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An Roinn Sláinte
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DUTY OF CANDOUR & BEING OPEN – POLICY PROPOSALS FOR CONSULTATION

MARCH 2021

This report summarises the policy proposals developed by the Duty of Candour Workstream and Being Open Sub Group in order to implement the relevant recommendations arising from the report of the Inquiry into Hyponatraemia-Related Deaths, for public consultation.

Foreword by Workstream Chair

This has been a remarkable process in an important cause.

Since Justice O'Hara's Hyponatraemia Inquiry Report was published in 2018, Health and Social Care in Northern Ireland has responded to the challenges laid out so clearly to change the culture and behaviours that had led, two decades before, to five avoidable children's deaths. However, as we have seen in a number of recent high-profile cases, there is still work to be done in order to ensure a consistently open and honest health and social care service.

Many of the old habits and behaviours that had enabled the poor practice in the first place have been corrected; better management, regulation and training have each made an impact. Nevertheless there is more to be achieved. O'Hara's flagship recommendations on legally enforceable organisational and individual duties of candour, with criminal sanctions, would require primary legislation in the Assembly, as will others of the 96 recommendations.

In order to explore the Duty of Candour and Being Open recommendations, we embarked on an ambitious and comprehensive co-production process, involving hundreds of HSC practitioners and clinicians, dozens of representative organisations, unions, Royal Colleges and professional bodies, but above all, thousands of patients, carers and service users, who have guided and assisted us in preparing this document.

The result is certainly comprehensive, detailed and clear in its messaging – more needs done to improve our fantastic health and social care service, to deliver better outcomes in a safe and transparent manner; this needs to be underpinned by legislation, strong

FOREWORD BY WORKSTREAM CHAIR

guidance and robust regulation. Above all it cries out for inspirational leadership from our managers whom we ask to champion the values outlined across the HSC.

This forthcoming public consultation offers a further opportunity for interested parties to provide insights and views on whether we have it right; and on the options for implementation; are there things we have missed? Any unintended consequences? Any improvements we could take on board?

The Department of Health will collate and analyse the submissions, engaging the Workstream again to help interpret and assess what the public has reported, and how best to proceed with final implementation recommendations to the Minister.

I pay tribute to those who have contributed to this extensive co-production exercise, leading to a more meaningful and grounded output; many hours, many pages, many meetings, latterly online only, of course have been invested. The two Workstreams, Duty of Candour and Being Open, merged in early 2020, better to integrate the final proposals; thank-you to Peter McBride who chaired the Being Open activity for the first two years, before moving to the USA; and thanks also to the past and current departmental staff across the IHRD programme, who helped throughout with wisdom and care.

We owe it to the bereaved families to see this assignment through to its conclusion.

Quintin Oliver

Chair, Duty of Candour Workstream, IHRD Programme

Contents

1. Executive Summary

1.1. This document summarises the policy proposals for a statutory Duty of Candour for Northern Ireland. These proposals have been developed for public consultation by the Duty of Candour Workstream and its Being Open Sub-group, as part of the Hyponatraemia Implementation Programme being taken forward by the Department of Health (DoH).

1.2. **Section 2** sets out a brief background into the Inquiry into Hyponatremia-Related Deaths, the establishment of the Duty of Candour Workstream, and an overview of the work it has undertaken. It also summarises the call for evidence, engagement with individuals and organisations, and involvement workshops.

1.3. Sections 3, 4 and 5 set out the policy proposals developed by the Workstream, and its Sub-group, for public consultation. **Section 3** outlines the proposed policy for a statutory organisational Duty of Candour.

1.4. **Section 4** sets out a range of policy options to implement a statutory individual Duty of Candour. Here, the Workstream has not recommended one particular option, but instead presents a number of options for public consultation, based on the Workstream's outreach, research and engagement work.

1.5. **Section 5** provides an overview of the proposed framework for openness and honesty within health and social care, including proposals for the guidance which will accompany any Duty of Candour legislation.

1.6. **Section 6** provides more information on how to respond to the public consultation, as well as the screening exercises completed by the DoH in respect of these policy

proposals. Further information is also included in respect of privacy, confidentiality and access to consultation responses submitted.

1.7. **Annex A** sets out a glossary of terms and abbreviations to support the Duty of Candour and Being Open policy proposals.

1.8. Consultation questions are incorporated throughout the document, and a separate composite list of all the consultation questions is also available on the Departmental website here.

2. Background

2.1. This section provides a brief background into the Inquiry into Hyponatremia-Related Deaths, the establishment of the Duty of Candour Workstream, and an overview of the work it has undertaken.

Inquiry into Hyponatraemia-Related Deaths (IHRD)

2.2. On January 2018, the report[1] on the Inquiry into Hyponatraemia-Related Deaths (IHRD)[2] was published following an extensive investigation into the deaths of five children in hospitals in Northern Ireland. After hearing evidence from a wide range of individuals and organisations, it concluded that the five deaths had been avoidable. It also concluded that the culture of the health service at the time, the arrangements in place to ensure the quality of services, and the behaviour of individuals had all contributed to those unnecessary deaths.

2.3. The report sets out 96 recommendations across 10 themes where Justice O'Hara identified failings in -

- Competency in fluid management;
- Honesty in reporting;
- Professionalism in investigation
- Focus in leadership;

[1] http://www.ihrdni.org/Full-Report.pdf

[2] Further information on the Inquiry can be found here http://www.ihrdni.org/

and

- Respect for parental involvement.

2.4. In developing the recommendations, the IHRD report was guided by five principles:

- That healthcare exists to serve the patient;
- That the quality of healthcare is dependent upon both clinical and non-clinical services;
- That the particular needs of children must be addressed;
- That leadership and candour must be accorded the utmost priority if the fullest learning is to be gained from the error;

and

- That progress should be subject to regular internal review.

2.5. One of the key recommendations made by the Inquiry related to the introduction of a statutory Duty of Candour for healthcare organisations and a separate Duty of Candour for all staff. Justice O'Hara also recommended that "criminal liability should attach to breach of this duty and criminal liability should attach to obstruction of another in the performance of this duty". Accompanying these two specific recommendations regarding the statutory duties of candour, were recommendations regarding the guidance, support and protection that should be provided for staff in order to create a more open and honest culture.

2.6. The recommendations made in respect of the statutory duties of candour were as follows:

Recommendations	
1	A statutory Duty of Candour should now be enacted in Northern Ireland so that:
1(i)	Every healthcare organisation **and** everyone working for them must be open and honest in all their dealings with patients and the public.
1(ii)	Where death or serious harm has been or may have been caused to a patient by an act or omission of the organisation or its staff, the patient (or duly authorised representative) should be informed of the incident and given a full and honest explanation of the circumstances.
1(iii)	Full and honest answers must be given to any question reasonably asked about treatment by a patient (or duly authorised representative).
1(iv)	Any statement made to a regulator or other individual acting pursuant to statutory duty must be truthful and not misleading by omission.
1(v)	Any public statement made by a healthcare organisation about its performance must be truthful and not misleading by omission.
1(vi)	Healthcare organisations who believe or suspect that treatment or care provided by it, has caused death or serious injury to a patient, must inform that patient (or duly authorised representative) as soon as is practicable and provide a full and honest explanation of the circumstances.
1(vii)	Registered clinicians and other registered healthcare professionals, who believe or suspect that treatment or care provided to a patient by or on behalf of any healthcare organisation by which they are employed has caused death or serious injury to the patient, must report their belief or suspicion to their employer as soon as is reasonably practicable.
2	Criminal liability should attach to breach of this duty and criminal liability should attach to obstruction of another in the performance of this duty.
3	Unequivocal guidance should be issued by the Department to all Trusts and their legal advisors detailing what is expected of Trusts in order to meet the statutory duty.
4	Trusts should ensure that all healthcare professionals are made fully aware of the importance, meaning and implications of the Duty of Candour and its critical role in the provision of healthcare.

6	Support and protection should be given to those who properly fulfil their Duty of Candour.

IHRD Implementation Programme

2.7. In response, the DoH established the Hyponatraemia Implementation Programme[3] to take forward the recommendations arising from the Inquiry[4]. The DoH identified over 200 people from different backgrounds to participate in the nine Workstreams which formed the core of the programme, to co-produce policies and procedures to implement the recommendations of the review. These individuals include service users and carers, representatives of the community and voluntary sector, people from health and social care organisations, regulators, professional bodies, Royal Colleges and trade unions, non-executive directors of health and social care organisations, and Departmental staff.

2.8. The Programme's Duty of Candour Workstream[5] is responsible for developing the detailed proposals to address the recommendations focusing on the statutory Duty of Candour. The Workstream's Being Open Sub-group is responsible for developing proposals for the guidance and support needed for organisations and staff to meet the spirit of the recommendations on candour in advance of a statutory duty coming into place[6]. The aim of both groups is to develop proposals

[3] https://www.health-ni.gov.uk/HIP

[4] https://www.health-ni.gov.uk/news/department-healths-response-report-inquiry-hyponatraemia-related-deaths

[5] https://www.health-ni.gov.uk/articles/ihrd-Workstream-1-duty-candour

[6] https://www.health-ni.gov.uk/articles/ihrd-Workstream-1-duty-candour-being-open-Sub-group

to ensure a consistent culture within the health and social care service which allows staff, service users, and carers to speak up when things go wrong.

2.9. Following initial induction sessions in October 2018, the groups alternated between separate group meetings and joint Workstream meetings throughout 2018 and 2019 before merging in 2020 to agree the policy proposals for public consultation. In October 2020, the draft proposals were reviewed and agreed by the IHRD Programme's Assurance Workstream, which independently reviews the proposals developed by individual Workstreams to implement the IHRD recommendations, against an assurance framework developed for the programme. This framework sets out the tests to be met and evidence to be provided by the HSC/Department in order to provide assurance that each recommendation has been implemented.

2.10. The IHRD Programme has a mechanism in place with the DoH Permanent Secretary to liaise with the families involved in the IHRD. To date, the Workstream has not engaged directly with the families in respect of the Duty of Candour recommendations.

Research

2.11. A number of research papers were commissioned by the Workstream in order to assist discussions, to better understand the approach to candour in other jurisdictions and lessons to be learned from their implementation of any policy or legislation, and to identify the legal issues that will impact upon this policy area.

These research papers were published in February 2019[7], and links to the papers are set out below:

Key Analysis Papers

- Individual Duty of Candour Options Research
- Duty of Candour – Key to successful implementation
- Discussion Paper on Human Rights and Legal Issues
- Duty of Candour – Guidance and Resources

Background Papers

- Statutory Duty of Candour in England
- Duty of Candour in other jurisdictions
- Why Trust is a Must in Organisations

Call for evidence

2.12. Alongside the publication of its research papers, the Workstream sought written submissions of additional evidence from stakeholders. Fifteen submissions were received and were considered by the Workstream. Organisational responses, which were published on the DoH website[8], were received from:

- Action Against Medical Accidents (AvMA);
- Pharmaceutical Society Northern Ireland;

[7] https://www.health-ni.gov.uk/articles/ihrd-get-involved-duty-candour#toc-4

[8] https://www.health-ni.gov.uk/publications/ihrd-duty-candour-and-being-open-call-evidence-submissions

- Professional Standards Authority;
- British Dental Association (NI);
- British Medical Association (NI);
- Northern Ireland Public Services Ombudsman;
- Nursing and Midwifery Council;
- General Medical Council;
- Royal College of Psychiatry (NI);
- The Medical Defence Union;

and

- The British Association of Social Workers.

Involvement and Engagement

2.13. The development of any policy is based on research, evidence and intelligence-gathering. Although the Duty of Candour Workstream and its Being Open Sub-group have a diverse membership, it recognised that the involvement of a further range of stakeholders was a crucial element for intelligence-gathering to consider how the recommendations could be put into place effectively. The emphasis was on pre-consultation scoping, through the engagement of a range of stakeholders to hear their views, concerns, barriers, perceptions etc. as to how Justice O'Hara's recommendations could be implemented with efficacy and without unintended consequences.

2.14. To support the development of proposals, the Workstream and Sub-group undertook an extensive programme of involvement and engagement to understand the impact of the proposals more profoundly amongst a range of stakeholders. This is in line with the approach developed from the outset of the programme of work, effectively to co-produce with people who deliver HSC services and people who use HSC services. This pre-consultation phase provided extensive evidence to support the policy-making process.

2.15. Beginning in May 2019, the groups held a number of involvement workshops to ask key stakeholders the question, “What does a Duty of Candour mean for Health and Social Care?”. At these workshops, attendees discussed the potential barriers to implementing the recommendations in relation to a Duty of Candour, what support would be needed to overcome these barriers and considered the issue of criminal liability for breach of the duty.

