Independent Patient Safety Council

Recommendations on a National Policy Framework for Open Disclosure in Healthcare in Ireland

January 2021

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Crowe Report to Department of Health re Open Disclosure

Foreword from the Chairperson

Dear Minister

On behalf of the Independent Patient Safety Council, I am pleased to present you with our recommendations for a national policy framework for open disclosure in healthcare in Ireland.

The ministerially appointed Council provides advice and guidance to inform policy direction in relation to patient safety policy and works in support of the promotion of a culture of patient safety throughout the health services. In January 2020, the Council was asked by the then Minister for Health to undertake an examination of open disclosure policy in healthcare at the national level and make recommendations to him in relation to the development of a national policy framework regarding open disclosure in healthcare in Ireland.

Open disclosure is an issue of concern for many patients and service users. While much has been done to advance it in our healthcare system in Ireland, barriers to, and potential for improvement in open disclosure remain. Our recommendations present high-level principles and approaches to implementation to support the development and embedding of a national policy framework for open disclosure in healthcare in Ireland.

We trust that you will find that these high-level principles and recommendations will support a coherent approach from which you and your department can develop the framework and its implementation, leading to an improved culture where open disclosure is integral to everyday practice within our health system.

While the recommendations now furnished are those of the Council alone, and come from the many perspectives of our expert members, our discussions benefitted substantially from the evidence and analysis gathered by Crowe and published in the report "Evidence to Support the Independent Patient Safety Council for the Development of Recommendations on a National Policy Framework for Open Disclosure in Healthcare in Ireland", and we thank them for their assistance.

I would like to take this opportunity to thank my fellow members of the Independent Patient Safety Council for their hard work and commitment to this project in a time of enormous pressure for all those working in our health system. I would also like to thank the National Patient Safety Office in the Department of Health for their excellent and consistent support. My thanks also to all those who contributed to discussions and requests for information.

Noeline Blackwell
Chair, Independent Patient Safety Council

January 2021

Introduction

Open disclosure is an open, consistent, compassionate, and timely approach to communicating with patients/service users and/or their support persons following adverse events and patient safety incidents. Open disclosure is the professional, ethical and humane response to patients/services users and their support persons involved in/affected by patient safety incidents/adverse events. When something has gone wrong with patient or service user care, this is referred to as an adverse event or patient safety incident.

It is important that health and social care staff and providers have clarity on what is meant by open disclosure in terms of what is to be disclosed and in what way. Whilst patients/service users and support persons are entitled to open, timely, and clear communication about all aspects of their care, including if and when something goes wrong, not all "open disclosure" requires a formal process. A tiered, proportionate response to open disclosure, appropriate to what has happened and the impact on the patient/service user or support persons, is the approach that is required, in line with legislative requirements, regulatory codes of conduct or ethics, and organisational policies. Whilst some degree of judgement may be required in individual cases as to the appropriate level of response and the way in which disclosure should take place, guidance on this should be key in open disclosure policies and training across all health and social care providers.

Examples of where less formal responses would be required include:

- Near misses and no-harm incidents
- No increased level of care required (e.g. a surgical procedure necessitated by the event or transfer to an operating theatre or intensive care unit)
- No, or minor, psychological or emotional distress

However, in the following circumstances, it is evident that a more formal response to a patient safety incident or adverse event is required:

- Death or significant injury following a patient safety incident or adverse event
- Permanent or considerable lessening of body function following a patient safety incident or adverse event
- Where there has been a requirement for a significant escalation of care or major change in clinical management (e.g. admission to hospital, surgical intervention, a higher level of care, or transfer to intensive care unit)
- Major psychological or emotional distress
- Where a patient/service user or support person requests a more formalised or escalated response.

The development of these draft recommendations has been based on the evidence provided in the Crowe report to the Independent Patient Safety Council and the Council's subsequent deliberations on its findings. The Council engaged in a process of drafting and refining recommendations, and has opted to present the recommendations grouped around key principles.

A set of recommendations is set out for each principle, to indicate how the Council believes these principles should inform the national policy framework and health and social care policy and practice, and how they should be implemented and monitored.

There is some degree of overlap with the principles on which the current HSE open disclosure policy is based and many of these recommendations reflect existing practice. This is not to suggest that such policies and practice are not in place or effective: quite the reverse, in that it is intended to support what is positive about the current policy and practice and to build on this and expand beyond the HSE. Considerable work has been undertaken in the HSE to improve the organisation's approach to open disclosure and these recommendations are intended to support this through the national policy framework.

The recommendations set out in this document, based on a set of key principles, are intended to apply across the entire health and social care sector and to all adverse events and patient safety incidents, including those requiring lower- and higher-level responses.

The recommended key principles underpinning the policy framework are as follows:

- **Open, Honest, Compassionate, and Timely Communication**
- **Patient/Service User and Support Persons' Entitlements in Open Disclosure**
- **Supporting Health and Social Care Staff**
- **Promoting a Culture of Open Disclosure**
- **Open Disclosure for Improving Health and Social Care Policy and Practice**
- **Clinical and Corporate Governance for Open Disclosure**

Principle 1: Open, Honest, Compassionate, and Timely Communication

1.1 Open disclosure[1] is defined as an open, consistent, compassionate, and timely approach to communicating with patients/service users and/or their support persons following adverse events and patient safety incidents. When something has gone wrong with patient or service user care, this is referred to as an adverse event or patient safety incident[2].

Open disclosure is a core component of excellent care within a compassionate and competent health and social care system, across all health and social care settings including those in the public and private sectors.

1.2 Communication with patients/service users and/or their support persons must be compassionate, truthful, timely, and clear. If things go wrong, the patients/service users and/or their support persons must be provided with information about what happened in a timely, open, compassionate, and honest manner. This applies to all patient safety incidents or adverse events.

1.3 Open disclosure must be considered an integral aspect of communication between health and social care staff and patients/service users and/or their support persons. Whilst there must be formal open disclosure processes in place for serious incidents resulting in patient harm, most patient safety incidents or adverse events do not require a formal process to be initiated and the disclosure of these incidents must be part of open and truthful communication to patients/service users and/or their support persons. Incidents resulting in more significant impact on patients/service users and/or their support persons will require a more formalised approach.

1.4 Open disclosure must be considered as an ongoing and fluid process as information becomes available rather than a one-off event.

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1 Whilst there are valid misgivings about the terminology, in the absence of a universally acceptable alternative and mindful of the wording in existing and forthcoming legislation and in many existing policies such as those in the HSE, for the purposes of the national policy framework, the Council recommends the use of the term "open disclosure" to refer to the communication between health and social care staff and health and social care service providers to patients and/or support persons in respect of patient safety incidents.

2 The term "patient safety incident" is used in HSE policies and in the Patient Safety Bill 2019. However, the application of the national policy framework to all health and social care means that broader terms are needed rather than solely referring to "patients", hence the use in this document of "adverse events and patient safety incidents".

1.5 It is important that health and social care staff (clinical and non-clinical) and patients/service users and their support persons have clarity and understanding of what open disclosure means, what type of incidents require open disclosure, the information that must be provided, how the process should be managed, what is disclosed, and how it works. If there is ambiguity, confusion, or doubt on any of these, open disclosure is less likely to happen in a consistent, effective, and appropriate manner.

1.6 There must be clarity in respect of the appropriate level of response to adverse events and patient safety incidents: health and social care staff must be clear on the types of incidents that require the initiation of a formal open disclosure process, which must include a timely initial discussion with the patient/their support person to advise them about what has happened and the facts that are available at that time. This will be followed at a later stage by a formal open disclosure meeting when more information relating to the incident becomes available.

1.7 The instigation of formal open disclosure should be in addition to timely communication to patients/service users and/or their support persons to advise them of what has happened.

Implementation of this principle

1.8 Building on the significant work already undertaken across the health and social care sector in developing open disclosure policies, there must be consistent policies on open disclosure across all health and social care service providers, clinical education providers, and health and social care regulatory bodies, aligning with the national framework principles, definitions, and provisions.

1.9 Health and social care providers must communicate their open disclosure policies and procedures to patients/service users and/or their support persons clearly and in a way that ensures they are understood.

1.10 Policies on open disclosure are intrinsically linked to patient/service user safety policies and incident management policies. They must be clear and consistent with these policies in respect of identifying when incidents occur, the requirements for disclosure to patients/service users and/or their support persons, the requirements for disclosure to the health and social care service providers as relevant, and the requirements for compliance with relevant legislation such as the provisions of the Patient Safety Bill 2019.

1.11 Health and social care providers must integrate and align open disclosure policy and practice with the contractual roles and responsibilities of health and social care staff and all relevant policies and procedures pertaining to the fulfilment of their contractual obligations.

Principle 2. Patient/Service User and Support Persons' Entitlements in Open Disclosure

2.1 In the event of an adverse event or patient safety incident, patients/service users and/or their support persons want an acknowledgement of what has happened, an explanation as to how or why it happened, a meaningful apology, and reassurance in relation to their on-going care and treatment and in relation to the steps being taken to try to prevent a recurrence of the same incident.

2.2 All adverse events and patient safety incidents must be **acknowledged** to the patients/service users and/or their support persons at the earliest opportunity that is practicable. This acknowledgement must consider the physical, emotional, social, and financial impact of the incident on the patients/service users and/or their support persons.

2.3 The patient/service user and/or support persons are entitled to **an explanation**, to be fully informed of the facts surrounding an adverse event or patient safety incident and its consequences (which may involve a process as the full facts in respect of an incident emerge); to be treated with empathy, respect, compassion, and consideration; and to be supported in a manner appropriate to their particular needs.

2.4 The patients/service users and/or their support persons must receive an **apology** or expression of regret for what has happened in respect of an adverse event or patient safety incident. An apology must be genuine, respectful, sincere, and personal to the individual and the given situation. An apology must be given at the earliest opportunity that is practicable, even if all the information relating to the adverse event or patient safety incidence is not yet available.

The apology must include:

(i) an acknowledgement of what it is that the service is apologising for;
(ii) an explanation of why or how the situation occurred;
(iii) the words *I am sorry for what has happened* and for how the situation has impacted the patient and/or their support person;
(iv) an outline of the steps taken or planned by the service to put things right.

It should include reference to the supports available to patients/service users and/or their support persons in relation to the incident and open disclosure, and all avenues for escalating disclosure processes and/or concerns.

2.5 Patient or service user **ongoing care and treatment** must not be compromised or delayed in respect of the disclosure of an adverse event or patient safety incident. If requested by patients/service users and/or their support persons, or in the patient/service user's best interests where appropriate, transfer of care to another clinician or to another health or social care provider must be facilitated when it is possible to do so. Patients/service users and/or their support persons exercising their right to seek recourse or redress must not be treated differently.

2.6 Patients/service users and/or their support persons have the right to escalate complaints or concerns about the disclosure process or the adverse event or patient safety incident itself – and be supported to do so – through any and all mechanisms available, including the right to seek legal or other redress.

2.7 The patient/service user right to confidentiality must be maintained throughout any open disclosure process.

Implementation of this principle

2.8 Consideration should be given to the provision of independent support services to all affected patients/service users and/or their support persons, should they need it. This support should be free and independent of the health or social care provider (separate and distinct from legal or policy obligations for health and social care providers to appoint a designated liaison person) and provided by suitably trained and competent personnel to support the patients/service users and/or their support persons for as long as is required. All patients/service users and/or their support persons involved in the aftermath of an adverse event or patient safety incident should:

- be enabled to participate in the open disclosure;
- be supported through the open disclosure process;
- have access, where needed, to independent support to help in the immediate aftermath of the incident and on an on-going basis for as long as is required;
- be informed by health and social care staff and/or health and social care providers of the independent support that is available to them and empowered to avail of it.

2.9 Support for patients/service users and/or their support persons must be accessible where special circumstances may make them more vulnerable (such as those with disabilities, mental health difficulties, etc.), including:

- policy guidance for open disclosure procedures for these categories of patients/service users;

- training for health and social care service providers and staff tailored to open disclosure for vulnerable patients/service users and support persons;
- the provision of patient/service user advocates with particular training in advocating for and communicating with people in these situations.

2.10 Open disclosure policies in health and social care providers must encompass procedures for the provision of information and apologies, and must include procedures for providing updated information to patients/service users and/or their support persons following internal reviews or investigations into adverse events or patient safety incidents.

2.11 There should be legal, indemnity, and employment protections for the provision of information and apologies by health and social care workers and/or health and social care providers in respect of open disclosure communications.

2.12 In the event that patients/service users and/or their support persons later wish to pursue formal, legal or other redress following an adverse event or patient safety incident, health and social care providers must also provide at this stage all the relevant information to facilitate patients/service users and/or their support persons to exercise this right.

Principle 3. Supporting Health and Social Care Staff

3.1. All open disclosure in relation to adverse events and patient safety incidents must be patient- or service-user-centred and place the needs of the patient/service user and/or support persons at the heart of the process. In addition, it is important to identify the staff involved in and/or affected by the adverse event or patient safety incident and to ensure that they are being supported in the immediate aftermath of the incident and on an on-going basis for as long as is required, in recognition of the impact of such incidents on staff. All staff in health and social care delivery must be:

- encouraged, facilitated, empowered, and obliged to recognise and report adverse events and patient safety incidents;
- prepared to participate in open disclosure through easy access to information, communication skills, training and education, and supportive procedures;
- supported through the open disclosure process.

3.2. Open disclosure involves multidisciplinary accountability and response. Clinical, non-clinical, and managerial staff must be identified within health and social care providers to lead and support the process. Open disclosure relates to all staff groups and not just clinical staff. All staff have a role in reporting adverse events and patient safety incidents. All staff have a role in supporting patients/service users, support persons, and colleagues involved in adverse events and patient safety incidents.

3.3. It must be recognised that failure to disclose openly to patients/service users and/or their support persons in relation to an adverse event or patient safety incident may be subject to consequences and that all health and social care staff must clearly understand their obligations in relation to open disclosure.

Implementation of this principle

3.4. Health and social care providers must include mechanisms in open disclosure policies to empower staff to report adverse events and patient safety incidents and to communicate with patients/service users and/or their support persons openly in relation to these incidents.

3.5. Health and social care staff must have access to and participate in appropriate training, guidance, and support in relation to open disclosure to patients/service users and/or their support persons. Each health and social care provider should designate specific personnel to lead on this.

3.6. Mechanisms to facilitate this type of training, guidance, and support to health and social care staff working outside organisational settings or in very small organisations must be put in place.

3.7. Health and social care professional regulatory bodies must include clear and unequivocal obligations for open disclosure in codes of conduct and ethics for regulated practitioners, aligned to the definitions and terminology set out in the policy framework.

3.8. Education and training bodies for all clinical professions must include modules in relation to communication skills, adverse event and patient safety incident management, and open disclosure in undergraduate, postgraduate, specialist training, and continuing education and development programmes.

Principle 4. Promoting a Culture of Open Disclosure

4.1. A supportive culture is critical to effective open disclosure. Recognition must be given to the importance of developing and maintaining a culture in which open disclosure takes place as a matter of course, in a patient- and service user-centred and compassionate way, by health and social care staff who are supported to do so. The health and social care system must avoid a "blame culture", which seeks to place responsibility for adverse events and patient safety incidents on individual health and social care staff, in favour of a "just culture", which promotes psychological safety.

4.2. A just culture is one based on fairness, which recognises the capacity for human error and the role of system and environmental factors in adverse events and patient safety incidents, and in which everyone seeks to learn and improve. It includes ensuring people are accountable for their actions and responsible for learning. This approach will better meet the needs of patients/service users and/or their support persons in relation to open disclosure and the management of adverse events and patient safety incidents. as well as patient outcomes.

Implementation of this principle

4.3. Culture change requires a multi-faceted approach and strong leadership. Health and social care providers must demonstrate that they have put in place effective processes by which they support the development of a positive and just culture for open disclosure.

4.4. Clinical and managerial champions must be identified by health and social care service providers to lead and promote open disclosure policy and practice.

4.5. Education and training programmes must be provided for all health and social care staff to support and promote a culture of open disclosure.

4.6. Health and social care providers must be able to demonstrate that staff are encouraged to disclose adverse events, patient safety incidents, or any concerns to patients/service users, support persons, and colleagues or managers.

4.7. Health and social care providers must be able to demonstrate that they have an "open disclosure by default" approach and that patients/service users and/or their support persons are provided with relevant information in a timely manner. Health and social care

providers and staff must not adopt a defensive approach seeking to minimise or delay the provision of information by any means.

4.8. Mechanisms to assess the culture and practice of open disclosure must be put in place by health and social care providers, to provide regular data on how it is working for patients/service users and for health and social care staff and what progress is being made towards a just culture rather than a blame culture.

4.9. Health and social care providers must identify and regularly monitor the patient/service user and health and social care staff experience of open disclosure. This information will then be used to:

- Inform policy;
- Support capacity building;
- Empower patients/service users and/or their support persons to speak up and ask questions;
- Assess how success is measured and encourage leadership;
- Shift to a proactive rather than reactive approach to safety and disclosure.

Principle 5. Open Disclosure for Improving Policy and Practice in Health and Social Care

5.1. Open disclosure is one essential component of the process of addressing an adverse event or patient safety incident and learning from this to improve services in the health and social care system.

5.2. Adverse events and patient safety incidents must be identified, managed, reported, disclosed, and reviewed, and learning derived from them.

5.3. An effective, accessible and timely open disclosure process may help to reduce the need for further escalation and minimise the impact involved following an adverse event or patient safety incident.

5.4. Actions must be taken to try to prevent a recurrence of such incidents. Patients/service users and/or their support persons must be involved in the process of management and review of adverse events and patient safety incidents and must be informed of the outcome of such reviews.

Implementing this principle

Continuing to build on the work of the health and social care providers and regulators:

5.5. The health and social care service providers and regulators must provide clarity and guidance, including clear guidance materials such as checklists, for health and social care staff in respect of the requirements to disclose and report on adverse events and patient safety incidents.

5.6. There must be provider-level and national mechanisms for recording, reporting on, and monitoring adverse events and patient safety incidents, the response to these, and the open disclosure associated with them, as happens within the National Incident Management System. Consideration should be given to the use of the National Incident Management System by other health and social care providers to record and report such incidents and disclosure.

5.7. Open disclosure processes should be as simple and as accessible as possible for patients and staff.

5.8. Health and social care providers must demonstrate that mechanisms are in place for learning and improvement in respect of adverse events and patient safety incidents and the disclosure process associated with these.

5.9. Open disclosure reports from health and social care providers must include examples of the types of incidents that led to policy changes thereafter as a section in the report and should be available for review by the appropriate regulatory bodies.

Principle 6. Clinical & Corporate Governance for Open Disclosure

6.1. Health and social care services must have governance frameworks with appropriate accountability structures in place which ensure that open disclosure occurs and that it is integrated with other clinical and corporate governance systems and processes, including clinical incident reporting and management procedures, systems analysis reviews, complaints management, and privacy and confidentiality procedures.

6.2. The governance framework for open disclosure encompasses health and social care provider policies, clinical governance frameworks, corporate governance frameworks, monitoring, regulation, and legislation.

Implementing this principle

6.3. It is important that the governance of open disclosure be based on a "comply or explain" concept, whereby compliance with obligations to disclose adverse events and patient safety incidents is expected and staff and/or health and social care service providers who have not complied must be accountable for providing explanations as to why this is the case.

6.4. Annual reporting by health and social care providers on open disclosure must be put in place. Reporting should be integrated with other related reporting, such as incident management, to ensure that it is not fragmented and that data can be captured and reported on in simpler, more useful ways. Examples of "good" annual reports, and/or templates for these, should be shared to promote excellence.

6.5. The inclusion of open disclosure as part of HIQA and Mental Health Commission guidance and monitoring should be considered, particularly in light of the proposed extension of this role to private hospitals.

6.6. The Patient Safety Bill 2019, on passing into law, must, before commencement of its provisions, be accompanied by a clear set of guidance materials for all health and social care service providers and practitioners to support the correct interpretation and application of the legislation.

6.7. The legislation must be considered as one part of an overall national policy approach to, and governance of, open disclosure and not as a single lever or tool for change.

6.8. Mechanisms for monitoring the implementation and application of the provisions of the legislation must be in place, with regular reviews undertaken and published.

Appendix: Crowe Report to Department of Health re Open Disclosure

Crowe

Final Report to

An Roinn Sláinte
Department of Health

Evidence to Support the Independent Patient Safety Council for the Development of Recommendations on a National Policy Framework for Open Disclosure in Healthcare in Ireland

January 2021

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Executive Summary

Background

In April 2020, the National Patient Safety Office (NPSO) in the Department of Health ("the Department") commissioned Crowe to provide evidence and support to the Independent Patient Safety Council (IPSC or "the Council") in relation to the development of recommendations to the Minister for Health for a national policy framework on open disclosure in healthcare in Ireland.

The aim of this project is to provide an evidence base in formulating recommendations applicable to the development of a coherent national policy framework regarding open disclosure across Irish Health Services and a wide range of health service organisations and health regulatory and educational bodies. The project sought to:

- Map the current national landscape in relation to open disclosure;
- Identify national and international best practices with regard to the operation of open disclosure
- Engage with relevant stakeholders;
- Benchmark Irish policies and approaches against international best practices;
- Identify best practices in relation to matters such as core founding principles implementation and healthcare practitioners' professional development;
- Consider barriers to implementation of open disclosure;
- Present options to the Council based on evaluation of the applicability of those best practices in the Irish context to enhance effective implementation of a culture of open disclosures across the health sector.

The key activities included in carrying out this task were a review of the current context for open disclosure, a literature review, consultation with key stakeholders and a survey aimed at patients, their families and the wider community.

Current Context for Open Disclosure

We conducted a review of the current policies, legislation, practices and requirements in relation to open disclosure and associated issues (such as serious incident management) that exist across the health sector in Ireland. These included:

- Civil Liability (Amendment) Act 2017
- National Treasury Management Agency (Amendment) Act 2000
- Patient Safety (Notifiable Patient Safety Incidents) Bill 2019.
- HSE Open Disclosure Policy
- HSE Incident Management Policy
- Other healthcare providers
- Dublin Fire Brigade Policy
- National Ambulance Service Policy
- HIQA Safer Better Healthcare Standards
- Health regulators codes of conduct
- Tusla Policy

Review of the Literature

The literature review included an in-depth examination of 237 sources from a literature search by the King's Fund Library Service. These sources included peer-reviewed journal articles, trade press, opinion or editorial pieces and examples of policies and agreements from a number of countries.

The key challenges and barrier to open disclosure included the fear of legal repercussions for health and social care staff, as well as a fear of the loss of reputation or trust. Blame culture was also cited as one of the key barriers to open disclosure for healthcare staff.

Supports for medical professionals discussed in the literature included:

- General training around open disclosure
- "Just-in-time" training before disclosure conversations
- Empathic communication skills
- Nonverbal communication skills.

Specific supports for medical professional following an adverse event is something that has received more attention in recent years due to them being seen as the "second victim" of an adverse event.

Looking at the patient perspective the literature identifies that the majority of patients do not feel satisfied with the disclosure and have certain expectations as to what the open disclosure process should involve, including the following:

- An apology;
- An explanation as to what happened;
- Acknowledgement of responsibility;
- An assurance that measures will be put in place to prevent it happening again;
- The process is carried out in a timely fashion;
- Effective communication throughout the process.

Additional considerations in relation to open disclosure that were covered in literature included the need to look at open disclosure as an ongoing, continuous process as supposed to a one-time event; the role of compensation to relieve financial distress that occurs due to an adverse event; children involved in the process of open disclosure, and; the debate around mandatory reporting.

Stakeholder Consultation

An extensive programme of consultation was carried out with a number of key stakeholder organisations and individuals. These key stakeholders came from all areas of healthcare. Each consultation followed a semi-structured approach, aiming to explore a number of key areas and questions.

While it was largely acknowledged by stakeholders that there has been significant movement in the last several years towards an increased awareness of openness and culture of open disclosure, it was agreed that there is a lot more work needed in this area. The culture both within health and social care in Ireland was seen as a vital area where change was still necessary and discussion around how to do this included the use of education and training, a peer led approach and leadership within healthcare settings.

The process currently in place in relation to open disclosure was seen as very bureaucratic and a process that currently didn't work for either healthcare staff or patients.

The challenges and barriers to open disclosure could be related back to the literature review, as well as some aspects that were more prominent in the Irish healthcare setting. These included:

- Culture both within healthcare and in wider society;
- Blame culture;
- Paternalistic culture;
- Fear of litigation and/or other professional consequences;
- The hierarchy within medicine and healthcare institutions;
- Appropriate communication skills;
- Time constraints in an environment where workload is already high.

When looking at areas within health and social care with particular issues maternity was flagged as an area of focus in terms of high-profile case with significant legal rewards. Certain categories of patients/service users were brought up as being particular areas of concern when it comes to open disclosure including children, those with mental health difficulties or intellectual disabilities, and those in residential settings.

Stakeholders were somewhat divided on this issue of the balance between autonomy and flexibility versus mandates and clarity. It was debated as to the best way forward and the extent to which mandating or compelling disclosure would be an effective tool to achieve the ideal outcome of open disclosure as the norm.

