and Safety Advisers Group outlines the core elements required to meet legal obligations to provide a duty of care to employees, as summarised below. In the event of a critical incident or potentially traumatic event managers should ensure that the following actions are taken:

- **Ensure that all employees affected have access to immediate practical and social support during and immediately after the event**

This may include organising transport home, contacting a family member, providing refreshments, organising time out, listening to their concerns, acknowledging what has happened etc.

- **Make employees aware of the Occupational Health, Employee Assistance and Staff Counselling Services available to them and enable them to attend if they request to**

This is not intended as a clinical intervention at this stage but provides an opportunity for staff to be assessed for possible post-traumatic stress reactions.

- **Provide factual information and normalise people’s reactions (not symptoms)**

People involved in an adverse event require information in relation to what happened, how, why, who and what is required of them in relation to notification, documentation, investigations etc. They need to be kept informed in relation to the factual information available in relation to the event and what plans are in place to manage the situation and their expected level of involvement in the same. They need to be provided with information in relation to the normal responses/reactions people may experience following an adverse event.

- **Promote proactive problem solving**

Research indicates that encouraging people to take an active role helps them to feel more in control of the situation.

- **Monitor staff to identify people who may be at-risk**

This includes following up with staff in the aftermath of an adverse event (how, when and how often you check in with them should be proportionate to the event and the level of distress demonstrated by the employee remembering that some staff can be adversely affected by minor/near miss events), checking in with them regularly, checking for symptoms of PTSD and referring to the appropriate services, if required. This demonstrates our genuine support for employees. It is important to maintain this support during and immediately after the event, during any absences/leave from work, on return to work and throughout the investigation and open disclosure process.

- **Provide speedy access to early intervention for people who report on-going distress**

Ensure timely and easy access to support services when they are required.

- **Ensure that appropriate organisational liaison and feedback occurs**

There should be a link between support services treating affected employees, the staff involved and management.

4.6.2.4: Staff debriefing

It is important to stress that critical incident de-briefing following an adverse event should not be deemed as mandatory for staff involved in the event but that it should be recognised as a valuable tool for health care services to have at their disposal. Staff should be encouraged to attend debriefing and advised of the benefits. Research into critical incident debriefing and Post Traumatic Stress Disorder (PTSD) has demonstrated unclear conclusions.

The purpose of staff debriefing is to:

- Evaluate the emotional and physical impact on all individuals involved.
- Provide support to reduce the isolation of staff.
- Relieve stress at an early stage.
- Reinforce team spirit.
- Decrease isolation at a time when staff may want to withdraw from social contact.
- Reduce dysfunctional reactions or health consequences over time.
- Identify the need for and provide counselling or support for all individuals, in relation to any trauma which may have resulted or emerged from the incident.

It should be recognised that positive debriefing can be undertaken at different levels and staff should be involved in the decision as to what level of debriefing they feel will be of most benefit to them. The level of debriefing will be dependent on the incident, the staff involved and the consequences of the event.

(See Appendix “C” of this document provides further information on the debriefing process)

4.6.2.5: Staff support person

All staff involved in an adverse event should have access to a staff support person and a contact number for their allocated staff support person should be provided immediately following the event. Line managers have a responsibility to ensure that effective measures are taken to ensure that safe working practices are promoted and that a post incident review is undertaken to identify where informal/formal incident de-briefing should be implemented/offered.

4.6.2.6: Training and education/Open Disclosure Support Networks

The service has a responsibility to ensure that all clinicians have access to training programmes and resources in relation to the open disclosure process and effective communication with service users following an adverse event. Staff trained in open disclosure can assist their colleagues through a peer support/buddy system.

A comprehensive and practical training programme/module will typically address the actual policy, inclusive of real life scenarios together with sample language. Training for the disclosure team is a crucial factor if open disclosure is to be implemented successfully. This is recognised nationally and internationally as a fundamental pre-requisite to an effective open disclosure process.^{30, 31, 32}

It is recommended that the service identifies trained individuals as leads in open disclosure within the service and who will form part of the membership of an open disclosure committee or alternative quality, risk management or governance committee.

4.6.2.7: Helping staff to help themselves

It is important that staff are aware that many of the feelings/symptoms they are experiencing following an adverse event are the norm i.e. a normal response to an abnormal experience and that making a conscious effort to work through it will ultimately help them to overcome this response.

³⁰ Department of Health and Children. "Building a Culture of Patient Safety"—Report of the Commission on Patient Safety and Quality Assurance. Dublin, Stationary office, 2008 page 82

³¹ Australian Commission on Safety and Quality in Healthcare: Evaluation of the Pilot of the National Open disclosure Standard, 2007 page 80.

³² Canadian Patient Safety Institute: Canadian disclosure guidelines, 2008 page 13.

It is equally important that staff recognise when this response is too intense or lasting too long and that they should contact their GP for help and advice when this is the case. Staff can also request referral to the Occupational Health Department or Employee Assistance Programme via their line manager or they can self-refer if preferred.

*(See Appendix “D” of this document entitled:
“Taking care of yourself in the aftermath of an adverse event”*

*See also the HSE and SCA staff support booklet:
Supporting staff following an adverse event.
The “ASSIST ME” model).*

Taking a structured approach to implementing Open Disclosure

5.1: Introduction

Health and social care services and the general public need to acknowledge that there are risks associated with healthcare and that the outcome for the service user may not always be what is expected. There is an absolute need to link this process with informed consent. As part of the consent process there is a need to explicitly discuss potential risks and complications. If this is done correctly in advance then a complication occurring may not equate to an adverse event and it can be explained as a complication previously discussed prior to the procedure.

Health and social care services have a responsibility to ensure that there are effective systems, processes and resources in place to identify, manage and reduce risks to members of the public and staff. This requires a culture that encourages the notification of adverse events when they occur and which also promotes open, honest and timely communication between staff and service users following an adverse event. A systems approach should be undertaken in relation to the review of adverse events, without the removal of professional/individual accountability.

The open disclosure process is identified under Theme 3 of the National Standards for Safer Better Healthcare 2012 titled “Safe Care and Support” which recognises that the safety of service users is paramount. *“Should an adverse event occur where a service user is harmed, services have formal arrangements in place to respond to this event and support the service user and their family. A high quality, safe service learns from all information relevant to the provision of safe services and particularly from situations where things have gone wrong”.*

Standard 3.5 under this theme states that *“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: Taking a structured change management approach to implementing the Principles of Open Disclosure within Health and Social Care Services.

Systems changes and changes in relation to the way we work can be achieved in a short time but changes in attitude and behaviour can take much longer. The following are examples of best practice guidelines, based on the themes of the National Standards for Safer Better Healthcare 2012, which may assist in the change management process which is required in health and social care services to implement the principles of open disclosure effectively.

5.2.1: Leadership, governance and management

Health and social care services need to be able to demonstrate, through good systems of clinical governance and quality assurance, that there is learning from adverse events and that appropriate actions are taken to try to prevent a recurrence of such events. Services need to ensure that service users and their families are involved in and can contribute to this learning.

5.2.1.1: Leadership:

- A Board Level Commitment is required in the service in relation to implementing the principles of Open Disclosure. This needs to be led at senior management level within health and social care services e.g. the Chairperson of the Board, Hospital/Group CEO, Executive/Senior Management Team, General Manager, ISA Manager, Regional Director of Operations, Director of Nursing and Clinical Director.
- Board/Senior Management Commitment should be evident in promotional materials within the service i.e. posters, patient information leaflets, website, staff induction/orientation programmes etc.
- Open disclosure leads should be identified within the service. These can be leads with existing responsibilities for clinical governance, risk management, quality and risk or complaints management. However, it is

recommended that the open disclosure leads identified should include leads at senior clinician level.

- The nominated open disclosure leads should be publicised within the service.
- It is recommended that the service sets up an open disclosure committee or that open disclosure is a standing item on the agenda of any existing quality and safety, clinical governance or alternative relative committee/forum.

If an organisation sets up a separate open disclosure committee the chair should be a member of the QPS Committee also. This committee will act as an advisory committee and have the responsibility of monitoring and assessing the performance of the service in relation to the related requirements of the National Standards for Safer Better Healthcare 2012 and also the HSE National Policy on Open Disclosure.

If open disclosure is subsumed into an existing QPS or alternative committee there should be a forum for leads to meet to advance implementation.

There should be service user participation/involvement on this committee. Committee members, including service user representatives, should have attended open disclosure training.

5.2.1.2: Local policy:

- Existing relevant local/internal policies should align with the National Standards for Safer Better Healthcare 2012, the National Policy on Open Disclosure 2013 and the National Guidelines on Open Disclosure 2013.

- The open disclosure policy in the service should align with and direct other related operational policies and the service's strategic objectives.
- The service should identify how open disclosure is embedded within risk management and clinical governance processes including complaints management.

5.2.1.3: *Visibility:*

- Raise awareness and understanding in relation to the principles of open disclosure and the service's internal policy among staff, service users and the public, making information visible to all.
- Promote the principles of open disclosure among staff via newsletters, team meetings, intranet, special interest meetings, governance meetings, quality and risk committees or any other existing applicable forums.
- Include information on open disclosure in promotional materials e.g. patient information leaflets, websites, posters etc.

5.2.2: *Person centred care and support*

Service users and their families may need considerable support following an adverse event. Service users can be supported by their families/support persons, staff within the service, trained patient advocates, counselling services, religious representatives etc.

- Identify what supports are available within the service for service users who require immediate or longer term support in the aftermath of an adverse event.
- Identify key contact personnel who will provide direct liaison with the service user during the open disclosure process.

- Identify what patient advocacy groups are currently operating within the service's catchment area and ensure that they are aware of the open disclosure policy and guidelines. Training may be offered to patient advocates/members of service user representative groups.

5.2.3: Effective care and support

5.2.3.1: Learning from adverse events

Consider:

- How adverse events/incidents are reported within the health and social care service.
- How are these incidents recorded and monitored?
- How does the service monitor if there are trends appearing?
- How does the service record and demonstrate the learning from adverse events?
- How does the service share learning from adverse events across the service and with other health and social care services?
- How does the service involve service users in the learning from adverse events and ensure that they are heard and can contribute to the learning and change process?

5.2.3.2: Audit

Include audit of open disclosure as part of on-going internal audit processes.

Suggested areas to audit are as follows:

- 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.
- The inclusion of open disclosure in the incident management process.

5.2.3.3: Support for staff

- Identify what supports are available within the service for staff who require immediate and longer term support in the aftermath of an adverse event.
- Establish what services are available for staff via the Employee Assistance Programme/Occupational Health Department.
- Consider what level of on-going support is available for frontline staff, how these staff are assessed in relation to their risk of personal harm and their ability to safely return to providing care to service users.
- Identify staff support person(s) and publicise their names and contact details within the service. A list of staff support persons and their contact details can be added as an appendix to the service's open disclosure policy document.
- Consider how the service manages the debriefing process for staff following an adverse event and what level of training staff have accessed to deliver this service, if applicable.
- Ensure that staff are involved in the review of the adverse event and the open disclosure process and that they are provided with an opportunity to contribute to the learning from the event.
- Identify what mechanisms are in place in the service to share learning within the service and with other services.
- Ensure that adverse events are discussed within the multidisciplinary team at ward/unit/directorate level.

5.2.3.4: *Training*

- Ensure training programmes in open disclosure are provided by appropriately trained staff.
- Organise open disclosure training for staff who may be involved in open disclosure meetings with service users i.e. consultants and other relevant clinical and managerial staff, leads in open disclosure, staff support persons etc.
- Align existing training programmes to incorporate open disclosure guidance.
- Revise internal and corporate induction/orientation programmes to incorporate open disclosure training for all staff groups.
- Revise staff handbooks, induction checklists, complaints procedure, quality and risk management procedures to incorporate guidance on open disclosure.
- Consider the inclusion of a question on open disclosure in staff recruitment interviews.
- Include service user/patient stories as staff very often relate better to service user experiences.
- Present anonymised open disclosure case scenarios at meetings of the multidisciplinary team, grand rounds, peer support groups etc.