2.16. These events included:

- Six workshops across all five HSC Trust areas with staff from a range of grades and disciplines;
- Three workshops with service users and carers, two sessions at PCC Membership Events and a further event hosted by the Workstream;
- Two workshops with the community and voluntary sector convened by NICVA;
- Workshops with representatives of the Social Work and Social Care sector;
- A workshop with Independent Health and Care Providers;
- A small workshop with a single Private Healthcare Provider;

- A workshop with Dentists;
- A small workshop with Pharmacy leads in Northern Ireland;
- A workshop with General Practice staff;

and

- A meeting with regulatory bodies for HSC Professionals.

2.17. The feedback from these workshops has been analysed and is published on the DoH website[9]. It has all been taken into account by the Workstream when drafting the policy proposals set out in this consultation document.

2.18. The Duty of Candour Workstream and the Being Open Sub-group have also had ongoing engagement with a number of stakeholder groups since the commencement of the programme, to raise awareness regarding the work of the programme, seek advice on best mechanisms to engage with particular sectors, and to explore proposals to implement the recommendations. Some of these engagements have been specifically related to the statutory Duty of Candour and / or Being Open, or alternatively the Chairs have participated as part of engagement activities relating to the overall implementation programme.

2.19. The individuals and organisations that have been engaged with include:

- Representative bodies for health and social care professionals;

[9] https://www.health-ni.gov.uk/sites/default/files/publications/health/IHRD%20-%20Duty%20of%20Candour%20and%20Being%20Open%20-%20Analysis%20from%20Involvement%20Events.pdf

- Regulatory bodies for health and social care professionals;
- Health and social care organisations, including HSC Trusts and their Boards;
- Oversight bodies, such as the NI Public Services Ombudsman, NI Police Ombudsman, and the NI Human Rights Commission;
- Political representatives;
- Chief Professionals and policy leads within the DoH;
- Community and voluntary organisations;

and

- Other key stakeholders such as the Northern Ireland Commissioner for Children and Young People, the Commissioner for Older People (NI), Trade Unions, Insurers, AvMA and the PSA.

2.20. The feedback from these engagements has been carefully and conscientiously taken into consideration by the Workstream when drafting the policy proposals within this consultation document.

2.21. The Workstream and Sub-Group also commissioned a public opinion survey to gain insight into service user and patient experience of openness, honesty and involvement when interacting with the Health and Social Care System. The survey – which ran for four days, from 22- 25 January 2021, attracting 2,295 valid responses – formed an important part of the pre-consultation involvement plan, and will provide important quantitative and qualitative evidence for consideration when finalising the policy proposals post-consultation.

2.22. The survey suggested that respondents generally felt that health and social care services in Northern Ireland were always or mostly open in interactions with them. However, when something had gone wrong with the service provided which impacted on the treatment or care received, respondents reported that the system was not as open or candid. A majority of respondents did not feel involved in the process to find out what went wrong, did not feel that they had received a full explanation of what went wrong, and did not receive an apology.

2.23. Respondents were also asked to consider openness in health and social care in circumstances where something has gone wrong and serious harm or death has occurred, and specifically asked about whether it should be a crime for individuals to withhold or alter information, cover up events, or provide false information. 75% of respondents felt that these behaviours should be a crime. Respondents were also provided with a free-text box to provide any additional comments that they may have in respect of this particular issue, and the overwhelming majority of the 1,005 written responses were strongly supportive of openness and honesty in these circumstances.

2.24. The full results of the survey are available here on the DoH website for consideration.

Terminology

2.25. During the course of its work, the Workstream has had several discussions regarding the preferred terminology for this policy. This debate has arisen due to the lack of widespread public awareness of the term “candour” and its meaning in a health and social care context. Although there is no clear, unified position on

this issue, various stakeholders have expressed a preference for the use of terminology such as "a duty of openness" or "openness", rather than candour.

2.26. However, for the purposes of this consultation exercise, the Workstream has decided to retain the use of the term "candour" to refer to the proposed legislative provisions, and in particular to refer to the statutory requirements of openness required of organisations and individuals when something goes wrong. In this context, "candour" is defined in the same terms as specified by Sir Robert Francis, Chair of the Mid Staffordshire Inquiry (2013), as follows:

"The volunteering of all relevant information to persons who have or may have been harmed by the provision of services whether or not the information has been requested or whether or not a complaint about that provision has been made."[10]

2.27. Whilst the definition of candour within this policy is used to refer to the legal requirement to provide information in specific circumstances, "openness" is defined as a culture which enables concerns and complaints to be raised freely without fear. It is also about enabling truthful information about performance to be shared with staff, patients, the public and regulators. Further information on the policy proposals developed in respect of openness in health and social care is set out in Section 5 of this paper.

1. Do you agree with the terminology and definitions adopted by the Workstream in respect of "openness" and "candour"? If yes, please provide any additional information and / or insights.

[10] https://webarchive.nationalarchives.gov.uk/20150407084231/http://www.midstaffspublicinquiry.com/report – paragraph 22.1, page 1442

2. If not, do you suggest a preferred terminology that should be used to describe this policy and the statutory duty? Please provide evidence to support any alternative proposal.

3. Statutory Organisational Duty of Candour – Policy Proposals

Introduction

3.1. This section sets out the policy proposals developed by the Duty of Candour Workstream to implement the IHRD recommendations relating to the statutory organisational Duty of Candour. The proposals below reflect the Workstream's view based on the evidence considered and feedback received.

3.2. This section is broken down as follows:

- Background – why has a statutory organisational Duty of Candour been recommended?
- Scope – to whom should the statutory organisational Duty of Candour apply?
- Routine Requirements – what should be required of organisations routinely under the statutory duty?
- Requirements when care goes wrong – what should be required of an organisation under the statutory duty, when significant harm or death occurs during the provision of health and social care services?
- Statutory Duty of Candour procedure – what process should be followed when significant harm or death occurs during the provision of health and social care services?

- Apologies – when and how should an apology be offered by an organisation?
- Support and protection for staff – what support should organisations be required to provide to staff in order to fulfil the statutory Duty of Candour?
- Reporting and monitoring – what should the statutory requirements be for organisations to report on, and monitor adherence to, the statutory duty?
- Criminal sanctions for breach – what should the criminal sanctions be for breach of the statutory organisational Duty of Candour?
- Obstruction offence – who should the obstruction offence apply to, in which circumstances, and what should the maximum penalty be?

3.3. The Workstream recognised that much of the practical detail required to explain how a Duty of Candour will work, will need to be provided in additional guidance developed at a later stage. A proposed framework for the development of this guidance is explained in more detail in Section 6; this will also follow a co-production approach.

Background

3.4. Justice O'Hara led a public Inquiry into the tragic and avoidable deaths of five children as a result of hyponatraemia. The Inquiry found that there had been a repeated lack of openness and honesty by the Health and Social Care system to the families involved, and that reputation and avoidance of blame were placed above honesty and duty. Therefore, Justice O'Hara recommended a statutory

Duty of Candour, to encourage consistency in openness and to avoid any confusion about what everyone should expect.

3.5. His recommendation built on the Francis Inquiry Report (2013) into the failings in care at Mid Staffordshire NHS Foundation Trust between 2005 and 2009, and the Donaldson report, 'The Right Time – The Right Place' (2014), into the quality and safety of care in Northern Ireland. Both reports made recommendations around increased openness and honesty throughout the health and social care system and led to a pledge by the Minister for Health in 2015 to introduce an organisational Duty of Candour in Northern Ireland.

3.6. The purpose of a statutory Duty of Candour is to ensure public accountability for the delivery of open and honest health and social care. It is not about penalising organisations or people for making mistakes; it is about ensuring organisations or individuals are open and honest about the mistake. Enforcement proceedings, and criminal liability, would be a means of accountability in circumstances where the behaviour of organisations and individuals is not appropriate.

3.7. The results of the recent public survey commissioned by the Workstream would suggest that patients and service users do not always experience openness and honesty whenever mistakes occur, thus reinforcing the continued need for the introduction of a statutory organisational Duty of Candour.

Scope

3.8. Justice O'Hara recommended that the statutory organisational Duty of Candour should apply to "every healthcare organisation". Therefore, the Workstream has decided that the scope of the Duty should include the following organisations:

- Health and Social Care Trusts – Belfast Health and Social Care Trust, South Eastern Health and Social Care Trust, Southern Health and Social Care Trust, Western Health and Social Care Trust, Northern Health and Social Care Trust, and the Northern Ireland Ambulance Service Trust.

- Establishments regulated by the Regulation and Quality Improvement Authority (RQIA) – statutory and independent establishments who may care directly for patients and clients on behalf of the HSC or as part of private arrangements direct with an individual. Includes dental practices, nursing homes, residential care homes, residential family centres, day care establishments, children's homes, independent healthcare establishments and residential special schools;

- Agencies regulated by RQIA – organisations that co-ordinate / facilitate / arrange care for patients and clients on behalf of the HSC or as part of private arrangements with individual users. Includes nursing agencies, domiciliary care agencies, independent fostering agencies, voluntary adoption agencies and adult placement agencies;

- GP Practices and Community Pharmacists;

- Organisations providing publicly commissioned or contracted health and social care services on behalf of the HSC, who do not fall within the scope of RQIA regulation;

- The DoH;

- The Health and Social Care Board;

- The Public Health Agency;
- The Regulation and Quality Improvement Authority;
- Business Services Organisation;
- Northern Ireland Blood Transfusion Service;
- Northern Ireland Guardian Ad Litem Agency;
- Northern Ireland Medical and Dental Training Agency;
- Northern Ireland Practice and Education Council;
- Northern Ireland Social Care Council;

  and

- Patient and Client Council.

3.9. It should be noted that alternative proposals have been advanced in respect of the scope of the statutory organisational Duty of Candour, including limiting the scope to regulated organisations that directly provide health and social care services.

3. Do you agree with the proposed scope of the statutory organisational Duty of Candour? If yes, please provide any additional information.

4. If not, do you have a preferred approach for the scope of the statutory organisational Duty of Candour? For example, should the scope be limited

to regulated organisations that directly provide health and social care services? Please provide evidence to support any alternative proposal.

Routine Requirements

3.10. The statutory organisational Duty of Candour should provide that the above organisations must act in an open and honest way in relation to the provision of health and social care services to patients and service users. This broad overarching statutory duty should ensure that the service received by patients, service users, carers and families is routinely and proactively open. Staff will be required and supported to give full and honest answers to any question reasonably asked by a patient about their treatment.

3.11. Further information on compliance with this element of the statutory organisational Duty will be included within the accompanying guidance to be issued by the DoH to support implementation of the statutory organisational Duty of Candour[11].

5. Do you agree with the routine requirements of the statutory organisational Duty of Candour? If yes, please provide any additional information.

6. If not, do you have a preferred approach for the routine requirements of the statutory organisational Duty of Candour? Please provide evidence to support any alternative proposal.

[11] Proposals for the structure of this guidance are included in Section 5 of this paper.

Requirements – When Care Goes Wrong

3.12. As well as these requirements to be proactively open and honest on a routine basis, there should be specific statutory requirements which would apply to organisations in circumstances where an unintended or unexpected incident occurred in respect of a patient or service user during the provision of health and social care services, and significant harm has been caused.

3.13. These statutory requirements should apply in relation to any unintended or unexpected incident that occurred in respect of a patient or service user during the provision of health and social care services, that has or may have resulted in:

a) The unexpected or unexplained death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition;
or

b) Moderate harm, serious harm, or prolonged psychological harm to the service user.

3.14. The inclusion of the term "may have resulted in" within this definition is intended to bring incidents which have the potential to cause significant harm in the future within the scope of these requirements. However, "potential harm" in this context would not include near misses, which are acts of commission or omission that could have harmed a patient but did not cause harm as a result of chance, prevention, or mitigation.

3.15. The various forms of "harm"[12] would be defined as follows:

- "Moderate Harm" would include:
  - Harm that requires a moderate increase in treatment;

    and

  - Significant, but not permanent, harm.
- "Serious harm" - a permanent lessening of bodily, sensory, motor, physiological or intellectual functions, including removal of the wrong limb or organ or brain damage that is related directly to the incident and not related to the natural course of the service user's illness or underlying condition.
- "Prolonged psychological harm" - psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days.

3.16. In circumstances where the above threshold has been met, the matter will constitute a "notifiable incident", and the organisation will have to comply with the statutory Duty of Candour procedure outlined below.

3.17. Throughout the policy development process, there has been some debate about the inclusion of "moderate harm" within the threshold. The inclusion of moderate harm would mirror the approach in other jurisdictions, such as England and Scotland. In order successfully to implement this approach, consideration will

[12] "Harm" in this context would also include self-harm.

have to be given to the potential impact on existing patient safety review mechanisms in Northern Ireland.

3.18. Further information on implementation of this threshold will be included within the accompanying guidance issued by the DoH to support implementation of the statutory organisational Duty of Candour.

