Public Consultation on the Introduction of the Duty of Candour Summary Report

February 2023

Contents

1. Introduction & Background

The NHS must be a place where an open, learning, non-blame culture thrives and people are made to feel welcome and respected, whatever their background.

Healthcare is increasingly complex and sometimes people may suffer harm. When they do, how NHS bodies deal with these situations is very important and can make a tremendous difference to people's experience and to their on-going relationship with their care provider. This is of vital importance in health care settings where people often have long standing relationships.

In general, people want to be told honestly about what has happened and be reassured that, where applicable, lessons have been learned. Staff too need to be supported through the process.

The introduction of the statutory duty of candour for NHS bodies in Wales will complement the existing professional duty of candour required of individual healthcare professionals by the Nursing and Midwifery Council, the General Medical Council, the General Pharmaceutical Council, the General Optical Council, and other professional regulatory bodies. The statutory duty of candour and the professional duties of candour have the same aims – to be open and transparent with people receiving care and treatment.

It is also important to recognise that various steps have already been taken with the aim of developing a "culture of openness" in the NHS in Wales. These include the introduction of the Putting Things Right arrangements with the principle of Being Open, better reporting and investigation of serious incidents, reviews of all deaths in hospitals and the publication of Annual Quality Statements by LHBs, NHS Trusts and the Welsh Government. Additionally, as in England and Scotland, we have also sought to learn lessons from real cases where harm has been caused and from the recommendations of national reports and reviews. This work has placed NHS bodies in Wales in a strong position to implement the duty of candour.

In order to fulfil the Welsh Ministers' commitment to engage with stakeholders when developing the duty of candour Guidance and Regulations, we embarked on an ambitious engagement process, involving stakeholder workshops and patient focus sessions. Many professional practitioners, clinicians, representatives from Royal Colleges and professional bodies and independent health care providers and, above all, members of the public, service users and their representatives provided feedback, which has guided and assisted us in preparing the draft Guidance and Regulations. This culminated in the public consultation process the analysis of which is outlined in this report.

We believe the successful implementation of the duty of candour across the NHS in Wales will encourage better decision making and ultimately deliver better outcomes for all people who access health services.

2. Consultation Details

The Duty of Candour public consultation ran from 20 September to 13 December 2022 and following requests, was extended for a few days until 16 December 2022.

Responses were received in numerous ways:

- Online via the Smart Survey portal
- Submitting a hard copy via email
- Completing the easy read consultation document and submitting via email
- Email
- Letter
- Verbal feedback via awareness training sessions with Executive Boards
- Stakeholder group with young people (aged 14-20).

The consultation wanted views on how to introduce the necessary changes to implement the Duty of Candour and consulted on:

- how the Duty of Candour is to be introduced to NHS organisations through new statutory guidance and statutory regulations
- amending the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 and the 'Putting Things Right' guidance 2023 to enable the Duty of Candour to function with them.

All consultation documents were available on the following page: The Duty of Candour | GOV.WALES[1] and a list has been provided below. A public information video about the Duty of Candour was also produced and available via this link (https://youtu.be/BFQBeOB3VCY).

- Consultation document
- Consultation document – easy read
- The Duty of Candour statutory guidance 2023
- Annex A – Trigger review process
- Annex B – Levels of harm framework
- Annex C – Duty of Candour procedure
- Annex D – Support for service user
- Annex E – Making a meaningful apology
- Annex F – Review process and record keeping
- Annex G – Reporting, publication
- Annex H – Case study examples
- Annex I – Frequently asked questions
- The Duty of Candour Procedure (Wales) Regulations 2023
- The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales)(Amendment)Regulations 2023
- Putting Things Right guidance 2023.

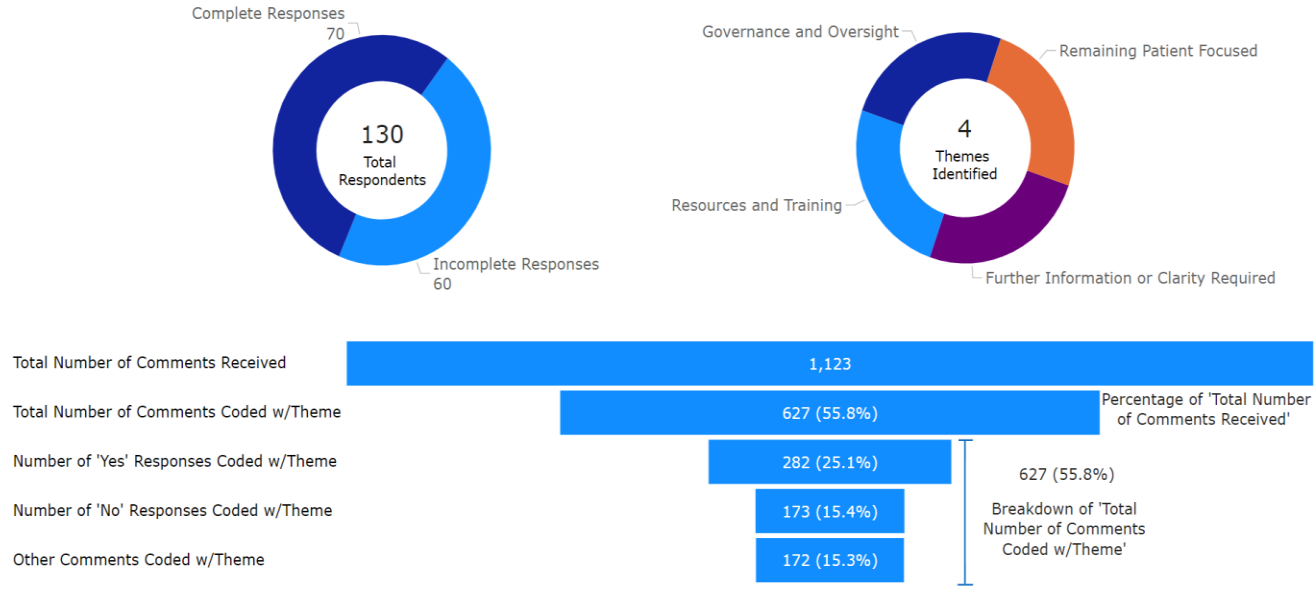
3. Analysis Methodology

[1]https://www.gov.wales/dutycandour#:~:text=Consultation%20description,wrong%20and%20harm%20has%20occurred.

All Consultation responses were received online via the Welsh Government Smart Survey. The responses received via email, which consisted of hard copies, letter responses and emails were also uploaded into the Smart Survey to ensure that a full data set with consistent formatting was available for analysis.

All data from the consultation was collated and an initial quantitative analysis was completed. This highlighted the number of both 'complete' and 'incomplete' responses, the response rate per question and for the applicable questions the yes/no percentage. The initial quantitative analysis of each question provided the early opportunity to highlight areas that respondents indicated would need to be considered further.

Each of the comments provided by respondents throughout the 40-question consultation were collated, along with the respondent ID and whether the respondent answered 'yes/no' or did not answer the question. There were occasions where respondents were not required to answer 'yes/no', or decided not to, but did provide a comment (this is outlined in Graphic 0.1 as 'Other Comments Coded w/Theme'). They were then grouped by question and chapter; the above steps provided the opportunity to analyse responses in a variety of ways. The chapters within the analysis mirror the consultation document, however sub-headings have been outlined throughout the report and focus specific areas of interest within the chapter.



Graphic 0.1: Breakdown of the number of comments, and comments coded with a theme.

The next step undertaken was the qualitative analysis of the respondent's comments to each question. In total the consultation received 70 complete responses and 60 that were incomplete, from this total of 130 responses, there were 1,123 comments. Using an inductive approach to the analysis, all comments were reviewed and considered, resulting in 4 themes with sub-themes linked to each of the themes as set out in Appendix A. Independently, another reviewer undertook a visual check of the themes against the comments received which provided consensus of the themes generated.

All comments were reviewed and where applicable coded with a theme and sub-theme, some comments had multiple themes and sub-themes attached to them. In total 627 comments were coded with at least one theme, equating to 56% of all comments. Comments that comprised of 'N/A; No Comment; No Answer; Don't Know' accounted for 235 responses; if these comments were filtered out of the thematic analysis, the percentage of comments that had a theme attached to them would rise to 70%.

Once all comments were reviewed and where applicable coded with a theme(s) and sub-theme(s), the data set was analysed and presented using Microsoft Power BI. Using the

Power BI software provided the opportunity to present a report that was interactive and easily accessible, offering the ability to highlight themes and sub-themes arising by question, chapter, respondent and whether the respondent answered yes or no. It also provided the opportunity to drill down into each theme and sub-theme to view the comments provided by respondents that were coded to that theme/sub-theme.

Sample Bias:

It is important to consider the sample size when analysing data and in the case of this consultation it was the number of respondents. The population of Wales[2] is 3,107,500, so to reach a confidence level of 95% (allowing for a 9% error rate) we required 119 respondents. We acknowledge there was a significant sample bias introduced, albeit in a positive manner, as the majority of respondents were either NHS organisations or professional groups that support NHS staff in one form or another.

We recognise and accept that the low number of citizen/service user responses indicates that the results obtained are less applicable to the wider population of Wales. Nevertheless, they were all carefully analysed and included within the consultation summary report. We also recognise that despite this lower number there were responses from 3rd sector organisations and advocacy groups such as the Community Health Councils (CHC's), which may also share the views of Citizen's more widely.

We have considered the reasoning behind the low number of responses, and acknowledge that the size, complexity and number of documents to be read, as well as the timing of the consultation may have been factors. A public awareness video was produced prior to the consultation and was available on the consultation page. However, it is unclear what further reach this video had via other communication channels. These are lessons which, will be shared to maximise learning for future consultations.

On further analysis of the respondents there is assurance that; as all Health Boards, NHS Trusts, Special Health Authorities, and many other professional organisations (e.g., Royal Colleges) responded to the consultation, the results strongly represent the professional views across the Welsh Government and NHS Wales landscape.

[2] ONS Census 2021
https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationestimates/bulletins/populationandhouseholdestimateswales/census2021

4. Summary of Respondents

The Duty of Candour consultation generated a total of 70 complete responses and 60 incomplete responses. Complete responses are those that were submitted as final, with the majority but not all the questions answered. Incomplete responses were not finalised prior to the consultation end date and in many cases no questions were answered at all.

The consultation did not require every question to be answered before submission and for the 70 complete submissions on average there were 52 responses to each of the 40 questions (a 75% completion rate).

For the 60 incomplete responses, the average number of responses for each of the 40 questions was only 1 (a 2% completion rate).

Throughout the report where questions have been answered in an incomplete submission their figures have been included in the yes/no percentages, and comments from these respondents have been recorded and considered in the thematic analysis.

Of the 70 completed responses, 50 respondents identified an associated professional organisation, 5 identified themselves as service users or citizens and 2 did not provide a response to this question. Within the list it is acknowledged that 13 respondents indicated they would like to remain anonymous.