(See Appendix “E” of this document for a sample “Organisational Readiness Checklist”)

The Open Disclosure Process

6

6.1: Introduction

Open disclosure is an on-going and continuous communication process and more than one meeting with the service user may be required, depending on the severity of the outcome for the service user.

The disclosure process will depend on the particular situation of the service user and their clinical, informational and emotional needs. Many common adverse events are related to inherent risks of investigations and/or treatment and therefore may not require a lengthy disclosure process. Although all complications should be discussed with service users, those which are not serious in nature will not usually require a formal disclosure process and are usually unlikely to require much analysis e.g. venepuncture wrong patient.

The objective of the disclosure meeting(s) is to provide factual information to the service user in a sensitive and empathetic manner in addition to arranging further supports if required and to facilitate their on-going care.

6.2: Types of disclosure

The type of disclosure required will be defined by the degree of harm the service user has experienced and the level of additional interventions/treatments required as a result of this harm. It will also depend on the nature of the event and when the adverse event becomes known e.g. the service user has been discharged home already or the service user has died as a result of an adverse event. Disclosure meetings may vary from disclosure at the patient's bedside/clinic setting to formal planned open disclosure meetings which will usually be required when a service user has experienced moderate/severe harm or the service user has died and a meeting with his/her family is required.

(See Table B overleaf)

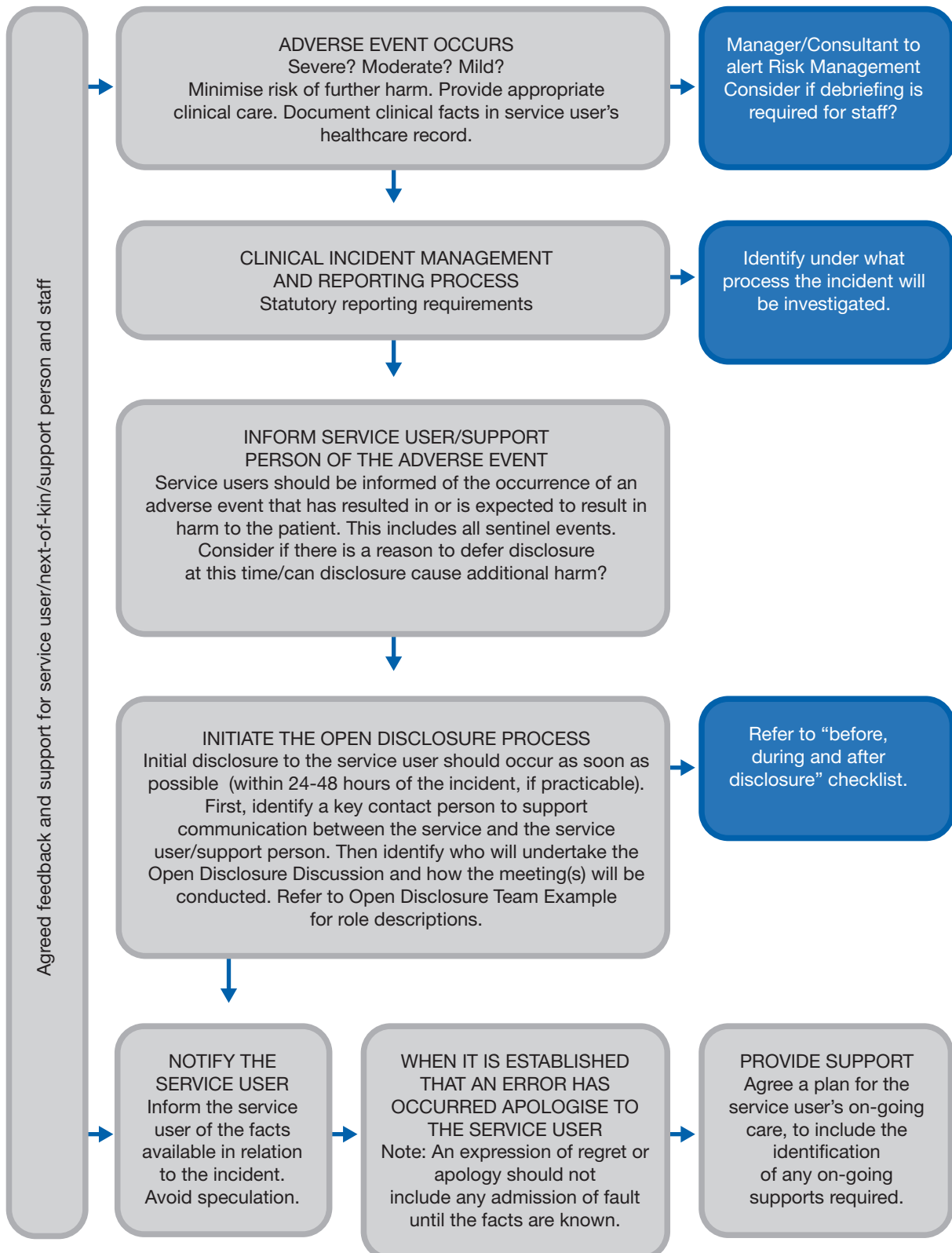
Table B: Types of disclosure

	Examples	Type of disclosure required (summary)	No of meetings
A. No harm	<p>Medication error – service user is asymptomatic.</p> <p>Transfusion error – wrong patient but compatible blood group.</p>	<ol style="list-style-type: none"> 1. Review the event with the staff involved. Anticipate potential questions/concerns the service user may have. 2. Disclosure to service user as soon as possible after the event by the most appropriate person(s) and including a senior member of staff. 3. Acknowledgement, factual explanation, apology for any concerns/distress caused to the service user and/or for any error if it is established that an error has occurred, reassurance regarding “no harm” experienced and regarding the steps taken or planned to try to prevent a recurrence of the event. 4. Document in the clinical record the salient points of the disclosure discussion and the details of any apology provided and/or actions agreed. 	Usually one meeting with the service user is sufficient. This will depend on actions agreed with the service user and/or if further facts need to be established.
B. Mild harm	<p>Medication error – patient is symptomatic but symptoms are mild and there is no loss of function.</p>	<ol style="list-style-type: none"> 1. Review the event with the staff involved. Anticipate potential questions/concerns the service user may have. 2. Disclosure to service user as soon as possible after the event by the most appropriate person(s) and including a senior member of staff. 3. Acknowledgement, factual explanation, apology for any concerns/distress caused to the service user and/or for any error if it is established that an error has occurred, reassurance regarding the harm experienced by the service user, their on-going care and steps taken or planned to try to prevent a recurrence of the event. 4. Document in the clinical record the salient points of the disclosure discussion and the details of any apology provided and/or actions agreed. 	Usually one meeting with the service user is sufficient. This will depend on actions agreed with the service user and/or if further facts need to be established..
C. Moderate harm	<p>Wrong site surgery – removal of toenail right great toe instead of left great toe. Further surgery and anaesthesia will be required.</p>	<ol style="list-style-type: none"> 1. Review the event with the staff involved. 2. Identify disclosure team, key contact person, disclosure lead and deputy discloser. 3. Plan disclosure meeting. 4. Anticipate potential questions/concerns the service user may have. 5. Disclosure to service user as soon as possible after the event by the most appropriate person(s) and including a senior member of staff. 6. Acknowledgement, factual explanation, apology for any concerns/distress caused to the service user and/or for any error if it has been established that an error has occurred, reassurance in relation to their on-going care involving the service user in any decisions made, reassurance in relation to the steps taken or planned to try to prevent a recurrence of the event. 7. Agree date for follow up meeting, if required. 8. Document in the clinical record the salient points of the disclosure discussion and the details of any apology provided and/or actions agreed. 	Will usually require more than one meeting with the service user. Depends on the factual information available, actions agreed and the wishes of the service user and/or their next of kin/family member/nominated support person.

Examples	Type of disclosure required (summary)	No of meetings
<p>a) Wrong diagnosis – e.g. organ removed based on incorrect pathology/histology.</p> <p>b) Administration of penicillin to a patient with a known penicillin allergy – patient dies.</p> <p>c) Wrong site surgery - patient has experienced significant harm</p>	<ol style="list-style-type: none"> 1. Review the event with the staff involved. 2. Identify disclosure team, key contact person and disclosure lead and deputy discloser. 3. Plan disclosure meeting. 4. Anticipate potential questions/concerns the service user may have. 5. Disclosure to service user as soon as possible after the event by the most appropriate person(s) and including a senior member of staff. 6. Acknowledgement, factual explanation, apology for any concerns/distress caused to the service user and/or for any error if it has been established that an error has occurred, reassurance in relation to their ongoing care involving the service user in any decisions made, reassurance in relation to the steps taken or planned to try to prevent a recurrence of the event. 7. Agree date for follow up meeting, if required. 8. Document in the clinical record the salient points of the disclosure discussion and the details of any apology provided and/or actions agreed. 9. When a service user dies as a result of an adverse event it is crucial that the channels of communication are opened as soon as possible with the service user's nominated next of kin/family member(s)/support person(s) in a sensitive and empathetic manner and with consideration to their grieving process. The sharing of information must comply with the service users confidentiality rights. 	<p>Will usually require more than one meeting. with the service user and/or their next of in/ family member or nominated support person. Depends on the factual information available, actions agreed and the wishes of those concerned.</p>

6.3: The stages of Open Disclosure

Algorithm 2: The stages of Open Disclosure:



6.3.1: *Reporting the adverse event*

Following the identification of the adverse event the person who identified or witnessed the event must report the event as per the requirements of the HSE Incident Management Policy.

6.3.2: *Managing the clinical care of the service user*

It is important to remember that the priority of the healthcare provider following an adverse event is to (a) manage any immediate risks to the service user/others (b) manage the clinical needs of the service user and (c) provide reassurance to the service user in relation to their condition and their on-going care.³³

It may be necessary to consider whether it is appropriate for the clinician to provide further care to the service user and this decision may be influenced by:

- The professional relationship between the clinician and the service user.
- Whether the clinician has the necessary expertise to deliver any additional care required by the service user.
- Whether the service user requests a transfer of their care to another clinician.
- The availability of other clinicians with the expertise to deliver the care required by the service user.
- The emotional state and degree of stress of the clinician and whether this may have an impact on his/her capacity to provide the necessary care to the service user.

6.3.3: *Preparation for an Open Disclosure meeting*

Adequate preparation for the disclosure meeting with the service user is crucial. A meeting which is well planned will have a more positive outcome for the service user, their family/support person(s) and also for the staff members involved:

³³ The Canadian Medical Protective Association. 'Communicating with your patient about harm; The Disclosure Roadmap': 2008, Disclosure of Adverse events.

- A preliminary discussion with the relevant members of the multidisciplinary team to establish the clinical facts at the time of the event should take place prior to meeting with the service user.
- Consideration should be given as to who should be present from the service at the disclosure meeting. The planning discussions should include all members of the healthcare team who will be involved in the disclosure process. Consider inviting trainees, if appropriate, as part of their learning experience.
- A key contact person should be identified who will act as the liaison with the service user. This person should not be the lead discloser.
- To establish the facts takes time. Not all of the facts need to be established prior to meeting with the service user.
- **Think ahead and anticipate potential questions. Plan in advance what you are going to say to the service user in relation to:**
 - (a) Their clinical condition
 - (b) What has happened?
 - (c) Treatment plans and the options available.
- It is recommended that the number of healthcare individuals involved in the disclosure meeting should be limited to four to five, if possible.
- Consideration should be given as to whether an interpreter or any additional services are required.
- Ensure that the service user is aware of the purpose of the meeting and encourage him/her to have a family member/support person present. The key contact person should establish who will be attending the meeting with the service user and their role i.e. family member, friend, solicitor.