7. Do you agree with the proposed definition for the significant harm threshold for the Duty of Candour procedure? If yes, please provide any additional information.

8. If not, do you have a preferred definition for the significant harm threshold for the Duty of Candour procedure? Please provide evidence to support any alternative proposal.

Statutory Duty of Candour Procedure

3.19. In the circumstances where the above threshold has been met, and it has been determined that a "notifiable incident" has occurred, the statutory procedure will require organisations to:

- Notify the patient or duly authorised representative[13] (collectively hereafter referred to as the "relevant person") as soon as reasonably practicable[14] after the organisation becomes aware that an incident, which meets the threshold for the Duty of Candour process, has occurred;

[13] "duly authorised representative" means a person lawfully acting on the patient's behalf when the patient is unable to act for themselves (i.e. due to a lack of capacity). Guidance issued by the DOH will address how this person will be identified in practice.

[14] Guidance issued by the DOH will address how this term will be defined in practice. Guidance has defined it in other jurisdictions as within 10 working days, or sooner, of the organisation becoming aware of the incident.

and

- Provide reasonable support to the relevant person in relation to the incident, including when giving notification. "Reasonable support" in this context will be defined further in subsequent guidance developed by the DoH.

3.20. Any notification must be followed up with a written notification, issued by the organisation to the relevant person, which should include:

- A written summary of the full facts available to the organisation in relation to the incident at the time of the notification;
- An apology;

and

- A written summary of the further action undertaken by the organisation in respect of the incident, including the outcome of any investigations or reviews.

3.21. Organisations will also be required to involve the relevant person in any subsequent investigations or reviews[15]. In the event of an incident which has resulted in a homicide, carried out by a service user under the active care of the HSC, organisations should also be required to involve the family of the victim, or their duly authorised representative, in any subsequent investigations or reviews.[16] Guidance issued by the DoH will provide further detail on compliance with these requirements.

[15] This requirement is of particular relevance to the "Statement of What You Should Expect If You are Involved in a Serious Adverse Incident" being developed by the SAI Workstream of the IHRD Programme.
[16] As above.

3.22. In the event that the organisation is unable to contact the relevant person as outlined above, or the relevant person declines to communicate with the organisation, then:

- The organisation must retain a written record of attempts to contact or to speak to the relevant person;

  and

- Any relevant penalties associated with breach of the Duty of Candour process do not apply, provided that reasonable attempts have been made to contact the relevant person.

3.23. Further information on compliance with the above requirements will be included within the accompanying guidance issued by the DoH to support implementation of the statutory organisational Duty of Candour.

9. Do you agree with the proposed requirements under the statutory organisational Duty of Candour when things go wrong? If yes, please provide any additional information or insights.

10. If not, do you have a preferred approach for the requirements under the statutory organisational Duty of Candour when things go wrong? Please provide evidence to support any alternative proposal.

Apologies

3.24. An apology, as required under paragraph 3.20 above, is to be defined as "a statement of sorrow or regret in respect of the unintended or unexpected incident". However, there has been some debate within the Workstream about the value of legislating for an apology as a requirement under the Duty of Candour procedure.

Whilst this approach has been adopted in other jurisdictions, there is a concern that legislating for an apology in these circumstances could lead to a standardised or formulaic approach, which does not guarantee a genuine and sincere apology for the patient, service user, carer or family involved.

11. Do you agree with the proposed legislative requirement to provide an apology as part of the Duty of Candour procedure? If yes, please provide any additional information or insights.

12. If not, do you have a preferred policy approach in respect of apologies in circumstances where the threshold for the Duty of Candour procedure has been met? Please provide any evidence to support any alternative proposal.

3.25. Further information on compliance with the requirement to provide an apology will be included within the accompanying guidance issued by the DoH to support implementation of the statutory organisational Duty of Candour. This would include, for example, guidance on the provision of a genuine apology, preferably in person, by an appropriate member of the organisation.

3.26. Any legislation drafted in respect of the Duty of Candour should also include a provision which clarifies that an apology or other step taken in accordance with the Duty of Candour procedure should not, of itself, amount to an admission of negligence or a breach of a statutory duty to provide health and/or social care services. In addition, the inclusion of this provision would not indemnify organisations or individuals against any liability where an apology has been offered in accordance with the Duty of Candour process, or to restrict the civil

rights of patients, carers or families to pursue damages where appropriate. These proposed policies have been included on the basis of feedback received to date, and are based on approaches adopted in other jurisdictions, in order to address some concern about the legal implications of apologising when something has gone wrong with a patient or service user's care or treatment.

13. Do you agree with the proposals in respect of apologies under the statutory organisational Duty of Candour? If yes, please provide any additional information or insights.

14. If not, do you have a preferred approach for the proposals in respect of apologies under the statutory organisational Duty of Candour? Please provide evidence to support any alternative proposal.

Support and protection for staff

3.27. Any successful organisational Duty of Candour will depend on each organisation providing adequate support and protection for staff to enable them to work within an open and honest culture. Therefore, it will be a statutory requirement for organisations to ensure that all employees who carry out the Duty of Candour procedure on its behalf receive:

- Relevant training and guidance on the Duty of Candour procedures;

  and

- Support to enable them effectively to adhere to their statutory individual Duty, and contribute to the organisation's statutory Duty of Candour requirements.

These statutory requirements are included in recognition of the importance of organisations providing adequate support and protection for staff to enable an open culture, and to enable staff to be able to fulfil their own individual Duty of Candour. The individual Duty cannot exist without the organisational supports and protections being in place.

3.28. Further information on compliance with the above requirements will be included within the accompanying guidance issued by the DoH to support implementation of the statutory organisational Duty of Candour. Proposed examples of the types of support and protection to be provided by organisations include, but are not limited to:

- Opportunities for reflective practice;
- Leadership to ensure the implementation of an open and just culture;
- Provision of adequate training on an ongoing basis in response to the needs of staff;
- Clear guidance on the requirements of the statutory Duty of Candour and how it should be fulfilled;

  and

- Clear systems in place to identify and disseminate learning in order to improve practice.

15. Do you agree with the proposals for support for staff under the statutory organisational Duty of Candour? If yes, please provide any additional information or insights.

16. If not, do you have a preferred approach for the support for staff under the statutory organisational Duty of Candour? Please provide evidence to support any alternative proposal.

Reporting and monitoring

3.29. Provision should be made within the statutory Duty of Candour legislation to require organisations to ensure that:

- Any statement made to a regulator or other individual acting pursuant to statutory Duty must be truthful and not misleading by omission;

  and

- Any public statement made by an organisation about its performance must be truthful and not misleading by omission.

3.30. It should also be a statutory requirement that organisations must publish a report on the Duty of Candour as soon as practicable after the end of the financial year. This report should include anonymised information regarding:

- Statistics regarding the number and type of incidents in which the Duty of Candour process was invoked;

- An assessment of the organisation's performance in respect of the Duty of Candour;

  and

- Information regarding the procedures and process the organisation has in place in relation to the Duty of Candour, as well as any changes that have been made to same.

3.31. Upon publication, organisations must share the report with the RQIA and the DoH.

3.32. Further information on compliance with the reporting and monitoring requirements will be included within the accompanying guidance issued by the DoH to support implementation of the statutory organisational Duty of Candour.

17. Do you agree with the proposed reporting and monitoring requirements under the statutory organisational Duty of Candour? If yes, please provide any additional information.

18. If not, do you have a preferred approach for the reporting and monitoring requirements under the statutory organisational Duty of Candour? Please provide evidence to support any alternative proposal.

Criminal Sanctions for breach

3.33. Criminal liability in this context relates to a breach of the Duty of Candour, or preventing another person from performing their Duty. It is not about penalising organisations, or people, for making mistakes; it is about holding organisations or individuals to account for their openness and honesty about a mistake when it occurs.

3.34. It has been recommended that oversight of compliance with the statutory organisational Duty of Candour should be undertaken by the RQIA[17]. Compliance would be monitored by review or inspection, and the range of enforcement powers currently available to the RQIA to improve performance would also be available. Implementation of this recommendation is being taken forward by Workstream 3 of the IHRD Programme.

3.35. Justice O'Hara also recommended that the power to prosecute should apply "in cases of serial non-compliance or serious and wilful deception". Therefore, criminal prosecution for a breach of the Duty would only be pursued in the most serious cases.

3.36. The following breaches of the statutory organisational Duty of Candour should be a criminal offence:

- Failure to notify the relevant person that a notifiable safety incident has occurred;
- Failure to provide the notification in line with the legislative requirements;
- Provision of a false or misleading statement to a regulator or other individual acting pursuant to the statutory Duty;

or

[17] IHRD Recommendation 8, "Regulation and Quality Improvement Authority ('RQIA') should ensure overall compliance and consideration should be given to granting it the power to prosecute in cases of serial non-compliance or serious and wilful deception".

- Publication of a false or misleading public statement by an organisation about its performance.

3.37. The maximum penalty for breach of these requirements should be a Level 5 fine (£5,000) on summary conviction. Provision should also be made for the prosecuting authority to issue Fixed Penalty Notices (FPNs) for breach, which would amount to 50% of the maximum fine available for the offence.

3.38. The Workstream gave extensive consideration to the appropriate level of the fine for breach of the statutory organisational Duty. Whilst the maximum penalty proposed by the Workstream would be significantly less that the maximum organisational penalty in other legislation – for example, Health and Safety at Work, Corporate Manslaughter or Fraud – it would be set at a higher level than the equivalent offence in England, the maximum penalty for which is £2,500. The Workstream remains conscious that a higher maximum penalty, or an indictable offence, could also divert significant finances away from the provision of frontline health and social care services, and therefore punish the public rather than direct accountability to those responsible for the breach.

3.39. The Workstream also noted that organisations would be subject to additional impacts when a fine is levied against them, thus increasing the negative consequences of criminal prosecution. These sanctions include:

- The potential organisational and individual leadership reputational damage that could be caused by a fine;

- The governance and audit impact, such as the qualification of accounts or additional conditions, on any organisation subject to a fine;

or

- The potential additional financial penalty in circumstances where costs are awarded against the prosecuted organisation.

3.40. Where an offence is committed by an organisation, and it is proved that it has been committed with the consent or connivance of, or attributable to any neglect on the part of any director, manager, secretary or other similar officer of the body corporate or any person purporting to act in such capacity, provision should be made for such persons to have proceedings issued against them, in addition to those which may be issued against the organisation.

19. Do you agree with the proposed criminal sanctions for breach of the statutory organisational Duty of Candour? If yes, please provide any additional information.

20. If not, do you have a preferred approach for the criminal sanctions for breach of the statutory organisational Duty of Candour? Please provide evidence to support any alternative proposal.

Obstruction offence

3.41. It should be a criminal offence wilfully to obstruct another in the performance of their duties under the organisational or individual statutory Duty of Candour.

3.42. The maximum penalty should be a Level 5 fine (£5,000) on summary conviction.

21. Do you agree with the proposed obstruction offence under the statutory organisational Duty of Candour? If yes, please provide any additional information.

22. If not, do you have a preferred approach for the obstruction offence under the statutory organisational Duty of Candour? Please provide evidence to support any alternative proposal.

23. Is there any additional evidence, or observations that you wish to provide in respect of the policy proposals for the statutory organisational Duty of Candour?

4. Statutory Individual Duty of Candour – Policy Proposals

4.1. This section sets out the policy proposals for implementation of the IHRD recommendations relating to the statutory individual Duty of Candour. The policy proposals set out in this section reflect the evidence considered and feedback received by the Workstream.

4.2. This section is broken down as follows:

- Background – why has a statutory individual Duty of Candour with criminal sanction for breach been recommended?
- Evidence and Feedback – an overview of the evidence and feedback received by the Workstream in respect of the statutory individual Duty of Candour.
- Policy Proposal – policy proposal to introduce a statutory individual Duty of Candour with criminal sanction attached for breach.
- Alternative Policy Proposals – alternative policy proposals for consultation based on feedback and evidence received by the Workstream.
- Scope – to whom would the statutory individual Duty of Candour apply?
- Routine Requirements – what should routinely be required of individuals under the statutory Duty.
- Requirements when care goes wrong – what should be required of individuals when significant harm or death occurs during the provision of health and social care services?

STATUTORY INDIVIDUAL DUTY OF CANDOUR – POLICY PROPOSALS

Background

4.3. The introduction of a statutory individual Duty of Candour was a key recommendation made by Justice O'Hara in January 2018. Justice O'Hara made this recommendation, having found that there had been a "repeated lack of openness with the families involved"[18], and that reputation and avoidance of blame were placed above honesty and duty. The intention behind this recommendation, was to "encourage consistency in openness and to avoid any ambiguity in expectation"[19].

