Open Disclosure
Pharmaceutical Society of Ireland
Code of Conduct Roadshow
2nd October, 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 following patient safety incidents
- the requirements of the revised HSE policy on open disclosure April 2019
- national developments in relation to open disclosure
- the provisions of Part 4 of the Civil Liability (Amendment) Act 2017, the 2018 Regulations accompanying Part 4 of this Act and what is pending in the Patient Safety Bill.

Background

- Recommendations: “Building a Culture of Patient Safety 2008
- Joint HSE/SCA approach supported by MPS
- Pilot October 2010- March 2013
- Launch of national documents November 2013
- On-going roll out of policy and programme across all health and social care services since 2013
- OD leads and trainers in all areas – national training programme
- Independent evaluation of pilot programme published in 2016
- QAV audit of x 4 early adopter sites in 2016

Background (continued)

- Matters arising in Cervical Check Screening Programme and subsequent Scally Report and recommendations (9) September 2018
- Protective legislation: Commencement of Part 4 of the Civil Liability Amendment Act 2017 – commenced in September 2018
- Establishment of National OD Office and National Steering Committee 2018-2019
- Training programme for doctors being established – Communication and OD
- Interim Revision of HSE National Open Disclosure Policy - launched June 2019
- Scoping work on supports for staff and service users following patient safety incidents – led by QAVD 2019-2020

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)

Note: Patient safety incidents include harm, suspected harm, no harm and near miss events

Pharmaceutical errors

- Prescribing
- Interactions
- Input error
- Directions
- No/poor counselling
- Overlooking
- Miscalculation
- Failure to question or act on concerns
- Mix-up
- Equipment
- Expired drugs
- Storage

- ❑ Pharmaceutical errors can and do happen.
- ❑ Every Pharmacist cannot be perfect all the time
- ❑ Mistakes can be hard to admit - punitive environment – fear of losing licence, reputational damage, fitness to practice, litigation, professional advancement, patient response
- ❑ Not admitting a mistake can have disastrous consequences.
- ❑ Reviewing and learning from mistakes leads to safer better systems, quality improvement and improved patient safety.
- ❑ "*To err is human – to cover up is unforgivable – to fail to learn is inexcusable"* (Sir Liam Donaldson CMO England)

Open Disclosure
The Drivers

Open Disclosure: The right thing to do

- 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

Open Disclosure: The Drivers

1. HSE Policy/Incident Management/YSYS

2 . Professional and Regulatory

- NMBI - code
- Medical Council - code
- HIQA - standards
- CORU - code
- Mental Health Commission
- Pre Hospital Emergency Care Council
- Pharmaceutical Society of Ireland – PSI Code of Conduct

Open Disclosure: The Drivers

3. **The Department of Health:** Government Policy/Code of conduct for staff (2018)