The breakdown of respondents who submitted complete responses were:

- 14 NHS representative/organisations. e.g. Health boards or NHS trusts
- 25 professional associations e.g. Royal Colleges, Community Health Councils, Legal associations
- 3 charities e.g. Fair Treatment for Women Wales (FTFWW), Learning Disability Wales (LDW)
- 8 independent providers e.g. independent hospitals, independent dentistry practices
- 5 from citizens/service users; and
- 2 did not answer the question.

There were additionally 60 incomplete responses which did not list an answer.
A list of respondents along with their associated organisations is at Appendix B[3].

[3] 13 respondents requested anonymity

5. Summary of Responses by Chapter

5.1 Chapter 1: Statutory Guidance for the Duty of Candour

Duty of Candour Guidance and Procedure

This section of Chapter 1 of the consultation invited respondents to highlight their views on the Duty of Candour guidance, as well as how useful they felt the supporting tools and case studies will be in aiding the implementation of the Duty.

	Question	Number of Responses	Yes %	No %
Q1	Is the guidance on when the Duty of Candour applies clear?	72	87.5%	12.5%
Q2	Is the flowchart at Annex A, a useful tool for determining whether the duty has been triggered?	62	91.9%	8.1%
Q3	Are the guidance and case studies useful in determining what is meant by harm that 'could' be experienced?	62	85.5%	14.5%
Q6	Do you consider the case study examples set out in Annex H to be sufficiently comprehensive to explain when the Duty of Candour would be generated?	59	81.4%	18.6%
Q8	Is the guidance on the operation of the Duty of Candour procedure at page 11 of the guidance clear?	53	94.3%	5.7%
Q9	Are the flow charts at Annexes C and F1 useful as an aid to understanding how the procedure will operate?	54	98.1%	1.9%

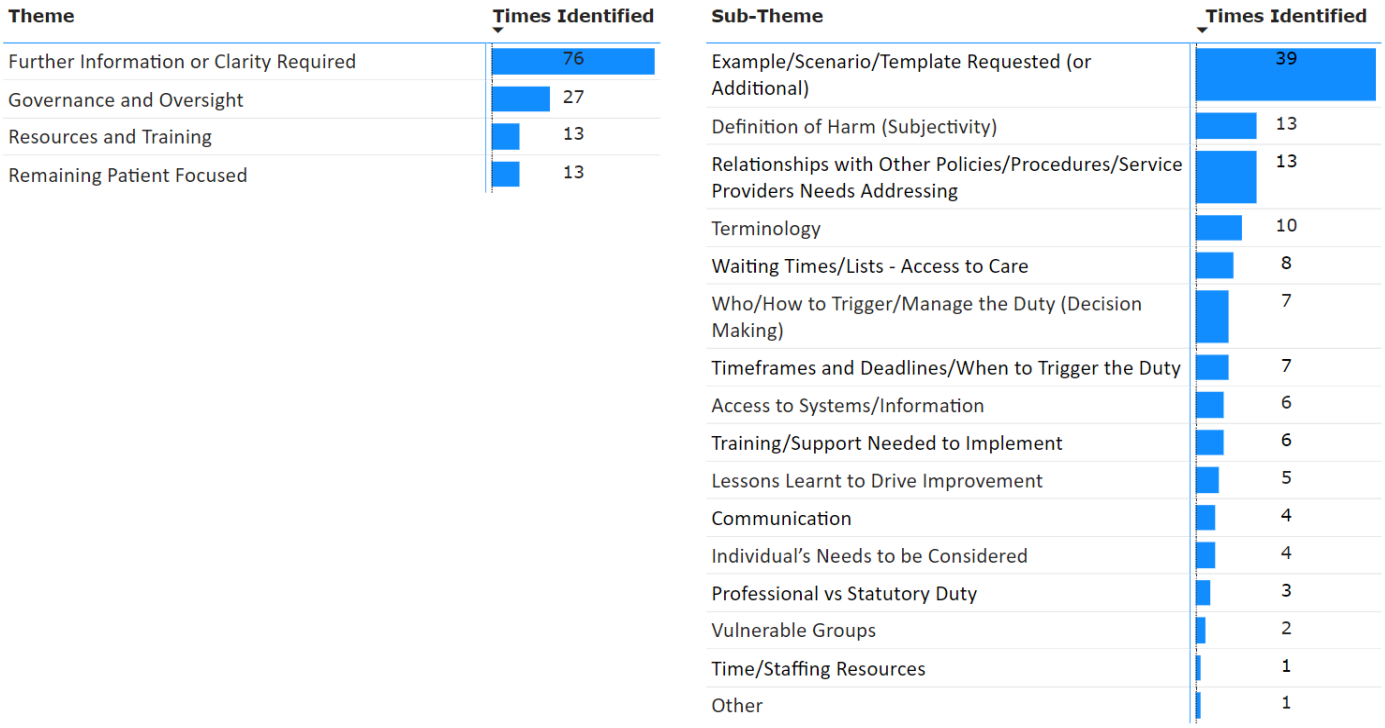
Graphic 1.1: Chapter 1 (Duty of Candour Guidance and Procedure) questions, number of responses and yes/no breakdown.

As highlighted above (graphic 1.1), the majority of respondents agreed that the guidance on when the Duty of Candour applies, and the operation of the Duty of Candour procedure is clear.

There were 9 respondents who felt that the guidance on when the Duty of Candour applies was not clear, with the main theme amongst those responses being the need for further information or clarity; and more specifically around the definition of harm, waiting lists and terminology being used within the guidance. A small number of respondents also queried who the guidance was aimed at, individual staff members or organisations? Others asked whether patients and their advocates could trigger the Duty; the latter point was also raised later in the consultation.

Welsh Government Response:
We welcome this feedback and have written a new chapter in the statutory guidance on harm, improved the definitions, provided greater clarity on the waiting list section and amended the terminology throughout. This will ensure that whilst the guidance is aimed specifically at the NHS organisations, it is more accessible to service users and their advocates.

Another common sub-theme amongst respondents was the need for further consideration around the relationships between the Duty of Candour and other policies and service providers. Some respondents highlighted that the role of independent service providers commissioned by an NHS Body to deliver treatment and care needed to be outlined within the guidance.



Graphic 1.2: Chapter 1 (Duty of Candour Guidance and Procedure) identified themes and sub-themes.

Questions 2, 3, 6 and 9 all aimed to determine if respondents felt that the flowcharts and case studies supporting the guidance were clear and useful aids to implement the Duty of Candour. The response was positive, however, the overwhelming theme from the comments provided was for further clarity or information; in particular, requests for more detail within the case studies and flowcharts, or additional examples for specific services or situations that could arise.

One national patient-led charity stated: "Participants were concerned that there were insufficient examples of patients using community mental health services [and] they also felt that there needed to be case studies referencing people accessing neurodivergent services" (Fair Treatment for the Women of Wales, Question 3).

This theme and sub-theme were predominant within the comments for Question 6 which had the highest disparity of responses within this chapter. Building on this, multiple respondents suggested creating a library of case studies highlighting when the Duty of Candour had been triggered, subsequently promoting good practice, and sharing of knowledge.

Welsh Government Response:
The flow charts have been updated and the case studies have been reviewed, resulting in the inclusion of additional case studies. These now specifically provide better examples of psychological harm, mental health, side effects and complications. As part of this process, we consulted with the Mental Health Users Forum, clinical experts in NHS practice and a Children and Young People's stakeholder group.

Duty of Candour Guidance and Procedure (Levels of Harm Framework)

	Question	Number of Responses	Yes %	No %
Q4	Do you agree that setting the threshold for triggering the Duty of Candour at moderate harm, severe harm or death reaches the right balance between informing service users and not overburdening NHS providers?	60	83.3%	16.7%
Q5	Does the harm framework at Annex B provide useful guidance on the type of harm that will fall into the categories of moderate, severe harm or death?	62	90.3%	9.7%

Theme	Times Identified
Further Information or Clarity Required	31
Remaining Patient Focused	8
Resources and Training	5
Governance and Oversight	5

Sub-Theme	Times Identified
Definition of Harm (Subjectivity)	24
Individual's Needs to be Considered	5
Example/Scenario/Template Requested (or Additional)	4
Time/Staffing Resources	4
Relationships with Other Policies/Procedures/Service Providers Needs Addressing	3
Communication	3
Terminology	2
Timeframes and Deadlines/When to Trigger the Duty	2
Professional vs Statutory Duty	1
Access to Systems/Information	1

Graphic 1.3: Chapter 1 Duty of Candour Guidance and Procedure (Levels of Harm Framework) questions, number of responses and yes/no breakdown – identified themes and sub-themes.

This section of Chapter 1 of the consultation invited respondents to highlight their views on the guidance provided around the Duty of Candour and specifically the levels of harm framework.

Over 80% of respondents agreed that the threshold for triggering the Duty of Candour should be moderate harm, severe harm, or death. However, 10 respondents disagreed with this statement and from their comments the predominant sub-theme was for more clarity and consideration to be given to the definition of harm and related categories due to potential subjectivity. Some respondents felt that the trigger for the Duty should be any harm experienced for the patient/service user, and others highlighted that the service users' definition of harm may be different to the service providers, as they are the ones experiencing it.

Welsh Government Response:
The Duty of Candour is about openness and honesty when things go wrong, when harm occurs, which currently is set at moderate or above. 'No harm' and 'Low harm' incidents represent the bulk of the number of closed incidents (83,408) per year with moderate or above incidents totalling 7,127 (7.87 %).

Low Harm and near miss incidents are still investigated by NHS bodies and lessons are learnt from them, but as there was minimal harm or harm didn't occur (in other words staff intervened to prevent it from occurring) there is no requirement to burden the organisation with the triggering of an organisational duty.

The feedback from stakeholders when developing the original policy intention was that there should be proportionality in the triggering of the Duty of Candour. Allowing all incidents to trigger the Duty would mean organisations would struggle to enact it fully and we would miss the opportunity to change the culture as intended by focussing on those harmed. The need to recognise the role of candour in responding to the physical and psychological injury a service user has sustained is well documented and therefore we intend to implement the triggering of the Duty at harm which is moderate or above.

It was also highlighted that the current number of 'moderate or above' patient safety incidents would result in the need for additional staffing resources to apply the Duty of Candour. Respondents that agreed with the proposed threshold also underlined that the level of impact on workloads will need to be analysed to ensure that it does not overburden services.

Welsh Government Response:

Recent data analysis utilising data supplied by all NHS Bodies, shows that 7.8% of reported incidents, that had been closed, would trigger the Duty of Candour each year (i.e. moderate harm or above). This is based on accurate grading at the end of the investigation verified by the Welsh Risk Pool. Additionally, a Regulatory Impact Assessment has been published that analyses the time taken for the Duty of Candour Procedure with the additional time required to complete it. This has also been published in both English and Welsh.

