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Evaluability Assessment of the Health and Social Care (Quality and Engagement) (Wales) Act 2020

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Views expressed in this report are those of the researcher and not necessarily those of the Welsh Government

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Glossary

| Acronym/Key word | Definition |
|-------------------------|---|
| CHC | Community Health Council |
| CVB | Citizen Voice Body (for Health and Social Care) |
| CRM | Customer Relationship Management |
| EA | Evaluability Assessment |
| FAQs | Frequently Asked Questions |
| HIW | Healthcare Inspectorate Wales |
| NDR | National Data Resource |
| PREMs | Patient Reported Experience Measures |
| PROMs | Patient Reported Outcome Measures |
| PTR | Putting Things Right |
| RPB | Regional Partnership Board |
| SHA | Special Health Authorities |

1. Background

The Health and Social Care (Quality and Engagement) (Wales) Act 2020

- 1.1 [The Health and Social Care \(Quality and Engagement\) \(Wales\) Act 2020](#) (hereafter referred to as 'the Act') received Royal Assent in June 2020 and was fully commenced in April 2023¹, with a new Citizen Voice Body for Health and Social Care (CVB) also becoming operational from this date.
- 1.2 The Act aims to protect and improve the health, care and wellbeing of the current and future population of Wales. It seeks to build on existing assets to help strengthen health and social services, supporting integration and better outcomes.
- 1.3 The Act's provisions include the duty of quality, the duty of candour, the CVB, and the requirement for NHS trusts to have a statutory Vice Chair. Continuous improvement in the quality of services is the central concept underpinning the provisions. Quality is viewed as a system-wide way of working, to enable safe, effective, person-centred, timely, efficient, and equitable services, in the context of a learning culture.

Evaluating the Act

- 1.4 The Welsh Government plans to evaluate the Act as part of their post-implementation review. The evaluation is intended to explore the Act's implementation and impacts to assess the extent to which the anticipated effects, costs and benefits are realised, for whom, how and why. It is therefore likely to incorporate measures of both outcome (i.e., what change can be observed as a result of the legislation, recognising the challenge around the extent to which this change can be attributed to the legislation) and process (i.e., what factors associated with the implementation of the legislation might explain the changes observed).
- 1.5 The evaluation is expected to align, where possible, with existing reporting processes and data collection to deliver an effective framework for demonstrating outcomes whilst minimising additional burden. The evaluation will also involve

¹ The only provision to be substantively commenced before this is section 24 that enables the Welsh Ministers, if they consider it appropriate, to appoint a vice chair of an NHS trust. This provision was brought into force by the end of 2021.

collecting new data to fill gaps in evidence, including gathering qualitative evidence from key stakeholders and service users.

- 1.6 Several areas and outcomes addressed in the Act are also being addressed by other policies and initiatives within the wider system. The evaluation is therefore expected to take account of the wider system in assessing impacts.
- 1.7 The evaluation will begin in 2023 and will assess the first three years post-implementation. The Evaluability Assessment (EA) on which this report is based was undertaken to help inform the evaluation.

The Evaluability Assessment

- 1.8 EAs are a way of collaboratively planning and designing evaluations to ensure they produce relevant and robust evidence to inform decision making and contribute to the wider evidence base ([Brunner, Craig, & Watson, 2019](#)).
- 1.9 In 2022, the Welsh Government commissioned Opinion Research Services (ORS) to undertake an EA of the Act. Its aim is to make recommendations on an appropriate programme to evaluate the Act's implementation and impact. This involved engaging with stakeholders and reviewing relevant documentation and literature to:
 1. Develop a theory of change for each area of the Act, including a visual outline of the inputs (financial and non-financial resources required for implementation); activities (key activities that have been or will be taken); and short-, medium-, and long-term outcomes (the changes that will result from implementation). The theories of change were also expected to identify the key assumptions, contextual factors, barriers and facilitators, and potential unintended consequences (positive and negative) associated with implementation.
 2. Identify key questions for the evaluation, evaluation options, methods, measures, existing and new data, and key groups of service users and stakeholders to involve in the evaluation.
 3. Consider the implications of the wider policy environment for the evaluation.
 4. Identify how the evaluation could take account of the [Well-being of Future Generations \(Wales\) Act 2015](#).

1.10 As part of the EA, two rounds of workshops and individual interviews were undertaken with Welsh Government, NHS and other key stakeholders. Separate workshops were held on each of the four parts of the Act in recognition that they involve quite separate, albeit connected, changes and different key stakeholders. Four round 1 workshops were held, involving six Welsh Government staff members and eight NHS and other key stakeholders. Seven round 2 workshops were held, involving ten Welsh Government staff members and ten NHS and other key stakeholders. Interviews were held with eight stakeholders who had a role which spanned more than one area of the Act, and/or had a unique role or experience profile. All stakeholders were identified by the Welsh Government.

Round 1 workshops: July-August 2022

- Developed a theory of change
- Explored which service users and stakeholders should be involved in the evaluation of the Act, and how this could be achieved
- Identified data sources, needs, and gaps in relation to evaluating the Act.

Round 2 workshops: September-October 2022

- Reviewed and refined the theory of change
- Identified evaluation questions, priorities, and approaches
- Considered the implications of the wider policy environment for the evaluation
- Identified links between the Act and the [Well-being of Future Generations \(Wales\) Act 2015](#) and related considerations for the evaluation.

Individual interviews: July-September 2022

- Explored similar areas to the Round 1 and 2 workshops, tailored in line with stakeholders' individual roles.

Literature and documentation review

- Reviewed key documentation relating to the Act, including the [Explanatory Memorandum](#); documents from the [duty of quality](#) and [duty of candour](#) public

consultations (including draft statutory guidance); implementation updates; and meeting minutes

- Reviewed recent relevant literature relating to potential evaluation approaches.