(See Tables C and D overleaf for guidance on a sample disclosure team)

Table C: Disclosure team example

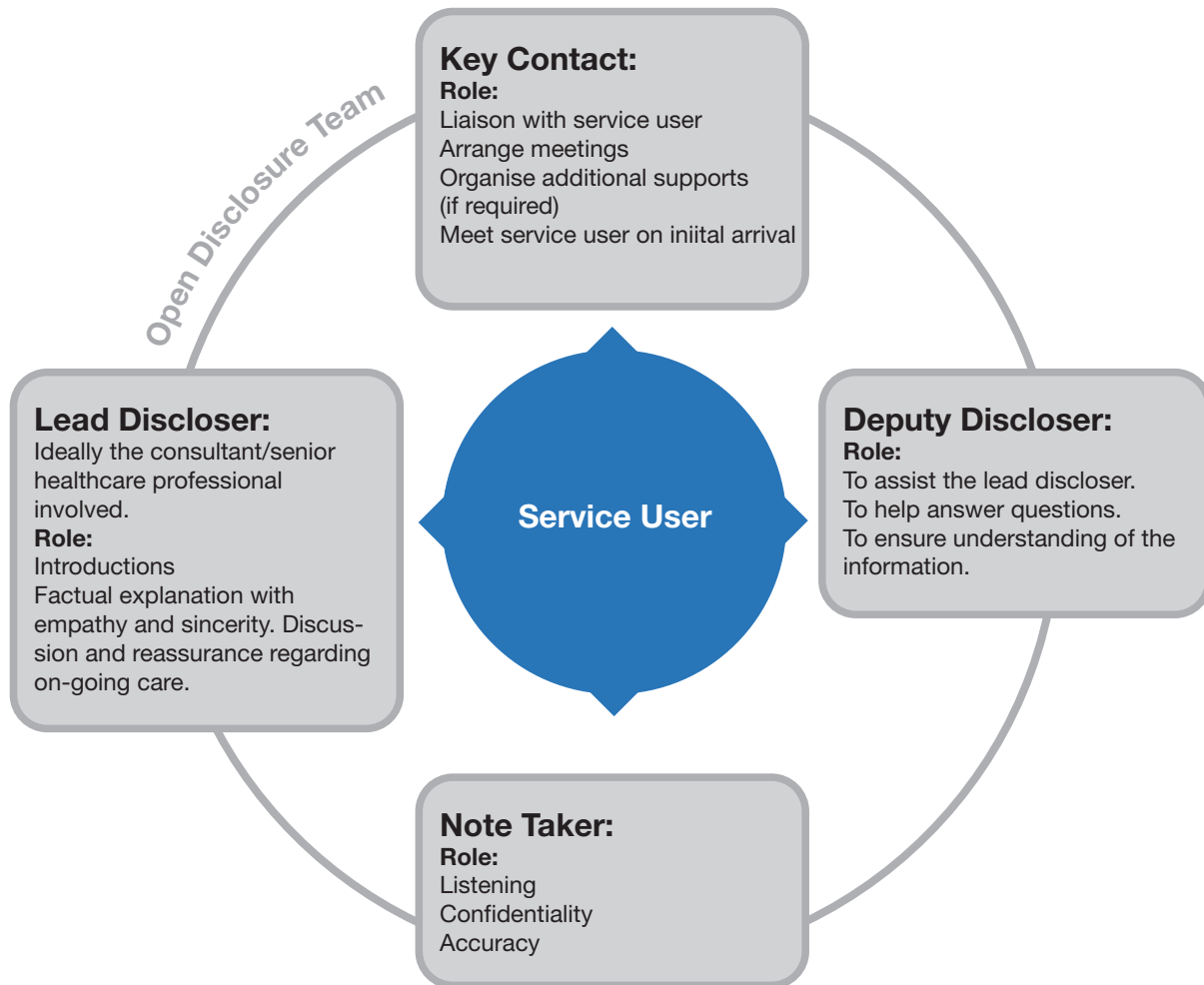


Table D: Considerations regarding who should attend the disclosure meeting

Have you considered...?

Does the Hospital Manager/Local General Manager know that an open disclosure meeting is happening?

Who else may need to know to know?

Clinical Director?

Director of Nursing?

Risk Management?

Indemnifier?

Allied Healthcare Professionals?

Public Health Nursing Staff?

Do any other members of the multidisciplinary team need to be informed?

6.3.4: *Disclosure lead – Who?*

A decision must be made as to who will lead the disclosure in addition to what other personnel should be present. This decision needs to take account of the following points:

- The service user's preference as to who should be in attendance.
- What has happened?
- Which healthcare provider knows most about what has happened?
- Which healthcare provider has an existing relationship with the service user?
- Who can explain the future care plan for the service user?
- Who in the service has had training/experience in relation to open disclosure?
- It is recommended and usually expected by service users and their families that the discussion is lead by the most senior clinician/senior professional who may be supported by other members of the multidisciplinary team who are providing care to the service user. If this person cannot be present his/her absence should be explained in a sensitive manner.
- Consider if the most senior clinician/most senior professional is the most appropriate person to lead in the disclosure? He/she may not be in a position at the time to disclose what happened, particularly if the outcome has been catastrophic for the service user? Consideration should be given to the impact of the adverse event on them and how they are coping.
- Consider the communication skills of the proposed lead discloser – good communication skills are critical to an effective disclosure process.
- Establish if there are multiple specialities involved and if so, who should be involved and who should lead out in the open disclosure process?

(Refer to Chapter 7: Specific Circumstances re multiple disclosures)

6.3.5: *When to disclose – Timing*

Ideally the disclosure process should commence immediately or as soon as possible after the adverse event i.e. as soon as the patient is physically and emotionally available to be told. Best practice indicates that open disclosure should occur within one to two days following the adverse event or from when the adverse event becomes known.³⁴ This may be dependent on the medical condition of the service user e.g. if a service user is administered the wrong medication they should be informed of the error immediately when the error is realised or if an adverse event occurs during a procedure in theatre the service user should be informed when they are awake and recovered from anaesthesia. If you wait on the service user to start asking questions this may have a negative effect on the process and it can increase the service user's level of anxiety. If the service user is no longer an in-patient it is important to give them enough notice to enable them to prepare for the meeting. Disclosure meetings should be undertaken in daylight hours and not during a night shift.

The appropriate timing of disclosure may not always be clear and can be dependent on a number of factors such as:

- The degree of harm the service user has experienced i.e. the clinical status of the service user following the adverse event.
- The availability of the service user i.e. when an adverse event becomes known following the service user's discharge home e.g. missed diagnosis.
- The availability and agreement of the service user to attend a meeting.
- The known facts available at that time.
- Multiple disclosures i.e. multiple service users involved.
- Consideration as to whether disclosure could be more harmful than beneficial?

(See section 6.3.9 of this document in relation to deferring disclosure)

³⁴ Canadian Patient Safety Institute: Canadian Disclosure Guidelines, Edmonton Canada, 2008 p.20.

6.3.6: *Where to disclose*

The key contact person, in liaison with the service user, should organise the location of the disclosure meeting. Consideration should be given to the following:

- The meeting may have to be arranged off site, depending on the type of adverse event.
- If a meeting in the service user's home is required a minimum of two staff should attend from the service and management should be informed that this meeting is happening.
- The key contact person should meet the service user on arrival.
- The room should be located away from the ward/unit/service and any out-patient clinic(s).
- The room temperature and ventilation should be considered according to season.
- Avoid barriers in the room between staff and the service user/family e.g. a desk. A round table is preferable.
- Put a "Do not disturb" notice on the door of the meeting room while the meeting is in progress.
- Select a quiet location.
- Consider if additional services are needed, such as wheelchair ramps, etc?
- Bleeps/mobiles to be turned off.
- Refreshments arranged.

6.3.7: *The initial disclosure discussion*

The first meeting with the service user should include the following:

- **An introduction of the team at the disclosure meeting and their roles as outlined below:**
 - The lead discloser who will be the main informative source.
 - The note taker who will take notes of the meeting.
 - Additional healthcare staff such as counsellor, nursing or other support persons who may be required to attend.
 - The key contact person should also be present as this is the person the service user may be most familiar with.

- The provision of factually correct information in relation to the adverse event. It may be the case that not all of the information is available at that time and the service user should be advised of this.
- The provision of factually correct information in relation to the service user's clinical condition. It is important to note that disclosure of information to family members/support persons should only occur with the consent of the service user.
- Establish what the service user understands already and is experiencing in relation to their condition and also establish what they understand in relation to what has happened to them.
- An expression of regret or apology in relation to the service user's condition and for what has happened to them, as appropriate. This will convey concern for the service user and demonstrate empathy for their situation. If it is established that an error has occurred an apology is called for and should be forthcoming.
- Provide information on the steps already taken and/or planned to try and prevent a recurrence of the adverse event.
- Provide information on the practical support mechanisms/services which are available for the service user and their family/support persons, as required.
- Consult with the service user in relation to the plans for their on-going care. The service user should be involved in the decision making in relation to the plan for his/her continuing care.
- Provide answers to any questions the service user has based on the facts available at the time. Where answers are not available advise the service user as to when you may be in a position to address their queries. Follow through on any assurances given.
- Allow time for the service user to express their feelings/anxieties/emotions and manage this with consideration, respect and dignity.

6.3.8: *Ending the disclosure meeting* ³⁵

- Ensure the service user has all the information they require.
- Seek further questions.
- Establish the service user's understanding of all the information provided at the meeting and any agreed actions.

³⁵ The Canadian Medical Protective Association 'Communicating with your patient about harm', Ottawa 2008 page 25

- Outline the next clinical steps e.g. investigations, treatments etc.
- Outline approximate timeframes for the investigation/review process.
- Provide information pamphlets to assist with on-going supports.
- Schedule further meeting dates.
- Advise the service user that their GP has/will be informed of the adverse event and any actions/treatments undertaken.
- Provide information to the service user regarding their nominated contact person and their role.

6.3.9: Deferred/postponing disclosure

Deferral, either temporary or permanent, may be a consideration in the following circumstances:

- The service user has died and has no known relatives.
- The service user has left the country and cannot be contacted.
- The service user refuses open disclosure – may not be ready.
- There may be a risk of violence perpetrated/threatened by the service user.
- There is no evidence that the service user will benefit from open disclosure.³⁶
- The service user is extremely ill or dying – disclosure to the nominated next of kin/family member(s)/support person(s) should be considered in these circumstances within the confines of patient confidentiality.

NOTE: *Only in exceptional circumstances, based on the clinical interests of a service user, is it likely that a service user will not benefit from open disclosure. The reason(s) for non-disclosure should be documented by the clinician in the service user's clinical record and senior management should be informed via internal governance processes. Decisions in relation to disclosure/non-disclosure should include input from the multidisciplinary team. The decision regarding disclosure may need to be revisited later when the service user is less vulnerable.*

³⁶ Final Report for the Australian Commission on Safety and Quality in Healthcare: Evaluation of the pilot of the National Open disclosure Standard, 2007 p.63.

Medical Protection Society, Education and Risk Management: Open Communication with Patients and families after a poor outcome, 2011

6.3.10: Closure for the service user

Psychological closure for the service user does not usually occur until the service user has experienced/obtained the following:

- (a) An acknowledgement in relation to what has happened.
- (b) An apology, where appropriate.
- (c) A satisfactory explanation in relation to what happened.
- (d) Appropriate answers to his/her questions.
- (e) Reassurance in relation to their on-going care and actions being taken by the service to try to prevent a recurrence of the event.