Although the general response to the questions within this chapter agreed that the guidance was clear, the theme identified most regularly was that the definition of harm and the examples provided needed to be further considered and developed. Several respondents highlighted need to for further information and examples of psychological harm incorporated into the guidance. It was also suggested by another respondent that there may need to be more examples of the 'low' and minimal' harm categories to support clinicians with determining when the Duty of Candour should be triggered.

As one citizen/service user highlighted: "It needs to be clear that psychological harm includes triggering trauma responses or mental health issues, exacerbating psychological symptoms or preventing recovery from mental health issues especially when this is for long periods of time" (Citizen/Service User, Question 1).

Welsh Government Response:

We welcome this feedback and recognise the need for further development around the harm framework and examples of psychological harm. These have been further developed following stakeholder involvement with the Mental Health User's Forum (a patient group). There are more examples now provided for each category where the Duty of Candour triggers to demonstrate the application of the category for psychological harm as well as other clinical case studies across the spectrum of harm to demonstrate when to trigger the duty and when not to.

Relationship with Professional Duties

This section of the chapter was comprised of one question looking for respondent's views on the whether the relationship between the professional Duty of Candour and the new statutory Duty of Candour was clear.

	Question	Number of Responses	Yes %	No %
Q7	Is the relationship between the professional Duty of Candour that many health professionals are subject to and the statutory duty of candour clear?	58	82.8%	17.2%

Theme	Times Identified
Further Information or Clarity Required	15
Resources and Training	4
Governance and Oversight	4
Remaining Patient Focused	1

Sub-Theme	Times Identified
Professional vs Statutory Duty	10
Training/Support Needed to Implement	3
Relationships with Other Policies/Procedures/Service Providers Needs Addressing	3
Example/Scenario/Template Requested (or Additional)	2
Terminology	2
Time/Staffing Resources	1
Who/How to Trigger/Manage the Duty (Decision Making)	1
Communication	1
Other	1

Graphic 1.4: Chapter 1 (Relationship with Professional Duties) question, number of responses and yes/no breakdown – identified themes and sub-themes.

Of the 58 responses to this question there were 10 respondents that highlighted that they did not feel the relationship between the professional and statutory Duty of Candour was clear. 7 of those 10 respondents highlighted that there needed to be more information or clarity around this relationship within the guidance. One respondent felt that it could be made clearer if 'professionals are expected to carry on with both their individual professional Duty of Candour and any that is triggered through the organisation they work for'. Another stated that they would welcome 'clarification on the duties and limitation of the individual clinician implication [versus] the NHS body'. Others highlighted that the threshold and terminology of the professional and statutory Duty of Candour does not appear to align. For example, one respondent referenced the professional duty within the GMC's Good Medical Practice is engaged 'when a patient suffers "harm or distress" when things go wrong. Therefore, this is a lower threshold, and it is likely the professional duty will be triggered more frequently'.

Whilst many respondents agreed that the guidance was clear, it was highlighted by some that training and support should be provided to ensure awareness and understanding of the relationship between the statutory and professional Duty of Candour, and the expectations on members of staff.

Welsh Government Response:

We are grateful for this feedback and have amended the section to improve clarity. The professional duty is one focussed on a professional's own practice and any action or omission that may have led to harm being experienced by a service user under their care. The organisational duty is one that covers all health care that has been provided, sometimes by multiple professionals, and the apology is undertaken for acts and or omissions resulting from the practice of others. It will be the legal duty of an NHS body in Wales, to apply the Duty of Candour to all service users to whom they provide healthcare. This contrasts with the professional duty which is a professional standard of the registrant.

Commissioned Services

This section of the consultation asked respondents if the Duty of Candour guidance is clear in relation to commissioned services, and if the supporting flowchart highlighted the procedure to follow for commissioned services in relation to the Duty.

	Question	Number of Responses	Yes %	No %
Q10	Is the guidance clear on how the Duty of Candour applies to commissioned services?	56	83.9%	16.1%
Q11	The procedure flow chart at Annex A1shows the procedure to follow when services are commissioned. Is the process clear?	52	90.4%	9.6%

Theme	Times Identified
Governance and Oversight	16
Further Information or Clarity Required	14
Resources and Training	2

Sub-Theme	Times Identified
Who/How to Trigger/Manage the Duty (Decision Making)	11
Terminology	8
Relationships with Other Policies/Procedures/Service Providers Needs Addressing	4
Other	2
Waiting Times/Lists - Access to Care	1
Vulnerable Groups	1
Example/Scenario/Template Requested (or Additional)	1
Time/Staffing Resources	1
Access to Systems/Information	1
Timeframes and Deadlines/When to Trigger the Duty	1

Graphic 1.5: Chapter 1 (Commissioned Services) questions, number of responses and yes/no breakdown – identified themes and sub-themes.

Over 80% of respondents felt that the guidance and procedure flowchart in relation to commissioned services was clear. However, a theme emerged amongst participants around governance and oversight, and more specifically whose responsibility it was to trigger and subsequently manage the Duty of Candour procedures in certain situations. Amongst the highlighted instances for further consideration were when social care provisions or independent providers are commissioned by an NHS Health Body, and when care has been provided by multiple NHS Health Bodies across boundaries (including Wales and England). The queries related to who should take responsibility, especially if there is a difference of opinion as to where the fault lies.

Respondents also underlined that more clarity was needed around the terminology used within the guidance and supporting flow chart. One respondent highlighted that the guidance does not specifically state the role of volunteers within services, and others highlighted that Annex A1 could be mis-interpreted ‘as suggesting if a provider is not an NHS body, the Duty does not apply to them’.

Welsh Government Response:

We have been very mindful that NHS services in Wales comprise of complex relationships, some of which are commissioned and some of which are hosted. We recognise that the relationships in those that deliver care on behalf of another body are often unique which makes it difficult to write generalised guidance. We have reviewed and strengthened the information in this section and in the flow chart, specifically mentioning the hosted relationship.

We have reduced the detail in some areas to ensure we remain as clear as we can and closer to the legislation in terms of whose responsibility for the Duty. This means organisations should also develop reporting and governance systems that best reflect the relationship with the provider to whom they have commissioned services from.

We have included a new section where the relationship between the Duty of Candour in social care and the Duty of Candour in the NHS is explained. We have detailed the need for both social care and health care partners to come together to minimise the duplication or multiple notifications with a service user or a family where significant harm has occurred. This is considered best practice to be expected by each partner equally.

Where more than one NHS body may be involved in the care pathway of the patient who has come to harm, we have strengthened the section relating to clear expectations of joint-partnership working in relation to communication with the patient and the sharing of information to enable one partner or another to fulfil their duty under the act.

The Annex flow chart has been made clearer. The question raised about whether and how volunteer services fall under the duty of candour is best understood as they enter into a contract of one form or another with an NHS body to operate within the NHS body's services. It is therefore considered the same as commissioning a non-NHS body. However, it must be related to the provision of healthcare as defined in the act.

Waiting Lists (Harm)

This section of the consultation asked respondents whether the guidance was clear in relation to triggering the Duty when harm occurs whilst service users are awaiting diagnostics and treatment. Building on this, it also asked respondents what further clarification would be helpful for service users and NHS organisations to understand when the Duty would be triggered in relation to harm occurring whilst service users are awaiting diagnostics and treatment.

	Question	Number of Responses	Yes %	No %
Q12	Is the guidance clear when harm to service users that occurs whilst waiting for diagnostics and treatment triggers the Duty of Candour?	58	74.1%	25.9%
Q13	What further clarification do you consider would be helpful for NHS organisations and service users with regards to harm sustained whilst waiting for diagnostics and treatment? Please provide any comments or further explanation.	43		

Theme	Times Identified
Further Information or Clarity Required	37
Resources and Training	11
Governance and Oversight	11
Remaining Patient Focused	4

Sub-Theme	Times Identified
Waiting Times/Lists - Access to Care	18
Example/Scenario/Template Requested (or Additional)	13
Relationships with Other Policies/Procedures/Service Providers Needs Addressing	7
Time/Staffing Resources	5
Definition of Harm (Subjectivity)	4
Training/Support Needed to Implement	4
Communication	4
Who/How to Trigger/Manage the Duty (Decision Making)	3
Access to Systems/Information	2
Terminology	1
Timeframes and Deadlines/When to Trigger the Duty	1
Other	1

Graphic 1.6: Chapter 1 (Waiting Lists (Harm) questions, number of responses and yes/no breakdown – identified themes and sub-themes.

A quarter of respondents felt the guidance around harm occurring when waiting for diagnostics and treatment was unclear. The predominant theme from responses was for further information and clarity around waiting times, the subsequent harm caused, and in what situation the duty would be triggered.

Multiple scenarios were raised by respondents, and further clarity was requested around unintended and unexpected harm caused by excessive waiting times. Respondents raised queries such as: 'Whilst it is stated that when a service user has been missed off a list incorrectly or not prioritised resulting in harm, it would be unexpected, would it not be a foreseeable element that a service user might then go on to suffer harm if not treated within a timely fashion, thereby causing potential expected harm?'

Others felt that deterioration resulting in harm whilst on a waiting list is 'unintended' and therefore should trigger the Duty when the harm threshold is met. As indicated in the graphic above many participants requested further case studies with more extensive detail to support the application of the Duty within this area.

Respondents also indicated that relationships with other guidance may need to be considered within this section of the Duty of Candour. Examples of such guidance outlined were NICE guidance regarding waiting times, and Referral to Treatment Targets (RTT), whilst another respondent suggested it could be helpful to link with 'Patient Reported Outcomes (PROMS) and Patient Reported Experience (PREMS) and whether there has been any correlation with harm sustained whilst waiting for diagnostics and treatment and an individual's outcome/experience'.

Concerns were also raised around the lack of resources in certain areas of NHS organisations including waiting list management and indicated that this may cause difficulties in implementing this section of the guidance.

Welsh Government Response:

We value the responses surrounding the section on harm to patients occurring during delays experienced whilst awaiting treatment or diagnostics.

We recognise that due to the global pandemic that there are significantly more patients on waiting lists than when the Health and Social Care Quality and Engagement Wales Act 2020 received Royal Assent. We have clearly understood the concerns of citizens and staff about the volume of patients who are waiting for care and how that wait may impact on them as harm.

We undertook further stakeholder engagement regarding this issue and have included some points raised in the re-write of the section, it is now included as part of the chapter on harm.

We also recognised that waiting lists and diagnostics is not wholly about secondary care and many waiting lists exist in primary care environments.

We accept that there may be inequity of resource to manage some lists in some organisations, but the guidance and the Duty of Candour remain integral along with the Duty of Quality, to improve the culture of organisations delivering care to our populations.

Reporting Requirements

This section asked respondents if they felt the requirement and subsequent process for Local Health Boards, NHS Trusts, and Special Health Authorities to publish their Duty of Candour reports was clear.

It also asked whether the proposed reporting dates were reasonable for primary care providers and Local Health Boards, NHS Trusts, and Special Health Authorities. Finally, it asked whether respondents felt it was reasonable for the annual Duty of Candour report to align with the existing Putting Things Right (PTR) report.

