Evaluation of the National Open Disclosure Pilot

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PREFACE

In October 2010 the State Claims Agency (SCA) and the Health Service Executive (HSE) with the support of the Medical Protection Society (MPS) commenced a two-year Open Disclosure Pilot project at two sites, the Mater Misericordiae University Hospital, Dublin and Cork University Hospital.

The project objective was to:

(i) Provide training and other resources to support managers, doctors and other healthcare professionals in engaging in the open disclosure process with patients and their families;

(ii) Provide support and guidance to healthcare professionals in relation to how to communicate with patients and their families following an adverse event and to manage the challenges in communication which can occur; and

(iii) To demonstrate the importance of open disclosure for patients and their families, health and social care staff and the wider organisation.

It was planned that the learning from the pilot project would be used to inform the development of (i) a national policy and supporting guidelines on open disclosure and (ii) a standardised national open disclosure framework to be implemented across all health and social care services that would progress, foster and practically support a culture of openness in an informed, sensitive, inclusive and safe environment.

An independent external evaluation of the project was proposed by the national project team to ensure independence, objectivity and transparency for all of the stakeholders involved. The evaluation of the project was deemed important in relation to assessing (i) the impact of the work undertaken within both pilot sites, (ii) progress to date, (iii) to what extent the project had met its objectives and (iv) whether change of practice has occurred.

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ACKNOWLEDGMENTS

The evaluation would not have been possible without the active participation and engagement of a wide range of healthcare professionals and managers. My warm thanks go to the two open disclosure leads, Angela Tysall (Health Service Executive) and Ann Duffy (State Claims Agency). They both played an active role in supporting the evaluation throughout its duration.

My thanks are also extended to the pilot leads in the two pilot sites, Celia Cronin (Clinical Governance Manager, CUH) and Catherine Holland (Risk Manager, MMUH) who contributed a great deal of learning and evidence from the pilots and assisted in organising interviews, focus groups and the launch of the on-line survey.

Many thanks are given to the healthcare professionals, national managers and the patient advocate who participated in the interviews, the healthcare professionals in CUH who participated in focus groups and the staff from both pilot sites who completed the on-line survey. All participants in the evaluation offered valuable insights, learning and suggestions, which have informed the evaluation findings and recommendations, as well as roll-out and implementation of open disclosure in all healthcare settings.

Dr. Jane Pillinger
EXECUTIVE SUMMARY

1. Introduction

This report documents the evaluation of the open disclosure pilot programme carried out by the Health Service Executive (HSE) and the State Claims Agency (SCA) between November 2010 and November 2012. The pilot was carried out in two acute hospitals, Cork University Hospital (CUH) and the Mater Misericordiae University Hospital, Dublin (MMUH). The learning from the pilots informed the development of the national policy and guidelines on open disclosure and the subsequent national roll-out of open disclosure. The evaluation was carried out during 2014 and it examined the activities and outcomes of the pilot and developments post-pilot up to the end of 2014.

The evaluation had three specific objectives:

• To evaluate the implementation of the open disclosure framework in the two pilot sites.
• To evaluate the role of the framework and policy in relation to national policy developments and the potential for roll-out across all healthcare settings.
• To benchmark the learning from the pilots and the implementation of the policy against international evidence based practices and the agreed principles on open disclosure.

Evaluation methodology

The evaluation drew on evidence to reflect the views and experiences of CEOs/senior managers, healthcare professionals and front line staff in implementing open disclosure in the two pilot sites. This evidence was collected through face-to-face interviews with twenty-one senior healthcare professionals and managers, three focus groups with staff who had attended the open disclosure training, and an on-line survey with responses from 339 staff at all levels in the two pilot sites. In addition interviews were also held with twelve national policy makers in the HSE and SCA and one patient representative.

Collaboration and partnership between the HSE and SCA

The collaboration and partnership between the HSE and SCA has been exemplary at both a strategic and operational levels. This unique partnership between the two organisations led to credibility, integrity of approach and shared learning. There was significant value in having this expertise and external resources. This enabled the two pilot hospitals to carry out work that would have been difficult to do internally. The commitment, expertise and enthusiasm of the national pilot leads were major factors leading to a successful outcome for the pilot.

Overview of the benefits of open disclosure in the pilot sites

The experience of the pilot echoes international evidence that open disclosure is beneficial for patients/family members, for health and social care staff, and for health and social care organisations. Participants in the evaluation repeatedly reinforced the importance of open disclosure in creating open, transparent, compassionate and humane communications in order to reduce patient harm. Open disclosure is increasingly viewed as a tool that is relevant across the whole continuum of care and in all health and social settings. It supports the principles of professionalism and medical ethics for patient-centred, good quality and safe patient care.

1 The evaluation covered Cork University Hospital (CUH), which also includes Cork University Maternity Hospital
In summary, the evaluation found the following positive outcomes from the pilot:

- The implementation of open disclosure in the two pilot hospitals has been an ambitious and groundbreaking development led jointly by the HSE and SCA. The pilot created a positive area for change at a time of significant challenges, poor staff morale and a negative external environment.
- Overall, the broad objectives of the open disclosure pilot were met, notably in providing supportive environment in each pilot hospital for the implementation of open disclosure.
- The two pilot hospitals demonstrate overwhelming evidence of the benefits of open disclosure for both staff and patients.
- Significant learning has been gained in relation to the management of adverse events and the integration of open disclosure into complaints handling.
- Strong commitment is evident amongst senior managers and healthcare professionals to implementing open disclosure and integrating it into risk and clinical governance procedures.
- The pilot reinforced the importance of openness and of giving timely responses to serious incidents, coupled with willingness and commitment to implement open disclosure in less serious events.
- Open disclosure has been relatively inexpensive to implement, and although there are cost implications from establishing systems, training and learning across the system, these costs will be offset by the considerable savings resulting from reductions in patient harm and legal claims in the long-term.

Although the evaluation found a high level of support for open disclosure, good levels of staff awareness and promising practices in this regard, a significant number of challenges and barriers are also highlighted.

2. Open disclosure pilot outcomes and achievements

The following specific activities were carried out in both pilot sites:

- The appointment of pilot leads responsible for implementing open disclosure (Clinical Governance Manager CUH and Risk Manager MMUH) who carried out a range of project activities and laid the groundwork for open disclosure.
- Strategic leadership for open disclosure through hospital Board approval of the project implementation plans, open disclosure committees to drive the pilot activities and early engagement with senior clinicians.
- A patient Safety Culture survey, carried out in July 2011, aimed to measure the safety and risk culture in both hospitals prior to commencement of the pilot.
- Up to 50 awareness raising sessions, including 30 minute briefings for staff, briefings for senior managers and governance committees and grand rounds for clinicians, reached more than 700 staff in the two hospitals. This was followed by 3.5 hour multidisciplinary accredited training sessions with more than 400 staff, which focused on communications skills, processes, practical scenarios and role-plays.
- Development and implementation of hospital policies and patient information leaflets on open disclosure, modelled on international best practice.
- Both hospitals engaged with the pilot leads in drafting the national policy and guidance on open disclosure, which were subsequently launched in 2013.
CUH and MMUH approached the pilot in the following ways:

- **CUH** developed a formal process for holding open disclosure meetings for adverse events, resulting in timely reporting and implementation of open disclosure. The pilot had an impact in endorsing the importance of open disclosure and open communications across the organisation, contributing to culture change.

- **MMUH** successfully integrated open disclosure into the complaints process and across the whole organisation. Patient Liaison Officers continue to play an active role in raising awareness, providing guidance and assisting in open disclosure at all levels. Post-pilot, MMUH has been a national pilot for NIMS (National Incident Management System) and has an on-line incident reporting system encouraging and facilitating a more timely response to open disclosure. The pilot is regarded as having played a significant role in culture change and in providing endorsement for open disclosure to take place across all levels of the organisation.

In both pilot sites learning from the experience of open disclosure provided an opportunity to cascade open disclosure across the whole organisation and at ward level.

Participants in the evaluation identified a range of benefits and impacts from the pilot for staff, patients/families and for hospitals in encouraging and supporting a culture of openness, a willingness to learn from complaints and incidents, higher quality care and follow-up, better patient satisfaction and improved clinician-patient trust.

**Leadership on open disclosure**

- The evaluation shows the importance of national and organisational leadership and support in the national roll-out of open disclosure. Effective governance of open disclosure is highlighted in the evaluation, for example, by ensuring that there are systematic ways to monitor, report and learn from open disclosure, including how learning is acted upon at the level of hospital executives and Boards, and nationally within the HSE Leadership Team.

**Open disclosure and adverse events**

- During and following the pilot the Risk Managers in both hospitals formalized the process of open disclosure with regards to adverse events. Open disclosure meetings have been held for all adverse events, the majority of which are preceded by an internal review into the incident.

- The learning from the evaluation is that incident reviews need good documentation and evidence, are carried out in a timely way and that all of the relevant staff are involved and consulted with.

- Disclosure at an early stage and giving an early apology are generally accepted as being important in preventing a situation from worsening, and in some cases in preventing a small error leading to further complications at a later stage. Greater distress for patients and staff is evident from incidents that are not dealt with in a timely manner.

- Improved systems for incident reporting carried out post-pilot provide a model for open disclosure to be implemented into incident reporting systems and processes in all healthcare organisations.

**Open disclosure and complaints handling**

- Effective complaints handling is widely regarded as being essential for high quality patient care. In MMUH, the pilot reinforced the approach that had commenced to integrate open disclosure into all aspects of the complaints system. This has been a very progressive way to implement open disclosure and represents very good learning for other health and social care organisations. A system is in place for gaining responses and learning at ward level and for making recommendations to change services where this is appropriate. The system has now been rolled-out to each Directorate to enable performance reports to be carried out at Directorate level.
A supportive environment for staff to disclose and learn from errors

- The evaluation points to the importance of staff support and staff dialogue in the implementation of open disclosure. The pilot put a significant emphasis on creating staff support systems so that staff feel safe and supported pre, during and post disclosure of adverse events.

- Although levels of staff support were reported as being very good in some clinical areas, particularly from line managers, these tended to be isolated examples. Overall, levels of staff support and the use of the ASSIST ME model were low, with some interviewees in the evaluation feeling isolated and unsupported during the open disclosure process. This points to the need for dedicated training for line managers and Clinical Directors in how to manage support for staff effectively.

Early management of incidents and apologies

- The evaluation found that early management of open disclosure and timely apologies are critical to a patient-centred approach. The way that communication is carried out can impact enormously on patient perceptions of the incident, levels of patient trust, medico-legal impacts, and how residual harm is mitigated.

- Participants in the evaluation stressed the importance of making apologies with integrity and compassion, and of having the right people informed and prepared to make an apology in advance of an open disclosure meeting.

- The evaluation captured the experiences of staff who had been involved in difficult cases resulting in open disclosure. There was an overwhelming perception that open disclosure was not only vitally important for the patient/family, but also that staff experienced a sense of relief and benefited from practicing open disclosure.

Learning from incidents and feedback loops

- Good communication and a supportive environment for staff are essential in facilitating staff and teams to discuss and agree an early solution, with discussions about how to prevent a similar incident arising again.

- The evaluation identified the importance of greater attention to be given to feedback loops and learning from errors, in addition to the significant inroads which have been made in the two pilot sites in relation to risk assessment and management. Emphasis is given to having a team approach to resolving and learning from errors as part of a fair and just approach.

- The evaluation points to the importance of effective implementation and management of staff feedback to enable learning from open disclosure to be integrated into changed working practices, resource allocation or systems changes where these are relevant to preventing future harm.

Reporting on open disclosure

- The pilot sites developed accountability structures during the pilot phase; however, there is room for further development in establishing open disclosure in clinical governance reporting and accountability structures, including incident reporting and management procedures.

- Open disclosure for smaller incidents and near misses is not documented, which impacts on the potential for organisational knowledge and learning from incidents as a basis for enhancing quality and patient safety at all levels.
Awareness raising and training

- Awareness raising and training sessions were instrumental in embedding open disclosure in each hospital, and constituted the most important and successful activities of the pilot in both hospitals in giving staff reassurance and preparation for open disclosure.

- The awareness raising and training were evaluated by participants as being of a high quality and played a significant role in the practical implementation of open disclosure. The training successfully used role-plays and interactive activities, helped participants gain knowledge, confidence and skills on how to apply open disclosure, respond to patients/families in a timely way, and develop new communications skills.

- Post-pilot there have been positive outcomes in integrating open disclosure into training provided in other relevant areas of hospital activity, for example, in induction training for new staff, staff briefings and training on complaints management, and training on risk analysis and incident reporting.

- Key learning from the training shows the importance of engaging clinicians and ensuring that training is provided in flexible and creative ways. Having a multidisciplinary approach to training is regarded as important as errors frequently arise that are the result of multiple issues.

Monitoring and auditing open disclosure

- Despite improved systems for implementing open disclosure in the two pilot sites, monitoring and auditing is not carried out in a systematic way. Having robust systems for reporting and feedback is important for institutional memory and documentation of events that could prevent future errors occurring.

- One of the issues highlighted by senior managers involved in the pilots is the need to have a reporting structure for open disclosure, including reporting on open disclosure at ward level on an ongoing basis.

Patient perspectives

- The evaluation did not include an analysis of patient/family perspectives on the implementation of open disclosure in the pilot sites. This represents a gap in the evaluation evidence and points to the need for further in-depth evaluation to take place on patient perceptions and experiences of open disclosure.

- Ensuring that a greater emphasis is given to patient/family feedback in pointing to what worked will be very beneficial in meeting expectations around the disclosure of adverse events.

- Post-pilot, patient perspectives have been more systematically integrated into the national roll-out of open disclosure through the patient representative group, Patients for Patient Safety Ireland and in involving patient representatives in a range of initiatives, including the launch of the open disclosure policy and guidelines and in the development of ongoing work to develop case scenarios for open disclosure training.

3. Impact of the pilot on culture change and patient safety

The open disclosure pilot is perceived by participants in the evaluation to have had a positive impact on culture (openness, transparency, learning), and a positive impact on patient safety (responding in a timely way, preventing and learning from errors). There is evidence of the pilot impacting on culture change at all levels of the organisation, including informing team meetings and disclosure in relation to lower level errors. Over half of respondents to the on-line survey and the majority of interviewees stated that the open disclosure pilot had led to positive culture change in their organisation, reinforcing a culture of open communications and transparency, which in turn had a positive impact on staff morale.
Similar positive feedback was given about the impact of the pilot on patient safety, which is believed to have reduced the number of claims. Nearly one-half of the respondents to the on-line survey stated that open disclosure had either fully or partially impacted on patient safety. This is despite the perceived enhanced risk environment resulting from greater pressures on staff and reduced staffing levels.

However, open disclosure is a long-term process and the evaluation found that there is still a great deal that needs to be done to fully implement open disclosure in the pilot sites. Culture change, resulting in openness and transparency, is identified as one of the most important areas for change, which can be impacted upon in multiple ways (leadership, training, staff support, learning).

4. National policy developments during and post-pilot

The learning from the pilots, international best practice and the drafting of the two hospital policies was used as the basis for drafting the national policy and guidance, which was launched by the Minister for Health on 12th November 2013. Three further supporting documents were also launched, including a staff support booklet, patient information leaflet and staff briefing guide. The policy and guidance is robust and detailed and is rooted in international best practice on open disclosure. The high profile consultation process and launch of the national open disclosure policy and guidance generated significant national interest in open disclosure.

Post-pilot, national policy developments and activities carried out by the national open disclosure team have further progressed the roll-out of open disclosure. Post-pilot the HSE/SCE national leads commenced a ‘train-the-trainer’ programme on open disclosure and are working with the Royal College of Surgeons Ireland (RCSI) on an e-learning programme. This has led to the development of high quality case scenarios and a training programme within RCSI for doctors.

Healthcare reorganisation has provided the potential for improved integration of open disclosure across all health and social care organisations (within the Clinical Directorate structure for hospitals, and the formation of hospitals groups and community healthcare organisations). Policy developments include integrating open disclosure into HSE policies on quality and safety and incident reporting, the inclusion of open disclosure in HIQA National Standards for Safer Better Healthcare 2012 and a focus given to open disclosure in the 2015 HSE Service Plan and under the provisions of the National Patients’ Charter, ‘You and Your Health Service’ 2010.

The reports and inquiries into system failures and lapses in healthcare quality in the Midland Regional Hospital, Portlaoise, and Galway University Hospital are also major drivers for change in culture, transparency and openness.

Overall, national managers and policy makers interviewed in the evaluation agree that, along with the open disclosure policy and guidelines, there is a robust and integrated policy framework in place. This has created a more accountable system, where clinical leadership and governance can more effectively implement, monitor and report on open disclosure. The key challenge is the effective implementation across all health and social care organisations.

5. Challenges and barriers to implementing open disclosure

The findings from the evaluation mirror international research showing that the main barriers to implementing open disclosure include concerns over increased litigation costs, fear of damaging or losing the relationship with the patient, fear of a loss of reputation or career progression, lack of institutional support, lack of training on how to practice open disclosure, and the emotional impact on clinicians of adverse events. The evaluation found that:

- Reduced staffing levels and resources, resulting in a lack of time to implement open disclosure, carry out investigations and release staff for training, was seen to impact on an increased risk environment and the potential for errors to occur.
A consistent issue raised by clinicians and the SCA during the evaluation was the need for legal protection on open disclosure, pointing to the need for greater attention to be given to the moral-ethical responsibilities of clinical roles and professional responsibilities in communicating with patients when errors occur.

Other challenges include the need for improved lines of accountability and support when an incident occurs, and guidance on how to give a formal response and under what circumstances.

An increasingly hostile environment, resulting from adverse media reporting, also had an impact on staff morale.

Despite the protections that can be afforded from legislation, many participants in the evaluation were clear that open disclosure can be implemented very effectively without legislation, given the existing policy framework in place for open disclosure, particularly within the HIQA Standards for Better Safer Healthcare 2012 and ongoing HSE policy developments on risk management and incident reporting.

6. Critical success factors

The evaluation identified the following critical success factors for open disclosure:

- A supportive hospital environment and organisational culture that impacts on all levels and areas of hospital activity, implemented through strong leadership from the hospital CEO, Board of Management and from buy-in from Clinical Directors and clinicians.
- Having a pilot lead in each hospital responsible for implementation, policy development, organising awareness raising and training, and championing open disclosure.
- External resources and expertise from the HSE/SCA to progress organisational policy, guidance and procedures on open disclosure.
- Sufficient resources within the hospital, including a risk management department in each hospital with expertise to support and engage clinical and non-clinical staff, in providing a supportive culture on open disclosure.
- Good quality training, led by trainers who are experienced clinicians and have an in-depth knowledge of open disclosure, including targeted training in clinical specialties, induction training and ongoing training to keep staff up-dated and motivated.
- A supportive culture for disclosure that promotes staff confidence and capacity to implement open disclosure across the whole organisation.
- Multidisciplinary approaches to reporting and learning from incidents, fostering team and peer support and peer learning.
- Clear guidance about how and when to carry out open disclosure, including how to report on and how to utilise the learning from incidents to prevent future errors.
- Open disclosure embedded as an integral part of relevant hospital policies on quality and patient safety.

7. Key recommendations

The key recommendations detailed below have the objective to build on the learning from the open disclosure pilot to progress a fair and just culture, and implement open disclosure across all health and social care organisations. The recommendations provide a framework for implementing open disclosure through continuous system-wide, organisational and team learning, reporting and quality improvement in order to achieve a change of culture, accountability, transparency and clinical ownership for open disclosure. The key recommendations are elaborated in more detail in the final section of the report.
Leadership of the HSE and of health and social care organisations: Implement a national resource framework and HSE leadership to progress and implement open disclosure and a fair and just culture across all health and social care organisations.

HSE / SCA pilot leads: Continue the successful partnership between the HSE and SCA and enable the pilot leads to take a strategic role in the roll-out of open disclosure, including the implementation of the national ‘train-the-trainer’ programme and e-learning module, and development of case studies, examples and guidance for health and social care professionals.

Pilot sites (MMUH and CUH): The two pilot sites are encouraged to continue to embed open disclosure through further training, identification of open disclosure champions in all Directorates, dissemination of learning from the pilot, and further implementation of staff support.

The roll-out of open disclosure (all health and social care organisations): The implementation of open disclosure in all health and social care organisations (hospital groups, hospitals, community healthcare organisations) should be fully completed within five years. During this time open disclosure should be fully integrated into all relevant health policies and clinical and corporate policies and procedures on quality and patient safety.

The building blocks for open disclosure (all health and social care organisations): Ensure that all health and social care organisations (hospital groups, hospitals, community healthcare organisations) put in place the essential building blocks for open disclosure, including measuring the culture of the organisation in relation risk, appointing key personnel and open disclosure champions, providing practical guidance for staff, and ensuring that open disclosure is a standard element of incident reporting and monitoring.

A supportive environment for staff to disclose and be supported throughout the process (all health and social care organisations): Provide an effective and inclusive system of support for staff, including clear responsibilities for line managers and teams, and team and peer support.

Training and awareness raising (all health and social care organisations): Provide awareness raising sessions for all health and social care staff, and implement more detailed accredited training for healthcare professionals and managers involved in open disclosure.

Organisational learning and feedback loops (all health and social care organisations): Implement an effective system for organisational and team learning, and staff feedback, following an adverse event.

Enhance the voice and involvement of patients and their families (HSE and all health and social care organisations): Provide an effective system for patient/family involvement, support and feedback, and ensure that patients’ perspectives are at the forefront of all open disclosure developments, including awareness raising and training.

Guidance materials (for all health and social care organisations): Produce and disseminate short and accessible guidance materials about open disclosure and information about support provided to staff.

Data, information management and further research on open disclosure (HSE/SCA and all health and social care organisations): Ensure that data and information is collected on open disclosure in a standardised way, carry out regular reviews and audits of the implementation of open disclosure and implement further research to identify the impact of open disclosure in incident management, in reducing claims and on patients’ perspectives of open disclosure.

Education providers and health and social care professional and regulatory bodies: Open disclosure should be fully and effectively integrated into training, guidance and policies implemented by health and social care education providers and health and social care regulatory and professional bodies.
Section 1:

Introduction

“To err is human, to cover up is unforgivable but to fail to learn is inexcusable.”

(Sir Liam Donaldson, Chief Medical Officer for the Department of Health in the UK, 2000)
1.1 Overview

The Health Service Executive (HSE), in partnership with the State Claims Agency (SCA), piloted an open disclosure programme for two years in two acute hospitals, Cork University Hospital (CUH) and the Mater Misericordiae University Hospital, Dublin (MMUH). The open disclosure pilot programme took place between November 2010 and November 2012 and the evaluation was carried out during 2014.

The open disclosure pilot programme had the objective:

To develop a standardised open disclosure framework across health services that will progress, foster and practically support a culture of openness in an informed, sensitive, inclusive and safe environment.

The open disclosure pilot programme led to the development of policies and processes to support and manage these challenges in communications. The learning from the pilot has informed national policy on open disclosure and the roll-out of open disclosure across all healthcare settings. The evaluation gives a particular focus to the work carried out in developing a supportive culture for open disclosure to patients and families where there has been an adverse event resulting in harm to a patient. The evaluation also takes account of and benchmarks the learning from the pilots in the light of international evidence and learning, for example, by drawing on the framework, principles and guidance established by the Australian Commission on Safety and Quality in Healthcare.

1.2 Evaluation objectives

The evaluation had three specific objectives:

• First, to evaluate the implementation of the open disclosure framework in the two pilot sites.
• Second, to evaluate the role of the framework and policy in relation to national policy developments and the potential for roll-out across all healthcare settings.
• Third, to benchmark the learning from the pilots and the implementation of the policy against international evidence based practices and the agreed principles on open disclosure.

The evaluation covered the management and governance, awareness raising and training, implementation of open disclosure and the outcomes from the pilots. It gave a specific focus to the effectiveness and appropriateness of the project activities and whether key objectives and principles on open disclosure have been achieved in practice. In particular, the evaluation sought to identify critical success factors and areas for development and to highlight barriers and challenges and how they can be managed. The impact of the open disclosure pilots in leading to a change in culture and communications, patient safety and the challenges /opportunities this provided for staff, were also evaluated. The evaluation drew on evidence to reflect the views and experiences of CEOs/senior managers, healthcare professionals, managers, and front line staff in implementing open disclosure.

Since the pilot there have been significant policy developments, including the publication of the national policy and guidelines on open disclosure, and integration of open disclosure into HSE policy on quality and safety and incident reporting. Open disclosure is also being driven in a systematic way by HIQA standards (discussed in more detail in Section 5). In addition to taking account of these recent policy developments, the evaluation sought to assess how open disclosure had been implemented post-pilot, both within the two pilot hospitals and in the development of national policy and practice developments led by the two national open disclosure pilot leads.
1.3 Evaluation methodology

The methodology used for the evaluation included face-to-face interviews with managers and healthcare professionals in the two pilot sites and with managers in the HSE and SCA; focus groups with staff in CUH; and an on-line survey distributed to staff in the two pilot hospitals.

Interviews in the pilot sites

Face-to-face interviews were held with managers and healthcare professionals involved in open disclosure in the two pilot sites. A total of thirteen interviews were carried out in CUH and eight interviews in MMUH. Interviews included the CEOs and members of the management team in each hospital, Clinical Governance Manager/Risk Managers involved in leading the pilot internally in each hospital, as well as Clinical Directors, Directors of Nursing and Midwifery, consultants, nurse managers, departmental heads and patient liaison officers. Interviewees were sent an evaluation briefing and consent forms were completed prior to the interviews. The interviews had an in-depth semi-structured format that lasted for between 1 hour and 1 hour and 30 minutes. Interviewees were very engaged with the issue and participated enthusiastically. All interviews (and focus groups) were digitally recorded and transcribed. Transcripts were coded, codes were verified, refined and followed by analysis of the data.

At national level interviews were held with the two Open Disclosure Project leads (HSE Quality Improvement Division and the State Claims Agency. In the HSE interviews were held with the National Director, Quality Improvement Division, the Director of the National Advocacy Unit (Quality Improvement Division), National Lead Service User Involvement (Quality Improvement Division), the National Incident Management Team (Quality Improvement Division), and the National Lead for Clinical Governance Development. In the State Claims Agency, interviews were held with the Director and the Head of Clinical Indemnity Scheme and the Clinical Risk Advisor with responsibility for Open Disclosure (Clinical Indemnity Scheme). In addition interviews were held with a representative from the Royal College of Surgeons Ireland and a patient safety advocate.

Focus groups

Three focus groups were held with staff at CUH. Focus groups were planned at MMUH but these did not take place because of other work commitment and the hospital’s preparation to be an Ebola centre at that time. Focus group participants were principally senior nursing and allied health professionals. Focus group participants had participated in the open disclosure training held in 2012. The focus groups sought to find out how useful the training had been and whether the pilot had provided participants with sufficient knowledge and confidence to practice open disclosure. In addition, questions were asked about the management of open disclosure and how it has been integrated into working practices post-pilot. These issues were important because the pilot in CUH had largely focused on the development of a process for adverse events, and it was interesting to identify other impacts that may have filtered through the organisation.

On-line survey

An on-line survey was distributed to staff working in CUH and MMUH by email invitation from the Clinical Governance Manager (CUH) and Risk Manager (MMUH). There were a total of 339 responses to the on-line survey, of which 211 were from CUH and 128 were from MMUH. A small number of respondents, eight from CUH and ten from MMUH, had been involved in open disclosure meetings during the pilot or post-pilot. The largest occupational groups responding to the survey were nursing and midwifery staff (36%) followed by administrative staff (19%), consultants and physicians (17%) and allied health professionals (11%). The occupational breakdown of respondents can be found in Figure 1. Around two-thirds of respondents were female and one-third male.
Figure 1: Breakdown of occupations of respondents to the survey

**Ethical code of conduct**

In assuring integrity, confidentiality and anonymity an ethical code of conduct for the evaluation was drawn up and agreed with the HSE, the SCA and the leads of the pilot projects. The evaluation adopted ethical research principles to ensure that there are no conflicts of interest and to ensure confidentiality. The evaluation was guided by the principles of ethical research drawn up by the ESRC\(^2\) which cover integrity and quality of the evaluation; participants being fully informed of what the evaluation will entail; confidentiality of information and anonymity of respondents; voluntary participation and written consent to participate; research independence and no conflict of interests.