6.3.11: Closing the open disclosure process

- Closure of the open disclosure process should occur by shared agreement between the service user and staff.
- All information requested by the service user and available from any investigation(s) which have been undertaken should be provided to the service user in an appropriately worded and accessible report.
- Consider ways in which the service user could be involved/have input in relation to practice improvement initiatives.
- Continue to keep the service user informed in relation to any actions/initiatives undertaken by the service to reduce the likelihood of a recurrence of a similar event.
- Feedback from service users, their families/support persons and from staff in relation to their open disclosure experience should be undertaken and any learning incorporated into improving the process for all parties involved.
- When a satisfactory conclusion cannot be reached for the service user he/she should be advised of the alternative courses of action which are open to him/her i.e. the complaints process, litigation process.

6.4: A note on expressing regret/saying sorry

For the purpose of this document an apology is a genuine expression of being sorry for what has happened to the service user i.e. an expression of being sorry for the adverse/unexpected outcome the service user has experienced as a result of their condition and/or their health care and, when applicable, for any error(s) which may have resulted in this adverse outcome for the service user. Expressing regret for a service user's experience or emotions is not an admission of liability e.g. "I am very

sorry that the procedure was not as straightforward as we had hoped and that you have experienced some of the complications we discussed”.

6.4.1: *Examples of expressing regret/apologising to service users:*

6.4.1.1: If it is clear that the adverse event experienced by the patient is related to their ongoing condition or related to a known side effect/complication of a procedure or treatment it is adequate to express your regret for their experience/ feelings and/ or for their condition.

e.g. “The symptoms you are experiencing are a known side effect of the treatment you are having. I am sorry that you are experiencing these symptoms.”

6.4.1.2: If it is unclear in the immediate aftermath of an adverse event as to whether an error has occurred it is adequate at this stage during discussions with the service user to express regret in relation to their experience and/or for their condition.

e.g. “I am sorry that you have experienced complications with your surgery/treatment and for the upset/anxiety this has caused you. We are reviewing your care to establish the facts in relation to what happened and we will keep you informed in relation to our findings”.

6.4.1.3: If, following a review/investigation of the adverse event, it is established that an error occurred it is imperative that there is an acknowledgment of responsibility and an apology provided as soon as possible thereafter.

e.g. “We have completed our review of your care and we have established that an error occurred. We are/I am very sorry that this has happened. On behalf of the organisation I would like to offer you my sincere apologies in relation to the error/harm you have experienced and for the distress that this has caused you”.

6.4.1.4: If, following a review/investigation of the adverse event, it is established that there was no healthcare provider error the service user should be provided with an explanation of the facts established. It is reasonable to express your regret to them again in relation to their experience/condition.

6.4.1.5: When it is clear from the outset that the healthcare provider is responsible for the harm to the service user it is imperative that there is an acknowledgment of responsibility and an apology provided as soon as possible after the adverse event occurs or after the adverse event becomes known to the healthcare provider e.g. wrong site surgery/missed diagnosis. It may still be unclear at this stage as to how/why the error occurred and the service user should be advised that a review of the event will be undertaken and that more information will be provided to them at a later stage when the facts have been established.

e.g. "Surgery was scheduled for your left eye. Your right eye was opened in error. I am very sorry that this has happened and for the distress this has caused you. We have not yet established how /why this happened and we have commenced a review of the incident. We will keep you informed in relation to our progress with the review".

6.4.1.6: A further apology may be necessary at a later stage in relation to any adverse findings established during the course of the review of the adverse event e.g. system errors identified.

6.4.2: General notes on apology

6.4.2.1: Following an adverse event where a service user has been harmed as a result of their health care an expression of regret or an apology is necessary and often very valuable.

6.4.2.2: An apology can restore the service user's trust and faith in both the service and staff involved directly in their care.

- 6.4.2.3:** An apology/expression of regret demonstrates that you are genuinely sorry for what has happened to the service user.
- 6.4.2.4:** Liability or blame should not be projected or accepted unless this has been investigated and agreed to.
- 6.4.2.5:** An apology should always be personal and include the words “I’m sorry”/“We are sorry” – expressing that you are sorry for both the service user’s condition and for their experience and, when applicable, for any error(s) which have occurred.
- 6.4.2.6:** An apology must be genuine and delivered to the service user in a sincere manner – the sincerity of the apology will be determined by the words used in the apology and the demeanour of the person delivering the apology including their non-verbal communication e.g. body language, facial expression, tone and pace of voice and body gestures.
- 6.4.2.7:** An apology/expression of regret can sometimes be inferred by the service user as an admission of liability therefore the exact words used and the context in which the apology is provided should be documented in the minutes of the disclosure meeting and in the clinical record.

(See Table E’ on pages 60-62 for examples of language which may assist during the open disclosure discussion)

6.5: Defamation

The Defamation Act 2009 Act defines defamation as the “publication, by any means, of a defamatory statement concerning a person to one or more than one person (other than the first-mentioned person), and “defamation” shall be construed accordingly.”

An actionable defamatory statement has three ingredients:

- it must be published,
- it must refer to the complainant and
- It must be false.

Publication of the defamatory statement may take the form of writing, spoken words, visual images, sounds or gestures and includes transmission through TV, radio and the internet.

It is possible during an open disclosure discussion that a healthcare professional/ other person can be defamed by virtue of a statement, either verbal or written, from another person. The person may not necessarily be named by that person but may be identifiable by virtue of what has been said. An important element in relation to the open disclosure discussion with service users is the avoidance of opinion, speculation and the attribution of blame to another individual e.g. alleging that another healthcare professional is incompetent. If the healthcare professional involved in the adverse event is not available to attend the disclosure meeting it is important that an explanation is provided to the service user in a sensitive manner as to why that person is not present/available to speak to the service user directly.

6.6: A note on the use of the word “error”

The use of the word “error” should be avoided before the facts of the case are known as it can infer a meaning of blame for an individual or for the service and it can also infer that the care provided was negligent or substandard. Research has demonstrated that when things go wrong in healthcare it is not usually due to a single failure but often a series of failures in the healthcare system.

Focusing on provider error, particularly when the facts are not known, promotes a punitive environment that undermines reporting and learning from patient safety incidents and ultimately the system changes needed to improve patient safety.³⁷

6.7: Success factors

The success of an open disclosure meeting(s) can be dependent on the following: ³⁸

- The manner and demeanour of healthcare staff involved – staff must be professional in their manner and appearance.
- The demonstration of a genuine, attentive, caring, understanding, empathetic, sensitive and sympathetic attitude towards the service user.
- Adequate planning in advance in relation to what you will say and how you will address potential questions/issues.
- Speaking clearly and slowly and in a language that can be understood easily i.e. avoiding medical jargon.
- Being proficient in active listening skills.
- Providing an acknowledgement of the adverse event to the service user.
- Providing a meaningful explanation and a meaningful expression of regret/apology, where appropriate.
- Recognising and managing the service user's non-verbal communication.
- Restorative justice e.g. refunding fees, on-going support. (Note: These need to be agreed prior to the open disclosure meeting) e.g. car park fees.
- Checking for understanding.
- Following through on agreed actions.
- Inviting/welcoming questions from the service user.
- Keeping communication channels open between the service user and the service.

6.8: Common pitfalls

- You are talking too much/not listening enough
- Failure to recognise the elements of a grief reaction
- Arguing or trying to prove you are right
- Defensive attitude
- Offering excuses
- Over use of the word “but”
- Failure to express enough empathy for the service user/family situation
- Focusing on points of disagreements rather than on points of solutions.

³⁷ Canadian Disclosure Guidelines, *Being open with service users and families*: Canadian Patient Safety Institute. page 12, 2011

³⁸ Final Report for the Australian Commission on Safety and Quality in Healthcare: Evaluation of the pilot of the National Open disclosure Standard, 2007 pages. 73-81.

- Speculating on the reasons harm occurred without factual evidence to support it at an early stage in the review process.
- Failure to follow through on actions agreed.
- Negative body language.
- Use of medical jargon.

6.9: Documentation

6.9.1: Documentation in the Healthcare Record

Documenting the open disclosure process is essential to ensure continuity and consistency in relation to the information that has been relayed to the service user.

Documentation which has been produced in response to an adverse event may have to be disclosed later in legal proceedings or in response to a freedom of information application. It is important that care is taken in all communications and documents stating as fact only, what is known to be correct. This should not inhibit the recording of events as thorough and accurate documentation will often assist rather than damage a defence, particularly where there is delay between any legal proceedings and the adverse event.

It is imperative that documentation in the healthcare record captures the following aspects of the disclosure process:

- The details of the adverse event and any actions taken/treatment provided.
- The date and time of all disclosure meeting(s).
- The disclosure team present (name individuals and roles).
- The family members/support person(s) present (named).
- The salient points of the discussion – facts presented, plan of care, actions agreed, questions raised and answers provided.
- The details of the apology/expression of regret given – exact wording.
- The details of any reactions/queries raised by the service user and response provided.
- Copies of any correspondence sent to the service user in relation to the adverse event/open disclosure process.

- Copies of any correspondence sent to the service user or other healthcare providers in relation to the care of the service user/ follow up actions.

6.9.2: *Documentation which may be held separate to the Healthcare Record*

An “open disclosure file”, separate to the healthcare record, should be opened to communicate other information not necessarily required for documentation in the healthcare record, e.g. minutes of the meetings, details of reviews undertaken, statements from staff etc. To allow for a comprehensive documented flow and structured file it may be advisable to separate the disclosure file into the following segments: pre, during and post disclosure. A checklist that can act as an aide memoire should be considered to ensure a professional and standardised approach is taken.

(See Appendix “F” for a sample checklist)

6.10: Confidentiality

Confidentiality is a fundamental component in the delivery of healthcare. Disclosure of information following an adverse event can only be given to the service user and his/her chosen confidante/ nominated support person. It should be noted that the ‘next of kin’ may not always necessarily be the person the service user wishes to have his/her information shared with. This specific information regarding sharing of clinical information and with whom, needs to be ascertained and documented from the outset of commencement in the provision of healthcare/treatment. When a service user is deceased the principles of confidentiality remain the same, in continuing after death.

Staff are expected to comply with the provisions of the Data Protection Acts 1988 and 2003 which state that personal information obtained from service users for the purposes of informing care, treatment or service provision should not be disclosed to a third party unless the service user has consented or unless the specific requirements of the legislation are complied with. (The legislation distinguishes between “sensitive” and “non-sensitive” data. For non-sensitive data, information may be shared (“processed”) where it is necessary to prevent injury or other damage to the health of the data subject. For sensitive data, information may be shared where it is necessary for medical purposes and is undertaken by a medical


professional). This also applies if a third party, such as a family member, makes a complaint regarding the care of a service user: it is essential in these circumstances to ensure that the service user has consented to their personal information being made available for any internal investigations/reviews.

Sharing of information on a strict ‘need to know’ basis between staff involved in a service user’s care is essential to the provision of safe and effective care. Similarly, an integral component of modern health and social care is the use of audit and quality assurance programmes to ensure that the care provided is of the highest quality when benchmarked against national and international standards. Consent from the service user is not usually sought in these circumstances except where identifiable data is being made available to a third party.³⁹

6.11: Examples of words/language – initial discussion with service user⁴⁰

These are examples of phrases that may assist in the disclosure process. Using the MPS A.S.S.I.S.T model of communication we have developed sample phrases to assist you in each part of the open disclosure discussion.

Table E: Sample language

STAGE OF PROCESS	SAMPLE PHRASES
Acknowledgement 	<p>We are here to discuss the harm that you have experienced/the complications with your surgery/treatment</p> <p>I realise that this has caused you great pain/distress/anxiety/worry</p> <p>I can only imagine how upset you must be</p> <p>I appreciate that you are anxious and upset about what happened during your surgery – this must have come as a big shock for you</p> <p>I understand that you are angry/disappointed about what has happened</p> <p>I think I would feel the same way too</p>

³⁹ Health Service Executive. *National Consent Policy, Quality and Patient Safety Directorate, Dublin, May 2013* page 38.