When looking towards a National Policy Framework, stakeholders identified a number of key aspects they wished to see incorporated into a policy framework for open disclosure which included a patient-centric approach, support for patients/service users and support persons, supports for health and social care staff; a policy that can be translated into all areas of healthcare, and specifics around open disclosure when dealing with special categories of patients/ service users.

The use of the term "open disclosure" was also brought up by a number of stakeholders who questioned if it was the appropriate term for this process.

Patient-Community Survey

A structured online survey was identified as the most appropriate form of engagement with patients, families and the community.

The survey was open to patients; their family members, carers, and/or support persons; members of the public; and patient advocacy and charitable organisations. There were 265 responses, 95 of which were from patients and/or support persons who had experienced adverse events and patient safety incidents.

Quantitative Analysis

The respondents to the survey came from each of the different areas listed above to whom the survey was open, as well as health and social care staff, those working in quality and risk and those working in patient safety or advocacy. The respondents were across a range of different age groups and regions, and there were both male and female respondents. The persons affected by the patient

safety incident also came from a range of different age groups and regions. Some of the significant findings from the survey are outlined below.

The majority (80%) of patient safety incidents from this survey took place between 2010 and 2020. In over half of the cases (65%) these incidents occurred in a hospital, and approximately a fifth (22%) took place within the screening service.

The survey indicated that there was significant dissatisfaction with how disclosure was handled in these incidents, and nearly three-quarters of patients or support persons did not receive an apology. A small minority of patients received follow up support. Patients and support persons were also asked who they believed should be involved in open disclosure from the side of healthcare services, most (74%) believed it should involve the senior doctor responsible for the patient's care.

In the cases discussed in this survey 69% of patients stated that they sought legal redress, and the reasons varied between determination of the full facts; as a deterrent for such future events; seeking a formal apology and; financial compensation for trauma and stress or additional healthcare needs. The majority of overall respondents (93%) stated that there should be access to compensation or redress separate from the legal system following a healthcare incident.

Qualitative Analysis

There were four questions in the survey that allowed for respondents to freely type a response. The themes that arose most frequently in the responses to the open-ended questions include:

- A shift from a 'blame' culture to one of openness;
- Fear of litigation/litigious culture;
- Training and support for staff;
- Patient liaison;
- A "human touch";
- Timing.

Concluding Comments

Open disclosure can be seen as very simple at its heart: the communication to patients/service users from health and social care staff and service providers when something has gone wrong in their care, but has a complex context and operation that will require a cohesive, consistent, national approach in order to bring about a culture of openness, fairness, and transparency.

The Independent Patient Safety Council has produced a set of recommendations to the Minister for Health in relation to a national policy framework for open disclosure in healthcare in Ireland. The task of the Department is to develop a national policy framework to support and drive this, and to give effect to the recommendations of the Council.

1 Introduction

1.1 General Introduction

Crowe was commissioned in April 2020 by the National Patient Safety Office (NPSO) in the Department of Health ("the Department") to provide evidence and support to the Independent Patient Safety Council (IPSC or "the Council") in relation to the development of recommendations to the Minister for Health for a national policy framework on open disclosure in healthcare in Ireland.

1.2 Background to the Project

The Independent Patient Safety Council was appointed by the then-Minister for Health, Simon Harris, and met for the first time in January 2020. The Council was appointed to provide advice and guidance to the Minister for Health from a broad range of perspectives on the development of patient safety policy. One of the first areas of focus for the Council is the development of recommendations in respect of a national policy framework on open disclosure in healthcare.

Open disclosure in the context of Irish healthcare is the term that has been adopted in Ireland to describe the broad processes which relate to patients being informed of adverse events and patient safety incidents which arose in relation to the healthcare which they have received. Other terms are in use in other jurisdictions, for example, "open communication" or "duty of candour" or "being open".

A number of recommendations on open disclosure were contained in the 2018 report of the Scoping Inquiry into the CervicalCheck Screening Programme conducted by Dr. Gabriel Scally, providing an impetus for the establishment of the Council and the work in relation to open disclosure.

1.3 Terms of Reference

The key question set out in the Request for Tender (RFT) documentation issued by the NPSO was the following:

What is a coherent approach to open disclosure in healthcare in Ireland and how can it be ensured that open disclosure is implemented and effectively embedded in Irish Health Services?

The key activities outlined in the RFT include the conduct of a literature review, consultation with key stakeholders, and the preparation of a report for the Independent Patient Safety Council of research findings answering the research question outlined above by:

- Mapping national and international measures (i.e. legislation, policies, practices, cultures and behaviours) in relations to open disclosure;
- Benchmarking Irish measures against national and international best practices; and
- Presenting a range of solutions-focused options for the Council of measures on response to the research question that deliver best outcomes for effective

implementation of open disclosures in health services including embedding a culture of open disclosure, where feasibility and implementation costs have been considered.

This is to be followed by a second phase of the assignment which entails supporting the Independent Patient Safety Council to produce recommendations on principles, approaches, and the implementation of open disclosure in healthcare in the Irish context.

1.3.1 Purpose, Aims, and Objectives of the Project

In the RFT, the principal aim of the project is as follows:

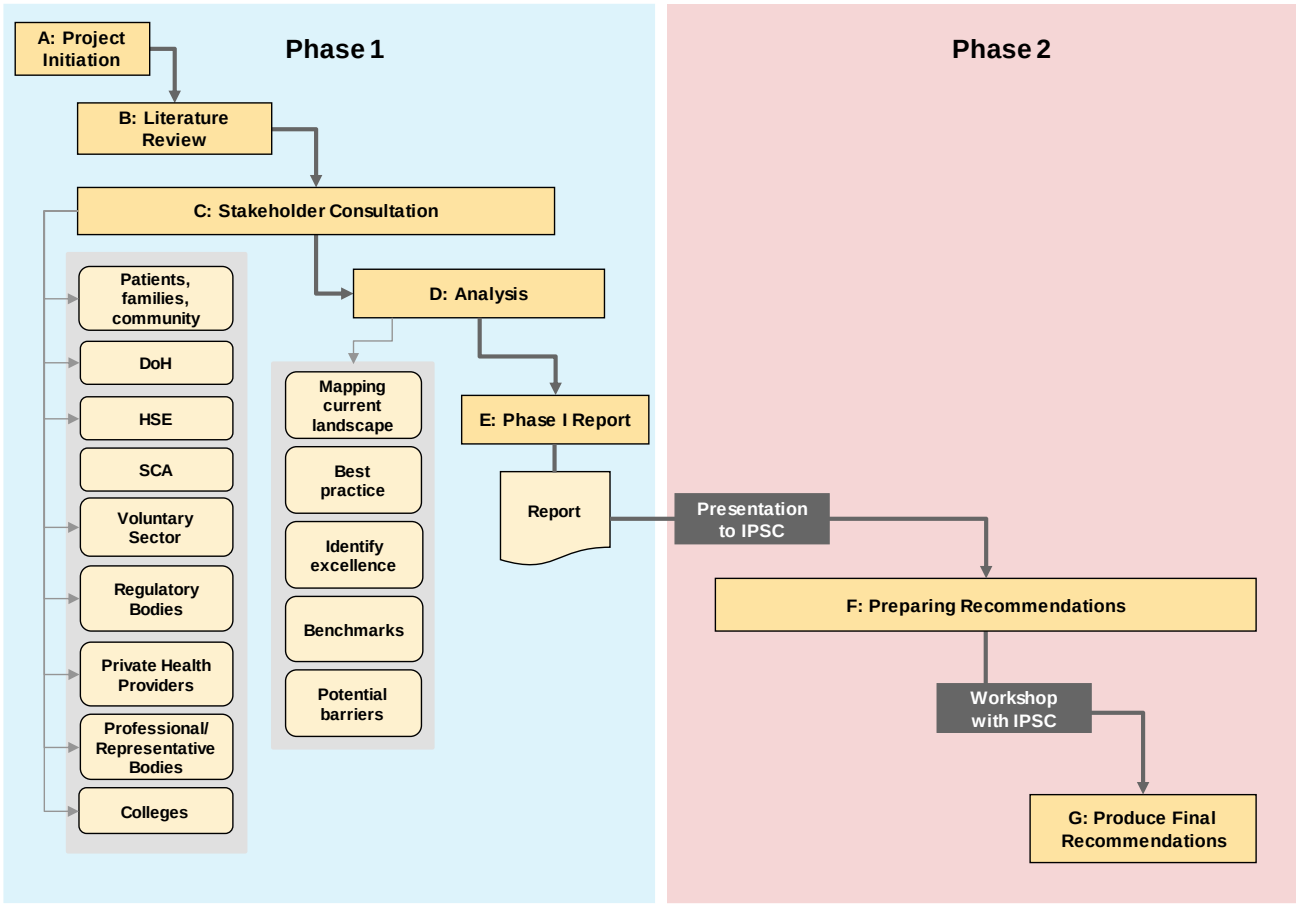
> ***Provide the Council with an evidence base in formulating recommendations applicable to the development of a coherent national policy framework regarding open disclosures across Irish Health Services and the wide range of health service organisations and health regulatory bodies.***

The project sought to:

- Map the current national landscape in relation to open disclosure
- Identify national and international best practices with regard to the operation of open disclosure
- Engage with relevant stakeholders
- Benchmark Irish policies and approaches against international best practices
- Identify best practices in relation to matters such as core founding principles implementation and healthcare practitioners' professional development
- Consider barriers to implementation of open disclosure
- Present options to the Council based on evaluation of the applicability of those best practices in the Irish context to enhance effective implementation of a culture of open disclosure across the health sector in Ireland.

1.4 Project Plan

The project plan proposed by Crowe is set out in the following diagram. We designed the project plan in line with the expectations of the Department in respect of this assignment.



Whilst the situation with Covid and the challenges in speaking to key stakeholders did have an impact on the timeline for Phase 1, the overall project was completed within the envisaged timescale by the end of 2020.

1.5 Summary of Methodology

Task	Activities
A: Project Initiation	Formal initiation of the project with the Department/NPSO
B: Literature Review	Literature review encompassing peer-reviewed and grey literature intended to examine the policy context nationally and internationally in relation to addressing the challenge in open disclosure policy development, conducted in conjunction with the King's Fund Library Service
C: Stakeholder Consultation	Extensive programme of consultations with key individuals and organisations, as well as stakeholders from other perspectives, using a combination of semi-structured interviews and surveys
D: Analysis	Collate and analyse the data collected via the literature review, desk research, and stakeholder consultation to provide insight in respect of the key requirements of the project
E: Report Preparation	Production of a report to the Project Steering Group, setting out the key findings and analysis from Phase 1 of the assignment
F: Preparing Policy Recommendations	Working closely with the Independent Patient Safety Council to develop a series of recommendations to the Minister for Health in respect of a coherent national policy framework regarding open disclosure which seeks to build a culture of open disclosure and enhance effective implementation across health services
G: Producing Policy Recommendations	Refinement of the draft recommendations into a final policy recommendation document for approval by the Council and the Department and for presentation to the Minister

2 Current Context for Open Disclosure

2.1 Background

A range of policies, legislation, practices and requirements in relation to open disclosure and associated issues (such as serious incident management) exist across the health sector. The aim of this assignment is to support the future development of a national policy framework to provide a consistent and coherent approach across the health system to which the various policies and practices can align.

2.2 Legislative Position

2.2.1 Civil Liability (Amendment) Act 2017

The current legislative foundation for open disclosure is the Civil Liability (Amendment) Act 2017. The Act sets out the general way in which open disclosure should operate. The Act is clear that undertaking open disclosure and the provision of an apology in line with the provisions of the Act does not invalidate insurance, constitute admission of liability or fault, and is not admissible in proceedings. It also provides for the process to be followed when open disclosure takes place. By including these protections, the 2017 Act was designed to support open disclosure by providing a mechanism to allow health practitioners to engage openly and provide comprehensive information about the patient safety incident at an open disclosure meeting without concern that this communication would comprise an admission of liability or an invalidation of indemnity cover in the event of legal proceedings.

The Civil Liability (Amendment) Act 2017 allows for voluntary disclosure and does not include any mandatory reporting of open disclosure incidents. The protections of the act can only be availed of if the process as set out is followed. This process is highly specified and involves completing documentation in advance of any open disclosure meeting taking place. If this process is not followed, health practitioners cannot avail of the protections of the Civil Liability (Amendment) Act 2017.

2.2.2 National Treasury Management Agency (Amendment) Act 2000

Under section 11 of the National Treasury Management Agency (Amendment) Act 2000 all health providers with indemnity by the State Claims Agency (SCA) must report any adverse incident to the Agency as soon as possible. The system used to capture this information is the National Incident Management System (NIMS). This system is used by HSE-funded hospitals to report clinical and non-clinical incidents.

2.2.3 Patient Safety (Notifiable Patient Safety Incidents) Bill 2019

The Patient Safety (Notifiable Patient Safety Incidents) Bill 2019 is designed to build on the 2017 Act. The Bill provides for mandatory open disclosure by health service providers and health practitioners of certain adverse events and patient safety incidents. The Bill includes a list of notifiable patient safety incidents that are externally reportable to the Health Information Quality Authority (HIQA), Chief Inspector of Social Services (CISS) and the Mental Health Commission (MHC). This external reporting is designed to contribute to learning and system-

wide improvements. The 2019 Bill extends the reporting requirements for notifiable patient safety incidents to private hospitals.

The Bill includes a schedule of notifiable safety incidents. The current list of notifiable incidents is predominately death related. These incidents require mandatory open disclosure to patients and / or their families and reporting to the appropriate agency. Part 1 of the schedule of notifiable incidents includes:

- Surgery performed on the wrong patient, at the wrong site, or wrong procedure resulting in unintended or unanticipated death;
- Unintended retention of a foreign object in a patient after surgery resulting in unintended or unanticipated death;
- Any unintended and unanticipated death due to anaesthesia, a surgical operation or medical procedure;
- Unintended or unanticipated death of a patient due to transfusion of ABO incompatible blood or blood components;
- Unintended or unanticipated patient death associated with a medication error;
- Unanticipated death of a woman while pregnant or within 42 days of the end of pregnancy from any cause related to, or aggravated by, the management of the pregnancy;
- An unanticipated or unintended stillbirth or perinatal death;
- An unintended death believed to be the suicide of a patient while being care for in a health service.

Part Two of the Schedule covers incidents related to the provision of therapeutic hypothermia. The Bill also allows for the Minister to specify additional notifiable incidents through regulation. This power will allow the Minister to regulate for notifiable patient safety incidents that have occurred in the course of a provision of a health service, or may occur, having regard to developments in clinical practice, healthcare and patient safety and an incident which having regard to such developments internationally, has occurred or may occur. and through learning from international evidence-based practice.

The Bill sets out the procedures explaining how health services providers should organise open disclosure with patients and provides for the key elements that a health service provider should prepare before making the open disclosure, including, appointing a designated person to liaise with the patient and their family for the duration of the process. At the meeting the health service provider is required to disclose all relevant information in relation to the incident, including:

- a description of the notifiable incident concerned;
- available information on current or future physical or psychological consequences of the notifiable incident;
- actions the health service provider has taken or proposes to take; and
- an apology where appropriate.

This information should be provided orally at the disclosure meeting and the patient or their family should also receive a statement in writing outlining the details either at the meeting or within five days.

Patients or their families affected by safety incidents can refuse to attend the open disclosure meeting, but they can change their mind up to five years from the date of the refusal and request the heath service provider make the open disclosure.

The obligation to carry out open disclosure and notify the appropriate regulator will be on the health service provider. Failure to comply with the legislation without reasonable excuse shall be an offence. Whilst this offence applies to health service providers rather than health practitioners, as defined within the Bill, it must be noted that health practitioners practising as health services providers may also be liable.

2.3 Current Policy Landscape

2.3.1 Department of Health

The government policy in relation to open disclosure is principally embodied in the Civil Liability (Amendment) Act 2017 and Patient Safety (Notifiable Patient Safety Incidents) Bill 2019 as discussed above. The intent of this legislation is to provide clear processes in relation to the protection of health and social care staff in relation to legal liability implications of open disclosure in order to facilitate a culture of open communication, and in the case of the Patient Safety Bill, to identify the circumstances under which open disclosure and reporting on adverse events and patient safety incidents is mandatory.

2.3.2 Health Service Executive (HSE)

The HSE has a comprehensive open disclosure policy, first launched in 2013 and revised in 2019. This policy is based on ten principles:

1. **Acknowledgement**
2. **Truthfulness, Timeliness and Clarity of Communication:**
3. **Clarity of Communication**
4. **Recognising Patient and Carer Expectations**
5. **Staff Support**
6. **Risk Management and Systems Improvement**
7. **Multidisciplinary Responsibility**
8. **Clinical Governance**
9. **Confidentiality**
10. **Continuity of Care**

The policy sets out the procedures for open disclosure within the HSE. It is clear that the provisions of the Civil Liability (Amendment) Act 2017 are separate and additional to the processes outlined in the HSE policy document and the latter explicitly advises staff to consider whether they wish to invoke the protection of the Act and the requirements that will pertain to such protection.

The policy identifies two levels of open disclosure according to the level of harm caused by the patient safety incident. A “low level response” is usually initiated for adverse events and

patient safety incidents where there has been no harm to the patient or the harm to the patient is minimal, whereas a high level response involves the full open disclosure process, to be put in place for adverse events and patient safety incidents where the patient has suffered a moderate or higher level of harm.

The document states that it is "*the policy of the HSE that patients are communicated with in an open, honest, transparent and empathic manner following adverse events and patient safety incidents, that they are provided with a sincere and meaningful apology when they are harmed as a result of a patient safety incident and that this communication process is initiated in a timely manner (ideally within 24 – 48 hours of the incident occurring or becoming known to the health services provider)*".

The policy is aligned with the HSE Incident Management Framework 2020, which considerably reformed the previous approach to responding to adverse events and patient safety incidents, and which is based on six principles:

- person-centred;
- fair and just;
- openness and transparency;
- responsive;
- improvement-focused
- learning.

The Incident Management Framework incorporates a commitment to open disclosure in Step 2 of its process: incident identification and immediate actions required, (i) Immediate Responses to the person directly affected and their families.

2.3.3 Tusla

Tusla has its own Incident Management Policy. One of the key principles in the policy is Incident Disclosure. This principle states that all incidents "should" be disclosed to the person affected, where applicable and appropriate. It is the responsibility of the line manager in this policy for deciding how disclosure should be managed. This policy specifies who should be disclosed to in the event of a young person in children's residential services. It also outlines that if it is decided not to disclose, reasons must be clearly recorded and outlines the disciplinary actions for not disclosing without a valid reason.

2.3.4 Other Healthcare Providers

Other healthcare providers outside of the HSE do not appear to have published policies on incident management or open disclosure, although it is evident that many of those in, for example, the voluntary sector follow the HSE policies. For example, in consultation with the RCSI Hospital Group they told us that they follow the HSE policies but deliver their own training for this area.

The National Ambulance Service (NAS) has its own policy for Management of Adverse Clinical Events. In relation to Open Disclosure section 7.4 covers notification of the affected patients and states that NAS has a policy of open disclosure to patients affected by an adverse clinical event and the affected person will be kept informed of the event and its outcome.

Dublin Fire Brigade, who provide pre-hospital emergency care services in Dublin, have an adverse clinical events policy and support open disclosure to patients. Within the paramedic and advanced paramedic training programmes, communication of adverse events is included, and the management of an adverse event, including the communication to patients and family members in respect of this, is part of the examination process for the trainees.

2.3.5 Health Regulators

Health Information and Quality Authority (HIQA)

The HIQA Safer Better Healthcare Standards set out what service providers should be doing to promote quality and safety in the services they provide and include a list of features under each standard that a provider meeting these standards are likely to include. Standards 3.3 and 3.5 relate to open disclosure.

Standard 3.3 states that:

"Service providers effectively identify, manage, respond to and report on adverse events and patient safety incidents"

Key features in provider policy and practice that would meet this standard are likely to include arrangement for identifying, managing, responding to and reporting adverse events and patient safety incidents, and classification of patient-safety incidents using an agreed taxonomy.

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."

Key features expected to be included in policies meeting this standard include: promotion of a culture which includes open disclosure following an adverse event; arrangements to support service users following an adverse event; ensuring service users can be involved in the investigation process and are kept involved; fair and transparent arrangements to support and manage staff involved in an adverse event.

Mental Health Commission

The Mental Health Commission jointly developed with HIQA a set of *National Standards for the Conduct of Reviews of Patient Safety Incidents*, which refers to open disclosure in the context of reviewing and managing patient safety incidents. As above, the standards are set out along with key features expected to be in place to align with the standard.

The glossary defines open disclosure as follows:

"Open disclosure: an open, consistent approach to communicating with service users when things go wrong in healthcare. This includes expressing regret for what has happened, keeping the service user informed, providing feedback on investigations and the steps taken to prevent a reoccurrence of the adverse event."

Standard 1 states:

"Service providers support a culture of patient safety that promotes trust, openness, empathy and respect in the review of patient safety incidents."

Theme 2 of the standards refers to a "person-centred approach", and references open disclosure in the description of the theme:

"Service providers promote a culture of open disclosure, active listening, supporting and actively engaging with service users and their families throughout the review process and having a review process that is informed by the experience of service users. Service providers respect service users' expressed preferences in relation to communication with family members."

Standard 6 advises that:

"Service users and their families are actively engaged with as part of the review of patient safety incidents, and their views are listened to, respected and responded to in a timely manner."

Features of practice likely to align with this standard include service users and their families being made aware of their rights; service users and their families being actively engaged with by service providers during the review process and informed of key developments as the review progresses; and service users and their families being advised of support and advocacy services available to them, among others.

Regulators of health and social care professionals

Most regulators for health and social care professionals make reference to open disclosure in their codes for conduct and ethics. Some regulators specifically refer to open disclosure, while others do not use that terminology but the principle behind it is included. There is also a variation in whether the code states if you "should" or you "must" openly disclose following a healthcare incident.

Section 67 of the **Irish Medical Council's** *Code of Conduct and Ethics* is on Open Disclosure and Duty of Candour. It states a duty to promote and support this culture and the entitlement of patients and their families, where appropriate, to open and prompt communication about adverse events that may have caused them harm. The code states what "should" be done when discussing the event including acknowledgement, and explanation of how, an apology if it is appropriate, assurance of an investigation and effort to reduce the chances of it happening again.

The **Irish Dental Council's** *Code for Professional Behaviour and Ethical Conduct* includes, under *Section 8 Adverse Events*, that you "must" tell a patient if an adverse event occurs including its nature and the possible consequences. They "must" respond to any questions from the patient openly, honestly and appropriately and use language the patient can understand. This code does not specifically use the term open disclosure.

The *Framework for a Code of Professional Conduct and Ethics* by **CORU** includes Acting in Accordance with the Principles of Open Disclosure as Section 14 of the code framework. This code states that you "must" ensure a patient is informed promptly, by an appropriate person,

openly and honestly following an adverse event about what happened, how it happened, their condition and an ongoing care plan. They must promote and support a culture of open disclosure.

Principle 7 in the *Code of Conduct* for the **Pharmaceutical Society of Ireland** is to "Be Open and Honest" and includes the promotion of open and honest communication and being honest when something goes wrong. This code does not specifically refer to open disclosure.

The **Nursing and Midwifery Board of Ireland (NMBI)** do not explicitly refer to open disclosure in their *Code of Conduct and Ethics* but indicated an intention to include "duty of candour" in a forthcoming update. The Code compels nurses and midwives to advocate for their patients, which encompasses honest and open communication about adverse events.

Pre-Hospital Emergency Care Council (PHECC) does not include anything in relation to open disclosure in their code.

3 Literature Review

3.1 Overview

The literature review has been undertaken following the completion of a literature search by the King's Fund Library Service. A search strategy was agreed with the Department and this resulted in approximately 300 sources being identified, including the following:

- Peer-reviewed journal articles >20 systematic reviews
- Trade press (e.g. BMJ/HSJ/Nursing Times, Nursing standard/Clinical risk)
- Opinion or editorial pieces which include opinions and editorials around open disclosure and adverse events
- Results from Ireland, England, Canada, Australia, Norway, US, Switzerland, France, Denmark, NZ, Spain, and Scotland
- Examples of policies and agreements include non-disclosure agreements (US); state apology and disclosure laws/policies (US); code of ethics (Italy); factual statement (Hong Kong); and standards of disclosure – two models of an agency model of consent and a person-based standard of disclosure (UK)

Some themes identified in the search include:

- Communication – barriers and challenges to health professionals being open in communicating adverse events;
- Clinician-patient communications – potential benefits and risks;
- Empathy often led to better patient outcomes and better patient safety;
- Efficiency, good teamwork, and handover were discussed in a number of articles.

Of the 344 sources from the King's Fund Library Service, 106 sources were deemed not relevant to open disclosure and one article was duplicated. Reasons that the sources were not considered relevant to open disclosure included the sources discussing:

- Whistleblowing or "speaking up" against other medical professionals;
- Communication between medical professionals with no mention of the patient;
- Root cause analysis;
- Opinion pieces speculating on legislation or recommendations;
- Communication specifically regarding medication.

While these sources include interesting information that would be relevant to a larger discussion around communication and creating an open culture in healthcare, they were not specifically relevant for open disclosure; sources that were more directly relevant to open disclosure were prioritised. The opinion pieces that speculated on legislation or recommendations were pieces that were written before the publication of the legislation or recommendation; the review focused in these types of articles to opinion pieces written after publication.

