Open Disclosure – How this affects the Medical Negligence Landscape

9th November, 2019

Building a Better Health Service | Seirbhís Sláinte Níos Fearr á Forbairt

National Quality Improvement Team

Objectives:

At the end of this presentation attendees will be briefed on :

- The importance of Open Disclosure for Patients/Staff and Organisations
- The requirements of the revised HSE Open Disclosure Policy, June 2019
- The impact of Open Disclosure on Litigation
- Part 4 of the Civil Liability Amendment Act 2019

Definition of Open Disclosure

The HSE defines Open Disclosure as:

*"an **open**, **consistent, compassionate** and **timely** approach to **communicating** with patients and, where appropriate, their relevant person following patient safety incidents. It includes **expressing regret** for what has happened, keeping the patient **informed** and **providing reassurance** in relation to **on-going care and treatment, learning** and the steps being taken by the health services provider **to try to prevent a recurrence of the incident".***

(HSE 2019)

Open Disclosure:
The right thing to do

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- Open disclosure is the professional, ethical and human response to patients involved in/affected by patient safety incidents

- It is what patients want and expect

- It is what we would expect for ourselves or a loved one

- Learning from past experiences

Barriers to Open Disclosure in Ireland

- Fear of Litigation
- Fear of Conviction Gross Negligence Manslaughter (Bawa Garba UK)
- Fear of Fitness to practice
- Fear of Media
- Fear with regard to reputation and career advancement
- Culture of blame and shame still exists
- Bullying culture
- Staff support systems not adequate/consistent across services
- Patient support systems not adequate/consistent across services
- Lack of training prior to this programme
- Difficulties for staff getting released for training/Lack of Resources preventing release for training – Consultant numbers down – staffing resources at all levels – huge demands for several training programmes – overlap of training programmes – OD not taught at undergraduate level for all disciplines
- Feelings of shame and embarrassment – feelings of letting the patient down
- Fear of patient/family's response
- CLA Approach to Open Disclosure – concerns for doctor/patient relationship
- Mandatory Open Disclosure – offences (financial and custodial) and risks

What do Patients Want?

NOTHINGABOUTME WITHOUTME

"*Our family did not get open disclosure. We felt excluded and badly treated and none of the undertakings to give us answers were honoured. We pursued the legal route for three years but that was fraught with lack of conclusions and we feared for our financial security. The long period of "guarded secrecy" has probably deprived me of finding out the truth of the details of my husband's death. I needed to have open disclosure at the time when it was still fresh in the minds of all the medical staff caring for him".* (Bernie O'Reilly)

"He said no money would compensate for the loss of XX but the apology was priceless".
(The Irish Examiner July 2016)

"*Obviously mistakes will happen, they're humans at the end of the day, but it's how they approached it afterwards".*
"Anybody I've spoken to who has lost a child in XX has said that it wasn't the death of their child that hurt them as badly as the lack of answers, the lack of facts and the time delays in getting those answers and facts" (2016)

"*Open disclosure is not about blame.*
It is not about accepting the blame.
It is not about apportioning blame.
It is about integrity and being truly professional

And the reason:

You hold our lives in your hands and we, as patients, want to hold you in high regard."

(Mrs Margaret Murphy)

What do patients / service users want?

Respect

Honesty

Empathy

To be informed about their situation by someone who is knowledgeable about it

Dedicated attention

To have their questions answered in language they understand

Professionalism

Competent, efficient service

To be listened to (and heard)

To be updated in a timely manner

Basic courtesy / friendliness

To be taken seriously

Follow-through

1. A timely and comprehensive explanation of what happened and why
2. Someone to acknowledge and apologise if things went wrong
3. A reassurance that steps have been taken to ensure the event will not happen again

Why do patients sue

- To get answers
- The need for acknowledgement and apology
- Patients felt rushed
- Felt less time spent/ignored
- The attitude of staff
- Patients wanted their perceptions of the event/their story validated

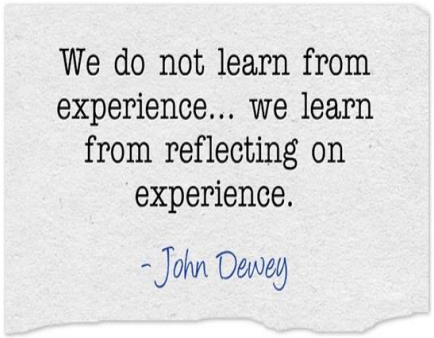
Why do patients sue?