⁴⁰ Australian Commission for Safety & Quality in Health Care. *Open Disclosure: Health Care Professional Handbook Canberra, 2003*

STAGE OF PROCESS

SAMPLE PHRASES

Sorry

I am so sorry this has happened to you

I am very sorry that the procedure was not as straightforward as we expected and that you will have to stay in hospital an extra few days for observation

I truly regret that you have suffered xxx which is a recognised complication associated with the x procedure/treatment

I am so sorry about the anxiety this has caused you

A review of your case has indicated that an error occurred – we are truly sorry about this and for the distress this has caused you

Story***Their Story***

Tell me about your understanding of your condition

Can you tell me what has been happening to you

What is your understanding of what has been happening to you

Your understanding of their Story: (Summarising)

I understand from what you said that xxx and you are very upset and angry about this. Is this correct? (i.e. summarise their story and acknowledge any emotions/concerns demonstrated.

Am I right in saying that you

Your Story

Is it ok for me to explain to you the facts known to us at this stage in relation to what has happened and hopefully address some of the concerns you have mentioned?

Do you mind if I tell you what we have been able to establish at this stage?

We have been able/unable to determine at this stage that

We are not sure at this stage about exactly what happened but we have established that We will remain in contact with you as information unfolds.

You may at a later stage experience xx and if this happens you should

STAGE OF PROCESS

SAMPLE PHRASES

Inquire

Do you have any questions about what we just discussed?

How do you feel about this?

Is there anything we talked about that is not clear to you?

Solutions

What do you think should happen now?

Do you mind if I tell you what I think we should do?

I have reviewed your case and this is what I think we need to do next - what do you think about that?

These are your options now in relation to managing your condition, do you want to have a think about it and I will come back and see you later?

I have discussed your condition with my colleague Dr x we both think that you would benefit from xx. What do you think about that?

Travel

”

Our service takes this very seriously and we have already started an investigation into the incident to see if we can find out what caused it to happen.

We will be taking steps to learn from this event so that we can try to prevent it happening again in the future.

I will be with you every step of the way as we get through this and this is what I think we need to do now.....

We will keep you up to date in relation to our progress with the investigation and you will receive a report in relation to the findings and recommendations of the investigation team.

Would you like us to contact you to set up another meeting to discuss our progress with the investigation?

I will be seeing you regularly and will see you next in..days/weeks.

You will see me at each appointment.

Please do not hesitate to contact me at any time if you have any questions or if there are further concerns – you can contact me by

If you think of any questions write them down and bring them with you to your next appointment.

Here are some information leaflets regarding the support services we discussed – we can assist you if you wish to access any of these services.

Open Disclosure: Specific circumstances

7

7.1: Fatalities

When a service user dies as a result of an adverse event it is vital that communication with the family/ support person is initiated early and maintained and that this communication is sensitive, empathetic and open. Taking into consideration the grieving process and the emotional needs of the family, the decision as to when it is an appropriate time to discuss what happened should be left to the family and the details of a contact person should be provided to them to make contact easier for them when they feel ready to do so.

The death may be reportable to the coroner and subject to requirements of the coroner and legislative provisions. It is vital for the family that contact is maintained with them by the key contact person assigned within the service. They will need information on the processes to be followed to establish the cause(s) of death and may also require additional supports such as bereavement counselling. It is important that the open disclosure discussion does not include speculation as to the cause of death when the case has been referred for a coroner's post mortem.

7.2: Paediatrics and neonates

When an adverse event involves a child, the clinical team in conjunction with the parents/guardians, need to make an informed decision as to what the child should be told. They should be given information having regard to their age, comprehension and emotional maturity. The child's best interest are of paramount importance and he/she should be involved in the decision making process. This principle is in keeping with legal and international human rights standards and ethical guidance which provide that the child's wishes should be taken into account and, as the child grows towards maturity, given more weight accordingly.⁴¹

⁴¹ Health Service Executive. *National Consent Policy, Quality and Patient Safety Directorate, Dublin, May 2013 page 44*

Children with disabilities have equal rights to express their views, with due weight according to their age, maturity and comprehension. Additional supports with disability and age appropriate assistance may be required in this regard.⁴²

In circumstances involving a neonate, the main principles remain. The clinical team in consultation with the parents/guardians must always act in the best interests of the neonate.

7.3: Service users with mental health issues

Disclosure of information relating to treatment issues, including disclosure of adverse events, applies equally to people with mental health illness as to others. Best practice and international human rights standards favour “supported decision making” where possible. It is important to give those who may have difficulty making decisions the time and support they need to maximise their ability to make decisions for themselves.⁴³

The timing of the disclosure is subject to the clinical team’s assessment of the impact on the service user and the service user’s ability to understand what they are being told.

In rare circumstances health and social care professionals may withhold information where they believe that providing the information would have a serious effect on the health of the service user i.e. clinical decompensation or harm to self or to others. The justification for such a decision needs to be evidenced and documented in the healthcare record. This decision should be revisited at a time when the service user is deemed to be in a less vulnerable position.

A respectful assessment of risk along with an environment of respect, empathy and collaboration will be vital when helping people with mental health illness during the disclosure process.

7.4: Service users with cognitive impairment

Best practice and international human rights standards favour “supported decision making” where possible. It is important to give those who may have difficulty

⁴² Health Service Executive. *National Consent Policy*, Quality and Patient Safety Directorate, Dublin, May 2013 page, p 44

⁴³ *Ibid*, page 27

making decisions the time and support they need to maximise their ability to make decisions for themselves. Service users with cognitive impairment should be involved as much as possible in communication about what has happened to them according to their level of capacity. The service user may have a legal guardian however it cannot be assumed that because a person is named in an Order or Power of Attorney that the person has the legal right to act in all circumstances on behalf of the person.

7.5: Service users with learning disabilities

Best practice and international human rights standards favour “supported decision making” where possible. It is important to give those who may have difficulty making decisions the time and support they need to maximise their ability to make decisions for themselves. Where a service user has difficulties in expressing their opinion verbally, an assessment should be made about whether they are also cognitively impaired. If they are not the service user needs to be supported by alternative communication methods. An appropriate advocate may be required to assist the service user in this regard.

7.6: Service users with visual/hearing problems

If a service user has difficulty communicating due to visual or hearing impairments, additional supports will be required and it should be established from the service user in advance of the meeting what supports they do require in an effort to make information more accessible to them. The use of an advocate should be considered. Their role is to identify the service user’s needs and feed them back to the health care provider. He/she should also ensure that the service user’s views are considered and discussed.

7.7: Language/cultural Issues

Service users with special language or cultural considerations (including recent migrants and visitors) may require additional supports. The need for interpreter services should be identified at the earliest stage of the process. The use of family to interpret should be avoided except in an emergency. The privacy rights of the service user must be considered. This can be achieved when a professional interpreter is trained to ensure accurate translation of medical terminology and healthcare dynamics.

Additional time will always be required for discussions involving an interpreter, and this should be planned for in advance.

7.8: Multi-service user/large scale disclosures

There may be times when a single event will require notification to a large number of people. Large scale disclosures need to be well thought out with some degree of rationale as to who needs to be targeted. The HSE Incident Management policy 2008 should be referred to with regard to HSE management notification. The following points need to be considered prior to contacting service users/families:

7.8.1: Risk assessment

A risk assessment will assist in identifying which service users have been potentially exposed to a safety incident/ adverse event and who are therefore at risk and require disclosure. Where the likelihood of exposure is high, the need to contact all affected service users is straightforward. When the likelihood of harm decreases the probability of harm in conjunction with weighing up ethical obligations is required. It is vital that this decision is made with the necessary input from all of the relevant parties and with consideration of a number of perspectives, including medical, ethical, legal, risk management and communications aspects to determine a structured, informed and targeted approach.

7.8.2: Locating identified high risk service users

Locating service users can present a challenge especially if the adverse event is in the distant past. Search methods need to be cross referenced with other systems and perhaps other services that service users may have been referred to in order to minimise omissions, those not at risk or deceased service users.

7.8.3: Communicating with high risk service users

Once the target population has been identified, communication with service users should happen as soon as possible after the event. A communication plan needs to be triggered, which should include mechanisms for the provision of information to service users and which may also include dedicated phone lines/ website to facilitate

timely responses. Best practice would determine that communication is undertaken concurrently. The initial disclosure should be undertaken in person especially when the likelihood of harm is high.

Large scale/multi-service user disclosures should pre-empt media involvement and other public releases of information that could identify at risk service users. This needs to be managed in a sensitive manner.

7.9: Research projects

Adverse events can also occur in the course of clinical trials. The obligation to disclose remains as it would for other service users. Additional obligations in reporting the adverse event(s) to the trial sponsor and other additional applicable safety monitoring bodies including the research ethics committee will also need to be undertaken.

7.10: Media involvement

Note: In relation to media involvement please refer to the media communications section of the HSE Incident Management Policy. Contact National/ Regional Communications offices for advice and support.

Large scale service user safety incident disclosures should anticipate and pre-empt media involvement. Preparation is one key factor in trying to ensure that the media have the actual facts associated with the incident(s). When meeting with the media it is crucial that those chosen to do so have the following capabilities and competencies. (These may seem quite obvious however the obvious is not always practised).

Staff meeting with the media should:

- Be good communicators with the ability to relay the extent of the issues in an informed and practical manner.
- Know their subject.
- Have prepared well in advance.
- Have the facts to hand and do not stray into hearsay.
- Have relevant contact numbers available that will practically assist the public if they are concerned or if it impacts on them directly.

- Be aware of data protection and confidentiality issues that may arise.
- Have experience in dealing with the media which is valuable. However it may not always be possible to have had previous media involvement.
- Ensure that prior to finalising the interview the interviewee should always know what the next steps in the management of the incident are.
- Be aware that in failing to prepare adequately, he/she can expect to fail. This can be quite a stressful time for staff and service users. In times of stress the 'norm' may not seem so normal hence informed preparation can powerfully assist at a time when the basics can be overlooked.

8.1: What is Open Disclosure?

The Australian Commission on Safety and Quality in Healthcare describes open disclosure as “an open discussion of incidents that result in harm to a service user while receiving healthcare. This includes expressing regret for what has happened, keeping the service user informed, providing feedback on investigations and the steps taken to manage the event and prevent a recurrence.”⁴⁴ The more recently published (revised from 2008) “Canadian Disclosure Guidelines”⁴⁵ describes disclosure as a “process of open communication and information sharing rather than a single conversation.” Open communication and open disclosure have the same meaning.

8.2: What are the main principles that guide/influence open disclosure?

Open disclosure is underpinned by 10 principles as follows:

- Openness and timeliness of communication.
- An acknowledgement of the event.
- An apology/expression of regret.
- Recognition of service user and care giver expectations.
- Professional support following an adverse event.
- The investigation of adverse events with outcomes focused on improving systems of care and integrated with risk management and quality.
- Multidisciplinary responsibility, focusing and embedding a fair and just culture.
- Good governance advises that open disclosure requires a system of accountability through the Chief Executive Officer, to ensure that quality improvement processes are undertaken and effective.
- Confidentiality with regard to a comprehensive review.
- Continuity of care for all persons affected by an adverse event e.g. debriefing sessions, applicable support networks.

⁴⁴ Australian Commission on Safety and Quality in Healthcare: ‘Open disclosure Standard- A National Standard for Open Communication in Public and Private Hospitals, Following An Adverse Event in Healthcare’ Australian Commission on Safety and Quality in Healthcare. Australia: April. 2008, page 1

⁴⁵ Canadian Service user Safety Institute. ‘Canadian Disclosure Guidelines- Being Open with Patients and Families.’ Edmonton, AB, Canada: Canadian Service user Safety Institute: 2011

8.3: *Is protected disclosure the same as open disclosure?*

Open disclosure and protected disclosure are different. Whistle blowing and health and safety legislation do not address the open disclosure of adverse events to service users.