	Question	Number of Responses	Yes %	No %
Q14	Is the requirement for Local Health Boards, NHS Trusts, and Special Health Authorities, to publish their candour reports clear?	54	98.1%	1.9%
Q15	In relation to the reporting flow chart set out in Annex G, is the process clear?	54	96.3%	3.7%
Q16	Are the annual reporting dates of 30th September for primary care providers and 31st October for Local Health Board's, NHS trusts and Special Health Authorities' reasonable?	51	84.3%	15.7%
Q17	Is it reasonable to suggest the Duty of Candour report should be aligned to the existing annual PTR report already in place to avoid duplication?	52	96.2%	3.8%

Theme	Times Identified
Governance and Oversight	18
Resources and Training	13
Further Information or Clarity Required	12
Remaining Patient Focused	4

Sub-Theme	Times Identified
Time/Staffing Resources	9
Timeframes and Deadlines/When to Trigger the Duty	9
Relationships with Other Policies/Procedures/Service Providers Needs Addressing	8
Example/Scenario/Template Requested (or Additional)	5
Access to Systems/Information	4
Professional vs Statutory Duty	3
Lessons Learnt to Drive Improvement	3
Other	2
Definition of Harm (Subjectivity)	1
Terminology	1
Who/How to Trigger/Manage the Duty (Decision Making)	1

Graphic 1.7: Chapter 1 (Reporting Requirements) questions, number of responses and yes/no breakdown – identified themes and sub-themes.

Overwhelmingly respondents agreed that the requirement and process for Local Health Boards, NHS Trusts, and Special Health Authorities to publish their candour reports was clear. There was also a consensus amongst respondents that the report should be aligned with the existing annual Putting Things Right (PTR) report, to avoid duplication.

All 8 respondents that answered 'No' to question 16, highlighted that the reporting timeframes of 30 September for primary care providers and 31 October for Local Health Boards, NHS Trusts, and Special Health Authorities may be difficult to achieve. Numerous respondents felt that only leaving a month between Health Bodies receiving information from primary care services and publishing the report may not be long enough. Some suggested that this short deadline may result in important data or information being overseen.

One sub-theme that arose regularly during this section was around time, staff and resources and there were concerns raised around the increased workload that reporting may cause. It was highlighted the impact of this increased workload will need to be considered given the potential volume of work that will be required

Welsh Government Response:

The Putting Things Right (PTR) report is published in September. The intention is not for organisations to receive a whole years' worth of data in one month, but that they regularly receive the data through Datix Cymru to enable more manageable processing and analysis of the data and more importantly the learning that has occurred. It is anticipated that this analysis and learning will be shared on a regular basis through the quality management system across organisations as well as outside of them to improve the safety of care being provided. It is important to Welsh Government that the data from the Duty of Candour is used on a regular basis to reduce error, encourage learning and improve the experience of service users and staff who work in those organisations.

For those organisations who do not fall under the PTR guidance and regulations the publication of their annual report can be as a stand-alone report or as part of their existing patient experience or quality report.

Whilst we recognise that the Duty is newly introduced in Wales it should be remembered that organisations already report a large volume of the patient safety incident data and the new Datix Cymru system is set up to minimise the resource required to harness this data in a useable way. We do however recognise that organisations will need to undertake an assessment of resource requirements that would be sensitive to local needs and systems to ensure that they meet their legal obligations under the act. The Regulatory Impact Assessment has been developed in conjunction with the NHS stakeholder organisations and reflects this assessment more broadly.

5.2 Chapter 2: Statutory Regulations for Duty of Candour

Notification, Contact and Apology

This section of the analysis asked respondents if they felt that the guidance around the notification, contact and apology procedure for the Duty of Candour was proportionate, appropriate, and comprehensive.

	Question	Number of Responses	Yes %	No %
Q18	Is the explanation of 'on first becoming aware' in the guidance sufficiently clear to enable NHS organisations to know when the Duty of Candour procedure must start?	54	87.0%	13.0%
Q19	In circumstances where the service user is unable or unwilling to be notified the Duty of Candour has been triggered, are the provisions setting out who may act on the service user's behalf sufficiently comprehensive?	52	92.3%	7.7%
Q20	Are the provisions at Regulation 7(3) which allow an NHS organisation to record when it will not be engaging with a service user or a person acting on their behalf, either because:(i) they have made reasonable attempts to contact them and failed or(ii) where the service user has determined, they do not wish to communicate about the duty, proportionate?	54	94.4%	5.6%
Q21	Do Regulations 7(2) and 7(3) strike the right balance between the needs of service users or persons acting on their behalf and level of burden placed on NHS organisations?	51	94.1%	5.9%
Q22	Do you agree that 'in-person' notification is appropriate and proportionate when informing a service user or their representative that the Duty of Candour has been triggered?	54	92.6%	7.4%
Q23	Do you agree that it is appropriate and proportionate that the NHS organisation has the choice of which form of 'in-person' notification is most appropriate, considering these factors above?	56	85.7%	14.3%
Q24	Does the guidance on how to make a meaningful apology set out at section 7e and Annex E of the guidance provide sufficient information and advice to ensure a personal, meaningful apology is conveyed?	55	87.3%	12.7%
Q25	Do you agree that 'in-person' notification should be followed up by a written notification?	55	96.4%	3.6%
Q26	Do you agree the requirement placed on NHS organisations to take all reasonable steps to send the written notification within two working days from the date of the in-person notification is reasonable and proportionate?	53	67.9%	32.1%

Graphic *2*.1: Chapter *2 (*Notification, Contact and Apology*)* questions, number of respondents and yes/no breakdown.

A high percentage of respondents agreed that the guidance proposed within this section of the consultation was clear, proportionate, and appropriate in relation to the notification, contact and apology procedure for the Duty.

Welsh Government Response:

We welcome this feedback which reinforces the method undertaken to write the procedure which was developed through extensive stakeholder engagement and sense checking with service users and advocacy groups.

Contact (Questions 18, 19, 20 and 21):

The governance and oversight theme was identified regularly in question 18 which focused views on the explanation of when 'first becoming aware'. More specifically respondents suggested that the timeframes for the when the Duty procedure must start may need to be more definitive. Respondents indicated that without definitive timescales for notifying the service user on 'first becoming aware', NHS organisations may take the full 30 days allowed. Respondents also indicated there is no maximum number of days for the 'period of reflection' outlined within the guidance. Another sub-theme that was raised within Question 18 was around who the responsibility to manage the Duty

would sit with regarding the ‘in-person notification’. One respondent referenced the guidance stating ‘the NHS body must nominate a person with sufficient experience, knowledge and understanding of the Duty of Candour’ to assist the service user throughout the process. They queried whether it should outline that this person would be a senior member of the clinical team but may also be an experienced manager.

Respondents of Question 20 and 21 (which asked views on Regulation 7(3) - which allows NHS bodies to record when they have made attempts to contact a service user unsuccessfully) strongly agreed that the regulations were proportionate and struck the right balance between the needs of the service user and the burden on NHS organisations. However, many respondents highlighted the need for further clarity around the term ‘reasonable attempts’ in relation to the number of times NHS organisations should attempt to contact the service user or the person acting on their behalf. Responses suggested that the term ‘reasonable’ should be quantified for consistency throughout NHS organisations.

Welsh Government Response:

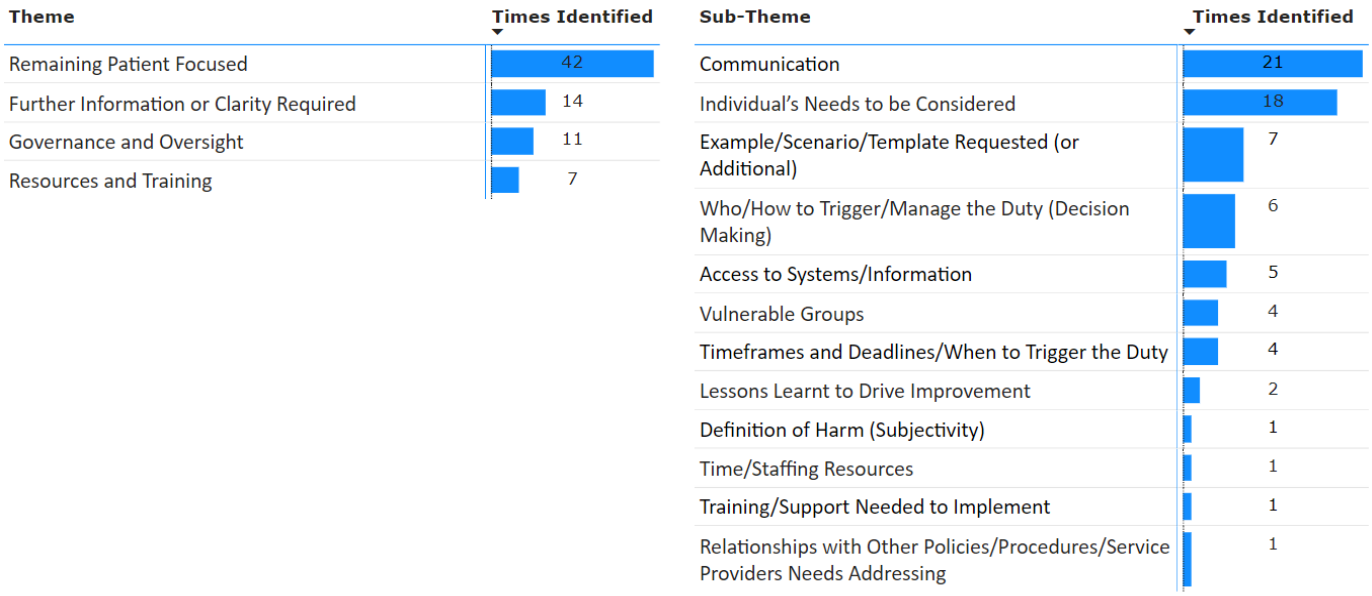
We recognise the concern about further clarity on the start date and have reviewed the guidance to ensure it follows the Act closely. Organisations are instructed to undertake the In-person notification as soon as they have ‘first become aware’ that the Duty of Candour has been triggered. However, it should be recognised that for some service users and their families, this may require some organisation is required to arrange a mutually convenient date and time to meet as well as ensuring the service user is notified using the method that best suits them. Additionally, the NHS training specifically mentions the need to undertake a short fact checking of the alleged incident (this is clear that it is not an investigation but to verify the validity of the reported facts). This safety net is important to avoid causing service users unnecessary distress or compounding psychological harm or injury.

We have reinforced in the guidance and the flow charts to clarify that NHS organisations should not take 30 working days in which to provide the in-person notification. The policy intent here is that service users are given a valid reason and explanation if the in-person notification is made later than 30 working days.