After initial review 237 sources that were examined in more depth. The principal themes identified in these sources are set out in the following sections. Not all sources are directly cited, with the most relevant papers quoted and others supporting the overall findings.

3.2 Challenges and Barriers to Open Disclosure

3.2.1 Fear of Legal Repercussions

The fear of legal repercussions is one of the most widely cited reasons for concern about open disclosure of adverse events by health and social care staff. There is a worry that an open disclosure statement will be used as an admission of guilt or wrongdoing in a legal case. This is especially true in places where it is perceived that "apology laws" are not in place or not adequate. "In Canada, apologies have been considered risky for two main reasons: first, the risk that an apology would be seen as an admission of fault or liability, and second, the risk that an apology would void liability insurance coverage" (McLennan, et al., 2015). These are valid concerns if the apology laws in place are not explicit in their language regarding what is covered by the law.

Health and social care staff frequently note that they are concerned that an apology will be used as an admission of guilt. Apology laws in the United States, Australia, and Canada have been used to protect apologies in the course of open disclosure to not be admissible as evidence of guilt in a legal case. However, the apology laws in these countries are done on a state-by-state basis, meaning that not every state has an apology law and some are worded differently from others. This leads to uncertainty around if and how much of an apology as part of an open disclosure process can be used as an admission of guilt and associated liability.

As medical professionals are not in the legal profession, it would be of benefit for them to receive clear guidance as to the legislation protecting disclosure that applies to them. Sattar, Johnson, and Lawton (2020) states that it was imperative that medical professionals "received education regarding the legal aspects of disclosure, including the legal protections that are currently in place." (Sattar, Johnson, & Lawton, 2020) Certainty around the legal protections available regarding disclosure could assuage the fears of legal repercussions.

3.2.2 Fear of Loss of Reputation or Trust

While multiple articles reviewed to date noted that a fear of damage to a healthcare professional's reputation was a concern, it was not stated to be a top concern, as other areas of concern overshadowed this one or has been interwoven with fear of legal repercussions (see above). A systematic review of literature relating to open disclosure stated that "Fear of a damaged professional reputation among colleagues and patients was frequently suggested as an obstacle to the disclosure of adverse events and patient safety incidents" (Ock, et al., 2017).

While articles to date have not looked at the fear of a damaged reputation closely, it has been noted that the emotional effects, such as "shame and humiliation" (McLennan, et al., 2015), embarrassment (Anon, 2016), and guilt (Ock, et al., 2017) should also be considered during the open disclosure process. The term used to discuss the emotional and psychological impact of adverse events on health and social care staff is "second victims" (Ozeke, et al., 2019). It is acknowledged that this term is not entirely appropriate, as it "can be seen as insensitive to the patient as well as dissipating the professional identity of the HCP [healthcare professional]" (Ozeke, et al., 2019), but it is currently the recognised term. The psychological and emotional effects of an adverse event on a healthcare professional can be compounded by ineffective or non-existent supports for the open disclosure process.

Mira et al (2015) stated that the experience of second victims is “related to post-traumatic stress disorder but with some extra factors” including “concerns about a loss of standing (feeling that event will mark them forever, a scarlet letter).” (Mira, et al., 2015) This implies that, while some may consider a loss of reputation an insufficient reason to not disclose, it can be part of a range of issues contributing to the reluctance to disclose and can have a negative impact on the medical professional’s health. This fear of a loss of reputation can lead to anxiety around career prospects, as medical professionals can be concerned that disclosure will lead to “being labelled as someone prone to making mistakes, and risk further career opportunities or perhaps even ultimately their current job.” (Byrth & Aromataris, 2014)

A specific issue surrounding the fear of a loss of trust is in relation to rural or small communities. An article examining the view of rural patients when dealing with an adverse event noted that there may be additional difficulty surrounding open disclosure if the healthcare professional(s) involved in the event know the patient or the family personally. “Social familiarity was mentioned as resulting in both patients and clinicians hesitating to pursue incident disclosure to preserve the social relationship and avoid personal repercussions” (Piper, et al., 2014). While this particular study was with a small sample of patients and clinicians, it is an important point to consider, as there may be personal relationships between health and social care staff and patients even outside a rural context. A loss of trust between two individuals could lead to social and personal consequences outside the medical setting.

3.2.3 Blame Culture

An additional fear for medical professionals in relation to disclosure is the fear of being blamed. A thesis completed by Duffy (2013) noted from respondents to a questionnaire that “fear of blame is also a considerable factor” (Duffy, 2013) in regards to disclosure. Sattar, Johnson, and Lawton (2020) stated in their systematic review: “One of the commonly cited barriers to disclosing adverse events was a culture of blame, where these cultural barriers were either organizational or professional in origin.” (Sattar, Johnson, & Lawton, 2020) If a culture of blame exists, then medical professionals will be less willing to disclose adverse events or near misses, as a blame culture will put the blame on the medical professional rather than system errors (Sattar, Johnson, and Lawton, 2020); the medical professional will be blamed for the event, leading potentially to a loss of reputation, and the medical professional becoming a second victim.

The move away from a culture of blame is essential. Medical professionals need to feel that they can disclose adverse events or near misses without fear of punishment or blame. Duffy (2013) noted that responses to the questionnaire included comments stating “that even with the supports available, most personnel will not avail of them, particularly those from the medical profession as ‘it can be seen as a sign of weakness.’” (Duffy, 2013)The section in relation to supports for medical professionals indicates that supports are only beneficial when they are fully accessed. If a culture of blame is in place, as described above where medical professionals will not avail of supports due to the stigma against using them, then these supports cannot be fully accessed by professionals and the negative emotional impact of the disclosure process will continue. Sattar, Johnson, and Lawton (2020) found that medical professionals “conveyed that they would be less likely to disclose future adverse events if they believed they had been unfairly blamed or shamed in the past.” (Sattar, Johnson, & Lawton, 2020)

Van Gerven et al, in their study on the psychological impact of adverse events on medical professionals, stated that a blame culture "is devastating for the psychological impact of a PSI [patient safety incident] on clinicians. Leaders should teach staff how to investigate and debrief following a PSI in a way that does not incur blame, by cultivating an environment of performance improvement instead of punishment to prevent blame-related distress." (Van Gerven, et al., 2016) An environment of "performance improvement instead of punishment" is not only beneficial to the wellbeing of the medical professional, but also to patients. Samanta and Samanta (2018) state: "Fear of reprisals, however, may lead to reluctance to disclose such events, thereby impeding true reflection and learning. Improving healthcare proactively through learning from adverse events will be undermined if doctors fear they will be blamed. In the absence of a culture that acknowledges error and supports reflective learning for remedial action, patients will continue to suffer avoidable harm." (Samanta & Samanta, 2018) By moving away from a culture of blame, medical professionals can use adverse events as learning opportunities to further improve patient safety in their organisations.

3.3 Support for Medical Professionals to Encourage Disclosure

3.3.1 Introduction

There is a variety of support for medical professionals that should be considered in order to facilitate and encourage open disclosure.

3.3.2 Lack of Adequate Training

A common theme as to why health and social care staff hesitate to disclose an incident to a patient is the reported lack of adequate training in the open disclosure process. In an article relating to interviews of stakeholders in Massachusetts (such as patient advocacy organisations and insurers for hospitals), "stakeholders noted that most physicians are not adequately trained or supported in disclosure processes, since such open communication about error is a radical departure from prior practices (often based on legal advice) and prevailing medical culture" (Bell, et al., 2012). This lack of training can affect health and social care staff in a variety of ways.

One of the largest areas of uncertainty for health and social care staff is around what should be disclosed to the patient and when such disclosures should be made. One article noted "that 'errors' did not necessarily occur as single isolated events. Rather, events compounded. Thus, faced with a chain of errors, health professionals needed to decide where along this chain Open Disclosure should be initiated" (Sorensen, et al., 2010). This uncertainty can be compounded when a patient has received care in different institutions and from other health and social care staff. There is uncertainty around how and whether to discuss other clinicians' errors with a patient (Lipira & Gallagher, 2014).

In the case of errors during procedures such as surgery, where multiple people are present, this can add additional complications in regards to open disclosure. In an article relating to barriers to surgeons to disclose, it is noted that "multiple people present during a procedure increases the chance that multiple people will have their own interpretation of an event. This can create discrepancies between team members in terms of what exactly happened and who was responsible. In these cases, it is difficult to create a consistent narrative to share with the patient, which can lead to confusion in the disclosure process" (Lipira & Gallagher, 2014). While this statement is specifically related to surgery, this can also be applied to errors that

occurred during care in other institutions and with other clinicians. Health and social care staff may not have sufficient insight into the incident that occurred and would be concerned about explaining the situation to the patient adequately.

The lack of open disclosure training is also noted in that health and social care staff may lack confidence in their communication skills. The articles suggested that training in open disclosure procedures would help to address this lack of confidence. Sorensen's article notes: "Clinicians involved in Open Disclosure expressed interest in learning how to communicate better with patients, to understand what patients wanted and how they could develop these skills" (Sorensen, et al., 2010). This desire for training specifically in relation to communicating during an open disclosure process highlights the lack of proper training in this area where communicating effectively is viewed by patients to be one of the most important aspects of open disclosure. This need for specific communication skills is addressed in more detail below.

3.3.3 Just in Time Training

Just in time training refers to training or coaching that occurs shortly before an actual disclosure conversation takes place. This is to reinforce previous training that may have taken place months (or even years) before the disclosure conversation, as these are infrequent conversations that medical professionals will take part in. Wu et al (2013) recommends offering refresher training "because most providers will have few disclosure conversations over the course of their careers. For this reason, additional support, such just-in-time in-person coaching (*e.g.,* from on-call Risk Managers or other specially trained staff) or on-line support of disclosure (*e.g.,* giving standard operating procedures and pointers) should be offered to providers to help them prepare for these infrequent conversations." (Wu, Boyle, Wallace, & Mazor, 2013)The combination of refresher training and just-in-time training will reinforce previous training and improve the chances of a successful disclosure conversation. Moore, Bismark, and Mello (2017) state that "prior research and expert recommendations suggest that providing disclosure training or "just-in-time" coaching can improve the prospects for successful dialogue." (Moore, Bismark, & Mello, 2017)

3.3.4 Empathic Communication Skills

When disclosing an adverse event, there is a high likelihood that the patient will not only be emotional, but they will also expect a certain level of empathy and emotional intelligence from the medical professional participating in the disclosure conversation. Iedema, Allen, and Sorensen (2011) note: "Clinicians are wary of both their own negative emotional responses and of the distress caused for those to whom the disclosures are made. These apprehensions are exacerbated by low levels of confidence in one's own communication skills and a perceived lack of ability to respond appropriately to others' feelings. It is evident from studies that investigate staff training in disclosure that the emotional dimensions of disclosure conversations are experienced as by far the most challenging (Iedema, Allen, & Sorensen, 2011)Medical professionals may find disclosure conversations difficult due to not only a lack of training in disclosure but also, as the quote above notes, due to the emotionally-charged nature of the conversation.

Eaves-Leanos and Dunn (2012) further note the lack of effective communication skills for emotionally charged conversations: "many physicians lack empathic communication skills because they have a strong need to control patients' thoughts, feelings, and decisions. Listening is a critical part of disclosure that is often not well developed among physicians."

(Eaves-Leanos & Dunn, 2012) While medical professionals may not agree with the entirety of the statement above, it does still highlight the need for effective, empathic communication skills that are necessary for successful disclosure conversations. Posner and Nakajima (2011) state that the Canadian Patient Safety Institute "recommends that health care providers receive education and training in how to participate effectively in a disclosure discussion. They also recommend that specific guidance and instruction in how to communicate effectively and respond to unintended patient outcomes and adverse events should be integrated into the undergraduate and postgraduate curricula for all health care providers." (Posner & Nakajima, 2011) Given the interest in specific training for disclosure that has been expressed by medical professionals, including training focussed on communication skills, this could greatly increase confidence and the chances of a successful disclosure conversation for both medical professional and patient.

As part of training around empathic communication skills, nonverbal communication skills should be included as well. Hannawa, Shigemoto, and Little (2016) note that "patients will most likely rely on their physician's nonverbal behaviors [*sic*] during a disclosure in making inferences about the error, the physician's competence, and implications of the error". They state that "when a physician discloses an error to a patient in a nonverbally detached way, the severity of the error becomes a significant negative predictor of patients' empathy and forgiveness of the physician. In other words, particularly in the context of severe errors, nonverbal involvement becomes a critical skill set." (Hannawa, Shigemoto, & Little, 2016) Without recognising the nonverbal component of communication, medical professionals could inadvertently alienate or induce further anxiety in the patient by communicating effectively verbally but in a detached way nonverbally.

3.3.5 Support for Medical Professionals as Second Victims

A phenomenon that has begun to receive more attention in recent years is the medical professional as the second victim of an adverse event. This acknowledges the long-term effects that an adverse event not only has on the patient, but also the medical professional involved. The lack of training in dealing with such difficult, emotionally-charged conversations can take their toll on medical professionals. Seys et al (2013) state in their systematic review that due to "the strong potential impact of adverse clinical events on a second victim, there is an identified need for specific support." (Seys, et al.) Kronman, Paasche-Orlow, and Orlander (2012) state: "Our results suggest a need for training programmes to provide trainees with structured, meaningful ways to cope with errors to prevent negative emotional responses." (Kronman, Paasche-Orlow, & Orlander, 2012) A lack of training and support have a negative impact on medical professionals. With the negative impact associated with disclosure, open disclosure in the future will continue to be difficult or avoided as much as possible, leading to a culture of secrecy rather than one of transparency.

While training around disclosure would help alleviate some of the negative impact on medical professionals, support should also be available. Mira et al (2015) state: "Our findings suggest that, as is the case in other countries, health professionals in Spain are not receiving training to coping with this aftermath. They do not receive the necessary support for coping with the task of telling patients about AEs." (Mira, et al., 2015) Support for the medical professional should not be confined to the disclosure conversation with the patient, but extend to further coping with the adverse event. Seys et al (2013) state that there needs to be "resources to help clinicians deal with the emotional impact of the adverse event and assure that they are treated respectfully and compassionately." (Seys, et al.)

An important aspect of offering support to medical professionals is that they are offered the opportunity to take full advantage of the supports given. Tokenistic offerings or partial offerings of support will not benefit them. Van Gerven et al (2016) found that professionals that actually received organisational support benefitted and that "partial support does not meet the needs of second victims." (Van Gerven, et al., 2016) Van Gerven et al found that the presence of organisational support did not benefit the second victims; it was only when the support was fully received that the professionals benefitted.

3.4 Patient Perspectives

3.4.1 Introduction

The patient perspective is at the heart of any evidence base in respect of open disclosure. The literature sources indicate a significant focus on health and social care staff in looking at open disclosure and the reasons why it might not be operated as it should from the patient standpoint. However, some of the evidence has been centred on patient experiences of adverse events and the disclosure around these. We look at the patient perspective in the literature for two purposes: to capture patient views of how open disclosure should operate to the benefit and satisfaction of patients, and to inform the patient and public engagement process for this assignment.

3.4.2 Patient Expectations

Of the articles read to date, those that focussed on the patients' expectations of an open disclosure process found that the majority of patients do not feel satisfied with the disclosure. They have expectations regarding what should occur during an open disclosure process, including:

- An apology;
- An explanation of what went wrong;
- Acknowledgement of responsibility;
- Commitment to prevent reoccurrence (Mazor, et al., 2013).

An important aspect of open disclosure to patients is timeliness. In an article regarding large scale adverse events in Veterans Hospitals in the United States, timing was noted as a particular issue: "Trust was impacted negatively by delays in discovering issues and then in notifying patients" (Maguire, et al., 2016). Patients want to be informed of an event requiring disclosure quickly after it has been discovered. One article states that "patients rate prompt attention as the most important" (Sorensen, et al., 2010).

Another overarching aspect of open disclosure that patients expect is effective communication. One article also notes: "that communication style is highly important to patients. How patients were treated, whether their experiences were valued and whether their questions were answered truthfully influenced patients' judgments about the merit of the process" (Sorensen, et al., 2010). Patients want open dialogue to occur; they want the open disclosure conversation to be "patient centred, respectful, and responsive" (Iedema, et al., 2011) and not "a one-way flow of information" (Iedema, et al., 2011).

Patients also want to see actions applied as a result of the open disclosure. One article noted: "Patients value expressions of regret and empathy, but without action, words of regret or

remorse may seem meaningless, empty or even insulting. Patients expect and appreciate help in righting whatever went wrong in their care, and they expect that individuals, teams and systems will work to prevent recurrences for future patients" (Mazor, et al., 2013). This is directly in agreement with patients expecting a commitment to prevent reoccurrence.

The definitions of what should prompt disclosure differ between patients and medical professionals. Patients include a broad variety of events as ones that should prompt disclosure, including events that medical professionals would see as "foreseeable complications". (Smeby, Johnsen, Marhaug, & Smeby, 2015) Birks (2014) states: "If the patient perceives harm, then regardless of how organisations, professionals and lawyers wish to classify this harm, patients who perceive they have suffered will feel they deserve a timely, supportive and informative conversation about their concerns." (Birks, 2014) The definition provided to medical professionals as to what prompts disclosure should be suitably broad to better meet patient expectations.

3.4.3 Challenges to Patient Engagement

Engaging with patients who have been involved in an open disclosure process is more difficult than engaging with patients more generally. There is the initial difficulty of identifying these patients, as well as the sensitive nature of the discussion.

Identifying patients who have been involved in an open disclosure process or adverse event is more difficult than it might originally appear. Two approaches to such patient identification have been identified in the initial review of the evidence: asking health and social care service providers to identify these patients and invite them to take part; and or using an open call to engage. Not all health and social care service providers will be willing to participate in the former approach, as one study found (Sorensen, et al., 2010). This approach relies on the cohort of patients preselected by the healthcare provider, which may bring in a bias towards choosing patients that had a more positive experience of disclosure.

One study engaged with both patients identified by healthcare providers as well as patients that were recruited through an open call mechanism (Iedema, et al., 2011). They received a relatively low number of patients through the open call mechanism, without being able to determine why patients declined to participate: "we do not know whether those who were aware of the study but not interested in discussing their experience were satisfied because of an effective incident disclosure, still too traumatised by the incident, or still too upset after an unsuccessful disclosure" (Iedema, et al., 2011). From the perspective of this assignment, whilst an open call for patients might draw in more participants, it is not possible to know with certainty why some would choose not to engage.

A study in which patients who believed that something had gone wrong in their cancer care were interviewed in regards to the incident noted the reasons in which a potential pool of candidates was narrowed down. The reasons given by potential candidates for not participating included not being comfortable talking about cancer/cancer care and not being comfortable talking on the phone (Mazor, et al., 2013) (interviews in this study were conducted over the phone). Of the cohort of those potential candidates that declined to participate, the majority of those (50 of 83) did not state the reason that they were uninterested in participating. The next largest cohort were those uncomfortable talking about cancer/cancer care (30 of 83) (Mazor, et al., 2013).

While our own survey garnered a fair number of responses (see Section 5), it should be recognised that there will still be a sizeable cohort of patients who have experienced open disclosure that did not engage with the survey. As noted above, the reason for their decision to not engage cannot be known, but it is important to note that the patients that did respond to our survey may not be totally representative of all patients who have experienced open disclosure. We are grateful to those that did respond and have included the results from the survey in Section 5, as their experience has been insightful into the operation of the open disclosure process in Ireland.

3.4.4 A Sincere Apology

As stated above, an apology is considered a critical component of the disclosure process for patients. While the inclusion of an apology is necessary, the apology itself should include certain elements or aspects. Heaton et al stated: "The structure of the ideal apology includes the four R's: recognition, responsibility, regret, and remedy." (Heaton, Campbell, Thompson, & Sadosty, 2016) Prothero and Morse further state that the provider must provide the following for a 'full' apology: "(a) accept responsibility for the incident, (b) express sincere regret, and (c) promise to resolve the problem from reoccurring by doing everything to make a permanent change." (Prothero & Morse, 2017)

Sincerity is noted in the literature as being an important aspect of the apology offered. Heaton et al noted: "That said, when asked to rate the importance of aspects of an apology, people indicate that intangibles matter much more than specific mechanisms or processes; specifically, sincerity, remorse, and empathy matter most." (Heaton, Campbell, Thompson, & Sadosty, 2016) Allan et al noted: "Our findings that other-focused statements influenced participants' ratings of sorriness and sincerity specifically appear to be in line with findings of other researchers that signs of remorse lead to more positive perceptions of wrongdoers." (Allan, McKillop, Allan, & Preece, 2015) Sincerity is cited as an important factor by patients in whether or not the apology is accepted.

As patients value that sincerity is an integral part of the apology, situations where medical professionals are induced or forced to apologise do not fulfil the patient's expectations of the apology. McLennan, Walker, and Rich noted that "if an apology is offered primarily from fear of punishment it has little value and is likely to end up doing more harm than good." (McLennan, Walker, & Rich, 2014) They further state: "Because the moral dimension of the apology is subverted, there is no sense of genuine acknowledgement and, hence, little chance of reconciliation. Like the professional, the patient is left feeling disempowered and disrespected and at odds with the institution upon which he or she is dependent." (McLennan, Walker, & Rich, 2014) Apologies forced by regulatory bodies (as was the case in the McLennan, Walker, and Rich article) or other institutions will not fulfil the patient's expectations of an apology and will likely cause further harm and deterioration of the patient-doctor relationship.

A forced apology can be considered part of a larger category of apologies called a token apology by Prothero and Morse (Prothero & Morse, 2017). A token apology is an apology but not one that is beneficial to the disclosure process. The other types of token apologies noted by Prothero and Morse are apology by proxy, apology with excuse, and pseudo-apology. Apology by proxy is an apology offered by someone other than the medical professional involved; patients often note that the medical professional involved should be the one to offer the apology. Apology with excuse and pseudo-apology both remove the responsibility for the error from the medical professional – apology with excuse moving the responsibility to other

parties, such as nurses, and the pseudo-apology moving the responsibility to the patient. “All of these token apologies create or accelerate the patient’s feelings of betrayal, loss of trust, and increased anger. Token apologies lack responsibility by the provider, are not accepted by patients or their kin, and they may demand further action from the provider and the institution, thereby increasing legal ramifications,” Prothero and Morse state.

3.5 Additional Considerations

3.5.1 Overview

While reviewing the literature, there were additional considerations in relation to open disclosure that were not easily included into the previous sections. They include themes arising in the literature that could contribute to the creation of open disclosure policies, procedures, guidelines, and legislation.

3.5.2 Open Disclosure as a Process

The literature reviewed suggests that open disclosure operates best when regarded as an ongoing, continuous process rather than a one-time event. Yardley, Yardley, and Wu stated: “The initial disclosure of an error should be seen as the start of a process, with ongoing discussions with the patient and their relatives.” (Yardley, Yardley, & Wu, 2010) The view of disclosure as a process allows patients to assimilate the information and continue to be involved and ask questions.

Koller and Espin (2018) note that healthcare providers that took part in their focus groups in Canada stated “the significance of having a plan following disclosure…They believed in repeatedly checking in with the family…follow-up was regarded as both a courtesy to the family, but more importantly as an ethical stance that supported prevention of future errors.” (Koller & Espin, 2018) While this particular group of providers acknowledged the need for the ongoing communication and dialogue with the patient and their family, this is not always the case. Birks, Harrison, and Bosanquet (2014) reviewed the implementation of the Being Open framework in the UK and found the following: “Only a small number of professional respondents recognised disclosure as a dialogue…Preparing health professionals for a disclosure conversation may exacerbate the belief that disclosure occurs at a single point in time; therefore, defining disclosure more explicitly as an ongoing process in any guidance, but also in training and education, may be helpful.” (Birks, Harrison, & Bosanquet, An exploration of the implementation of open disclosure of adverse events in the UK: a scoping review and qualitative exploration, 2014) While the difference in these two perspectives may be due to the different groups consulted, it is still important to note that including a definition of disclosure as a process may be beneficial to shift thinking in that direction.

Viewing open disclosure as a process should also encourage timely disclosure, with the inclusion of further disclosure conversations as information becomes known. Patients want to know as soon as possible after the error or near miss, when all the information may not be available yet. Practicing open disclosure as a process encourages errors or near misses to be discussed early, before information is available, with the procedures in place to facilitate further conversations as information becomes available.

The continuation of dialogue between medical professionals or healthcare provider can contribute to reassurances that there are steps being taken to prevent the error from

happening again. The prevention of a similar error happening to another person is frequently cited as a necessary component of a full apology and successful disclosure. Moore, Bismark, and Mello (2017) note that important practices for a communication and resolution programme supported by their interviews included “asking patients a few months after the reconciliation process concludes whether they wish to provide feedback, and…reaching out to patients on the anniversary of the event to update them on what the hospital is doing to improve safety and assure them that they have not been forgotten.” (Moore, Bismark, & Mello, 2017)

3.5.3 The Role of Compensation

Compensation should be offered to relieve financial distress that occurs due to the adverse event. This could include covering costs such as travel costs to the hospital, hotel stays for family, and any additional care required due to the event. Any medical bills arising from the event should not be sent to the patient or their family for payment. Connor, Coates, and Yardley noted that patients “want assurances that they will not suffer financially due to an error, and financial burdens following an adverse event can exacerbate the effect of other forms of trauma.”