4. **Indemnifying Bodies:** SCA/MPS/MDU/MEDISEC

5. **Royal Colleges:** RCSI, RCPI, ICO, ICGP, Faculty of Radiologists

6. **WHO**

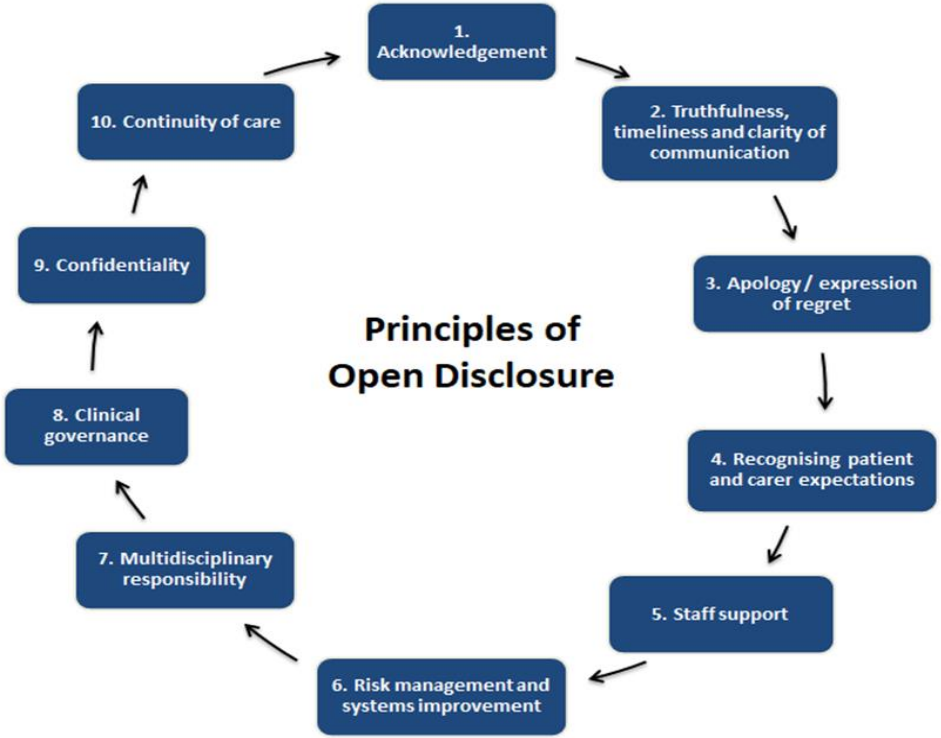
7. **Media**

Open Disclosure
The Principles

The Principles of Open Disclosure

1. Acknowledgement
2. Truthfulness, timeliness and clarity of communication
3. Apology/Expression of Regret
4. Recognise Patient and Carer expectations
5. Staff Support
6. Risk Management and Systems Improvement
7. Multidisciplinary Approach
8. Clinical Governance
9. Confidentiality
10. Continuity of Care

CARE COMPASSION TRUST and EMPATHY



7 Principles

1. Put the Patient First
2. Act professionally
3. Communicate effectively
4. Work with others
5. Show leadership
6. Maintain Competence
7. Be Open and Honest

The Ten Commandments of Patient Safety and Quality (Summary) ISQua

1. **Be authentic and genuine** – be nice to our patients
2. **Show compassion and care** – prioritise the needs and expectations of patients
3. **Collaborate and work together** – team work – co-design health services with patients and consumers
4. **Be inclined to Emotional Intelligence** – put emphasis on the emotive aspect of care - IQ + EQ
5. **Confront and speak up** – empower people and ourselves to confront and speak up on issues and situations
6. **Be expressive of your feelings –** don't bottle things up
7. **Integrate and coordinate** – provide seamless access to care as opposed to fragmented /segregated care
8. **Embrace continual learning** other than blaming and shaming
9. **Embed human factors and ergonomics** - design a health system to make it difficult for healthcare providers to make mistakes.
10. **Love** – the secret of quality is love – love of our profession, role, patients

Reference: OTCHI, Elom Hillary | FISQua, MPH, MA (Org. Devt), PGD, BSc Expert, International Society of Quality in Healthcare (ISQua) Technical Director, AfIHQSA

Managing Open Disclosure using the MPS A.S.S.I.S.T Model of Communication

A – Acknowledge – problem and impact

S – Sorry – express regret

S – Story – hear patient's story and summarise back to them

I – Inquire – seek questions to be answered, provide answers, give information

S – Solution – seek patient's ideas on the way forward – agree a plan

T – Travel – avoid abandonment – continued care – increased contact.

Summary of HSE Revised Policy on Open Disclosure

June 2019

Our Values
Care Compassion Trust Learning

Our Values
Care Compassion Trust Learning

Summary of the Key Policy Requirements

Our Values
Care Compassion Trust Learning

- 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
- 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)

Information to be Provided at an Open Disclosure Meeting

Our Values
Care Compassion Trust Learning

- ❑ 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
- ❑ Agreed actions and next steps
- ❑ Learning identified
- ❑ Information on actions being taken to establish further information and to try to prevent a recurrence
- ❑ Communication plan – follow up – further meeting(s)
- ❑ Information on designated person
- ❑ Supports available
- ❑ CLA OD – provide relevant form

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.