In relation to the sub theme in response to question 18, it is important that the skills, knowledge and aptitude of the person who undertakes the in-person notification is carefully considered. In some organisations that may be a senior manager but in primary care or in services commissioned by a Health board that may not be reasonable or achievable and a clinician may be the person who provides the in-person notification.

We welcome the positive feedback that we have managed to strike the balance correctly between burden and proportionality. It is not the intent of the statutory guidance to be prescriptive about the number of attempts to contact a service user that would be seen as reasonable. There are many situations which will have unique factors influencing this decision such as the severity of harm or service user specific issues. Nevertheless, the organisation must be able to justify that it has considered these factors when taking in to account this requirement and what is reasonable and proportionate.

<u>Notification (Questions 22, 23 and 25):</u>



Graphic 2.2: Chapter 2 (Notification) identified themes and sub-themes for questions 22,23 and 25.

Questions 22, 23 and 25 all invited respondent's views on the procedure and guidance around the 'in-person' notification, and specifically the appropriateness of this approach. The predominant theme that was highlighted within this section was remaining patient focused and the sub-themes; communication and the individuals needs to be considered. Respondents indicated that appropriate communication methods will need to be considered on an individual basis and take in to account factors such as preferred language and whether the service user is digitally literate. A number of respondents suggested that service users should be made of aware of the support available to them throughout the 'in person' notification process.

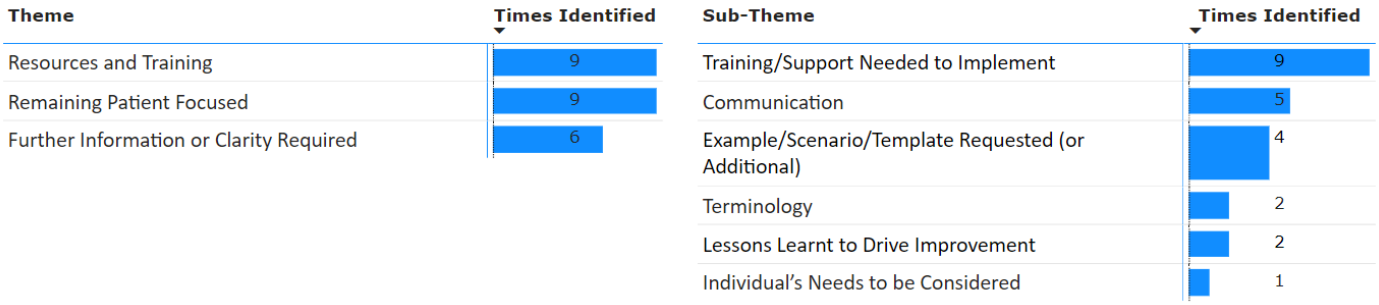
It was also highlighted the 'in-person' communication and follow up written notification should be personal, and it was agreed that the written notification will provide clarity and transparency for the service user whilst reinforcing what has been communicated in person.

One national charity underlined: "The written follow up is absolutely vital to older people who may suffer more than minimal harm. We hear repeatedly from older people where they have not been able to take information in fully during stressful times when hearing it for the first time, and so a written follow up is essential" (Age Cymru, Question 25).

Welsh Government Response:

We concur that the appropriate communication methods will need to be considered on an individual basis. It is important to take into account factors such as preferred language and whether the service user is digitally literate or has access to technology that may enable the in-person notification delivered virtually.
The guidance relating to the in-person notification and the written notification guidance has been strengthened and is clear on how this should be delivered, and the importance of patient centred and personal communication.

Apology (Question 24):



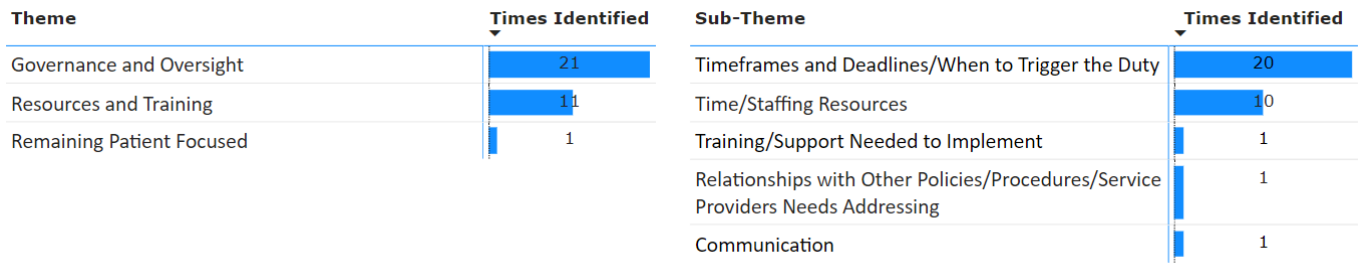
Graphic 2.3: Chapter 2 (Apology) identified themes and sub-themes for question 24.

Question 24 asked respondents whether the guidance was sufficient to ensure a personal and meaningful apology. Although a high percentage of responses agreed the guidance was sufficient (87%), respondents highlighted that there would need to be additional training and support provided to implement the guidance. Some respondents highlighted that staff would need training in handling difficult conversations and effective communication to avoid causing further harm or distress. It was also highlighted that training and guidance would need to consider communicating sensitive issues and furthermore communicating these issues to people with protected characteristics under the Equality Act 2010. Respondents also felt that training materials should include examples of where an apology has been effective as this would share learning and good practice. Finally, it was felt by some that the guidance should clearly outline that an apology does not equate to an admission of legal liability.

Welsh Government Response:

There are already a number of effective published guides on the delivery of an effective apology and a review of the supporting literature evidences the need for careful preparation and training. We have added additional references to excellent resources on making an effective apology and improved the guidance on how to deliver this successfully. We have also included the key factors to ensure an apology is sincere in the NHS training video.

Written Notification (Question 26):



Graphic 2.4: Chapter 2 (Written Notification) identified themes and sub-themes for question 26

Question 26, which focussed on the timing of the written notification, generated the largest disparity in responses within this section. 32% of respondents disagreed that the 'requirement placed on NHS organisations to take all reasonable steps to send the written notification within 2 working days from the date of the in-person notification' was proportionate. As highlighted in the graphic above, the sub-theme that was identified most within responses was around the timeframes and deadlines. Respondents overwhelmingly felt that the 2-day requirement would be unrealistic and unachievable, and it was suggested that this timeframe should be extended to 5-7 days. Strongly interlinked with this were concerns raised around time, staffing and resource pressures that a 2-day timeframe would place on teams. It was highlighted that additional resources would be required if this timeframe was to be kept and the inequity of resource to achieve this in primary care compared to that of Health Boards.

Welsh Government Response:

We welcome this feedback, which was also raised separately by NHS key stakeholders. We have considered these responses and have amended the Candour Procedure Regulations and the Guidance to now reflect that the written notification must be delivered within 5 working days after the day the in-person notification has taken place. We were also concerned that this would cause a disparity with the PTR regulations where written receipt of a concern must be made within 2 working days of the notification and so we have also amended the PTR regulations from 2 to 5 working days.

Training and Support

This section of the consultation asked respondents if they felt that training requirements and support provisions for staff was proportionate, it also provided the opportunity respondents to outline any training that they felt would be required for NHS staff to ensure successful implementation of the Duty of Candour.

	Question	Number of Responses	Yes %	No %
Q27	Do the training requirements cover all the staff that require training?	51	88.2%	11.8%
Q28	What type of training do you think would be required by NHS staff in addition to the current NHS training for the Duty of Candour to be successful? Please provide any comments or further explanation.	51		
Q29	Are the provisions related to staff support proportionate?	53	86.8%	13.2%

Theme	Times Identified
Resources and Training	64
Further Information or Clarity Required	4
Remaining Patient Focused	4

Sub-Theme	Times Identified
Training/Support Needed to Implement	26
Communication	12
Example/Scenario/Template Requested (or Additional)	8
Time/Staffing Resources	5
Lessons Learnt to Drive Improvement	5
Relationships with Other Policies/Procedures/Service Providers Needs Addressing	4
Vulnerable Groups	3
Access to Systems/Information	3
Individual's Needs to be Considered	3
Professional vs Statutory Duty	1
Terminology	1
Who/How to Trigger/Manage the Duty (Decision Making)	1

Graphic 2.5: Chapter 2 (Training & Support) questions, number of responses and yes/no breakdown – identified themes and sub-themes.

A high majority of respondents agreed that the training requirements and support provisions outlined were appropriate and proportionate. The predominant theme and sub-theme for this section were concentrated on time, resources and the training and support needed to implement the duty.

Training Provisions (Questions 27 and 28):

Respondents highlighted in Question 27 that training may need to be extended to a wider group of staff members to include non-clinical support and administrative staff. It was felt this was needed to ensure awareness of the Duty of Candour, but also because staff members in these areas may be involved in incidents that trigger the Duty.

Question 28 asked respondents what training they felt would be required, in addition to current NHS training, for the Duty of Candour to be successful. The most common sub-theme was around communication; respondents highlighted that staff would need training in areas such as making a meaningful apology, supportive and active listening, and handling difficult and conflicting situations, amongst others. Respondents highlighted that it was key for staff to be equipped with the skills to engage and communicate with service users sensitively and personally. Another suggestion was for staff to be trained on the categorisation of harm, so that it can be correctly determined to aid the Duty of Candour process.

Respondents also felt that training should be offered in a range of ways to support individuals learning styles and their roles. Face-to-face, online/virtual sessions, training videos, and scenario-based learning were all suggested. Some participants also felt that there should be a level of mandatory training with bespoke training for specific roles.

Welsh Government Response:

We agree with the feedback provided that the training may need to be extended to a wider audience of clinical and non-clinical staff in order to reach the right proportion of NHS staff. It is accepted that this may need to be undertaken as additional training, however it should be recognised that many professionals will have already undertaken specific candour training and advanced communication training which this will build upon. With that in mind a new Regulatory Impact Assessment was completed to reflect the increased numbers of additional staff to be trained.

Awareness training is now available for all NHS staff and the advanced training has also been developed for the use by a wider group of staff. It remains the NHS organisations responsibility to develop an organisational training needs analysis to ensure the right staff are aware and trained.

Support Provisions (Question 29):

In response to Question 29, participants highlighted the importance of support for staff members, as one respondent commented; ‘an incident that results in the Duty of Candour being triggered will be traumatic for the staff member as well as the service user’. Another respondent felt that there was an opportunity ‘to highlight the importance of staff raising concerns if they do not feel supported, [or felt] discouraged or prevented from reporting a notifiable adverse outcome’. The respondent suggested that the guidance could signpost relevant support and guidance for professionals around raising concerns.

Welsh Government Response:

Lessons learned from the global pandemic have demonstrated, not only how support and wellbeing for staff is intrinsic to a sustainable workforce but also in creating a culture of safety where staff feel able to speak up about safety and feel valued. We agree that the consultation document didn't adequately address this. There is now a section on staff support and Annex D1 not only addresses this for a member of staff who may have been involved in an incident, but also outlines support for those undertaking the Duty of Candour notification or procedure.