It should be noted that, in one study focusing on compensation by Murtagh et al, the offers “were also more likely to be seen as a self-interested when they were more generous.” (Murtagh, Gallagher, Andrew, & Mello, 2012) The study found that “[r]espondents viewed apologies and disclosures, identical in wording, as more self-interested when accompanied by generous compensation offers.” (Murtagh, Gallagher, Andrew, & Mello, 2012) These generous offers in this study were more likely to be seen as a mechanism to avoid a lawsuit. While this reaction was in a specific study conducted through vignettes, it is an interesting finding to bear in mind during compensation offers.

3.5.4 Children in the Open Disclosure Process

While much of the literature regarding open disclosure is specifically in relation to disclosure to adults, there is some literature and research regarding disclosure to children. Disclosure of events and errors in relation to children complicates the process. As the patients are not at the age of majority, the involvement of their parents/guardians is necessary, but the involvement of the child directly in the disclosure process is less clear. However, the timing of disclosure even to the parents may be delayed due to the medical professional’s concern of the “parents’ state of mind and their ability to handle potentially upsetting information.” (Koller & Espin, 2018) While this is a valid concern, it should not delay the disclosure process.

One study by Koller et al noted that “many” participants in their study “suggested that parents should be told first, followed by a determination of whether the child should be told.” (Koller, Binder, Alexander, & Darch, 2019) However, this can lead to a difficult situation for the medical professional in situations where the parents shield information regarding errors from their children. Koller and Espin noted that this situation was difficult, “particularly when they were aware of a child’s wish and ability to understand medical events.” (Koller & Espin, Views of children, parents, and health-care providers on pediatric disclosure of medical errors., 2018) Koller and Espin noted that children that were consulted stated “that the child’s wish should be considered paramount in disclosure situations overriding the desire of the parents to withhold information.” (Koller & Espin, Views of children, parents, and health-care providers on pediatric disclosure of medical errors., 2018)

The decision to disclose to the child will be dependent on the child. For consideration is not just the age of the child, but also the "temperament and emotional stability" (Koller, Binder, Alexander, & Darch, 2019) of the child. As noted above, discussion with the parents may influence whether the child is included in disclosure conversations. This approach implies that each disclosure process involving paediatric patients should be on a case-by-case basis.

A literature review by Koller at al noted that both the United Kingdom's National Patient Safety Agency's Being Open and Australia's Open Disclosure Framework specifically address disclosure in cases involving children:

> *"While the United Kingdom relies on age of consent (16 years) as a guideline for the disclosure of medical errors to paediatric patients Australia's Open Disclosure Framework states that the clinical team and parents need to decide together how to involve young patients. In so doing, Australian policy appears to promote a shared or collaborative form of decision making and one that acknowledges the significance of adopting a case-by-case approach. In particular, Australian policies appear to be most aligned with current research that supports a nuanced, case-by-case analysis of several variables, including patient capacity to receive disclosure information."* (Koller, et al., 2016)

During Koller's focus groups on disclosure that included the views of children, parents, and health-care providers, all three groups preferred Australia's approach to open disclosure and its utilisation of a case-by-case approach. It was also noted by health-care providers during the focus groups that "the lack of appropriate policies that specifically target pediatric [*sic*] issues as a main concern." (Koller & Espin, Views of children, parents, and health-care providers on pediatric disclosure of medical errors., 2018)

3.5.5 Mandatory Reporting

While there has been debate regarding the impact of mandatory reporting on disclosure, the literature reviewed did not believe it to be particularly effective. Perez et al (2014) stated that mandatory reporting laws have not stimulated adequate levels of reporting activity as they fail to recognize that medical errors are largely a private experience, and legislating morality and personal behavior is impractical." (Perez, et al., 2014) Mastroianni et al (2010) stated that "the impact of mandatory disclosure laws may be limited by the difficulty of enforcing them. To our knowledge, none of the states with disclosure laws has plans to monitor the occurrence or quality of disclosures." (Mastroianni, Mello, Sommer, Hardy, & Gallagher, 2010)These two findings may seem contradictory, but in fact indicate that current mandatory reporting legislation may be inadequately constructed overall.

A study conducted in Norway – a country with mandatory reporting legislation – highlighted that the lack of a mechanism for enforcement impacts on the level of reporting taking place. Smeby, Johnson, and Marhaug (2015) found that, in their study of cases in which there should have been documented disclosure, 32.1% of cases had no documentation of patient disclosure. Only 54.9% of cases had documented patient disclosure, with the remaining 13% being a patient-identified injury with no need for patient disclosure. (Smeby, Johnsen, Marhaug, & Smeby, 2015) This was attributed at least in part to the divergence in opinion of what constitutes an adverse event for patients and for medical professionals, with patients defining an adverse event much more broadly than medical professionals. Smeby, Johnson, and Marhaug (2015) further noted that "surgical complications were not generally perceived to

be reportable incidents (Smeby, Johnsen, Marhaug, & Smeby, 2015)". A clearer definition of what constitutes a reportable event may be necessary for mandatory reporting legislation to work as intended.

In England, the Care Quality Commission (CQC) regulates the statutory duty of candour. A report by the Action against Medical Accidents (AvMA) on CQC inspection reports and regulation of the duty of candour in October 2018 stated that the CQC requires improvement in how it regulates the statutory duty of candour. This report found that the CQC "has no idea of how many individual allegations about organisations breaching the duty of candour it receives and no system in place to ensure that allegations, indicating serious breaches, are dealt with." (Blythe, 2016) The AvMA found the CQC reports to be of inconsistent quality, with 13% of CQC reports either not mentioning duty of candour at all or in a superficial way (Blythe, 2016). This indicates that, while there is a mechanism in place to monitor the implementation of duty of candour and enforce it, it is a function that is not functioning properly. There is a body in place to enforce duty of candour, but it does not have a mechanism to monitor any breaches of duty of candour.

4 Stakeholder Consultation

4.1 Overview

As set out in the RFT and Crowe's proposal document to the Department, an extensive programme of consultations with key individuals and organisations, as well as stakeholders from other perspectives, was a fundamental activity in this assignment. We set out here an overview of the process and the themes identified arising from this consultation exercise.

4.2 Approach

We worked with the Department to develop an initial list of stakeholder organisations and individuals for interview and survey engagements, which was refined as we went through the process (for example, where it was recommended to consult with a different or additional individual or organisation).

We used a semi-structured interview approach for each stakeholder interview. The consultations took place principally by videoconference meetings, with some phone discussions, due to the Covid restrictions. Additional patient and community engagement was undertaken by means of an online survey.

4.3 Consultation Process and Challenges

The impact of Covid on the capacity of many of the stakeholders to respond in a timely fashion and find time to participate was an issue in some cases. Many if not most of those with whom we sought to engage are working in aspects of health and social care most directly impacted by Covid. Other less direct impacts include difficulty in contacting some organisations due to offices being closed and staff working from home.

However, we made substantial progress in engaging with stakeholders across all the different "constituencies" with perspectives on open disclosure. These include:

- Policymakers (Department of Health)
- Health and social care service providers (HSE, primary care providers, voluntary providers, etc)
- Statutory bodies (e.g. Tusla, Health Research Board)
- Healthcare regulators (professional regulators, e.g. Nursing & Midwifery Board of Ireland, CORU; and other regulatory bodies including HIQA, Ombudsman's Office, etc)
- Patient advocacy representatives
- Healthcare professional representative bodies (IHCA, INMO, etc)
- Clinical education providers (colleges)
- Medical indemnity providers (including State Claims Agency)

4.4 Key Themes

4.4.1 Questions Explored with Stakeholders

For the most part, we followed a semi-structured approach to each consultation, aiming to explore the following principal areas and questions:

- How well current policy and practice is working in their view;
- What should change;
- What should stay the same or be preserved in future approaches;
- What the challenges/barriers are to open disclosure;
- Any areas (sector/service/site) with particular issues or features impacting on how open disclosure operates;
- The balance between autonomy and judgment versus mandated procedures and behaviours, and the trade-off between flexibility and principles versus clarity and specificity for healthcare workers;
- What features they would like to see in a policy framework.

An overview of the principal responses to each of these core areas of discussion is set out below. These are views expressed to Crowe by stakeholders; they do not represent our findings in relation to the process but rather the opinions of those we consulted. Some may be conflicting due to the differing perspectives and opinion among stakeholders.

4.4.2 Current Policy and Practice

Overarching Views

On the positive side, there has been seen to be movement towards an increased awareness and culture of open disclosure. It was frequently expressed that things had improved and moved on substantially within the last several years, with particular reference to the body of work undertaken within the HSE in the development of open disclosure policies, the roll-out and training associated with these, the refining of the policy, and the associated and related work on incident management, all of which was very positively viewed. However, most expressed the view that more work was needed, and that full implementation of the policies into day-to-day practice and culture was some way off.

A view expressed throughout the consultations, from the majority of stakeholders, was that the current processes do not work as effectively as they could for patients/service users or for health and social care staff or service providers. Some felt there was still some lack of clarity on when and how formal open disclosure should operate, and the implications of informal open disclosure communications that took place outside, for example, the procedures of the Civil Liability (Amendment) Act 2017. This echoes the findings in the literature in relation to lack of confidence among health and social care staff in identifying what to disclose in what circumstances and in what way.

“Open disclosure”, evidently seen by many as referring to a formal process inclusive of meetings, forms, and so on, was viewed as time-consuming and onerous by some, particularly from the perspective of health and social care staff. Time to engage with the training for and understanding of open disclosure policies was cited as a concern, with some

seeing the implementation of open disclosure obligations (in relation to formal processes) as another set of responsibilities that were difficult to deliver on with limited time and resources.

Some stakeholders suggested that the current legislation and open disclosure policies do not enable open, honest conversation and creates a "gap" between patients/service users and clinicians. This was driven by a perception of open disclosure procedures being administrative and legalistic, and not including the "human" element of the communication between patient/service user and their caregiver(s).

Regulation

Stakeholders recognised that health and social care regulatory bodies have been building open disclosure obligations into professional codes of practice and/or ethical standards. However, more consistency on these would be welcomed by stakeholders. The scope of regulatory bodies to consider open disclosure was discussed by some: for example, the potential for HIQA to provide guidance materials and include open disclosure in its monitoring activities.

Some gaps in the capacity for regulatory bodies to be involved in relation to cases where open disclosure may be involved were highlighted, such as the Office of the Ombudsman being precluded from examining cases where clinical judgement may be a key factor (unlike in some other jurisdictions), but where some such cases may not meet the threshold for consideration by the Medical Council, thereby leaving no external regulatory body to deal with a patient/service user complaint.

The absence of professional regulatory frameworks including codes of conduct or ethics for non-clinical health and social care staff was identified by some as an issue when patients/service users and/or support persons were seeking to escalate their concerns about disclosure of, for example, health records.

Legislation

The provisions of the Civil Liability (Amendment) Act 2017 and the Patient Safety (Notifiable Patient Safety Incidents) Bill 2019 were met with varying responses from stakeholders. There was broad agreement from stakeholders that, although the principle of ensuring that open disclosure processes were separated from possible legal liability issues was welcome, to support health and social care staff and health service providers' capacity to engage in open disclosure, the actual procedures as specified in the Civil Liability (Amendment) Act 2017 were perceived by many as unwieldy, bureaucratic, legalistic, and possibly detrimental to the desired ethos and principles of open disclosure in terms of ensuring timely, "human", communication between health and social care staff and patients or families following adverse events and patient safety incidents.

Concerns were expressed in relation to legally mandating open disclosure in specific circumstances as proposed in the Patient Safety Bill. These concerns include:

- Doubt that such measures would be effective in bringing about the necessary culture change to facilitate improved communication around adverse events and patient safety incidents and a potentially counterproductive effect on health and social care staff' willingness to be open in the face of legal penalties for failure to comply with specific legally-prescribed disclosure procedures;

- Recognition of the challenge in enforcing and monitoring the effective application of the provisions of the legislation;
- Concern that in protecting the open disclosure process from legal liability in relation to legal redress, patients/service users might face additional challenges in the event that they opted to pursue legal action and could not use information communicated to them about the adverse event or patient safety incident.
- Concern that the specification of particular types of adverse events and patient safety incidents for which mandatory open disclosure applies consequently creates a separate group of adverse events and patient safety incidents to which this does not therefore apply, and which is not the same as the Category 1 Events (Major/Extreme events in relation to patient harm) in the HSE's Incident Management Framework.

Feedback from patient/service user and advocacy stakeholders and from the survey suggests that there continue to be adverse events and patient safety incidents following which patients/service users and support persons face considerable difficulties in establishing the facts, receiving explanations, and being offered apologies and/or assurances in relation to what has been done to minimise the opportunity of a recurrence of such an incident. The absence of a legal obligation to disclose has at times been a clear concern of patients in such situations.

The changes to the disclosure procedures outlined in the Patient Safety Bill go some way to addressing stakeholder concerns in relation to the bureaucratic nature of these in the existing legislation.

4.4.3 What Should Change About Open Disclosure in Ireland

There was a near-unanimous consensus among stakeholders that the culture within health and social care in Ireland needs to change to reflect an embedded ethos of open communication and disclosure. It was recognised that culture change is challenging and, as above, that much progress has been made, but stakeholders described concerns that this is not consistent or universal across all aspects of health and social care.

Stakeholders agreed in the main that a less bureaucratic process for open disclosure would be desirable for patients/service users, health and social care staff and providers, and others, although some highlighted the difficulties in doing this within a litigious society where legal proceedings were common: if policies and practices intend to support open disclosure by reducing the concerns around admission of liability or other legal or indemnity implications, they are difficult to do so without being specific and prescriptive in how this is achieved.

The education and training of new entrants to the clinical professions and for those in health and social care already is seen as a critical element for moving towards a more open culture of communication. Stakeholders would like to see more building on education and training in communication skills with specific focus on open disclosure, throughout the health and social care staff education and training journey and included in obligatory continuing professional development.

The need to ensure that non-clinical health and social care staff have strong education and training in relation to open disclosure was emphasised by many.

Patients/service users and advocates suggested that access to patient/service user information should be improved and made quicker and simpler. Several described

administrative barriers and attempts to find reasons not to provide information following an adverse event or patient safety incident.

It was suggested by health and social care staff that a peer-led approach was needed, and that, for example, junior doctors learn most from senior doctors whom they respect and emulate. Leadership and "champions" from both clinical staff and health and social care service provider management will be needed to drive change, according to some stakeholders.

4.4.4 What Should Stay the Same

The positivity towards the significant work being undertaken within the HSE was reflected in this aspect of the discussions with stakeholders. Many said the underlying principles and ethos of open disclosure should be preserved.

The current open disclosure and incident management policies in the HSE were seen as well-crafted but challenging to fully implement. Building on these and working to implement and embed these in a changed culture was mooted by many stakeholders.

There was support for the maintenance of legal protections for open disclosure and apologies by health and social care staff, although in a different, less bureaucratic manner. Stakeholders wanted to see this continue to reduce fear and concerns around litigation and redress proceedings after adverse events and patient safety incidents.

4.4.5 Challenges and Barriers to Open Disclosure

Time and again, the issue of the culture within healthcare – and wider society – was raised as a significant challenge to open disclosure. The existence of what was described as a "blame culture" (as discussed in the literature review, Section 3.2.3), seeking to identify the failings of a named individual clinician for a patient safety incident or adverse outcome, was asserted by many of the stakeholders we interviewed. Stakeholders frequently alluded to the need to shift this to a "just culture" where the capacity for human error is acknowledged and health and social care staff can be supported in being open with patients and families or other sport persons. This is not to negate the requirement to investigate such incidents nor that there should not be consequences for poor professional practice, however.

A further aspect of culture was the claim by some stakeholders that the Irish health system retains a paternalistic culture in some instances towards patients, with clinicians making judgements about what patients may or may not need to be informed. This was seen by many as reducing in recent years, but individual anecdotes illustrate that this is not yet entirely a thing of the past.

A very commonly-cited challenge was the fear of litigation – and/or other professional consequences – in relation to an adverse event or patient safety incident. There was concern among clinical health and social care staff and service providers in respect of how to communicate openly and honestly with patients and families when adverse events and patient safety incidents occurred without negating or impinging on medical indemnity and legal liability concerns. The wish to avoid legal repercussions was mentioned several times as a reason why full and open disclosure to patients might not always take place in a timely fashion. The fear of litigation as a barrier to open disclosure is discussed in the literature in Section 3.2.1 and illustrates that it is a common problem in many jurisdictions.

The hierarchy within medicine and healthcare institutions was raised a number of times as a challenge for more junior health and social care staff to disclose adverse events and patient safety incidents, whether to patients and families or to colleagues and/or superiors. Concerns about impact on professional standing or advancement, fear of the reaction of a superior, and not feeling empowered to act were often mentioned in this regard.

Communication skills were described as extremely important and the need to be well-trained and supported to communicate with patients and families in relation to adverse events and patient safety incidents, including the use of appropriate and understandable language when talking to a patient. The importance of effective and empathic communication is emphasised in the literature, as outlined in Section 3.3.4.

As mentioned earlier, time constraints were cited a number of times: for many in the health and social care sector, workload is high and time to engage in training or in the administrative side of the current open disclosure process is difficult to find. Stakeholders called for dedicated and protected training time and an assessment of the impact of implementing processes with significant time implications.

4.4.6 Areas within Health and Social Care with Particular Issues

When asked if any particular area within or aspect of health and social care had particular issues or challenges in respect of open disclosure, several stakeholders cited the maternity sector as an area potentially needing focus in relation to implementation and improvement, due to the scale of legal awards and high-profile cases in this area of healthcare.

Many stakeholders brought up concerns in relation to particular categories of patients/service users. These included:

- **Children**: concerns in relation to communicating with children following adverse events and patient safety incidents were identified. This extends to the principles of informed consent in advance of health interventions, including the concept of informed permission rather than consent, when parents or guardians are giving this. Open disclosure to parents and children was considered to require a tailored approach and additional training.
- Those with **mental health difficulties**: the complications in relation to mental health and the need to ensure not to cause additional stress or psychological harm to patients in this area were raised as a challenge.
- People with **intellectual disabilities**: stakeholders had concerns where understanding of the implications of open disclosure communications may be difficult.
- Those in **residential settings**, who may be vulnerable in terms of both their capacity to understand and be properly informed and their continued dependence on the health and social care staff who may have been involved in an adverse event or patient safety incident that caused them harm. In most cases, patients/service users can leave the care setting in which an adverse event or patient safety incident occurred, or can change health or social care service provider or staff member(s), but those in residential care settings may not be able to do so, making this community particularly vulnerable in relation to this issue.

4.4.7 *Balance between Autonomy and Flexibility versus Mandates and Clarity*

We asked stakeholders to consider whether open disclosure approaches should favour autonomy for health and social care staff, to allow for "doing the right thing" and communicating with patients/service users in appropriate ways according to the judgement of the staff member and to allow for a flexible approach, or whether there should be more mandates and specified approaches to provide clarity and consistency.

Stakeholders were somewhat divided on this issue. Whilst most acknowledged that ideally the culture would change to one where open disclosure was absolutely the norm and there would be no barriers perceived to complete openness with patients, the extent to which mandating or compelling disclosure was an effective tool for this was disputed, as discussed in the literature.

In particular, there were concerns about making disclosures legally mandatory with substantial penalties, as this was viewed as potentially counterproductive, undermining the clinician-patient relationship. With the potential for an adverse event or patient safety incident and the disclosure in relation to this to be investigated within an employment relationship (i.e. within the HSE or other provider) and to be taken to a professional regulatory body, with possible repercussions in both processes, several stakeholders believed that adding a legal penalty was unnecessary.

However, particularly from a patient perspective, concerns about the past record of non-disclosures in healthcare meant that mandates had support, as it was expressed that waiting for culture change and voluntary compliance with principles of open disclosure was too slow a means of change for patients and families.

The inclusion of mandates (whether legal or related to employment) for open disclosure was considered by some to be helpful to address the issue of junior health and social care staff being empowered to disclose by removing the choice, and thereby reducing the impact of inappropriate influence of senior staff who might not wish to disclose.

4.4.8 *Looking to a National Policy Framework*

Definitions

As we engaged with stakeholders over the course of this project, it is evident that the terminology and definitions relating to the communication of adverse events and patient safety incidents and adverse outcomes to patients/service users and support persons is varied. Whilst "open disclosure" was used most commonly within the research and consultation, other descriptions such as "duty of candour" were used. Stakeholders recognised issues with the term "open disclosure", including the implication of some other kind of disclosure, the perception that disclosure could be seen as a choice, and so on. However, some had concerns about using "duty of candour" due to a negative perception of the duty of candour legislation in the UK.

As noted in the Australian Open Disclosure National Policy Framework about the same issue with terminology, whilst many have misgivings about the term "open disclosure", there is no clear alternative for which there is unanimous support and "open disclosure" is well-understood by those involved, so the term "open disclosure" may be the most pragmatic terminology for the immediate future.

In considering definitions or terminology, if it is to align with existing legislation and policy, it should be noted that the existing and forthcoming legislation, the Civil Liability (Amendment) Act 2017 and the Patient Safety (Notifiable Patient Safety Incidents) Bill 2019, use the term "open disclosure", as does the HSE policy and most other policies referring to this issue.

The Civil Liability (Amendment) Act 2017 refers to "open disclosure" in the context of a formal process:
"Where a health services provider discloses, in accordance with this Part, at an open disclosure meeting, to— (a) a patient that a patient safety incident has occurred in the course of the provision of a health service to him or her, (b) a relevant person that a patient safety incident has occurred in the course of the provision of a health service to the patient concerned, or (c) a patient and a relevant person that a patient safety incident has occurred in the course of the provision of a health service to the patient"

The Patient Safety Bill uses the same terminology but references "notifiable incidents" specifically.

As noted earlier, it is evident that some stakeholders perceive "open disclosure" as a formal process rather than encompassing communication with patients/service users when things go wrong, whether this means an informal but open discussion in the event of a minor incident or something requiring a much more formal approach. Stakeholders will need clarity on the definition and operation of open disclosure, regardless of terminology, in day-to-day practice in health and social care.

Features of a National Policy Framework on Open Disclosure

When asked, stakeholders identified a number of key aspects they wished to see incorporated into a policy framework for open disclosure. These are summarised below.

- A **patient-centric approach** was identified by most stakeholders as the foundation for a national policy framework.
- **Support for patients/service users and support persons:** patients/service users and support persons need support as it can be difficult to navigate the system and ask the right questions to get the answers they need. Open disclosure can be overwhelming for them, and there should not be additional hurdles for them to deal with in the process.
- **Supports for health and social care staff:** stakeholders recognised that this process can be difficult on health and social care staff and can cause them a significant amount of stress. The impact of the difficult process on medical professionals is discussed in the literature in Section 3.3.5.
- A policy approach that can be translated to **all areas of health and social care** and not just the hospital setting; this extends to non-hospital care such as community services and to non-HSE healthcare, such as that delivered by small independent practices in general practice and dentistry, for example.
- Specifics around open disclosure when dealing with special categories of patients/service users, such as children and vulnerable adults. This reflects the literature review, which includes an explanation of the necessity of having specific guidelines around open disclosure when dealing with children.

5 Patient-Community Survey

5.1 Introduction

A fundamental element of the stakeholder consultation process for this assignment is engagement with patients, families, and the community. Crowe discussed the potential mechanisms for such engagement with the Department, and the two options identified as most appropriate for this engagement were:

- an open call for submissions from the public
- a structured online survey accessible to the public

The pros and cons of each approach are set out below

	Approach	
	Call for submissions	**Survey**
Pros	■ Low barriers to participation ■ Potential to capture ideas or information not anticipated ■ Avoids issues relating to arranging in-person consultations like focus groups in the current environment	■ Structured responses ■ Consistency in information provided ■ Quicker and easier to analyse ■ Less likely to elicit responses including personal health data as this can be flagged in question text ■ Avoids issues relating to arranging in-person consultations like focus groups in the current environment
Cons	■ Large variety in structure and content of submissions – difficult to analyse and compare ■ May not deliver the information we are seeking ■ May include sensitive details and personal health data ■ Challenges in publicising and ensuring people are aware	■ Some barriers to participation, e.g. access to internet ■ May miss out on some information due to pre-determined questions ■ Challenges in publicising and ensuring people are aware

Having regard to the pros and cons set out above, we identified a **structured online survey** as the preferred option for patient/family/community engagement. This was agreed with the Council in July 2020.

5.2 Approach to Patient-Public Survey

The survey was developed using LimeSurvey software and hosted by Crowe on a dedicated domain name with a secure server. The survey was publicised by the Department and a link made available on the Department website and social media. Opportunities to facilitate downloadable versions or paper copies sent by post were included.

Patient advocacy and charitable organisations were invited to participate in the submission of authorised responses from their organisations and/or to promote the survey among their members and those they support.

The survey was open to patients; their family members, carers, and/or support persons; and members of the public and was open for a little over three weeks. There were 265 responses, 95 of which were from patients and/or support persons who had experienced adverse events and patient safety incidents.