Section 103 of the Health Act 2007 allows for health service employees to make protective disclosures.⁴⁶ Protected disclosure has also been described as ‘whistle blowing’.⁴⁷ If an employee reports a work place concern in good faith and on reasonable grounds it will be treated as a ‘protected disclosure’. It ensures that employees are not liable for damages as a result of making a disclosure.

8.4: *What impact does the culture of a service have on open disclosure?*

The safety culture of an service can be described as ‘the product of individual and group values, attitudes, perceptions, competencies and patterns of behaviour that determine the commitment to, and the style and proficiency of an service’s health and safety management.’⁴⁸ Open and honest communication by healthcare professionals can be considered a characteristic of a culture of safety.⁴⁹

8.5: *Is there a national standard on open disclosure?*

The “National Standards for Safer Better Healthcare 2012” specifically address the requirement for open disclosure to take place following an adverse event. Standard 3.5 states that “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.”

8.6: *Can my indemnity be vulnerable if I disclose? (MPS and SCA)*

The State Claims Agency and the Medical Protection Society both fully endorse open disclosure.

⁴⁶ Health Service Executive. ‘Protected Disclosures of Information’-Explanatory leaflet for Health Service Employees. Dublin 2010

⁴⁷ Department of Health. ‘An Organisation with a Memory’: Report of an Expert Group on Learning from Adverse Events in the NHS. The Stationary Office. London 2000, page 64

⁴⁸ Ibid, page 84

⁴⁹ Emergency Care Research Institute. ‘Culture of Safety’ Healthcare Risk Control. Risk and Quality Management Strategies 21; Supplement A: November 2005

The Director of the SCA has stated that:

“At the heart of open disclosure lies the concept of open, honest and timely communication, service users and relatives must receive a meaningful explanation.”⁵⁰

The MPS state in their ‘Member’s Handbook’:⁵¹

“In our experience many complaints arise from poor communication. Once you have established the facts, we advocate a policy of full and open communication. An explanation may be all that is needed to reassure a service user and avoid any escalation. A wall of silence after an adverse event can provoke complaints and legal action. If it is clear that something has gone wrong, an apology is called for, and it should be forthcoming. The SCA and MPS can assist services when preparing for open disclosure meetings.”

8.7: Should near miss events be disclosed?

The debate that surrounds the disclosure of near miss or close call events is one that can cause division of opinions among the healthcare team. The need to disclose when there is no harm, but the potential for harm exists is influenced by the potential likelihood of severe consequences in the future. If it is unknown if harm has occurred it is recommended that disclosure takes place.⁵² In conclusion, healthcare providers and services should consider what the reasonable person would want to know about the near miss event under the circumstances.

8.8: Do service users want to know if they have been involved in an adverse event?

Research has demonstrated that the vast majority of service users would wish to be informed if they have been involved in an adverse event. The following should be provided to the service user as a minimum: an acknowledgement of the event, a description of the event, an explanation as to how/why the event occurred, information on the steps being taken to try to reduce a recurrence of the event and an apology, where appropriate, for what has happened.

⁵⁰ Emergency Care Research Institute. ‘Culture of Safety’ Healthcare Risk Control. Risk and Quality Management Strategies 21; Supplement A: November 2005, page 1

⁵¹ Medical Protection Society. ‘A Guide to MPS Membership (Ireland)’ London, September 2010, page 15

⁵² Canadian Patient Safety Institute. ‘Canadian Disclosure Guidelines’. Edmonton, AB, Canada; Canadian Service user Safety Institute 2008 p 18

8.9: *I am uncertain what to disclose as we can't say what went wrong yet?*

Following an adverse event the service user needs to be informed promptly in relation to what has happened. It is not unusual that all the facts surrounding the adverse event may not have been established at that time. It is important to inform the service user of the facts as available at that time. It is vital to avoid speculation and hearsay. The service user should be alerted to approximate and realistic time frames regarding the review of the adverse event and when answers to their queries may be available.

8.10: *What is the difference between an apology and an expression of regret?*

An apology is an expression of regret. An apology should be forthcoming when a service user has been harmed when receiving care/treatment. In practice an apology should not be taken to mean that liability is admitted by the service. The following explanation is taken from the National Health Service in the United Kingdom. “An apology is a meaningful sincere expression of sorrow or regret for the harm caused as a result of a patient safety incident”.⁵³ A patient safety incident is “any unintended or unexpected incident that could have or did lead to harm for one or more service users receiving healthcare.”⁵⁴

The Canadians are similar in their approach to apologising, referring to an apology as “a genuine expression of being sorry for what has happened.”⁵⁵ The words “I’m Sorry” should be part of any apology. The delivery of an apology should convey sincerity. The Canadian Medical Protective Association state “an effective apology is one of the most profound healing processes between individuals, groups, or nations.”

8.11: *If a disclosure is made, is the likelihood of being sued increased?*

To date there is no evidence to indicate that litigation increases following disclosure, the evidence in fact supports a levelling off and a decrease in litigation following prompt and honest disclosures.

⁵³ National Patient Safety Agency. ‘Saying Sorry When Things go Wrong - Being Open - Communicating Patient Safety Incidents with Patients their Families and Carers’ NHS: November, 2009 page, 38

⁵⁴ Ibid, page 39

⁵⁵ Canadian Patient Safety Institute. ‘Canadian Disclosure Guidelines- Being Open with Patients and Families.’ Edmonton, AB, Canada; Canadian Patient Safety Institute 2011 page 19

Opinion supports that lack of disclosure can be an alienating factor in the doctor-service user relationship.⁵⁶ Poor communication following an adverse event can lead to service users/families seeking assistance from the legal profession to endeavour what went wrong in the course of their care/treatment. A number of studies have been undertaken to establish if there is a link with an increased litigation rate following disclosure.

In 2001, the University of Michigan Health System introduced an extensive claims management programme, with disclosure as a central and fundamental component.⁵⁷ At the beginning, three main principles were identified around risk management/claims response, “compensate quickly and fairly, defend vigorously and reduce service user injuries by learning from their experience”.⁵⁸ The number of new claims has fallen since the introduction of the disclosure programme. The average claims processing time has reduced from 20.3 months to just 8 months, with total insurance reserves dropping by more than two-thirds. Average litigation costs have more than halved.⁵⁹

(Year)							
1999	2000	2001	2002	2003	2004	2005	2006
(Claims)							
136	122	121	88	81	91	85	61

UMHS number of new claims since the introduction of the open disclosure programme in 2001.

8.12: What about retrospective incidents, discovered after a service user is discharged?

A risk assessment will assist in identifying the potential severity for the service user(s) and will therefore assist making an informed decision as to the urgency of contact.

⁵⁶ Witman, AB., Park., DM., Hardin., SB. ‘How do Service users Want Physicians to Handle Mistakes?’ A Study of Internal Medicine Service users in an Academic Setting. *Archives of Internal Medicine* 1996; 156: 2565-9

⁵⁷ Ibid, page 213

⁵⁸ Boothman, RC., Blackwell, AC., Darrel, A. et al. ‘A Better Approach to Medical Malpractice Claims? The University of Michigan Experience.’ *Journal of Health and Life Sciences Law* 2009; 2 (2): 125-47, page 139

⁵⁹ Boothman, RC., Blackwell, AC., Darrel, A. et al. ‘A Better Approach to Medical Malpractice Claims? The University of Michigan Experience.’ *Journal of Health and Life Sciences Law* 2009, page 144

When the likelihood of exposure is high the need to contact should be assumed. The probability of harm in conjunction with weighing up ethical obligations is required. An informed clinical decision needs to be made by the Consultant. If the decision made is not to contact the service user(s) the rationale for this decision should be documented in the healthcare record.

8.13: *How should the service user be contacted when the adverse event becomes known following their discharge from hospital /the service?*

It is recommended that contact is made with the service user via telephone or face to face communication e.g. missed diagnosis on an x-ray - the service user should be contacted and advised that their consultant wishes to meet with them to discuss a review of their x-ray. An appointment should be facilitated as soon as possible and the service user should be advised to bring a support person with them to the meeting. The details of the meeting can then be confirmed, in writing, to the service user/family.

8.14: *What should I say when discussing the care provided by others to a service user?*

A service user or their family may ask about the quality of care provided by another team or by a separate healthcare institute. Caution is advised in this instance, as the facts of previous care provided may not be known at that time. It can be difficult to comment on a service that was provided by another service/team, therefore the service user/family need to address their questions directly to the providers rather than via a third party. The service user should be facilitated to address their questions.

8.15: *How many family members should attend a disclosure meeting?*

Prior to meeting with the family and as part of the organisational preparation, those attending the first disclosure meeting should be confirmed in advance. Numbers should be kept at a reasonable level, (this can be flexible depending on circumstance.) In large families it is advisable that one or two family members are nominated to represent the family. Prior to meeting with the service user and their family it is important that the contact person establishes how many family members will be attending and in what context they will be present. The title and roles of all persons present should be explained again at the beginning of the open disclosure meeting. Consider the balance in relation to the number of staff members and family members attending.

8.16: How many healthcare members should be present at a disclosure meeting?

It is important that disclosure teams are kept tight and applicable. A disclosure team usually consists of the disclosure lead (usually the service user's consultant), a deputy lead, a scribe (who can be the key contact) and perhaps the risk manager and/or director of nursing/service manager. It is advisable that no more than 4-5 healthcare staff attend. If there are more the service user may feel uncomfortable and the disclosure meeting has the potential to develop into what might appear to the service user to be a defensive meeting. The service user should be advised in advance of the meeting as to who will be in attendance and the role of each member of staff attending. The title and roles of all persons present should be explained again at the beginning of the open disclosure meeting.

8.17: What if a service user wants to bring a solicitor with them to the disclosure meeting?

The main objective of the disclosure process is to meet with the service user to allow a transparent meeting(s) to occur in order to ascertain and convey the facts of what actually happened and to provide support for the service user. It is not a legal meeting or a 'fishing expedition' to establish if a case can be taken against a service. Having solicitors present may change the nature and dynamics of the meeting and staff may feel more defensive and guarded if they feel they could be subjected to a legal cross-examination. This may in turn impact on how successful the disclosure meeting is for all of the parties involved. It may be the case that a solicitor is present purely for supportive reasons. Ultimately an informed decision needs to be taken locally whether to proceed with the disclosure meeting in the presence of a solicitor.

If a service user insists on bringing their solicitor to the disclosure meeting the role of the solicitor, in their attendance at the meeting, should be established and a decision made as to whether the meeting should go ahead depending on the context in which the solicitor is attending. The health and social care service may need to seek advice from their own solicitor as to whether he/she should also be present.

At the start of the meeting, everyone attending should introduce themselves by name and state why they are there and it should be explained that the meeting is meant to be an informal and open exchange of information and that it is not meant to be a forensic, legal exercise. All of this should be documented in the meeting notes.

8.18: What if a service user wishes to record the meeting using a recording device?

If a service user wishes to record a disclosure meeting using a recording device this should be facilitated in the interest of openness and transparency. However, it is advisable that the health and social care service should also record the meeting using their own recording device. Recording the meeting may, however, change the dynamics of the meeting as staff may be more guarded in their responses. The service user may be happy for the health and social care service to record the minutes of the meeting in writing and to receive a copy of these minutes as a record of the meeting.

If a recording device is used the recordings may be typed verbatim and a copy sent to all parties for verification. When the minutes of the meeting have been agreed and signed off by all persons present the recording can then, by mutual consent, be deleted.

8.19: What happens in relation to communicating with the service user's GP following an adverse event?