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
  - Documented in clinical/care record
  - ensure that the patient is informed at a later date of the disclosure – what was disclosed and who to

Governance of Open Disclosure

- Primary responsibility and accountability for the effective management of patient safety incidents remains at organisational level where the patient safety incident occurs.
- Effective governance arrangements are required to support timely and effective open disclosure.
- Governance arrangements must support the effective management of open disclosure.
- The accountability arrangements for open disclosure must be clearly defined.
- Governance arrangements for open disclosure should clearly set out the roles, accountabilities and responsibilities at all levels of the service.

Open Disclosure
Legal considerations and Legislation

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

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

Patient Safety Bill - pending

This Bill is still being drafted (as of 3 October 2019)

"A Bill to provide for mandatory open disclosure of serious reportable patient safety incidents, notification of reportable incidents, clinical audit to improve patient care and outcomes and extend the Health Information Quality Authority remit to private health services"

(Department of Health 5 July 2018)

Note:

General Scheme of Bill is available via link below

https://health.gov.ie/blog/publications/general-scheme-patient-safety-bill-5-july-2018/

Legal Services Regulations Act 2015

This act (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

WHO 2019 – Speak up for Patient Safety

Strategies to Promote Openness and Transparency

Dr Albert Wu
ISQUA Webinair
September 2019

Further information

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

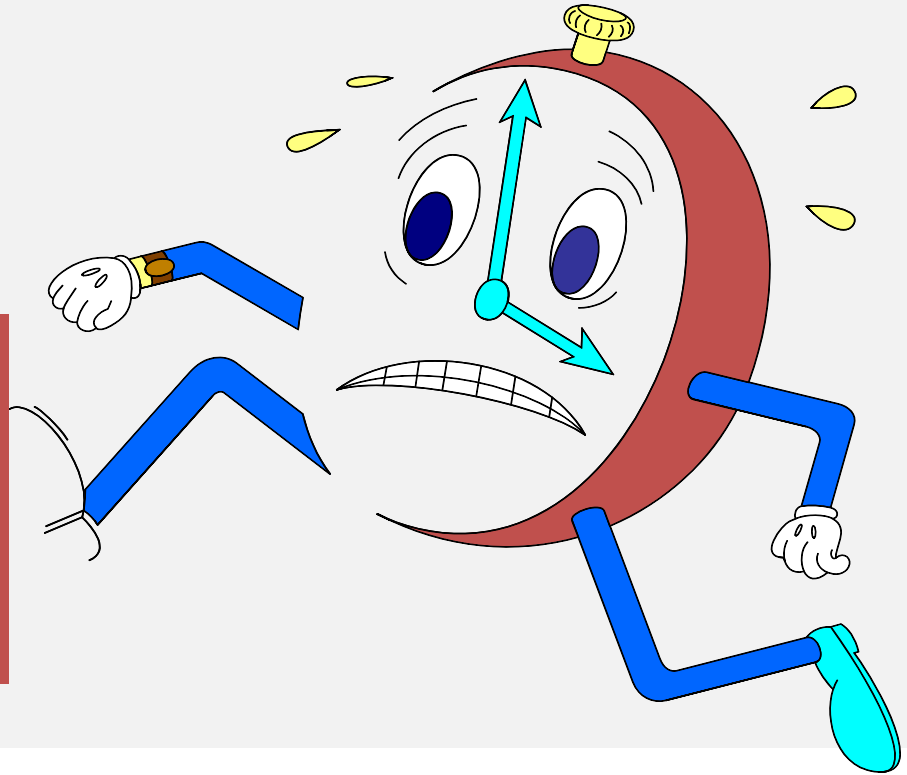
Email: opendisclosure.office@hse.ie

Contact Details:

Email Opendisclosure.office@hse

www.hse.ie/opendisclosure

Thank you for your time and attention….any questions ?



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