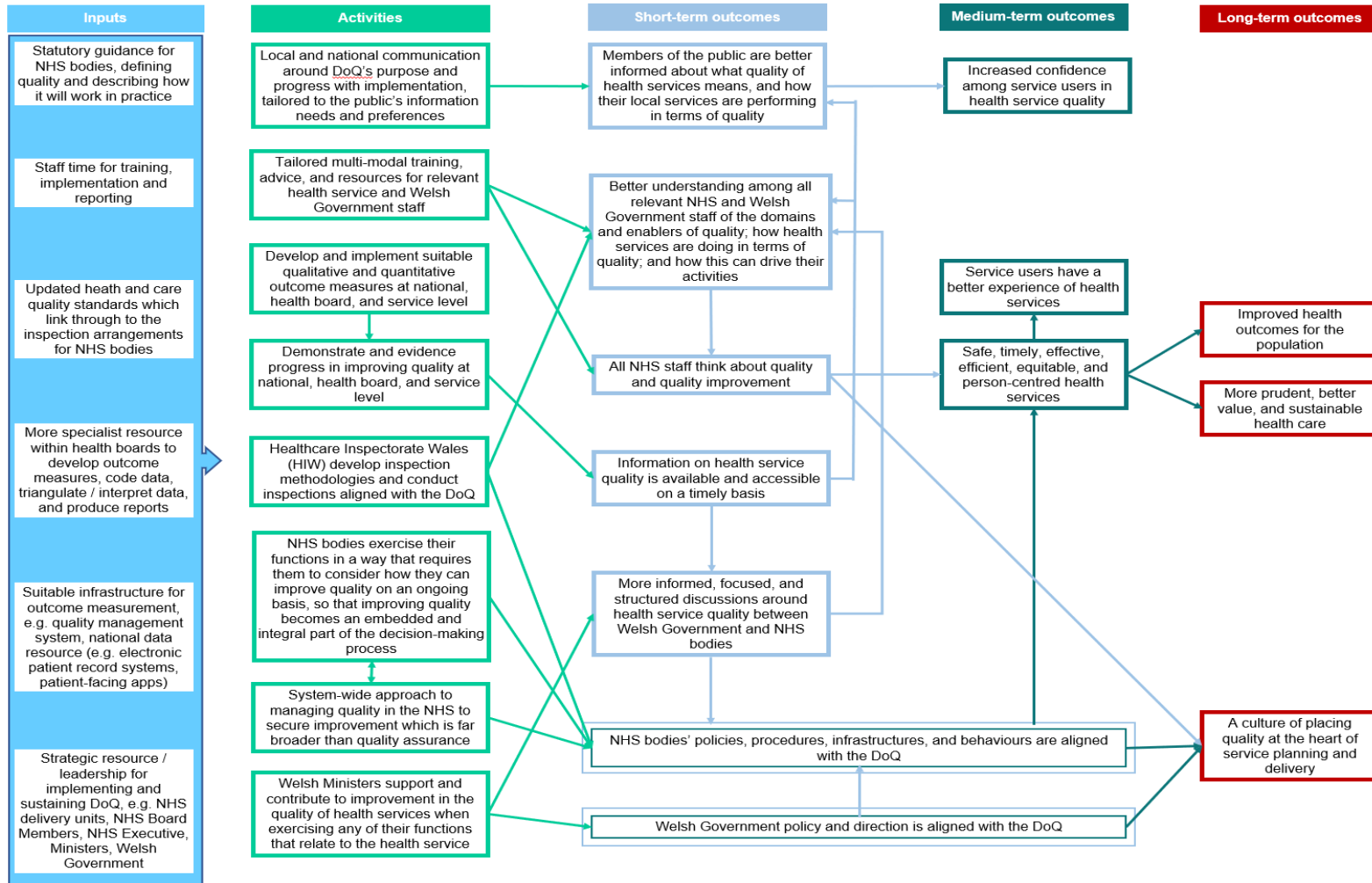
- 1.11 Insight from the documentation review, workshops and interviews informs the sections of the report which discuss each part of the Act; the wider policy environment; links between the different parts of the Act; and links with the [Well-Being of Future Generations \(Wales\) Act 2015](#). This insight was combined with our knowledge and expertise, as well as insight from methodological literature, to inform our desk-based work to develop outcome measures; identify considerations and implications for the evaluation; and to make recommendations on an evaluation approach.
- 1.12 Sections 2-5 outline the findings of the EA in relation to each area of the Act in turn, presenting the theories of change and outlining possible outcome measures and data sources for evaluating them. The activities and outcomes are not necessarily in order of priority. Where stakeholders discussed prioritisation, this is highlighted in the narrative.
- 1.13 Section 6 continues to discuss data for the evaluation; the implications of the wider policy environment; the links between the different parts of the Act; and how the evaluation could take account of the [Well-Being of Future Generations \(Wales\) Act 2015](#). Section 7 concludes with our recommendations for conducting the evaluation.
- 1.14 At the point of data collection, discussions were still taking place to refine plans for delivering the duty of quality, duty of candour and CVB. Consequently, their theories of change, and evaluation recommendations that depend on them, will likely need to be revisited and developed further at a later stage.

2. Duty of quality

Theory of change

- 2.1 The theory of change for the duty of quality is presented below.

Figure 1: Theory of change for the duty of quality



Activities

2.2 The key activities involved in delivering the duty of quality are as follows:

- **Local and national communication around the duty of quality’s purpose and progress with implementation, tailored to the public’s information needs and preferences.** Stakeholders highlighted the need to engage with members of the public to understand which aspects of health service quality would be meaningful to them, and to incorporate this into reporting. According to stakeholders, a key consideration when implementing this activity will be the type and format of the communication, ensuring it is coherent, consistent, and accessible. They also felt the communication should be “drip-fed” so the public do not feel that the focus on quality is something new.
- **Tailored multi-modal training, advice, and resources for relevant health service and Welsh Government staff,** including, for example, case studies, videos, and e-learning. Stakeholders suggested local events which promote and share learning on quality could also form part of this activity, as well as larger, centralised events. They noted that training would need to be ongoing to ensure new staff are included, and that existing staff are kept up to date as implementation evolves.
- **Develop and implement suitable qualitative and quantitative outcome measures at national, health board, and service level.** This activity is underpinned by the quality enabler referred to as “data to knowledge”, which means triangulating data into information and knowledge to develop an understanding of the quality of services, which can then be used to inform learning and strategic decision-making, and guide quality improvement (Welsh Government, 2022).
- Stakeholders highlighted the need for health boards to have flexibility around which outcomes they report on under the duty of quality, reflecting what is meaningful and relevant to their service users and local residents. Work was

undertaken during the implementation stage to develop, test, and refine duty of quality outcome measures (including international benchmarking).