It is important that the service user's GP is informed of the details of:

- (a) The adverse event
- (b) Actions taken
- (c) Any treatment provided
- (d) What has been disclosed to the service user
- (e) The planned on-going care and follow-up of the service user. The service user should be informed that their GP will be made aware of the detail surrounding the adverse event and their subsequent care.

8.20: How do I deal with my own distress?

(See Appendix "D" of this document which provides practical information for staff in relation to coping with the impact of an adverse event. See also the booklet Supporting staff following an adverse event. The "ASSIST ME" model).

8.21: Are training sessions on Open Disclosure available?

Training sessions are available for all healthcare staff and should be arranged locally through the risk manager/service manager. The SCA, in conjunction with the HSE, runs an accredited half day workshop for all healthcare staff entitled "Communicating with Service Users and their Families following Adverse Events in

Healthcare”. This session is free to attend. The Medical Protection Society (MPS) also runs workshops for doctors entitled “Mastering Adverse Outcomes”.

Open Disclosure and the relevant stakeholders' positions in the Republic of Ireland

The State Claims Agency

“At the heart of open disclosure lies the concept of open, honest and timely communication. Service users and relatives must receive a meaningful explanation”. (Ciarán Breen, Director of the SCA)

The Medical Council of Ireland

“Guide to Professional Conduct and Ethics for Registered General Practitioners”

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

The Draft Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives, February 2013.

“Safe quality practice is promoted by nurses and midwives actively participating in incident reporting, adverse event reviews and open disclosure”

The HSE Incident Management Policy 2008

“Open communication/disclosure is a vital component of the incident management process.... All incidents should be disclosed to persons affected. The person affected and/or next of kin must be kept informed”

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

“A Service user can expect open and appropriate communication throughout your care especially when plans change or if something goes wrong.”

The MPS Members Handbook

“In our experience many complaints arise from poor communication. Once you have established the facts, we advocate a policy of full and open communication. An explanation may be all that is needed to reassure a service user and avoid any escalation.

A wall of silence after an adverse incident can provoke formal complaints and legal action. If it is clear that something has gone wrong, an apology is called for and it should be forthcoming. Contrary to popular belief, apologies tend to prevent formal complaints, rather than the reverse”.

Standard 3.5: National Standards for Safer Better Healthcare 2012

“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.”

List of symptoms associated with Post-Traumatic Stress Disorder (PTSD)⁶⁰

Symptoms of PTSD: Re-experiencing the traumatic event

- Intrusive, upsetting memories of the event.
- Flashbacks (acting or feeling like the event is happening again).
- Nightmares (either of the event or of other frightening things).
- Feelings of intense distress when reminded of the trauma.
- Intense physical reactions to reminders of the event (e.g. pounding heart, rapid breathing, nausea, muscle tension, sweating).

Symptoms of PTSD: Avoidance and numbing

- Avoiding activities, places, thoughts, or feelings that remind you of the trauma.
- Inability to remember important aspects of the trauma.
- Loss of interest in activities and life in general.
- Feeling detached from others and emotionally numb.
- Sense of a limited future (you don't expect to live a normal life span, get married, have a career).

Symptoms of PTSD: Increased anxiety and emotional arousal

- Difficulty falling or staying asleep.
- Irritability or outbursts of anger.
- Difficulty concentrating.
- Hypervigilance (on constant "red alert").
- Feeling jumpy and easily startled.

⁶⁰ www.helpguide.org/.../post_traumatic_stress_disorder_symptoms_treatment.htm (accessed March 24th, 2013)

Other common symptoms of Post-Traumatic Stress Disorder (PTSD)

- Anger and irritability
- Guilt, shame, or self-blame
- Substance abuse
- Feelings of mistrust and betrayal
- Depression and hopelessness
- Suicidal thoughts and feelings
- Feeling alienated and alone
- Physical aches and pains.

Information on the debriefing process⁶¹

Levels of debriefing

Level 1: Informal

- Where: At Ward/Unit level.
- Who: Can be group debrief or 1-1.
- Facilitated by: Ward/Unit Manager.
- When: As soon as reasonably practicable after the event.
- Environment: Open and non-judgemental – allows all participants to vent their feeling and discuss the event.

Level 2: Informal/formal

- Where: At local level i.e. Ward/Unit or may be hosted off site away from where the incident occurred.
- Who: Can be group debrief or 1-1.
- Facilitated by: Specialist Manager or Practitioner e.g. Senior Nurse, Occupational Health Practitioner/Health and Safety Advisor.
- When: As soon as is reasonably practicable after the event.
- Environment: Open and non-judgemental – allows all participants to vent their feeling and discuss the event.

Level 3: Formal

- Where: Away from the area of work or place where the incident occurred.
- Who: Preferably 1-1 but dependent on what staff involved feel would be more beneficial to them – under the direction of the trained de-briefer/counsellor.
- Facilitated by: Person trained in Critical Incident De-briefing or Counsellor.
- When: As soon as is reasonably practicable after the event.
- Environment: Open and non-judgemental – allows all participants to vent their feeling and discuss the event.

⁶¹ Perry, Giles and Firkins, Gary, 2010, "South Staffordshire and Shropshire Healthcare NHS Foundation Trust, Critical Incident Debriefing Policy," Document Reference: R/GRE/hs/04

Requirements of the debriefing process

- Confidentiality.
- Debrief records are not noted on any personal or personnel files.
- Feedback to management that is seen as essential is only as per what is agreed by the member(s) of staff involved.
- Preservation of the staff members' human rights.
- There must be a complaints process in operation in relation to the de-briefing service.

Taking care of yourself in the aftermath of an adverse event

Suggested “things to do” which may assist your response to an adverse event

DO	WHY?
1. Talk to a friend/colleague/line manager about your experience and your feelings	Talking to someone may help to reduce feelings of isolation and stress. Talk is the most healing mechanism.
2. Take time to relax	Relaxation techniques can be helpful as stress is completely normal at a time like this. Learn some stress management strategies and use them frequently. Give yourself time to recover from the crisis.
3. Get enough sleep	Sleep is always important but especially now. Make sure you allow enough time for a full night's sleep. If you have difficulty sleeping for more than a week you should consult with your GP.
4. Get some exercise	A brisk walk is good for the body and has a calming effect on the mind as well. Mild exercises can help to combat stress. Don't overdo it or push yourself beyond your limits!

DO

WHY?

5. Maintain a good diet

Foods can help tame stress in several ways. Comfort foods, like a bowl of warm oatmeal, boost levels of serotonin, a calming brain chemical. Other foods can cut levels of cortisol and adrenaline, stress hormones that take a toll on the body over time. And a healthy diet can counter the impact of stress, by shoring up the immune system and lowering blood pressure.

6. Follow a structured schedule

But allow some flexibility in case you are unable to follow through. Learn to accept that you are not capable of doing all things all the time. You are healing. Keep your life as normal as possible. Prioritize your time – write down the things you have to do in the order that they have to be done.

7. Spend time with family and friends

Don't isolate yourself. It is important to have people around you or available to you at this time.

8. Take time for leisure activities

Do not withdraw from others or normal leisure/social activities. Do something you find enjoyable.

9. Expect the incident to bother you

Remember that the critical incident response is a temporary and normal reaction to an abnormal event. You are having a normal response to an abnormal experience and making a conscious effort to work through it will ultimately help you to overcome the stress and pain.

DO

WHY?

10. Realise that others around you may be under stress also

If others are involved help them as much as possible by sharing your feelings and checking out how they are doing.

11. Learn about post-traumatic stress

This will assist you in recognising the symptoms and feelings you are experiencing which are a normal reaction to the event and to also recognise those feelings and symptoms which you are experiencing which may be worrying in nature and which may require additional intervention from your GP, Employee Assistance Programme (EAP) and/or Occupational Health Department (OH).

12. Contact your GP/EAP/OH department if you are concerned that your response to the event is too intense or lasting too long.

Talk to your line manager who can assist you in this matter and who can organise referral to EAP/OH for you. Remember that you can self-refer to EAP/OH if you prefer. It is also important to talk to your GP about how you are feeling.

D

Things to avoid

1. Do not drink alcohol excessively.
2. Do not stay away from work unnecessarily.
3. Do not withdraw from significant others.
4. Do not use legal or illegal substances to numb consequences.
5. Do not have unrealistic expectations for recovery.
6. Do not reduce the amount of leisure activities.
7. Do not look for easy answers.
8. Do not be hard on yourself or others.
9. Do not make any major life changes or decisions at this time.

Remember: You are normal and your reactions are the normal reactions of one who has experienced an abnormal event.

Contains references:

- (1) Managing the Impact of a Critical Incident: A Guide for Managers and Supervisors at the University of Washington, APS Healthcare, 2010
- (2) Normal Reactions to an Abnormal Event, Staff Information Leaflet, Kentucky Community Crisis Response, Community Response Team.

Checklist for the implementation of the principles of Open Disclosure^{62, 63}

Section A: Leadership	COMMENT	REVIEW DATE
Is there Board level/Senior Management level commitment to implementing the principles of open disclosure?		
How is this evident to staff working in the service?		
Have leads in open disclosure been identified?		
Are there leads in open disclosure who are working at senior clinician level?		
How are staff made aware of who these leads are?		
Are appropriate resources allocated to open disclosure? E.g. orientation, training, education, service user information leaflets.		
How does the service provide information to members of the public in relation to its commitment to the principles of open disclosure?		

⁶² Clinical Governance Service/Readiness Checklist - The Victorian clinical governance policy framework, Quality and Safety Unit, Department of Health, Melbourne, Victoria Australia June 2013

⁶³ NPSA Being Open – clarification on actions in NPSA- 2009- PSA003 May 2010

Section B: Open Disclosure Committee

COMMENT

REVIEW DATE

Has an open disclosure Committee been established or is open disclosure a standing agenda item for an existing committee?

Does this committee have a service user representative or receive input from service user representative groups?

How are the terms of reference and membership of this committee defined and communicated?

Does the committee include senior clinical representation from across the service?

Section C: Local Policy Comments

COMMENT

REVIEW DATE

Does the service have a policy on open disclosure?

How is this policy communicated to all staff?

How does this policy align with and direct other operational policies and the service's strategic objectives e.g. complaints management policy, incident reporting, incident management and incident review processes etc?

Section D: Support for Service Users

COMMENT

REVIEW DATE

What supports are available for service users who require immediate or longer term support in the aftermath of an adverse event?

Has the service identified key contact personnel who will provide direct liaison with the service user/support person during the open disclosure process?

Has the service identified the Service User Advocacy Groups which are currently operating within the service?

If yes, are the members of these groups aware of the open disclosure policy and guidelines?

Section E: Support for Staff

COMMENT

REVIEW DATE

What services are available within the service to support staff who require immediate and longer term support in the aftermath of an adverse event?

What supports are available for staff through existing EAP/ Occupation Health Services?

Are there nominated staff support persons within the service?

	COMMENT	REVIEW DATE
How are staff made aware in relation to who the nominated staff support persons are within the service and how to access them?		
Does the service offer debriefing to staff following an adverse event?		
What training is provided to staff to ensure they are trained adequately to provide a debriefing service?		
How does the service ensure that adverse events are discussed regularly within the multidisciplinary team at ward/unit level?		

Section F: Training

	COMMENT	REVIEW DATE
Do staff have access to open disclosure training?		
Has the service's identified leads in open disclosure attended training in open disclosure?		
Is open disclosure included in staff induction/orientation programmes and staff handbooks?		
Are open disclosure cases discussed at relevant staff meetings, grand rounds, peer support groups etc.?		

Section G: Visibility**COMMENT****REVIEW DATE**

How does the service promote the principles of open disclosure among staff e.g. via newsletters team meetings, intranet, special interest meetings, governance meetings, quality and risk committees or any other suitable existing forums?