It is difficult to measure the extent to which the healthcare professionals who participated in interviews, focus groups and who responded to the on-line survey did so because they were already carrying out open disclosure and believed that it promoted better quality and patient safety. However, previous studies have shown that this is often the case, where volunteers are a self-selected group of open disclosure advocates. (Iedema et al. 2008a)

The interview guide for pilot sites and for national managers, focus group questions, and evaluation briefing are included in Appendix 1.

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\(^2\) ESRC (Economic and Social Research Council) Framework of Research Ethics, 2010, updated, September 2012
Section 2:

Background to the open disclosure pilot programme
2.1 Open disclosure: international evidence


As the USA National Patient Safety Foundation’s Lucian Leape Institute argues:

…the impact of transparency—the free, uninhibited flow of information that is open to the scrutiny of others—has been far more positive than many had anticipated, and the harms of transparency have been far fewer than many had feared. (2015, vi)

The demands and complexities of modern medicine pose potential risks resulting in patient harm. As the surgeon Atul Gawande states medicine is not an exact science, but is based on “…constantly changing knowledge, uncertain information, fallible individuals, and at the same time lives on the line”. (2002: 4) However, international research suggests that many adverse events resulting in patient harm are preventable. The findings of the landmark US Institute of Medicine’s (2000) report ‘To Err is Human’ estimated that between 44,000 and 98,000 Americans die each year from preventable causes. Evidence cited by Sheard et al. (2014) shows that errors occur in 0.4 – 16% of hospital admissions, with studies showing that as many as one in 10 patients were harmed while receiving hospital care, and that 63% of harm was preventable and avoidable. The World Health Organisation (WHO) suggests that industries that have a perceived higher risk, such as aviation and nuclear industries, have a significantly better safety record than healthcare. In aviation there is a 1 in 1000 chance of a traveller being harmed when in an aircraft, compared to a 1 in 300 chance of a patient being harmed during healthcare. (WHO, undated) As a result education and training has a crucial role to play in preventing harm through greater openness and transparency. (Keller 2009)

Despite this, international evidence shows that a relatively small proportion of adverse events are disclosed to patients, and that an even smaller proportion of cases of disclosure meet the needs and expectations of patients/family members. (Iezzoni et al 2012, Iedema 2011) International evidence reviewed by the Australian Commission on Safety and Quality in Health Care (ACSQHC 2012) and by Sheard et al. (2014), amongst others, shows that communication is a major factor in promoting openness and transparency, including a willingness to learn from errors. In this context a healthcare system that is open and transparent and that regards patients and their families/carers as key partners in healthcare will enable critical care information to be shared, with benefits for clinical decision-making, clinical outcomes and the prevention of patient harm. According to the United Kingdom’s National Patient Safety Agency, “being open when things go wrong is clearly fundamental to the partnership between patients and those who provide their care”. (2009: 6)

In Ireland, as well as internationally, a greater emphasis is now given to preventing patient harm, particularly where this results from avoidable errors. This has been implemented through improved systems for quality and safety, risk management and incident reporting. In addition, in Ireland, inquiries into system failures and lapses in healthcare quality, most recently Inquiries in the Midland Regional Hospital, Portlaoise, and Galway University Hospital have been important drivers for the prevention of patient harm and the implementation of open disclosure.

- The report of the Chief Medical Officer (Holohan 2014) to the Minister of Health found a series of failures in the duty of care and breach of trust, including a failure to disclose adverse events to patients and to disclose that reports had been completed on adverse events. This was seen to compromise the delivery of good quality patient-centred care. The report highlighted the obligation for disclosure with regards to harm, potential harm or suspected harm as a result of an adverse event to a patient and/or family and in respect of a review of a person’s record/care. The report specifies the importance of carrying out look backs, desk-top reviews, clinical audit and multidisciplinary team reviews as part of the delivery of quality and patient-centred care.
However, the report pointed to confusion regarding the practice of disclosure to patients and called for better consistency and understanding, as well as assurance and confidence to healthcare professionals about their obligations to disclose. The report recommends the full implementation of the national open disclosure policy.

- HIQA’s (2013) report into the tragic death of Savita Halappanavar in Galway University Hospital found a series of system errors that resulted in her death. In the light of the investigation and recommendations, HIQA provided specific advice to health and social care organisations about the need to promote an open and just culture that requires full disclosure of mistakes, errors, near misses and patient safety concerns, in order that system-based analysis can take place to identify learning. HIQA argued that this needs to be balanced against the importance of holding to account those whose competencies and performance have fallen below what is reasonably expected of them. HIQA also recommended that in line with the Future Health – A Strategic Framework for Reform of the Health Service (Department of Health 2012) a formal communication and sharing of learning and information on safety incidents should be carried out between healthcare services and the Clinical Indemnity Scheme to “…enable the effective prioritisation and development of tailored quality and safety programmes across services nationally. This learning should actively inform the respective Clinical Care Programmes and relevant guidelines and guidance. (p.31)

Similarly, across the world there has been an increased emphasis given to implementing organisational responses to open disclosure; both as a core component of patient-centred care and as a strategic response to rising legal costs. In particular, there has been a great deal of learning from Australia since the implementation of the Australian Open Disclosure Standard where substantial research and evaluation of open disclosure has been carried out by the Australian Commission on Safety and Quality in Health Care, including evaluation of the National Open Disclosure Standard Pilot, investigation of patients and healthcare professional disclosure experiences, and opinions on legal aspects of open disclosure in Australia. The most recent evaluation of the Standard suggests that disclosure is more effective as an ethical practice that prioritises organisational and individual learning from error than solely as an organisational risk management strategy, and that open disclosure has been found to create significant benefits for the health system and patients by fostering cultures of openness and trust. (Australian Commission on Safety and Quality in Health Care 2012)

2.2 The open disclosure pilot programme

2.2.1 Background

The report of the Commission on Patient Safety and Quality Assurance (DOHC 2008) recommended the development of a culture of open disclosure of adverse events. As the Chairperson of the Commission, Dr. Deirdre Madden, states:

> When such adverse events occur there must be a system in place that ensures that all those affected are informed and cared for, and that there is analysis and learning from the error to try to prevent the recurrence of such an event.

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3 This includes the Open Disclosure Standard in Australia in (2003); the UK’s ‘Being Open - Communicating Patient Safety Incidents with Patients, their Families and Carers’ (2005, revised in 2009) and the Canadian Disclosure Guidelines (2008). In New Zealand open disclosure is a patient right as part of the Health and Disability Service Standards. Specific open disclosure policies from the USA include the Harvard hospitals consensus statement on open disclosure ‘When things go wrong: Responding to adverse events’ (2006) and the University of Michigan Hospital disclosure programme (2001).
The Commission made system-wide recommendations to resolve systemic problems related to incident investigations and reports into adverse events. These problems were related to weak governance structures, lack of clinical audit, lack of senior clinical leadership, lack of structured incident reporting processes, inconsistent analysis of adverse events, lack of clarity of reporting relationships, and poor working relations between clinicians and management. The report sets out a Patient Safety Framework based on “Knowledgeable patients receiving safe and effective care from skilled professionals in appropriate environments with assessed outcomes.” (DOHC 2008:3)

The decision to carry out a pilot programme on open disclosure arose because it was evident that there was limited engagement with patients and family members in relation to adverse events and subsequent claims. This was an area that the SCA believed needed to be further developed in Ireland, particularly as international best practice showed that open disclosure not only resulted in fewer claims, but also enhanced the experience of patients/family members following an adverse event. The SCA approached the HSE to carry out a joint initiative, which fitted with HSE plans and objectives on quality and patient safety.

The HSE/SCA project team invited expressions of interest to participate in the pilot project. The choice of the two pilot sites – Cork University Hospital (CUH) and the Mater Misericordiae University Hospital, Dublin (MMUH) - reflected the need to have two large acute hospitals in different parts of the country. Both pilot sites expressed an interest in participating in the pilot as they had previously had adverse events that they hoped to learn from and had begun to implement open disclosure within their organisations. Although it was important to have the right people in place for the pilot, the two national project leads were clear from the outset on the need for additional champions with expertise in open disclosure to progress the roll-out of open disclosure in all health care settings. This would free up the project leads to take a more strategic role in the implementation of open disclosure nationally and to embed learning amongst university education and training providers.

In MMUH a serious incident in 2006 had taught the hospital a lot about the importance of open disclosure. The case was investigated and staff involved in the case at the time spoke about the honesty, information sharing and communication with the family. Feedback from family members showed an acknowledgment of this approach and the importance of learning from mistakes so that they can be prevented in the future. In CUH open disclosure became an important part of risk and clinical governance after CUH was cited in a HIQA investigation in 2008 that identified a failure of communication surrounding an error made in the interpretation of a patient’s breast cytology in the pathology laboratory at CUH. Senior managers drew on early guidance from the national open disclosure leads in this and other cases of delayed diagnosis. The Clinical Governance Manager at CUH found this early guidance especially useful, including guidance from University of Michigan Hospital (2002), which was found to be concise and helpful as part of her own journey.

The project leads from the HSE and SCA were informed by an evidenced-based approach to open disclosure. One of the project leads reviewed international literature and evidence on open disclosure in a thesis for an MSc in Health Care (Duffy 2013), and information on international best practices was collected and updated on a regular basis. The pilot was also informed by the findings and recommendations of the Commission on Patient Safety and Quality Assurance (DOHC 2008), and particularly by the standards and practices introduced by the Australia Commission for Safety and Quality and Healthcare (2003), Canadian Patient Safety Institute (2008), as well as by international research on open disclosure. (For example, Vincent 2001 & 2003, Gawande 2003, Wu 2000, Wu et al. 2009)

The Australian definition of open disclosure was used as a basis for defining open disclosure in Ireland:

An open, consistent approach to communicating with patients when things go wrong in healthcare. This includes expressing regret for what has happened, keeping the patient informed, providing feedback on investigations and the steps taken to prevent a recurrence of the adverse event. (Australian Commission on Safety and Quality in Health Care, 2003)
2.2.2 Collaboration and partnership between the SCA and HSE

*It is nothing more than putting patients back in the centre of care.* (Director, SCA)

The evaluation found significant strengths from the positive collaboration between the SCA and the HSE at a strategic level, and specifically between the two national open disclosure leads from the SCA and the HSE. Both organisations brought different expertise, knowledge and perspectives to the pilot. The SCA has a role to advise and assist State agencies on matters of clinical and non-clinical risk, and uses an evidence-based approach to risk and claims management. Under the Clinical Indemnity Scheme, the SCA manages clinical negligence claims taken against health and social care organisations.

All senior managers interviewed in the evaluation from the HSE and the SCA spoke about the immense value of the partnership, and as the Director of the SCA stated, “...it was a seminal idea and it was the one partnership we wanted from the start.” He highlighted the importance of two state organisations with different goals “coming together with a shared goal”. The SCA were clear that it would have been impossible for them to do this work without the partnership with the HSE.

Core to partnership were the complementary skills, experience and commitment of the two project leads from the HSE and the SCA, who created an excellent dynamic, working relationship, shared learning, expertise and a passion for open disclosure. Many of the managers interviewed in the evaluation gave consistent positive feedback about the collaboration. As one manager said, “it worked really well and there was a lot of mutual respect”. The two national pilot leads were equally positive about their working relationship and shared expertise. As the SCA lead stated:

> There has been a very good partnership between the two organisations, and a joint project from the start…as the State’s indemnity body it has been good to collaborate with the HSE… It is important that if the right people are involved who care about the issue then it is likely to be successful...you need to have the right mentality and mindset”.

Similarly, the HSE lead stated:

> This would not have worked if we hadn’t worked well together – it was very balancing and we kept each other on our toes…we had complementary skills and approaches and we delivered well together; people commented on the good relationship between us. It is an excellent example of collaboration and partnership working.

Post-pilot the two national leads took on a major role in rolling-out open disclosure, undertaking training and workshops across the length and breadth of the country. It is clear that the resource of two national leads is insufficient to sustain this role.

2.2.3 The value of an external resource: national open disclosure leads

There is overwhelming evidence from the evaluation that the pilot could not have been implemented without the expertise and resource of the national pilot leads from the HSE and SCA. There was significant value to having external human resources and a relatively small budget for printing and other costs. The Clinical Governance Manager (CUH) and Risk Manager (MMUH) spoke of the importance of external resources and support, in providing expertise for the awareness raising and training, and support in writing and agreeing the policy for each hospital.

The value of the external resource enabled the two hospitals to carry out work that would have been difficult to do internally. As one CEO stated, “It had to be, we wouldn’t have been able to do it alone, it was really important to have the dedicated support”. The leads from the pilot sites stated that the open disclosure pilot programme gave them access to external resources and expertise that did not exist in-house. As a result, the support from the national open disclosure team was seen to be vital:

> We wouldn't have done it at such an early stage ourselves…now there are several national policies and guidance that have been implemented, that would make it easier now. We were at the very early stages of development of open disclosure. (Clinical Governance Manager)
In relation to the training, having clinicians with expertise and knowledge of open disclosure, was critical to engaging healthcare professionals. The national HSE open disclosure lead stressed the importance of this.

According to the national lead for the HSE:

*Training is absolutely critical...[open disclosure] is a challenging topic that can cause difficulties, complex questions come up, and some participants are critical that it is too early and that we should wait for legislation. Local level staff were clear that they did not think that they could do this without support.*

This was reiterated by the pilot leads in CUH and MMUH, who stated that they had insufficient time, resources and expertise to provide training on open disclosure. However, by the time the pilot had ended they had gained sufficient expertise themselves that would enable them to lead out on open disclosure training in their respective hospitals.

As the lead from the SCA noted there has been a lot of learning about the approach taken in the pilot programme and particularly in pitching it at the right level:

*It has taught me and has shown me so much about the importance of implementation and structures, about practicalities and personalities, it wouldn't work if we were to go in heavy handed...it is important to be believable, respected and liked.*

Aside from the two national pilot leads, expertise was given from other national personnel relating to (i) the Patients’ Charter ‘You and Your Health Service’ and patient involvement, (ii) Quality and Safety, as well as (iii) experts from the SCA, and (iv) Dr Deirdre Madden, Cork University Hospital, Chairperson of the Commission on Patient Safety & Quality Assurance.
Section 3:

Implementation of the open disclosure pilot
3.1 Introduction
This section documents the evaluation findings regarding the implementation of the main activities of the pilot in CUH and MMUH, during and post-pilot.

The outcomes and impact of the pilot on a culture of openness and on patient safety, as well as barriers encountered, are discussed in more detail in Section 4.

Key achievements and outcomes from the pilots: summary

Key achievements and outcomes from the pilots overall:
• Deployment of dedicated resources at local and national level for the implementation of open disclosure.
• A collaborative approach between the HSE and SCA, and between national leads and pilot leads in the two pilot hospitals.
• Creation of a supportive framework around the process, with learning captured for pilot sites and national policy.

Key achievements and outcomes of the pilot in CUH:
• A systematic process and policy for implementing open disclosure in adverse events, resulting in more timely responses to open disclosure meetings with family members.
• Effective integration of open disclosure at a senior management level and across the whole hospital, with an effective ‘trickle down’ effect on culture, confidence and capacity of staff to implement open disclosure.

Key achievements from the pilot in MMUH:
• Open disclosure meetings are carried out routinely and systematically as part of the management of serious complaints and in all adverse events, and implemented through more timely responses and reporting.
• MMUH has had a pro-active approach, resulting in open disclosure being integrated across all levels of the organisation through the complaints system. Patient Liaison Officers integrate open disclosure into all of their work, including training on complaints.
• Leadership has helped to change culture and to enable open disclosure to be implemented and embedded in the hospital, with an impact on staff confidence and capacities to implement open disclosure.

3.2 Project activities in CUH and MMUH

3.2.1 Overview of project activities
Table 1 sets out the main project activities in the two pilot sites. Similar activities were carried out in both pilot sites, although the specific emphasis given to open disclosure varied across the two hospitals.
# Table 1: Pilot project activities in CUH and MMUH

<table>
<thead>
<tr>
<th>Project activity</th>
<th>CUH</th>
<th>MMUH</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Project management and pilot lead roles</td>
<td>Clinical Governance Manager appointed as pilot lead (November 2011)</td>
<td>Risk Manager appointed as MMUH pilot lead (November 2011)</td>
</tr>
<tr>
<td>2. Project implementation plans (November 2010)</td>
<td>Open disclosure Committee established for the pilot, led by the pilot lead Draft plan drawn up by national pilot leads and discussed with CUH pilot lead Plan presented to CUH Group EMB and endorsed, following amendments (March 2011)</td>
<td>Open Disclosure Committee established for the pilot, chaired by the CEO Draft plan drawn up by national pilot leads and discussed with MMUH pilot lead Plan presented to Hospital Board and endorsed by Board and CEO (January 2011)</td>
</tr>
<tr>
<td>3. Pilot activities and focus agreed (2011)</td>
<td>Specific focus agreed for developing and implementing an open disclosure process for adverse events</td>
<td>Specific focus agreed to integrate open disclosure into complaints management and handling of adverse events, with the aim to embed open disclosure across the whole hospital</td>
</tr>
<tr>
<td>4. Patient Safety Culture Survey (July 2011)</td>
<td>Survey carried out using the Manchester Patient Safety Framework (led by the CUH Clinical Governance Team)</td>
<td>Survey carried out using the Manchester Patient Safety Framework (completed by 353 staff)</td>
</tr>
<tr>
<td>5. Awareness raising and training to support staff engagement (March-September 2011)</td>
<td>Awareness raising sessions held through face-to-face engagement with staff at ward and unit level, regular walkabouts to wards and departments and grand rounds with clinicians. CUH Clinical Governance Team coordinated introductory information/feedback sessions with staff 3 days of back-to-back awareness sessions held for staff (each lasting 30 minutes, attended by approximately 210 staff)</td>
<td>Awareness raising sessions held with hospital board, senior management committee, medical executive, nursing executive and council, NCHD clinical teaching sessions (x2), grand rounds, Journal Clubs (x7), theatre nursing staff, and included in staff induction 7 days of back-to-back awareness raising sessions for staff (each lasting 30 minutes) held in the hospital auditorium. Attended by 513 staff</td>
</tr>
<tr>
<td>6. Accredited training (2011)</td>
<td>6 accredited training sessions (3.5 hours) targeted to all healthcare professional groups and non-clinicians, and further developed across the CUH Group</td>
<td>14 accredited training sessions (3.5 hours), with CPD points for healthcare professionals, targeting consultants, nursing staff, PAM and senior management; 190 staff members trained</td>
</tr>
<tr>
<td>7. Policy framework (2012-13)</td>
<td>CUH group policy &amp; guidance document on open disclosure Drafting and agreeing a CUH hospital open disclosure policy CUH hospital group patient information leaflet</td>
<td>MMUH open disclosure policy drawn up (launched February 2013)</td>
</tr>
<tr>
<td>8. National open disclosure policy framework and guidance (2013)</td>
<td>Feedback and engagement in the drafting of the national policy and guidance on open disclosure</td>
<td>MMUH patient information leaflet Feedback and engagement in the drafting of the national policy and guidance on open disclosure</td>
</tr>
</tbody>
</table>
3.2.2 Pilot leads in each hospital

Having pilot leads in each hospital (Clinical Governance Manager, CUH and Risk Manager, MMUH) to lead on open disclosure during the pilot and post-pilot was essential to driving the implementation of open disclosure. Both were widely regarded by colleagues as having done a huge amount to build awareness and promote open disclosure during the pilot. This points to the need in the longer-term for health and social care organisations to appoint open disclosure officers/champions who play a key role in coaching and supporting clinicians in open disclosure, and instilling a culture of staff support.

The pilot leads were instrumental in laying the groundwork for management and staff engagement and encouraging participation in the awareness raising and training sessions. However, several respondents spoke about the pressure of work faced by pilot leads and Risk Managers. While doing excellent work, they needed a larger team to provide the ongoing support and engagement on open disclosure that is required for full and effective implementation in the longer-term. In both hospitals, being able to approach the Risk Management departments for help and support has been important. This has helped to promote a climate of openness, a fair and just culture, and an increase in the numbers of staff reporting errors. Several consultants spoke about the value of having a central office responsible for risk management, which provided an open door and a supportive culture for staff in implementing open disclosure.

3.2.3 Patient Safety Culture Survey

In March 2011 a pre-culture survey was carried out using the Manchester Patient Safety Framework (MaPSaF) in CUH and MMUH. The MaPSaF is a tool used by the UK NHS to help organisations and healthcare teams assess their progress in developing a safety culture, including open disclosure. The survey tool is a team-based self-reflection exercise, which aims to establish how quality and safety is perceived by staff. Due to time limitations it was decided to run the survey as an on-line tool at both pilot sites. Feedback on the survey was that it was too long, contained errors and needed to be re-designed if it was to become a useful tool for generating accurate results. Despite this, survey findings demonstrated a clear commitment to patient safety within both hospitals. The survey findings showed that the majority of respondents in both hospitals considered their respective team and organisation to be either a level C (bureaucratic) or a level D (proactive) or between these two levels of the MAPSAF tool. The survey provided a baseline against which future progress on open disclosure can be measured.

3.2.4 Project implementation plans

A project implementation plan proposal was drawn up by the national open disclosure leads, which aimed to provide a structured approach to implementation in line with international best practice. The proposal set out the responsibilities of the pilot sites in implementing open disclosure across the themes of: preparation, leadership, local policy, visibility, support for staff and patients, training, audit and evaluation. Consultations were held with both pilot sites and the project proposal was signed off by the CEO, Clinical Director and Director of Nursing at both sites.

Both pilot sites agreed to take a similar approach, embedded in a phased implementation plan. The phased approach was stressed as being important because open disclosure was new for many staff and is a process that requires a long-term and phased approach to culture and system change. The national project team was keen to ensure that this phased approach was evidence-based and informed by the learning from other countries. In CUH significant internal restructuring led to some of the plans being delayed, although a clear implementation plan was drawn up at an early stage, setting out the key people responsible and timelines.

The two pilot sites took different approaches in the implementation plans drawn up, although both carried out awareness raising and training, and the development of a hospital policy. In CUH, following discussion between the CUH lead and the national open disclosure leads, a decision was made to focus specifically on developing and implementing open disclosure in the context of serious adverse
Evaluation of the National Open Disclosure Pilot

events. MMUH took a broader approach, with the aim to integrate open disclosure at all levels of the organisation, in adverse events and in complaints management. Both pilot sites chose activities that were realistic for them to achieve, particularly because the pilots took place at a time of significant organisational change. During the process of implementation regular contact was maintained between the two pilot sites and the national pilot leads.

3.3 Leadership, governance and management of open disclosure in the pilot sites

International evidence shows that a leadership culture that promotes the values and behaviours required to fully implement open disclosure (in the context of high quality care, compassion, openness, engagement of staff and a commitment to learning), will result in higher levels of quality and patient safety. (National Patient Safety Agency 2009, National Patient Safety Foundation, Lucian Leape Institute 2015, O’Connor et al. 2007, Piper and Iedema 2011, Studdert et al 2007, Sorensen et al. 2008, Conway et al. 2011)

From the outset the pilot gave a strong focus to the engagement of senior managers in order to gain senior endorsement of the project implementation plans. Initially and throughout the pilot there was a good level of engagement at senior management level. The open disclosure project implementation plans were presented to the CUH Executive Management Board and the MMUH Hospital Board by the HSE/SCA open disclosure leads. Project implementation plans were formally endorsed by the CEOs and Clinical Directors of both hospitals.

This early engagement with leaders helped to gain senior level buy-in with the pilot and was deemed important in establishing the corporate endorsement of the principles underpinning open disclosure and a culture of openness and transparency. For example, the HSE pilot lead stated that engagement with the Executive Management Board was key to implementation in CUH:

In Cork it was key that there was a meeting with the EMB and to agree a change management proposal and implementation plan, which they had involvement in. The proposal was amended based on their feedback and there was active participation…Being signed off by the EMB helped to embed the project.

This marked an important milestone in gaining leadership, at least in the initial stages, for the pilot in each hospital. Leadership was a key issue raised consistently throughout the evaluation, and staff at all levels spoke about the importance of open disclosure being driven at a senior level in order to promote clinician engagement and strategic direction. Interviews with the CEOs and Clinical Directors of CUH and MMUH also stressed the importance of leadership in establishing a culture of open disclosure in the organisation.

The pilot took place at a time of significant organisational change in both hospitals. Medical governance was in a state of change from a Divisional model to a formal Clinical Directorate system in MMUH and CUH. One of the problems in CUH at the start of the pilot was that there was no accountability structure to lead and drive open disclosure. The pilot commencement was delayed until the new Directorate structure was in place. In MMUH Clinical Directors were in the process of being appointed just as the pilot commenced. Having Clinical Directors in place was subsequently important in giving leverage and senior level buy in to the pilots and both hospitals reported that they had a deep commitment to the new Directorate structure and to embedding open disclosure through the system.

An Open Disclosure Committee, chaired by the CEO, was established at MMUH. A similar committee was established at CUH as a sub-committee of the Clinical Governance Committee, the establishment of which was delayed because of the reorganisation into a clinical directorate structure. Although it was recommended that two patient representatives be invited to join the open disclosure committees, it appears that this was not implemented.

4 The clinical directorate model, introduced in 2013, has led to the appointment of Clinical Directors with the authority to lead on and report on clinical governance; it aims to provide better accountability and responsibility within hospitals and is based on a structure of a lead Clinical Director and four speciality Clinical Directors. All consultants report to the Clinical Director relevant to their speciality.
Post-pilot senior managers and the CEOs of MMUH and CUH stated that the structures were working well in fostering better accountability, openness and honesty, with a lead for open disclosure in each Directorate, alongside a key member of staff (Risk Managers) driving implementation and providing feedback. Senior managers also stressed the importance of ensuring that the new Directorate structures promoted evaluation and regular feedback on the implementation of open disclosure and the extent to which it had filtered through all levels of the organisation. However, there is less evidence that open disclosure has become a routine area of reporting and discussion at hospital governance and management meetings, and this is an area identified for further development. In CUH open disclosure is reported to the Quality and Safety Committee in the context of formal investigations that are carried out. However, it is not a standing agenda item on the Risk Management or the Quality and Safety Committees. There is a commitment in CUH to examine ways in which open disclosure can be reported upon regularly so that senior managers are kept informed, are able to chart trends in activity on adverse events, and can provide a point from which open disclosure can be further disseminated from the top down to encourage greater reporting of incidents.

Learning from the pilots in both hospitals demonstrated the value of Clinical Directors who were active champions of open disclosure; this leadership has contributed significantly to gaining buy-in across the organisation and to engaging clinical teams.

Despite the implementation of the Clinical Directorate structure and mechanisms that are in place for incident reporting and support provided from the Risk Management departments, some staff remain unclear about lines of accountability and who to turn to in the case of an incident at ward level. This is an area that was less developed during the pilot and points to the need for better systems to be put in place to ensure that staff have clear lines of accountability so that they know where to go to for support when an incident occurs. That said, generally in nursing there are clear lines of accountability in relation to disclosure, particularly when smaller incidents occur. However, many senior managers expressed frustration that during and after the pilot that they had insufficient time to devote to open disclosure in the light of other demands.

3.4 Engagement of clinicians

The national project leads and pilot leads in CUH and MMUH expressed disappointment in relation to the involvement and leadership from clinicians during the pilot. This, as the SCA project lead stated, is work that is “very personality driven and requires a change in behaviour, which at times can be challenging”. In both hospitals clinical engagement was hugely challenging during the pilot. Attempts were made to engage clinicians in multiple ways, through clinical governance meetings, the Boards in both hospitals, the consultant body in a medical forum, grand rounds with NCHDs and consultants, and awareness raising in various other forums. The learning from the pilot is that it is important to engage clinicians in multiple ways, for example through doctor’s meetings, journal clubs, medical forums, engagement with Clinical Directors and senior managers at Executive and Board levels, as well as through grand rounds. In particular, the grand rounds were seen as a good way to do this, allowing time for discussion and feedback. Grand rounds were carried out in both CUH and MMUH (including a grand round for the whole hospital in MMUH and in CUH participants were invited to attend from Mallow and Bantry hospitals). Grand rounds, as a teaching tool for clinicians, appear to be one of the most valuable forms of learning and engagement for clinicians about open disclosure.