- **Demonstrate and evidence progress in improving quality at national, health board, and service level.** This should be achieved through more transparent, regular, and interactive reporting and communication on health service quality, according to stakeholders. Having the right infrastructure to enable the data collection and analysis which supports reporting and communication would be key to implementing this activity. Stakeholders felt that additional specialist staff may be required to achieve this.
- **Healthcare Inspectorate Wales (HIW) develop inspection methodologies and conduct inspections aligned with the duty of quality.** HIW will have to consider the new [Quality Standards 2023](#) which the Welsh Ministers will produce in relation to the provision of health care by and for Welsh NHS bodies, when conducting reviews and investigations (Welsh Government, 2022).
- **NHS bodies exercise their functions in a way that considers how they can improve quality on an ongoing basis, so that improving quality becomes an embedded and integral part of the decision-making process.** Stakeholders noted that this would prompt quality-driven improvement projects. How this high-level activity is implemented in practice from April 2023 may need to be explored further as part of the evaluation.
- **System-wide approach to managing quality in the NHS to secure improvement which is far broader than quality assurance.** Broadly, this will involve NHS bodies working with patients and teams from across the healthcare system in Wales to build on the positive existing quality culture within the Welsh health care system to deliver outcomes that matter, using the available resources in a sustainable way (Welsh Government, 2022). According to the [statutory guidance](#), NHS bodies should designate appropriate senior leads to take responsibility for implementing and overseeing the duty of quality. However, all officer and non-officer board members are responsible for ensuring that due consideration is given to the

duty. How this high-level activity is implemented in practice from April 2023 may need to be explored further as part of the evaluation.

- **Welsh Ministers support and contribute to improvement in the quality of health services when exercising any of their functions that relate to the health service.** Welsh Ministers will have to consider whether they are taking their decisions with the intention of improving the quality of health services. The duty of quality obliges Welsh Ministers to ensure health services are organised and delivered in a way which aims to achieve system-wide, continuous improvement in the quality of health services; to ensure that relevant national bodies have a cohesive and collaborative approach to system-wide improvement; to issue guidance to NHS bodies on how they comply with the duty; and to produce annual reports outlining how they have complied with the duty of quality (Welsh Government, 2022).

2.3 Linked with the final three activities, the [duty of quality statutory guidance](#) states that Welsh Ministers and NHS bodies are responsible for ensuring and encouraging shared learning and expertise around quality improvement on an ongoing basis. This could be enhanced through learning from high-performing care systems around the world, according to the guidance. It also states that NHS bodies should assess their “readiness for change” to understand where any capability gaps lie by using regular assessments, investigations, and measurement, and putting plans in place to address any weaknesses (Welsh Government, 2022).

2.4 The activities link to the intended short-, medium- and long-term outcomes of the duty, which are explored in turn below.

Short-term outcomes

2.5 The first short-term outcome is that **members of the public are better informed about what quality of health services means, and how their local services are performing in terms of quality.** Stakeholders noted the importance of a shared understanding between stakeholders and the public of the meaning of quality in health services.

- 2.6 The second short-term outcome is **better understanding among all relevant NHS and Welsh Government staff of the domains and enablers of quality; how health services are doing in terms of quality; and how this can drive their activities**. Stakeholders emphasised that raising awareness of the duty of quality was fundamental to achieving this outcome, linking it to the training and communication activities.
- 2.7 The third short-term outcome is that **all NHS staff think about quality and quality improvement**. Stakeholders identified that the duty of quality is an organisational duty. NHS Board members would therefore take overall responsibility for ensuring its implementation, but it should cascade throughout the organisation's structures. A culture of distributed leadership is key to encouraging staff at all levels to implement new ideas to improve quality, according to the [statutory guidance](#), which also highlights the need for leaders to champion improvements in quality (Welsh Government, 2022).
- 2.8 Stakeholders highlighted that the second and third short-term outcomes are dependent on a collective cultural change within the NHS to place quality at the heart of improving outcomes and clarify all staff's understanding of their contribution to achieving and sustaining this. Some felt that, although this change would start to take place immediately following the duty's implementation, it would continue evolving, and need to be sustained, over the medium- and long-term.
- 2.9 The fourth short-term outcome is that **information on health service quality is available and accessible on a timely basis**. Welsh Ministers and NHS bodies must produce annual quality reports on the steps they have taken to implement the duty of quality. In addition, NHS bodies must develop an "always on" reporting mechanism, meaning that organisations collate, monitor, and make information about the quality of their services readily available to the public. The [duty of quality statutory guidance](#) includes suggested evidence for organisations to include in their reports. A key consideration is the amount of data to publish in the reports and how it is presented, according to stakeholders, who felt it was important to select the data carefully to foster understanding of health service quality among all interested parties.

- 2.10 Stakeholders noted there are many groups which would be interested in the reporting. These included HIW, Welsh Government, Audit Wales, NHS Delivery Units, Improvement Cymru², and the public, emphasising that all reporting should be appropriate to the relevant audiences and published on a timely basis.
- 2.11 The fifth short-term outcome is **more informed, focused, and structured discussions around health service quality between Welsh Government and NHS bodies**. Some stakeholders saw this as one of the most important short-term outcomes. Some noted these discussions had started to happen already in board meetings, reflecting the changing narrative and expectations around quality in line with the duty. Stakeholders reflected that, previously, these discussions tended to focus on finances or other issues, with quality as something of a secondary consideration. The introduction of the duty of quality should ensure these conversations are driven primarily by quality improvement, whilst still including other important issues. The importance of having access to the right data and a shared understanding of quality to inform these discussions was noted.
- 2.12 The sixth short-term outcome is that **NHS bodies' policies, procedures, infrastructures, and behaviours are aligned with the duty of quality**. This outcome spans short- and medium-term because, although it should start to emerge immediately following the Act's implementation, some elements of it are not expected to be seen until later, in tandem with the replacement of older strategies, for instance.
- 2.13 The seventh short-term outcome is that **Welsh Government policy and direction is aligned with the duty of quality**. This also spans short- and medium-term, for the same reason as in 2.12. Some stakeholders saw this as one of the most important outcomes. They felt that achieving this outcome would require a culture shift and strong leadership.