4.4. Justice O'Hara also recognised that Sir Robert Francis, in the latter's report on the Mid Staffordshire NHS Foundation Trust Public Inquiry (2013), had similarly recommended the introduction of a statutory individual Duty of Candour for England, and that his recommendation had not been enacted, "on the basis that they are already placed under an 'ethical duty' of honesty by their professional organisations"[20]. In this regard, Justice O'Hara noted[21] in his report that the evidence to his Inquiry had "revealed obvious weakness in the call of the "ethical duty"' imposed by Professional Regulators. That is why he chose to recommend that a statutory "Duty of Candour attach to individuals as well as organisations in the event of death or serious harm and that criminal sanctions should apply"[22].

4.5. Specifically, Justice O'Hara recommended that a statutory Duty of Candour should now be enacted in Northern Ireland so that "every healthcare organisation

[18] Paragraph 8.101of the IHRD Report
[19] Paragraph 8.106 of the IHRD Report
[20] Paragraph 8.105 of the IHRD Report
[21] Paragraphs 8.105 & 8.106 of the IHRD Report
[22] Paragraph 8.106 of the IHRD Report

and everyone working for them must be open and honest in all their dealing with patients and the public"[23]. Furthermore, he recommended that "criminal liability should attach to breach of this duty and criminal liability should attach to obstruction of another in the performance of this duty"[24]. Accompanying the statutory Duty of Candour, he also recommended that unequivocal guidance should be provided detailing what is expected in order to meet the Duty, as well as support and protection for those who properly fulfil the Duty.

Evidence and Feedback

4.6. Based on the evidence gathered and the feedback received to date, the Workstream was unable to reach a unified policy position in respect of the introduction of a statutory individual Duty of Candour, with accompanying criminal sanctions for breach of that Duty. A significant difference of opinion remains regarding the implementation of a statutory individual Duty and, in particular, the inclusion of criminal liability for breach.

4.7. It is important to note that feedback from regulated health and social care professionals and their professional bodies has highlighted that a statutory individual Duty of Candour – and in particular, the introduction of individual criminal liability for breach – could be perceived as overly harsh, given that other comparable jurisdictions have decided not to implement similar policies. They have indicated that such an approach could have unintended consequences, where fear of litigation and a culture of blame could have the opposite effect. Feedback has also suggested that this approach could have a negative impact

[23] Recommendation 1(i) of the IHRD Report
[24] Recommendation 2 of the IHRD Report

both on the morale of existing staff and the recruitment and retention of staff, if this jurisdiction were perceived to be a less attractive location to work as a consequence.

4.8. It should be noted that the Workstream has also heard suggestions that the introduction of a statutory Duty of Candour could be beneficial for morale if it results in a cultural change where staff are supported and protected to raise concerns, and to be open routinely. In addition, the public survey commissioned by the Workstream has demonstrated that many patients and service users do not routinely experience openness and honesty whenever something has gone wrong with their care and treatment. Respondents to the survey also strongly favoured the criminalisation of deliberate actions which prevent candour and honesty in these circumstances.

4.9. As a result of the range of evidence, feedback and views, the Workstream has identified three possible, high-level policy approaches for dialogue during public consultation rather than agreeing a single policy approach for implementation of the recommendations relating to a statutory individual Duty of Candour with criminal sanctions for breach.

4.10. The first policy proposal outlines a policy proposal for implementation of the recommendations made by Justice O'Hara, as written.

4.11. Two further, alternative, policy approaches are also included for consultation, in response to feedback and evidence received from some stakeholders within the health and social care sector, regarding the introduction of the statutory individual Duty of Candour, and in particular the inclusion of criminal liability for breach.

4.12. Section 4 also set out proposals for the potential scope of, and legislative requirements for, a statutory individual Duty of Candour which would be equally applicable to each of the three high-level policy approaches for the Duty. Again, these proposals reflect the evidence and feedback considered by the Workstream, and are included for consideration during public consultation.

Policy Proposal – Statutory Individual Duty of Candour with criminal sanction for breach

4.13. Based on the evidence gathered and the feedback received to date, the Workstream has identified a policy approach which would implement the recommendation made by Justice O'Hara in respect of a statutory individual Duty of Candour.

4.14. This policy approach would introduce a statutory individual Duty of Candour, which would include a series of legislative requirements that have to be adhered to by staff within its scope. Policy proposals in respect of these legislative requirements are set out later in this section.

4.15. Breach of these requirements would constitute a criminal offence. Whilst the Workstream has not agreed upon a maximum penalty for breach of the statutory individual Duty, comparable offences in other sectors tend to be punishable summarily, with a fine being the maximum penalty.

4.16. Adoption of this policy option would fully implement the recommendations made in respect of the statutory individual Duty of Candour. It enshrines Justice O'Hara's view that existing oversight mechanisms within health and social care have not been sufficient to ensure that candour takes place. It would represent a

strong stance against unacceptable behaviours with very clear accountability mechanisms and repercussions for breach, whilst representing a unique policy approach to support an open culture.

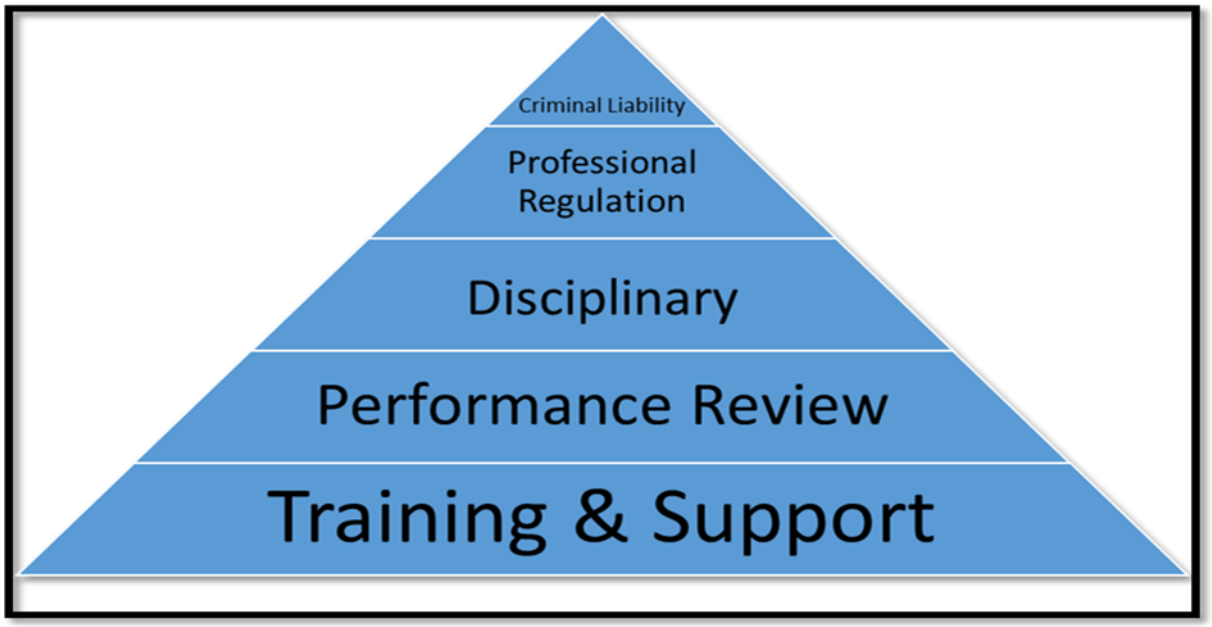
4.17. Criminal liability in this context would relate to a breach of the requirements of the statutory individual Duty of Candour and to obstruction of another in the performance of this Duty. A breach of the Duty would not penalise individuals for making mistakes in the provision of health and social care services. Instead, the focus of criminal liability is about whether individuals are open and honest about mistakes which have been made, or accidents which have happened.

4.18. It is important to note that, in respect of prosecution for breach of the statutory Duty of Candour, Justice O'Hara recommended that "consideration should be given to granting [the RQIA] the power to prosecute in cases of serial non-compliance or serious and wilful deception"[25]. In respect of any criminal sanction, the evidential threshold for conviction requires proof "beyond reasonable doubt" regarding the act and the intention. Criminal prosecutions for breach are likely only when investigation has found evidence of deliberate and intentional breach of the Duty.

4.19. The introduction of a statutory individual Duty of Candour with a criminal sanction for breach would underpin and strengthen, rather than replace, the existing oversight mechanisms such as training, performance review, disciplinary procedures and professional regulation. It would form part of a range of mechanisms which contribute towards, and provide oversight of, candour,

[25] Recommendation 8 from the IHRD Report

openness and honesty in the health and social care sector, proportionate to the circumstances.



4.20. Furthermore, this range of mechanisms could also include enhanced oversight through amendments to staff contracts, as recommended by Justice O'Hara[26].

4.21. In line with the recommendations, feedback and evidence from other jurisdictions has also emphasised the importance of support mechanisms to protect staff, and to ensure that the culture within the service becomes one of openness and learning.

[26] Recommendation 5 from the IHRD report states that "Trusts should review their contracts of employment, policies and guidance to ensure that, where relevant, they include and are consistent with the Duty of Candour."

4.22. Therefore, a statutory individual Duty of Candour would not be introduced in isolation. As recommended by Justice O'Hara, its introduction would be accompanied by a statutory organisational Duty of Candour, which would include legal requirements for HSC organisations to protect and support staff to fulfil their individual statutory Duty. As a result, organisations would be in breach of their Duty if they failed to provide this support and protection. Additionally, organisations and individuals would also be criminally liable if they obstruct another in the performance of their statutory individual Duty of Candour (proposals in relation to obstruction are included in Section 3).

24. Please provide comments on the policy proposal for the statutory individual Duty of Candour outlined above.

Alternative Policy Proposals

4.23. The Workstream acknowledges that there is significant opposition from some to a statutory individual Duty of Candour with criminal sanctions for breach of that Duty. In the main, representative groups for health and social care professionals have opposed the implementation of a statutory individual Duty due to the perception that it is disproportionate, and that the inclusion of criminal sanctions could create fear amongst staff, leading to morale loss, defensive practice and consequential difficulties for recruitment and retention. Opponents have also highlighted the absence of an equivalent statutory provision in other jurisdictions.

4.24. Initial opposition suggested that the existing professional Duty of Candour was adequate for individuals. This mirrored the argument made in England, when they were considering the introduction of a statutory Duty of Candour and whether or not it should apply to individuals. At the time, the government accepted the view

that strengthening and supporting the existing professional requirements would be sufficient. Justice O'Hara specifically referenced this in his report and said that he would consider such an argument stronger, had the evidence to his Inquiry not revealed obvious weakness in the call of 'ethical duty'. The Workstream considered O'Hara's counter argument strong enough to reject the option not to have an individual Duty at all.

4.25. Instead, the Workstream has identified two alternative policy proposals to reflect the breadth of the evidence and feedback received. These proposals both include a statutory Duty of Candour for individuals but provide alternative options relating to the criminal sanctions for breach.

Alternative Proposal (a) - Statutory individual Duty of Candour without criminal sanction attached for breach

4.26. This approach would introduce a statutory individual Duty of Candour with specific legislative requirements for staff within its scope, without attaching criminal liability for breach of these requirements. In the event that an individual member of staff breached these requirements, employers and professional regulators would continue to be ultimately responsible for oversight.

4.27. Implementation of this option would address the relevant IHRD recommendations in part by introducing a statutory Duty of Candour for individuals. This would send a strong message that individual members of staff are legally responsible for contributing to candour and honesty. This proposal goes further than the approach adopted in England and is closely aligned with the draft legislation shortly due to commence parliamentary scrutiny in the Republic of Ireland.

4.28. The proposal would also remove the main issue which has proven to be unpopular during engagement with stakeholders – criminal liability for breach of the statutory individual Duty.

4.29. However, this option would not implement recommendation 2 from the IHRD report, due to the absence of criminal liability for breach. As a consequence, oversight of candour, and accountability for breaches, would remain with employers and professional regulators, an approach which Justice O'Hara found to be inadequate. Whilst the legislative requirements within the statutory Duty of Candour would send a compelling message, they could ultimately be perceived as symbolic only, without a meaningful and independent sanction attached for breach.

Alternative Proposal (b) - Statutory individual Duty of Candour without criminal sanction for breach, and separate criminal offences for withholding information, destroying information, or providing false or misleading information.

4.30. The approach would introduce a statutory individual Duty of Candour with specific legislative requirements for staff within its scope, without attaching criminal liability for breach of these requirements.

4.31. Instead, a criminal offence would be separately introduced which applies to staff in the health and social care sector who are proven to have wilfully, intentionally, or maliciously:

- Suppressed or concealed information;
- Distorted or otherwise altered information;

and / or

- Destroyed information.

which would assist an inquiry or investigation that has been initiated into an incident which has resulted in serious harm being caused to, or the death of, a service user. Other behaviours which have been suggested for inclusion within the scope of this offence include "aiding and abetting" another person to conceal the truth, or "conspiring to hide the truth".