Engagement with Clinical Directors was paramount to the pilots. Evidence from the evaluation shows that post-pilot the new Clinical Directorate structure in both hospitals has helped to bring open disclosure closer to clinicians. According to one CEO:

*It is important to look at early warning scoring and get all consultants on board; the new Clinical Director and the directorate teams make it more possible, getting them on board, that’s how they trickle it down at all levels.*
The evaluation shows that the pilot led to a shift in the views and approaches of clinical leaders. For example, the pilot in CUH helped to persuade consultants about the need to have a timely response to disclosure. MMUH cited a case of a consultant who resisted disclosure but was persuaded by the Risk Manager to have a timely and open response on the basis that this would reduce the potential of problems arising for him at a later stage. The consultant in question thanked the Risk Manager for persuading him and recognised the benefits of an early disclosure. A further issue is that in some cases team members, often nursing staff, disclose errors to patients because the consultant is unwilling to do so. In one case a senior nurse spoke of a consultant who was very “guarded” about disclosure after an error was made; however, following discussion in her team it was decided to tell the patient what had happened and “that we were sorry”.

3.5 Awareness raising and training

Awareness raising sessions and training workshops constituted the most important and successful activities of the pilot in both hospitals. The training team was made up predominately of the two national open disclosure project leads, both of whom had clinical backgrounds. The national project leads were also supported in the educational component by another clinical risk advisor from the SCA. Learning from this and from the post-pilot ‘train-the-trainer’ programme is that having clinical backgrounds helps enormously in engaging clinicians. Prior to and during the course of the pilot the national leads developed a strong knowledge base on open disclosure, rooted in an awareness of international best practice, which brought credibility to the training. In addition, training resources were prepared and a training pack distributed to participants. The training pack evolved as a tool during the pilot, with additional information and amendments included as the training and awareness raising progressed. Indeed, the two pilot leads engaged in substantial learning and reflection in order to continually adapt and enhance the materials, which was helped by a robust approach to feedback through an evaluation form completed by people completing the training.

Initially the national team had planned for training sessions of 3.5 hours. However, discussion with and feedback from the EMB in CUH led to a revised plan, consisting of 30 minute awareness raising sessions and grand rounds for doctors, followed up by 3.5 hour multidisciplinary CPD accredited training sessions for a smaller number of staff.

3.5.1 Awareness raising sessions

Approximately fifty awareness raising sessions were held in both pilot sites. The sessions were advertised internally to all staff groups and the CEOs of both hospitals sent communication to managers requesting that staff be released to attend the sessions. The awareness sessions were delivered in open sessions in the auditorium at both sites to all staff and also in presentations to smaller groups, including clinical governance committees, nursing and senior administration committees, medical committees, induction training for new doctors, and grand rounds at both sites. The awareness raising sessions aimed to reach a wide cross-section of staff and provided staff with a ‘taster’ of open disclosure in preparation for the training workshops. The awareness raising sessions were widely considered to be very successful by the national pilot leads, the two hospitals and by participants. There was good turnout and staff attending in both hospitals appear to have found the sessions very useful and interesting. All awareness sessions were evaluated by the national open disclosure leads, which helped to inform the ongoing development and content of the sessions.

Fifty-six (26.9%) of respondents to the survey had attended the awareness raising session. Figure 2 shows that the majority of respondents from MMUH found the awareness raising session to be either ‘extremely useful’ or ‘very useful’, whereas the majority of respondents from CUH found them ‘very useful’ or ‘fairly useful’. A very small number from CUH and none from MMUH stated that the sessions were ‘not useful’.
As well as raising awareness, the feedback from the on-line survey, interviews and focus groups, showed that the sessions helped to communicate something positive to staff, which was highlighted as an issue in CUH:

The timing was very good for the awareness sessions. We had had moratoriums and we were down to the bare bones at the time, we had stopped communicating because it was always bad news... but suddenly there were sessions in the main auditorium about something more positive...There was good buzz around the place and a lot of discussion around them. (Clinical Governance Manager)

3.5.2 Training workshops

The preparation of the training workshops drew on advice and training from the Medical Protection Society (MPS), including training materials. The MPS provided a two-day workshop on delivering open disclosure workshops to the national open disclosure leads and Clinical Risk Advisors at the SCA. The national project leads also attended the MPS “Mastering Adverse Outcomes” half day workshop.

The half day (3.5 hour) training workshops, which followed several months after the awareness raising sessions, were an attempt to delve more deeply into open disclosure, give participants an opportunity to discuss open disclosure in their work, raise concerns and ask questions, and explore a number of case studies. The training workshops provided CPD points (from Royal College of Surgeons Ireland, Royal College of Physicians Ireland, Pharmaceutical Society of Ireland and Nursing Board).

A range of resources were provided at the workshop, including a workbook and reference materials presented in a professionally presented ring-binder: ‘Communicating with patients and their families following an adverse event’. This contained materials on open disclosure and policy in Ireland, the open disclosure process, information about what patients expect from healthcare professionals when an adverse event occurs, the clinician perspectives and considerations, in addition to further resources and reading. The resources were found to be very useful by the majority of respondents to the on-line survey, the interviews and focus groups. Several participants in focus groups stated that the workbook was a useful reference for information when open disclosure was being carried out.
Thirty respondents (16.4%) had attended the 3.5 hour workshop on open disclosure. Respondents were asked whether the workshop had prepared them for implementing open disclosure in their organisations. The responses are illustrated in Figure 3, which shows that the vast majority of respondents felt that the workshop had either fully or partially prepared them for open disclosure. Larger numbers felt fully prepared in MMUH, compared to CUH where the majority felt partially prepared.

![Figure 3: How did the workshop prepare you for implementing open disclosure (n=30)](image)

Overall, comments on the training were very positive, with many rating the training as excellent. In summary, the following feedback was given to the training:

- The training helped to embed open disclosure in each hospital.
- Many participants valued the role-plays and interactive nature of the training.
- The importance of clinical managers being trained and becoming champions was a consistent message made in response to the training.
- Several respondents spoke of the need for staff to be released for training at all levels (including portering, catering, cleaning supervisors, and allied healthcare professionals).
- A small number of participants felt that the training was at too low a level; these participants were already practicing open disclosure and in these cases suggestions were made to have training at different levels and targeted to different audiences.
- Important issues were raised about the fact that some incidents arise because of long-term cases of neglect, for example, resulting in pressure sores. It was suggested that training could look more deeply at improved communication and the need to look at problems that arise over time.

Responses, particularly from nursing and allied health staff of all grades, highlighted the positive impact that the workshop had in giving reassurance and preparation about how to say sorry to a patient, in having openness and transparency, as well as giving the member of staff confidence in adopting and implementing open disclosure in their working practices. Several respondents noted that they had increased awareness of when and how to practice open disclosure, and the importance of being honest from the outset and encouraging staff to be open in any adverse situations that occur. The training workshops had also been important in raising awareness of the “right things to do” and in reducing fear around being honest and open with families, particularly as in the past there has been a tendency to restrict how much information is provided to patients and their families.
Feedback on the training – comments from focus groups and interviews

The following quotes illustrate a selection of the main feedback on the training.

The training made me more aware of open disclosure, there is a structure there for a follow up, this has been an advantage. (Focus Group 1)

Open disclosure is a method of working that people should be doing anyway…it is important that you support, resource and teach staff and come back and support them subsequently. (Interview, Consultant 3)

Positive consequences – the training was important. It empowered people to go and do [open disclosure]. It was also part of what is happening anyway, but it helped to alleviate doubts and hesitation about the issue. (Focus Group 2)

One of my consultant colleagues attended the training. Following that there was an inappropriate intervention by a member of the team…the consultant was really good and we went straight in and told the patient what had happened. (Focus Group 1)

The training totally opened my eyes, it galvanized me to think and gave me permission, we may be going in that direction but we still have fear that we would be hung out to dry…the permission bit is important. A lot of people didn't go to the training. I felt empowered but if I didn't have the backing of my clinician, the experience of disclosing to a patient would have been different and it wouldn't have carried as much weight. (Focus Group 3)

The training certainly empowered us to bring our consultants along, in changing thinking. There was one incident where the consultant didn't want to meet with the family as he didn't really take their complaint on board. But I persuaded him, and it empowered us to spread the word to others. (Focus Group 3)

I realised after the open disclosure training that open disclosure is integral to everything we do…I could see this after the training and empowered me…before that I would have been reluctant to release staff. (Interview, Nurse Manager)

The training was very useful as it was another way of getting around to how you communicate…it brought another awareness to the staff about being open honest and communicating and the benefits of being honest from the outset. We have consultants who meet the patients/families early on and they have a positive outcomes, there are real benefits 100% of dealing with issues quickly…there are some consultants who don’t and the cases go on for ages. (Interview, Clinical Governance and Standards Manager)

We had become very cautious about everything because of the fear of litigation…when I did the training, it gave me the authority to be a bit humane again, that we could say we are sorry. (Interview, Acting Director Midwifery)

One of the problems is that often we feel that if we say sorry we are admitting guilt, but the training helped me to address that and has enabled me to express an apology and that it was ok, and that I was confident to do that because there is a policy on this. (Interview, Acting Director Midwifery)

The training confirmed that my practice of being open and frank about things is the right way forward; it provided me with the resources to be able to informally disseminate the importance of open disclosure to my staff. (Interview, Consultant 1)

The training was excellent, it was well attended by nursing and allied health staff and the feedback was very positive. However, there were very few medical representatives…all stakeholders have to be at the training in the future. (Interview, Directorate Nurse Manager)
Requirements for training workshop

Several participants in the focus groups questioned the requirement to attend the awareness raising sessions as a prerequisite for attending the training workshop. As one participant stated:

I wasn’t sure if it was necessary or perhaps an impediment…that you had to do the awareness session to be trained, we could have had some pre-reading…there were certain people who didn’t attend because they hadn’t attended the awareness raising. You could have a briefing document to send round to people. (Focus Group 3)

Training for specific groups healthcare professionals

Although the case studies used in the training were found to be interesting, some allied healthcare professionals, including occupational therapists and physiotherapists, stated that the examples given in the training were either too medically orientated and/or of dramatic medical errors. However, allied health professionals generally found the training to be very helpful. A speech and language therapist spoke of the value of the training to herself and the team:

We had an incident where a member of the team did the wrong assessment of a patient - at the end of the day the knowledge gained from the training was really useful because it gave me a process to enable my colleague to help her work through the issue and an opportunity for the team to discuss policies and procedures. (Focus Group 1)

The result of this is that open disclosure is a standing agenda item on speech and language therapy team meetings. The case represented important learning for the whole team and was a “wake up call, as everyone is extraordinarily busy, things do happen”. (Focus Group 1)

The role of the multidisciplinary team

Suggestions were made for examples of smaller cases that would be relevant to everyday practice, with case examples that showed the role of the multidisciplinary team, to show best practice on open disclosure where multiple professionals were involved. As one participant stated: “…there could have been more focus on the role of the multidisciplinary team…the role-plays were one-to-one, but often we would be communicating in a team”. (Focus Group 2) In particular, there was a strong argument made to implement multidisciplinary team working to avoid making mistakes and in fostering learning across all disciplines. As one nurse manager stated, open disclosure works if there is a team approach, which needs to be the focus of the training:

It is only by working together that we will get optimum results and it has to be that every single member of the team involved with patients is empowered and supported so that they can give the best possible care. (Directorate Nurse Manager)

Implementing training at all levels, including ward / departmental level

Several participants highlighted the importance of training being provided at unit/ward level so that all staff can become aware of how to implement open disclosure and play a role in open disclosure. Relevant team-based scenarios and examples of incidents of harm could be used as a basis for learning in a department or team. Some nursing staff stated that they would appreciate guidelines on how and when to escalate an issue to their line manager:

…you know instinctively what to do, and we do all really know what to do, but specifically if there were some guidelines it would be helpful. (Focus Group 1)

Nursing staff, in particular, suggested that more time should be available for peer review and reflection on lessons learnt. A large number of staff called for additional and ongoing training, and to consider more flexible approaches. In particular, this should take account of staff turnover and sustain institutional memory.
The training was of huge benefit, but it was difficult to get people to go on training...if they
could group a package of training together that would be good...You could break it up and
take it to directorates/departments at their monthly meetings. (Clinical Director 2)

Similarly, many participants in the evaluation stated that open disclosure training should be carried
out with all managers and filter through to all staff:

You need to chip away at it, it's easy to say you can’t get people to attend training, make it
attractive, make it appealing, get the buy in.... (CNM3)

A large number of participants in the evaluation believed that training on open disclosure should be
mandatory. However, both pilot sites pointed to the difficulties in releasing staff for training in the
current climate. Some hospitals that are now implementing open disclosure post-pilot have made
training on open disclosure mandatory. For example, Temple Street Children’s Hospital is
implementing mandatory training on open disclosure as a way of driving it through the organisation.

Having the time to carry out open disclosure can be very difficult and suggestions were made to have
a core group of staff who are trained to respond to incidents as soon as they arise in order to enhance
the process and timeliness of disclosure and investigations.

Engagement of clinicians

The bulk of attendees at the awareness raising and training workshops came from a nursing
background. As one Directorate Nurse Manager noted, it is vital that consultants and medical staff
engage in open disclosure training:

My experience is that patients want to talk to a doctor when something goes wrong, it is
vital that doctors attend training as it is in their best interests....I have sat at the table where
responses to patients have been less than satisfactory...We need to get consultants and
medical staff on board and to embrace the whole team.

One of the problems repeatedly made during the evaluation is the difficulty in releasing staff for
training. Although the pilot sites both aimed to run awareness and training sessions at different times
of the day, this did not appear to have resolved the difficulties in reaching consultants.

It is difficult to get staff to attend hand hygiene training and it would be hard to see how all
staff could be released for training on open disclosure. So it would be unrealistic to do this;
rather we need to move the responsibility down to managers to ensure that everyone
understands open disclosure”. (CEO 2)

Several consultants responding to the on-line survey and in interviews stated that they knew about
the pilot but did not attend the training because of a lack of time and work pressures and because
the training was held at a time that conflicted with patient contact. Suggestions were made to hold
the training in the evenings to facilitate consultant involvement. Furthermore, staffing pressures meant
that there was limited time for learning and reflection within teams, particularly following an adverse
event

It’s not an issue of time management, if it is that easy how have we got it wrong, there are
a lot of staff working over and above their hours, we are so often fire fighting,...reflective
practice is very difficult, it is paramount for student nurses but it falls off in the clinical
environment. (Directorate Nurse Manager).

E-learning

A large number of participants stated that the training should be shorter, and could include pre-reading
sessions on-line and an e-learning programme. In addition, having resources, videos and practical
information on-line was seen as one way to reach a wider range of staff and students, for example,
through HSE Land and the HSE open disclosure web site.
An interactive approach with case scenarios and examples

These are the elements of open disclosure training that had the most positive feedback for learning and understanding of open disclosure. The evaluation found that staff value practical scenarios and examples that explore open disclosure. An example of an approach taken at MMUH, in producing an interactive video of a reenactment of an inquest in the Coroner’s Court, shows the value of helping staff prepare for inquests. As the Risk Manager at MMUH said: “People like something visual”. Having an interactive method of learning was particularly important in building confidence in managing open disclosure meetings and in enhancing communications skills. This is relevant as the evaluation found that there is a need for more concrete examples, role play and case studies.

Learning from the training workshops

The main learning from the workshops reported in the on-line survey is illustrated in Figure 4. Of the thirty responses, the largest number stated that they had a better understanding of how to apply open disclosure (64% CUH, 53% MMUH). This is followed by having better awareness of the need to respond to patients, families or relatives in a timely way (36% CUH, 42% MMUH); being more at ease in meetings (18% CUH, 32% MMUH); improved confidence in implementing open disclosure (27% CUH, 26% MMUH); and 26% from MMUH stated that they had gained new communication skills. Other issues raised included having endorsement to carry out open disclosure as it was now a hospital policy and having knowledge of the policy and the process of carrying out open disclosure. The findings from the on-line survey mirror the findings from focus groups and interviews.

![Figure 4: Learning from the workshops (n=30)](image)

It is interesting to note that the training workshop had a fairly good impact on helping to change practice, as shown in Figure 5. In CUH, 36% of respondents stated that the workshop had helped to change their practice, 18% stated that this was partial. However, 36% stated that the workshop had not helped to change their practice. The responses from MMUH differ in that 32% stated that the workshop had helped to change practice, 42% partially and 11% not.
Overall the training workshops had an impact on building confidence about when and how to disclose. Some participants believed decisions about when to disclose needed to be embedded in professional experience and practice. Several participants spoke about the need for open disclosure to come from “within yourself”, and that it is important to have “honesty in yourself in order to change others”.

3.5.3 Training developments post-pilot

Since the pilots ended open disclosure has been integrated into training provided in other relevant areas of hospital activity. This is a positive outcome of the open disclosure pilot.

- Following the pilot CUH and MMUH pilot leads have carried out training on open disclosure for all new interns and open disclosure is introduced as part of induction training for doctors and new staff. In MMUH a one-page briefing on open disclosure is included in the induction manual.
- Patient Liaison Officers at MMUH provide regular staff briefings and training on open disclosure as part of training on complaints management and reporting. The aim is for local resolution at ward level to avoid a situation building up into a formal complaint.
- Training on risk analysis in both hospitals has also included an introduction to open disclosure. In CUH the training was carried out across hospital Directorates with a cross-section of staff across different grades and disciplines. This is recognised as being an essential part of the open disclosure process.
- Risk Managers at CUH and MMUH integrate open disclosure into training on incident management and reporting for staff.
- Training has been carried out for the senior management team on systems analysis, which is planned to be rolled-out across Directorates in CUH in the future.

3.6 Staff support

The evaluation points to the importance of staff support and that an opportunity for staff dialogue is integral to the successful implementation of open disclosure.

International evidence has highlighted the importance of supporting staff in open disclosure. Research on the experiences of adverse events (Madden 2013, O’Connor et al. 2010, Wu et al. 2009, Wu 2000,
Vincent 2001 & 2003, Sorensen et al. 2008, Shannon et al. 2009), shows that patients and/or their families often feel sad, anxious, depressed, afraid, angry and frustrated. However, good communication was found to play a major role in reducing trauma experienced by patients and/or their families, with clear explanations of what, why and how an error occurred and lessons for future prevention. Supporting staff through this process requires significant time and expertise from managers, which the evaluation found was often compromised by a lack of time or awareness of the support needs of staff. This is particularly important as research shows that providing support and healing for clinicians is vital as they are often the ‘second victim’ when adverse events occur. (Madden 2013, Munro 2015, Wu 2000)

The pilot put a significant emphasis on creating staff support systems and improved resources for staff so that staff feel safe and supported pre, during and post disclosure and in the aftermath of adverse events:

*In the pilots we put a lot of emphasis on staff support and staff training…our materials on staff support have been taken up by Australia and we have given them permission to use them. We also put a lot of emphasis on creating a compassionate and supportive environment for staff, and we very much focused training on staff needs and how important it is that they are valued and supported when they get it wrong. (HSE national pilot lead)*

As one senior manager noted, “There is an onus on the organisation to put support in place for staff when traumatic situations occur”. A Directorate Nurse Manager added staff support also includes the opportunity to reflect and learn from an incident and a key role is given to “…encouraging staff to do a reflective practice piece and to support staff in acknowledging mistakes”. Both pilot sites spoke of the importance of peer support and the need to encourage it further.

In relation to findings from the on-line survey, Figure 6 shows the level of support that respondents received from line managers and the organisation overall in implementing open disclosure. Ninety-three respondents to the survey answered this question. The majority stated that they received support from their line manager, peers and the organisation overall in implementing open disclosure. However, 15% from CUH and 19% from MMUH answered that they had not received support, and smaller numbers stated that they had received partial support. Overall respondents to the on-line survey felt that there was sufficient leadership in the organisation in supporting the implementation of open disclosure, with a smaller number stating that there was limited or partial leadership for implementing open disclosure.
Both hospitals have used the employee ASSIST ME programme, implementation of which was an important aspect of the pilots. In practice, staff support takes place through the line management structure. In most cases staff participating in the evaluation stated that they had very supportive line managers and that they valued the support from peers, particularly where errors were discussed in teams. However, in several cases, particularly amongst senior staff, little formal support was provided.

Support from line managers to staff involves a team based and learning approach and there is a general perception that staff receive sufficient support:

*The line manager is an important source of support, staff are very well supported through the process of open disclosure, we’ve had positive feedback from staff about this. In big incidents…we need to do debrief, give support and follow up, and it is important for the line manager to know their responsibilities in giving support.* (Clinical Governance and Standards Manager)

However, several respondents stated that there was insufficient dedicated time in the week to reflect back and provide support. Comments from staff included: “staff are time poor”, and “there is a relentless demand on everybody, you don’t get time to reflect”. One consultant had felt unsupported in an incident and stressed the need for a member of staff to have good support from the very start of the process, regardless of what has happened:

*People were very helpful during the process, but no one asked if I was OK…it was a very difficult experience for me, and only once did someone come back to me after the event to ask if I was ok.*

This was reiterated by the CEO of MMUH, who stated that adverse events create significant stress and difficulty for staff. They pointed to the different ways to support staff to disclose in the first place, but also to support them during an inquiry into an adverse event, during the open disclosure process and after. As one CEO stated:

*We are supporting staff through every way possible - occupational health, counselling, support from peers and Clinical Directors to enable them to work through it, there I would always try and instill that with staff…we all make mistakes and you do feel awful afterwards, it can be a huge agony for staff, its about getting this culture in place.*

A key issue raised in the evaluation is creating the time and space to support an individual to tell their story in a non-threatening and supportive environment. In addition, the teams who lead on open disclosure need to be appropriately supported and resourced:

*There are a small number of individuals leading on this and it is difficult in the current context of all the other things that people have to do.* (Consultant 3)

### 3.7 Integrating open disclosure into incident reporting and management

A key finding from the evaluation is that open disclosure needs to be fully captured in incident reporting. Improved systems provide an opportunity to integrate open disclosure into all incident reporting systems/processes. Aside from open disclosure, both hospitals have been involved in substantial policy developments to reduce and manage risks in order to promote quality and safety and prevent future harm. Post-pilot this has resulted in a more pro-active approach to risk analysis, learning from incidents and better systems to prevent, detect and mitigate incidents. National policies on risk management and quality and safety have also had an impact - in both hospitals staff are more aware of how to prevent an incident and each Directorate has a risk register.

However, Risk Managers in both hospitals are acutely aware of the need for ongoing awareness raising and training, as they are aware that there are incidents and near-misses that are not being reported.

In the event of critical incidents, hospitals policies exist on the reporting and management of near misses, incidents and serious incidents:
In CUH a flow chart and guidance has been produced to inform staff what to do and how to respond in each of these cases. In the case of a serious incident (marked in red) the policy sets out the immediate steps to be taken when an incident is identified, what to do and who to report to within 24 hours. All incidents, irrespective of whether they are clinical or non-clinical, are reported on an incident report form, which are subsequently logged into the National Incident Management System (NIMS). CUH issues quarterly reports and this information is disseminated to departments and line managers in order that they can identify activity trends over a period of time.

In MMUH incident reporting is made directly onto an on-line system for reporting incidents, which has been effective in speeding up the process of reporting and in giving timely responses. This represents extremely good practice. According to MMUH’s Risk Manager, the electronic system has worked very well. It uses a traffic lights system, which was developed in reporting radiology results. All incidents are assessed and reviewed by the Risk Manager. If there is a serious adverse event resulting in serious harm the case is referred to the Incident Review Group (made up of the Clinical Director, Director of Nursing, Quality and Risk Managers, and Chaired by the CEO) to decide if a review should be carried out. The incident reporting forms ask a question about whether a meeting has been held with or notification given to next of kin/guardian. This provides an important prompt for the implementation of open disclosure and an obligation on the relevant manager to immediately contact the family. This approach has been effective in managing and avoiding adverse medical events. Direct data entry by medical staff has facilitated an early response system. In practice, most incidents resulting in harm are the result of falls. This has led MMUH to introduce a falls risk procedure, led by the Falls Manager who assesses patients for falls risk, which is registered on an electronic system which identifies if there is a high, medium or low risk of falls.

Prior to the development of the hospitals’ policies a review of existing policies on risk management and incident management was carried out to ensure that they were aligned with open disclosure guidance, and integrated into clinical governance processes. The two hospital pilot leads were of the view that open disclosure should be captured more effectively in incident reporting. This is an area where hospitals can build open disclosure into their internal and external reporting processes, in capturing whether open disclosure took place and the outcomes of this. In serious incidents, a formal process exists for open disclosure meetings, in which case the open disclosure process is noted on the incident file, but in relation to less serious incidents and near misses, this information is not captured when incidents are managed at local level. Capturing where open disclosure takes place is also relevant where small errors or near misses occur. As one participant in the focus group in CUH stated: “Even if it is small, it’s about saying what has happened, explaining why it has happened, and that there is honesty and openness about this”. (Focus Group 2)

According to the national SCA open disclosure lead, effectively integrating open disclosure in incidents management at all levels is crucial for culture change and learning from incidents:

This goes back to how well incidents are managed locally, and how wards are aware of their top incidents over the last quarter, we often just look at incidents but not the other side, so open disclosure could be part of incident management, CNMs should be asking for incidents relevant to them and then to ask if open disclosure has happened, it has to be part of the culture. We shouldn’t wait for a red or orange case, open disclosure should be normal business at all levels…and it is important that leaders on the wards are trained and empowered so that this is normal practice.
3.8 Policy development on open disclosure

The development of a policy on open disclosure in both hospitals was an important outcome of the pilot. When the pilots commenced, policy development was at a formative stage. International best practice was particularly important in guiding the early development of open disclosure. This included guidance from the University of Michigan Hospital, UK National Patient Safety Agency and the Australian Commission for Safety and Quality in Health Care. Both hospitals drafted and subsequently agreed hospital policies on open disclosure modelled on international best practice. The learning from the pilots, international best practice and the drafting of the two hospital policies was used as the basis for drafting the national HSE policy and guidance.

3.8.1 CUH and MMUH policies on open disclosure

Regarding the open disclosure policies drawn up in CUH and MMUH, the majority of participants in the evaluation were aware of the policies, although few were aware of the contents of the policies. Awareness of the policies was much higher amongst senior managers. Clinical staff were less aware of the hospital policies, with many referring to paper and information overload and the need to have simple forms of policy dissemination. As well, participants in the evaluation highlighted the need to further embed and reinforce the hospital policies on open disclosure through awareness raising and training.

“We need to spend a lot more time reinforcing the HSE policy and the hospital’s policy on open disclosure. There is a need for huge education around this. If you are on board with people and build trust early on, you can disclose things early on.” (Director of Nursing)

CUH and MMUH policies are regarded by senior staff to be comprehensive and relevant to staff in each hospital context. A review of the policies carried out under the evaluation found the policies to be clear and fit for purpose, and in line with the national policy and guidance on open disclosure. In MMUH plans are in place to review the policy in 2015 to check its continued relevance and coherence with the national HSE policy. In MMUH, open disclosure had been practiced in the hospital prior to the pilot, but having a policy in place was an important outcome of the pilot:

“The pilot enabled us to question how we were doing it and to have procedures in place, the policy really highlighted if protocol was being followed and ensuring that all staff were on board…having the policy in the hospital and the national policy gives it more credibility…it is important to have a policy and it gives it credibility for people to follow.” (CEO 1)

3.8.2 National open disclosure policy and guidance

The HSE and SCA launched a national policy and national guidelines on open disclosure on 12th November 2013, which drew on the learning from the implementation of the open disclosure pilot, international evidence and feedback from groups and bodies nationally. Three further supporting documents were also launched, including a staff support booklet, patient information leaflet and staff briefing guide. The launch of the policy and guidelines represented a significant shift in understanding about the need for culture change in achieving open and transparent relationships between patients and health and social care professionals. The conference heard presentations from national and international speakers and experts, as well as learning from the pilots. The conference was very well attended and the evaluation forms completed by participants from across the health sector in Ireland were very positive about the event itself, as well as in relation to the importance and relevance of the new policy framework on open disclosure.