- The experience of "second harm" – poor or no communication after the patient safety incident occurred
- To seek financial compensation
- To enforce accountability
- To correct deficient standards of care
- To try to prevent a recurrence of the incident

Benefits for Patients

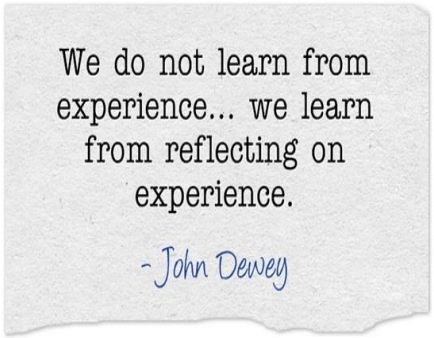
- The process can assist with providing closure for the patient/family and quicker emotional recovery.
- It can help to rebuild trust and confidence within healthcare.
- OD facilitates patient involvement in decisions relating to their ongoing care.
- OD prevents patient misconceptions in relation to the cause of the adverse event.
- Patients are more willing to continue an effective relationship with the Health Care Provider.
- Feelings of desertion after an adverse event are a major contributor to litigious intent.

Benefits for Staff



- Fulfilling professional, ethical and moral obligations to truthfully disclose information on harmful incidents.
- Improved staff recovery
- It encourages a culture of honesty and openness.
- Staff are more willing to learn from patient safety incidents
- It enhances management and clinician relationships
- It leads to better relationships with patients and their relevant persons
- Maintains personal and professional integrity
- Lightens the burden of guilt and shame
- Allows for reflective learning

Benefits for Organisations



- Enabling healthcare professionals to mitigate ongoing negative consequences of harmful incidents
- Enabling healthcare professionals to manage the stress and affective consequences of a harmful incident or complaint
- Facilitating a full and frank incident investigation which can be used to improve safety and quality
- Improved system responsiveness to patient needs
- Improved clinical communication skills resulting in better care, diagnostic skills and patient-centred outcomes

Impact of Open Disclosure on Litigation

University of Michigan Health System

2002, Adopted full disclosure policy-
Moved from, “Deny and defend” to
“Apologise and learn when we’re wrong, explain and vigorously defend when we’re right and view court as a last resort”

August 2001-August 2007
Ratio of litigated cases : total reduced from 65-27%.
Average claims processing time reduced from 20.3 months to 8 months.
Insurance reserves reduced by > two thirds.
Average litigation costs more than halved.
Savings invested into patient safety initiatives

Summary of the Key Policy Requirements

- ❑ Patients have the right to full knowledge about their healthcare and especially when things go wrong.
- ❑ Capacity must be presumed and patients who lack capacity have an equal right to be supported to engage in Open Disclosure.
- ❑ Open Disclosure must involve empathy and compassion towards all those affected.
- ❑ Know the trigger events – harm, suspected harm, no harm and near miss events.

Preparation for Open Disclosure

- ❑ Assess level of OD required – low or high level.
- ❑ Face to face meeting ideally.
- ❑ Consider if OD will be managed under the protections of Part 4 of CLA Act 2017 – if yes ⟹ CLA procedure.
- Establish facts.
- Consult with MDT.
- Establish team – who will make the disclosure?
- Consider who OD will be made to?
- Where and when will OD occur?
- Support for patient/relevant person to help prepare for meeting (formal OD meetings).
- Appointment of designated person (key contact person).

Our Values

Care Compassion Trust Learning

Information to be Provided at an Open Disclosure Meeting

- ❑ Introductions.
- ❑ Acknowledgement and description of what happened and the facts available.
- ❑ Acknowledge impact on the patient.
- ❑ Sincere and meaningful apology.
- ❑ Outline of care plan and treatment – ensure understanding.
- ❑ Actions being taken to establish further information and to prevent recurrence.
- ❑ Learning identified.
- ❑ Agreed actions and next steps.
- ❑ Communication plan – follow up – further meeting(s).
- ❑ Information on designated person.
- ❑ Supports available.
- ❑ CLA OD – provide relevant form.

Additional Information

Clarification of Information

- All additional information obtained must be provided in a timely and supportive manner.
- Clarification requests through designated person – respond factually and in a timely manner.

Providing a safe, supportive environment for staff

- Provide a safe, supportive and caring environment for staff involved in or affected by patient safety incidents.
- Ensure that the impact of patient safety incidents on staff is recognised and managed in a caring, supportive and compassionate manner.
- Provide services to support staff who are involved in and/or affected by patient safety incidents.
- Ensure that staff have access to training on the open disclosure policy relevant to their role.

Deferral of Open Disclosure

- Only in rare and exceptional circumstances will OD not happen.
- Always consider disclosure to relevant person – within confines of patient confidentiality.
- Situations:
  I. Patient and/or relevant person cannot be contacted.
  II. Patient refuses open disclosure.
  III. Patient is too ill and unable to participate in OD.
  IV. Doctor has concerns that OD may put patient at risk (at the time) of causing harm to themselves or to others.
- IV above – must be
  - consensus of more than 1 clinician.
  - agreed by most senior clinician.
  - documented in clinical/care record with rationale provided.
  - revisited at a later stage – no later than 4 weeks.
  - communicated to local accountable officer.