5.3 Survey Content

In developing the survey content, we reviewed examples within the literature of survey tools used in similar engagements in other jurisdictions, to identify the key themes explored in patient surveys and any sample question formats that might be useful to consider for this exercise.

A set of draft questions was presented to the Council in July and a working group of a small number of Council members continued to work with Crowe in developing the survey content. The final version (attached as a separate document) was agreed with the working group and the Department before being launched online.

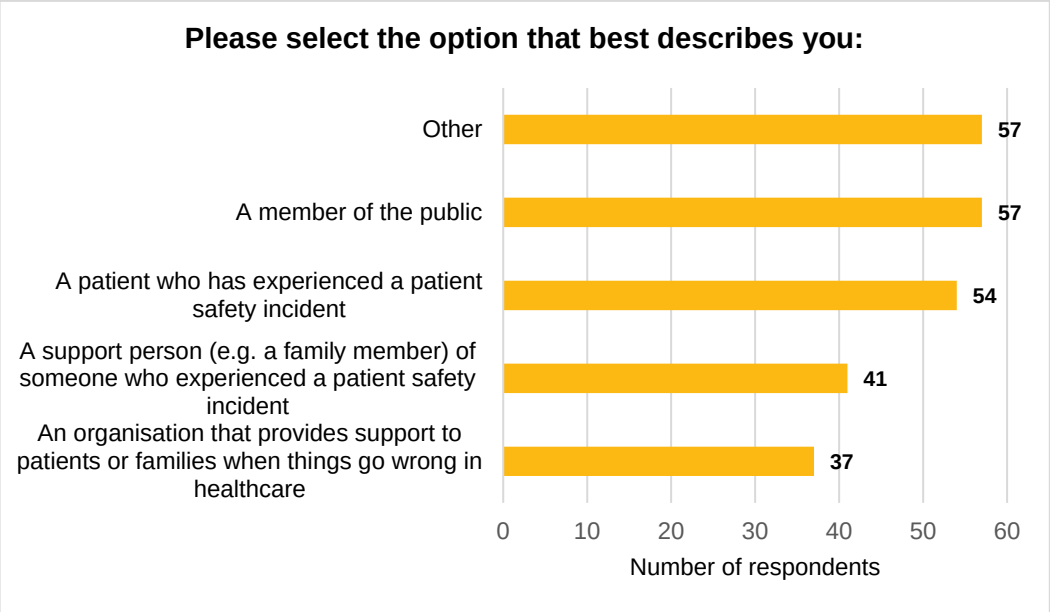
5.4 Quantitative Analysis

5.4.1 Overview

The following analysis details the answers by respondents to questions. Some questions were specifically for patients, some were specifically for their support person, and some were for all respondents. Questions specifically for a particular group of person will be noted as such.

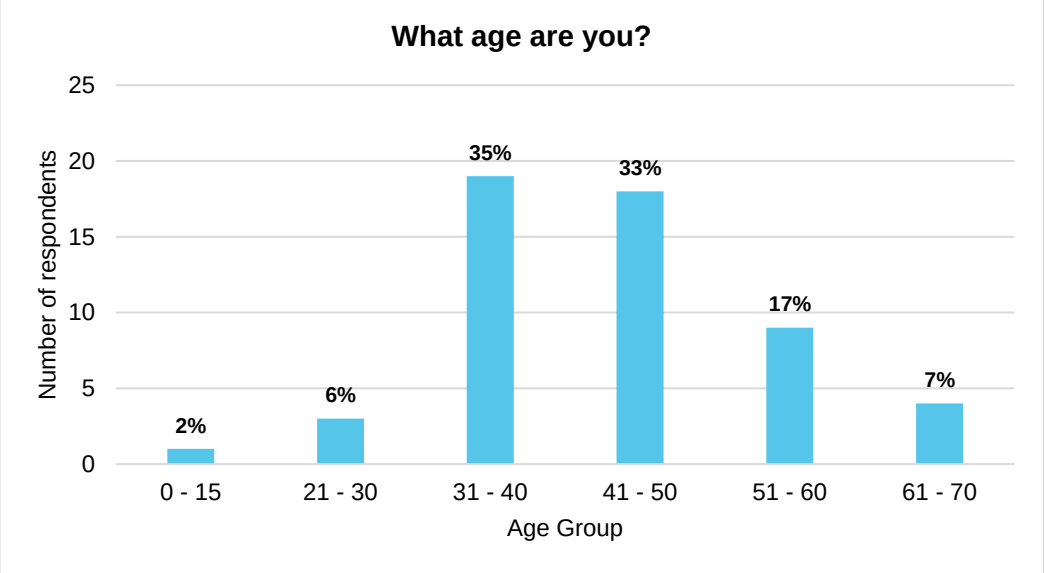
5.4.2 Profile

This set of questions was intended to provide a profile for those responding, as well as those that were affected by a patient safety incident. A patient safety incident was defined at the beginning of the survey as “an event or circumstance during health care which could have, or did result in unintended or unnecessary harm to a patient: this could be an error in care or where someone was placed at risk of harm.”

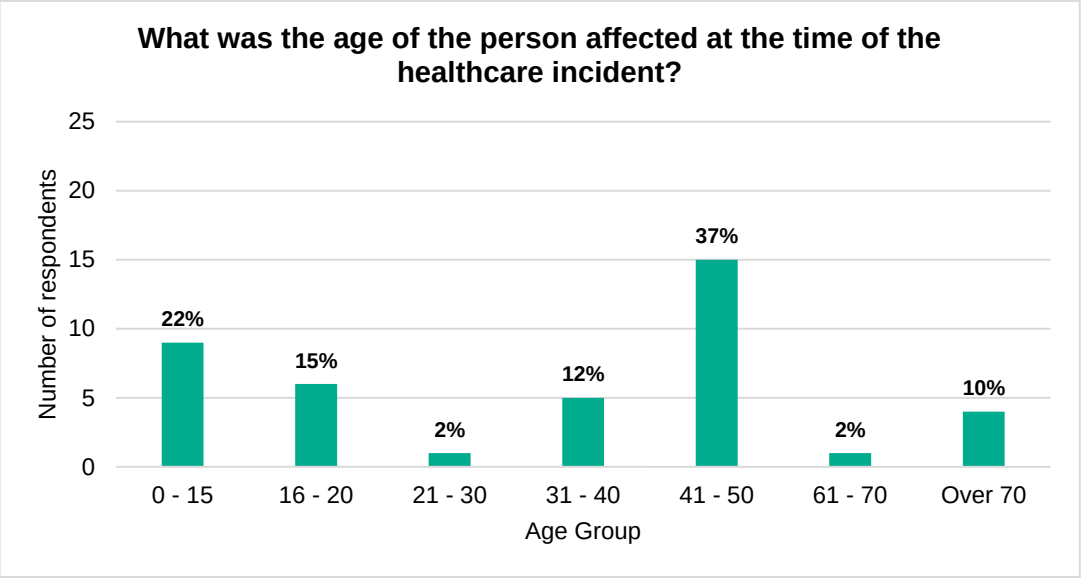


Of those who chose “Other”, 50 provided more details, with over half (27) of these indicating that they were health and social care staff. Other groups of respondents included those working in quality and risk (6) and those working in patient safety or advocacy (9). The largest group that responded to the survey were members of the public, followed by patients that had experienced a patient safety incident.

Patients who experienced a patient safety incident were asked for their age.

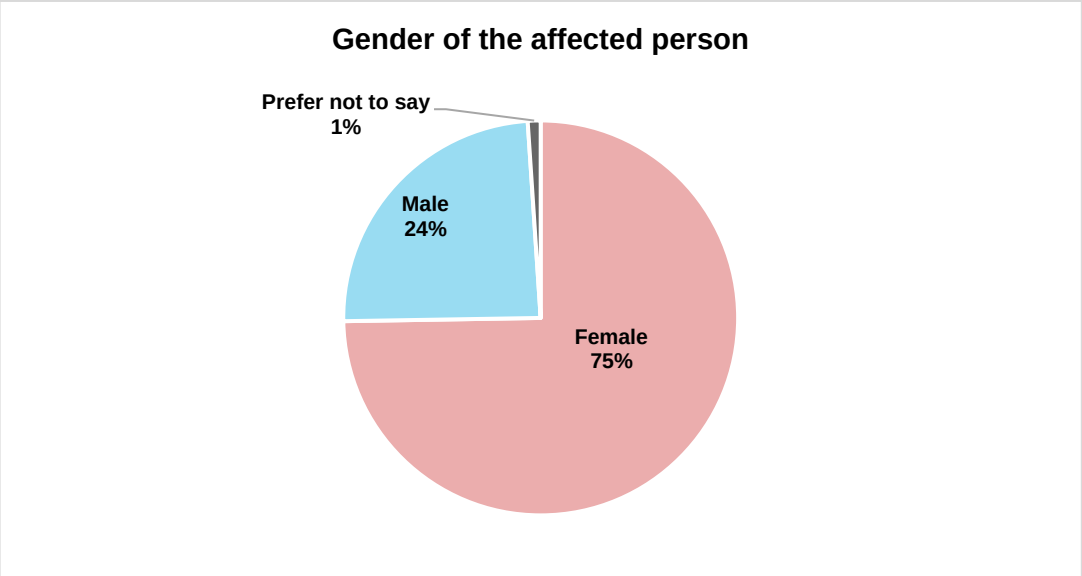


The results above show that the majority of patient respondents were between 31 and 50. No patient respondents were between 16 and 20 years old, or over 70.



Respondents who identified as a support person of someone who experience a patient safety incident were asked the age of the person affected at the time of the safety incident. The responses above show that the ages at the time of the incident were spread more evenly across the age groups. There were very few between the ages of 21 and 30, as well as between 61 and 70. No support persons indicated that the person affected was between 51 and 60 at the time of the incident.

Patients were asked their gender, while the support persons were asked for the gender of the affected person. As these two separate questions were focused on the gender of the patient affected by a patient safety incident, the responses have been combined.

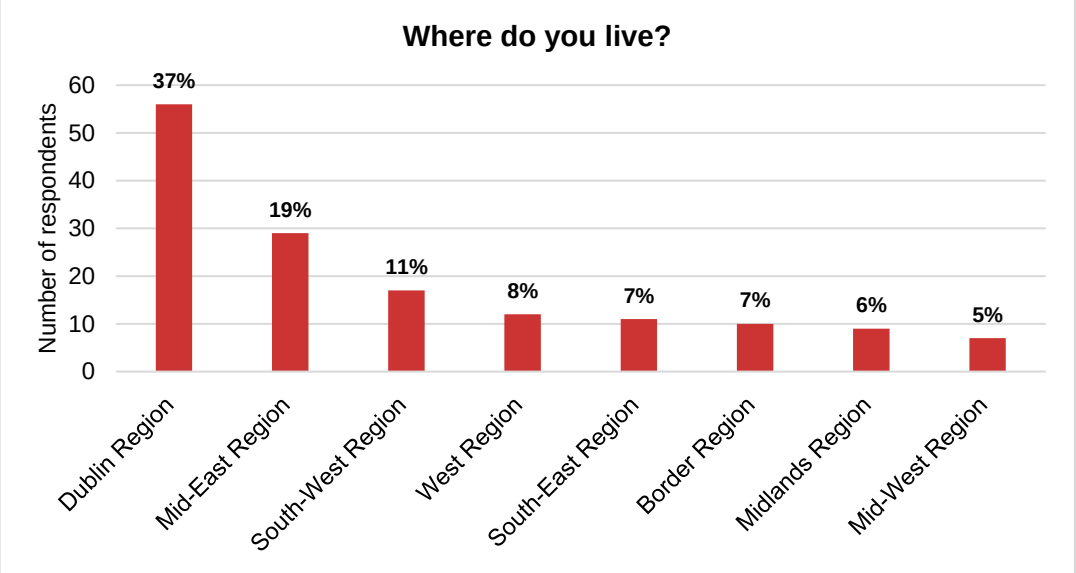


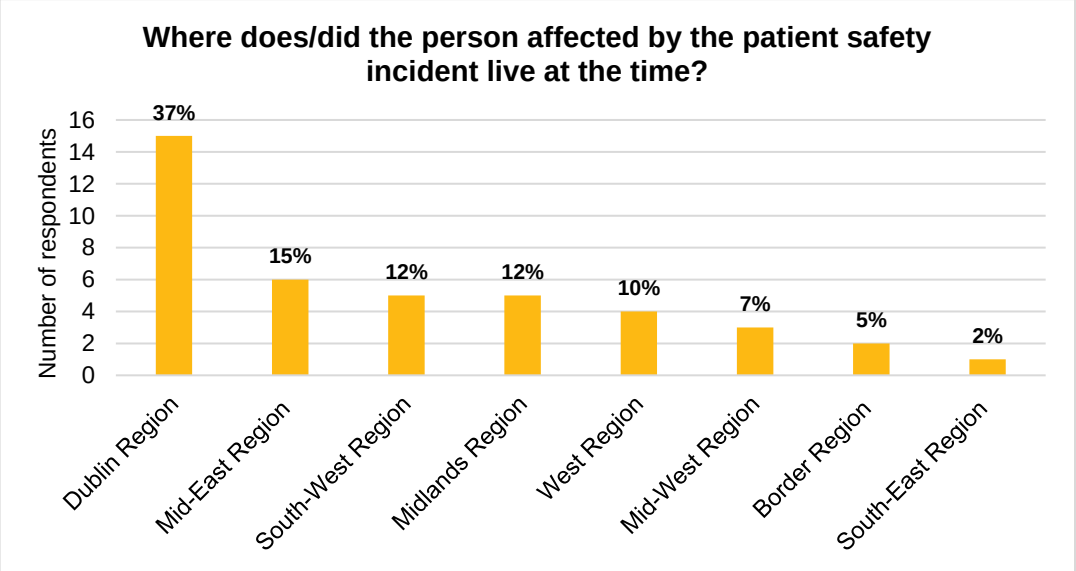
The majority (75%) of the patients affected were female. While the support persons indicated an even split between male (n. 20) and female (n 20) patients affected, the majority of patients that responded to the survey were female (n 51).

Patients, support persons, and members of the public were then asked where they lived. These were separated into the following regions:

- Border Region (Cavan, Donegal, Leitrim, Monaghan, Sligo)
- West Region (Mayo, Roscommon, Galway & Galway City)
- Mid-West Region (Clare, Tipperary, Limerick City & County)
- South-East Region (Carlow, Kilkenny, Wexford, Waterford City & County)
- South-West Region (Kerry, Cork & Cork City)
- Dublin Region (Dublin City, Dún Laoghaire–Rathdown, Fingal, South Dublin)
- Mid-East Region (Kildare, Meath, Wicklow, Louth)
- Midlands Region (Laois, Longford, Offaly, Westmeath).

These regions apply to the question posed to support persons as to where the patient lived at the time of the incident.

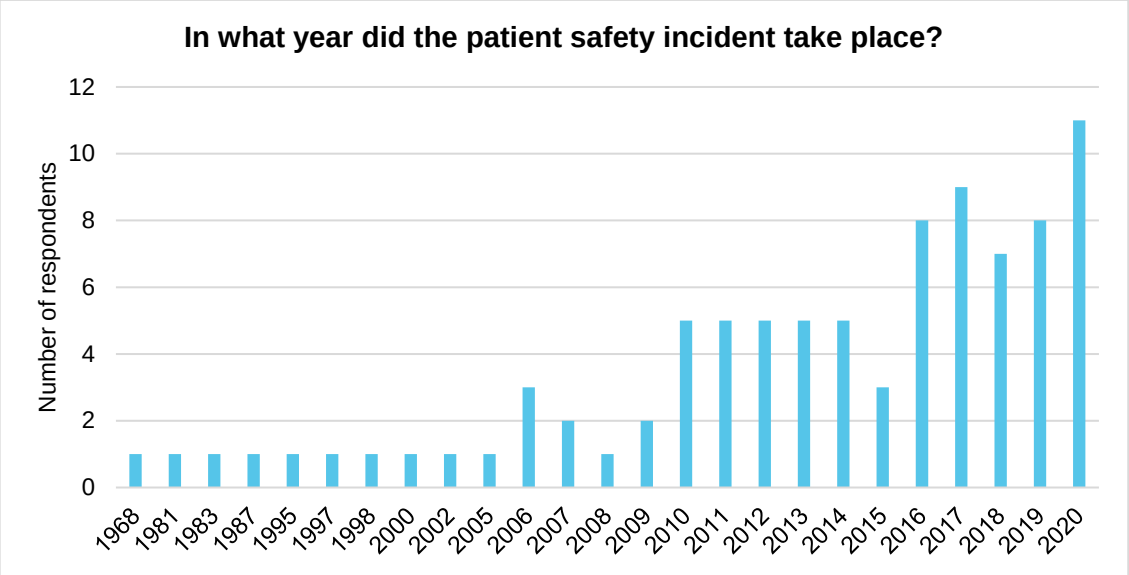




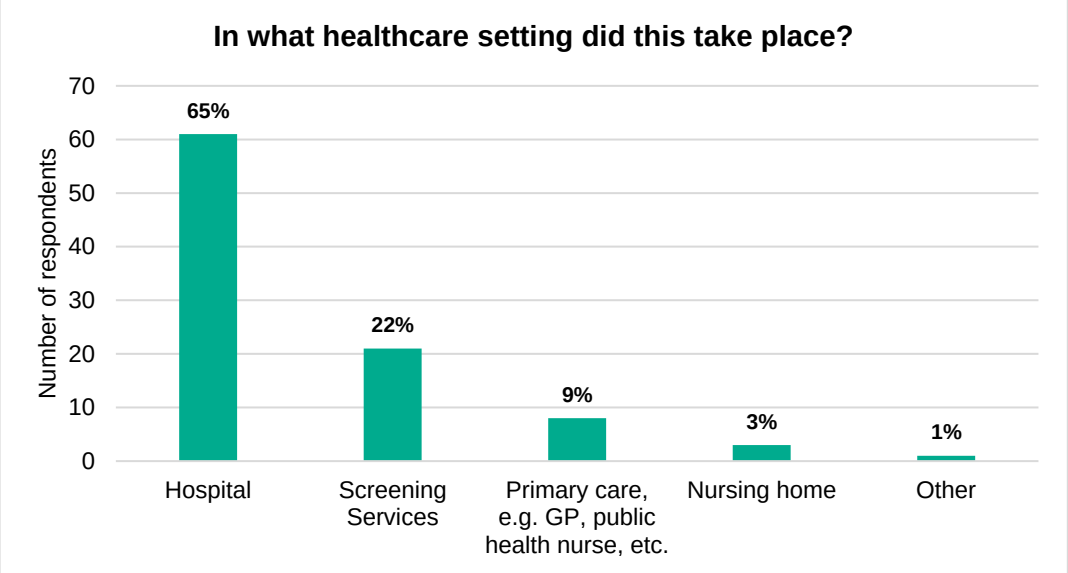
While the profiles of where respondents lived and where the patient was living at the time of the incident were slightly different, the Dublin region had the highest numbers of respondents and patients at the time of the incident.

5.4.3 Experience of the Patient, Family, and/or Support Persons

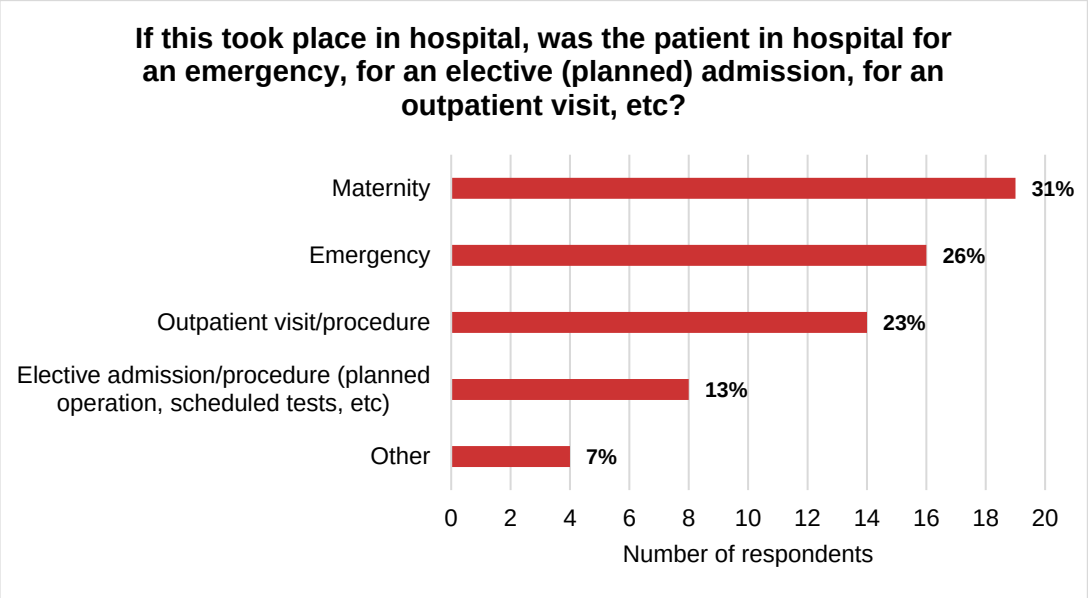
Both patients and support persons were asked to identify when the patient safety incident took place.



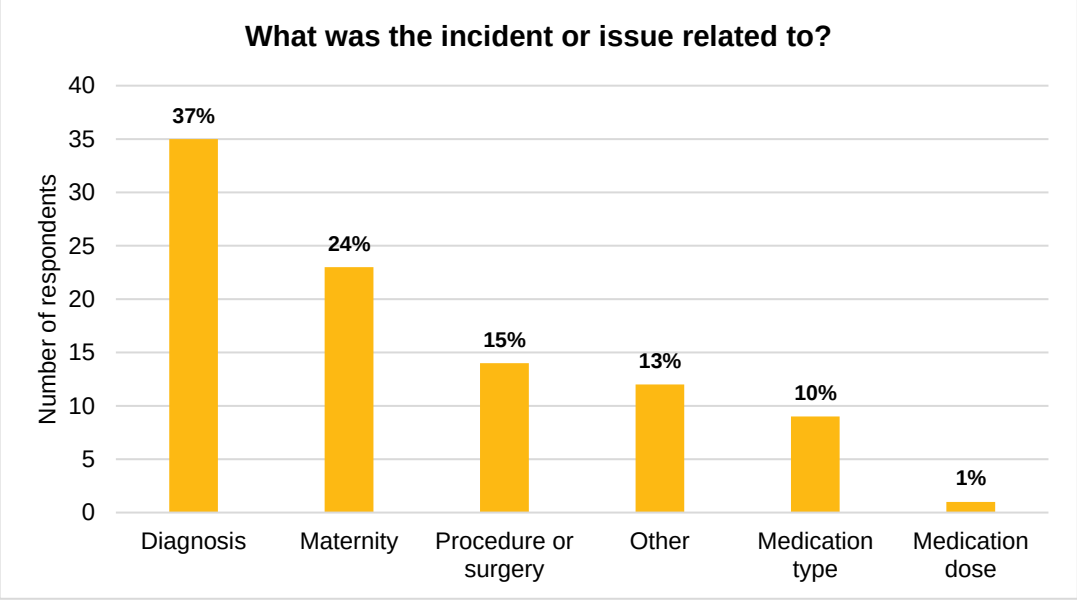
The majority (80%) of these respondents indicated that the incident took place between 2010 and 2020.



Patients and support persons were then asked where the patient safety incident took place. Over half of these respondents (65%) indicated that the patient safety incident took place in a hospital. Screening services had the next largest number of incidents, with 22% of respondents indicating that this was where the incident took place.



Both patients and support persons who stated that the incident took place in a hospital were then asked why the patient was in the hospital. Most patients were in the hospital for maternity reasons, an emergency, or an outpatient procedure. Very few were in the hospital for elective admission. Those who answered “Other” did not give further details.

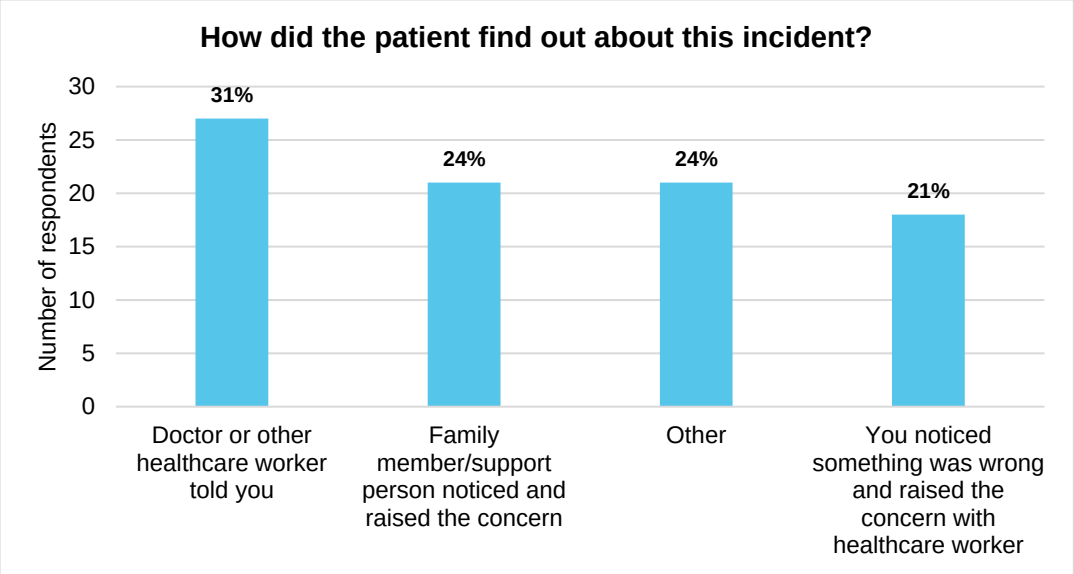


Over half of patient and support person respondents stated that the incident was related to diagnosis or maternity. The respondents who chose “Other” had a wide variety of incidents, with all 11 answers being different types of incidents, including post-surgical infection and “neglectful care”.