The national open disclosure policy sets out the principles of open disclosure and the open disclosure process and gives a strong focus to staff support and implementing the ASSIST ME model of staff support. It is a robust and detailed policy that is rooted in international best practice on open disclosure.

5 These documents are published on the HSE’s web site at www.hse.ie/opendisclosure
Most staff participating in focus groups and interviews stated that they were aware of the national HSE policy and guidance. However, the majority had not read the policy and guidance. This is an important finding from the evaluation and suggests the need for more efforts to be made to disseminate the policy and guidance, and distill it into simplified guidance. Overall participants in the interviews and focus groups who were aware of the policy stated that there is good documentation and guidance in place if an adverse incident arises, and most knew where to reference to policy, even if they had not read it in detail.

*It is important to have a policy in place, it helps us when we take students through their practice and we say there is a hospital policy. When our students make mistakes they are learning all the time.* (Focus Group 3)

Staff who were aware of the HSE policy and guidance generally found them useful and comprehensive, with practical queries and questions addressed that were seen as beneficial, for example, in meeting with a family after an adverse event. The importance of embedding this across the organisation was raised consistently throughout the evaluation:

The open disclosure policy is about common sense values, we need to make sure that we inculcate this through the organisation. In many cases staff are already doing this – it reflects the values from which they work and the reasons why they work in health. (CEO 2)

However, responses to the on-line survey showed a relatively low awareness of the national policy and guidelines. Of those responding to these questions, 28 from CUH and 19 from MMUH were aware of the policy, as against 19 from CUH and 14 from MMUH who were not aware of the policy. Awareness of the national guidelines on open disclosure was also fairly low with 24 in CUH and 15 in MMUH responding to the question stating that they were aware of the guidelines, against 24 in CUH and 15 in MMUH who were not aware of the guidelines.

Figure 7 shows that the majority of the eighty respondents who were aware of the policy found the policy to be fairly useful or very useful, with fewer numbers finding it extremely useful or not useful at all. Figure 8 shows a similar response was given to the usefulness of the guidelines, with the majority of the seventy-eight respondents who were aware of the guidelines stating that the guidelines are very useful or fairly useful.

![Figure 7: Usefulness of the national policy on Open Disclosure (those aware of the policy, n=80)](image-url)
Figure 8: Usefulness of the national guidelines on Open Disclosure (those aware of the guidelines, n=78)

In relation to how comprehensive the policy and guidelines are, the majority of respondents who were aware of the policy and guidance stated that these were comprehensive, followed by a smaller number stating that there are some gaps. This is illustrated in Figure 9.

Figure 9: Comprehensiveness of the policy and guidelines (aware of the policy and guidelines, n=80)
Many respondents to the evaluation found the guidance too long and detailed, and some commented on the need for clinical, speciality, or occupation specific guidance and examples. As one consultant stated, “forget the policy document, provide simple easy to read materials”, and another stated that, “we are shrouded in paperwork and policies”. A key issue raised by many staff is how the policy is communicated to staff. Although several consultants stated that policy overload meant that they had not read the policy and guidance, they did know where to find the policy if there was an adverse event. However, this approach does somewhat negate the objective that the policy and guidance are intended to raise awareness, particularly in using the open disclosure process as part of the broader prevention and detection of errors.

Suggestions were made by several participants in the evaluation for “simple and easy to digest information and guidance” synthesizing the open disclosure policy in a user-friendly way, so that it can have an impact in all clinical and non-clinical settings. As one senior manager stated, “We need the ‘abc’ guide to open disclosure”. Another suggested having a one-page flyer written simply and setting out the main principles of open disclosure that could be displayed in clinical settings. As another senior manager commented: “The national policy is too long and needs to be condensed and made more accessible to staff on the ground. We need a simple web site and resources that can be easily accessed”.

Having a policy framework on open disclosure has assisted in providing transparent practices and procedures, which address how open disclosure enhances quality and patient safety, and how support is provided to staff. A finding from the evaluation is that it is important that open disclosure policies acknowledge the needs of patients for information and support immediately after an event has occurred, in planning ongoing patient care, and in providing guidance and systems in relation to how an adverse event will be investigated, reported and acted upon. It is also important that open disclosure policies are visible and accessible to patients, for example, in the patient handbook. The national policy on disclosure has been very useful in guiding local hospital policies, and further developments are needed to embed open disclosure into the standards, Codes of Conduct and practices of professional and regulatory bodies.

### 3.9 Implementation of open disclosure in practice

#### 3.9.1 Implementation of the open disclosure in adverse events

During and following the pilot the Risk Managers in both hospitals formalised the process of open disclosure in adverse events, prior to and following an incident review.

Both hospitals post-pilot have developed more systematic ways of investigating incidents using system analysis / root cause analysis, and better systems for reporting to quality and safety committees. For example, in CUH this is carried out through monthly reports to the Executive Quality and Safety Committee. However, these reports do not identify whether an open disclosure meeting has taken place. This is an area that Risk Managers in both pilot sites identify as being important in future reporting.

The Risk Manager is the contact person for the family during the process. Risk Managers have a role in facilitating the open disclosure process and keeping in contact with families:

> In the event of a critical incident, when that has been identified, the immediate reaction is for the family and the patient and your feelings for them. We consider straight away what do we need to do for the family and to arrange to meet with them. It is important that the key people are at the table and that the key people are informed. (Risk Manager)

The role of the Risk Manager is to facilitate the process, to establish and keep links with the family and the organisation, and to be the contact person for both. A key role is to build the trust of the family on the basis that the family needs to know that: “…you are open and honest and they can trust you.
and that you are not hiding anything, and that the report will be open and transparent”. (Risk Manager)

However, building trust has become all the more difficult in the light of recent media reporting: “there is huge bad publicity and there is this huge mistrust out there”. (Risk Manager)

In some cases an open disclosure meeting is held prior to an incident review, but in most cases it takes place after the full review has been completed. Sometimes an open disclosure meeting is held to inform family members about the process, in preparation for a formal open disclosure meeting. No formal report is made of the open disclosure meeting, although minutes are taken and held on the incident file.

There are benefits of an immediate meeting where the consultant meets the family:

*This can be much more productive and easier for everyone, rather than something that is formal now. A recent example we had was of two consultants who met with the family straight away, without the hospital being involved…the family appreciated this.* (Risk Manager)

Both pilot sites spoke of the fact that they have become much more comfortable with open disclosure since the pilot, which has helped them to be less defensive and to appreciate how families can be supported.

Open disclosure meetings vary in relation to patients’ expectations and outcomes, suggesting the need for a flexible and individualised approach to open disclosure. However, the evaluation found a large degree of consensus that open disclosure meetings can be effective in providing compassionate and transparent communications that meet patients’ different expectations and in responding to different individual needs.

Although the CUH pilot focused on serious incidents, there is recognition of the need to look at capturing open disclosure across all incidents. This is particularly relevant as many nursing and midwifery staff reported that they were already practicing open disclosure on a routine basis for smaller incidents at ward level.

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**3.9.2 The implementation of open disclosure through the complaints process**

According to Robert Francis QC (2013), author of the UK’s Public Inquiry into Mid Staffordshire NHS Foundation Trust, effective complaints management is crucial to detect early warning signs that can avoid harm:

*A complaints system that does not respond flexibly, promptly and effectively to the justifiable concerns of complainants not only allows unacceptable practice to persist, it aggravates the grievance and suffering of the patient and those associated with the complaint, and undermines the public’s trust in the service.*

Effective complaints handling is widely regarded as being essential for high quality patient care. In this context all feedback, including complaints, offers valuable information that forms the basis for improvements in quality and patient safety. The review of UK complaints systems (NHS 2013) recommended that it is essential that there is an organisational ethos and culture of openness to enable this to happen, so that both patients and their friends or relatives and the staff involved feel supported.
The Ombudsman’s Office is due to report on an investigation on how complaints are handled by public hospitals in Ireland. The investigation was carried out because of concern about the low level of complaints made to the HSE and to ensure that there is access to an efficient and effective complaint handling system that enables health and social care organisations to learn from mistakes and prevent their recurrence. Both pilot hospitals have seen a rising number of complaints in recent years, which principally concern communications and waiting times. However, both pilot sites stated that it is very difficult to measure whether complaints have reduced as a result of the open disclosure pilot because there are so many variables to take into account.

In MMUH, the pilot reinforced the approach that had commenced to integrate open disclosure into all aspects of the complaints system. This is important as it filters through to every level of the organisation and has resulted in good communications and integration between incident management and complaints processes. This approach has been a very progressive way to implement open disclosure and represents very good learning for other health and social care organisations.

In MMUH metrics for categorising complaint cases, led to the development of the computerized system for complaints management in 2012. Complaint responses are built into the system, with specified timeframes for responses. All information about the management of complaints and open disclosure is held on the system (correspondence, logs of phone calls, reports etc.). The management and tracking of complaints has been effective in identifying trends across particular wards or departments on specific issues, that once highlighted can be acted upon. A breakdown of the types of complaints is reported on under different Patient Charter headings.

This has resulted in open disclosure being effectively built into the complaints system. When a complaint is made it is referred to the relevant persons in the relevant Directorate for their response, following which a response is made by the complaints team and a decision is made about whether a review needs to take place. If a review has been carried out a response is formulated and a decision is made about whether to make a recommendation to meet with the patient or family, and to implement any changes in service provision, resource allocation or policy. Recommendations are fed back to the staff concerned to ensure that there is learning to prevent re-occurrence. Concrete suggestions are invited from the staff/team involved and the team explores how recommendations can be implemented.

The impact is that a system is in place for gaining responses and learning at ward level and for making recommendations to change services where this is appropriate. The system has now been rolled-out to each Directorate to enable performance reports to be carried out at Directorate level.

MMUH is currently revising the complaints policy to align it with the new Directorate structure and with the policy on open disclosure. According to the Clinical Governance and Standards Manager at MMUH, open disclosure has been effectively integrated into complaints management. Patient Liaison Officers play a key role and policy and procedures ensure that complaints are dealt with at a local level in ensuring that patients/families receive all information. As one Patient Liaison Officer at MMUH stated:

Open disclosure in the Mater, it is literally very open and is a very positive thing for the organisation, there is a lot of dialogue and people want to make things better, and we encourage a meeting with family and to do this quickly; we encourage open communications. Patient Liaison Officers will be in attendance and will write notes and will then give notes to the family, everything is documented and we are keen to ensure that people don’t have to repeat their case…it makes it worse when you have to repeat your story over and over again.

Staff and managers involved in complaints management stated that the open disclosure pilot added strength to the complaints policy. The pilot was regarded as a highly positive development, particularly in enhancing skills for staff who may find it difficult to deal with complaints. In this context, open disclosure “gives us more leverage”. Although there was a sense that open disclosure was already being implemented in complaints management prior to the pilot, the pilot provided a hospital
framework and validated the process for staff. As the Clinical Director at the time of the pilot stated, “…it gave people confidence”. The role of Patient Liaison Officers has been very important in embedding open disclosure at all levels. According to the national pilot lead from the SCA:

Patient Liaison Officers are very good, they know the system inside out and they are perfect for that role [of open disclosure], they can help to reduce fear and show that there is another way.

In MMUH Patient Liaison Officers regard open disclosure as a standard practice in their work. As one Patient Liaison Officers stated:

Open disclosure is very much a part of what we do, we are very aware of open disclosure and how it relates to our complaints mechanisms. It is definitely the way to go and we apply it in dealing with complaints. Open disclosure meetings can be very helpful for patients and staff.

3.9.3 Conducting open disclosure meetings following an adverse event

During and since the pilot in CUH and MMUH open disclosure meetings have been held for all adverse events, the majority of which are preceded by an internal review into the incident. The incident review aims to establish the main facts and causes of the incident, and any action needs to be taken to resolve any harm caused or to prevent a similar occurrence. Open disclosure meetings are usually led by the Clinical Director and attended by key clinicians involved in the adverse event and the Risk Manager.

The main challenge in holding an open disclosure meeting is in getting the whole team on board and to get the right person in place to be the lead in the meeting. In CUH the Clinical Governance Manager and/or the Risk Manager and in MMUH the Risk Manager, provide all of the relevant information to the team and talk through the process. Both pilot leads in CUH and MMUH spoke about the importance of remaining in touch with a family member during the process of investigation and reporting, of building a relationship of trust and having a willingness to speak to the family at any time if they need support or clarification. Where disclosure has already taken place, a formal open disclosure meeting is organised to apologise. This is carried out in consultation with the family and when they are ready. In some cases a pre-family meeting takes place to brief a family on what is likely to happen in a formal open disclosure meeting, although at this stage it is stressed that they will not be given any answers until a full investigation has taken place. In some cases the Risk Manager will go into mediation with the families, as they are the contact point between the SCA and the family.

In addition to the support provided from the Risk Managers family support is provided by front line staff. In CUH, the vast majority of cases of adverse events have been in the area of cancer care. A key point of learning from the evaluation is the importance of building and sustaining effective relationships and communications between families and Clinical Nurse Specialists. In some cases CUH provides support through referrals to a local charity in Cork for counselling support for families, for which external funds have to be sourced to pay for this.

All formal open disclosure meetings are minuted, although the meeting minutes are not sent to the family. There is no structured follow up call after the open disclosure meeting, but family members are invited to make contact with the Risk Manager at any time. It is also anticipated that by the time of the formal meeting contact will have been made several times to arrange dates of meetings to give background information about who will be present at the meeting. In CUH, for example, family members are also invited to view the Board Room where open disclosure meetings are held – this helps to familiarise families with the layout of the room. The use of the Board Room is aimed at showing respect to the family and holding the meeting at the highest level.
3.9.4 Timeframes in implementing open disclosure

It is evident from the evaluation that the way that adverse incidents are dealt with determines the future management of the incident. Having a timely response is therefore crucial. Several participants spoke about the need to tighten the guidance on the timeframes that are currently in place to deal with serious incidents, so that investigations, debriefing of staff and that meeting with patients/family members is carried out in a timely manner. Research shows that patients want a timely response, and that the quicker the process the more likely that there will be a satisfactory outcome. (O’Connor et al. 2010, Iedema et al. 2009)

The pilot reinforced the need for a timely response, which can prevent further problems, reduce stress for patients and staff, and lead to fewer formal complaints, incidents and claims:

*It is important to have a timely response, if open disclosure takes place immediately it will reduce complaints…people often get very frustrated and if there is no communication the situation worsens. We see it happening all the time…our experience is that if we had not managed [an incident] with a timely response there would have been complaints.* (Patient Liaison Officer)

Feedback from the pilot sites shows that disclosure at an early stage and an early apology are generally accepted as being important to preventing a situation from worsening, and in some cases to preventing a small error leading to further complications at a later stage. However, this does depend on the level and extent of the error. As one consultant at CUH stated: "On the medical side it is a more common issue as we are dealing with complex issues".

Greater distress for patients and staff is evident from incidents that are not dealt with in a timely manner. However, there are difficulties highlighted in the evaluation in having dedicated time for staff to carry out investigations, which often slows down the process and affects the quality and integrity of the reviews. One senior nurse spoke of the importance of responding immediately and to do so by telephone immediately after the event, rather than later as this takes time and is excessively formal. She underscored the importance of meeting with the family members as quickly as possible. Sometimes waiting for the clinical team to respond can take time and an early meeting with the family is good practice.

Having a timely response is crucial for patients, families and the organisation. However, the process is often very long:

*This is often taking months and we need to look at this so that it can be timely. As an organisation if we are to complete the reviews in a timely manner (which is 3-6 months at the moment), it is very difficult…you are pulling people out of what they are doing and they have a lot of other responsibilities. It’s not working at the moment what we are doing… often it is rushed which is not always the best way.* (Risk Manager)

Clinicians not having the time to engage in reviews, and the importance of a timely response to disclosure was repeatedly reiterated:

*Open disclosure is about recognising that something is wrong and confirming that with the patient and the family. Often the time lag is too long, getting the team into the meeting can be like herding in sheep, some will follow some won’t, some will do everything rather than engage. Personally I just want to acknowledge and that the team say that something is wrong…to stay open in communicating with patients/families; ask for feedback and to ask if they think there is anything that they think should be done.* (Directorate Nurse Manager)

3.9.5 Making apologies

The open disclosure policy gives guidance on making apologies. This is modelled on the Australian Open Disclosure Standard, which specifies that the open disclosure process should involve an expression of regret, explanation of what has occurred, and a description of the action being taken to manage the incident and prevent recurrence. In this context a recent evaluation of the Australian open disclosure standard (ACSQHC 2012) suggests that an expression of regret should be changed
to ‘saying sorry’, and that specific guidance is needed on how to say sorry within either an apology or an expression of regret.

The evaluation looked at what stage an apology is made and how. There were varying responses to this from staff involved in the pilot, which to some extent relates to the type or severity of the incident. These range from the need to make an immediate apology, to waiting to make an apology until all of the facts have been collected and analysed. Differences, however, were observed in respect of disclosure after an incident has taken place and a formal apology being made following a review or investigation. Some staff stated that they were nervous about giving an apology until all the facts were in place, but recognised that this needed to be balanced with the need for early disclosure and acknowledging what had happened in a compassionate way.

Hospital managers in the pilot sites stressed the importance of having the right people informed and prepared to make an apology in advance of an open disclosure meeting. In most cases the Risk Managers facilitate and support the process, and Clinical Directors take the lead. In incidents that need to be investigated, it is considered good practice to have an early meeting to inform the family member about how an investigation will be carried out and what will happen. This can avoid a perception from family members that information is being withheld. As one Patient Liaison Officer stated:

*People get angry if there is no response or it isn’t quick… we promote it [open disclosure] in dealing with complaints to be upfront and not to be afraid to apologise if something happens.*

A key issue was raised about the importance of making sure that apologies were made with integrity and compassion. Interviewees involved in open disclosure meetings highlighted the importance of good communications, of being open and honest and apologising straight away. In some cases an explanation is all that is needed, particularly if there is a misunderstanding. As one respondent stated, “the days of not telling people or not answering questions don't work any more”, another said that, “people have expectations, it is common sense”. In particular:

*It is important to ask if there is anything that is not understood, to give clear explanations, as well as a chronological history of what happened. And it is important to sympathise and acknowledge what has happened and the grief caused. (Director of Nursing)*

An early apology is crucial:

*We discuss it with the Risk Manager, the head of the unit and other members of the team as well. We make an apology as quickly as possible and once we have come to a conclusion that an error has been made we act quickly. My experience is that people are very pleased to be informed and for an apology to be made. We also tell the woman what has been put in place to make sure that this wouldn't happen again. It is significant for the patient concerned to hear this…whether she decided to take action or not, it is important that we are open. We told the woman that she could phone us at any time if she needed to meet again. (Acting Director of Midwifery)*

Several participants in the evaluation stated that it is important also that “we are not apologising for everything”. This points to the need to ensure that the integrity of staff is protected, so that an apology is given based on professional decisions, which may not always meet the expectations of the patient.

### 3.10 Examples of open disclosure in practice

The evaluation sought to gain feedback about how open disclosure had been implemented in practice and the perceived outcomes for patients and staff. Some interviewees and focus group participants stated that they had been involved in difficult cases resulting in open disclosure, there was an overwhelming sense that open disclosure was not only vitally important for the patient/family, but also that staff experienced a sense of relief and benefited from practicing open disclosure.
As mentioned above, all serious incidents result in open disclosure meetings. In recent years there have been around four serious adverse events resulting in reviews in both hospitals, all of which now result in a formal process of open disclosure meetings. However, it is not possible to quantify the level of open disclosure actually taking place, particularly for less serious incidents and near-misses, as this is not documented.

The following are some examples of how staff involved in open disclosure perceived the process of disclosure. They provide a snapshot of how open disclosure was implemented during and post-pilot. For the sake of anonymity they are not identified by hospital or clinical area:

- **Example 1:** A small error led to a series of events that resulted from an inadequate checking system. Following prompting by the Risk Manager, a timely response was given to the patient and family, which the consultant concerned realised resulted in a better outcome. The review process led to 30 staff being interviewed, enabling staff to be supported and to learn from the error. The learning from the incident was that staff faced work pressures, stress and tiredness from having no breaks. This led the hospital prioritising new resources to relieve staff pressure and better implementation of checking systems.

- **Example 2:** In an incident that resulted from an error, following discussion in the team, the nurse concerned carried out open disclosure, which she believed prevented further problems from arising. The family responded positively after an explanation and an apology, as they were concerned that the hospital was holding back information. The information was included in the discharge letter to the GP and a copy was given to the patient. The learning was that open disclosure made “a huge difference”.

- **Example 3:** Following disclosure of a serious error, a formal apology was made. A family member came back to the Risk Manager and stated that they were very happy with the process and thanked the hospital for fully applying open disclosure.

- **Example 4:** Following an incident in catering regarding a patient with an allergy being given the wrong food, the Catering Manager carried out a full open disclosure process. The nurse reporting on this example, stated that she was very impressed with “the way that it was handled” and that there was a quick apology to the patient.

- **Example 4:** Communication with a patient immediately after a medical error led to full disclosure by the medical team. There was a successful outcome to the disclosure and it was not necessary for it to be escalated to the Clinical Director.

- **Example 5:** An apology was given to a family member by a senior nurse following a complaint by a family member who was unhappy with the care of her mother. A telephone call led to a timely response immediately after the event and an early meeting was held with the family.

- **Example 6:** Disclosure of an error by a senior midwifery manager and Risk Manager was carried out without the support of the consultant. The disclosure took place because they believed that the patient concerned deserved an apology and the patient concerned was grateful that she had been informed of the error.

- **Example 7:** A consultant with a disappointing experience of implementing open disclosure felt unsupported by the organisation. A delay in disclosing led to mistrust between the patient and the consultant. The view of the consultant was that the organisation was protecting itself and failing to have a full, open and honest disclosure at an early stage. The learning from this incident for the consultant concerned was that patients appreciate an honest and timely response and that an early meeting would have helped to build trust and potentially avoid litigation.

- **Example 8:** A medical error led a senior nurse to explain to the family what had happened, because she believed that it was serious enough for the family to know. She felt that the consultant responsible should have engaged directly with the family. However, the consultant concerned did not see this as an issue because it was not classified as a critical incident.
Example 9: In a case of the mismanagement of a patient that led to a further medical complications, a nurse brought her concern to the consultant’s attention that mistakes had been made and suggested that an open disclosure should be made to the patient. The consultant responded by saying that ‘he was not sure if it would have turned out any differently’. The member of staff concerned stated that: “It still bothers me to this day…I thought that the consultant should have brought everyone together who was involved, but this didn’t happen.”

3.11 Learning from open disclosure and the causes and consequences of incidents

International research shows that having systems in place to understand and learn from the causes and consequences of incidents is a cornerstone for patient safety improvement. (Larizgoitia et al. 2013) Issues of staff feedback were highlighted in HIQA’s (2013) report into the death of Savita Halappanavar. The absence of policy to facilitate staff feedback on how an incident is managed led HIQA to suggest that staff should be involved in proactively identifying opportunities for improvement as part of an open and just culture of patient safety and quality, and particularly “…to involve staff in identifying new mechanisms to ensure open disclosure becomes an established norm in our healthcare system”. (2013, p.155) In particular, HIQA argues that an open and just culture is not a ‘blame-free’ culture but a culture requiring “…full disclosure of mistakes, errors, near misses and patient safety concerns in order that system-based analysis can take place to identify learning”. (p.155)

The evaluation found that although significant inroads have been made in the two pilot sites in relation to risk assessment and management, the learning from incidents has tended to take place only in the context of serious incidents. There is a strong case for greater resources to be given to carrying out root cause analysis as part of risk assessment, in order to inform future actions to reduce risks. Root cause analysis can be helpful in identifying the cause of an incident by reconstructing the sequence of events and questioning at each stage the underlying contributing and causal factors. (Runciman et al. 2009) This is particularly important if there is to be a feedback loop and learning from errors. Several participants in the evaluation spoke about the importance of this, for example, in closing the loop following the submission of an incident report:

'It's important that there is learning from the event…that there is follow up in the team. We do this now and we make sure that we address the issue afterwards. It doesn't always happen though…and there are some cases where our hands are tied, there are some cases where a recommendation can't be implemented. (Focus Group 2)

The pilot and subsequent policy changes emphasise the importance of a team approach to resolving and learning from errors, as part of a fair and just approach. For example, the Acting Director of Midwifery, CUH, spoke of how a team approach had been implemented in medication management to ensure that there is learning from drug errors. As a senior nurse in MMUH noted: “The team responsible need to know they are listened to and they have many opportunities to talk about what they do”.

3.12 Monitoring and documenting open disclosure

The evaluation found that open disclosure is not documented, monitored and audited in a systematic way. Both pilot sites raised this as an important issue, particularly in relation to capturing where open disclosure is being implemented and the outcomes of this. The Clinical Governance Manager at CUH stated that open disclosure is being carried out extensively at the hospital because it is an integral part of the relationship that consultants have with patients: “Talking to consultants we have found that a lot of open disclosure is taking place”. However, there are no mechanisms in place to document how often open disclosure takes place, in which clinical or non-clinical areas, and under what circumstances. When a serious incident is escalated to the national incidents team, there is a question on the incident report asking if there has been communication with the family. However, there is no reporting back on this or checking whether open disclosure took place.
Having robust systems for reporting and feedback is important for institutional memory and documentation of events that could prevent future errors from occurring. As one focus group participant stated: “If the documentation doesn’t back up the experience or if not documented properly, you won’t remember”. Others saw the value of having documentation on day-to-day events in the nursing notes and feedback via incidents forms. This is particularly relevant if there is no knowledge if open disclosure took place in the past and no learning from previous errors. As one senior nurse manager stated, there are no mechanisms in place to document less serious cases where open disclosure has taken place:

*It is important to document this, for learning as well as for the future. This would need to be part of the risk management process…often the meetings take place but we don’t document them…it is important that we have ways to debrief the team so that everyone is part of the process of feedback. You could have someone 10 years down the line having a complication and someone would inadvertently say that was related to something that happened earlier. You would go to the patient’s notes, if you had a duplicate copy of the incidents form or another way to document it in the patient’s notes that might help. (Focus Group 3)*

The only circumstances under which open disclosure meetings are documented is where there has been a serious adverse incident, in which case this is recorded on the investigation file held by the Risk Manager. Other less serious cases where open disclosure takes place are not documented and are not routinely included in the patient’s file. Consultants do not capture whether there has been a full and frank discussion with family, or whether an incident has been fully disclosed. One of the problems is that this type of documentation of communications with patients is rarely completed by consultants.

One of the issues highlighted by senior managers involved in the pilots is the need to have a reporting structure for open disclosure, including reporting on open disclosure at ward level on an ongoing basis. This is a way of reducing levels of distress for patients, and also enhancing institutional and organisational learning on open disclosure. Several respondents stated that reporting on open disclosure should be introduced as a standing agenda item, through the Quality and Safety Committees in each hospital.

It is evident from the pilot that the way in which staff feedback is managed and implemented impacts on how learning from open disclosure and adverse events is integrated into changed working practices, resource allocation or systems changes, where this is relevant. Of particular relevance is how learning is fed back and how this can lead to meaningful dialogue in teams and across different specialties. According to the CEO of MMUH “That is an area where we can further develop conversations within the services”.

Other participants in the evaluation spoke about this being an issue of staff “integrity”, on the basis that “…people have a desire to do their work properly and well in the first place”. (Focus Group 1)

However, a number of participants in the evaluation noted that limited staff feedback is given in practice. The Clinical Governance and Standards Manager at MMUH stated that one of the weaknesses in the system is that there is often insufficient time and systems in place for follow up and to ‘close the loop’. However, she anticipated that once the Directorate structure is fully embedded in the hospital, this will facilitate better systems for follow up to ensure that a mistake is not repeated.