Open Disclosure to the Relevant Person

- Requires the consent of the patient.
- If the patient is unable to provide consent the decision to disclose must
  - be undertaken by most responsible person involved in the care of the patient.
  - involve consideration of the known will and preference of the patient - instruction provided by the patient.
  - involve consideration regarding who the disclosure will be made to.
  - Involve disclosure of only the relevant information
  - be documented in clinical/care record.
  - ensure that the patient is informed at a later date of the disclosure – what was disclosed and who to.

Open Disclosure Meeting – Follow up

- Follow up letter containing the information provided at the open disclosure meeting, the name and contact details of the designated person, the details of the apology provided and of any actions agreed.
- Follow up contact by designated person.

The Civil Liability (Amendment) Act 2017 and 2018 Regulations

Protective legislative provisions in Part 4 of the Civil Liability Amendment Act 2017 (CLA Act) –
Commenced in September 2018

1. *Open disclosure:*
   - *(a) shall not constitute an express or implied admission of fault or liability*
   - *(b) shall not, notwithstanding any other enactment or rule of law, be admissible as evidence of fault or liability and*
   - *(c) shall not invalidate insurance or otherwise affect the cover provided by such policy*

Provisions of Part 4 of the CLA Act 2017

2. *Information provided, and an apology where it is made, shall not*

(a) constitute an express or implied admission, by a health practitioner, of fault, professional misconduct, poor professional performance, unfitness to practice

(b) be admissible as evidence of fault, professional misconduct, poor professional performance, unfitness to practise, in proceedings to determine a complaint, application or allegation

What you need to know about Part 4 of the CLA Act 2017

- Part 4 of the CLA Act 2017 relates to **voluntary** open disclosure
- There are 8 regulations that accompany Part 4 of the CLA Act 2017
- Staff can opt to seek the protective provisions of the Act or not.
- To avail of the protective provisions within Part 4 of the Act open disclosure **must** be managed **strictly in accordance** with the procedure as set out within the Act and the regulations that accompany Part 4 of the Act
- The protections of the Act will be automatic when OD is managed as per the procedure set out in Part 4 of the Act

What is different about managing Open Disclosure under Part 4 of the CLA Act?

In addition to the HSE Policy requirements:

- The relevant prescribed statements (forms) must be prepared and signed by the health services provider and provided to the patient/relevant person, as appropriate.
- A copy of all forms must be kept on record by the health services provider – in a file separate to the clinical/care record
- The name of the designated person (key contact person) must be documented in a file separate to the healthcare record e.g. OD file/Incident Management File

What are the regulations?

There are 8 regulations

The regulations take the form of prescribed statements which staff are obliged to

- Complete
- Sign (signed by principal health care practitioner or another person deemed appropriate by the health services provider)
- Provide (relevant forms) to patients as set out in the procedure
- Maintain on record in a file separate to the healthcare record e.g. OD file or incident management file

Prescribed Statements

Form A - Statement of Information Provided at an Open Disclosure Meeting
Form B - Statement of Non-Attendance patient or Relevant Person at open disclosure meeting
Form C - Statement of Non-Attendance patient and relevant person at open disclosure meeting
Form D - Refusal to accept Statement
Form E - Statement of Additional Information
Form F - Request for Clarification Meeting
Form G - Statement of Clarification of Information
Form H - Statement of Steps Taken to Establish Contact

Available:
https://www.hse.ie/eng/about/who/qid/other-quality-improvement-programmes/opendisclosure/open-disclosure-legislation/civil-liability-forms.html

Legal Services Regulations Act 2015

Part 2A (32B) - not yet commenced - contains the following protections for an apology in clinical negligence claims:

(1) An apology made in connection with an allegation of clinical negligence—

(a) shall not constitute an express or implied admission of fault or liability, and

(b) shall not, despite any provision to the contrary in any contract of insurance and despite any other enactment, invalidate or otherwise affect any insurance coverage that is, or but for the apology would be, available in respect of the matter alleged.

(2) Despite any other enactment, evidence of an apology referred to in subsection (1) is not admissible as evidence of fault or liability of any person in any proceedings in a clinical negligence action.

Maintaining the Ethos of Open Disclosure

- **Open Disclosure: Maintaining our Values:** Care, Compassion, Trust and Learning
- **Open Disclosure: The right thing to do**
- Open Disclosure : What we would expect for ourselves or for a loved one
- Open Disclosure: The professional, ethical and humane response
- Open Disclosure: The empathic response to all those involved in and/or affected by patient safety incidents

Further information

- www.opendisclosure.ie or www.hse.ie/opendisclosure
- National documents – policy, guidelines, staff support booklet
- Resources for clinicians, organisations and trainers
- Open disclosure site leads/group leads/CHO leads/NAS Leads
- Yammer.com support forum
- National Open Disclosure Office

  Email: opendisclosure.office@hse.ie

Contact Details:

Email Opendisclosure.office@hse

Angela.tysall@hse.ie

Website: www.hse.ie/opendisclosure

For further information

Full policy and additional resources (including Staff Support Booklet)
www.hse.ie/opendisclosure

Contact the National Open Disclosure Office
Email: opendisclosure.office@hse.ie