Medium-term outcomes

² Improvement Cymru is the improvement service for NHS Wales. Its aim is to support the creation of the best quality health and care system for Wales so that everyone has access to safe, effective, and efficient care, in the right place, and at the right time. For further information, see [Improvement Cymru - Public Health Wales \(nhs.wales\)](https://www.nhs.uk/improvement-cymru/)

- 2.14 Stakeholders suggested all medium-term outcomes were equally important. The first medium-term outcome is **increased confidence among service users in health service quality**.
- 2.15 The second medium-term outcome is that **service users have a better experience of health services** because a focus on the quality domains should have implications for the way in which those services are experienced. One stakeholder suggested the renewed focus on quality introduced by the duty may also improve NHS staff's working environment. This could be considered further in future iterations of the theory of change for the duty of quality.
- 2.16 The third medium-term outcome is **safe, timely, effective, efficient, equitable, and person-centred health services**. These are the domains of quality for guiding incremental improvement in health services, as outlined in the [duty of quality statutory guidance and quality standards](#). "Safe" refers to preventing avoidable harm, maximising the things which go right, and learning from when things go wrong to stop them from happening again. "Timely" means getting access to high-quality advice, guidance, and care quickly and easily, in the right place, first time, prioritising those with greatest need. "Effective" means that the health care system reflects evidence-based best practice to ensure that people receive the right care which enables them to achieve the best outcomes. "Efficient" means taking a value-based approach to improve the outcomes which matter the most in a sustainable way which avoids waste. "Equitable" refers to a health system which enables everyone to achieve their potential for a healthy life, regardless of personal characteristics. "Person-centred" means that our health care system meets people's needs and ensures that their preferences, needs, and values guide decision-making between individuals and health service professionals.

Long-term outcomes

- 2.17 The first long-term outcome is **improved health outcomes for the population**. This reflects the fundamental purpose of the duty of quality. Stakeholders emphasised that, when seeking to achieve this outcome, organisations should consider how to meet the needs of current and future users of health services, at a population level, rather than simply delivering a service. In this regard, it links this

with prudent and value-based healthcare discussed below. This outcome will need multiple measures, which are not yet clearly defined, stakeholders noted.

2.18 The second long-term outcome is **more prudent, better value, and sustainable health care**. This reflects that the duty of quality supports the application of prudent and value-based healthcare principles, referred to in the [National Clinical Framework](#) (2021) as “prudent in practice”. This moves practice towards person-centred care which supports people to stay well, manage their conditions, and access specialist support when needed. Furthermore, value in health care encourages an increased focus on meeting service users’ needs and managing their expectations, involving them in decision-making around their health and care, and using resources creatively to ensure resources are best spent to improve service user outcomes (Welsh Government, 2022). Accordingly, stakeholders highlighted the need to use resources effectively to provide needs-led and sustainable health care.

2.19 The third long-term outcome is **a culture of placing quality at the heart of service planning and delivery**. Stakeholders noted that culture change would take time. It would be achieved in part through improved understanding of the quality of services and what determines it among relevant NHS and Welsh Government staff, and the activities of training, reporting, and communication. Strong leadership was also said to be at the heart of this outcome’s achievement, as was the short- to medium-term outcomes of alignment of NHS bodies’ policies, procedures, infrastructures, and behaviour, and Welsh Government policy and practice, with the duty of quality.

Unintended outcomes

2.20 Although these are not captured in Figure 1, stakeholders noted several potential unintended outcomes which could arise from implementing the duty of quality. Stakeholders highlighted these unintended outcomes are simply possibilities, and that some may be negative, arising on the way to achieving positive outcomes:

- The duty of quality could place additional pressure on healthcare providers through the increased volume of work which could arise from its implementation. This could be counterproductive and risk reputational

damage to services if staff become over-burdened to such an extent that it causes safety issues.

- Stakeholders noted that NHS staff retention may become more challenging in the short-term through increased pressures. However, stakeholders also pointed out that NHS staff recruitment and retention may improve in the longer term due to the greater emphasis on quality (and safety). At present, stakeholders felt that some NHS staff were leaving due to the frustration of being unable to make changes to improve health care quality.
- Stakeholders anticipated an increase in Freedom of Information requests, which could lead to more work for the relevant NHS staff.
- Stakeholders noted the potential for increased costs over the shorter term while the duty of quality is being introduced, despite anticipation of cost savings over the longer term through an increased focus on safe, effective, and efficient healthcare.

Barriers and facilitators

- 2.21 Stakeholders perceived a lack of clarity around the expectations on staff within different organisations, such as the Welsh Government, HIW, and health boards, in implementing the duty of quality. However, since the stakeholder workshops and interviews, the [statutory guidance](#) has been published, which should help to clarify roles and responsibilities.
- 2.22 Stakeholders noted that implementation of the duty of quality is constrained by what health services can reasonably be expected to provide. For example, health services are already providing a lot of performance information to boards and committees. The need for them to consider how they can incorporate the specific reporting, information, and communication requirements of the duty of quality into their business-as-usual practices without any dedicated funding for this was highlighted.
- 2.23 A potential facilitator to the duty of quality's implementation was the Welsh Government acting as a "role model" to the relevant organisations, ensuring quality informed all of its decision-making and policy. It was felt this was needed to achieve

the required focus on quality improvement among the relevant organisations. The importance of strong leadership at all levels throughout the NHS was also said to be a key facilitator.