Governance and Oversight

This section of the consultation asked respondents if Regulations 10 and 11 will assist NHS organisations with establishing effective governance structures and provided the right level of leadership to fulfil the Duty of Candour.

	Question	Number of Responses	Yes %	No %
Q30	Do Regulations 10 and 11 assist NHS organisations in establishing an effective governance structure to ensure compliance with the Duty of Candour procedure?	53	96.2%	3.8%
Q31	Do the regulations assist an organisation in providing the right level of leadership to fulfil its Duty of Candour responsibilities?	54	90.7%	9.3%

Theme	Times Identified
Resources and Training	6
Governance and Oversight	6
Remaining Patient Focused	1

Sub-Theme	Times Identified
Who/How to Trigger/Manage the Duty (Decision Making)	6
Time/Staffing Resources	3
Training/Support Needed to Implement	3
Lessons Learnt to Drive Improvement	1

Graphic 2.6: Chapter 2 (Governance and Oversight) questions, number of responses and yes/no breakdown – identified themes and sub-themes.

There was overwhelming agreement that Regulations 10 and 11 will assist NHS organisations in establishing effective governance structures and to provide the right of leadership to fulfil its Duty of Candour responsibilities.

Only a small number of respondents disagreed with either of the questions posed within this section. However, some comments highlighted that adequate training and resources will need to be in place to fulfil the Duty of Candour. Others felt that there may need to be further clarity around the seniority of the staff member who will manage the process, and others suggested that the guidance should, 'be clear that, if the responsible officer is not a relevant clinician, he/she/they will ensure appropriate clinical input to the candour procedure'.

Welsh Government Response:
We recognise that the feedback indicated the regulations will assist organisations in establishing governance structures and leadership. Training of board members is part of the Regulatory Impact Assessment and all NHS boards have already received specific training in respect to the Duty of Candour. It is felt the guidance and regulations are very clear on the seniority of staff who will lead this process. The level of detail suggested in terms of specifying how a responsible officer undertakes this Duty is not supported at this time as this Duty applies across a wider and complex landscape and NHS bodies must be free to organise how they deliver this Duty locally to reflect their local population and their organisation.

5.3 Chapter 3: Minor Amendments to the Putting Things Right Regulations; and

5.4 Chapter 4: Amendments and Updates to the Putting Things Right Guidance

Putting Things Right

These chapters of the consultation invited participants views on the relationship between the Duty of Candour and Putting Things Right (PTR), and the proposed changes to the Putting Things Right Regulations.

	Question	Number of Responses	Yes %	No %
Q32	Do you agree the time limits under the PTR Regulations should, when the Duty of Candour is triggered, run from the date of the in-person notification rather than the date the NHS organisation would have been notified of the incident?	50	90.0%	10.0%
Q33	Do you think changing the 'Putting Things Right' rules like this will cause problems? For example, do you think it would be better to not tell the person what has happened if it is in their best interest? A flow chart is available in Annex F1.	50	54.0%	46.0%
Q34	Is the link between the Duty of Candour and the PTR process clear in the guidance and Annex F1?	53	90.6%	9.4%
Q35	Are the proposed changes to the PTR guidance in respect of the Duty of Candour and PTR amendment Regulations clear?	49	100.0%	0.0%
Q36	Do you think that the changes made to the PTR guidance are sufficient to provide clarity on how Duty of Candour interacts in the PTR procedures?	49	87.8%	12.2%

Graphic 3/4.1: Chapters 3 and 4 questions, number of responses and yes/no breakdown.

Besides Question 33, there was a consensus within these sections that the changes to the Putting Things Right guidance in relation to the Duty of Candour was clear.

Question 33:

Theme	Times Identified
Remaining Patient Focused	31
Further Information or Clarity Required	3
Governance and Oversight	3
Resources and Training	1

Sub-Theme	Times Identified
Individual's Needs to be Considered	21
Communication	5
Professional vs Statutory Duty	2
Relationships with Other Policies/Procedures/Service Providers Needs Addressing	2
Vulnerable Groups	1
Training/Support Needed to Implement	1
Timeframes and Deadlines/When to Trigger the Duty	1
Lessons Learnt to Drive Improvement	1

Graphic 3/4.2: Chapters 3 and 4 identified themes and sub-themes for question 33.

Question 33 underlined a clear contrast of opinions, with 54% of respondents agreeing that changing the Putting Things Right rules to the below, will cause problems:

'The person must be told if something went wrong with their care, in accordance with the objective behind the Duty of Candour. [However], they do not need to be involved in the process or the investigation, if that is what is best for them'

Although there are conflicting views on this question, the remaining patient focused theme and the individuals needs to be considered sub-theme arises on both sides of the argument. For respondents that answered 'no', changing the rules will not cause problems. It was felt that adults with capacity have the right to know when things have gone wrong, and it is not for Health Bodies to decide when it is in the best interest of service users to not know. Respondents also highlighted that if a service user lacked capacity to understand what has happened, then an appropriate person acting on their behalf should be informed and included in further decisions.

Participants also underlined that if the Putting Things Right rules were not changed and there was no scope to disclose incidents this would cause a conflict between the professional and statutory Duty of Candour.

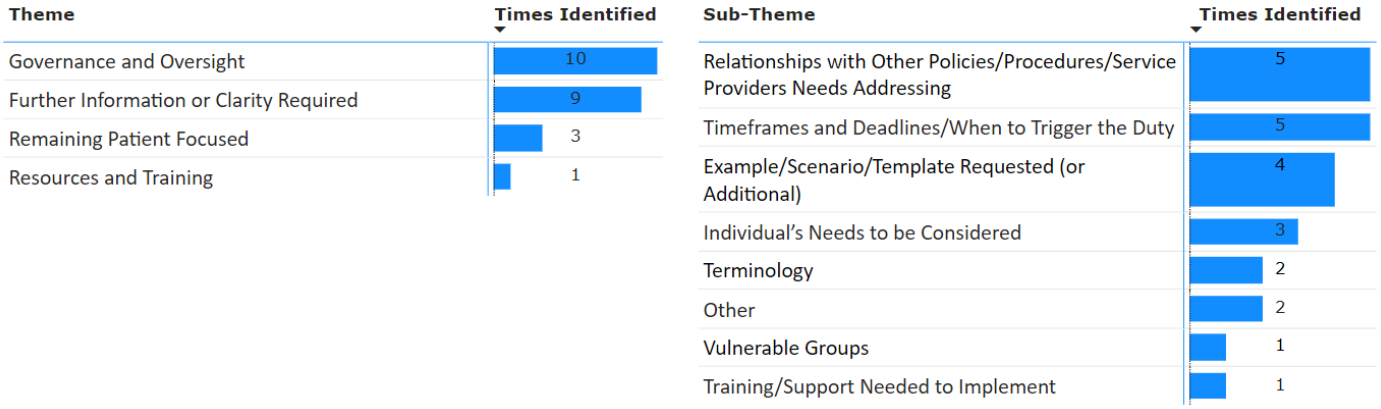
Respondents on both sides of the argument indicated that they felt an approach of openness and transparency was important. However, those that felt changing the rules could cause problems, underlined that there will be exceptional occasions where it would be in the best interest of service users not to be informed of an incident. Examples of these occasions provided by respondents included: where it will cause too much distress and not alter the outcome, where it could cause the service user to lose confidence in their treatment or provider, or it would have an adverse effect on the service user's mental health and wellbeing. In these circumstances, it was suggested that a level of flexibility should be incorporated into the guidance, and the reasoning behind the decision will need to be clearly recorded. One respondent stated that they 'would not want legislation forcing people to be informed of incidents where it genuinely would do them more harm than good'.

Welsh Government Response:

It is accepted that the feedback was mixed on question 33 and that both groups of responses highlighted significant consequences to the amendments as consulted which were unintended. After very careful evaluation the decision was made to ensure that service users are always informed of the concern raised. However, it is not compulsory to involve the service user or someone acting on their behalf in an investigation where it is felt, or the service user has indicated it is not in their best interest. We consulted on the candour regulations to include the caveat on disclosure where such disclosure would prejudice a criminal or safeguarding investigation. We have therefore retained that caveat.

Questions 32, 34, 35 and 36:

	Cwestiwn	Nifer yr Ymatebion	% Ydyn	% Nac ydyn
C32	Ydych chi'n cytuno y dylai'r terfynau amser o dan y Rheoliadau Gweithio i Wella, pan gaiff y Ddyletswydd Gonestrwydd ei sbarduno, ddechrau o'r dyddiad y rhoddir gwybod ar lafar yn hytrach na'r dyddiad y byddai Sefydliad y GIG wedi cael gwybod am y digwyddiad?	50	90.0%	10.0%
C34	A yw'r cysylltiad rhwng y Ddyletswydd Gonestrwydd a'r broses Gweithio i Wella yn glir yn y canllawiau ac yn Atodiad F1?	53	90.6%	9.4%
C35	A yw'r newidiadau arfaethedig i'r canllawiau Gweithio i Wella mewn perthynas â'r Ddyletswydd Gonestrwydd a'r Rheoliadau Diwygio Gweithio i Wella yn glir?	49	100.0%	0.0%
C36	Ydych chi'n credu bod y newidiadau a wneir i'r canllawiau Gweithio i Wella yn ddigon i egluro sut mae'r Ddyletswydd Gonestrwydd yn rhyngweithio â'r gweithdrefnau Gweithio i Wella?	49	87.8%	12.2%



Graphic 3/4.3: Chapters 3 and 4, questions, identified themes and sub-themes for questions 32, 34, 35 and 36.

Only 5 respondents disagreed with the statement outlined in Question 32, and the common sub-theme was around timelines and deadlines. The respondents felt that the Putting Things Right and Duty of Candour timelines should align to avoid any delays and ensure a timely notification for the service user.

The final 3 questions of this section did not raise as much disparity within the responses. The vast majority felt that the changes to the Putting Things Right guidance and the links to the Duty of Candour guidance were clear and sufficient. Some participants requested more detail within the flowchart in Annex F1 to set out the link between the Putting Things Right and Duty of Candour processes.

Welsh Government Response:

It is recognised that there needed to be further clarity on the interaction between duty of candour and the PTR process to ensure timely notification to the service user. Further review was undertaken and discussions with key stakeholders developed the policy intention to bring the duty of candour and PTR process as closely aligned as possible. With that in mind the amendments to PTR outlined in these questions were removed and instead the timeline starts from the day upon which the organisation received notification of the concern. In a duty of candour situation this is considered to be when the organisation "first becomes aware" that the duty has been triggered.
A completely reworked annex now demonstrates both the PTR pathway and the Duty of Candour pathway and how these interrelate and flow together. We are most grateful for this feedback.

5.5 Chapter 5: Integrated Impact Assessments

Integrated Impact Assessments (Protected Characteristics)

This chapter of the consultation asked participants for their views on how the proposals in this consultation may impact people with protected characteristics as defined under the Equality Act 2010.