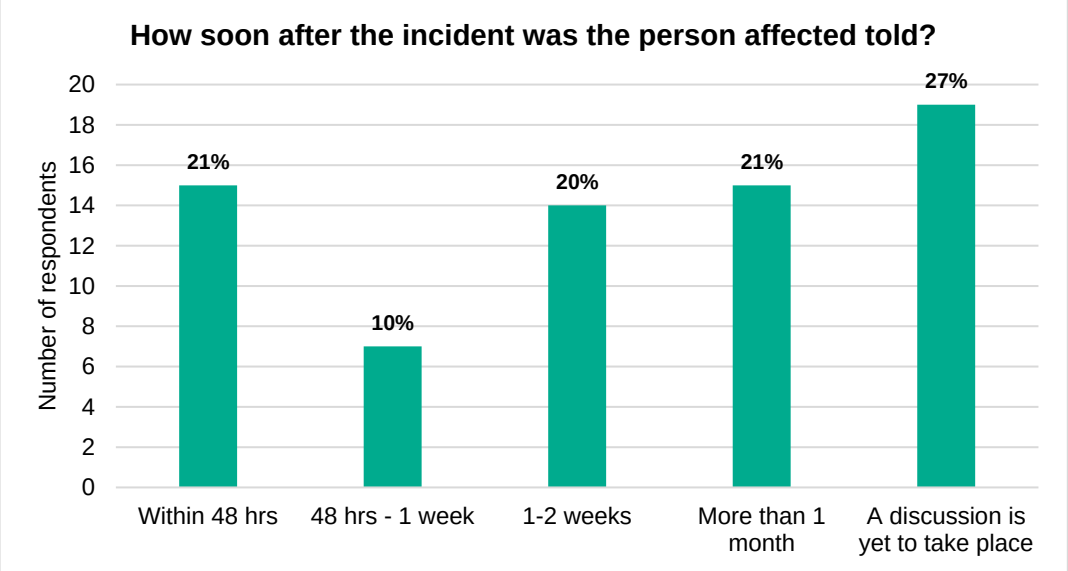
When asked about the seriousness of the incident on a scale from 1 to 10, with 1 being least serious and 10 most serious, patients rated the incident an average of 9.13 and support persons rated the incident an average of 8.7. Both patients and support persons rated the seriousness of the incidents quite high.

5.4.4 *Awareness and Disclosure of Patient Safety Incident*

This section focused on the discovery and disclosure of the patient safety incident.

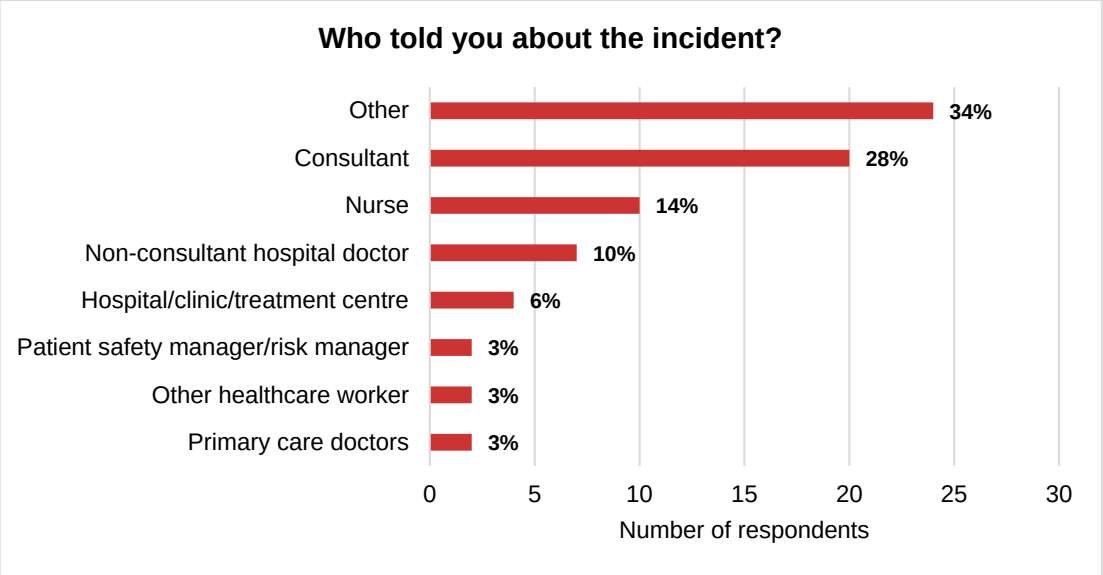


Slightly more patients and support persons stated that the doctor or other healthcare worker were the way in which the patient found out about the incident. Almost a quarter of the respondents selected “Other”. Of those that selected “Other”, five respondents found out through media/news, four respondents found out through external reviews (such as RCOG), four found out when their child died, and the other respondents provided a range of responses.

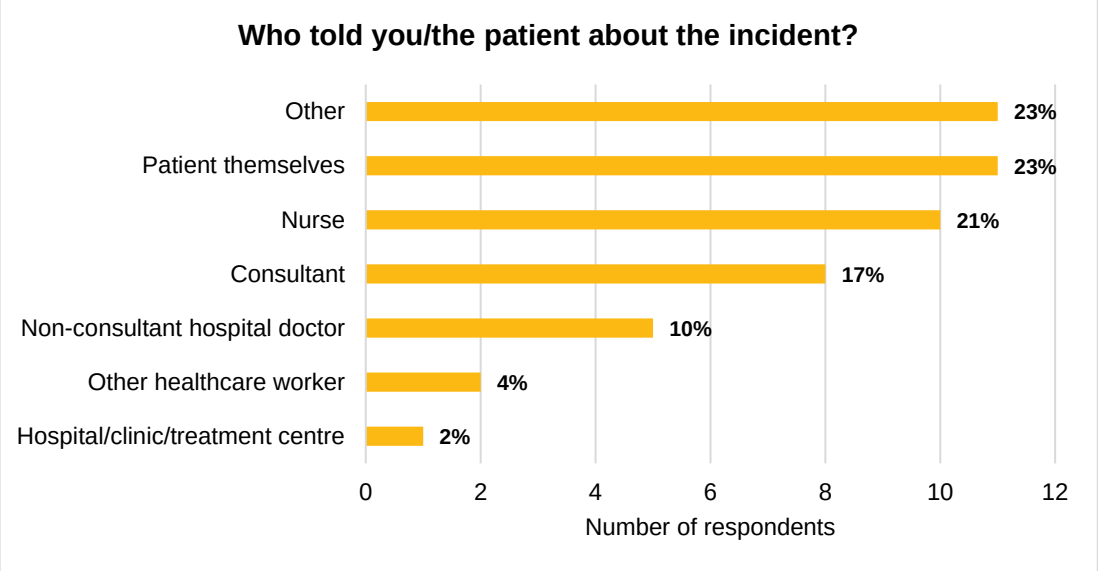


Approximately half of respondents (51%) stated that the patient was told about the incident within 2 weeks of the incident taking place. There were, however, 27% respondents that stated that a discussion had not yet taken place at the time of the survey. No respondents stated that the patient was told within 1 month of the incident.

Both patients and support persons were asked about who told them about the incident. As the question for support persons included both the support person and the patient in the question, it has been shown separately.



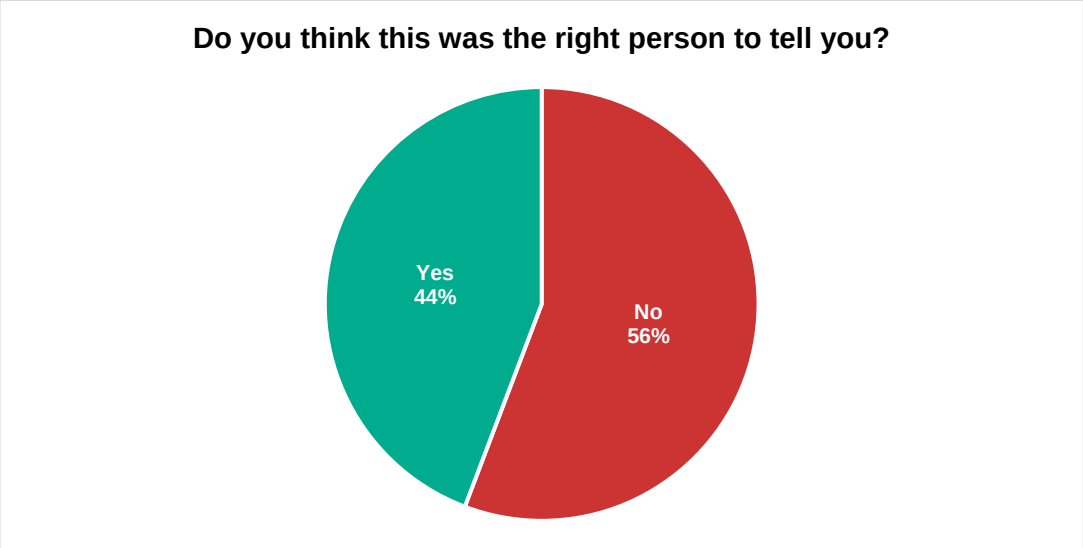
The graph above shows that, other than those that selected “Other”, respondents indicated that hospital healthcare staff (consultant, nurse, non-consultant hospital doctor) told just over half (52%) of the patients about the incident. Those that selected “Other” are discussed below.



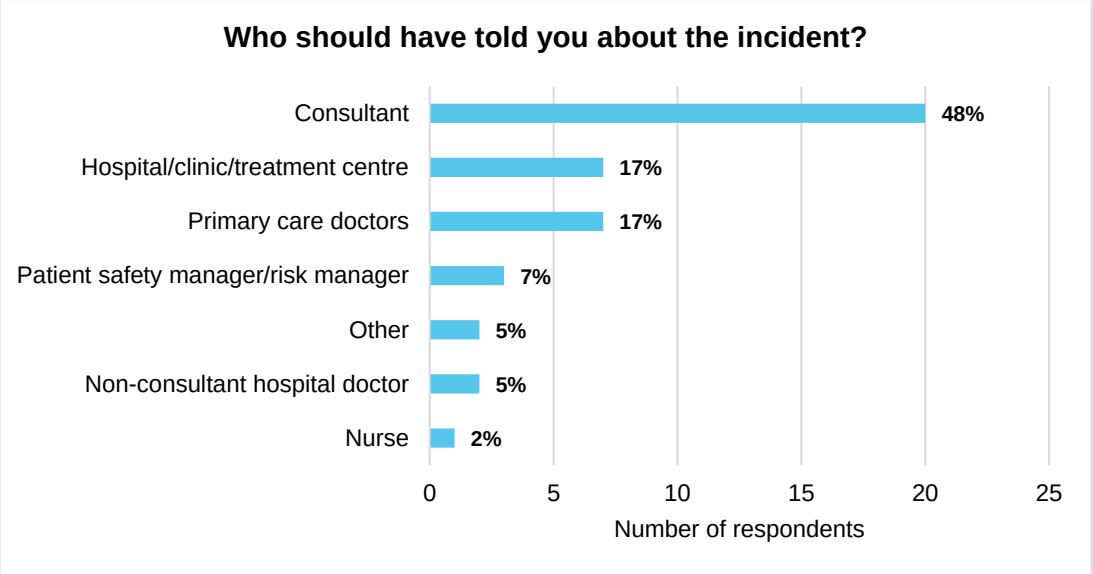
Almost half of support persons indicated that hospital healthcare staff told them/the patient about the incident. No support persons indicated that a patient safety manager/risk manager or primary care doctor told them/the patient about the incident.

Both graphs above show that a significant portion of respondents selected “Other” for who told them or the patient about the incident. The most common answer (12) for “Other” given was the patient themselves, the support person, or another family member. Another common

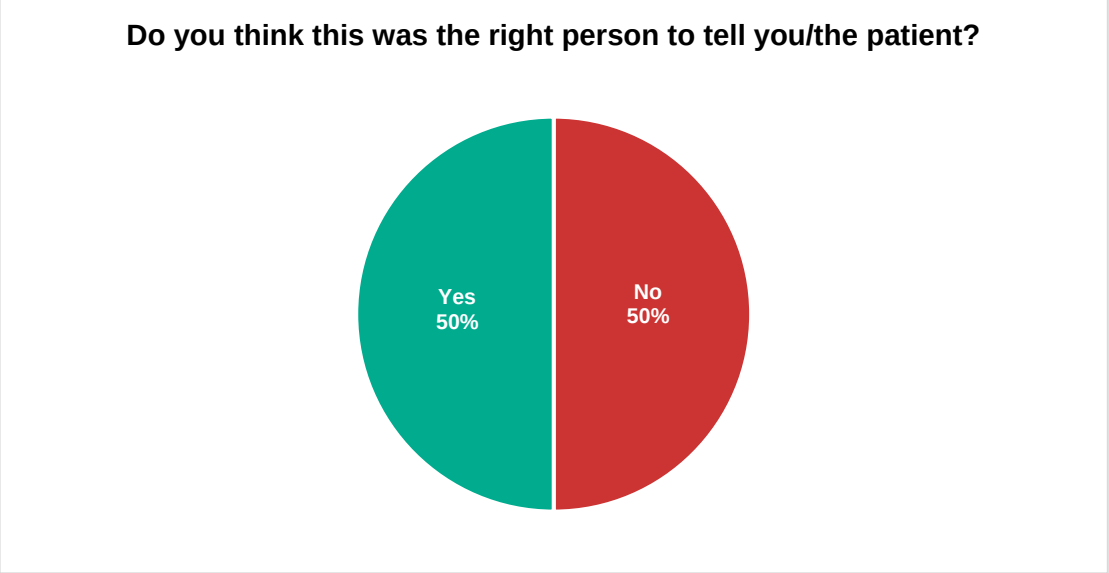
answer was a healthcare professional not directly involved in the incident, such as a different consultant than the one involved. Three respondents stated that they learned about the incident through the media.



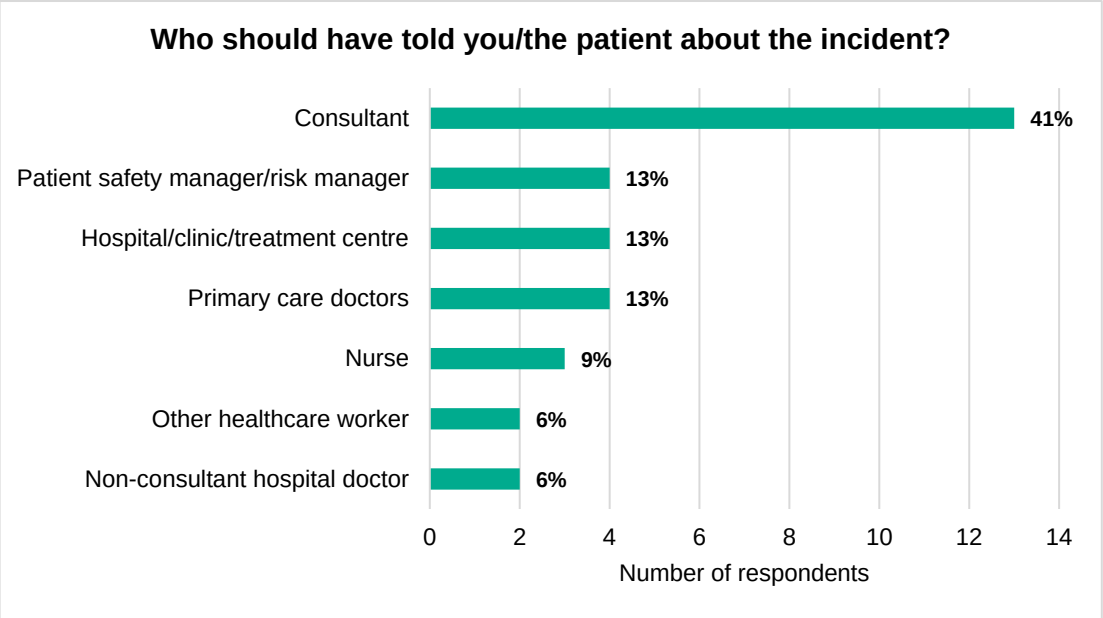
Slightly more than half of patients believed that it was not the right person to tell them. Those that stated that it was not the right person to tell them of the incident were then asked who should have told them.



Almost half of those patients that felt that the person who told them about the incident was not the right person stated that the consultant should have told them about the incident. The rest of the respondents were spread across the other options, although no patient thought that any other healthcare worker should be the person to tell the patient about the incident. Of those that selected “Other”, one of the responses was a consultant, but a different one than the one involved in the incident. The importance of the right person informing the patient of the incident is discussed in the literature (Section 3.4.4): if someone not involved in the incident is the one to inform the patient, the patient may see if as an apology by proxy. This type of apology can be very damaging to the patient-provider relationship.



Support persons were evenly split in relation to whether the person who told them/the patient about the incident was the right person to do so.

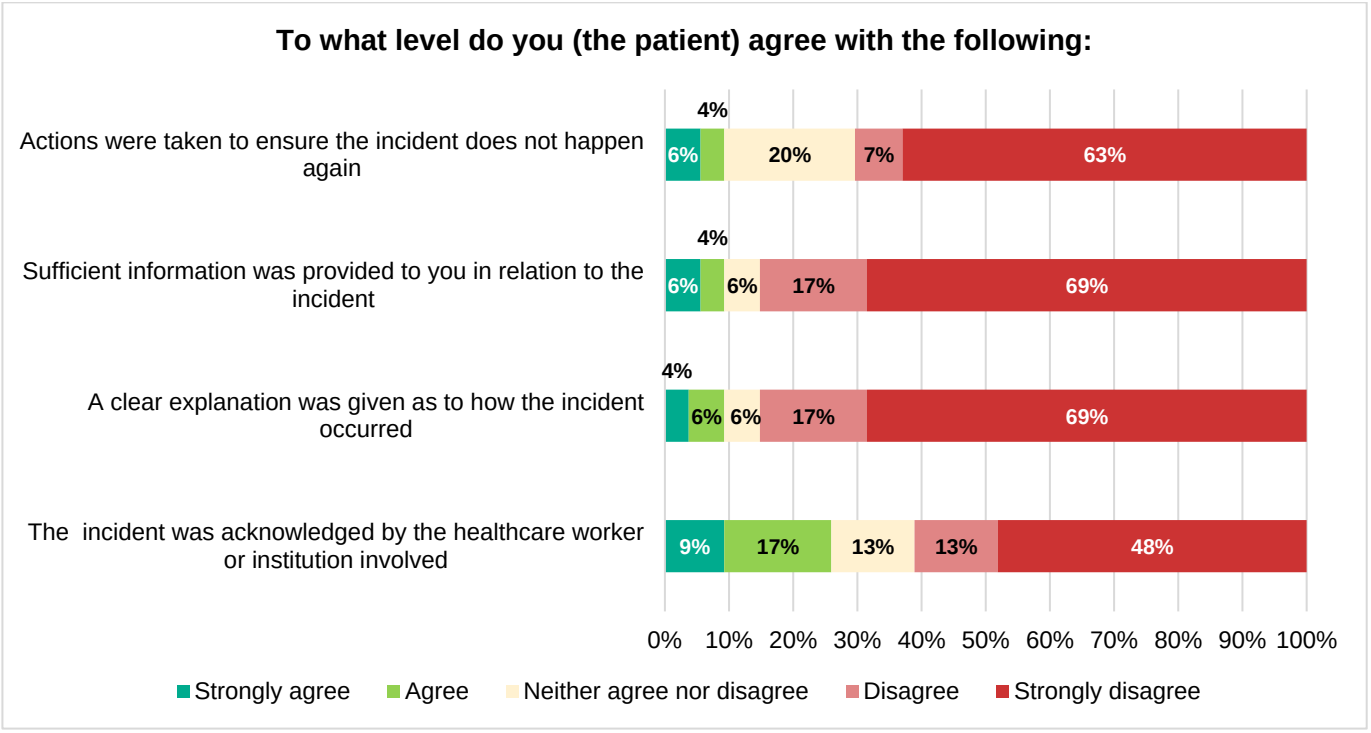


As with patients, a significant number of support persons felt that it should have been the consultant to tell them/the patient about the incident. Very few support persons thought that it should be any other healthcare worker than the ones already listed. No support persons stated that the person to tell about the incident was a person not identified in the list.

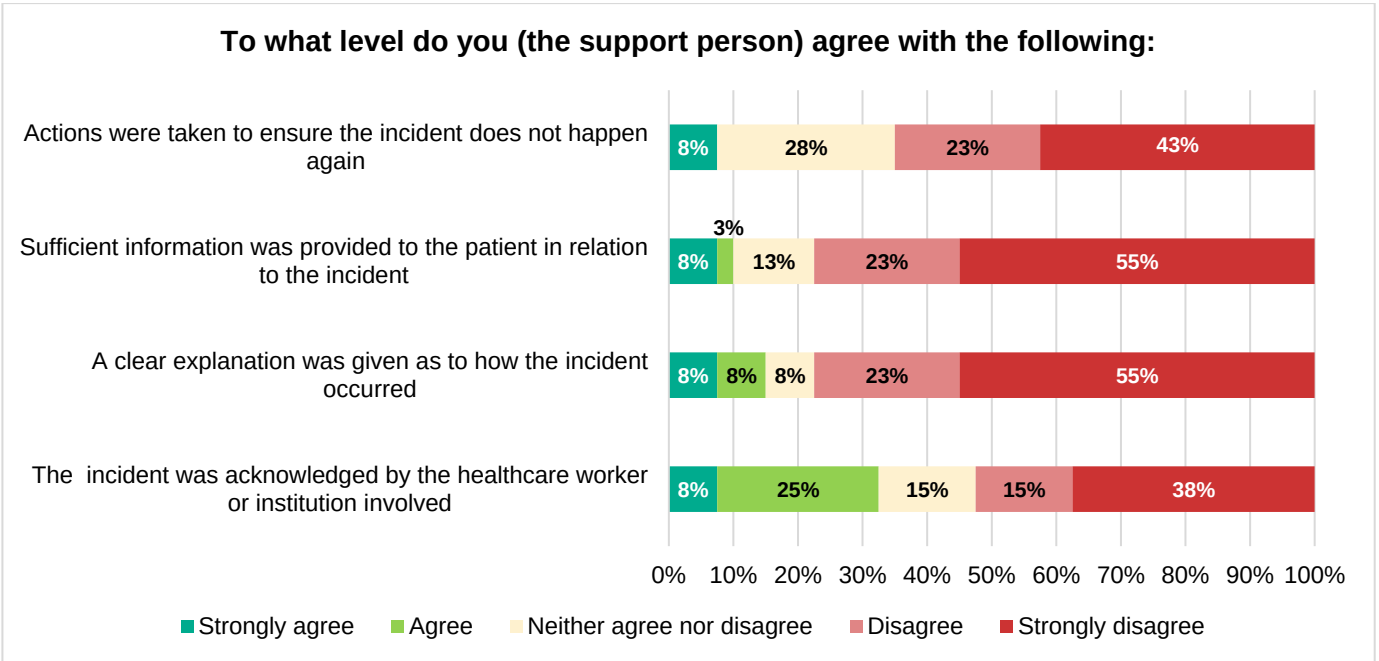
The patients and support persons were then given four statements and asked to indicate what level they agree with each statement, from Strongly Disagree to Strongly Agree. The four statements they were asked to rate their level of agreement with were:

- The incident was acknowledged by the healthcare worker or institution involved;
- A clear explanation was given as to how the incident occurred;

- Sufficient information was provided to you in relation to the incident;
- Actions were taken to ensure the incident does not happen again.