- 2.24 Both a barrier and a facilitator to the implementation of the duty of quality and the other parts of the Act was the amount of time the NHS had to prepare for it. Stakeholders emphasised that the NHS needed sufficient time to prepare, yet doubted that this would materialise. This is linked to the unintended outcome of placing additional pressure on healthcare providers.
- 2.25 Another barrier was said to be the ongoing nursing workforce shortage. Stakeholders noted this was a systemic problem which also constrained the implementation and impact of other related duties and legislation.
- 2.26 The need for greater collaboration and integrated working between health boards and partners such as social services to improve service quality was also noted.

Possible outcome measures and data sources

- 2.27 The following table sets out possible outcome measures and data sources for the duty of quality's evaluation:

Table 1: Possible outcome measures and data sources for evaluating the duty of quality

| Outcome | Outcome measure(s) | Possible data sources (* indicates potential new data collection need) |
|--|--|---|
| Short-term: Members of the public are better informed about what quality of health services means, and how their local services are performing in terms of quality. | Public understanding of the meaning of quality in health services. Extent of knowledge of local health service performance among members of the public. | National Survey for Wales (hereafter National Survey) ³ (new questions): Whether have sought to find out how health services are performing, and if so, how useful this information was; (existing questions) whether can find out how local |

³ The National Survey for Wales is undertaken by the Welsh Government. It involves a representative sample of around 12,000 people each year and covers a wide variety of topics. It is currently implemented over the telephone and online but has been face-to-face in the past and may be again in future. Further information is available on the [National Survey for Wales webpage](#).

| Outcome | Outcome measure(s) | Possible data sources (* indicates potential new data collection need) |
|--|---|--|
| | | <p>health services are performing; whether would like more information about how local health services are performing.</p> <p><i>*Qualitative research with members of the public.</i></p> |
| <p>Short-term: Better understanding among all relevant NHS and Welsh Government staff of the domains and enablers of quality; how health services are doing in terms of quality; and how this can drive their activities.</p> | <p>Extent of understanding among relevant staff of the domains and enablers of quality.</p> <p>Extent of understanding among relevant staff of how health services are doing in terms of quality, and of how this can drive their work.</p> <p>Whether discussions about quality in NHS board and committee meetings, and in meetings between the Welsh Government and the NHS, reflect the domains and enablers of quality, refer to data on how health services are doing; and apply these to drive activities.</p> | <p>NHS board and committee meeting notes (<i>*a check box could be introduced to determine whether quality discussions are taking place</i>). Qualitative analysis of discussion content could add depth).</p> <p>NHS staff survey⁴: Explore possibility of developing new NHS staff survey questions to assess staff's understanding of how health services are doing in terms of quality, and of how this can drive their work.</p> <p><i>*Qualitative research with relevant NHS and Welsh Government staff.</i></p> |
| <p>Short-term: All NHS staff think about quality and quality improvement.</p> | <p>Extent to which NHS staff think about quality and quality improvement.</p> | <p><i>*Qualitative research with NHS staff.</i></p> <p>NHS staff survey: Explore possibility of developing</p> |

⁴ The NHS staff survey collects the views and experiences of NHS staff about working in their organisations. Results are published for individual NHS organisations. National-level results are published with a breakdown by organisation type, staff group, and demographic characteristics. Some existing questions on the NHS staff survey address the outcomes and outcome measures suggested in the tables in this report. If feasible, a bespoke NHS staff survey could be considered where questions in the existing staff survey do not provide the necessary data.

| Outcome | Outcome measure(s) | Possible data sources (* indicates potential new data collection need) |
|--|---|--|
| | | new question to assess extent to which NHS staff think about quality and quality improvement. |
| Short-term: Information on health service quality is available and accessible on a timely basis. | Extent to which information is made available to a range of audiences on a timely basis. Extent to which information meets the needs of, and is accessible to, those who want to use it. | Annual reports and ‘always on’ reporting on quality *Qualitative research with members of the public. *Qualitative research with other audiences for information on health service quality, e.g., HIW, Welsh Government, Audit Wales, NHS Delivery Units, Improvement Cymru. |
| Short-term: More informed, focused, and structured discussions around health service quality between Welsh Government and NHS bodies. | Extent to which more informed, focused, and structured discussions around health service quality are taking place between the Welsh Government and NHS bodies | Minutes of meetings between Welsh Government and NHS bodies, from before and after the Act comes into force. *Qualitative research with relevant staff from the Welsh Government and NHS bodies. |
| Short-medium-term: NHS bodies’ policies, procedures, infrastructures, and behaviours are aligned with the duty of quality | Extent to which NHS bodies make policy decisions which are aligned with the duty of quality | NHS bodies’ policy and procedure documents. *Qualitative research with NHS staff. |
| Short-medium-term: Welsh Government policy and direction is aligned with duty of quality | Extent to which Welsh Government strategy and policy documents align with the duty of quality | Welsh Government strategy and policy documents |

| Outcome | Outcome measure(s) | Possible data sources (* indicates potential new data collection need) |
|---|---|--|
| Medium-term: Increased confidence among service users in health service quality | Extent of service users' confidence in health service quality | National Survey (existing question): views on the state of health services in Wales. *Qualitative research with service users. |
| Medium-term: Service users have a better experience of health services | Service users' satisfaction with the health services they have received | Patient Reported Experience Measures (PREMs) ⁵ National Survey (existing questions): satisfaction with health care/services used. *CIVICA ⁶ data on service user experience *Qualitative research with service users. |
| Medium-term: Safe, timely, effective, efficient, equitable, and person-centred health services | Extent to which health services are safe, timely, effective, efficient, equitable, and person-centred | HIW inspection reports Annual quality reports and "always on" reporting |
| Long-term: Improved health outcomes for the population | Service user health outcomes | Patient Reported Outcome Measures (PROMs) ⁷ A range of population health data is available which could be used to measure this outcome. Discussions would be needed as to the most appropriate to use |

⁵ Patient Reported Experience Measures (PREMs) measure patients' experiences of NHS care.