The need to have feedback from incident reporting was highlighted by several staff at CUH. In most cases incident forms are sent to the risk management department with no follow-up, unless it is a serious incident:

*The importance of follow up is that we need to touch base and discuss issues in the team… the central team need to talk and communicate more with us how they are managing incidents, and involve us more; there are mistakes we have made and [it is] important that we all follow it through together. (Clinical Nurse Manager 3)*

Team communication is also essential if open disclosure is to be carried out professionally and in promoting a just and fair culture. Several participants in the evaluation stated that it is important that staff debriefings and discussion take place in a supportive way, particularly where a member of staff
is directly affected. In one case a member of staff stated that she had not followed through with a serious incident because she thought another member of staff was carrying this out. She stated that:

*I learnt my lesson from that to follow through and check through on every incident, support the staff and check that everyone is all right, that my door is open.* (Clinical Nurse Manager 3)

### 3.13 Patient perspectives on adverse events and open disclosure

The evaluation did not include an analysis of patient/family perspectives on the implementation of open disclosure in the pilot. This represents a gap in the evidence of the implementation of the pilots and points to the need for further in-depth evaluation to take place in the future on patient perceptions and experiences of open disclosure, and whether they differ substantially from those of clinicians. Ensuring that a greater emphasis is given to patient feedback in pointing to what works would be very beneficial in meeting expectations around the disclosure of adverse events. The evaluation included one interview with one family representative who had experienced an adverse event at CUH, resulting in the death of her son. Based on her experience, this family member has subsequently taken on a patient advocacy role at a national and international level.

Patient involvement in healthcare safety has become an increasingly important focus in policy. It is a policy priority of the World Health Organization’s World Alliance for Patient Safety, where ‘mobilisation and empowerment of patients’ is one of six action areas of the ‘Patients for Patient Safety’ programme. (WHO 2004)

Research suggests that patients are very aware of patient safety issues and expect accountability (Bismark et al. 2006, Boothman et al. 2009, Chan et al. 2005, Truog et al. 2011, Sheard et al. 2014), with up to 42% experiencing a patient safety incident or adverse event in their own care or that of a family member. (O’Connor et al. 2010) Research also suggests that patients have a wider definition of patient safety incidents than healthcare professionals, where patients often include within the definition of patient safety incidents poor communication and interpersonal skills, poor service quality, and non-preventable adverse events. (O’Connor et al. 2010) Patients attribute patient safety incidents to a lack of time with patients; overwork, stress or fatigue on the part of health professionals; failure to work or communicate as a healthcare team and understaffing. (O’Connor et al. 2010) Evidence from other countries shows the benefits of open disclosure for patients in receiving a meaningful apology when an error has occurred. (Duclos et al. 2005, Espin et al. 2006, McDonald et al. 2009) It will be meaningful if patients feel that their concerns and distress have been acknowledged and are reassured that lessons will be learnt by the organisation to prevent harm from reoccurring. (NPSA 2009)

Patients have high expectations of open disclosure. Emotional trauma resulting from an adverse incident can be mediated if there is good communication and if information is provided in a timely way. Research exploring patients' and family members' perceptions of open disclosure of adverse events carried out in Australia (Iedema 2008a) points to positive outcomes, as well as their concerns, resulting from meetings with staff following an adverse event. Concerns included disclosure not occurring promptly or too informally, disclosure not being adequately followed up with tangible support or change in practice, staff not offering an apology, and disclosure not providing opportunities for patients to meet with the staff originally involved in the adverse event. Interviewees who expressed satisfaction about the disclosure process were typically those whose expectations of a full apology, formal disclosure and an offer of tangible support were met. The study found that patient satisfaction is enhanced if there is a combination of formal open disclosure, a full apology, and an offer of tangible support. Patients/family members wanted a full apology, an adequate recognition of what the adverse event means to them and a clear plan of how the patient will be supported after the adverse event, physically, emotionally, clinically and financially. A further study from the USA (Hobgood 2008) shows that higher preferences for reporting were found in younger patients and those with less education. Survey evidence found that 98% of patients wanted disclosure, 45% wanted the error reported and
35% stated that they would be less likely to take legal action if informed of the error. In all three categories there was no relation with race/ethnicity, gender, age and education, with the exception of an increased desire for reporting in younger patients and those with less education.

Patient/family feedback on the experience of open disclosure is important because disclosures are often complex events, which can be experienced in different ways by different patients/family members. Family responses to open disclosure, from the perspective of senior managers in both pilot hospitals, are that there is appreciation that disclosure took place. As one Risk Manager said there are varying responses:

…in the ones I have been involved in there has been a mixture of being very angry and wanting to blame for what had happened, to the very opposite of people being very thankful for openness and honesty.

Several participants in the evaluation made suggestions about how patient involvement in open disclosure, as part of healthcare safety, could be implemented. Suggestions included having a general set of questions in patient feedback surveys, such as “Were you happy that you were told everything about your care and treatment?”; “If anything went wrong were you informed of this and in a timely way?”; “Were you satisfied with the outcomes?”. Another suggestion was to gain patient feedback in reporting on open disclosure and incidents to Quality and Safety Committees.

The following are some examples of how the national open disclosure programme has included patient perspectives on open disclosure:

- The national open disclosure leads delivered an information session to members of the National Patient Consultative Forum at the start of the pilot, and discussions were held with several patient advocates. Quotes were used from patients and patient advocates in training workshops. In addition, case scenarios were used in the training to exemplify the impact of adverse events on staff, patients and their families.

- In October 2011, MMUH held a Quality & Patient Safety Conference ‘New Frontiers, New Challenges’, with a presentation from Loretta Evans, the mother of Colin Evans. Her presentation “A Mother’s Story” spoke of her experience and interaction with MMUH following an adverse event, where systems failure resulted in the death of her son.

- The launch of the National Open Disclosure policy and Guidelines at Farmleigh, Dublin in 2013, included a presentation from Margaret Murphy, a patient advocate who spoke of her experiences following the death of her son which resulted from a series of clinical errors and lapses in healthcare quality, and the importance of open disclosure.

- The patient advocacy group, Patients for Patient Safety Ireland (PFPSI), has identified open disclosure as a key priority. PFPSI is currently working with the HSE to draw up resources for the e-learning programme. This is involving focus groups with patients on open disclosure, the development of patient stories and a patient perspective, and a DVD. Several members of the group will participate in the ‘train-the-trainer’ programme and assist in the delivery of training nationally.

One patient advocate was interviewed as part of the evaluation. She has had substantial involvement nationally and internationally in promoting open disclosure and has been represented on the HSE Risk Committee, Commission for Patient Safety and Quality Assurance, and is a lay member of the Medical Council. Her insights were extremely valuable for the evaluation, particularly in pointing to the need for greater involvement of patients in healthcare quality. She spoke about recurring problems arising in complaints about “poor communications, behaviour, attitudes, patients feeling dismissed or diminished” and called for an effective process of open disclosure that results in an honest account that the error could have been prevented and that measures will be taken to ensure that it does not re-occur. She spoke about the impact on family members of the absence of a full, honest and open disclosure of an adverse event, and the fact that patients/family members are quick to notice if a clinician is not being fully open and honest.
From a patient perspective, we can sense if somebody is giving spin, we have a sixth sense in these situations. When corporate damage limitation kicked in, there was muddying of the waters, one doctor said it was an issue about loyalty to colleagues, this was misplaced as we needed to know and understand.

She went on to say that:

*The whole dynamic changes when it goes to open disclosure, it becomes clean, transparent and open and the family and the patient becomes part of the equation, and the family and the patient are able to accelerate the learning...time and again you hear families saying that they want these people to acknowledge what has happened and to become better clinicians than they were previously. If there is open disclosure, there is a better chance for system wide learning and dissemination.*

Her recommendations for the future development of open disclosure included ensuring that patients/family members are integral to the development of policies, procedures and training of health care staff. Regarding training and awareness raising, she stated that patients/family members should participate in the development and design of training, in presenting their experiences in the training itself and in pointing to what would have worked in making the experience of disclosure more positive. She suggested that open disclosure should be written into the healthcare professionals’ contracts, with support and tools to enable clinicians to practice open disclosure in a full and honest way. In addition, she was positive that there is now a national HSE policy, but stressed the importance of having sufficient resources for full implementation of the policy and regular evaluation of its implementation and sustainability. She was clear that it is critical that future evaluations address the patient experience.

In Ireland, there is a need for greater attention to be given to patients’ perspectives on adverse events. This includes the need for constant and supportive communication, offering tangible support to families, and improvements to clinical practice informed by patients’ perspectives to rule out re-occurrence of adverse events. Good practices exist within the HSE Quality Improvement Division through the implementation of the National Patient’s Charter ‘You and Your Health Service’ and the introduction of a number of mechanisms to ensure that patient/service user experiences are integrated into policies and procedures on patient safety and service improvements. In this context open disclosure offers an important opportunity to acknowledge patient roles in healthcare quality developments by creating and enabling an environment for clinicians and patients to discuss adverse events and address how such events can be prevented from occurring again.
Section 4:

The outcomes and impact of the open disclosure pilot

“We want to instill a culture...of being open and honest and not having a culture that people are scared and not wanting to speak out...the pilot has been critical to delivering that, where people feel more at ease in delivering open disclosure. .”

(CEO 1)
4.1 Introduction

This section looks at the impact of the pilot in these two areas, followed by a discussion of the main challenges and barriers managers and healthcare professionals experience in implementing open disclosure.

In both pilot hospitals senior managers and clinicians spoke about the benefit that the pilot had in creating a greater identity with open disclosure in clinical issues and incidents. According to an Operations Manager: “Open disclosure was a dramatic step forward for us from what we have been doing, we now see it as blending into everything”. At the time open disclosure was regarded as a very new issue, and both hospital pilot leads were clear that open disclosure has become far more embedded since the implementation of clinical governance structures, and also in the light of the importance given to open disclosure in national standards and policies. Clinical Directors in both pilot hospitals stated that it would now be easier to implement the pilot with the Directorate structure in place and in the light of improved application of risk policies and change management in both hospitals.

4.2 Impact of the open disclosure pilot on culture and patient safety

4.2.1 Impact on the culture of the organisation

The UK Commission on Patient Safety (2009) defines culture as: The product of individual and group values, attitudes, perceptions, competencies and patterns of behaviour that determine the commitment to, and the style and proficiency of an organisation’s health and safety management.

In recognition that culture change is a long-term process, participants in the evaluation showed a high level of commitment to changing culture, seeing it as a central component of patient-centred and high quality care. Some staff pointed to the fact that there is a high level of commitment from nurses, who are often far better at communicating because they have high levels of patient contact. In contrast, one consultant stated that: “…consultants are more likely to be guarding their space… there is a different culture amongst different professional groups”. Nurses will often flag a deterioration or a potential error, but as one nurse manager stated when nothing happens it leads to disappointment.

In some cases the implementation of open disclosure was embraced in the pilot sites because staff had previously worked in other countries that had established a culture of openness. For example, two senior clinicians had worked in the UK where there was a strong culture of openness; they reported on a significant culture change when they returned to work in Ireland and welcomed the pilot as an opportunity to create a similar ethos of openness in Ireland.

Responses to the on-line survey about the impact of the open disclosure pilot in changing the culture of the organisation are shown in Figure 10. Of the sixty-one responses, the impact is seen as being largely positive in both organisations, with one half of all respondents in CUH and MMUH stating that there had been a change in the organisation, nearly one-quarter in CUH and just over one-third in MMUH stated that there had been a partial impact. However, just over one-quarter in CUH and 15% in MMUH stated that there had been no impact on changing the culture of the organisation. One of the issues raised by several healthcare staff is the need to address defensive behaviour, which is firmly embedded in professional culture and leads to a reluctance to say sorry.
Both pilot sites highlighted the importance of the open disclosure pilot as an important learning exercise. As MMUH’s Clinical Director stated that the pilot provided valuable learning for the hospital as part of the overall development of quality and safety:

*It allowed a structured approach and process to be put around the doctor-patient relationship and a helpful system change that was of benefit to the patient.*

Several senior managers and the CEOs in both hospitals spoke positively of the benefits of the pilot in reinforcing a culture of openness and transparency:

*Some of our nursing staff are brilliant at getting it right for patients and getting the consultants to sit down and to take issues on board and to look at what we have done wrong and how we contributed to it.* (Director of Nursing)

Generally, feedback from the pilot is that open disclosure has helped to reinforce a cohesive approach and a culture of open communications, enabling staff to resolve issues within their teams. A culture of open disclosure and transparency was widely viewed as being the norm in maternity services in CUH, particularly as women are informed and empowered as partners, and appreciate openness and transparency. Communication is a vital element of the shift towards an emphasis on empowering women. As a midwifery manager stated:

*You have a very demanding public. It is important to know that you did the right thing, sometimes it is that it hasn’t been communicated to the woman…this is the most important thing.*

In cases of perinatal deaths the Clinical Director for Women and Children at CUH stated that:

*…there is an open process involving support and debriefing with parents or family members, providing information about the formal complaints process…in most cases people want time and they want to be heard…I am very honest with patients about the system and what we work within.*

A change in culture is reflected in the comments made about the impact of the open disclosure pilot. This helped staff to: “…acknowledge that we all make mistakes, we are human and this happens” and “to be clear if a mistake has been made.” Another clinician stated that: “It is a very good thing to say that we made a mistake, but also to be clear when we didn’t make a mistake and for the woman to know that”. Part of this culture change is to respond quickly: “…the first question if there is an incident is ‘has the woman been informed’.” Notwithstanding these positive changes, most staff
consulted in the evaluation acknowledged that culture change has to be a long-term objective and for this reason training and leadership on open disclosure need to be sustained in the long-term:

“There is still a culture change that needs to happen, although the pilot was good in helping to make this change, there is still a closed culture in Ireland...We need to have further training and to make sure that it is permeated through the whole organisation.” (Director of Nursing)

One Clinical Director reiterated the importance of continuing to work on open disclosure and that in order to do this:

“We want to be on a journey to make the Mater the safest hospital, a lot is down to resources. If we have a good resource framework and have a complete team around that, and get down into the clinical areas...this is important so that the directorate is working with the clinical areas to ensure good quality processes.” (Clinical Director 1)

One element of the change in culture is that internal communications with staff have improved, facilitating a culture of openness within the organisation. As one interviewee stated:

“The pilot was very seamless and was managed very well internally. We saw it as a very positive development for us in reinforcing open communications...The more you do it, the easier it becomes...it is important to learn from people who are good communicators, and to ensure that there is always someone with you who is a good communicator. You are on the stage every day of the week.” (Clinical Governance and Standards Manager)

Another interviewee stated that open disclosure gets easier the more you do it, also reflecting the importance of culture change coming from the actual implementation of open disclosure over time:

“The experience of doing open disclosure is that it gets easier the more you do it. When you go through a case, there is often defensiveness, but going through it can lead to learning and a softening.” (Director of Nursing)

Several Clinical Directors spoke about the value of the pilot in helping to promote an open culture. In one case a Clinical Director stated that: “The pilot was well received, I think it has done the institution well”. The clinical lead for the pilot in CUH spoke about the value of the pilot of moving away from the ‘don’t tell and protect’ culture towards a culture of openness:

“We are in a good place now, in the past there was often a big gap in communication and a paternalistic view of medicine.” (Clinical Director Medicine)

This change in culture was also reflected in the way open disclosure enhances working practices:

“It makes your life easier, it’s about telling patients and their families, they have a right to know.” (Director of Nursing)

Furthermore, the pilot helped staff to manage open disclosure more effectively, which has been good for staff morale and culture change:

“The pilot helped me to deal with and manage cases more effectively. It created a better awareness in myself, it was very traumatic when I was dealing with that situation [in a case of a previous adverse incident], but when I look back we didn't get it right...the other thing I have learnt through training, one has to step in the shoes of vulnerability, to ask 'how would I react?'” (Directorate Nurse Manager)

Similarly, having a systematic approach across the organisation was regarded as being very important to changing culture in MMUH:

“The learning from the open disclosure pilot has been very useful for the hospital. It has helped us to think about how to systemize it at all levels. Although we were doing open disclosure before the pilot, it has led to good awareness in the hospital. We now have a control mechanism in place at the high end, but not at the low end.” (Clinical Director)
One Directorate Nurse Manager stated that the “pilot moved us towards a culture of full open disclosure”. However, she noted that not all stakeholders were on board and that some consultants were still reluctant to talk to families if an error occurs. She went on to say that consultants need to understand how families are feeling and that there is a need to talk in a language that families understand. Several respondents highlighted the need for a change in attitude, particularly amongst some consultants, who were seen to be paternalistic. In particular, issues were highlighted about the need to see patients as partners on the basis that:

…patients are their own experts and have a good understanding of their own treatment and illness; there needs to be a more equal partnership approach informed by knowledge sharing and good communication skills. (Focus Group 1)

Overall, the clinicians and leads in both pilot sites categorically stated that the pilot helped to raise the profile of open and transparent communications and change culture. Post-pilot, the pilot leads in both hospitals highlighted the need for rolling out further training on complaints and incident management as a way of embedding improved communications and sustaining culture change.

4.2.2 Impact on patient safety

Feedback from the pilot sites is that the implementation of open disclosure has had a positive impact on patient safety, which in turn may have helped to reduce the number of claims. As the project lead from the SCA stated:

We believe that certain complaints didn’t escalate because we responded in a timely way. We don’t have proof of this but we are getting positive feedback about culture change.

The on-line survey sought to find out whether the open disclosure pilots and subsequent implementation of open disclosure in the two hospitals had had an impact on patient safety. Figure 11 shows, of the sixty-two respondents to this questions that perceptions about the impact on patient safety is relatively high. The majority of respondents to this question in MMUH (47%) stated that open disclosure had had an impact on patient safety, with fewer (27%) stating that this was partial and 26% stating that this was not the case. In contrast, there was an equal distribution of respondents (35%) at CUH stating ‘yes’ and ‘no’ to this question about the impact of open disclosure on patient safety, and 30% stating that it was partial.

![Figure 11: Impact of the pilot patient safety (n=62)](image-url)
Several interviewees and focus group participants spoke about the impact of the pilot on fostering better systems to promote patient safety. As the pilot lead in CUH stated:

*What we have learnt from the pilot is that incidents are often analysed and the causes are related to a small error down the line that escalated into a larger problem.*

Despite an increased risk environment, it is clear that open disclosure protects both the safety of patients and staff:

*We want to know that we work in a safe environment and that if we get something wrong that we do something about it…If the organisation is doing open disclosure, then they must give full backing to the staff member or staff members concerned, that there is a dedicated number of people who are there for staff to say we are going to work through this.*

(Directorate Nurse Manager).

### 4.3 Difficulties and barriers in implementing open disclosure

In summary, barriers to implementing open disclosure highlighted by participants in the evaluation include:

- Insufficient training and uncertainties about how to give a formal response and under what circumstances, particularly if there is limited consultant willingness to apologise.
- Personal issues faced by clinicians, such as: guilt, embarrassment, fear of reaction from peers and fear of being reported to fitness to practice.
- Lack of clarity about medico-legal issues in the context of open disclosure, including a persistent fear that disclosure could lead to adverse consequences for staff, a fear of litigation and the need for legal protection when apologies are being made.
- Reduced staffing levels and resources, resulting in a lack of time and staffing resources to implement open disclosure, also impacting on an increased risk environment and the potential for errors to occur.
- An increasingly hostile environment, resulting from adverse media reporting.
- Differences in expectations between staff and patients/families.

The main barriers to implementing open disclosure include: concerns over increased litigation costs, a fear of damaging or losing the relationship with the patient, fear of a loss of reputation or career progression, lack of institutional support, absence of training in how to practice open disclosure and the emotional impact on clinicians of adverse events (O’Connor et al. 2010). Perez et al. (2014) identify intrapersonal, interpersonal, institutional, and societal barriers faced by clinicians. They conclude that interdisciplinary efforts are needed to address the systemic and pervasive nature of the problem, with a focus on resolving ethical and social-psychological barriers through education, learning, a supportive learning environments and user-friendly guidelines at an institutional level.

The evaluation mirrored these findings but also showed that in an Irish context there were additional pressures and barriers on staff from adverse media publicity and concerns about an increased risk environment resulting from funding and staffing cuts. Forty-five respondents to the on-line survey gave feedback about whether they had experienced difficulties in implementing open disclosure in their work. Figure 12 shows that the majority responding to this question had experienced no difficulties or barriers; 28% of respondents from CUH and 36% from MMUH stated that they had not experienced any barriers. Smaller numbers had experienced ‘barriers’ or ‘some barriers’.
4.3.1 The impact on open disclosure of an increased risk environment

The evaluation has found that contributing factors, such as reduced staffing levels and increased levels of patient activity, play a part in increasing the risk of an incident occurring. According to international research, contributing factors may be external, organizational or related to a staff factor, and a contributing factor can in some cases be a precursor of an incident. (Runciman et al., 2009) In this context, it is relevant that contributory factors highlighted in this evaluation are taken into account in future funding and policy developments in healthcare.

Many clinicians spoke about the potential for an increased risk environment impacting negatively on open disclosure, highlighting underlying problems of systems being under pressure, staff pressure and burn out, external decisions about budgets and follow through care in the community, all having a risk impact. This results in “staff who are stressed and under pressure”. Specific issues were raised about the loss of very experienced and highly trained staff, significant increases in patient activity, more complex healthcare diagnosis and treatments, an increase in high acuity medicine and medical interventions, an ageing population and higher patient expectations, all of which impact on a challenging external environment. Staffing shortages and work pressures have added to the difficulties faced by clinicians in having the time to implement open disclosure. In particular, the time involved in inquiries and incident review processes is seen as problematic as the staff involved have so many other responsibilities.

Shortages in staffing and resources were seen to increase the possibility of errors occurring. As one consultant at stated “medical errors are waiting to happen”. This was seen to have an impact on the capacity and time for staff to implement open disclosure. Several consultants spoke of the impact of the moratorium combined with increase in patient activity on increasing risk to patients. In CUH there has been a 40% increase in activity along with a moratorium on staffing.

We are pushing people through the system with less capacity…it is having an effect on staff and demoralisation leads to more errors; we have overcrowding in EDs, which leads to more risks, including cross-infection and higher mortality. (Consultant 2)

In MMUH, the current environment of cost containment and the staff moratorium, impacts on open disclosure and also for the potential of more incidents arising. In MMUH the budget has been reduced by €50 million in a 3-4 year period. However, where there are potential risk issues identified at Directorate level, the CEO overrides this by making sure there are sufficient staff in place, which impacts on the overall hospital budget:
The potential for risk occurring has increased, we have had an increase in emergency department attendances, which is up by 12%; we need 50 acute beds to deal with people coming through the emergency department, but we only have 20. (CEO 1)

Healthcare professionals spoke about the greater work pressures they faced, such as an increase in falls, length of stay metrics resulting in tighter demands from reduced length of stay in hospital, as well as national targets to reduce waiting times. One CEO stated that the government’s political priorities to reduce waiting times, along with a “naming and shaming” approach by the media means that, “It has been difficult to sustain the morale and commitment of people in the organisation”. As one respondent stated, there has been a cumulative impact:

There is no doubt every department has suffered a reduction in staff, in the first couple of years you survive, you become leaner, but the last couple of years so, you have reorganized/ restructured but you are still losing staff, particularly nursing and clerical/admin in the front line areas, which leads to delays in patients seeing consultants. (Operations Manager).

The moratorium on staffing has particularly affected nursing, clerical and administrative staff and both pilot hospitals had to employ agency staff in order to provide safe levels of care. However, this has an impact on the organisation as agency staff are by their nature transient and do not necessarily have an organisational commitment or are unlikely to have received training in open disclosure. As several senior managers stated in the evaluation, agency staff do not always see themselves as being part of the organisation and often have lower levels of experience.

Some of these issues are related to external challenges and are outside of the control of the hospitals themselves. For example, at the time of the evaluation one CEO cited 91 patients on delayed discharge, resulting from inadequate levels of service in the community and the non-delivery of home care packages and Fair Deal.

Several participants in the evaluation stated that the moratorium on staffing should not be an excuse not to engage in systems and processes on open disclosure:

Even though we have shortages of staff, it doesn't stop you talking to a family and having an immediate response when something goes wrong…Everyone is accountable for the care that they give to a patient, if they see something that has occurred due to neglect, if someone has a pressure sore, the family has to be told. People will get angry if you hide things. (Director of Nursing)

In addition, these issues are mediated to some extent by better systems for risk identification, reporting and management of risk:

There is no doubt that the risk environment has increased…However, to be optimistic we have improved patient facilities and more advanced treatments in the hospital, we have ever improving IT systems and ICU, we are not static to the risk environment, but I have no doubt that it is challenging…HSE policies on safety and risk are very important but the onus is on us to meet and manage risk and to identify where there is a serious risk. (Clinical Director 1)

4.3.2 Adverse media publicity working against open disclosure

The evaluation took place during a year of two major reports on hospital inquiries in relation to systemic errors and lapses in quality and patient safety. This resulted in substantial media reporting, which was seen as having an adverse impact on staff morale. Several Clinical Directors and consultants interviewed in the evaluation spoke about the negative effect of this media coverage on openness and transparency, fostering an environment and culture where medical teams and clinicians are defensive and fear being open as this could lead to them being publicly ‘named and shamed’ in the media.
One consultant spoke of the media reporting of Portlaoise Hospital where a consultant was covertly recorded speaking in a clinical consultation on a bereavement, which was subsequently broadcasted on national television. Issues were raised in the interviews about the need to manage expectations more effectively and to put in place more effective mechanisms for managing negative perceptions towards healthcare providers. As one consultant stated “In high risk areas of medicine…things go wrong because we are human”; another stated that “media commentators want a head to roll, this works against open disclosure”. In addition, in this climate some consultants were concerned about meetings being recorded by the patient or the family and at ward level the use of mobile phone recordings and photos were taking place on a daily basis. According to one nurse, “…this leads to huge fear”. (Focus Group 1) This has led to staff becoming more defensive about what they say and how they react to incidents and “…is making people nervous about implementing open disclosure”. Having appropriate information and support available to staff is widely viewed as being critical to countering these fears.

4.3.3 Fear of litigation

The evaluation found that a fear of litigation remains a major barrier to open disclosure. A consistent issue raised by clinicians and the SCA during the evaluation was the need for legal protection on open disclosure. The importance of addressing protection in litigation has been raised by the Medical Council (2014) as being crucial to creating a supportive environment for open disclosure that meets the expectations of patients. The SCA has also highlighted the need for legal protection.

Feedback from a range of professionals is that clinicians may resist being fully open and honest. This points to the need for a greater focus to be given to the moral-ethical responsibilities of clinical roles, particularly to professional responsibilities in communicating with patients when errors occur:

There isn’t 100% buy-in for fear of being struck off if there is a mistake…clinicians are not fully reassured…need to remind everybody that admitting error/apology is not going to affect litigation, of the importance of being honest instead of a cover up…there has to be learning from it and we have to turn it into an improvement. (Clinical Director 2)

Several clinicians stated that legislation will give doctors confidence that they are protected by law. Similarly, legal change is regarded as being important for patient outcomes, and as one patient advocate interviewed in the evaluation stated:

This could help to promote better clinician-patient openness and collaboration, provide a more effective form of clinician accountability for open disclosure and also provide clarity for legal roles in negotiating adverse events and related claims.

A number of clinicians and senior managers interviewed in the evaluation believe that it is important to have legal protection, as exists in Australia, in giving apologies. As the Director of the SCA stated in the evaluation, feedback from solicitors and evidence from claims management in the SCA shows that where open disclosure and an apology is carried out, patients/family members are less bitter and litigious if they know that clinicians are genuine about learning from mistakes. However, he is clear that:

To support open disclosure is absolutely the right thing to do, but clinicians need to be able to be free to say things that will not be used against them in court, we need a greater reassurance and legal protection for this.

In addition, concerns were expressed about Freedom of Information legislation in permitting access to internal files and documentation from internal reviews, which are intended to form the basis of learning. As the Director of the SCA stated:

It is not that you want to deny families access to this information, an adverse event review has a purpose for learning in the organisation…staff are worried that what they said at the time would end up in a litigious situation, this makes people cautious of what they say and write down.
This shows the importance of gaining the right balance between the learning for the organisation and the right for patients/family members to have as much relevant information as possible. On this basis, legal discovery of certain information may need to be protected to enable clinicians to maximise learning from an adverse event, while also enabling patients/family members to have information about their case and reassurance that learning has taken place.