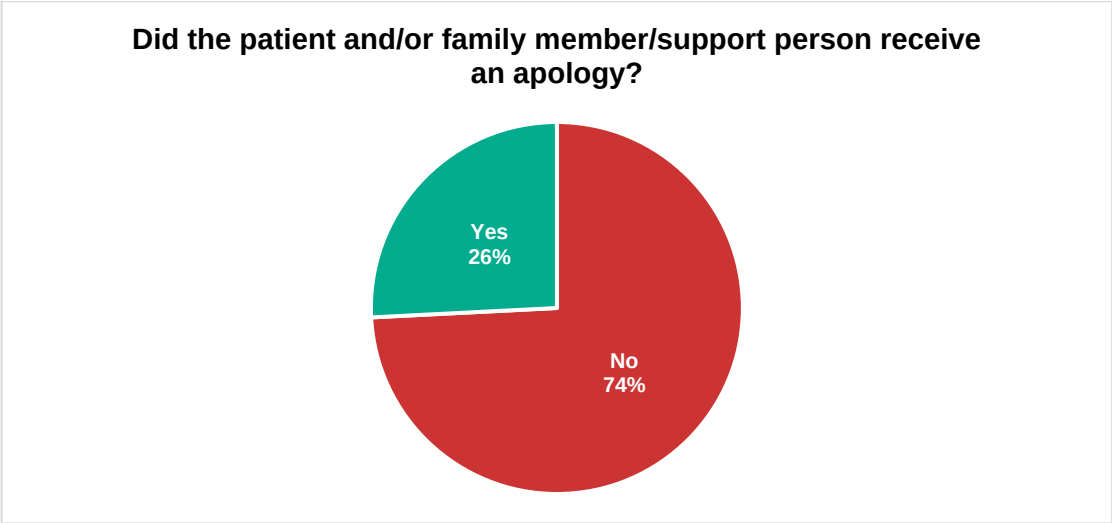


The majority of patients either disagreed or strongly disagreed to the first three statements, relating to actions for prevention (70%), sufficient information (86%), and a clear explanation (86%). Over half of patients (61%) disagreed or strongly disagreed that the incident was acknowledged. Only a quarter (26%) agreed or disagreed with the statement that the incident was acknowledged.



While support persons were slightly more likely to agree with the statements, many of them still disagreed or strongly disagreed with each statement. Only 8% agreed in any capacity that actions were taken to ensure the incident does not happen again. Approximately three quarters (78%) of support persons disagreed or strongly disagreed that sufficient information and a clear explanation was given. Just over half (53%) disagreed or strongly disagreed that the incident was acknowledged.

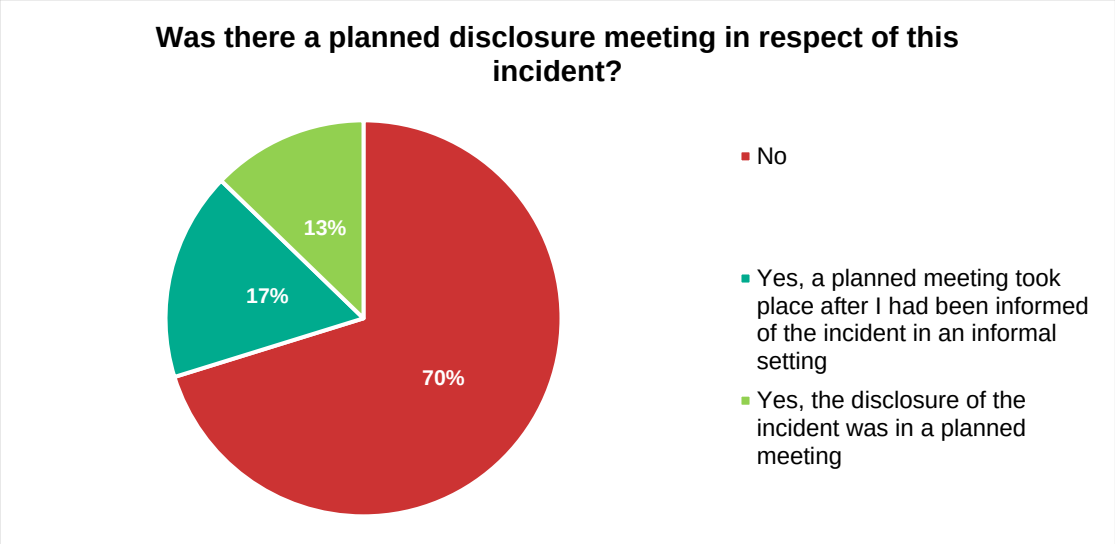
The graphs above show that many patient and support persons did not feel that actions were taken for prevention in the future, that sufficient information was provided, or that a clear explanation was given. Slightly more respondents agreed that the incident was acknowledged, but many still felt that it had not been.



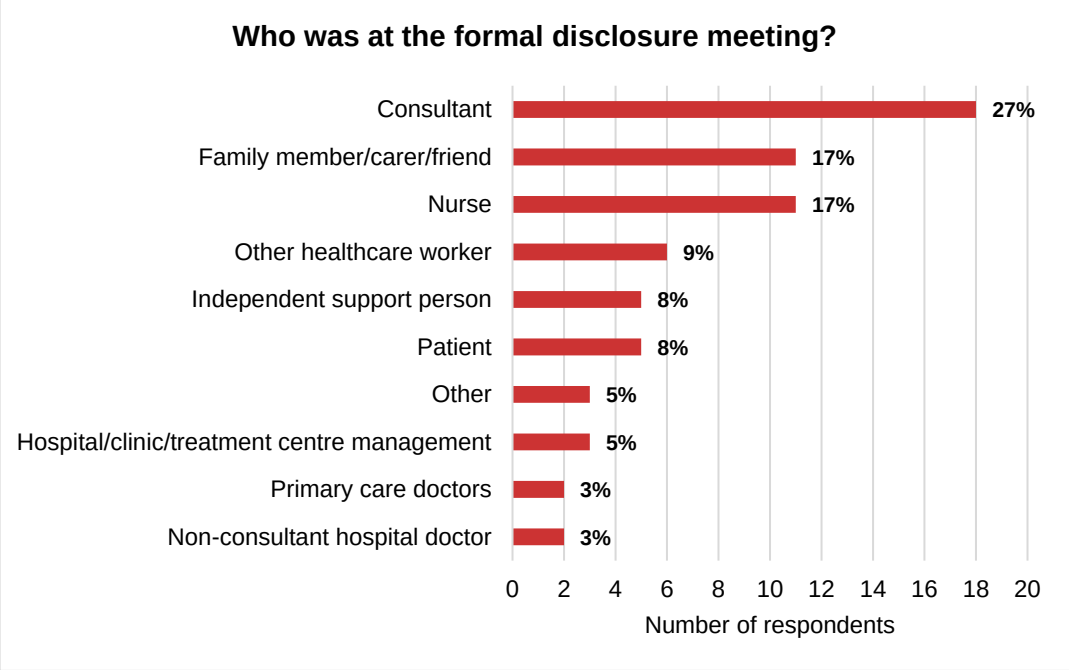
Approximately three quarters of patients and support persons stated that the patient and/or support person received an apology. There was only a very small difference between patients stating they received an apology (28%) and support persons stating that an apology was received (23%). Even with these differences, the majority of both patients and support persons agreed that no apology was received.

5.4.5 *Planned or Formal Disclosure Process*

This section asked questions in relation to a disclosure process that was planned or formal.



A significant percentage (70%) of patients and support persons stated that there was no planned disclosure meeting. While 17% stated that there was a planned meeting after an informal disclosure, only 13% stated that the disclosure took place in a planned meeting.



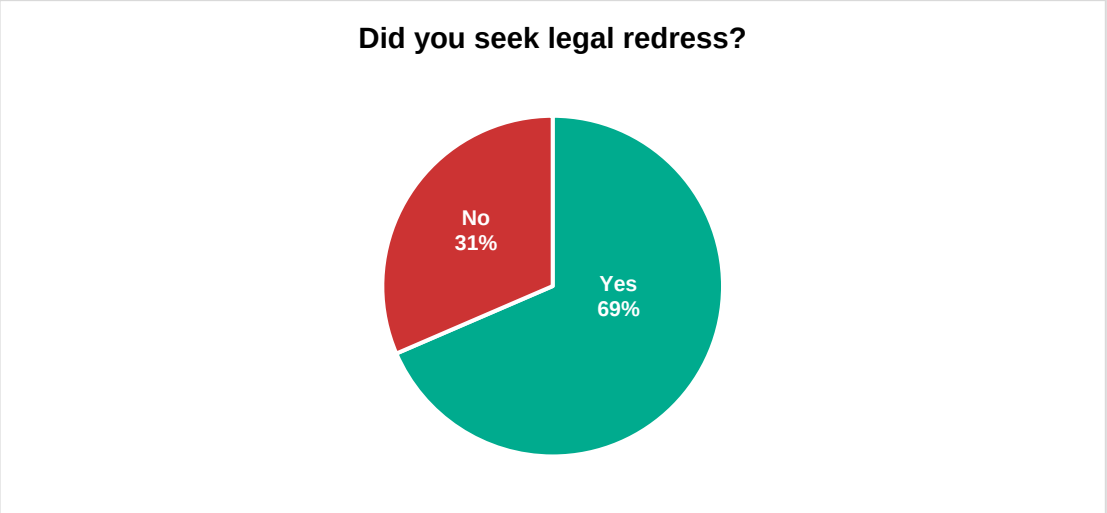
Just over a quarter of those who stated that they had a planned disclosure meeting stated that the consultant was also present. Very few stated that a primary care doctor or non-consultant hospital doctor was present.

The patients and support persons who indicated that they had had a planned disclosure meeting were then asked to rate the preparedness of the person or persons giving information

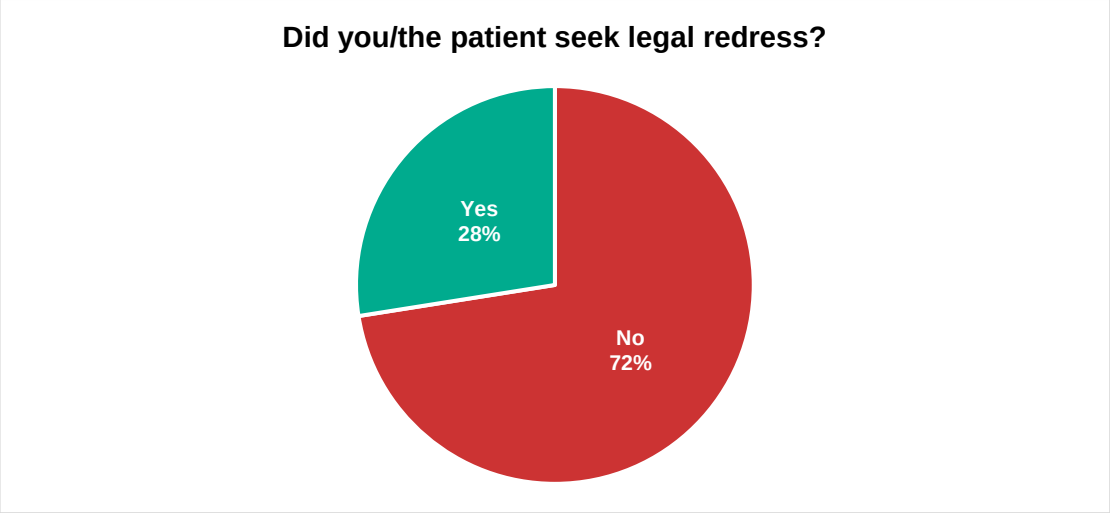
in the meeting. They were asked to rate between one and five, with one meaning minimally prepared and five meaning very well prepared. Patients on average rated the preparedness of the person at 2.6; support persons rated the preparedness of the person at 2.7. This indicated that the patients and support persons did not feel that the person giving information at the planned disclosure meeting was very well prepared.

5.4.6 Further Actions

This section focused on what actions were and were not taken after the incident.

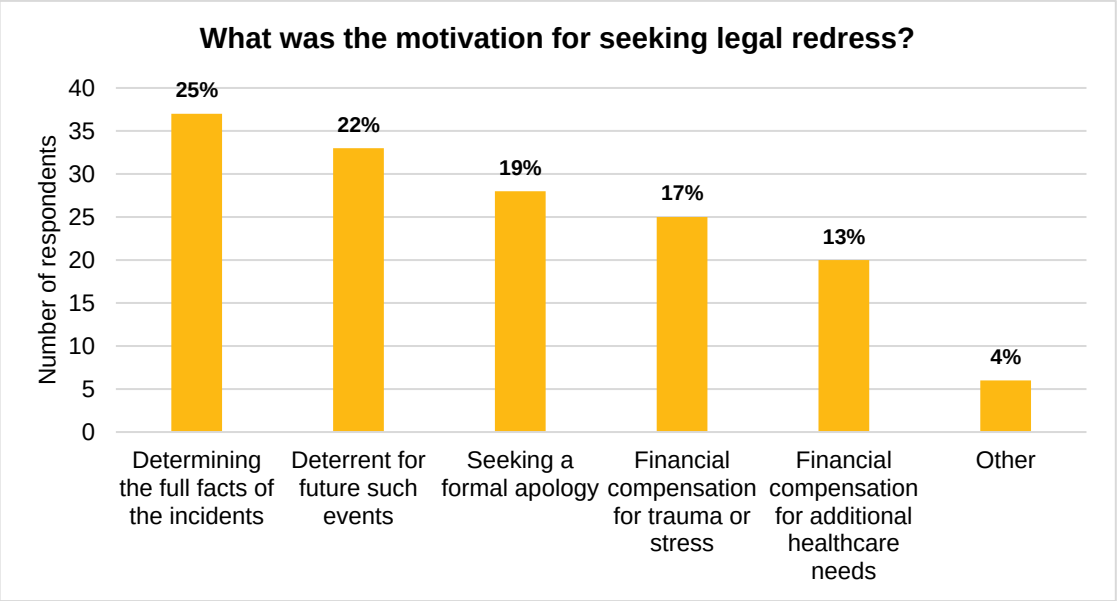


The majority (69%) of patients stated that they sought legal redress. This is starkly different from the responses of support persons, which can be seen in the graph below.



The majority of support persons stated that they/the patient did not seek legal redress. It is very interesting that the two groups diverged on this particular topic.

Those that responded that they did seek legal redress were then asked about their motivation for doing so.



The motivation for seeking legal redress by both patients and support persons was spread across the various reasons. Only 30% indicated that there was a financial reason for seeking legal redress. Those that indicated “Other” stated reasons such as justice and accountability as their reasons for seeking legal redress.

The literature corroborates these findings, as patients are looking for the following during an open disclosure process:

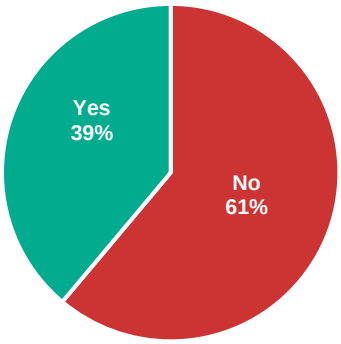
- An apology;
- An explanation of what went wrong;
- Acknowledgement of responsibility;
- Commitment to prevent reoccurrence (Mazor, et al., 2013).

Approximately a third of those who sought legal redress do not fall under the above categories, while the remaining two-thirds of those who sought legal redress did so in order to obtain the information and apology that could be addressed through a robust open disclosure process.

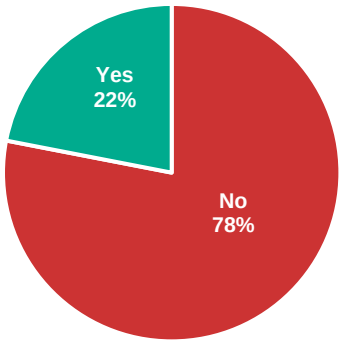
5.4.7 Support

This section was focused on the support (or lack thereof) received by patients after a patient safety incident.

Has there been follow-up or support for you in relation to the incident?



Has there been follow-up or support for you/the patient in relation to the incident?

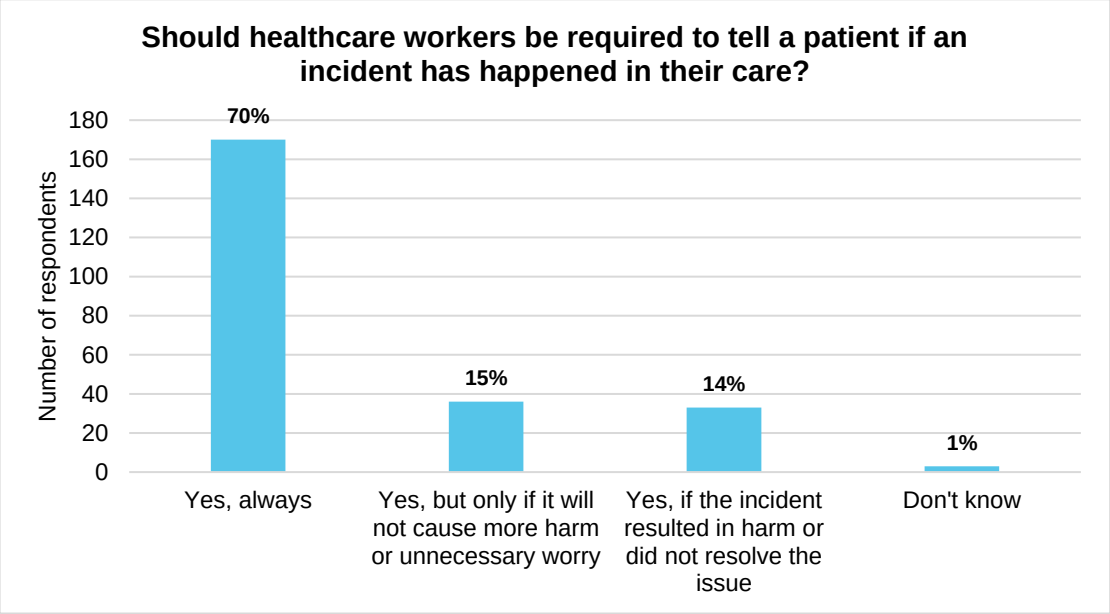


Although slightly more patients stated that there had been follow-up or support for them in relation to the incident, a large percentage of patients and support persons stated that there had not been any follow-up or support for the patient in relation to the incident.

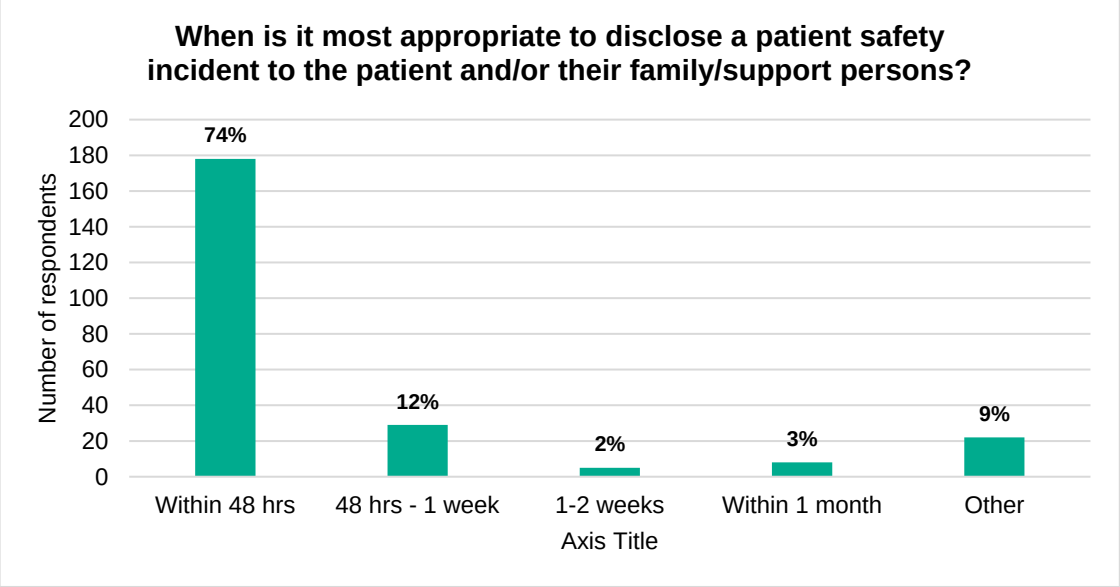
Those that stated that they had received follow-up or support were asked to rate the support on a scale from 1 to 5, with 1 being poor and 5 being excellent. The average answer was 3, illustrating that those that received support did not find it excellent but also did not find it poor.

5.4.8 *Views on Open Disclosure*

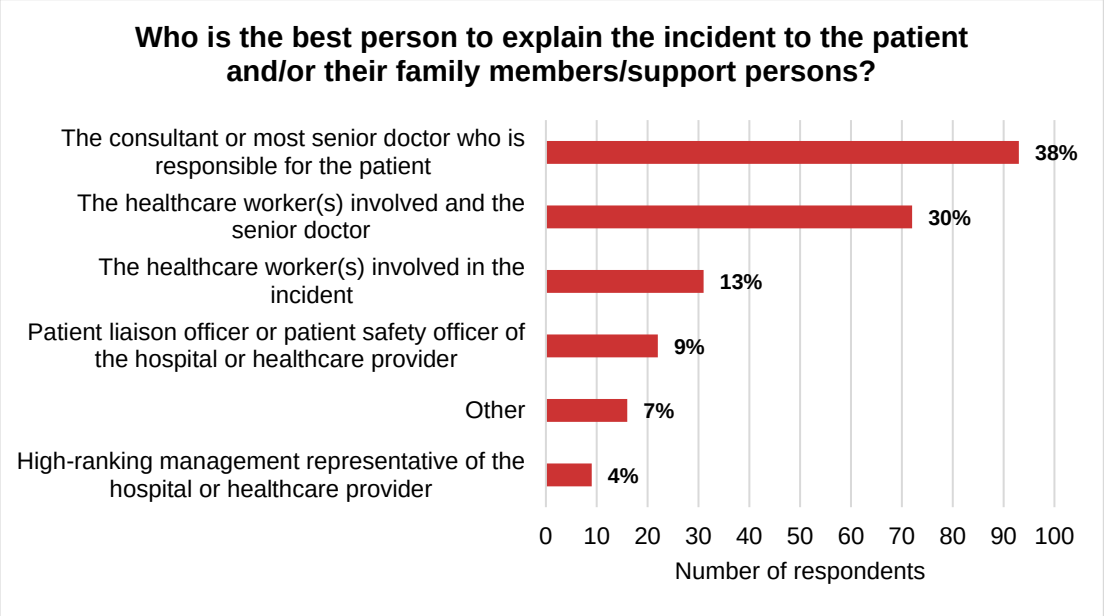
All respondents to the survey were then asked for their views on open disclosure based on the set of questions in this section of the survey. Members of the public, members of organisations that provide support to patients or families when things go wrong, and those that selected the “Other” category were shown the following the questions.



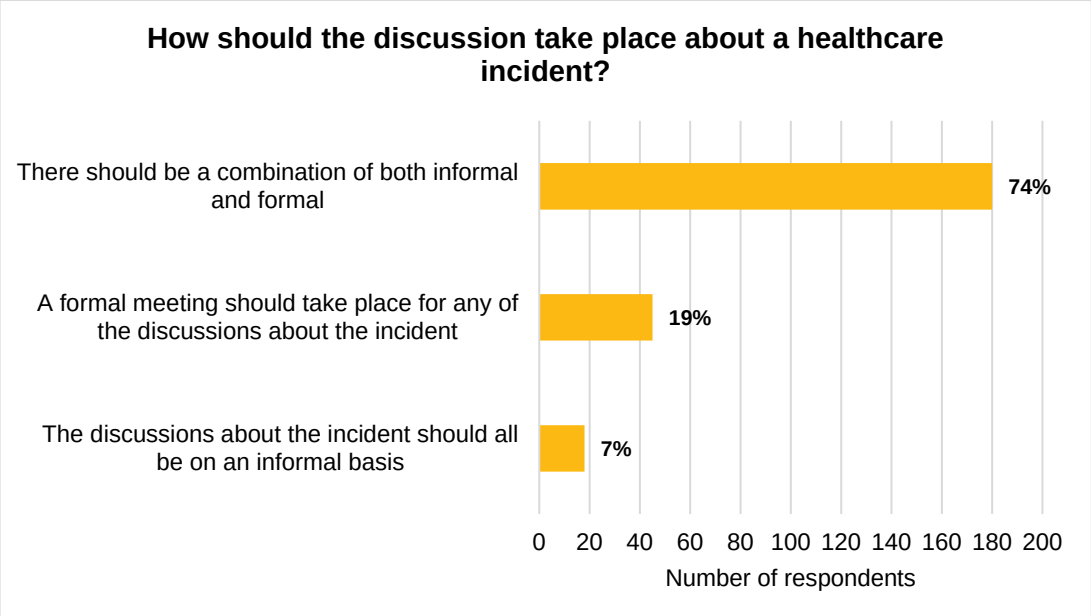
A large percentage (70%) of respondents felt that healthcare workers should always be required to tell a patient if an incident has happened in their care. Approximately 30% felt that they should but that it should depend on the amount of harm caused or potential for harm. Very few respondents did not know.