⁶ CIVICA is a feedback system which has recently been implemented across Wales's health boards. It gathers patient feedback on many aspects of their experience. The extent of crossover between the patient experience data which is collected via CIVICA and the PREMs data is unclear.

⁷ [Patient Reported Outcome Measures](#) (PROMs) measure health gain in NHS patients undergoing certain surgeries.

| Outcome | Outcome measure(s) | Possible data sources (* indicates potential new data collection need) |
|--|---|--|
| Long-term: More prudent, better value, and sustainable health care | Multiple outcome measures, on which data is already collected more generally | Existing data sources relating to these outcomes |
| Long-term: A culture of placing quality at the heart of service planning and delivery | Extent to which there is a culture of placing quality at the heart of service planning and delivery | NHS staff survey: Explore possibility of developing new questions to assess extent to which there is a culture of placing quality at the heart of service planning and delivery ⁸ |

Implementation evaluation

2.28 Possible data sources which could help evaluate the duty of quality’s implementation (activities) overlap considerably with those in the outcomes table above. They include:

- local and national communications around the duty’s purpose and progress with implementation
- the content of training, advice, and resources for relevant NHS and Welsh Government staff
- NHS board and committee meeting notes and minutes
- Welsh Government policy and strategy documents
- HIW documentation and inspection reports
- annual quality reports and “always on” reporting
- qualitative research with the public, and relevant NHS, Welsh Government, HIW, and Improvement Cymru staff.

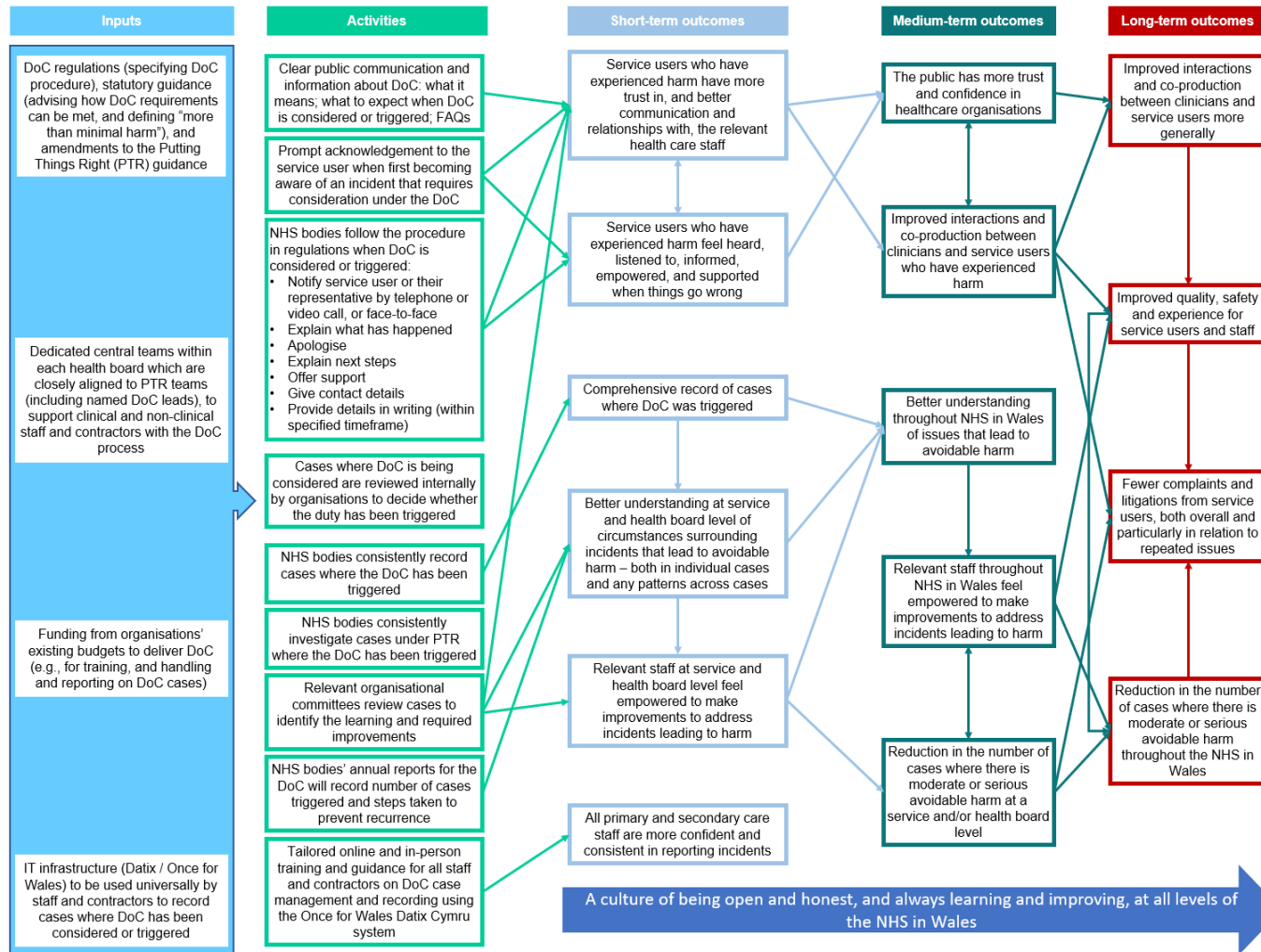
3. Duty of candour

⁸ The [Australian Hospital Survey on Patient Safety Culture](#) includes numerous questions on this, which could be adapted and considered for use in the Welsh NHS context.