The Commission on Patient Safety recommended the introduction of legislation to provide legal protection for open disclosure, which would be carried out in compliance with national standards and on the basis that litigation could not be used against a person engaging in open disclosure. (DOHC 2008) The Minister for Health made an announcement for legislation in 2013, which would provide legal protection and permit medical professionals to inform patients and their families of incidents that have caused harm. At the time of writing the evaluation report, recommendations were being considered by the Law Reform Commission, and it is anticipated that legal provisions on open disclosure will be included in the forthcoming Health Information Bill. This will have the objective of providing legal protection for statements made in good faith by health care providers in compliance with national standards. In Australia, where open disclosure is well embedded, apology legislation has been enacted to protect statements of apology or regret. This expressly excludes statements containing acknowledgements of fault/liability in the definition of the apology, and an apology is not considered to be an admission of fault or liability.

Despite the protections that can be afforded from legislation, many participants in the evaluation were clear that open disclosure can be implemented very effectively without legislation, given the existing policy framework in place for open disclosure, particularly within the HIQA Standards for Better Safer Healthcare 2012 and ongoing HSE policy developments on risk management and incident reporting. This view is reinforced by the Medical Protection Society (MPS). Speaking at the Launch of the open disclosure policy in 2013, Dr. Stephanie Bown stated that:

...a change in culture would be more effective than legislation in ensuring that patients receive an open and honest explanation when something has gone wrong, as well as an apology where appropriate.

The MPS has substantial experience of open disclosure, including open disclosure training, indemnity, representation and advice for doctors. The MPS’s experience is that most complaints arise from poor communication and recommends that after the facts have been established, there should be full and open communication. Often an explanation may be all that is needed to reassure a patient and avoid any escalation. However:

A wall of silence after an adverse incident can provoke formal complaints and legal action. If it is clear that something has gone wrong, an apology is called for, and it should be forthcoming. Contrary to popular belief, apologies tend to prevent formal complaints rather than the reverse. (Bown 2013)

Similarly, the UK National Patient Safety Alliance ‘Being Open’ framework, suggests that:

Being open about what happened and discussing patient safety incidents promptly, fully and compassionately can help patients and professionals to cope better with the after effects….Openness and honesty can also help to prevent such events becoming formal complaints and litigation claims. (NPSA 2009:4)

Research on improving legal protection suggests that disclosure processes should recognise the twin issues of patients’ expectations and providers’ liability risk, with disclosure and apology being approached together rather than separately. (Allen et al. 2010, Mastroianni et al. 2010, Hyman et al. 2010) Although legal protection in encouraging, honesty, openness and willingness to admit fault are crucial. Evidence suggests that legislation should not be the principle way in which policy makers change culture. Rather, a change in culture appears to be most effective when it comes from within health and social care organisations themselves. In particular, leadership and workforce development is of crucial importance in providing healthcare staff with the skills and support to implement open disclosure and hold difficult conversations. (Mastroianni et al. 2010, Gallagher et al. 2007, Gallagher et al. 2005, Gallagher et al. 2006)
The forthcoming Health Information Bill aims to give more assurance to professionals in relation to open disclosure by fostering and supporting a culture of open disclosure. In particular, the Bill aims to establish a legal framework to enable information to be used to enhance healthcare and patient safety.

4.4 Critical success factors and benefits of the pilot

Critical success factors

In summary, the critical success factors for the effective implementation of open disclosure, drawn from the evaluation, include the following:

- A supportive hospital environment and organisational culture that impacts on all levels and areas of hospital activity.
- Strong leadership from the hospital CEO, Board and management; getting buy-in from senior management, especially Clinical Directors and clinicians, is absolutely crucial if they are to act as role-models and champions for other staff.
- Having a pilot lead in each hospital responsible for implementation, policy development, organising awareness raising and training and championing open disclosure.
- External resources and expertise from the HSE/SCA in the development and implementation of organisational policy and procedures on open disclosure.
- Sufficient resources within the hospital, including a risk management department in each hospital with expertise to support and engage clinical and non-clinical staff is viewed as being essential to providing a supportive culture on open disclosure.
- Support from and implementation by managers and leaders within the hospital with expertise and time to embed an open disclosure culture, linked also to the roles of Risk Managers, Clinical Directors and Patient Liaison Officers.
- Good quality training, led by trainers who are experienced clinicians and have in-depth knowledge of open disclosure, to train staff in the relevant skills and experience to carry out open disclosure, including targeted training in clinical specialties, induction training and ongoing training to keep staff up-dated and motivated.
- Healthcare staff engaged in open disclosure meetings having excellent communication skills, compassion, listening skills and an open culture, and carry out open disclosure in a timely way.
- A supportive culture for disclosure that promotes staff confidence and capacity to implement open disclosure across the whole organisation.
- Multidisciplinary approaches to reporting and learning from incidents, fostering team and peer support and learning.
- Clear guidance about how and when to carry out open disclosure, including how to report and how to utilise the learning from incidents.
- Open disclosure embedded as an integral part of relevant hospital policies on quality and patient safety.
- Having sufficient time and resources for timely responses, internal reviews, reflection, learning and structured follow-up.
- Feedback, follow up, discussion, learning and reflection from adverse events and open disclosure meetings, on the basis that this impacts on widespread organisational and team learning to prevent future errors from occurring.
### 4.5 Benefits of the open disclosure pilot for staff, patients and the two pilot hospitals

Table 2 summarises the main benefits of the open disclosure pilot identified by healthcare staff in the two pilot sites:

**Table 2: The benefits of the open disclosure pilot**

<table>
<thead>
<tr>
<th>Benefits for staff</th>
<th>Benefits for patients</th>
<th>Benefits for the hospital (CUH and MMUH)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Encouraged a culture of honesty and openness within both pilot hospitals;</td>
<td>• Openness and transparency increases trust and confidence in the organisation and enhances patient-clinician relationships;</td>
<td>• Open disclosure shows that a hospital is committed to quality and patient safety;</td>
</tr>
<tr>
<td>• Staff became more willing to learn from adverse events, incidents and complaints;</td>
<td>• Patients and their families can make informed decisions about healthcare, as part of the process of consent to care;</td>
<td>• Awareness and understanding of medical errors and adverse events is improved, which supports prevention and ongoing quality improvements;</td>
</tr>
<tr>
<td>• The training and support provided during the pilot provided greater clarity about how open disclosure can be carried out, providing greater confidence amongst staff;</td>
<td>• Open disclosure can help recovery and closure following an adverse event;</td>
<td>• Encourages timely responses to adverse events and investigation and identification of systemic problems;</td>
</tr>
<tr>
<td>• Communication and transparency has improved with benefits for staff and patients/families;</td>
<td>• Patient satisfaction is enhanced and patients/family members are viewed as being partners in their care;</td>
<td>• Improves staff morale and avoids the escalation of complaints and adverse events to litigation;</td>
</tr>
<tr>
<td>• Improved clinician-patient trust, professional responsibility, integrity and respect for patients;</td>
<td>• Improved understanding of patient perspectives and needs, including how incidents are viewed from the perspective of patients and their families.</td>
<td>• Creates an open and transparent culture, based on good communications, learning from incidents and complaints, which enhances the profile and image of the hospital.</td>
</tr>
</tbody>
</table>
Section 5:

National policy developments and the national implementation of open disclosure post-pilot
5.1 National policy and service developments impacting on open disclosure post-pilot

The evaluation took account of the significant policy developments and activities carried out by the national open disclosure project team post-pilot. The pilots took place prior to the implementation of a range of relevant national policy developments, including the healthcare reorganisation (leading to a clinical directorate structure for hospitals and the formation of hospitals groups, and community healthcare organisations). In addition, the reports on Midland Regional Hospital, Portlaoise, and Galway University Hospital are major drivers for change in culture, transparency and openness and both identified open disclosure as an area for improvement. The HIQA National Standards for Safer Better Healthcare (2012) and the establishment of implementation teams in all hospitals, along with other key policy developments have led to alignment between quality and patient safety initiatives and open disclosure. In this context open disclosure has become an increasingly important feature in the assurance of quality and safety. Overall, national managers and policy makers interviewed in the evaluation agree that, along with the open disclosure policy and guidance, there is a robust and integrated policy framework in place. The key issue is now to implement open disclosure.

HIQA Standards on Better Safer Healthcare (HIQA 2012) include open disclosure as a core element of the quality and safety assurance mechanisms. The Standards provide an important framework for the implementation of open disclosure across all healthcare settings. They are currently being implemented on a voluntary basis and will affect the licensing of healthcare organisations from 2016. One standard is specifically relevant to open disclosure. Standard 3.5 requires 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”. In addition, Standard 5.7 requires that “Members of the workforce at all levels are enabled to exercise their personal and professional responsibility for the quality and safety of services provided”. The Standards set out the features of a service that are required and guidance is provided in implementing open disclosure following an adverse event, the involvement of service users, support for staff and learning from adverse events. HIQA inspections will focus on an examination of policies, procedures, protocols and guidelines, staff training, documentation of adverse events and discussions with patients and staff. The standards, features of the service and guidance on open disclosure can be found in Appendix 2.

In preparation for meeting the standards, a national HSE quality assessment and improvement tool has been developed to assist hospitals in meeting the standards. This contains eight workbooks, which set out guidance on emerging, continuous and sustained improvements and guidance on how to verify the selected level of quality. Two workbooks are relevant to open disclosure: i) Workbook 3: Safe Care and Support, which covers the Standards contained in 3.5 on open disclosure and ii) Workbook 5 on leadership, governance and management. A similar set of tools is currently being drawn up for primary care.

The 2015 HSE Service Plan (HSE 2015) for the first time set a strategic priority to: “Implement HSE Open Disclosure policy across all health and social care settings”. (2015, p.9) A KPI sets the objective that: “All hospitals and Community Healthcare Organisations will have participated in level 2 briefings by end of Quarter 3”. (p.11) This will be monitored for implementation.

HSE policy developments on quality and safety

A new national policy framework for clinical governance on quality and safety has been implemented in the HSE, with clinical standards requiring that healthcare teams be accountable for the quality, safety and experience of patients. This is embedded in leadership, responsibility and accountability for good clinical care, and principles on clinical governance in decision-making, and in promoting a culture of trust, openness, transparency, respect and care. On this basis open disclosure is viewed as being central to good clinical governance, which ensures that people receive the care they need “in a safe, nurturing, open and just environment arising from corporate accountability for clinical performance”. (HSE 2012, p. 2) The substantial policy developments within the HSE on the alignment of open disclosure with governance on quality and safety, also mark a shift in emphasis on the
terminology from clinical governance to governance for quality and safety, which has implemented a system for quality and safety that front line staff can engage with. According to the Co-Chair of the HSE National Incident Management Team, Ireland is developing a best-practice approach to incident management and that the policy represents ‘state of the art’, particularly in linking risk management to incident management. She stressed the importance of promoting good quality investigations and recommendations that address the causes of incidents and how to prevent them in the future. This will in the long-term result in costs savings, reduced harm and a more open and transparent healthcare system.

Open disclosure and clinical governance on quality and safety: ‘Report of the Quality and Safety Clinical Governance Development Initiative – Sharing our Learning’ (HSE 2014a)

The implementation of the national framework on clinical governance commenced in 2011 through a three-year pilot project under the ‘clinical governance development initiative’, which was implemented in demonstration sites in five hospital action projects (one of which was CUH) and two primary care teams. The outcomes and evaluation are contained in the Report of the Quality and Safety Clinical Governance Development Initiative – Sharing our Learning. (HSE 2014a) Specific reference is made to the centrality of open disclosure in the clinical governance system, on the basis that the open disclosure process integrates and supports other clinical governance processes, including clinical incident reporting procedures, systems analysis reviews, complaints management and privacy and confidentiality procedures. The report consolidates learning, with recommendations for health service providers, policy makers and commissioners as a basis for informing future action plans. The learning documented in the report identifies the importance of a commitment to strategically defining quality in an organisation, implementing a model for quality improvement, education and training of staff on quality, and a mechanism for measuring quality through good quality data and transparency in measuring decisions. Core to this is active listening with patients and staff, implementation of structures and processes on quality and safety, leadership and management, and proactive performance management and support for staff. The evaluation of the initiative noted that quality and patient safety processes, such as open disclosure and patient partnership, have been strengthened. Suggestions are made for quality and safety in relation to: (i) board member and executive walk-rounds; (ii) putting quality and safety on every agenda; (iii) using multidisciplinary team prompts; (iv) introducing safety pauses; and (v) targeted quality improvement programmes. The HSE open disclosure national lead engaged directly with the project. The process has led to the implementation of a system for annual controls assurance in the HSE, which has been supported with a management controls handbook, with reporting on open disclosure.

HSE Safety Incident Management Policy (HSE 2014b): The policy makes a strong commitment to open disclosure and brings together a suite of policies into one consolidated policy on incident management. It specifies that safety incident management occurs within the framework of the principles of open disclosure, integrated risk management, just culture and fair procedures. All safety incidents are identified, reported and investigated, and disclosed in accordance with the national open disclosure guidelines. The policy aims to promote timely responses to incidents and to enhancing the quality of and learning from incidents in “…an environment within which individuals and groups are encouraged to report, investigate, disseminate and implement learning from safety incidents promptly”. (2014, p.3) The safety incident management process covers: prevention and planning; management and investigation of safety incidents; circulation of reports and recommendations; and national learning. At all stages of the safety incident management process there is a requirement to capture data from service levels upwards to the national level through the National Incident Management System (NIMS) (formerly the National Adverse Events Management System), with appropriate data protection. Resources and support for incident management are provided nationally through the National Incident Management Team (NIMT) via training and management support to enhance the quality of incident reporting. This has enabled the NIMT to focus on distilling learning from completed incident investigations and to better inform local and national safety interventions.
There is a suite of additional HSE policies and guidance that are relevant to open disclosure, which are listed in Appendix 2. They cover policy and guidance on integrated risk management (2011), guidance for quality and safety committees (HSE 2013a), guidance for investigation of incidents and complaints (HSE 2012), guidelines for serious incident management and look back reviews (HSE 2008), model of care development checklist for national clinical programmes (2014) and management controls handbook for senior clinicians covering reviews of quality assurance processes (HSE), amongst others.

National Incidents Management System (NIMS) is a web-based system to manage incidents throughout the incident life-cycle (when the incident occurred; when it is reported, logged and investigated; recommendations and learning), which has the capacity to identify emerging trends. It has been developed using international best practice standards. The system allows for ameliorating actions, as well as open disclosure, to be noted as part of incident investigations. The roll-out of NIMS is viewed by managers to be an opportunity to further develop reporting on open disclosure.

One of the open disclosure pilot sites, MMUH, is currently a pilot site for NIMS, which the SCA Clinical Risk Advisor stated “…had been very pioneering and progressive in embracing technology” through the electronic system for incident reporting. However, it remains unclear at this stage how hospitals will report on open disclosure, particularly how different types of disclosure will be captured and the impact of disclosure in giving patients/families closure.

There appears to be consensus that open disclosure should be a mandatory field and that secondary fields could be developed to flesh out the context, type and timing of open disclosure and provide evidence needed for audit and inspection. A further issue raised is how NIMS data and HSE serious incidents data can be triangulated so that attention can be given to the highest risks/incidents in specific hospital groups and community healthcare organisations. In addition, MMUH’s involvement in the HSE’s quality improvement initiative has led to a series of quality improvements, including the implementation of a Board dashboard on clinical and quality care.

In addition to open disclosure being integrated into HSE policies on clinical governance of quality and patient safety, there is scope for open disclosure to be included in governance and quality standards for annual service agreements with non-statutory agencies (under section 38 acute and non-acute service, section 39 voluntary and community services). A template has been drawn up for service agreements (for the seven hospital groups and nine community health organisations), with a commitment to include open disclosure in the template for annual service agreements.

5.2 Feedback from national managers and policy makers on the open disclosure pilot and post-pilot developments

5.2.1 Feedback on the open disclosure pilot

Feedback from national policy makers and managers is that the open disclosure pilot has successfully led to national engagement on open disclosure. Key issues were raised about the sustainability of the open disclosure funding and the need for further resources for national implementation in all health and social care organisations. Both pilot hospitals were viewed as being successful in implementing open disclosure with MMUH singled out as having integrated open disclosure into complaints at all levels, which was regarded as a positive approach to embedding open disclosure as part of seamless care for patients in a very fragmented system.

National managers and policy makers interviewed for the evaluation consistently praised the skill, dedication and effectiveness of the two pilot leads from the HSE and SCA, and attributed much of the success of the pilot to their determination and commitment. According to the HSE’s National Lead for Clinical Governance Development “They [the national pilot leads] have done an amazing job”. The SCA Clinical Risk Advisor stated that “a huge amount of ground has been covered [by the two pilot leads] but it needs to be sustained and this needs resources”. The Director of the SCA and the
HSE National Director for Quality and Patient Safety, both reiterated the strategic importance of the partnership, and the effective and exemplary way in which the joint programme had been implemented by the national leads. The importance of the pilot, particularly the partnership between the HSE and the SCA, has according to the HSE Director of Quality and Patient Safety, resulted in an unprecedented effort on behalf of the HSE and the national pilot leads:

Open disclosure has been a significant undertaking, it has been a highly ambitious initiative in a challenging environment, but is an important part of the wider agenda to improve engagement with patients and front line staff, it’s about democratic engagement and fits well with the broader agenda on the basis that we are doing things differently…overall it is a very welcome part of the overall drive for better quality and safety but there are challenges in the current environment.

The view of national managers is that staff engagement and understanding of open disclosure had been very high in both pilot sites. In addition, the focus given to staff support and wellbeing, including implementation of the ASSIST ME model, was regarded as being an important part of the pilot and integral to open disclosure. In particular, senior managers stressed the importance of staff involvement in investigations in line with the critical incident stress debriefing policy published by the HSE in 2012, which aims to support staff throughout the process of managing and investigating incidents.

Training and resource materials

The training and practical resources produced during the pilots were reported to be practical and user friendly. Several national managers attended open disclosure training. According to the HSE National Lead for Clinical Governance: “I did the training in the Mater – it was excellent…with a very participatory approach”. She stressed the importance of further disseminating the training through ‘train-the-trainer’, guides, case studies relevant to different clinical areas, and information about ‘who to go to’ to enable staff to have a safe place to tease out relevant issues.

National managers widely support further development of training and awareness raising by integrating open disclosure into all training carried out on induction, risk management, reporting, complaints and team working; through e-learning; and the ‘train-the-trainer’ methodology. These will enable awareness to filter down to hospitals, primary and community care. Issues were also raised about the need for trainers with clinical backgrounds, or for training to be co-facilitated by a trainer with experience in training methodologies and a clinician, and to give a focus to multidisciplinary training.

5.2.2 National roll-out of open disclosure

The pilot took place at a very early stage of evolution and development of open disclosure, which helped to give profile and leverage to open disclosure. In the current context there is a comprehensive set of policies and procedures in place and there is greater engagement of hospitals, particularly in preparation for meeting the HIQA standards. However, all national managers stressed the importance of not losing the momentum from the pilots and ensuring that the learning is widely disseminated.

National managers are of the view that there are sufficient levers for effective leadership and governance on open disclosure across all health and social care organisations. According to the HSE’s National Lead for Clinical Governance Development:

There is very good practice in place in relation to roll-out, support, leadership, resources, policy, training etc. as part of the roll-out process. It comes in with a mandate at the highest level of the organisation. This is progressing very well in acute hospitals, but not so much in primary care, mental health and disability services, as well as nursing homes.

Although there is a view that the pilots were well resourced (this was suggested by the Director of Advocacy and the National Director of Quality and Patient Safety), there is a general view that the national roll-out has been poorly resourced. The Director of Advocacy believed that this “…is unsustainable and new resources are needed if we are to be serious about implementing open
disclosure”. The evaluation confirms this finding, particularly because a resource of two national leads and a relatively small budget, while adequate for a pilot in two hospitals, is insufficient if there is to be a robust and systematic approach to open disclosure across all health and social care organisations. **This is particularly important as this evaluation recommends that open disclosure be fully implemented within five years. To do so requires significant investment of resources in training and support across the healthcare system.**

In this context the key issues raised for the national roll-out concern:

- The importance of culture change (transparency, openness and honesty) as the basis for implementing open disclosure.
- The twin issues of ensuring that there is leadership for open disclosure within hospitals, and the need to “get the issues into the hearts and minds of front line staff” (HSE National Lead for Clinical Governance).
- The critical role of leadership and the active role of Clinical Directors in the roll-out of open disclosure (with suggestions that open disclosure be explicit in the job descriptions of senior management and Clinical Directors).
- The importance of monitoring and auditing open disclosure as part of incident reporting, and to include this as a standing agenda item at executive and board meetings.
- The introduction of effective and regular feedback loops following an incident.
- The need for resources to support implementation and specific emphasis to be given to developing and implementing open disclosure in primary care, mental health and disability services. Additional points were made about the need to start a process for rolling out open disclosure into public and private nursing homes.
- The implementation of the new hospital groups and community healthcare organisational structure is seen as an opportunity for better integration between hospital and primary and continuing community care, and better coordination of the outcomes of open disclosure across health and social care organisations.
- Future monitoring and formative evaluation of open disclosure so that there is regular feedback and learning from the different ways in which open disclosure is being implemented, including perceptions of patients and families involved in open disclosure meetings (for example, through Quality and Patient Safety Audit function, the implementation of HIQA Standards, and including a mandatory question on open disclosure in the NIMS database). There will also be a process in place for monitoring the implementation of the 2015 KPIs set out in the HSE Service Plan.
- The need for additional resources for the implementation of monitoring and reporting systems.
- Suggestions were made by several managers to put in place a phased programme of implementation of open disclosure across all health and social care organisations so that is it fully implemented within five years, and to implement a mid-term evaluation to track progress and learning, and final evaluation after five years.

**5.2.3 Practitioner education:** preparing the future workforce

A key recommendation made by many participants in the evaluation is the need to fully embed open disclosure into beginning and ongoing practitioner education programmes, on the basis that these people will be the future health and social care professionals and managers. Suggestions from national managers included the following:

- Examine methods of education and bring people together (pre-registration level) through multidisciplinary education programmes.
• Include a module on open disclosure in all undergraduate programmes.
• Provide ongoing professional training and development in an integrated way to multidisciplinary teams of the future.

An example of good practice is the introduction of open disclosure, communications and the principles contained in the Patient’s Charter ‘You and Your Health Service’ under a module in the Masters Programme run in the Department of Pediatrics at University College Cork, run by the Clinical Director for Women and Children. A further example is open disclosure training for doctors carried out in a partnership between the RCSI and the HSE open disclosure leads (as noted above).

An example of good practice is the introduction to open disclosure, communications and the principles contained in the Patient’s Charter ‘You and Your Health Service’ under a module in the Masters Programme run in the Department of Obstetrics and Gynaecology at University College Cork, and based at Cork University Maternity Hospital (CUMH). A further example is open disclosure training for doctors carried out in a partnership between the RCPI and the HSE open disclosure leads (as noted above).

In addition, open disclosure is an important element of professional ethics and codes of practice. Professional bodies have an important role to play in promoting open disclosure through their registration, education and in matters related to the practices of health professionals, including promoting high standards of professional conduct and fitness to practice. Codes of Conduct generally include reference to open disclosure as part of the provision of safe and high quality care. There is significant scope for greater engagement with professional and regulatory bodies, including the role that they play in embedding open disclosure through supportive guidance. This has already commenced for doctors, nurses, midwives and pharmacists. The Code of Conduct for Nurses and Midwives states that: “Safe quality practice is promoted by nurses and midwives actively participating in incident reporting, adverse event reviews and open disclosure”. (Draft Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives February 2013) The Pharmaceutical Society of Ireland has six principles in the Code of Conduct, one of which is to: “Ensure that he/she practices, and encourages others to operate, in as open and transparent a manner as possible”. The Core Competency Framework covers: 4.4 Identifies and manages medication safety issues “Identifies, documents, acts upon and reports errors to include clear and open communication with patients”. The Medical Council’s (2013) Code of Conduct refers to the Council having “…a culture that encourages openness, integrity and accountability” and that it promotes “integrity and honesty”. It states that:

Patients and their families are entitled to honest, open and prompt communication with them about adverse events that may have caused them harm. (Medical Council, Guide to Professional Conduct and ethics for registered medical practitioners)

Similarly, the Medical Council’s (2004) A Guide to Ethical Conduct and Behaviour highlights the importance of open disclosure in the context of complaints, which principally concern a lack of communication or discourtesy on the part of the doctor (para. 3.10), and the Medical Council’s Statement of Strategy 2014 – 2018, sets a priority to address open disclosure alongside standards of good professional practice and effectively handling concerns about patient safety. Dealing with patients with honesty and openness is integral to building trust. A recent survey by the Irish Medical Council’s (2014) Talking about Good Medical Practice: Views on what it means to be a good doctor, highlighted the importance of openness, honesty and transparency as being fundamental to public trust in doctors. The survey found that 77% of patients were confident that their doctor would tell them if a mistake had been made. However, 63% of doctors agreed that doctors should disclose all significant medical errors. Openly disclosing adverse events and communicating honestly with patients and their families is viewed as a challenging but critical competency for a good doctor and the report highlights room for development in this area.
5.2.4 Open disclosure and legal claims

The evaluation took place at too early a stage to be able to evaluate the impact of open disclosure on claims. However, participants in the evaluation believed it would be important in the future to monitor claims, in order to provide evidence that open disclosure has an impact on reducing claims. This, participants believed, would be an additional driver to encourage reluctant clinicians to implement open disclosure. Senior managers spoke of the importance of the open disclosure pilot in reducing claims:

*We have perfect evidence that it reduces the number of issues that go to formal litigation and it can reduce the adversarial nature of that process. It makes it much easier to resolve. There is very good evidence and we see it in practice. It’s helpful for the staff involved as well as it can hang over people. To say I am sorry - that should not have happened.*

(Consultant 3)

Evidence from other countries shows a significant impact of open disclosure on reducing claims. For example, the Mater Hospital, Brisbane, Australia reported a reduction in claims saving $2 million AUD over 4 years. (Wu 2009a) Singapore Academic Hospital had received no cases that proceeded to litigation over a two-year period, saving approximately $500,000 (Singapore Dollars) per year. (Wu 2009b). In the University of Michigan Hospital legal cases had halved following the implementation of open disclosure, saving an average of $2 million (US dollars). (Boothman et al. 2009, Kachalia et al. 2010) In a further study patients reported that they were twice as likely to sue a doctor if they had not been told the truth. (Fallowfield and Flessig 2003)

In the future it will be important to analyse the number of claims submitted to the SCA under NIMS. NIMS has been recently amended to include a field on whether open disclosure has taken place, although it is not a mandatory field at this stage. Within the next five years it should be possible for the SCA to assess claims and whether the claims profile has been affected by open disclosure. This is something that the SCA is committed to, and can be facilitated through reporting on trend data through the SCA's analysis and reporting on claims and adverse events⁶.

5.3 Open disclosure developments carried out by the national open disclosure project team post-pilot

The open disclosure project leads learnt a huge amount about how to implement good quality training. They used the learning from each training session to improve the quality and content of the training. Post-pilot around 120 training workshops have been carried out with hospitals across the country using the same methodology developed in the pilot sites, in addition to support and guidance for hospitals on implementing open disclosure. The national pilot leads are aware that training is one element of the implementation of open disclosure, and recognise that is an essential part of ongoing culture change and learning in relation to how to communicate effectively, for example, in breaking bad news and giving apologies in an honest, compassionate and transparent way.

Post-pilot the HSE/SCA national leads commenced a ‘train-the-trainer’ programme on open disclosure. The experience of the programme shows the importance of having trainers (or co-trainers) with clinical backgrounds and expertise, in order to have credibility and an evidence base around clinical issues. This is evident, for example, in the area of radiology where specialist knowledge is needed in carrying out training on open disclosure. Overall, the HSE pilot lead and other national managers perceive that the initial ‘train-the-trainer’ programme has been unsuccessful. This led to staff criteria and a job description being drawn up for applicants for the programme and the targeting of clinicians as trainers.