How does the service include information on open disclosure in promotional materials e.g. service user information leaflets?

Section H: Audit**COMMENT****REVIEW DATE**

What audit processes are in place in relation to measuring and evaluating open disclosure within the service?

How does the service measure itself against the HIQA Standards for Safer Better Healthcare 2012 which relate to open disclosure and communicating with service users and their families following an adverse event? (Standard: 3.5)

Section I: Clinical Governance**COMMENT****REVIEW DATE**

What structures/processes are in place within the service to ensure that open disclosure is integrated with other clinical governance processes including clinical incident reporting and management procedures, systems analysis reviews and privacy and confidentiality procedures?

What internal processes are in place to manage situations where there is a difference of opinion among staff as to whether open disclosure should happen or not?

What internal processes are in place to manage situations where disclosure should have happened but did not happen?

Signed:

Date:

CEO/General Manager/Service Manager:

Pre, during and post disclosure, Sample Checklist

BEFORE	Note taking
Service user’s full name	
Healthcare record number	
Date of birth	
Date of admission	
Diagnosis	
Key healthcare professional(s) involved in service user’s care	
Date of discharge (if applicable)	
Date of adverse event	
Description of adverse event	
Outcome of adverse event	
Agreed plan for management of adverse event	

BEFORE (continued)**Note taking**

Agreed professional to act as contact person with service user

Date of first meeting with service user

Location of first meeting (other details such as room booking, arrangements to ensure confidentiality if shared ward etc.)

Person to be responsible for note taking identified

Lead discloser identified

Deputy discloser identified

Other staff identified to attend the disclosure meeting

Anticipated service user concerns/queries

Meeting agenda agreed and circulated

SERVICE USER**Note taking**

Additional supports required by the service user, if any?

The service user has been advised to bring a support person to the meeting?

The service user consented to the sharing of information with others such as designated family members/support person?

It has been established that the service user requires an interpreter? If yes, provide details of language and arrangements that have been or to be made.

DURING**Note taking**

There been an acknowledgement of the adverse event in relation to the service user's experience

An apology/expression of regret provided

The service user was provided with factual information regarding the adverse event

The service users understanding of the adverse event was established

The service user was provided with the opportunity to:

- tell their story
- voice their concerns and
- ask questions

DURING (continued)***Note taking***

Empathy and understanding were conveyed

The next steps in relation to the service user's ongoing care were agreed and the service user was involved in the decisions made.

The service user was provided with information in relation to the supports available to them.

Reassurance was provided to the service user in relation to the ongoing communication of facts when the information has been established and available –
continuity provided

Next meeting date and location agreed

AFTER

Circulate minutes of the meeting to all relevant parties for timely verification.

Follow through on action points agreed.

Continue with the incident review.

Keep the service user included and informed on any progress made –
organise further disclosure meetings.

Draft report to be provided to the service user in advance of the final report.

Offer a meeting with the service user to discuss the review report and allow for amendments if required.

Follow through on any recommendations made by the incident review team.

Closure of the process is mutually agreed.

When closure/reconciliation was not reached the service user was advised of the alternative courses of action which are open to them i.e. the complaints process, litigation process.

A summary of Clinical Governance processes

Text on Quality and Safety Clinical Governance Development

Introduction

Achieving safe and quality care requires the vigilance and cooperation of the whole workforce including service users and members of the public. Improving quality and protecting service users from harm is all our responsibility – clinical governance delivers the leadership and accountability systems to achieve this.

Clinical governance is the system through which healthcare teams are accountable for the quality, safety and satisfaction of service users in the care they have delivered.

For health care staff this means: specifying the clinical standards you are going to deliver and showing everyone the measurements you have made to demonstrate that you have done what you set out to do.

Effective governance recognises the inter-dependencies between corporate, financial and clinical governance across the service and integrates them to deliver high quality, safe and reliable healthcare.

Vision

It is anticipated that the further development implementation and ongoing commitment to quality and safety will create an environment where each individual as part of a team:

- knows the purpose and function of leadership and accountability for good clinical care;
- knows their responsibility, who they are accountable to and their level of authority;
- ***understands how the principles of clinical governance can be applied in their diverse practice; and consistently demonstrates a commitment to the principles of clinical governance in decision making resulting in:***

- a culture of trust, openness, respect and caring which is evident among managers, clinicians staff and service users; and
- Clinical governance being embedded within the overall corporate governance arrangement for the statutory and voluntary health and personal social services in realising improved outcome for service users.

Guiding principles

To assist healthcare providers a suite of ten guiding principles for quality and safety, for the Irish health context, were developed with a title and descriptor. It is proposed that the principles inform each action and provide the guide for managers and clinicians in choosing between options.

Figure 1: Guiding principles



It is recommended that each decision (at every level) in relation to clinical governance development be tested against the principles set out in Figure 1 and described in Table 4.

Table 4: Guiding principles descriptor

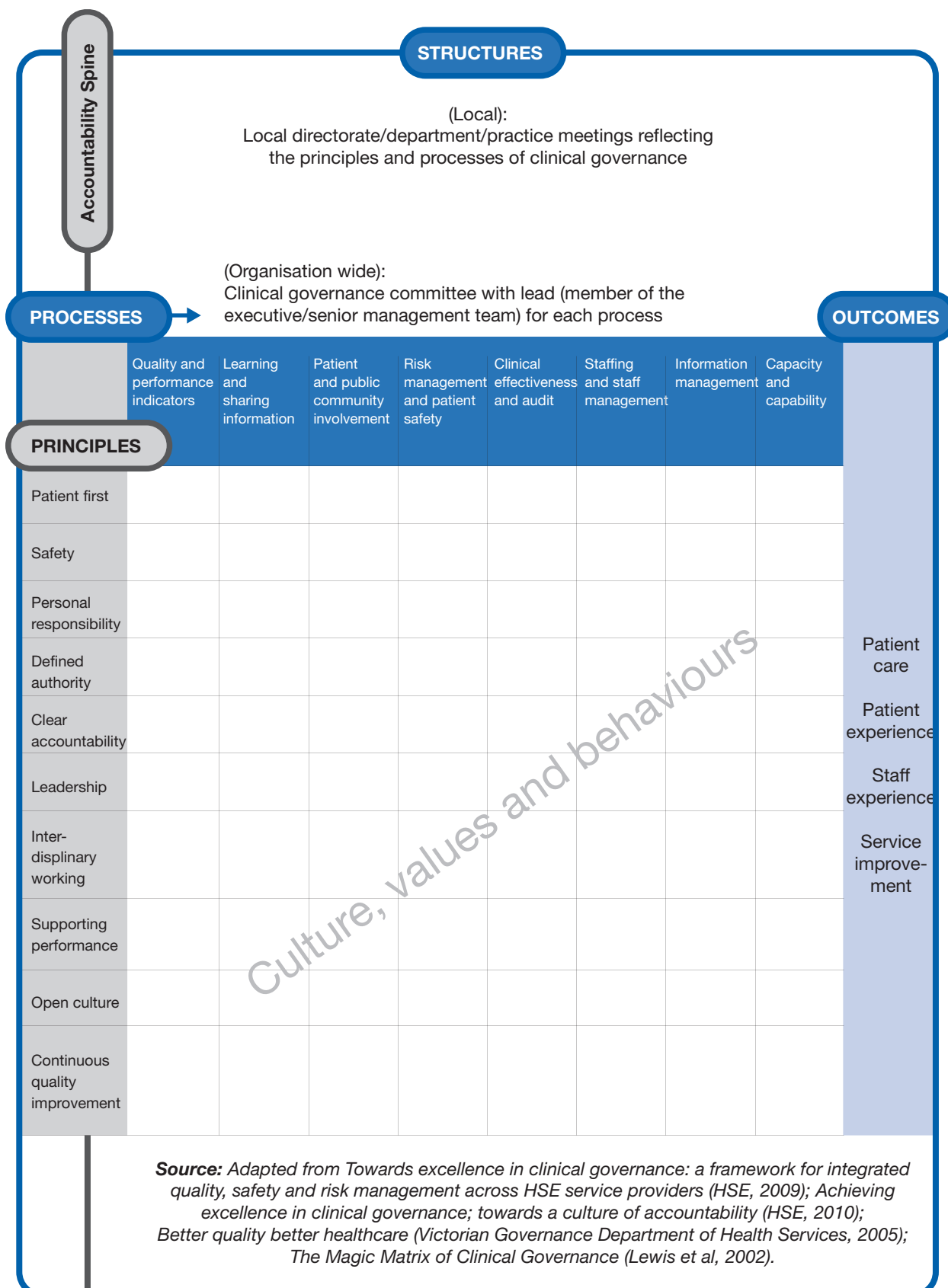
PRINCIPLE	DESCRIPTOR
Service user first	Based on a partnership of care between service users, families, carers and healthcare providers in achieving safe, easily accessible, timely and high quality/service across the continuum of care.
Safety	Identification and control of risks to achieve effective efficient and positive outcomes for service users and staff.
Personal responsibility	Where individuals as members of healthcare teams, service users and members of the population take personal responsibility for their own and others health needs. Where each employee has a current job-description setting out the purpose, responsibilities, accountabilities and standards required in their role.
Defined authority	The scope given to staff at each level of the service to carry out their responsibilities. The individual's authority to act, the resources available and the boundaries of the role are confirmed by their direct line manager.
Clear accountability	A system whereby individuals, functions or committees agree accountability to a single individual.
Leadership	Motivating people towards a common goal and driving sustainable change to ensure safe high quality delivery of clinical and social care.
Inter-disciplinary working	Work processes that respect and support the unique contribution of each individual member of a team in the provision of clinical and social care. Inter-disciplinary working focuses on the interdependence between individuals and groups in delivering services. This requires proactive collaboration between all members.

PRINCIPLE	DESCRIPTOR
Supporting performance	Managing performance in a supportive way, in a continuous process, taking account of clinical professionalism and autonomy in the serviceal setting. Supporting a director/ manager in managing the service and employees thereby contributing to the capability and the capacity of the individual and service. Measurement of the service users experience being central in performance measurement (as set out in the National Charter, 2010).
Open culture	A culture of trust, openness, respect and caring where achievements are recognised. Open discussion of adverse events are embedded in everyday practice and communicated openly to service users. Staff willingly report adverse events and errors, so there can be a focus on learning, research and improvement, and appropriate action taken where there have been failings in the delivery of care.
Continuous quality improvement	A learning environment and system that seeks to improve the provision of services with an emphasis on maintaining quality in the future not just controlling processes. Once specific expectations and the means to measure them have been established, implementation aims at preventing future failures and involves the setting of goals, education, and the measurement of results so that the improvement is ongoing.

Processes for clinical governance

To facilitate quality and safety clinical governance development each health service provider establishes the supporting structure and processes. Donabedian (1966) classical model of quality (structure, process and outcomes) is used in the clinical governance matrix to illustrate the clinical governance approach (*see Table 5*).

Figure 2: Clinical Governance Matrix



Effective arrangements for the following eight processes support the achievement of good clinical governance:

- Quality and performance indicators – an agreed process for the collection, reporting, trending and review
- Service user service user and public community involvement
- Risk management and service user safety
- Clinical effectiveness and clinical audit
- Learning and sharing information pertaining to quality and safety
- Staffing and staff management (recruitment, induction/ordination, credentialing, continuing professional development, performance management etc.)
- Information management
- Capacity and capability for quality and service user safety.


Further information can be located at www.hse.ie/go/clinicalgovernance

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NOTES



Get involved!

Find out about how you can get involved in improving health services in Ireland.

The HSE is actively inviting service users to get involved on patient forums and quality improvement initiatives. To find out more contact:

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Quality & Patient Safety Directorate,
Health Service Executive, Oak House,
Millennium Park, Naas, Co. Kildare

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