4.32. Whilst the Workstream has not agreed upon a maximum penalty for breach of the statutory individual Duty, comparable offences in other sectors tend be punishable summarily with a fine being the maximum penalty.

4.33. This approach would implement the relevant IHRD recommendations in part by introducing a statutory individual Duty of Candour. While it would not implement recommendation 2 as written it would implement the spirit of the recommendation by introducing a separate criminal offence that targets the particular behaviours which limit candour when things go wrong. These behaviours are already criminal offences in other sectors and settings, and a similar offence was introduced for HSC staff in England through the Care Act 2014. By uncoupling the individual Duty of Candour from criminal liability for these particular behaviours, this policy would hopefully reduce the fear of criminal liability linked to the Duty of Candour and the misconception that it will criminalise mistakes in health and social care settings.

4.34. However, the introduction of any criminal offence could still be perceived as harsh and create fear amongst staff, thus impacting on morale and recruitment or

retention. The absence of a direct and individual criminal sanction for breach of the statutory individual Duty could also reduce confidence in this policy approach.

4.35. **The options set out above represent three potential policy approaches for implementation of the recommendations made in respect of the statutory individual Duty of Candour, for consideration by stakeholders, to whose advice the Minister will give conscientious consideration.**

25. Please provide comments on the alternative policy proposals outlined above.

26. If you do not agree with any of the three high-level policy proposals, do you have a preferred alternative policy approach for implementation of the recommendations relating to the statutory individual Duty of Candour? Please provide evidence to support an alternative proposal.

Scope

4.36. Justice O'Hara recommended that a statutory Duty of Candour should now be enacted in Northern Ireland so that "[e]very healthcare organisation and everyone working for them must be open and honest in all their dealings with patients and the public". Therefore, it is proposed that the scope of the statutory individual Duty of Candour should include every employee that works for an organisation within the scope of the statutory organisational Duty.

4.37. It should be noted that alternative proposals have been advanced in respect of the scope of the statutory individual Duty of Candour, including limiting the scope to registered professionals who directly provide health and social care services.

4.38. Further information on the application of a statutory individual Duty would be provided within accompanying guidance for staff produced by the DoH.

27. What is your preferred policy approach in respect of the scope of the statutory individual Duty of Candour? Please outline the reasons for your preference, and provide evidence to support your reasoning.

Routine Requirements

4.39. Individuals within the scope of the statutory individual Duty of Candour must act in an open and honest way in relation to the provision of health and social care services to patients and service users. This would include openness in all circumstances, from routine interaction with patients on a day-to-day basis, to openness to improve performance, as well as candour when things have gone wrong. Further information on compliance with this overarching requirement will be included within the accompanying guidance issued by the DoH to support implementation.

Requirements When Care Goes Wrong

4.40. In recommendation 1(vii) of his report, Justice O'Hara recommended that:

"Registered clinicians and other registered healthcare professionals, who believe that treatment or care provided to a patient by or on behalf of any healthcare organisation by which they are employed has cause death or serious injury to the patient, must report their belief or suspicion to their employer as soon as is reasonably practicable".

4.41. Therefore, it is proposed that legislation for a statutory individual Duty of Candour should include provision which requires individual members of staff to:

- Report any instances of treatment or care which would constitute a "notifiable incident" under the statutory organisational Duty of Candour;
- Participate openly and honestly with any subsequent investigation that may be instigated;

  and

- Participate openly and honestly with any other review, investigation or statutory process which may be undertaken in relation to the notifiable incident (e.g., complaints investigation, Serious Adverse Incident reviews, Coroner's Investigations, Morbidity and Mortality reviews, etc.).

4.42. A "notifiable incident" in this context would be defined as outlined in paragraphs 3.13 to 3.16 of this document.

4.43. Further information on compliance with the requirements of the statutory individual Duty of Candour will be included within the accompanying guidance issued by the DoH to support implementation.

4.44. Stakeholder inputs have indicated that there may be a case to include exemptions from the requirements of a statutory individual Duty of Candour within the legislation, to allow for circumstances where clinical or professional judgement or other extant legal obligations determined that candour may not be appropriate in certain contexts. Beyond this high-level feedback, insufficient information has been received to date to allow the Workstream to develop a policy position on this

issue. Therefore, the Workstream has requested further insights from stakeholders on this matter as part the consultation exercise, to further develop policy in this regard, if necessary. It is also important to note that any such exemption would only be considered appropriate where it was adequately justified, and subject to independent challenge.

28. Do you agree with the proposals in relation to the requirements under the statutory individual Duty of Candour? If yes, please provide reasons for your agreement.

29. If not, do you have a preferred approach for the requirements under the statutory individual Duty of Candour? Please provide evidence to support any alternative proposal.

30. Do you have any comments to make on the case for exemptions from the requirements under the statutory individual Duty of Candour? Please provide evidence to support your position.

31. Is there any additional feedback that you wish to provide in respect of the policy proposals for the statutory individual Duty of Candour? If so, please provide evidence to support alternative proposals, if possible.

5. Being Open Framework – Policy Proposals for Being Open Guidance

Introduction

5.1. In his Inquiry into Hyponatraemia-Related Deaths, alongside recommendations focusing on specific clinical practices, Justice O'Hara made recommendations concerning openness and candour. These arose from his experience throughout the Inquiry and to reflect the seriousness of his concern he deliberately set out the first two recommendations as being the introduction of a statutory Duty of Candour for organisations and individuals, with associated criminal sanctions for breach of these duties. His stated intention in recommending these statutory duties was to encourage a culture of openness and honesty within the health and social care system:

"All that is required is that people be told honestly what has happened and a legally enforceable Duty of Candour for individuals will not threaten those whose conduct is appropriate." (Paragraph 8.105, IHRD Report)

"It is to encourage consistency in openness and to avoid any ambiguity in expectation that I endorse the Francis recommendations. I recommend that a Duty of Candour attach to individuals as well as organisations in the event of death or serious harm and that criminal sanctions should apply." (Paragraph 8.106, IHRD Report)

5.2. The purpose of this proposed framework is to set out the **mechanisms** through which such cultural change can be facilitated. It makes explicit the **measures** that need to be put in place to ensure that staff are supported and enabled to

proactively exercise candour, and the responsibilities that sit with organisations to both enable and exhibit candour. It makes clear the **expectation** that candour and openness are exhibited routinely in day-to-day practices, as well as when something has gone wrong. The product of this will be that staff are supported to work in an open and candid way, and that the public experience openness and candour in all of their dealings with the health system. This policy also highlights the circumstances in which candour may be **qualified**, taking into account issues such as safeguarding procedures, mental capacity, confidentiality and the rights of individuals as well as next of kin, among others.

5.3. Openness in this context is defined as a culture which enables concerns and complaints to be raised freely without fear. It is also about enabling truthful information about performance to be shared with staff, patients, the public and regulators[27].

5.4. Candour, in line with the definition provided by Sir Robert Francis, is defined as:

"The volunteering of all relevant information to persons who have or may have been harmed by the provision of services whether or not the information has been requested or whether or not a complaint about that provision has been made."[28]

Key Principles

5.5. Our policy framework for openness and candour in health and social care is informed by the following five key principles:

[27] This is an amalgam of Sir Robert Francis' definitions of "Openness" and "Transparency".

[28] https://webarchive.nationalarchives.gov.uk/20150407084231/http://www.midstaffspublicinquiry.com/report – paragraph 22.1, page 1442

BEING OPEN FRAMEWORK – POLICY PROPOSALS FOR BEING OPEN GUIDANCE

Routine Openness - Openness and Honesty will be exhibited and experienced routinely in all aspects of Health and Social Care;

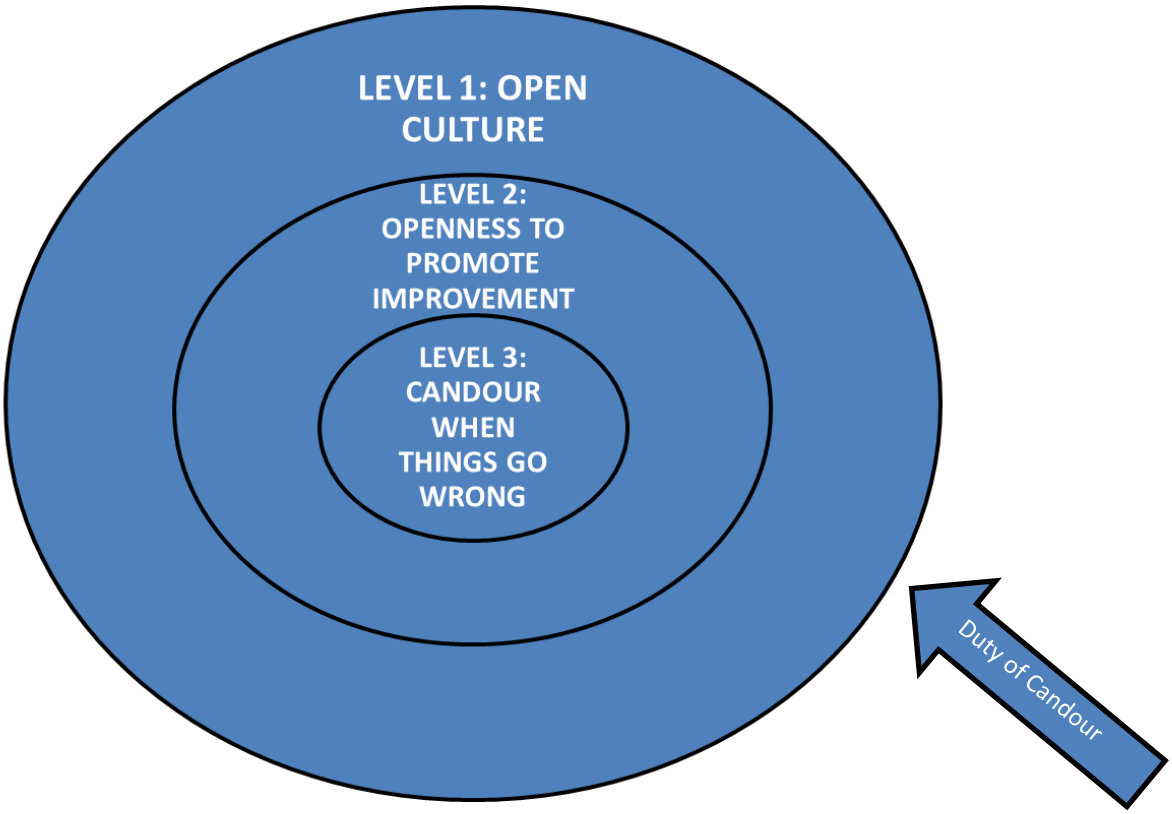
Openness to promote learning - When things go wrong, openness and honesty will result in comprehensive learning that is widely shared resulting in service improvement;

Candour when harm or death has occurred - When things go wrong and harm or death has resulted, Openness and Honesty will be exhibited and experienced in all aspects of the consequent investigations and engagement with family and carers;

Support for Openness and Candour - Staff and patients will be provided with help and support to exercise and experience openness and honesty routinely in all circumstances; and

The governance of Openness and Candour – governance and accountability measures will be in place to monitor candour and ensure routine openness and honesty.

Conceptual Framework



5.6. To ensure that the focus of the health and social care services' understanding of openness and candour is not limited to circumstances in which something has gone wrong, this policy is written in such a way as to explicitly include all aspects of openness on a continuum; starting with routine openness, when there are no exceptional circumstances through to openness and candour when a mistake has been made that has caused harm or death. The policy sets out the expectations on organisations, staff, individuals who use the services and their family members/carers.

5.7. The three Levels of Openness and Candour are:

1. Routine Openness

The day-to-day expression of openness, and how this will be enabled and experienced by staff and patients

2. Openness to promote learning

The expression of openness when something untoward has happened, but no harm has been caused. While there is an expectation of learning across all three contexts, the focus of this one is on learning and the dissemination of learning.

3. Candour when something has gone wrong and harm or death has been caused

The requirements under a statutory Duty of Candour under these conditions specify that information will be offered in a timely way with a "full and honest explanation of the circumstances". Other requirements specify that the information will not mislead by omission and that individuals and organisations will not prevent others from exercising their responsibilities under candour.

5.8. Using this framework, this section will elaborate on the proposed rights and responsibilities of organisations, staff and patients in relation to openness and candour at each level. It is proposed that this framework will be used in order to develop the guidance being developed for organisations, staff and patients around openness, and to support the implementation of the Statutory Duty of Candour.

32. Do you agree with the policy proposals in respect of the Being Open Framework? If yes, please outline your reasoning.

33. If not, do you have a preferred policy approach in respect of openness and candour in health and social care? Please provide evidence to support alternative policy proposals.

Level 1: Routine Openness

What should service users and carers expect of the services at Level 1?