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⁶ The most recent data for 2013 was reviewed in two internal unpublished reports: ‘Analysis of cases reviewed by the Clinical Risk Team at the State Claims Agency’ (2014) and ‘Clinical Adverse Events Notified to the State Claims Agency under the terms of the Clinical Indemnity Scheme’ (2014).
Having two facilitators is also seen as a way of giving the training depth and quality. In addition, a blended programme of initial e-learning, followed by face-to-face interactive training, could have the role of extending learning, while also taking account of the difficulties staff have in being released for longer training.

As part of the development of the HSE/SCA open disclosure training, an open disclosure training day was organised by the HSE, SCA and the RCSI as part of a three-day training programme in ‘human factors and patient safety’ for doctors. The training was evaluated as being of high quality, interactive and very relevant to the participants. In particular, the trainers drew up four different scenarios (covering missed diagnosis, delayed diagnosis, complication of procedure with poor informed consent and wrong site surgery) that were acted out as role-plays with a group of actors. The HSE, SCA and RCSI plan to continue this work and are in the process of producing video clips of different clinical scenarios and patient stories for use in training in Ireland. The importance of having high quality and practical scenarios that are relevant to clinical specialties is an important finding from the evaluation, and the work being carried out by the HSE, SCA and RCSI is a good example of how these activities can be further progressed with other professional and regulatory bodies. This is an example of good collaboration and partnership and is a model for rolling out training with other professional bodies in health and for integrating into CPD professional development programmes.

An e-learning programme is currently being developed in partnership between the HSE and the RCSI. This is a positive development as a finding from the evaluation is that e-learning is one way to further disseminate awareness about open disclosure and also to provide learning prior to training. A further positive development, also in line with the findings of the evaluation, is that the programme is involving Patients for Patient Safety Ireland, who are assisting with the development of patient perspective through focus groups to draw up patient stories and a DVD. Several members of the group will participate in the ‘train-the-trainer’ programme and will assist in the delivery of training nationally.

The national project team is undertaking work to develop a specialist approach to open disclosure, starting with an initiative to address specific difficulties arising in relation to radiology and open disclosure. This is being developed with the Faculty of Radiologists through ongoing work with RCSI and RCPI under the quality assurance programme in relation to open disclosure in radiology, mammography, gastroenterology and histopathology. Work is currently ongoing with the Faculty of Radiologists in the development of specific guidelines on open disclosure for radiologists and the development of case scenarios on radiology.
Section 6:

Evaluation findings and recommendations for the further development of open disclosure across all health and social care organisations
6.1 Evaluation findings

6.1.1 Introduction

This final section draws together the main findings and recommendations from the evaluation. The experience of the open disclosure pilot echoes international evidence that open disclosure is beneficial for patients/family members, for health and social care staff and for health and social care organisations. Participants in the evaluation from the pilot sites (in the interviews and focus groups, and on-line survey respondents) repeatedly reinforced the importance of open disclosure in creating open, transparent, compassionate and humane communications in order to reduce patient harm. Open disclosure is also recognized as being an integral part of quality and patient safety in Irish hospitals, and post-pilot the pilot sites highlighted the enabling environment resulting from the greater alignment of open disclosure within recent national policy developments on quality and patient safety. Open disclosure is a tool that is relevant across the whole continuum of care and in all health and social settings. It supports the principles of professionalism and medical ethics for patient-centred, good quality and safe patient care. Although the evaluation found a high level of support for open disclosure, good levels of staff awareness and promising practices in this regard, a significant number of challenges and barriers were also highlighted.

In summary, the evaluation findings are as follows:

• The implementation of open disclosure in the two pilot hospitals has been an ambitious and groundbreaking development led jointly by the HSE and SCA. It has been important in creating a positive area for change at a time of significant challenges, poor staff morale and a negative external environment.

• Open disclosure is relatively inexpensive to implement and although there are cost implications from establishing systems, training and learning across the system, these costs will be offset by the considerable savings resulting from reductions in patient harm and legal claims, that will result from implementing open disclosure in the long-term.

• Overall, the broad objectives of the open disclosure pilot were met, notably in providing support in each pilot hospital for the implementation of open disclosure and through awareness raising and training. However, constraints existed during the pilot largely as a result of the introduction of new clinical directorate structures. Despite this, there was good engagement with senior managers during the pilot and post-pilot this has impacted on the culture of both hospitals.

• The two pilot hospitals demonstrate overwhelming evidence of the benefits of open disclosure for both staff and patients. Staff participating in the on-line survey, in interviews and focus groups gave a very positive evaluation of the awareness raising sessions and training workshops, which along with other pilot activities have contributed to a positive impact on the culture of the organisation and patient safety.

• The evaluation points to significant learning from the open disclosure pilot in relation to the management of adverse events and the integration of open disclosure into complaints handling. Critical success factors include the importance of leadership, clinician engagement, staff training and involvement, and patient perspectives.

6.1.2 A culture of openness and transparency

From the clinicians’ perspective, the evaluation confirms the importance of inter-relationship between the four domains of transparency and open disclosure recently established by the USA National Patient Safety Foundation’s Lucian Leape Institute (2015). These cover:

• Transparency between clinicians and patients, through disclosure after a medical error, during care and after care;
• Transparency among clinicians themselves, through peer review and information sharing within healthcare organisations;
• Transparency of health care organisations with one another, through regional or national collaboration;
• Transparency of both clinicians and organisations with the public, through data and public reporting on quality and safety.

However, the evaluation points to the importance of two additional domains of transparency, notably:
• Transparency between clinicians and hospital management, through staff support and providing a supportive environment to disclose;
• Transparency between healthcare organisations, patients and their families, as well as representative patients’/service user organisations, in the development of open disclosure policies, training and practice.

The evaluation, informed by international evidence, has shown that open disclosure is a core element of culture change in health and social care organisations, leading to enhanced communications, patient-centred care and better quality of care and patient safety. This is essential in relation to the HSE’s policy on consent to care and the right of patients to receive timely and transparent information when an error has occurred. In this respect, good communications following an adverse event can strengthen doctor–patient relationships and have a positive impact on reporting and learning from incidents.

The open disclosure pilot had a positive impact on culture (openness, transparency, learning), and a positive impact on patient safety (responding in a timely way, prevention and learning from errors). There is evidence of the pilot impacting on culture change at all levels of the organisation, including informing team meetings and disclosure in relation to lower level errors. However, open disclosure is a long-term process and there is still a great deal that needs to be done to fully implement open disclosure in the pilot sites. Culture change, resulting in openness and transparency, is identified as one of the most important areas for change, which can be impacted upon in multiple ways (leadership, training, staff support, learning). However, culture change is regarded as a long-term issue, requiring ongoing resourcing, commitment and leadership.

The evaluation found a strong commitment amongst senior managers and healthcare professionals to implementing open disclosure and integrating it into improved risk and clinical governance procedures. The pilot was widely regarded as reinforcing openness and in giving a greater emphasis to a timely approach to addressing serious incidents and to informing patients and families as soon as an incident has occurred. All participants in the evaluation were clear that being open and transparent is the best way to support patients and their families when something goes wrong. The interviews and focus groups with staff in both pilot sites show a willingness and commitment to implement open disclosure in less serious events. Although it is evident that responses to adverse events should be proportional to the severity of the event, implementing open disclosure for near misses and small errors, as well as in adverse events, remains an important part of culture change.

In addition, the evaluation found wide support amongst healthcare professionals for the disclosure of adverse events to patients and their families. Patients require honest and timely disclosure, an apology where appropriate and assurances that the incident will not happen again. However, research consistently suggests that there is a gap between disclosure practice and reality. (O’Connor et al 2010) Although healthcare is delivered by multidisciplinary teams, much of the research that has been conducted has focused on physicians’ experiences. In this context, other healthcare professionals (in the context of multidisciplinary teams) who play a role in the disclosure process should be reflected in disclosure policies, implementation and monitoring.

Participants in the evaluation consistently highlighted the importance of open disclosure in creating a culture of patient involvement and participation, including ways in which the voice of patients and their families is incorporated into all levels of decision-making and service delivery (e.g. through
patient feedback mechanisms and focus groups, patient representatives on relevant committees, patient surveys), as well as through feedback on the open disclosure process itself. Similarly, staff involvement in the implementation of open disclosure shows the importance of ongoing change in culture and practice, as well as during the process of reviews/inquiries and learning from adverse events.

There is a clear finding from the evaluation of the importance of moving from a culture of the national ‘naming and shaming’ focus on hospital performance (for waiting lists and trolleys in emergency departments), which several senior managers stated reduces the capacity of hospitals to deal with their strategic priorities and fully implement open disclosure. Similarly, other contributory factors were found to work against open disclosure, notably the staffing moratorium, resource constraints and adverse media reporting.

6.1.3 HSE/SCA partnership and the role of the national open disclosure leads

The collaboration and partnership between the HSE and SCA has been exemplary, both at a strategic and operational level. This created a unique partnership between the two organisations that led to credibility, integrity of approach, shared learning and complementary skills. Senior managers in the pilot sites, national policy makers and managers from the HSE and SCA commented on the added value of the partnership during the pilot and post-pilot. The pilot benefited substantially from the national expertise and resources, with both pilot sites stating that they would not have been able to implement open disclosure at such an early stage of development.

The uniqueness and success of this partnership, and the commitment, expertise and enthusiasm of the national pilot leads, has no doubt been one of the key factors leading to a successful outcome for the pilot. There are significant strengths from the HSE/SCA partnership. There has also been a very significant interest in and engagement from key national managers in the HSE and SCA, including how open disclosure has been effectively integrated into policies and standards on quality and patient safety.

6.1.4 Learning from the pilots in CUH and MMUH

Healthcare professionals involved in the two pilot sites widely support open disclosure and have incorporated it into their practice. The pilot gave staff more confidence, organisational endorsement of open disclosure and a framework under which open disclosure can be implemented. Some were already practicing open disclosure prior to the pilot. However, the pilot provided a policy framework and guidance that has helped to reinforce and further embed open disclosure. In both pilot sites there is substantial learning from the experience of open disclosure in managing adverse events. This learning provides an opportunity to cascade open disclosure across the whole organisation and particularly at ward level.

A key factor in leading to the success of the pilot was having a lead person with responsibility for open disclosure in each pilot hospital who drove the pilot, and post-pilot in sustaining this role, linked to a central department with a clear responsibility to lead on open disclosure.

The two pilot sites took different approaches to the implementation of the open disclosure programme, although both were successful in engaging key leaders and senior managers in the pilot, in drawing up implementation plans and policy frameworks, and in providing high quality awareness raising and training sessions.

- MMUH successfully integrated open disclosure into the complaints process and across the whole organisation. Patient Liaison Officers continue to play an active role in raising awareness, providing guidance and assisting in open disclosure at all levels. Post-pilot, MMUH has been a national pilot for NIMS and has an on-line incident reporting system encouraging and facilitating a more timely response to open disclosure. The pilot is regarded as having played a significant role in culture change and in providing endorsement for open disclosure to take place across all levels of the organisation.
• CUH developed a formal process for holding open disclosure meetings for adverse events, which resulted in timely reporting and implementation of open disclosure. The pilot had an impact on endorsing the importance of open disclosure and open communications across the organisation and contributing to culture change.

Both pilot sites experienced initial difficulties in implementing open disclosure because they were in the process of organisational change. However, the embedding of new Clinical Directorate structures in both hospitals post-pilot has created an enabling environment for open disclosure.

6.1.5 Leadership for open disclosure

Leadership is an important pre-condition for culture change, open communication and transparency required for open disclosure as part of a culture of quality and patient safety. The evaluation shows the importance of national and organisational leadership and support in the national roll-out of open disclosure. Effective governance of open disclosure is also highlighted, for example, by ensuring that there are effective ways by which open disclosure is monitored, reported upon and how learning is acted upon at the level of hospital executives and Boards, and nationally within the HSE Leadership Team.

Specific issues were raised in the evaluation about the need for greater engagement of the HSE Leadership Team in embracing open disclosure as part of strategic policy developments, and also for the Leadership Team to participate in training on open disclosure. Some national policy makers and managers stressed the importance of open disclosure being driven by hospitals themselves, as well as by the HSE, and of additional resources being allocated for implementation.

6.1.6 Early management of open disclosure and timely responses

The evaluation found that early management of open disclosure and timely apologies are critical to a patient-centred approach. The way that communication is carried out can impact enormously on patient perceptions of the incident, levels of patient trust, medico-legal impacts, and how residual harm is mitigated. It is evident that the integrity given to apologies is crucial to patient/family satisfaction with the outcomes of open disclosure.

The importance of early intervention and communication was highlighted throughout the evaluation as benefiting both patients and hospitals. However, it is evident that there are different expectations of patients and hospital staff about what issues should be disclosed.

6.1.7 Reporting on open disclosure

The pilot sites developed accountability structures during the pilot phase. However, there is room for further development in establishing open disclosure in clinical governance reporting and accountability structures, including incident reporting and management procedures.

Open disclosure is captured in the two pilot sites largely in relation to serious incident reporting and complaints handling, with information captured on the adverse event file. However, reporting to quality and risk management committees is not carried out in a systematic way. It is very clear from the evaluation that open disclosure is taking place at ward level on a regular basis. Open disclosure for smaller incidents and near misses is not documented. This impacts on the potential for organisational knowledge and learning from incidents as a basis for enhancing quality and patient safety at all levels, and the development of best practice approaches to open disclosure.
6.1.8 A supportive environment for staff to disclose and learn from errors

A strong focus was given in the pilot to creating a supportive environment for staff to disclose. This was implemented through a project implementation plan in each pilot hospital, setting out culture change to create a supportive environment for staff using a step-by-step approach. Notwithstanding the challenges faced by staff, the pilot was successful in pressing for and gaining buy-in for a supportive environment for staff to disclose.

Although levels of staff support were reported as being very good in some clinical areas, particularly from line managers, these tended to be isolated examples. Overall, levels of staff support and the use of the ASSIST ME model were low, with some interviewees in the evaluation feeling isolated and unsupported during the open disclosure process. This points to the need for dedicated training for line managers and Clinical Directors in relation to how to effectively manage and carry out support for staff.

6.1.9 Awareness raising and training

The awareness raising and training sessions helped considerably to prepare staff for integrating open disclosure into their work. However, concerns were expressed about the low level of participation of consultants in the sessions and that many of the staff participating in awareness raising and training sessions were either practicing open disclosure or were open to incorporating it into their practice. The effectiveness and relevance of the awareness and training, the methodology and approach taken, the quality of the training materials and the training pack, and the expertise of the national pilot leads that delivered the training, were very positively evaluated.

Key learning from the training shows the importance of ensuring that training is factored into the working schedules of clinicians and provided at the time when clinicians are free, for example, early evenings. Finding different and flexible ways of reaching all staff, including junior doctors, and integrating open disclosure into all ongoing education/training programmes on complaints handling, incident reporting, and quality and safety can help to further embed learning in an organisation. Having a multidisciplinary approach to training is regarded as important as errors frequently arise that are the result of multiple issues. Providing short training slots in multidisciplinary team meetings can be one way of ensuring that teams integrate open disclosure as a core part of their work.

6.1.10 Challenges and barriers in implementing open disclosure

Despite substantial progress in implementing open disclosure during and after the pilot, the evaluation points to a number of persistent barriers regarding perceived fears of the medico-legal consequences of disclosure and fears in relation to fitness to practice complaints. Similarly, lack of preparedness or willingness to implement open disclosure, concerns about an increased environment of risk in the light of funding and staffing shortages and recent adverse media reporting, were also seen as significant barriers to the full implementation of open disclosure.

The evaluation found that hospital priorities, staffing pressures and difficulties in having a timely response to incident review processes need to be more effectively balanced with patients’ need for information at an early stage. Lack of resources, resulting in under-resourcing of staffing, work pressures and a lack of time, is widely seen as a barrier to open disclosure.

The confidentiality of clinicians was highlighted in the light of recent adverse media reporting, for example, in relation to media reporting of clinician’s names. In addition, concerns were expressed about access to records, files and documentation to inform incident review reports under Freedom of Information. This has reinforced fears about the potential negative effects on clinicians’ professional reputation, litigation and reporting to fitness to practice. This has led to calls for legislation for a protective environment for disclosure, alongside culture change and a supportive environment to disclose.
6.1.11 Sustainability of open disclosure

A consistent message from participants in the evaluation was that momentum from the pilots needs to be sustained, particularly in resourcing, progressing and embedding national policy and guidance across all hospitals, sustaining culture change in the long-term, and ultimately implementing open disclosure in all health and social care settings.

The creation of hospital groups, community healthcare organisations and multidisciplinary primary care networks, provide an organisational structure within which open disclosure can be progressed in primary and continuing community care, mental health services, social care settings and in health and wellbeing settings.

6.1.12 Impact of the pilot on open disclosure nationally

A key outcome from the pilot was the development, launch and high level of interest in the national policy and guidelines on open disclosure. The open disclosure pilot initiated and raised the profile of open disclosure nationally. The production and dissemination of the national HSE/SCA policy and guidelines on open disclosure was drawn up during and following the pilot phase and in consultation with the pilot sites. This was mirrored by a high profile consultation process and subsequent launch of the national open disclosure policy and guidelines by the Minister for Health, which, along with presentations from the pilot sites, generated significant national interest in open disclosure. The national policy framework on open disclosure is regarded as being a significant step forward in creating a culture of openness and transparency for staff and patients, and reflects an effective collaboration between the HSE and SCA.

6.1.13 Integration and alignment of open disclosure with other key policy areas

The alignment of open disclosure with the new policy framework on incident management, quality and patient safety is a positive development, resulting in a robust and integrated policy framework. Feedback from national HSE managers and from senior managers in the two pilot sites is that the implementation of open disclosure requires a sustained and long-term approach as part of ongoing and future strategic and policy developments to improve the quality of health and social care in Ireland. In this context, open disclosure is seen as part of a wider culture change in health and social care provision that enables and promotes service user/patient involvement and participation, and enhanced quality and patient safety.

At the national level, the integration of open disclosure in HIQA standards, HSE policies on quality and patient safety, and the introduction for the first time of KPI’s on open disclosure in the 2015 HSE Service Plan, all foster a greater potential for health and social care organisations to implement, own and support open disclosure at senior levels of management, leadership and governance. In this context open disclosure has the potential to become an important driver for quality improvement and systems learning across hospitals, as part of leadership and clinical governance on quality and safety. National clinical leads and local clinical governance champions are now in place, with more effective reporting arrangements. This has created a more accountable system, whereby clinical leadership and governance can more effectively implement, monitor and report on open disclosure.

Nationally open disclosure is an important part of the wider agenda to improve engagement with patients and front line staff, as well as to enhance quality and patient safety and open disclosure under the provisions of the National Patients’ Charter, ‘You and Your Health Service’ 2010.

A number of other policy priorities, including the development of a national policy and legislation on consent and the potential of a forthcoming legal framework to provide legal clarity and protection for clinicians when apologising to patients, will have an important bearing on open disclosure in the future.
Box 10 summarises the main recommendations suggested by managers and staff in the two pilot sites and national managers to further embed open disclosure in health and social care.

**Box 10: Summary of suggestions made by participants in the evaluation for the future implementation of open disclosure**

a) *Engagement at all levels and with all healthcare staff* and create strong leadership to form a supportive environment for staff to disclose and learn from incidents.

b) *Training and awareness* to instill culture change and staff engagement with open disclosure; integration of open disclosure into mandatory and specialty-specific training; and in undergraduate and post-graduate programmes for doctors, nurses, midwives and allied health professionals.

c) *Development of user-friendly and specialty and occupational specific examples and case scenarios* and short, accessible guidance materials to improve understanding.

d) Embed open disclosure through an organisational learning approach: including methods for auditing, measuring and providing feedback, reflection and learning from incidents at all levels, which can result in system changes and team learning.

e) *Supportive culture for staff*: Have a supportive culture for staff across the whole spectrum of adverse events from near misses and no-harm events and events with serious and catastrophic outcomes for patients and their families; give greater attention to staff involvement in learning from incidents and in implementing open disclosure.

f) *Multidisciplinary and specialist knowledge*: Have a multidisciplinary approach to disclosure, alongside learning and guidance that is informed by a specialist approach, covering different healthcare professions, occupations and medical specialties.

g) *Patient perspectives*: Give a greater focus to the experience of and feedback from patients/families to adverse events and open disclosure; treat patients/families as equal partners in healthcare; and enhance patient/family perspectives on open disclosure practice. Ensure patients are at the centre of any decision-making and discussion about quality improvements and service provision, and are facilitated to contribute to the effective implementation of open disclosure.

h) *Resources and expertise*: Sufficient national resources, including expertise dissemination and system-wide learning to fully implement open disclosure; further research, data and auditing of open disclosure and an improved evidence-base as a basis for system-wide, organisational and team learning.

**6.2 Recommendations**

Recommendations are made for the future role, development and implementation of open disclosure in the pilot sites and in all health and social care settings. Under each heading there is a key recommendation, which contains further detailed recommendations. The recommendations are informed by the evidence collected in the evaluation from the pilot sites and nationally, as well as by international research and best practice on open disclosure.
1. Leadership of the HSE and health and social care organisations

Key recommendation: Implement a national resource framework and HSE leadership to progress and implement open disclosure and a fair and just culture across all health and social care.

a) Provide a national resource framework to enable the national open disclosure leads to have sufficient resources and administrative support, to continue their work in implementing open disclosure. Deploy additional staffing resources to ensure full open disclosure implementation across all health and social care organisations.

b) Provide training for members of the HSE Leadership team to enable them to fully appreciate and champion open disclosure within relevant and emerging HSE policy developments and change management processes.

c) Promote a fair and just culture and implement open disclosure through continuous system-wide, organisational and team learning, reporting and quality improvement.

d) Embed and champion open disclosure in management, governance, leadership and reporting, with senior managers taking a lead in championing, mentoring and supporting junior staff to implement open disclosure.

e) Show visible organisational commitment to open disclosure, based on a value system that actively promotes support for staff and patients following an adverse event.

f) Promote learning from adverse events through the National Clinical Care Programmes (joint initiative between the HSE/Forum of Irish Postgraduate Medical Training Bodies).

2. HSE / SCA pilot leads

Key recommendation: Continue the successful partnership between the HSE and SCA and enable the pilot leads to take a strategic role in the roll-out of open disclosure, including the implementation of the national ‘train-the-trainer’ programme and e-learning module, and development of case studies, examples and guidance for health and social care professionals.

Take a strategic role

a) Enable the national leads to step back from the current focus of supporting individual hospitals so that they can play a more strategic role in providing expert advice, while also maintaining links and contacts already established with hospitals embarking on open disclosure in order to sustain momentum and provide guidance on auditing, monitoring and reporting on open disclosure.

b) Carry out periodic visits to hospitals to sustain the visibility and support already given to open disclosure and provide updates on a regular basis.

Train-the-trainer

c) Further develop the ‘train-the-trainer’ methodology, approach and practical resources to build capacity in the system.

d) Ensure that trainers are equipped with the skills and knowledge to deal with complex questions and case scenarios; it is imperative that this is carried out in partnership with clinicians in order to give the training credibility.

e) Ensure that trainers gain sufficient skills in order to act as on-site experts in supporting staff when open disclosure meetings take place and in assisting with the preparation for difficult meetings if they arise.
f) Develop a suite of high-quality training materials, setting out a step-by-step approach for an interactive training methodology, guidance on how to use case scenarios, and how to promote discussion, manage role-plays and gain feedback.

g) Organise an annual national meeting with trainers so that they can be updated and supported in their roles.

**E-learning module**

h) Progress and finalise the e-learning module and introduce a requirement that open disclosure, via the e-learning module, be a mandatory part of induction for all new staff.

i) Encourage and incentivise all health and social care staff to complete the e-learning module and provide CPD points for completing the e-learning programme.

j) Introduce a requirement that the e-learning module is completed prior to open disclosure training.

**Examples and case scenarios**

k) Draw up a wider range of examples and case scenarios to promote learning from real examples. These should be specific to a wide range of clinical and non-clinical areas and drawn up in consultation with different specialties and/or occupational groups, professional associations and health and social care training/education providers.

l) Include in these examples and case scenarios smaller and medium risk incidents, in addition to examples that have catastrophic consequences for patients.

**Guidance for health and social care professionals**

m) Draw up short and clear guidance, in the form of one or two page fact-sheets that focus on all levels of incidents and in the day-to-day interactions with patients and families. This means distilling the experience of open disclosure in managing adverse events to enhance the practice of open disclosure at ward level.

n) Tailor the guidance for different specialties, clinical areas and occupation groups. Specific guidance, for example, should be drawn up for radiology so that there is clarity about how open disclosure can be implemented through an informed and specialist approach in the event of a radiology error.

o) Include in the guidance procedures for managing communication and interaction with patients after an incident has arisen, how to carry this out in a timely way and in relation to specific incidents that arise. Have clear guidance about immediately providing patients with information and in taking preliminary advice from insurers.

p) Guidance should be written clearly, provide practical examples and be drawn up in consultation with health and social care professionals, and be accessible and relevant to a wide range of clinical and non-clinical staff.

q) Produce a model one-page flyer for display in clinical areas that states that the hospital supports a culture of open disclosure and sets out what this means in practice. Other examples of materials that can be developed include a small card containing simple facts about open disclosure and the ASSIST ME model, which can be slipped into a wallet or pocket, or short one-page guidance for clinicians.

r) Use the services of NALA to proof guidance materials for ‘plain English’ and accessibility.

s) Promote more good news stories for media reporting, including the effectiveness and benefits of open disclosure.
Open disclosure web site

t) Provide accessible information and guidance on the HSE open disclosure web page, linked to the SCA web site. Aim to provide podcasts of constructive learning and experiences from patients and staff, examples and case scenarios, in addition to all relevant policy and short guidance documents.

Ensure that open disclosure is accessible to all health and social care staff and patients

u) Put in place guidelines for staff on how to communicate with all patients/families in inclusive ways, for example, people with disabilities, people who speak different languages, and deaf people who communicate through sign language.

v) Draw on resources and guidelines from the Citizen’s Information Board and the National Disability Authority on communicating in accessible and inclusive ways.

w) Consider these issues in respect of HSE policy and guidelines on capacity to consent.

3. Pilot sites CUH and MMUH

Key recommendation: The two pilot sites are encouraged to continue to embed open disclosure through further training, identification of open disclosure champions in all Directorates, dissemination of learning from the pilot, and further implementation of staff support.

a) Continue to embed open disclosure through a new programme of awareness raising, grand rounds and training, updating of new staff and ensuring that training reaches all staff.

b) Implement training at the level of the Directorates, so that it is firmly embedded into these structures and across all teams.

c) Identify open disclosure champions in all Directorates who will drive and oversee the open disclosure programme.

d) Disseminate learning from MMUH’s on-line system for reporting of incidents to other hospitals and hospital groups and the experience of integrating open disclosure into complaints handling.

e) Disseminate the learning from CUH on the formal process established for the management of open disclosure following adverse clinical events and implement a system for documenting open disclosure meetings and their outcomes.

f) Further embed staff support in both pilot sites, including the development of guidance for line managers specifying the benefits of the ASSIST ME model, the different types of staff support that can be provided, the responsibilities of line managers to support staff immediately after an incident has occurred, during an incident review if this is carried out and during and after the open disclosure process.

g) Provide evidence for health and social care organisations beginning the journey towards open disclosure about the benefits of open disclosure, with evidence of how it has been tested and evaluated in the two pilot sites, and how it has been developed in Ireland in line with international evidence-based best practice.

h) Each pilot site should report back to the leadership team that originally approved the open disclosure implementation plan and policy, in order to show evidence of implementation. This should include an analysis of incident reports and investigations where open disclosure has taken place.
4. Roll-out of open disclosure (all health and social care organisations)

**Key recommendation**: The implementation of open disclosure in all health and social care organisations (hospital groups, hospitals, community healthcare organisations) should be fully completed within five years. During this time open disclosure should be fully integrated into all relevant health policies, and clinical and corporate policies and procedures on quality and patient safety.

**Hospitals and hospital groups**

a) All hospitals and hospital groups in Ireland should implement a framework for open disclosure to take place for all clinical adverse incidents by the end of 2016, with a view to fully implementing open disclosure within five years.

b) Ensure that open disclosure is a standing agenda item for reporting at Board and Executive level and through relevant quality and patient safety committees.

c) Emphasise how open disclosure is integral to clinical and corporate policies and procedures on quality and patient safety.

d) For hospital groups, put in place group-wide open disclosure policies, processes, training and shared learning.

e) Drive open disclosure through the new CEO’s hospital groups.

f) Identify open disclosure champions in each hospital group who will drive and oversee the open disclosure programme.