	Question	Number of Responses	Yes %	No %
Q37	What are your views on how the proposals in this consultation might impact? on people with protected characteristics as defined under the Equality Act 2010 on health disparities on vulnerable groups in our society Please provide your comments.	45		

Theme	Times Identified
Remaining Patient Focused	16
Further Information or Clarity Required	9
Resources and Training	9
Governance and Oversight	1

Sub-Theme	Times Identified
Vulnerable Groups	9
Communication	9
Training/Support Needed to Implement	8
Lessons Learnt to Drive Improvement	6
Access to Systems/Information	1
Relationships with Other Policies/Procedures/Service Providers Needs Addressing	1
Individual's Needs to be Considered	1

Graphic 5.1: Chapter 5 (Integrated Impact Assessments (Protected Characteristics) question, number of responses – identified themes and sub-themes.

Some respondents indicated that the implementation of the Duty of Candour should have a positive impact on equity and provide the opportunity for healthcare providers to learn and improve. However, numerous respondents outlined that there would need to be consideration for the additional support offered and provided for those with protected characteristics as defined under the Equality Act 2010. Participants outlined that service users within this group may need access to additional support throughout the Duty of Candour process.

This statement us outlined by one Health Board representative in the following statement: "For some protected characteristic groups consideration must be given as to how the Duty of Candour is discharged in particular to ensure that the person is supported and if required that their advocates [are] present, in addition this may require different formats or types of communication tailored to the person's needs" (Aneurin Bevan University Health Board, Question 37).

Welsh Government Response:

It is a key central ethos of the duty of candour that service users and their families or representatives are treated with openness, honesty and transparency. It is imperative to avoid previous situations in the NHS where patients or staff concerns are ignored and hidden, and this is especially important for those who are vulnerable or seen as a minority group. The need for strong advocacy where the service user is supported to be central to this process is an absolute tenant of the approach we are implementing for the Duty of Candour. The feedback clearly highlights significant concerns about the need for the right support and access to that support, without which we may not realise our goals for an open and honest culture. We have again improved the guidance on support for service users in the guidance and annexes.

It was underlined that the communication methods used will need to be flexible and tailored so they are appropriate for the individual; ensuring that they understand the impact that the Duty of Candour being triggered will have on them and the support that they can access. It was felt that any communication should be offered in the service users first language, with some respondents highlighting that the British Sign Language (BSL) Act 2022 will need to be considered and facilitated. Furthermore, respondents indicated that any adjustments that can be made to accommodate service users should be acted upon. As highlighted in responses to Question 33, multiple respondents once again stated that the offer of advocacy and support will need to be clear for those with protected characteristics, and additional provisions may well be required.

Welsh Government Response:

We welcome this recurrent theme and agree that building on the existing training provided and including this in the guidance and training for Duty of Candour will aim to enable staff to consider how they will meet the service user's needs.

Another theme that arose within this section was resources and training, and respondents highlighted that for the outlined provisions to be implemented, additional training, resources and support will be required for staff. As highlighted in responses to Question 27 and 28, respondents stated that staff members will need training on communication. Building on this, they will need to 'understand the impact of the Duty of Candour, concerning individuals with protected characteristics, [those with] health disparities and who are identified as the most vulnerable in society' to ensure that they can effectively communicate with service users that have a protected characteristic.

Welsh Government Response:

Training will need to reflect these considerations, however in the guidance we have endeavoured to express the need for this to be an active consideration and proactive offer especially around communication and advocacy and we have referenced Llais (Citizen Voice Body), which is a new body which will represent the interests of the public in respect of health services and social services and is due to be operational from April 2023.

Some suggestions were made by respondents that could support training and improvement following the implementation of the Duty of Candour in relation to those with protected characteristics. Some examples were:

i. Collate 'potential scenarios for the impact of the Duty of Candour, taking into account the range of individual protected characteristics'
ii. Collate 'case studies following the implementation of the regulations, [and] include how people from these groups perceive interactions relating to the duty, with a view to improving the experience for all parties'
iii. A patient panel to be formed specifically relating to the Duty of Candour.

All three of the suggestions above support the statement provided by one respondent that the impact of the Duty of Candour on those with protected characteristics under the Equality Act 2010 will need ongoing monitoring to ensure that it is positive and driving learning and improvement.

Welsh Government Response:
We are grateful for these suggestions which have been included in the ongoing work being undertaken around quality and safety systems across Wales. Welsh government have already commissioned a robust evaluation programme for the introduction and ongoing impact of the Duty of Candour by an external expert group. We will ensure this, and the other consultation feedback points are shared with them to help shape their work.

Integrated Impact Assessments (Welsh Language)

This chapter of the consultation asked participants for their views on how the proposals in this consultation would have an impact on the opportunities for people to use the Welsh language, and whether it would be positive or negative.

	Question	Number of Responses	Yes %	No %
Q38	We would like to know your views on the effects that the Duty of Candour proposals would have on the Welsh language, specifically on opportunities for people to use Welsh and on treating the Welsh language no less favourably than English.For example, what effects do you think there would be? How could positive effects be increased, or negative effects be mitigated?Please provide your comments.	44		
Q39	Please also explain how you believe the proposed Duty of Candour policy could have positive or negative effects on opportunities for people to use the Welsh language or treat it no less favourably than the English language? Please provide your comments.	45		

Theme	Times Identified
Remaining Patient Focused	23
Resources and Training	21
Governance and Oversight	3
Further Information or Clarity Required	1

Sub-Theme	Times Identified
Communication	23
Time/Staffing Resources	16
Training/Support Needed to Implement	4
Timeframes and Deadlines/When to Trigger the Duty	3
Example/Scenario/Template Requested (or Additional)	1
Access to Systems/Information	1

Graphic 5.2: Chapter 5 (Integrated Impact Assessments (Welsh Language) questions, number of responses – identified themes and sub-themes.

The two themes which arose regularly within this chapter were interlinked and respondents highlighted that providing Welsh communications would be dependent on access to resources. Many participants mirrored comments with Question 37 in stating that additional provisions would be required, to ensure that service users received all correspondence and communication in their preferred language. It was felt the offer of bi-lingual services would be necessary to support Welsh speakers in understanding the impact that the Duty of Candour would have on them. One participant underlined that the notion of the 'Active Offer' should be embedded into the Duty to increase the positive impact on the Welsh language.

Many participants highlighted that there would need to be practical considerations for the above to be implemented successfully such as ensuring translation services have sufficient resources, and training in place. One respondent suggested that if there were no Welsh speaking staff available for the initial notification with the service user then the follow-up notification must be bi-lingual to ensure clarification for the service user. Another practical consideration that was highlighted was around timeframes and deadlines. It was suggested that these may need to be extended when translation services are required, whilst others highlighted that this may have a negative impact and delay the notification and contact for service users.

Welsh Government Response:

We recognise that the majority of the respondents to this consultation were professional organisations, Royal Colleges and NHS organisations. As such we have discussed the need to be aware of bias in the themes and responses that have been analysed. We are therefore mindful that the Welsh language must be an active offer and whilst there may be logistical difficulties each organisation must put in place adequate systems to ensure that service users are communicated with in the most appropriate manner for the service user and not for the organisation. It is not acceptable to describe the need to translate a letter or communicate in Welsh as a reasonable rationale for delays to notification. In many cases service users can be disadvantaged where English is not their first language, and their understanding is greatly enhanced when communicated in Welsh. The service users' needs should always be central to how we manage situations where harm has occurred to a service user during the delivery of healthcare.

5.6 Additional Comments

The final section of the consultation asked participants to highlight any additional issues and feedback that they felt had not been addressed throughout the consultation.

	Question	Number of Responses	Yes %	No %
Q40	We have asked several specific questions. If you have any related issues which we have not specifically addressed, please use this space to report them:Please provide your comments.	52		

Theme	Times Identified
Further Information or Clarity Required	17
Governance and Oversight	12
Resources and Training	10
Remaining Patient Focused	9

Sub-Theme	Times Identified
Relationships with Other Policies/Procedures/Service Providers Needs Addressing	11
Definition of Harm (Subjectivity)	5
Time/Staffing Resources	5
Communication	5
Example/Scenario/Template Requested (or Additional)	3
Terminology	3
Training/Support Needed to Implement	3
Lessons Learnt to Drive Improvement	3
Other	3
Professional vs Statutory Duty	2
Access to Systems/Information	2
Vulnerable Groups	1
Who/How to Trigger/Manage the Duty (Decision Making)	1
Individual's Needs to be Considered	1

Graphic 6.1: Additional comments, number of responses– identified themes and sub-themes.

A range of themes and sub-themes arose within the last chapter of the consultation. Some suggestions and issues that were raised within this chapter have been highlighted and addressed previously within the summary report such as: the definition of harm, time and staff resources, and communication with service users amongst others.

However, the main sub-theme that arose was around relationships with other policies/procedures/service providers and participants underlined some areas where further information or considerations may be required, such as:

i. There are major contract changes planned within primary care in April 2023, and some respondents felt that the additional workload from those changes and the introduction of the Duty of Candour will need to be further considered. Another respondent felt that the introduction of the Duty for independent providers should align, so that all providers are implementing the Duty of Candour at the same time.
ii. One respondent felt that the guidance is very much aimed at NHS organisations and needs to further consider independent providers.
iii. Currently the Putting Things Right process can be put on hold when there is also an Adult Safeguarding referral submitted in relation to a concern. This is due to the statutory requirements of [the Social Services and Wellbeing Act 2014] (SSWBA) for Safeguarding enquiries/actions to take place in a timely manner. It therefore follows that that some incidents that would generate a Duty of Candour may also require referral to Safeguarding. It is felt that some guidance will be required on how this would be managed
iv. Building on the previous point, a respondent highlighted that clinicians may need to start conversations with a patient prior to the Duty of Candour being triggered. It may be that other policies would expect them to do this and there may be a need for additional guidance on how to approach those conversations and whether the Duty would be triggered at that point.

Welsh Government Response:

We welcome these comments and feedback and agree that the relationship between the Duty of Candour and other policies and procedures and service providers is very important. Whilst it is recognised that the delay in the introduction of the independent health care providers duty was unfortunate and regretful it is the absolute intention to ensure that this is developed as closely aligned to the NHS duty of candour to strengthen both by doing so. It is important to recognise NHS care being provided by an independent provider is still subject to the NHS duty of Candour from the 1st of April 2023. Whilst we recognise the significant amount of change currently happening, we do not feel that delaying the introduction of the duty of candour is the right thing to do for service users or the NHS.

We would like to take the opportunity to emphasise that this is not new. We have been undertaking the Being Open principles in the PTR process and the Duty of Candour only builds further on this and the professional duty of candour already in place.

As previously stated, it is indeed the process that the Duty of Candour notification may be delayed due to safeguarding or criminal investigation processes but that is a decision made on an individual situational basis and not an automatic approach.