5.9. Service users and carers should expect to be partners in their care, participating in decision making about their treatment in as far as they want to be[29]. This should include as a minimum that:

- All information about a service user's treatment and care will be proactively offered to them and shared with them to whatever extent they wish;
- The information that is shared will be tailored in such a way that it is easily understandable to them, and they will be enabled to understand the options available and will participate in the decisions about which options to follow and the potential consequences of these options;
- Service users will have control over who else has access to this information, specifically in relation to their families, next of kin or carers, in accordance with their capacity to do so;
- Service users can expect that their information will be shared with them in a compassionate way, with professionals who are competent to answer their questions and help them make

[29] This approach is in line with other initiatives within the sector, including the implementation of the Mental Capacity (Northern Ireland) Act 2016, as well as the Shared Decision-Making Framework currently being developed by the CEC, and the requirements introduced by the Autism Act (Northern Ireland) 2011 & Autism Strategy, for example.

decisions and understand the potential consequences of their decisions;

and

- Service users will be supported and enabled to navigate their way within the health system to whoever is best placed to inform them about their care.

What will be expected of individuals using the services at Level 1?

5.10. Service users will have the opportunity to participate in the decision-making about their care if they wish and share responsibility for decision-making about that care.

5.11. Service users will identify and access support to help understand the information and navigate the health system according to their individual needs.

34. Do you agree with the policy proposals at Level 1 of the Being Open Framework for Service Users and Carers? If yes, please outline your reasoning.

35. If not, do you have a preferred policy approach in respect of Level 1 of the Being Open Framework for Service Users and Carers? Please provide evidence to support alternative policy proposals.

What should staff working in health and social services expect at Level 1?

5.12. Health and social care services staff can expect to work in an environment where they are encouraged, facilitated and enabled to work in an open and candid way; This should include as a minimum that:

- Opportunities will be created for staff to reflect on their work routinely in their teams;
- Staff can expect to be given the time and opportunity to give and receive feedback routinely, reflect on their practice and the practice of others and proactively engage in improving services based on this feedback;
- Staff can expect to have clarity about what is expected of them in relation to open and candid practice with their patients and service users;
- Staff can expect to be trained and supported to deliver this, within clear policies and procedures;

  and

- Staff can expect to be managed by senior staff who themselves exhibit openness and candour, within an organisation that supports, encourages and models these behaviours on a daily basis.

What is required of health and social care staff at Level 1?

5.13. Health and social care staff will be expected to behave in an open and honest way routinely, within the parameters of their organisation's openness guidance. This includes as a minimum that:

- Staff will be expected to engage with patients and service users proactively, offering information about their treatment and engaging them in the process of decision making;

  and

- Staff will be expected to participate in the opportunities offered by their employers to reflect on their work and give and receive feedback, in particular to promote and normalise routine openness.

36. Do you agree with the policy proposals at Level 1 of the Being Open Framework for Staff? If yes, please outline your reasoning.

37. If not, do you have a preferred policy approach in respect of Level 1 of the Being Open Framework for Staff? Please provide evidence to support alternative policy proposals.

What should organisations expect at Level 1?

5.14. Health and social care organisations can expect to receive clear guidance on their responsibilities to create an open and honest culture routinely for their staff, service users, carers and families. This should include as a minimum that:

- Organisations can expect support to develop policies and procedures which will assist them in exercising their responsibilities for promoting an open and transparent culture;
- Organisations should expect the commitment of all staff to comply with the requirements and spirit of an open and honest culture in their dealings with individuals, carers and families who use their services as well as with others who work within the service;

  and

- Organisations should expect the senior leadership of the services to lead by example in modelling the way for an open an honest culture both within the organisation and in dealing with the external environment i.e. within and outside health and social care services.

What will be required of health and social care organisations at Level 1?

5.15. Healthcare organisations will be required to create the environment in which their staff can work in an open and candid way. As a minimum these include:

- Organisations will be expected to create routine and frequent opportunities for staff to reflect on their practice, give and receive feedback and participate in service improvement as a consequence;

- Organisations will be expected to provide support and training to their staff to improve open practice and create mechanisms for staff to exhibit openness and candour;

- Organisations will also be expected routinely to publish data about the performance of the whole organisation and components within it, this can cover a wide range of material including minutes of meetings, performance data, waiting times etc. In doing so they must act within the specific requirements of the Duty of Candour where such statements must be truthful and not mislead by omission;

  and

- Organisations will be expected to support the training and development of senior leaders (including Executive and Non-Executive Directors) to enable them to both facilitate the development of an open and honest culture and to model appropriate behaviours. Such training should also support their ability appropriately to scrutinise the performance of the organisation in its efforts to promote such a culture.

38. Do you agree with the policy proposals at Level 1 of the Being Open Framework for Organisations? If yes, please outline your reasoning.

39. If not, do you have a preferred policy approach in respect of Level 1 of the Being Open Framework for Organisations? Please provide evidence to support alternative policy proposals.

What is the relevance of the Statutory Organisational Duty of Candour in the context of Level 1 Openness?

5.16. The organisational Duty of Candour will place a statutory duty on health and social care organisations to create the environment in which their staff can exhibit openness and candour routinely. For this to be achieved, as a minimum, it is expected that:

- Organisations will be required to create reflection and feedback opportunities for all of their staff and provide systems that support their staff to participate in these;
- Is respect of employees, the organisations should provide of training, including induction and clarity in contracts[30] of employment which sets out specific requirements on openness and candour;
- Organisations will also be required to set up the appropriate systems and policies to support openness and candour routinely, including

[30] IHRD Recommendations 5 and 7 require the inclusion of compliance with the Duty of Candour and openness to be included in employment contracts of HSC employees with disciplinary action for breaches of contract.

clear guidance on the circumstances in which openness and candour may be qualified such as where there is an issue with capacity, confidentiality of the rights of next of kin;

and

- Organisations will also be required routinely to publish relevant data publicly such as Board minutes and papers, including performance data on safety, risk and activity. Sanctions for failure to meet these responsibilities are set out under IHRD recommendation 8[31] and 86 (iii)[32] where the Regulation Quality Improvement Authority may become the oversight agency.

What is the relevance of the Statutory Individual Duty of Candour in the context of Level 1 Openness?

5.17. The individual Duty of Candour will place a responsibility on all individuals to be open and candid in all of their dealings with patient and service users using the services in line with their organisation's openness guidance. This will include:

- Staff understanding the qualifications to openness that might apply because of capacity, confidentiality or the rights of the individual as well as of next of kin;

[31] IHRD Recommendation 8: Regulation and Quality Improvement Authority ('RQIA') should review overall compliance and consideration should be given to granting it the power to prosecute in cases of serial non-compliance or serious and wilful deception. (IHRD Report 2018)

[32] IHRD Recommendation 86 (iii) The Department should expand both the remit and resources of the RQIA in order that it might: scrutinise adherence to Duty of Candour (IHRD Report 2018)

and

- Were staff to fail to exercise their individual Duty of Candour routinely within these guidelines, it would be expected that this would be dealt with through normal line management performance management processes.

Level 2: Openness to promote learning

What should service users expect of the services at Level 2?

5.18. Individuals using the services can expect that where mistakes have been made, but no harm has been caused, the system will learn from these mistakes and disseminate that learning to prevent the mistake recurring. In particular, individuals who use health and social care services should expect that, where there has been human error:

- Those involved shall receive further training and guidance to prevent it happening again;
- If a near miss or no harm incident occurs, that could potentially have an impact on their care or treatment, individual service users should receive any information about that incident that is relevant to them;
- That health and social care organisations will learn from near miss events to prevent harm to other users of the service, and where there is learning for other services that this learning is disseminated to the wider health and social care system;
- That health and social care organisations will involve and co-produce with service users and carers, the outworkings of learning in such circumstances which result in service developments or quality improvement initiatives;

and

- That health and social care organisations will provide a mechanism to actively listen and support individual service users, carers or families who highlight where harm has been caused.

What is expected of individual service users at Level 2?

5.19. It is expected that individual service users, carers and families are interested in the improvement of safety and quality of services for themselves and other users of the services. In particular it is expected that:

- Where the potential for harm has been identified that individual service users, carers or families will bring this to the attention of health and social care staff;

  and

- Where there are opportunities for quality improvement that individual service users, carers and families would engage with the service to support such initiatives.

40. Do you agree with the policy proposals at Level 2 of the Being Open Framework for Service Users and Carers? If yes, please outline your reasoning.

41. If not, do you have a preferred policy approach in respect of Level 2 of the Being Open Framework for Service Users and Carers? Please provide evidence to support alternative policy proposals.

What can health and social care staff expect at Level 2?

5.20. Health and social care staff can expect to be supported when a mistake has been made that has caused no harm to ensure that the mistake does not recur. As a minimum staff should expect that:

- If the mistake happened because of a system or procedural weakness, then that will be remedied;
- If a mistake has happened because of human error, then the staff involved can expect further support and training to ensure it does not happen again;

  and

- Staff can expect that when they report a mistake where no harm has been caused, their organisation will respond appropriately to capture the learning from the mistake and disseminate that learning where appropriate.

What is required of health and social care staff in Level 2?

5.21. Health and social care staff are expected to support the organisation and individual service user in learning from mistakes and near misses to improve the safety of the services provided. In particular it is expected that:

- Staff are required to report immediately if they have made a mistake or error that caused no harm but had the potential to do so;

- Staff are required to report immediately where they believe others have made such errors;
- Staff are expected to participate in capturing the learning from such events, and to undertake further training if it is required;

  and

- Staff actively involve and co-produce with individuals, service users and carers (where possible), any service development or quality improvement initiatives as a result of the learning.

42. Do you agree with the policy proposals at Level 2 of the Being Open Framework for Staff? If yes, please outline your reasoning.

43. If not, do you have a preferred policy approach in respect of Level 2 of the Being Open Framework for Staff? Please provide evidence to support alternative policy proposals.

What can health and social care organisations expect at Level 2?

5.22. Health and social care organisations can expect their staff to be open and candid when a mistake has happened, and no harm has been caused and to learn from such experiences so that harm is not caused in the future. As a minimum, organisations should expect that:

- Staff will report near misses, errors and mistakes where harm has not been caused but where there is potential for harm to occur;

- Staff will engage with the organisation in identifying and learning from such errors to improve safety for service users;

  and

- Staff will engage in the dissemination of learning from such events.

What is required of health and social care organisations at Level 2?

5.23. Health and social care organisations will be required to ensure meaningful systems are in place to facilitate staff quickly and easily to report if a mistake has been made. As a minimum it is expected that:

- Organisations are required to ensure that the culture and environment is conducive to staff reporting these mistakes immediately and openly;

- Organisations ensure that any learning is captured and disseminated, and any required system change implemented;

- Organisations ensure that any further training needs are identified and facilitated;

  and

- Organisations participate meaningfully in the regional dissemination of learning.

44. Do you agree with the policy proposals at Level 2 of the Being Open Framework for Organisations? If yes, please outline your reasoning.

45. If not, do you have a preferred policy approach in respect of Level 2 of the Being Open Framework for Organisations? Please provide evidence to support alternative policy proposals.

What will be the relevance of the Statutory Organisational Duty of Candour at Level 2?

5.24. The organisational Duty of Candour will place a statutory duty on organisations to create an environment in which staff are supported to report mistakes when no harm has been caused, create the mechanisms by which any learning or system change is captured and ensure that this learning is disseminated regionally. To fulfil this requirement, it is expected that:

- The organisation is responsible for supporting staff to report errors, including the requirement to report errors made by others;
- The organisation is responsible for providing an environment where learning and service improvement are the normal reaction to errors;

  and

- The organisation is also required routinely to publish relevant data publicly such as Board minutes and papers, including performance data on safety, risk and activity. Sanctions for failure to meet these

responsibilities are set out under IHRD recommendation 8[33] and 86 (iii)[34] where the Regulation Quality Improvement Authority recommended oversight body.

What will be the relevance of the Statutory Individual Duty of Candour at Level 2?

5.25. The individual Duty of Candour will place a responsibility on all individuals to be open and honest if they have made a mistake that has caused no harm, or if they have observed such errors. It will require them to participate in any consequential system improvements or additional learning opportunities. This will include:

- Staff understanding the qualifications to openness that might apply because of capacity, confidentiality or the rights of the individual as well as next of kin;

  and

- Were staff to fail to exercise their individual Duty of Candour routinely within these requirements, it would be expected that this would be dealt with through normal line management performance management processes.

[33] IHRD Recommendation 8: Regulation and Quality Improvement Authority ('RQIA') should review overall compliance and consideration should be given to granting it the power to prosecute in cases of serial non-compliance or serious and wilful deception. (IHRD Report 2018)

[34] IHRD Recommendation 86 (iii) The Department should expand both the remit and resources of the RQIA in order that it might: scrutinise adherence to Duty of Candour (IHRD Report 2018)

Level 3: Candour when something has gone wrong and harm or death has been caused

What can an individual using health and social care services expect at Level 3?