**Community healthcare organisations**

a) From 2015 onwards, implement a plan for open disclosure in non-hospital settings. This should start with a primary care open disclosure implementation project, led by the National Director for Primary Care and implemented through a ‘train-the-trainer’ approach led by the national open disclosure leads in the HSE and SCA. The project should give a specific focus to GPs and offer training and guidance for GPs in partnership with ICGP, the IMO and MPS. The objective is that within five years open disclosure will be implemented in primary and community care.

b) Take the learning from this as the basis for implementing open disclosure into mental health services, disability services and residential care for older people. It will be necessary to draw up guidance that is specific to each sector.

c) Ensure that open disclosure is effectively integrated into the work of primary care teams and across the wider community healthcare organisations. Align and coordinate open disclosure between hospital and primary/community care so that it is an integral part of communication during handover and hospital discharge, for example, to ensure that GPs are aware that if an adverse event has occurred that open disclosure has taken place.

d) Seek funding for a primary care open disclosure implementation project, with the objective of sharing learning and good practice approaches across all primary care teams.

e) Develop the ‘train-the-trainer’ programme for community healthcare organisations to include sector-specific guidance, case scenarios and resources relevant to primary care teams and GPs.

f) Draw together evidence, case scenarios that are relevant to a diversity of health and social care settings, and particularly in providing guidance on implementing open disclosure and communicating with people with mental health difficulties, people with physical and sensory disabilities and older people, and consider the implications of this in relation to consent policy.
5. The building blocks for open disclosure (all health and social care organisations)

Key recommendation: Ensure that all health and social care organisations put in place the essential building blocks for open disclosure. This should include measuring the culture of the organisation in relation to risk, fully implementing open disclosure in all relevant policies and procedures on quality and risk, appointing key personnel and open disclosure champions, providing practical guidance for staff and ensuring that open disclosure is a standard element of incident reporting and monitoring.

a) Measure the culture of the organisation in relation to addressing risk and ensure that open disclosure is embedded within a support structure for staff. Carry out a culture survey, or if resources are not available for this, conduct focus group discussions with groups of staff to measure perceptions of quality. This will form an important benchmark for measuring the impact of open disclosure on culture over time.

b) Ensure that clear processes and procedures are in place for open disclosure, drawing on the HSE policy and guidance. Ensure there are sufficient resources and key personnel (including open disclosure leads and champions who have expertise in open disclosure), training and awareness raising, guidance and resources for sustaining open disclosure in the longer-term.

c) Define and implement a resource framework that includes a team led by the Risk Manager/Open Disclosure Champion who are responsible for implementing open disclosure, with resources earmarked for awareness raising and training.

d) Ensure accountability and clinical ownership for open disclosure; ensure that Clinical Directorates have clear guidance and goals on how to implement open disclosure across Directorates.

e) Provide sufficient time and staffing resources to deliver open disclosure effectively.

f) Provide guidance for staff on how to document in the patient’s healthcare record the details of open disclosure discussions including when, where and under what circumstances open disclosure discussions have taken place and a summary of the salient points of the open disclosure discussion.

g) Integrate reporting on open disclosure into all complaints handling, incident reporting and incident management procedures, and document the timing and nature of disclosure, indicating if disclosure has taken place and the outcomes of disclosure.

h) All managers should be responsible for monitoring complaints and incident reporting and management with a checking system to ensure that open disclosure has taken place in their area of responsibility.

6. A supportive environment for staff to disclose and be supported through the process (all health and social care organisations)

Key recommendation: Provide an effective and inclusive system of support for staff, including clear responsibilities for line managers and teams, and peer and team support.

a) Provide enhanced systems of staff support as part of the process of instilling a culture of openness and transparency. Ensure that there is an effective system in place to create a safe environment for staff to disclose and support for staff at all levels during the open disclosure process.

b) Provide staff with access to support services following an adverse event and set out specific responsibilities for line managers and teams in relation to providing support utilizing the HSE ASSIST ME model and/or other occupational health support services.
c) Promote and validate an organisational culture of line manager and peer support as part of a fair and just culture.

d) Provide a system for regular staff feedback on how open disclosure is working in practice, what is working and what is not working, and whether it is taking place at all levels of the organisation.

e) Encourage clinicians to implement open disclosure as a means of allaying fears over fitness to practice. This is particularly important because evidence shows that disclosure can significantly reduce errors that lead to fitness to practice complaints and it is also likely that the outcomes of investigations will be less penalizing if there is evidence of disclosure.

7. Training and awareness raising (for all health and social care organisations)

Key recommendation: Provide awareness raising sessions for all health and social care staff, and implement more detailed accredited training for healthcare professionals and managers involved in open disclosure.

a) Training, education and awareness raising should be the starting point for implementing open disclosure. This is core to changing culture and to ensuring that there is openness and transparency following an adverse event.

b) Brief all staff in open disclosure and provide more detailed training for staff most likely to be involved in open disclosure discussions with patients and their families.

c) Carry out training for key staff involved in incident management and reporting and members of hospital quality and safety committees to ensure that senior managers and Clinical Directors cascade learning and champion open disclosure through all levels of the organisation.

d) Cascade training down to clinical teams, and implement multidisciplinary team responses regarding the kind of apologies to make and when to apologise.

e) Consider making open disclosure briefing/awareness mandatory for all health and social care staff and open disclosure training mandatory for all clinical and management staff including nurses, midwives, doctors and Allied Healthcare Professionals.

f) Ensure that there is protected time for staff to attend training. The HSE should carry out a short feasibility study to determine what the implications of this would be for hospitals, as well as for all health and social care organisations.

g) Incentivise clinicians to attend open disclosure training, by holding training at times when clinicians are available and in shorter blocks of time to ensure participation.

h) Ensure that training provides information and builds knowledge and skills in relation to how open disclosure benefits patients, staff and the organisation.

i) Provide real life case scenarios in training, simulated with patient and staff actors, to enable participants to review a range of strategies and communication skills required to manage different types of adverse events.

j) Include response procedures to adverse events, emphasise communication in relation to breaking bad news, apologising, listening and responding compassionately, and show the importance of taking patient experiences into account to improve the disclosure process. Give practical guidance on how to apologise and demonstrate how important ‘saying sorry’ is when apologising or expressing regret.

k) Provide CPD points for attendance at training on open disclosure.

l) Include patients’ experiences and perceptions of open disclosure, and Involve patients/family members who have been affected by an adverse event and/or open disclosure in training.
8. Organisational learning and feedback loops (for all health and social care organisations)

Key recommendation: Implement an effective system for organisational and team learning, and staff feedback, following an adverse event.

a) The experience of implementing open disclosure, or the consequences of not doing so, should become the basis for organisation learning, reflection and quality improvement.

b) Support and change practice by involving people who have engaged positively with open disclosure, using them as a resource for support and learning.

c) Consider implementing peer review processes so that learning can be translated into enhancements in quality and patient safety.

d) Enable multidisciplinary teams to carry out reflective practice and a learning approach following adverse events so that there is learning from what went wrong. This should play a key role in fostering a culture where incidents are discussed as opportunities for learning about how to prevent and deal with adverse events, as the basis for improved quality and patient safety.

e) Provide guidance on how multidisciplinary teams can engage in training, discussion and learning post-incident, and ensure that time is prioritised for this.

9. Enhance the voice and involvement of patients and their families (for the HSE and all health and social care organisations)

Key recommendation: Provide an effective system for patient/family involvement, support and feedback, and ensure that patients’ perspectives are at the forefront of all open disclosure developments, including awareness raising and training.

Patient/family feedback and support during the open disclosure process

a) Ask for patient/family feedback following an adverse event and whether their experience met with their expectations. Use this as the basis for learning and improvement going forward.

b) Provide both short-term and long-term support to patients/family members affected by an adverse event, in recognition of the diversity of patients’/family members’ needs for support, which may include the need for information and support on an ongoing basis for several months after an event.

c) Examine how patient advocacy, both through independent advocacy and advocacy provided by health and social care professionals/Patient Liaison Officers, can be further developed in supporting patients/family members after an incident has occurred and pre, during and after open disclosure.

Patients’ perspectives at the forefront of open disclosure developments

d) Continue, through the HSE Quality Improvement Division, to promote patient/service user involvement, with a specific focus on gaining patient feedback in open disclosure.

e) Carry out open disclosure implementation projects in partnership with patients and families, and do so in line with the requirements of the national Patient’s Charter, ‘You and Your Health Service’ 2010.

f) Support senior managers to ensure that they have the required skills for effective communication in managing patient involvement and feedback, and ensure that there is learning from feedback.
g) Carry out patient surveys and practice-based research to measure patient expectations and experiences of open disclosure as part of the management of adverse events. Practice-based qualitative research should point to ways to improve patient satisfaction.

h) Ensure that all reporting on incidents and complaints in the future includes specific questions about patient/family perceptions of open disclosure, for example, asking, “was the patient told?” “what were they told?” “did the patient fully understand what she/he was told?” and “what arrangements have been put in place to communicate further information to the patient/family?”

i) Commission a study in the two pilot sites to review the experiences of patients/families involved in adverse events and open disclosure processes, as a basis for enhancing overall quality and patient safety, and specifically to enhance awareness about open disclosure from a patient/family perspective.

10. Data, information management and further research on open disclosure (for the HSE/SCA and all health and social care organisations)

Key recommendation: Ensure that data and information is collected on open disclosure in a standardised way, carry out regular reviews and audits of the implementation of open disclosure, and implement further research to identify the impact of open disclosure on incident management, in reducing claims and on patients’ perspectives of open disclosure.

a) Implement standardised open disclosure outcome and process measurements, including a standardised HSE templates for reporting on open disclosure to ensure that all reporting on open disclosure, including KPIs, is systematic and comparable across all health and social care organisations.

b) Develop a system for auditing and reviewing the work carried out in the roll-out of open disclosure. For example, this could be carried out as part of the development of the QPSA audit function, which has involved clinical auditors carrying out an audit of the incident management process in 2014. It is suggested that a specific QPSA audit be carried out on open disclosure in 2016. This audit could also include the role of education and awareness raising in terms of how it can lead to change in organisational culture and working practices in the longer-term.

c) Carry out joint HSE/SCA research on the linkage between open disclosure and trends in incident and complaints reporting.

d) The impact of open disclosure on the reduction in claims will need to be tested out in the future, with data collected through appropriate monitoring and reporting. From 2016/2017 onwards the SCA should begin to track claims over the previous four or five years. This should examine whether claims were made after open disclosure took place in serious incidents.

e) Introduce systems to regularly monitor and evaluate open disclosure, including feedback from both patients and staff, with a view to enhancing the quality and implementation of open disclosure. This should ensure that reporting on open disclosure is supported through new technology, for example, through the Quality Dashboard and other relevant incident reporting arrangements.

f) Carry out a pilot in the open disclosure pilot hospitals (CUH and MMUH) on the implementation of a system for tracking data on open disclosure through incident and complaints reporting, and how best to assess clusters of issues that need to be taken into team and organisational learning.

g) Include open disclosure as a mandatory question on NIMS and supplement this with a range of secondary fields in the database linked to HIQA standards. Include open disclosure in the annual reporting on incidents and claims. This is important in ensuring that senior managers have an oversight of how open disclosure is being managed and implemented and to inform learning across the organisation.
h) Consideration should be given to piloting and reporting on open disclosure under NIMS in the two pilot sites. This could commence with MMUH, which was a national pilot site for NIMS through the development of the innovative on-line reporting system.

i) Open disclosure as policy and practice is still in its early stage of development and to date remains a relatively under researched area. The evaluation was unable to fully evaluate the impact of disclosure on patients/families following adverse events for practical and ethical reasons. This is, however, an important area for future research and evaluation, particularly in providing an evidence base for patient/family perceptions and expectations of open disclosure in all health and social care settings.

11. Education providers, health and social care professional and regulatory bodies

Key recommendation: Open disclosure should be fully and effectively integrated into training, guidance and policies implemented by health and social care education providers and health and social care regulatory and professional bodies.

a) Include open disclosure in under-graduate and post-graduate training programmes, and in core and ongoing training for health and social care professionals, for example, provided by nursing and midwifery planning and development units, the National Board for Curriculum Development and the Higher Education Authority. Incorporate open disclosure into relevant training in other areas, such as obstetrics emergencies.

b) Work with university and college providers, professional regulatory bodies, professional associations and healthcare trade unions in the development of their individual roles in providing initial education and ongoing professional development on open disclosure as part of communications, and quality and patient safety.

c) Continue the excellent collaboration and partnership with the RCSI and RCPI in developing case scenarios using actors to role play staff and patients/family members.

d) Work closely with all health and social care professional and regulatory bodies, including Ireland’s multi profession health regulator, CORU, to encourage them in having a direct role in providing resources, guidance and training for their members, and to include the requirements for open disclosure in their Codes of Conduct/Codes of Practice and other professional guidance documentation.

e) In addition to providing CPD points for training, professional and regulatory bodies should consider offering accreditation for the submission of documented evidence of personal reflection on the management of adverse events and open disclosure, including evidence of learning from the research literature and practical learning from adverse events.

f) Establish an education provider forum, led by the HSE and Department of Health, for promoting good practice in under-graduate, post-graduate and ongoing professional development of health and social care professionals.
Appendicies and References
Appendix 1: Evaluation materials

i) Interview guide for staff, managers and clinicians who participated in the pilot and/or who were involved in Open Disclosure meetings

Prior to the interview a short introduction will be given of the aims and objectives of the evaluation and the confidentiality and ethics of the evaluation. An information sheet and consent form will be given to all interviewees to sign. Participants will be asked for information about their job title and role in the Open Disclosure pilot.

1. What is your understanding of Open Disclosure and how it has been applied in your hospital?
   - Are you aware of your hospital’s policy/guidelines on Open Disclosure?
   - Are you aware of the HSE’s national guidelines on Open Disclosure?
   - How helpful have these been to you in preparing for and implementing Open Disclosure?

2. What are the main elements of the Open Disclosure process in your hospital?
   - How has the Open Disclosure process been implemented?
   - How has your hospital developed Open Disclosure procedures?
   - Who is normally involved in Open Disclosure meetings?
   - What have been the main benefits of being a pilot site?

3. Please describe any specific Open Disclosure meetings / sessions that you have been involved in.
   - How has Open Disclosure been carried out (pre-meetings, communications prior to meeting, during meeting, follow up)
   - How did you plan for Open Disclosure and who did you involve in the process?
   - Could you say a few words about how patients/family members were supported. Were they given the opportunity to record the OD meeting?
   - How were apologies made and received?
   - How was the meeting recorded/minuted? Was this record shared with the patients/family members?
   - What follow-up communication was carried out with patients/family members?
   - How did patients/family members perceive the outcomes and what feedback did you receive from them during and after the process?
   - How would you describe the outcomes?
   - How have staff been supported through the process? (e.g. use of ‘Assist Me’ guidelines)

4. Please could you give some feedback on the workshops/awareness raising and resources provided by the HSE on Open Disclosure.
   - Was the training sufficient to enable you to implement Open Disclosure?
   - How useful were the resources provided (workbook and reference materials)
   - What was the most important learning for you?
   - Do you think further training is necessary?
   - Was sufficient support provided during and after the workshops from the HSE team?
   - Any other feedback on the methods used in the training or the resources provided?

5. How is information about the Open Disclosure process (and the HSE policy) disseminated to staff?

6. How have staff and clinicians been involved in Open Disclosure? Have there been any specific barriers/challenges to getting full involvement from all staff and/or clinicians?

7. What has worked for your hospital? Have practices and methods of communications changed?
8. Did you encounter any barriers or difficulties? If so, how were they managed?

9. Have there been any perceived changes in patient safety culture within the hospital?

10. What are the main benefits of Open Disclosure? Has your hospital benefited from being one of the pilot sites?

11. Do you anticipate any problems or risks related to Open Disclosure?

12. Finally, do you think that the principles of Open Disclosure have been applied in your hospital? What else do you think needs to be done? Do you have any suggestions about the implementation of Open Disclosure in your hospital and nationally?

ii) Interview guide – National policy makers

The objective of the interview is to identify a) how Open Disclosure is integrated into and can be further progressed in key HSE policies, and b) to gain feedback on the implementation and development of Open Disclosure policy across all healthcare settings.

1. What have been the main drivers for Open Disclosure nationally?

2. What have been the main successes and challenges in progressing Open Disclosure nationally?

3. How do you think that Open Disclosure has impacted on quality and patient safety, and a change in culture in acute hospital settings?

4. To what extent have the two pilot projects set an appropriate framework for the implementation of Open Disclosure nationally?

5. How has Open Disclosure been integrated into national policy frameworks on patient safety? What challenges still remain and what do you foresee as being important to implementation in the future? How will this be further developed under the planned Patient Safety Agency?

6. What is your view about the proposal for forthcoming legislation on Open Disclosure and what would represent a best practice approach to this?

7. What else do you think needs to be done to fully implement Open Disclosure in a) hospital settings and b) primary and community care settings?

8. How can financial and staffing resources be mobilized for training and support in roll-out Open Disclosure across the HSE?

9. How do you see Open Disclosure developing in the next five years? What opportunities and challenges does this present?

10. What suggestions do you have for the development of leadership, management and governance of Open Disclosure across all healthcare settings in the future?

11. Any other comments or feedback that you think are relevant to the future development of Open Disclosure across the HSE.

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7 For example, HSE Incident Management Policy, Quality and Patient Safety, National Healthcare Charter, Clinical Governance processes and national clinical programmes as well as HIQA National Standards for Safer Better Healthcare 2012.
iii) Focus group questions

As part of the national evaluation, focus group discussions will be held to discuss the role and impact of Open Disclosure.

The following four questions will guide the discussion in the focus group:

1. What is your understanding of Open Disclosure and how it has been applied across the hospital and in the Directorate where you work?

2. What are the main benefits of Open Disclosure for your practice (in dealing with adverse events and communicating with patients/family members)?

3. What are the main enabling factors, as well as challenges or difficulties, in implementing Open Disclosure?

4. What suggestions do you have for the future implementation of Open Disclosure?

iv) Evaluation Briefing

EVALUATION OF THE NATIONAL OPEN DISCLOSURE PILOT PROJECT

Background

Between 2010 and 2011 the HSE and the State Claims Agency ran a national Open Disclosure Pilot project at two sites, the Mater Misericordiae University Hospital, Dublin and Cork University Hospital. The pilot project provided awareness raising and training for doctors and other healthcare professionals to support them in engaging in the Open Disclosure process. The pilot led to the development of a national policy and guidelines on Open Disclosure.

The evaluation of the pilot project will inform the implementation of a standardised national Open Disclosure framework across all health services. The objective is to progress, foster and support a culture of openness in an informed, sensitive, inclusive and safe environment.

What are the objectives of the evaluation?

• To evaluate the implementation of Open Disclosure in the two pilot sites.

• To evaluate the learning from the pilots in relation to international evidence based practices and agreed principles on Open Disclosure.

• To evaluate the learning in relation to the role of national policy developments and implementation across acute healthcare settings.

What will be covered in the evaluation in the two pilot sites?

• Were the project objectives met, and were sufficient resources, including awareness raising, training and support, deployed to meet the objectives?

• What worked in the pilot projects, what were the main enabling factors and what were there any barriers to implementation of Open Disclosure?

• What has been the main impact of the pilot, for example, in relation to changing practice and culture and to how staff manage and deal with adverse events, as well as the impact on claims, complaints and patient safety?

• What is the main learning from the pilot project for staff/patients and the organisation overall, and in relation to how Open Disclosure can be implemented in all healthcare settings?
How will the evaluation be carried out?

In each pilot site staff and managers participating in the pilots will be invited to complete a questionnaire, which will be followed up by interviews and focus groups. A final evaluation report will be completed by the end of July 2014.

The evaluation is being carried out by an independent evaluator, Dr. Jane Pillinger.
Appendix 2: Policy developments impacting on open disclosure – additional information


Standard 3.5

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.

Features of a service meeting this standard are likely to include:

3.5.1 Promotion of a culture of quality and safety which includes open disclosure with service users, and where appropriate their families and carers, following an adverse event.

3.5.2 Arrangements to support service users following an adverse event. Service users are informed about and provided with information on support services, including independent patient support services, and how to access them.

3.5.3 Ensuring service users have the opportunity to be involved in the investigation process following an adverse event and are kept informed of progress.

3.5.4 Actively seeking and taking into account the needs and preferences of service users affected by an adverse event.

3.5.5 Fair and transparent arrangements to support and manage staff who have been involved in an adverse event. The fitness of such staff to return to work is ascertained before they return to normal duties.

Standard 5.7

Members of the workforce at all levels are enabled to exercise their personal and professional responsibility for the quality and safety of services provided.

Features of a service meeting this standard are likely to include:

5.7.1 Teams and individuals who are supported and managed to effectively exercise their personal, professional and collective responsibility for the provision of high quality, safe and reliable healthcare.

5.7.2 Promotion of a culture of openness and accountability throughout the service, so that the workforce can exercise their personal, professional and collective responsibility to report in good faith any concerns that they have in relation to the safety and quality of the service. Individuals reporting these concerns are not negatively affected as a result.

5.7.3 Facilitation of members of the workforce who wish to make protected disclosures about the quality and safety of the service in line with legislative requirements.

HIQA Guidance on Open disclosure

All adverse events that have caused harm should be disclosed to the service users involved. Harm is the impairment of the structure or function of the body and or any detrimental effect arising there from. Harm includes disease, injury, suffering, disability and death. When an adverse event occurs the first priority is prompt and appropriate clinical care of the service user in order to minimise the impact of the adverse event or prevent further harm and this is reflected in a service’s arrangements for disclosure and management of adverse events.
International evidence and research highlights that open, honest and transparent communication between service providers and service users is important following an adverse event as this can help service users, their families and carers understand and come to terms with what has happened and any potential implications for their health. The evidence also suggests that service users also want to know what the service provider intends to do to prevent similar events occurring in the future.

Open disclosure refers to the open and honest discussion of incidents that have caused harm to a service user while receiving healthcare. It is an ongoing communication process with service users and their families or carers. This process includes the initial conversation and follow-up conversations in which the service user is provided with information of any investigation, associated timelines and the actions the service provider intends to take to prevent a similar incident happening again. Service users are also invited to participate in the investigation if they so wish.

Service providers develop and implement clear open disclosure arrangements in partnership with service users and independent patient support services where relevant. Open disclosure arrangements reflect the fact that different levels of harm may occur as a result of an adverse event and that accordingly different levels of management of the event and communication with service users may be required.

Examples:

- Service providers have clear and documented open disclosure policies and procedures with associated timelines.
- Service providers provide education and training on open disclosure to members of the workforce specific to their role.

**Support for the workforce**

When a service user experiences an adverse event, individual members of the workforce involved in the care of the service user are also affected by the event and may require support and advice. Service providers have arrangements in place to facilitate members of the workforce to access any assistance or support they may require.

Examples:

Service providers have in place peer support arrangements that can be information or formal, including team briefings.

People working in the service are provided with information on the different support systems currently available for members of the workforce. These support systems may include employee assistance schemes, external counselling services and internal peer support programme.

Service providers keep members of the workforce who have been involved in an adverse event updated on the investigation and its outcomes.

**Protected disclosure**

Protected disclosure as set out in the Health Act 2007 provides legal safeguards for individuals who wish to report serious concerns they have about standards of safety or quality in Irish health and social care services.

Members of the workforce are informed of the protected disclosure arrangements in place in their service and given details about how to make a protected disclosure as part of their induction training in patient safety. Information on the protected disclosure arrangements in place in a service are made publicly available to members of the workforce.
Example:

- Information on the protected disclosure arrangements in place, including how to make a protected disclosure or who to contact for information about this, is available on the staff intranet and is displayed on staff notice boards throughout a hospital.


2. National Clinical Programmes Model of Care Development Checklist Governance for Quality and Safety (HSE Clinical Strategy and Programme Division and the Quality and Patient Safety Division 2014)

The checklist provides a guide to National Clinical Programme teams in the development of models of care in each national clinical programme. The completion of the Checklist (updated October 2014) assists leads in ensuring that quality and safety governance arrangements are incorporated in the model/pathways of care and is a requirement prior to authorisation of the model by the National Director. It specifies that a culture of trust, openness, respect and caring is evident among managers, clinicians and staff on the basis that: “It is about people receiving the right care, at the right time, from the right person in a safe, honest, open and caring environment”. The objective is that it will assist clinical leads in determining the structures and processes for quality and safety. Specific reference is made to Open Disclosure (HSE 2014, p.3). Specific questions are included in the checklist about whether the model of care:

- Links with existing risk management processes in line with national policy and standards regarding: risk identification, recording and reporting risk mitigation/risk reduction incident/adverse event reporting, learning from mistakes, applying learning from incidents to promote a culture of patient partnership, and promoting a culture of openness and accountability.
- Provide a mechanism for any team member to raise concerns about the quality and safety of the service (for example Protected Disclosure, Trust in Care or Good Faith Reporting).
- In addition, the checklist asks about the system of corporate governance to meet the necessary standards for accountability, integrity, openness and transparency.

3. Quality and Safety Committee: Guidance and Sample Terms of Reference (May 2013)

Guidance and sample terms of reference in establishing i) Quality and Safety Board Committees and ii) Quality and Safety Executive Committees. This guidance contains a standard meeting agenda aligned with the themes of the National Standards for Safety Better Healthcare (2012). Reference is made to progress on implementation of open disclosure policy.

4. Quality and Safety Walk-rounds (May 2013)

Toolkit providing a structured approach to bring senior managers and front line staff together in discussion about quality and safety to prevent, detect and mitigate patient/staff harm.

5. Safety Pause Information Sheet (May 2013)

Practical guide on why, who, when and how approach to the Safety Pause, which aims to increase safety awareness and assists teams in being proactive about the challenges they face in providing safe high quality care for patients. It centres on one question ‘what patient safety issues do we need to be aware of today’ resulting in immediate actions. Although not specifically focusing on open disclosure, the information sheet is relevant in preventing mistakes or errors from occurring.
6. Guiding principles on clinical governance (HSE 2012)

Open disclosure requires “a culture of trust, openness, respect and caring is evident among managers, clinicians, staff and patients” (p.2). It is one of the ten principles of good clinical governance, on the basis of an open culture: “A culture of trust, openness, respect and caring where achievements are recognised. Open discussion of adverse events is embedded in everyday practice and communicated openly to patients. Staff willingly report adverse events and errors, so there can be a focus on learning, research and improvement, and appropriate action taken where there have been failings in the delivery of care” (HSE 2012).

7. Clinical governance development Matrix (HSE 2012)

The matrix is designed to assist the development of clinical governance, based on the principles, structures, process and anticipated outcomes of good clinical governance.

8. Quality and Patient Safety: Clinical Governance Development: an assurance check for health service providers (HSE 2012)

The document provides a series of practice statements regarding: i) clinical governance structures and ii) clinical governance processes to assist the implementation of clinical governance arrangements in preparation for meeting theme 5 on leadership governance and management of the National Standards for Safer Better Healthcare (2012).

9. Quality and Safety prompts for multidisciplinary teams (HSE 2012)

Provides a guide for local multidisciplinary teams to use in discussing quality and safety at team meetings in line with the principles for good clinical governance and aligned with the themes of the National Standards for Safer Better Healthcare (2012). Under ‘Safe Care’ questions include: ‘Do we identify, openly disclose, manage, investigate and escalate incidents adverse events and near misses?’ (Q20); ‘How do we receive and discuss reports on the number and type of incidents?’ (Q21); and ‘Do we learn from incidents and implement quality improvements?’ (Q22).

10. Corporate governance system to improve efficiency, accountability, openness and transparency in line with best practice (HSE 2011)

The clinical governance system is based on overall responsibility and governance from the Board for the hospital group or community healthcare organisation and a quality and safety committee of the Board; and leadership and management from an Executive Management Team, with a quality and safety executive committee and committees for quality and safety.
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Evaluation of the National Open Disclosure Pilot


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