Theory of change

3.1 The theory of change for the duty of candour is presented below.

Figure 2: Theory of change for the duty of candour



Activities

3.2 The key activities involved in delivering the duty of candour are:

- **Clear public communication and information about the duty of candour: what it means; what to expect when it is considered or triggered; FAQs (Frequently Asked Questions).** Stakeholders felt the CVB could also facilitate this activity as part of their interactions with the public.
- **Prompt acknowledgement to the service user when first becoming aware of an incident that requires consideration under the duty of candour.** The initial notification should be in-person with follow-up in writing. Stakeholders gave some examples of how the process might work in practice. For instance, a practitioner who makes a drug error may have to disclose this to the patient immediately. A doctor may then need to do some blood tests. The practitioner making the error may then explain the incident to the doctor, making it clear they have discussed the incident with the patient. The practitioner's manager may need to investigate to ascertain whether there have been any similar errors, and if so, take appropriate action. Stakeholders noted that the practitioner who made the error may not necessarily be the lead contact for the service user's family.
- **NHS bodies follow the procedure in regulations when the duty of candour is considered or triggered:**
 - **Notify service user or their representative by telephone or video call, or face-to-face**
 - **Explain what has happened**
 - **Apologise**
 - **Explain next steps**
 - **Offer support**
 - **Give contact details**
 - **Provide details in writing (within specified timeframe).**

Stakeholders noted that communication with service users around the duty of candour should be aligned with their language and communication needs

and preferences: for example, not making the initial contact with a deaf service user over the telephone.

- **Cases where duty of candour is being considered are reviewed internally by organisations to decide whether the duty has been triggered.** This would be expected to follow a robust and consistent process.
- **NHS bodies consistently record cases where the duty of candour has been triggered** using the appropriate incident reporting system.
- **NHS bodies consistently investigate cases under PTR where the duty of candour has been triggered**, in line with The [National Health Service \(Concerns, Complaints and Redress Arrangements\) \(Wales\) Regulations 2011](#) which set out the [Putting Things Right \(PTR\)](#) process for raising concerns (complaint, claim or reported patient safety incident) about NHS treatment or services in Wales, or future legislative arrangements.
- **Relevant organisational committees review cases to identify the learning and required improvements.** Organisational committees may be duty of candour-specific committees or existing quality and safety committees.
- **NHS bodies' annual reports for the duty of candour will record numbers of cases where the duty has been triggered and steps taken to prevent recurrence.** Consistent recording, reporting, and documenting of cases where the duty of candour has been triggered are facilitated by the [statutory guidance](#) and supporting documentation, which clearly explain, and provide illustrative examples and case studies of, the kinds of incidents that would trigger the duty of candour. It will also be supported by the online training package, which is being developed to support NHS bodies with the duty's implementation.
- **Tailored online and in-person training and guidance for all staff and contractors on duty of candour case management and recording using**

the Once for Wales Datix Cymru system⁹. Stakeholders highlighted the training would reduce subjectivity and variation between individuals and services around how information on duty of candour-triggering incidents is recorded. They also noted it should aim to inform staff and contractors on the benefits of the duty of candour and alleviate any concerns over the additional workload associated with its implementation. Stakeholders suggested duty of candour leads should be appointed in each health board to lead on training and guidance, and implementation more broadly.

- 3.3 The activities link to the intended short-, medium- and long-term outcomes of the duty, which are explored in turn below. The achievement of all short-, medium-, and long-term outcomes was seen by stakeholders to be dependent on a cultural shift towards being open and honest, a better understanding of issues that lead to avoidable harm, and always learning and improving, at all levels of the NHS in Wales. However, there was some feeling that existing processes for learning, and sharing learning, needed improving within and across primary and secondary care settings, within health boards, and across Wales.

Short-term outcomes

- 3.4 The first short-term outcome for the duty of candour is that **service users who have experienced harm have more trust in, and better communication and relationships with, the relevant health care staff**. The duty of candour process emphasises that effective, personalised communication is key in building trust between health care staff and service users who have experienced harm.
- 3.5 Some stakeholders felt this was the most important short-term outcome. Key elements of the process which stakeholders noted might facilitate this are prompt, “in person” notifications (followed up in writing), providing personalised contact, for example, including a handwritten signature on letters, and making a meaningful, personalised apology. Not informing service users who have experienced harm

⁹ Once for Wales is a concerns management system programme which is aimed at bringing consistency to the use of the electronic tools used by all NHS Wales health bodies. Datix Cymru is part of the Once for Wales Concerns Management system. Datix is a Risk Management Information System to collect and manage data on adverse events, as well as data on complaints, claims, and risk.

openly and honestly from the outset can make them lose trust, induce feelings of anger, and make them more likely to complain or take legal action.

- 3.6 In addition, stakeholders emphasised the importance of public communication and information, including clear messaging and explanation to ensure understanding.
- 3.7 The second short-term outcome is that **service users who have experienced harm feel heard, listened to, informed, empowered, and supported when things go wrong**. Stakeholders felt this outcome was closely linked to the first short-term outcome. Where service users do not wish to communicate further with NHS bodies about the incident, this should also be recorded, and the person's wishes respected, according to the [guidance](#). Stakeholders felt it could be empowering for health service staff to ask a service user (and their carers or families, if relevant) how they would like the health service to address the incident which triggered the duty of candour, and how (if at all) and how often they would like to be contacted about it.
- 3.8 The third short-term outcome is a **comprehensive record of cases where the duty of candour was triggered**. This is linked to the concurrent improvements in reporting instigated by the new [National Patient Safety Incident Reporting Policy](#) and the [PTR](#) process for investigating concerns as set out in [The National Health Service \(Concerns, Complaints and Redress Arrangements\) \(Wales\) Regulations 2011](#). Explanation of the process for recording incidents which trigger the duty of candour, and indeed those which do not trigger the duty but where triggering was considered, is provided in the [statutory guidance](#).
- 3.9 The Datix Cymru or equivalent system will be used for recording and reporting incidents. There is a prompt on the Datix Cymru system to ask those completing and/or reviewing the incident report whether or not the duty of candour has been triggered and to record the level of harm. The system also facilitates the documentation of reasons the duty was not triggered.
- 3.10 Stakeholders noted that Datix Cymru was already widely used in health boards across Wales, but not necessarily by independent contractors. This could potentially lead to issues with consistently recording cases where the duty of candour is

triggered, which they felt could potentially be overcome by making the use of Datix Cymru a contractual requirement.