6 Conclusion/Next Steps

It is recognised that despite only 130 responses being received the quality of the responses and the detail in some of the feedback has been such that clear thematic analysis has been possible. Whilst the smaller sample size has been noted it remains significant in terms of a 95% confidence interval and 9% error rate. It is however recognised that the responses predominantly were from NHS bodies, professional organisations and the independent sector with only a small number of citizens/service users.

The statutory guidance has been redrafted to respond to the consultation feedback and is also available in Welsh. We undertook the rewriting of several sections to improve clarity, these include: a new harm chapter which includes definitions of moderate/severe and death, a section on unintended/unexpected harm, a section on side effects and complications. We also strengthened and reviewed the section on waiting lists and diagnostic delay causing harm following the feedback from the consultation and have improved mental health examples of psychological harm.

We have developed in partnership with key stakeholder's and the Children's Commissioner for Wales' office a chapter on the duty of candour and its application to children and young people.

We have strengthened the 'could experience' section and introduced a new section on deliberate harm and just culture. Additionally, we have changed the Candour Regulations so that the written notification has increased from 2 working days to 5 working days after the in-person notification.

The Putting Thing Right Regulations have been amended so that written acknowledgement must be made within 5 working days to bring the Putting Things Right procedure in line with the amended timeline for the Duty of Candour.

Further amendments were also made to the Putting Things Right Regulations to remove the requirement to advise a patient (or their representative) of the notification of a concern, and the requirement to send a copy of the notification of the concern, where notification under the candour regulations has already been given to them.

We also incorporated the Heads of Patient Experience Network (HOPE) amendments and updated the safeguarding section in the Putting Things Right guidance and introduced the role of the Llais (CVB) replacing the role of the CHC's in guidance

This report represents a significant analysis of the consultation responses from citizens and professionals across Wales and the feedback has been critical in the redrafting of the statutory guidance, Regulations and supporting materials to ensure that the Duty of Candour is implemented effectively to improve the experience of service users across the NHS and continue to build and effective open and transparent culture.

Appendices

Appendix A: Identified Theme and Sub-Theme Definitions

Theme(s)	Definition
Further Information/Clarity Required	The respondent underlines that the guidance is not clear or concise, and/or additional information is required.
Resources and Training	The respondent has highlighted that the implementation of the statutory guidance will require additional resources or training.
Governance and Oversight	It is highlighted that oversight, decision making and expected responsibility under the new statutory duty needs further consideration.
Remaining Patient Focused	The respondent has indicated the need for the guidance to further consider the individualistic needs of all patients, ensuring that the duty remains patient focused with information and support available.

Theme(s)	Sub-Theme(s)	Definition
Further Information/Clarity Required	Waiting Time/Lists – Access to Care	It was felt that the guidance needed to be clearer about the duty in relation to those waiting to access care.
	Professional and Statutory Duty	It is felt that there needed to be further information and guidance on the professional and statutory duties to ensure that they align, and it is clear for all service providers.
	Vulnerable Groups (at Risk of Harm)	The comment underlined that there needed to be more information and consideration for vulnerable groups (e.g., children).
	Definition of Harm (Subjectivity)	Although the levels of harm framework were included, it was felt that more information and guidance was required around the definition of harm due to the subjectivity between individuals/teams.
	Example/Scenario/Direction Requested (or Additional)	The respondent indicated that further examples, case studies or templates would be beneficial and support their understanding and implementation of the guidance.
	Terminology	It was highlighted that the terminology used within the guidance needed to be made clearer or reviewed to make it more accessible.
Resources and Training	Time/Staffing Constraints	It was felt that the implementation and reporting of the duty will cause an increase to workload and subsequently pressure on teams.
	Access to Systems/Information	The respondent indicated that there were concerns around not having access to certain systems or information to implement or report the duty.

	Training/Support Needed to Implement	It was felt that for the guidance to be implemented in practice, colleagues would need further training and support to build their knowledge and confidence.
Governance and Oversight	Who/How to Trigger/Manage the Duty (Decision Making)	There was a concern highlighted around who the responsibility sits with to trigger and subsequently manage/investigate, or how this should be done in certain instances. This can also include queries around whether patients are able to trigger the duty.
	Relationships between Other Policies/Procedures/Service Providers Needs Addressing	The respondent highlighted that there was an overlap or dependency on another policy, procedure or service provider that needed to be addressed for the Duty to be implemented.
	When to Trigger the Duty, Timeframes and Deadlines	The respondent highlighted a concern or query regarding when the Duty should be triggered and/or the expected timeframes for triggering and reporting of the Duty.
Remaining Patient Focused	Communication	It was highlighted that communication methods and the terminology used with patient's needed to be clear, open, and honest, as well as considered appropriate for the individual to obtain a clear understanding.
	Lessons Learnt to Drive Improvement	It was highlighted that the information from triggering the Duty should drive change and improvement so that similar incidents do not happen again.
	Individual's Needs to be Considered	The respondent highlighted that the guidance and implementation of the duty will need to reflect individualistic needs, and this may mean tailoring the guidance to those needs or being flexible.

Appendix B: List of Respondents

Respondent ID	Name of Respondent	Respondent Type
204137889	Jemaimah Morgan, Betsi Cadwaladr University Health Board	NHS professional/organisation representative
204214468	Qaisar Jaffri, Talking Teeth Dental Practice	Independent provider representative/organisation
204710996	Paul Stephens	Not specified.
205098384	Dr Luke John Davies, The Royal College of Surgeons	Professional association/ representative
205901902	Tim Davies, Cardiff & Vale University Health Board	NHS professional/organisation representative
206144548	Jonathan Rees, National Pharmacy Association	Professional association/ representative
206386763	Millie Tozer, Independent Healthcare Providers Network	Independent provider representative/organisation
205931873	Lauraine Clarke	Citizen/Service user
206503239	Not specified.	Not specified.
206526768	Richard Lee	Citizen/Service user
199998947	Anonymous	Anonymous
200466352	Anonymous	Anonymous
200910752	Anonymous	Anonymous
201424447	Anonymous	Anonymous
206525447	John Charles	Citizen/Service user
206526730	Rochelle Keenaghan, Royal College of Physicians (RCP)	Professional association/ representative
206541267	Tony Sawyer	Citizen/Service user
206549759	Patricia Canedo, Medical Protection Society (MPS)	Independent provider representative/organisation
206550735	Anonymous	Anonymous
206558669	Anonymous	Anonymous
204506403	Anonymous	Anonymous
206574138	Matthew Armstrong, Boots UK (Community Pharmacy Contractor)	Independent provider representative/organisation
205889018	Anonymous	Anonymous
206578361	Anonymous	Anonymous
206581670	Olivier Denève, The College of Optometrists	Professional association/ representative
206628194	Stephanie Muir, Cwm Taf University Health Board	NHS professional/organisation representative
205484334	Anonymous	Anonymous
207660077	Wendy Herbert, Welsh Ambulance Service NHS Trust	NHS professional/organisation representative
207661075	Darrell Baker, Royal Pharmaceutical Society	Professional association/ representative
206380048	Anonymous	Anonymous
207664779	Optometry Wales	Independent provider representative/organisation
207666700	Susan Ward, Welsh Nursing and Midwifery Committee (WNMC)	Professional association/ representative

206441161	Anonymous	Anonymous
207669153	Penny Gripper	Citizen/Service user
207672323	Julie Richards, Royal College of Midwifes Wales	Professional association/ representative
207691233	Ceri Davies, Royal College of Surgeons England	Professional association/ representative
207699552	Nick Unwin, Royal College of Nursing Wales	Professional association/ representative
207701820	Royal College of General Practitioners Cymru Wales Response	Professional association/ representative
207732442	Mark Harris, Director of Legal & Risk and Welsh Risk Pool Services, NHS Wales Shared Services Partnership	NHS professional/organisation representative
207733164	Michael Devlin, Medical Defence Union	Professional association/ representative
207734263	Natasha Wynne, Marie Curie Cymru	Independent provider representative/organisation
207751793	Board of Community Health Councils	Professional association/ representative
207771194	Louise O'Connor, Assistant Director. (Legal Services/Patient Experience) Hywel Dda University Health Board	NHS professional/organisation representative
207820428	Sara Moseley Head of GMC Wales, General Medical Council Wales	Professional association/ representative
207825297	Calum Higgins - CSP Public Affairs and Policy Officer for Wales, Chartered Society of Physiotherapy Wales	Professional association/ representative
207828823	Rocio Cifuentes MBE, Children's Commissioner for Wales	Professional association/ representative
207829548	Katherine Lowther, The Royal College of Psychiatrists Wales	Professional association/ representative
207830112	Nigel Downes - Interim Deputy Director of Nursing, Quality and Patient Experience, Velindre NHS Trust	NHS professional/organisation representative
207831745	Anonymous	Anonymous
207834073	Kerry Robertshaw Professional Development Lead - Advanced Practice, WAST	NHS professional/organisation representative
207836693	Mary Barratt, Quality & Assurance Manager, Betsi Cadwaladr University Health Board	NHS professional/organisation representative
207845810	Christine Owen Quality & Performance Improvement Manager, NHS Wales Delivery Unit	NHS professional/organisation representative
207846848	Rachel Podolak - /National Director (Wales), British Medical Association Cymru	Professional association/ representative
207848317	Christie Owen, British Dental Association Wales	Professional association/ representative
207849527	Dave Thomas, Audit Wales	Independent provider representative/organisation
207850741	Association of Anaesthetists	Professional association/ representative
207852010	Ana Ramos, Association of Personal Injury Lawyers	Independent provider representative/organisation
207855617	Angela Hughes, Cardiff and Vale University Health Board	NHS professional/organisation representative
207857995	Helen Twidle, Age Cymru	Charity organisation/representative

207860004	Aneurin Bevan University Health Board	NHS professional/organisation representative
207860985	Health Inspectorate Wales	Professional association/ representative
207862876	Melanie Harries on behalf of the Quality & Safety Team, NHS Wales Delivery Unit	NHS professional/organisation representative
207863754	Russell Goodway - Chief Executive, Community Pharmacy Wales	Professional association/ representative
207864080	Michelle Morris Public Service Ombudsman, Office of the Public Services Ombudsman for Wales	Professional association/ representative
207864410	Fair Treatment for the Women of Wales (FTWW)	Charity organisation/representative
207866003	Professional Standards Authority for Health and Social Care	Professional association/ representative
207866273	Valerie Billingham, Health and Care Lead, Older People's Commissioner for Wales	Professional association/ representative
207866567	Naila Noori (she/her), External Affairs Officer (Wales), Tess Saunders, Policy and Public Affairs Officer (Wales), David Davies, Professional Practice Lead (Wales), Royal College of Speech and Language Therapists; Royal College of Podiatry; Royal College of Occupational Therapists,	Professional association/ representative
207866914	Dr Grace Krause, Learning Disability Wales	Charity organisation/representative
207867124	Digital Health Care Wales	NHS professional/organisation representative

Appendix C Copy of the Consultation

consultation-document_0.pdf