5.26. When a serious incident has occurred, and harm or death has been caused, service users, or appropriately identified carers or next of kin can expect[35]:

- The organisation to appoint a family liaison person to support the individual, carer or next of kin to navigate the health system and keep them informed of the process, as set out in the DoH 'Statement of What You Should Expect If You are Involved in a Serious Adverse Incident';
- A 'Sincere Apology' for what has happened to be offered as soon as possible after the event. An apology does not imply guilt, or that there has been actual wrongdoing. Apologies might be offered by a number of individuals involved, but the most senior person offering an apology will reflect the seriousness of the event[36];
- Immediate, or as soon as possible, engagement with senior health and social care personnel who will explain in as accessible a way as

[35] Department of Health "Statement of What You Should Expect If You are Involved in a Serious Adverse Incident" 2020. and HSC Board 'A Guide for HSC Staff: Engagement/ Communication with Service Users/ Family/ Carer following a SAI' January 2015

[36] As part of the development of the statutory duties of candour, consideration is being given to the inclusion of protection against liability for making an apology when something has gone wrong and potentially caused harm or death of a patient/service user.

possible, as much as is known about what has happened and what the next steps will be;

- Processes to be initiated and what these will seek to achieve, in line with the DoH 'Statement of What You Should Expect If You are Involved in a Serious Adverse Incident', as per IHRD Recommendation 37 (i)'[37];

- The opportunity to participate in the subsequent investigation into or review of the incident, including (where appropriate):

    - Setting the terms of reference for any investigation or review;

    - Agreeing the level and form of engagement and communication on the process;

    - Access to relevant records and documents;

    - Being formally advised of the lessons learnt and changes that have been effected;

      and

    - Being afforded the opportunity to provide feedback on this process at its conclusion.

[37] IHRD Recommendation 37 (I)*Trusts should seek to maximise the involvement of families in SAI investigations and in particular: trusts should publish a statement of patient and family rights in relation to all SAI processes including complaints (IHRD Report 2018)*

- The health and social care personnel engaging with the individual, carer or next of kin will have the following skills and competencies between them, so there may be a number of people involved:
    - **Compassion** - the ability to be sensitive and empathise with the individual, carer or next of kin;
    - **Competence** – the ability to understand the individual circumstance of the serious incidence and explain what has happened in an accessible way as far as possible;
    - **Seniority** – depending on the seriousness of the situation, there will be present someone whose seniority reflects the seriousness with which the organisation is taking the issue – e.g. Medical Director, Chief Executive, or Chair of the Board in the most serious cases.
- The information provided will be provided in a timely[38] manner giving a full and honest explanation and not mislead by omission, as required under a statutory Duty of Candour;
- A description of how the individual, carer or next of kin will be able to be involved, if they wish, in these processes and the support that they will be given to participate in a meaningful way, as set out in IHRD recommendation 37;

[38] "Timely" to be defined within the Duty of Candour legislation, but practice in other jurisdictions is generally within ten working days of becoming aware of the incident.

and

- The additional support that will be given, if desired, to the individual, carer or next of kin over the forthcoming period, both as emotional support and support to engage meaningfully with the organisation, such as the right to be supported or represented by an independent advocate, as per IHRD recommendation 37 (iv)[39].

What is expected of individual service users, carers and next of kin at level 3?

5.27. For the individual service user that has survived a serious adverse incident , and has capacity (which is assumed unless proven otherwise) it is expected that they:

- Communicate their needs and requirements with the service to the best of their ability;

  and

- Participate in any subsequent process to a level which they find comfortable.

5.28. In the circumstances where the individual has died, or has been assessed as not having capacity, information will be sought on whom has been identified by the individual as able to act on their behalf, in accordance with existing guidance and

[39] IHRD Recommendation 37 (iv) *Trusts should seek to maximise the involvement of families in SAI investigations and in particular: a fully funded Patient Advocacy Service should be established, independent of individual Trusts, to assist families in the process. It should be allowed funded access to independent expert advice in complex[39] cases (IHRD Report 2018)*

statutory requirements. Where this is not available, processes will be introduced so that there is absolute clarity about who has a right to information, involvement and/ or the right to act on behalf of the individual. In situations such as this, there may be discord and disagreement within families about who should lead their involvement, and as far as possible clarity about the individuals' wishes needs to be firmly established routinely upon entry into the health and social care system.

5.29. Where individuals have been identified appropriately as next of kin or delegated by the individual to act on their behalf, the rights set out in the section for the individual apply.

46. Do you agree with the policy proposals at Level 3 of the Being Open Framework for Service Users and Carers? If yes, please outline your reasoning.

47. If not, do you have a preferred policy approach in respect of Level 3 of the Being Open Framework for Service Users and Carers? Please provide evidence to support alternative policy proposals.

What can health and social care staff expect at level 3?

5.30. Health and social care staff can expect to be supported by their organisation when something has gone wrong and harm or death has occurred. In particular they can expect:

- Clarity from their employer e.g. line manager or responsible Director about the consequent processes;

- Support from the organisation for the emotional impact of what has happened (for example, staff welfare services);
- To be treated justly if they have made a mistake;

  and

- Support and protection for acting in an open and candid manner through the process of review and any subsequent investigation (including, but not limited to, access to legal support, trade union support etc).

What is required of health and social care staff at level 3?

5.31. Health and social care staff will be required to explain openly and candidly what has happened, both actions taken/ omitted by them and action taken/ omitted by others. In particular:

- Staff will be expected to be open and honest about what has happened, providing all information and not withholding or changing any, as set out in their contract of employment[40];
- Staff will be expected to produce any written material that is relevant, and any other information that might be required;

[40] IHRD Recommendations 5 and 7 require the inclusion of compliance with the Duty of Candour and openness to be included in employment contracts of HSC employees with disciplinary action for breaches of contract

- Staff will also be expected to participate fully in any subsequent processes[41]. Where appropriate, staff may be required to apologise to individuals, carers or next of kin, or be involved in providing support to them;

  and

- Staff appointed to act in a family liaison capacity following a serious adverse incident are expected to comply with the requirements of the DoH 'Statement of What You Should Expect If You are Involved in a Serious Adverse Incident' in providing information to individuals affected.

48. Do you agree with the policy proposals at Level 3 of the Being Open Framework for Staff? If yes, please outline your reasoning.

49. If not, do you have a preferred policy approach in respect of Level 3 of the Being Open Framework for Staff? Please provide evidence to support alternative policy proposals.

What can health and social care organisations expect at Level 3?

5.32. Health and social care organisations can expect to have clear guidance on the legal and operational requirements they must fulfil whenever death or harm has been caused by an error.

[41] IHRD Recommendations 32 and *Failure to report an SAI should be a disciplinary offence and 35 Failure to co-operate with investigation should be a disciplinary offence* to be included in employment contracts of HSC employees

What is required of health and social care organisations at Level 3?

5.33. In alignment with the expectations of individuals, carers and next of kin, health and social care organisations will provide:

- Immediate, or as soon as possible, engagement with those affected by senior health and social care personnel who will explain, in as accessible a way as possible, as much as is known about what has happened and what the next steps will be;

- The information provided will be provided in a timely manner giving a full and honest explanation and not mislead by omission, as required under a statutory Duty of Candour;

- Health and social care personnel engaging with the individual, carer or next of kin, will have the following skills and competencies between them, so there is the expectation that there may be a number of people involved:

    - **Compassion** – the ability to manage the raw emotions that the individual, carer or next of kin may be experiencing;

    - **Competence** – be suitably qualified to understand as far as possible what has happened and explain it in an accessible way;

      and

    - **Seniority** – depending on the seriousness of the situation, there will be present someone whose seniority reflects the

seriousness with which the organisation is taking the issue – e.g. Chief Executive or Chair of the Board in the most serious cases.

- A 'Sincere Apology' for what has happened will be offered as soon as possible after the event. An apology does not imply guilt, or that there has been actual wrongdoing. Apologies might be offered by a number of individuals involved, but the most senior person offering an apology will reflect the seriousness of the event;[42]

- An explanation of what the next steps will be, the processes that will be initiated and what these seek to achieve, in line with the DoH 'Statement of What You Should Expect If You are Involved in a Serious Adverse Incident' IHRD recommendation 37 (i);[43]

- An engagement with the individual, carer or next of kin on how they wish to be involved in these processes (including the right not to participate) and to provide the support needed to participate in a meaningful way, as set out in IHRD recommendation 37;

- Additional support will be given, if desired, to the individual, carer or next of kin over the forthcoming period, both as emotional support and support to engage meaningfully with the organisation, such as the

[42] Feedback to date has identified the need for greater legal clarity around liability and/or protection when offering an apology

[43] IHRD recommendation 37 (I) *Trusts should seek to maximise the involvement of families in SAI investigations and in particular: trusts should publish a statement of patient and family rights in relation to all SAI processes including complaints (IHRD Report 2018)*

right to be supported or represented by an independent advocate, IHRD Recommendation 37 (iv)[44];

and

- The organisation will appoint a family liaison person to support the individual, carer or next of kin to navigate the health system and keep them informed of the process, as set out in the DoH 'Statement of What You Should Expect If You are Involved in a Serious Adverse Incident'.

50. Do you agree with the policy proposals at Level 3 of the Being Open Framework for Organisations? If yes, please outline your reasoning.

51. If not, do you have a preferred policy approach in respect of Level 3 of the Being Open Framework for Organisations? Please provide evidence to support alternative policy proposals.

What will be the relevance of the Statutory Organisational Duty of Candour in the context of Level 3 Openness?

5.34. The Organisational Duty of Candour places a statutory duty upon organisations to provide all accurate information to individuals, carers and next of kin, and to

[44] IHRD recommendation 37 (iv) *Trusts should seek to maximise the involvement of families in SAI investigations and in particular: a fully funded Patient Advocacy Service should be established, independent of individual Trusts, to assist families in the process. It should be allowed funded access to independent expert advice in complex[44] cases (IHRD Report 2018)*

other appropriate authorities when death or harm has been caused as a consequence of an error. This requires the information to be provided:

- As soon as possible after the adverse event;
- Proactively rather than having to be requested;
- Fully and honestly;
- Without misleading by omission;

  and

- Fully and honestly in response to any question reasonably asked.

5.35. This duty applies throughout any subsequent process, and the organisation will be required to provide the opportunity for the individuals, carers and next of kin, meaningfully to be involved in any subsequent processes.

What will be the relevance of the Statutory Individual Duty of Candour in the context of Level 3 Openness?

5.36. The individual statutory Duty of Candour places a legal requirement on individuals to be open and candid with information they have about a situation where death or harm has been caused. Individuals are required to share this information, and not inhibit others from sharing it.

5.37. HSC contracts of employment will be amended to reflect this requirement as set out in IHRD recommendation 5[45] and consequences for non-compliance for staff will be a disciplinary offence as set out in IHRD recommendation 7[46].

52. Is there any additional feedback that you wish to provide in respect of the policy proposals for the Being Open Framework? If so, please provide evidence to support alternative proposals, if possible.

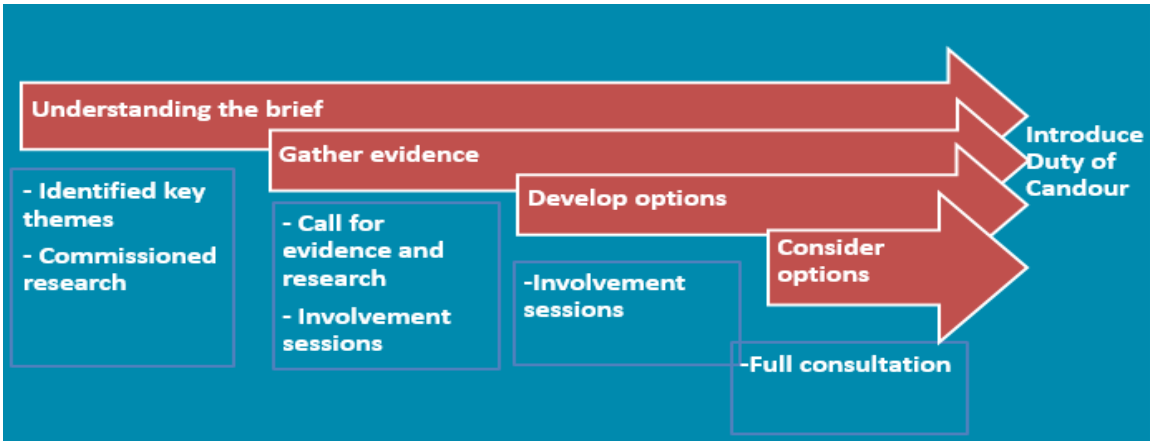
[45] IHRD recommendation 5: *Trusts should review their contracts of employment, policies and guidance to ensure that, where relevant, they include and are consistent with the Duty of Candour (IHRD Report 2018)*

[46] IHRD recommendation 7: *Trusts should monitor compliance and take disciplinary action against breaches*

6. Consultation

Consultation Overview

6.1. To date, the Workstream and Sub-group have undertaken a staged approach to co-produce Duty of Candour and Being Open policy proposals, as set out in the following diagram:



6.2. This consultation exercise seeks to build on the extensive pre-consultation involvement and engagement previously undertaken by the Workstream and Sub-group, in order to further develop the policy proposals for implementation.