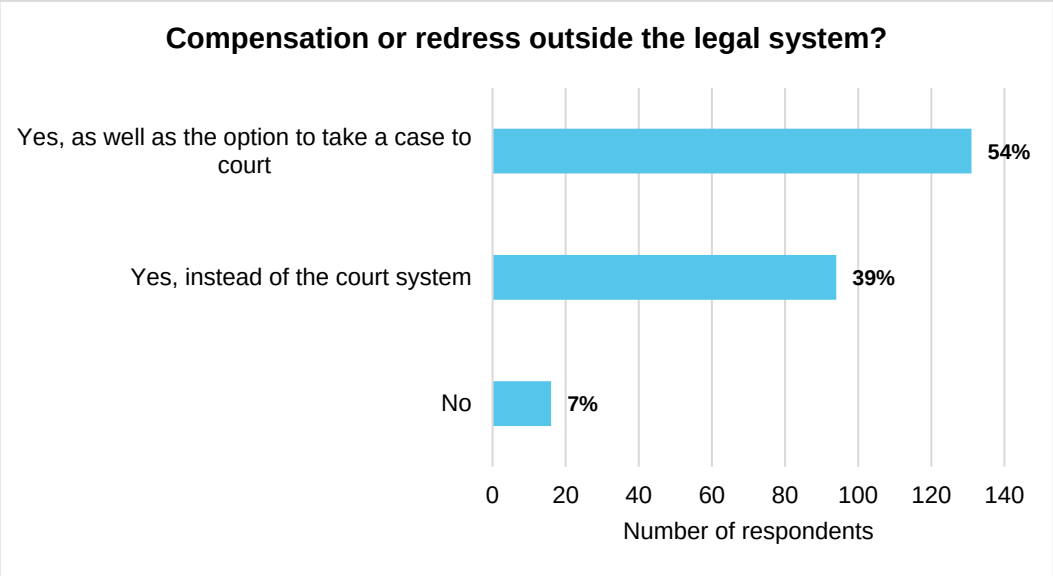
In relation to the timing of the disclosure, almost three quarters of respondents felt that it should be within 48 hours of the incident. Those that stated “Other” mainly advocated for disclosing at an appropriate time for the situation, with one respondent stating that it should not be prescriptive. Many stated that it would depend on the situation.



While there was not an overwhelming preference for who would be the best person to explain the incident, 68% stated that a senior doctor should be involved in the disclosure process. A minority of respondents felt that non-healthcare staff would be the best person to explain the incident. Those who selected “Other” stated that who should be involved would be dependent on the situation.



Almost three quarters of respondents felt that there should be a combination of both formal and informal discussions about a healthcare incident. A small minority of under 10% stated that discussions should all be informal.



When respondents were asked if there should be access to compensation or redress separate from the legal system following a healthcare incident, the majority of respondents (93%) stated that there should be. These were split between allowing the option to take a case to court or just settling outside the court system. A small minority did not think there should be compensation or redress separate from the legal system.

5.5 Qualitative Analysis

5.5.1 Overview

There were four questions in the survey that allowed for respondents to freely type a response. These questions were as follows:

- Why is it difficult to ensure that adverse events and patient safety incidents are communicated clearly and in a timely manner?
- What should change to make this easier and more effective so that patients and families get all the information they need in relation to a patient safety incident?
- What kind of culture and behaviours would be necessary to support openness and honesty about healthcare incidents?
- Please add any further views in relation to open and honest conversations with patients and families about adverse events and patient safety incidents.

While there were four distinct questions, there were themes that were common across all four questions. The themes that arose most frequently in the responses to the open-ended questions include:

- A shift from a ‘blame’ culture to one of openness;
- Fear of litigation/litigious culture;
- Training and support for staff;
- Patient liaison;
- A “human touch”;
- Timing.

5.5.2 Shift from Blame Culture

Respondents believed that the current culture in Ireland is one in which blame is assigned to the individual. Blame is assigned rather than an assessment and discussion of the error in order to prevent its reoccurrence. All respondents who made note of the culture of blame agreed that there was an urgent need to change from a culture of blame to an open, transparent culture. The new culture would need to accept that some mistakes are due to errors and mistakes in a system rather than an individual.

A system which expects perfection in human performance is doomed to failure. A system which examines human performance and limits the expectations accordingly, and not only learns the lessons from mistakes but takes measures to prevent a reoccurrence is a far better way to support honesty and openness.

Respondents advocated for a move away from a blame culture in order to encourage openness and honesty, as respondents believed that the blame culture encourages covering up mistakes and error.

Many respondents also noted that medical professionals are human and thus fallible. Respondents recognise that medical professionals will make mistakes, but that they should not be blamed or punished for this. These mistakes should be used as an opportunity to learn and prevent these mistakes from happening in the future. A culture of blame will only blame and punish the individual and prevent essential lessons from being learnt.

5.5.3 Fear of Litigation

A shift away from litigation to other means of dealing with these incidents would remove the terror workers feel when something goes wrong. Patients and families would also benefit from a kinder more compassionate model than litigation.

A large number of respondents stated that one of the main barriers to disclosure was the fear of litigation. This fear of litigation is due to a litigious culture in Ireland; errors or adverse events are not discussed between patients and health and social care staff, but there is instead a "custom of 'settling on the steps of the court'". This litigious environment is not conducive to transparency or learning from errors. Instead, it breeds an adversarial culture in which patients and health and social care staff are directly opposing each other rather than working together for the benefit of the patient.

This fear of being taking to court only encourages medical professionals to not disclose errors. Some respondents noted that court appeared to be the only way to get answers or an apology from some medical professionals. Respondents also noted that they felt that going through the legal system was the only way to receive support needed due to the incident.

In our experience we never wanted any of this, we do not want to be on a legal journey, it is a gruelling process. If there was another way for our family and other families like us to get the support and care we need for our family.

Respondents suggested that there be an alternative to litigation in order to receive answers regarding what happened, an apology, and compensation. No fault compensation was mentioned on multiple occasions as something that should be implemented in Ireland.

5.5.4 Training and Support for Staff

Respondents also noted that training and support for staff would be necessary for open disclosure to function properly. Comments regarding training included not only training specifically around open disclosure, but communication in general for medical professionals. The training in open disclosure was specifically mentioned by many respondents, as respondents felt that medical professionals weren't clear on the open disclosure process.

There also needs to be support for the health care providers involved - good people make mistakes when systems and resources are not robust.

Also they may not be trained in how to communicate effectively in these circumstances and tend to revert to formal impersonal language that is not readily understood.

Some respondents also made note that medical professionals may not be receiving adequate support in order to encourage open disclosure. This includes giving medical professionals the time to have disclosure conversations in an appropriate setting, as well as more general support in the form of resources and support from managers. Inadequate resources, such a staffing problems, timing, and long shifts were also noted by respondents as things that should be changed to support open disclosure. Staffing shortages in healthcare were noted multiple times as something that needs to be addressed.

Supports for the "second victim" were also noted by some respondents. More than one respondent suggested cognitive behavioural therapy training for medical professionals to help mitigate negative thoughts or emotions due to adverse events.

5.5.5 Patient Liaison

Many respondents suggested that there be a dedicated person in each healthcare facility that would be available to patients and their families not only during the initial open disclosure conversation, but throughout the entire process. Respondents recommended that patients and their families be given the contact details of a person that could answer their questions in relation to the open disclosure process. This person would also inform patients about open disclosure in general and what patients should expect from the process.

Appoint a communication officer/case officer to communicate with patients and families so that they feel heard. Most people just want to have communication and can understand things better if they are being listened to.

Having a patient liaison present would also help to balance out disclosure meetings that some respondents had noted were unbalanced in terms of those present from the healthcare facility and those for the patient. This patient liaison could act in support of the patient rather than the medical professional, helping the patient to feel that there were more people "on their side" in the disclosure meeting.

Respondents that recommended a patient liaison in some form noted that the main purpose of this person would be to listen to the patient. This liaison could also help to address another point that many respondents noted: the use of technical or overly formal language. Many respondents wanted things to be explained to them in simple, easy-to-understand language.

5.5.6 *A "Human Touch"*

Another theme that arose through many of the responses, although not always directly addressed, is the inclusion of a "human touch" in open disclosure. Respect and empathy were emphasised as crucial elements that need to be considered and often are not seen as included currently. A sincere apology was also mentioned multiple times as something that should be included in a disclosure conversation.

Say sorry properly. Provide support to patient. Treat them like people not combatants.

A repeated suggestion by multiple respondents regarded the setting of the disclosure conversation. Respondents felt that these conversations should be held in a non-clinical room, such as a board room or day room. The provision of tea and coffee was suggested. One respondent noted that "being called to a meeting in a clinical office seems to be a bit off-putting" and another respondent detailed her disclosure in a clinical room, stating that they "felt so uncomfortable". A space with privacy was emphasised as necessary for these discussions.

Many respondents stated that the patient should be the focus of any disclosure process. Some respondents suggested treating the patient as a member of the "team" in the provision of their healthcare.

5.5.7 *Timing*

One area in which there was some disagreement among respondents was in regards to the timing of the disclosure. There were two opposing viewpoints as to when the patient should be told: as soon as possible, or when the facts had been established. While the word "timely" was used by some respondents, others advocated for a more measured approach, allowing for time to gather all information and investigate the incident before disclosing to the patient. This would allow for all questions to be answered at the time of the disclosure conversation rather than requiring the patient and their family to have to wait for answers.

Time should be allowed for all staff involved in the safety incident to convey, meet and gather all the facts of events before communicate with patients and families in order to be able to answer as many questions as possible.

Families and patients should be supported and informed as soon as possible

More than one respondent suggested an initial meeting informing the patient of the event and advising that an investigation would be conducted, followed by a later discussion of the findings of the investigation. However, more than one respondent discussed their personal experience of waiting many months for communication in relation to the results of an investigation and the anxiety and frustration caused by such a delay.

6 Concluding Comments

Open disclosure can be seen as very simple at its heart; the communication to patients/service users from health and social care staff and service providers when something has gone wrong in their care, but has a complex context and operation that will require a cohesive, consistent, national approach in order to bring about a culture of openness, fairness, and transparency.

The Independent Patient Safety Council has produced a set of recommendations to the Minister for Health in relation to a national policy framework for open disclosure in healthcare in Ireland. The research and analysis set out in this report have informed the Council in its consideration of appropriate recommendations to inform future policy on this issue.

The task of the Department is to develop a national policy framework to support and drive this, and to give effect to the recommendations of the Council. The findings set out in this report will, we trust, be helpful to the Department in this process.

We would like to take this opportunity to thank the members of the Independent Patient Safety Council, its Chair Noeline Blackwell, the National Patient Safety Office in the Department of Health, and all those who engaged with the consultation process for working constructively with Crowe and giving valuable time and insight to support the research and the development of the deliverables.

Given the particular circumstances in the last year, with Covid restrictions in place for the duration of the assignment and the impact of the pandemic on the health and social care services, we are grateful for the time and input from those who had to deal with disruption and diversion in their usual roles, but still engaged with this research. This is indicative of the importance placed on this issue by key stakeholders, which is a very positive starting point for the development of the policy framework.

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Appendix 2: Survey

Patient/Family/Community Survey on Open Disclosure in Healthcare

This survey is intended to help the work of the Independent Patient Safety Council,who are developing recommendations on a national policy framework for open disclosure in healthcare in Ireland.

Open disclosure refers to open, accurate, and timely communication to patients and their families and/or support persons in relation to adverse events and patient safety incidents.

A patient safety incident is an event or circumstance during health care which could have, or did result in, unintended or unnecessary harm to a patient: this could be an error in care or where someone was placed at risk of harm.

Crowe is conducting this survey along with other research on behalf of the Independent Patient Safety Council, having been commissioned to do so by the National Patient Safety Office in the Department of Health.

This survey is anonymous and confidential. Please do not include in your responses any personal details, such as names of patients or healthcare workers, or potentially identifying details, such as the name of a hospital in relation to a particular incident.

The survey questions comprise mostly tick-box options, with a small number of free-text boxes. The survey should take around 10- 20 minutes to complete.

This survey is available online at https://www.crowesurvey.com/index.php/813294/lang-en if you would prefer to complete it this way.

This survey will close on **Friday 16th October 2020**.

Please return the survey by post to:

Vanya Sargent
Crowe
Marine House
Clanwilliam Place
Dublin 2
D02 FY24

OR

Scan and return via email to vanya.sargent@crowe.ie

Should you have any queries in relation to this survey, please contact Shannon Scott (shannon.scott@crowe.ie) or Vanya Sargent (vanya.sargent@crowe.ie) via email or by phone at 01-4482200.

Profile Questions

A patient safety incident is an event or circumstance during health care which could have, or did result in, unintended or unnecessary harm to a patient: this could be an error in care or where someone was placed at risk of harm.

Please select one option that best describes you:

A patient who has experienced a patient safety incident* where something did not go according to plan

A support person (e.g. a family member) of someone who experienced a patient safety incident where something did not go according to plan

An organisation that provides support to patients or families when things go wrong in healthcare

A member of the public

Other

***See above definition of patient safety incident**

If other, please give details.

If you are a **PATIENT** who experienced a patient safety incident, please go to **p3** (red border).

If you are a **FAMILY MEMBER/CARER/SUPPORT PERSON** of someone who experienced a patient safety incident, please go to **p11** (blue border).

All other respondents, please go to **p19** (grey border).

This section is for PATIENTS

What age are you?
0 - 15
16 - 20
21 - 30
31 - 40
41 - 50
51 - 60
61 - 70
Over 70

What is your gender?
Female
Male
Prefer not to say

Where do you live?
Border Region (Cavan, Donegal, Leitrim, Monaghan, Sligo)
West Region (Mayo, Roscommon, Galway & Galway City)
Mid-West Region (Clare, Tipperary, Limerick City & County)
South-East Region (Carlow, Kilkenny, Wexford, Waterford City & County)
South-West Region (Kerry, Cork & Cork City)
Dublin Region (Dublin City, Dún Laoghaire–Rathdown, Fingal, South Dublin)
Mid-East Region (Kildare, Meath, Wicklow, Louth)
Midlands Region (Laois, Longford, Offaly, Westmeath)

Experience of the Patient

In what year did the patient safety incident take place?

In what healthcare setting did this take place?
Hospital
Nursing home
Primary care, e.g. GP, public health nurse, etc.
Screening Services
Other

If other, please give details.

If this took place in hospital, were you in hospital for an emergency, for an elective (planned) admission, for an outpatient visit, etc?
Emergency
Elective admission/procedure (planned operation, scheduled tests, etc)
Outpatient visit/procedure
Maternity
Other

If other, please give details.

What was the incident or issue related to?
Diagnosis
Procedure or surgery
Medication type
Medication dose
Maternity
Other

If other, please give details.

On a scale of 1 - 10 (1 being least serious and 10 most serious), how serious were the effects of this incident for you?

	1	2	3	4	5	6	7	8	9	10
Seriousness	O	O	O	O	O	O	O	O	O	O

Awareness and Disclosure of Patient Safety Incident

How did you find out about this incident?
Doctor or other healthcare worker told you
You noticed something was wrong and raised the concern with healthcare worker
Family member/support person noticed and raised the concern
Other

If it was a doctor or other healthcare worker who told you, how soon after the incident were you told?
Within 48 hrs
48 hrs - 1 week
1-2 weeks
Within 1 month
More than 1 month
A discussion is yet to take place

If you or a support person raised the concern, how soon after the incident was raised did a discussion with a healthcare professional or institution take place?
Within 48 hrs
48 hrs - 1 week
1-2 weeks
Within 1 month
More than 1 month
A discussion is yet to take place

Who told you about the incident? Please tick all that apply if more than one person was involved when you were told.

- ☐ Consultant
- ☐ Non-consultant hospital doctor
- ☐ Primary care doctors
- ☐ Nurse
- ☐ Other healthcare worker
- ☐ Hospital/clinic/treatment centre
- ☐ Patient safety manager/risk manager
- ☐ Other

If other, please give details.

Do you think this was the right person to tell you?

Yes ○ No ○

If not, who should have told you about the incident? Please tick all that apply.

- ☐ Consultant
- ☐ Non-consultant hospital doctor
- ☐ Primary care doctors
- ☐ Nurse
- ☐ Other healthcare worker
- ☐ Hospital/clinic/treatment centre
- ☐ Patient safety manager/risk manager
- ☐ Other

If other, please give details.

To what level do you agree or disagree with each of the following statements:

	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
The incident was acknowledged by the healthcare worker or institution involved	O	O	O	O	O
A clear explanation was given as to how the incident occurred	O	O	O	O	O
Sufficient information was provided to you in relation to the incident	O	O	O	O	O
Actions were taken to ensure the incident does not happen again	O	O	O	O	O

Did you receive an apology?

Yes O No O

Planned or Formal Disclosure Process

Was there a planned disclosure meeting in respect of this incident?
Yes, the disclosure of the incident was in a planned meeting
Yes, a planned meeting took place after I had been informed of the incident in an informal setting
No

If there was a formal/planned disclosure meeting, who was at this meeting? Please tick all that apply.

- ☐ Consultant
- ☐ Non-consultant doctor
- ☐ Primary care doctor
- ☐ Nurse
- ☐ Other healthcare worker
- ☐ Hospital/clinic/treatment centre management Patient
- ☐ Family member/carer/friend
- ☐ Independent support person
- ☐ Other

If other, please give details.

How would you rate the preparedness of the person or persons giving you information in the formal disclosure meeting? Please rate this on a scale of 1 to 5 where 1 means minimally or not at all prepared and 5 means very well prepared with relevant information for you.

	1	2	3	4	5
Preparedness	O	O	O	O	O

Further Action

Did you seek legal redress?

Yes ○ No ○

If yes, what was the motivation for seeking legal redress? Please tick all that apply.

- ☐ Seeking a formal apology
- ☐ Determining the full facts of the incidents
- ☐ Deterrent for future such events
- ☐ Financial compensation for additional healthcare needs
- ☐ Financial compensation for trauma or stress
- ☐ Other

If other, please give details.

Support

Has there been follow-up or support for you in relation to the incident?

Yes ○ No ○

How would you rate this support? (Rating of 1-5: Poor to Excellent)

	1	2	3	4	5
Support	○	○	○	○	○

PLEASE CONTINUE TO THE SECTION FOR ALL RESPONDENTS ON P19.

This section is for FAMILY MEMBERS/CARERS/SUPPORT PERSONS

What was the age of the person affected at the time of the healthcare incident?

0 - 15	41 - 50
16 - 20	51 - 60
21 - 30	61 - 70
31 - 40	Over 70

What is the gender of the person affected by the patient safety incident?
Female
Male
Prefer not to say

Where do you live?
Border Region (Cavan, Donegal, Leitrim, Monaghan, Sligo)
West Region (Mayo, Roscommon, Galway & Galway City)
Mid-West Region (Clare, Tipperary, Limerick City & County)
South-East Region (Carlow, Kilkenny, Wexford, Waterford City & County)
South-West Region (Kerry, Cork & Cork City)
Dublin Region (Dublin City, Dún Laoghaire–Rathdown, Fingal, South Dublin)
Mid-East Region (Kildare, Meath, Wicklow, Louth)
Midlands Region (Laois, Longford, Offaly, Westmeath)

Where does/did the person affected by the patient safety incident live at the time?
Border Region (Cavan, Donegal, Leitrim, Monaghan, Sligo)
West Region (Mayo, Roscommon, Galway & Galway City)
Mid-West Region (Clare, Tipperary, Limerick City & County)
South-East Region (Carlow, Kilkenny, Wexford, Waterford City & County)
South-West Region (Kerry, Cork & Cork City)
Dublin Region (Dublin City, Dún Laoghaire–Rathdown, Fingal, South Dublin)
Mid-East Region (Kildare, Meath, Wicklow, Louth)
Midlands Region (Laois, Longford, Offaly, Westmeath)

Experience of the Family and/or Support Persons

In what year did the patient safety incident take place?

In what healthcare setting did this take place?
Hospital
Nursing home
Primary care, e.g. GP, public health nurse, etc.
Screening Services
Other

If other, please give details.

If this took place in hospital, was the patient in hospital for an emergency, for an elective (planned) admission, for an outpatient visit, etc?
Emergency
Elective admission/procedure (planned operation, scheduled tests, etc)
Outpatient visit/procedure
Maternity
Other

If other, please give details.

What was the incident or issue related to?

Diagnosis
Procedure or surgery
Medication type
Medication dose
Maternity
Other

If other, please give details.

On a scale of 1 - 10 (1 being least serious and 10 most serious), how serious were the effects of this incident for the patient?

	1	2	3	4	5	6	7	8	9	10
Seriousness	O	O	O	O	O	O	O	O	O	O

Awareness and Disclosure of Patient Safety Incident

How did you/the patient find out about this incident?
Doctor or other healthcare worker told you/the patient
Patient noticed something was wrong and raised the concern with healthcare worker
You/other family member/support person noticed and raised the concern
Other

If other, please give details.

If it was a doctor or other healthcare worker who told you, how soon after the incident were you told?
Within 48 hrs
48 hrs - 1 week
1-2 weeks
Within 1 month
More than 1 month
A discussion is yet to take place

If the patient or you or another support person raised the concern, how soon after the incident was raised did a discussion with a healthcare professional or institution take place?
Within 48 hrs
48 hrs - 1 week
1-2 weeks
Within 1 month
More than 1 month
A discussion is yet to take place

Who told you/the patient about the incident? Please tick all that apply if more than one person was involved when you were told.

- ☐ Consultant
- ☐ Non-consultant hospital doctor
- ☐ Primary care doctors
- ☐ Nurse
- ☐ Other healthcare worker
- ☐ Hospital/clinic/treatment centre
- ☐ Patient safety manager/risk manager
- ☐ Other

If other, please give details.

Do you think this was the right person to tell you/the patient?

Yes O No O

If not, who should have told you/the patient about the incident? Please tick all that apply.

- ☐ Consultant
- ☐ Non-consultant hospital doctor
- ☐ Primary care doctors
- ☐ Nurse
- ☐ Other healthcare worker
- ☐ Hospital/clinic/treatment centre
- ☐ Patient safety manager/risk manager
- ☐ Other

If other, please give details.

To what level do you agree or disagree with each of the following statements:

	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
The incident was acknowledged by the healthcare worker or institution involved	O	O	O	O	O
A clear explanation was given as to how the incident occurred	O	O	O	O	O
Sufficient information was provided to you in relation to the incident	O	O	O	O	O
Actions were taken to ensure the incident does not happen again	O	O	O	O	O

Did the patient and/or family member/support person receive an apology?

Yes O No O

Planned or Formal Disclosure Process

Was there a planned disclosure meeting in respect of this incident?
Yes, the disclosure of the incident was in a planned meeting
Yes, a planned meeting took place after I/we/the patient had been informed of the incident in an informal setting
No

If there was a formal/planned disclosure meeting, who was at this meeting? Please tick all that apply.

- ☐ Consultant
- ☐ Non-consultant doctor
- ☐ Primary care doctor
- ☐ Nurse
- ☐ Other healthcare worker
- ☐ Hospital/clinic/treatment centre management Patient
- ☐ Family member/carer/friend
- ☐ Independent support person
- ☐ Other

If other, please give details.

How would you rate the preparedness of the person or persons giving you/the patient information in the formal disclosure meeting? Please rate this on a scale of 1 to 5 where 1 means minimally or not at all prepared and 5 means very well prepared with relevant information for you.

	1	2	3	4	5
Preparedness	O	O	O	O	O

Further Action

Did you/the patient seek legal redress?

Yes ○ No ○

If yes, what was the motivation for seeking legal redress? Please tick all that apply.

- ☐ Seeking a formal apology
- ☐ Determining the full facts of the incidents
- ☐ Deterrent for future such events
- ☐ Financial compensation for additional healthcare needs
- ☐ Financial compensation for trauma or stress
- ☐ Other

If other, please give details.

Support

Has there been follow-up or support for you/the patient in relation to the incident?

Yes ○ No ○

How would you rate this support? (Rating of 1-5: Poor to Excellent)

	1	2	3	4	5
Support	○	○	○	○	○

PLEASE CONTINUE TO THE SECTION FOR ALL RESPONDENTS OVERLEAF ON P19.

Views on Open Disclosure

This section is for ALL respondents

Should healthcare workers be required to tell a patient if an incident has happened in their care – this could be a mistake or something unplanned or unexpected related to their care?
Yes, always
Yes, but only if it will not cause more harm or unnecessary worry
Yes, if the incident resulted in harm or did not resolve the issue
Don't know

When is it most appropriate to disclose a patient safety incident to the patient and/or their family/support persons?
Within 48 hrs
48 hrs - 1 week
1-2 weeks
Within 1 month
More than 1 month
Other

If other, please give details.

Who is the best person to explain the incident to the patient and/or their family members/support persons?
The healthcare worker(s) involved in the incident
The consultant or most senior doctor who is responsible for the patient
The healthcare worker(s) involved and the senior doctor
Patient liaison officer or patient safety officer of the hospital or healthcare provider
High-ranking management representative of the hospital or healthcare provider
Other

If other, please give details.

How should the discussion take place about a healthcare incident?
A formal meeting should take place for any of the discussions about the incident
The discussions about the incident should all be on an informal basis
There should be a combination of both informal and formal

Should there be access to compensation or redress following incidents in healthcare that is separate from taking a case through the legal system (such as a no-fault compensation programme)?
Yes, instead of the court system
Yes, as well as the option to take a case to court
No

Difficulty Communicating

Why do you think it can be difficult to ensure that adverse events and patient safety incidents are communicated clearly and in a timely manner to patients?

Easier and More Effective Communication

What should change to make this easier and more effective so that patients and families get all the information they need in relation to a patient safety incident?

Cultures and Behaviours

What kind of culture and behaviours would be necessary to support openness and honesty about healthcare incidents?

Further Views

Please add any further views in relation to open and honest conversations with patients and families about adverse events and patient safety incidents.

Many thanks for your time in completing this survey. If you have any questions, please contact Shannon Scott (shannon.scott@crowe.ie) or Vanya Sargent (vanya.sargent@crowe.ie) via email or by phone at 01-4482200.