How to respond

6.3. The consultation documentation will be available via the Department's website at:

www.health-ni.gov.uk/consultations/duty-of-candour

6.4. If, for any reason, you are unable to access the electronic versions of the documents you can request a paper copy by e-mailing IHRD.implementation@health-ni.gov.uk or by writing to the address below. The document and/or questionnaire may also be requested in an alternative format by also contacting this address.

6.5. The closing date for responses is **2 August 2021.** We would strongly encourage you to respond using the online questionnaire hosted on Citizen Space. Alternatively responses can be made by letter or e-mail to**:**

E-mail: IHRD.implementation@health-ni.gov.uk

Written: IHRD Implementation

Department of Health

Room D1

Castle Buildings

Stormont Estate, BELFAST

BT4 3SQ

Screening Outcomes

6.6. The DoH has screened the policy proposals in respect of their equality, rural, regulatory and economic impact. Whilst full impact assessments have not been completed to date in respect of the policy proposal, it is recognised that the impact will have to be screened again following the consultation exercise once the policy proposals have been further developed, and full impact assessments conducted

where necessary. In order to assist with this process, the Workstream has requested feedback on the potential impact of the policy proposals as part of the consultation exercise (see questions 53 and 54 below).

Data Protection

6.7. For this consultation, we may publish all responses except for those where the respondent indicates that they are an individual acting in a private capacity (e.g. a member of the public). All responses from organisations and individuals responding in a professional capacity will be published. We will remove email addresses and telephone numbers from these responses; but apart from this, we will publish them in full. For more information about what we do with personal data please see our consultation privacy notice (link below).

6.8. Your response, and all other responses to this consultation, may also be disclosed on request in accordance with the Freedom of Information Act 2000 (FOIA) and the Environmental Information Regulations 2004 (EIR); however all disclosures will be in line with the requirements of the Data Protection Act 2018 (DPA) and the General Data Protection Regulation (GDPR) (EU) 2016/679.

6.9. If you want the information that you provide to be treated as confidential it would be helpful if you could explain to us why you regard the information you have provided as confidential, so that this may be considered if the Department should receive a request for the information under the FOIA or EIR.

6.10. A link to a privacy notice in relation to this policy and consultation exercise is included below:

https://www.health-ni.gov.uk/publications/privacy-notice-ihrd-programme-Workstream-1-duty-candour-being-open

53. Do you have any feedback or data which may be relevant to the potential impact of the policy proposals within this consultation exercise, in particular in relation to the following areas:

• Equality;

• Human Rights;

• Rural Needs;

• Regulatory; and

• Economic Impact?

54. Do you have any feedback in respect of the potential indicators that could be used in order to measure the effectiveness of this policy?

55. Do you have any feedback or suggestions on how best to engage and involve stakeholders on the development and implementation of this policy going forward?

Annex A – Glossary of Terms

1. A glossary of terms and abbreviations to support the Duty of Candour and Being Open policy proposals.

Term used	What it means
Advocate	Family member, friend, trusted co-worker, or a hired professional who can ask questions, write down information, and speak up for you so you can better understand your illness and get the care and resources you need
Apology	A statement of sorrow or regret in respect of the unintended or unexpected incident
Arms-length bodies	Arm's-length bodies (ALBs) within Health and Social Care refers to the wide range of public bodies, including non-ministerial departments, non-departmental public bodies, executive agencies and other bodies. These include the Public Health Agency, Health and Social Care Board, Northern Ireland Social Care Council etc.
As soon as reasonably practicable	Guidance issued by the Department of Health will address how this term will be defined in practice. Guidance has defined it in other jurisdictions as within 10 working days, or sooner, of the organisation becoming aware of the incident.
Breach	An act of breaking or failing to observe a law, agreement, or code of conduct
Candour	The volunteering of all relevant information to persons who have or may have been harmed by the provision of services whether or not the information has been requested or whether or not a complaint about that provision has been made
Care Act 2014	Sets out local authorities' duties in relation to assessing people's needs and their eligibility for publicly funded care and support
Compassion	The ability to be sensitive and empathise with the individual, carer or next of kin
Competence	The ability to understand the individual circumstance of the serious incident and explain what has happened in an accessible way as far as possible

Term used	What it means
Co-production	A highly person centred approach which enables partnership working between people in order to achieve positive and agreed change in the design, delivery, and experience of health and social care
Criminal liability	Held legally responsible for breaking the law
Criminal sanctions	Penalties or other means of enforcement used to provide incentives for obedience with the law, or with rules and regulations
Donaldson Report-Right time, right place (2014)	A report outlining the findings from an expert examination of the application of health and social care governance arrangements to ensure the quality of care provision in Northern Ireland
Duly Authorised Representative	A person lawfully acting on the patient's behalf when the patient is unable to act for themselves (i.e. due to a lack of capacity)
Duty of Candour	Responsibility to be open and honest when things go wrong
Fixed Penalty Notice	A notice that offers the alleged offender the opportunity to pay a fine, in which case the matter is not prosecuted
Francis Inquiry Report (2013)	The Francis Inquiry report examined the causes of the failings in care at Mid Staffordshire NHS Foundation Trust between 2005 and 2009
Health and Social Care	The publicly funded healthcare system in Northern Ireland
Health and Social Care Trusts	Provide integrated health and social care services across five different geographical areas in Northern Ireland and also the regional Ambulance Service Trust
Hyponatraemia	Low sodium concentration in the blood
Inquiry into Hyponatraemia-Related Deaths	Investigation into the deaths of five children in hospitals in Northern Ireland
Moderate Harm	"Moderate Harm" would include: Harm that requires a moderate increase in treatment; and Significant, but not permanent, harm.
Near miss	Events that didn't harm anyone, but could have. They are not accidents, but they could have been accidents if the circumstances had been slightly different.

Term used	What it means
Notifiable Safety Incident	In circumstances where the significant harm threshold has been met, a matter will constitute a “notifiable incident”, and the organisation will have to comply with the statutory Duty of Candour procedure
Openness	A culture which enables concerns and complaints to be raised freely without fear. It is also about enabling truthful information about performance to be shared with staff, patients, the public and regulators.
Personal and Public Involvement (PPI)	The active and effective involvement of service users, carers and the public in Health and Social Care services
Policy	A set of ideas or a plan of what to do in particular situations that has been agreed to, officially, by a group of people
Professional body	A body of persons engaged in the same profession, formed usually to control entry into the profession, maintain standards, and represent the profession in discussions with other bodies
Prolonged psychological harm	Psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days
Quality Improvement	Systematic and continuous actions that lead to measurable improvement in health and social care services and the health status of targeted patient groups
Regulator	A regulator is a person or organisation appointed by a government to regulate an area of activity such as health. Regulators work to: - Set standards of competence and conduct that health and care professionals must meet in order to be registered and practise - Check the quality of education and training courses to make sure they give students the skills and knowledge to practise safely and competently - Maintain a register that everyone can search - Investigate complaints about people on their register and decide if they should be allowed to continue to practise or should be struck off the register - either because of problems with their conduct or their competence
Regulatory body	Public organisation or government agency that is set up to exercise a regulatory function

Term used	What it means
Relevant person	The patient, or a duly authorised representative, involved in a notifiable safety incident
Safeguarding	Actions taken to protect vulnerable groups from harm.
Sanction	A threatened penalty for disobeying a law or rule
Scope	The range of the subject matter to be considered
Serious Adverse Incidents	Any event or circumstance that led or could have led to serious unintended or unexpected harm, loss or damage to patients
Serious Harm	A permanent lessening of bodily, sensory, motor, physiological or intellectual functions, including removal of the wrong limb or organ or brain damage that is related directly to the incident and not related to the natural course of the service user's illness or underlying condition
Significant Harm	Harm which is considerable, noteworthy or important.
Statement of Rights	An explanation of what service users, carers and families should expect if involved in a Serious Adverse Incident
Statutory	The laws that a company, a government organisation, or the members of a particular sector must obey
Trade Unions	Organisations formed by workers from related fields that work for the common interest of its members
Unintended or unexpected incident	Circumstances where a patient or service user's care or treatment results in an outcome which was not intended or anticipated at the outset of proceedings

2. Abbreviations

Term used	Stands for	What it means
AvMA	Action Against Medical Accidents	UK charity for patient safety and justice
BDA NI	British Dental Association	Trade union for dentists in the UK
BHSCT	Belfast Health and Social Care Trust	Provides integrated health and social care services for the Belfast area
BMA	British Medical Association	Trade union and professional body for doctors and medical students in the UK
BSO	Business Services Organisation	Provides a broad range of regional business support functions and specialist professional services to the health and social care sector in Northern Ireland
CEC	Clinical Education Centre	Design and deliver education that supports Nurses, Midwives and Allied Health Professionals across Northern Ireland
COPNI	Commissioner for Older People Northern Ireland	The Commissioner for Older People for Northern Ireland is an independent champion for older people, who safeguards & promotes their interests.

Term used	Stands for	What it means
DoH	Department of Health	Government department responsible for government policy on health and social care matters
GDC	General Dental Council	Organisation which regulates dental professionals in the United Kingdom
GMC	General Medical Council	Public body that maintains the official register of medical practitioners within the United Kingdom
GP	General Practitioner	Medical doctor that treats all common medical conditions and refers patients to hospitals and other medical services for urgent and specialist treatment
HSCB	Health and Social Care Board	Statutory organisation. Responsible for commissioning health and social care services for the population of Northern Ireland
IHRD	Inquiry into Hyponatraemia-Related Deaths	Investigation into the deaths of five children in hospitals in Northern Ireland

Term used	Stands for	What it means
MDU	Medical Defence Union	A medical defence organisation in the United Kingdom, offering indemnity for clinical negligence claims and expert advice for its members
NHSCT	Northern Health and Social Care Trust	Provides integrated health and social care services for the Northern area
NIAS	Northern Ireland Ambulance Service Trust	The ambulance service that serves Northern Ireland
NIBTS	Northern Ireland Blood Transfusion Service	An independent, Special Agency of the Department of Health responsible for the collection, testing and distribution of blood donations
NICCY	Northern Ireland Commissioner for Children and Young People	Promoting the rights of children and young people in Northern Ireland
NICVA	Northern Ireland Council for Voluntary Action	A membership and representative umbrella body for the voluntary and community sector in Northern Ireland
NIGALA	Northern Ireland Guardian Ad Litem Authority	Represents children who are subjects of public law and adoption proceedings before the courts in Northern Ireland

Term used	Stands for	What it means
NIHRC	NI Human Rights Commission	Champions and guards the rights of all those who live in Northern Ireland
NIMDTA	Northern Ireland Medical and Dental Training Agency	Trains medical and dental professionals for Northern Ireland
NIPEC	Northern Ireland Practice and Educational Council	Supports the development of nurses and midwives by promoting high standards of practice, education and professional development
NIPSO	NI Public Services Ombudsman	An independent body providing an impartial and free examination of complaints about a range of public services
NMC	Nursing and Midwifery Council	The regulator for nursing and midwifery professions in the UK
PCC	Patient Client Council	An independent statutory organisation that represents the voice of patients, clients and carers on health and social care issues in Northern Ireland

Term used	Stands for	What it means
PHA	Public Health Agency	Regional organisation for health protection and health and social wellbeing improvement
PSA	Professional Standards Authority	Helps protect the public through work with organisations that register and regulate people working in health and social care. An independent body, accountable to the UK Parliament
PSNI	Pharmaceutical Society Northern Ireland	Regulatory and professional body for pharmacists in Northern Ireland
RCPsyc	Royal College of Psychiatry (NI)	Professional medical body responsible for supporting psychiatrists and in setting and raising standards of psychiatry in the United Kingdom
RQIA	Regulation and Quality Improvement Authority	Independent body responsible for monitoring and inspecting the availability and quality of health and social care services in Northern Ireland
SAI	Serious Adverse Incident	Any event or circumstance that led or could have led to serious unintended or unexpected harm, loss or damage to patients

Term used	Stands for	What it means
SEHSCT	South Eastern Health and Social Care Trust	Provides integrated health and social care services for the South Eastern area
SHSCT	Southern Health and Social Care Trust	Provides integrated health and social care services for the Southern area
WHSCT	Western Health and Social Care Trust	Provides integrated health and social care services for the Western area