- 3.11 The fourth short-term outcome is a **better understanding at service and health board level of circumstances surrounding incidents that lead to avoidable harm – both in individual cases and any patterns across cases**. This is facilitated by the recording, investigation, documentation, and review of cases where the duty of candour has been triggered, as well as the sharing of learning at all levels of the NHS in Wales.
- 3.12 The fifth short-term outcome is **relevant staff at service and health board level feel empowered to make improvements to address incidents leading to avoidable harm** based on learning from investigations where the duty has been triggered. Making improvements would be facilitated by the local review processes and systems which NHS bodies will develop as part of the duty of candour's implementation; and the culture and processes for learning and improving in place within specific services and across health boards.
- 3.13 The sixth short-term outcome is that **all primary and secondary care staff are more confident and consistent in reporting incidents**. Stakeholders felt this was the third most important short-term outcome, behind “service users who have experienced harm have more trust in, and better communication and relationships with, the relevant health care staff” (1st), and “service users feel heard, listened to, informed, empowered, and supported when things go wrong” (2nd). This outcome is supported by the [statutory guidance](#), which details the duty of candour reporting process, and by training and ongoing learning. They also linked increased staff confidence to having the support of their organisation in reporting and discussing duty of candour-triggering incidents, and to a culture of being open and honest. Some stakeholders noted that reporting incidents has been less consistent in primary care.
- 3.14 Stakeholders suggested the provision to consistently record incidents using Datix Cymru (as discussed under the third short-term outcome) would encourage and remind staff to have conversations with service users about incidents which trigger the duty of candour.

Medium-term outcomes

- 3.15 The first medium-term outcome is **the public has more trust and confidence in healthcare organisations**. Stakeholders felt this was the most important medium-term outcome, along with the second one, reflecting that service users should be placed at the heart of the duty of candour.
- 3.16 The second medium-term outcome is **improved interactions and co-production between clinicians and service users who have experienced harm**. Stakeholders associated this outcome with health care staff becoming more adept at handling incidents which trigger the duty of candour in line with the process set out. They also noted this outcome reflected a more equal, honest, and open relationship developed through communicating about incidents which trigger the duty of candour. Stakeholders cautioned that if interactions and co-production with service users and their families around the duty of candour do not improve sufficiently, this could lead to higher levels of complaints.
- 3.17 The third medium-term outcome is **better understanding throughout the NHS in Wales of issues that lead to avoidable harm**. Identifying repeated issues and patterns, rather than isolated incidents, would be particularly key to achieving this understanding.
- 3.18 The fourth medium-term outcome is **relevant staff throughout the NHS in Wales feel empowered to make improvements to address incidents leading to harm** based on learning from investigations where the duty has been triggered. The facilitators of the third and fourth medium-term outcomes are similar to those detailed for the related short-term outcomes, but at an across Wales level.
- 3.19 The fifth medium-term outcome is a **reduction in the number of cases where there is moderate or serious avoidable harm at a service and/or health board level**. This is dependent on the medium-term outcome around NHS staff feeling empowered to make improvements to address incidents leading to harm, and on the culture and processes for learning and improving being in place. It is important to note that there may be a discrepancy between the numbers of reported cases (which is known) and actual cases (which is unknown). Improvements in incident recording and reporting, which may be supported by the additional focus the duty of

candour places on reporting, could make it appear as though the number of incidents has increased, when in reality, this may not be the case. In addition, ascertaining the number of cases where there is moderate or serious avoidable harm is complicated because the use of Datix Cymru is not compulsory for independent contractors. These issues also have implications for evaluation, as discussed in section 6.

Long-term outcomes

- 3.20 The first long-term outcome is **improved interactions and co-production between clinicians and service users more generally**. This is linked to the second medium-term outcome but extends it to include service users more generally who may not have experienced harm. Stakeholders suggested this might occur through word of mouth (i.e., service users who have experienced harm talking to their family and friends).
- 3.21 The second long-term outcome is **improved quality, safety, and experience for service users and staff**. This would be achieved through improved interactions, improvements made to address incidents leading to avoidable harm, and a reduction in the number of cases of avoidable harm.
- 3.22 The third long-term outcome is **fewer complaints and litigations from service users, both overall and particularly in relation to repeated issues**. The [duty of candour guidance](#) emphasises that poor or delayed communication is likely to result in service users making complaints or taking legal action and may also mean they do not feel there has been openness and honesty in the process from the outset. However, stakeholders noted there may be an initial increase in the numbers of complaints and litigations after the duty of candour's implementation, before they start to decrease over the longer-term. This is linked to awareness raising and people being informed more consistently when things go wrong.
- 3.23 The fourth long-term outcome is **reduction in the number of cases where there is moderate or serious avoidable harm throughout the NHS in Wales**.

Unintended outcomes

3.24 Although these are not captured in Figure 2, stakeholders noted several potential unintended outcomes which could arise from implementing the duty of candour. These are:

- As already outlined, an initial increase in the numbers of reported cases where there is moderate or serious harm.
- Potentially, more redress cases (linked to an initial increase in the numbers of reported cases where there is moderate or serious harm), and the financial impact of this. Stakeholders felt the extent of the increase in cases and the associated financial impact were hard to predict.
- There may be an increase in negative publicity from service users, their carers or families, following the duty's implementation due to service users being informed more consistently when things go wrong.
- The NHS may be placed under additional strain through the requirement to implement the duty of candour, potentially leading to workforce attrition. Remaining staff may become disengaged or feel that changes are imposed on them due to the additional workload pressure. Conversely, it was also suggested that staff may become more satisfied in, and engaged with, their work through being instrumental in improving the safety of health services.

Barriers and facilitators

3.25 Stakeholders identified several barriers to implementing the duty of candour. Firstly, stakeholders noted that implementing additional processes and the associated work to alter behaviour and culture may add strain onto an already stretched system and stretched staff, especially within larger organisations and primary care settings. This may mean health service staff struggle to follow the duty of candour process as well as expected. It may also impact on staff retention and/or their mental wellbeing. However, it was also suggested the increase in workload caused by implementing the duty of candour largely reflects what organisations should have been doing anyway to investigate and understand things which have gone wrong.

3.26 A further barrier was said to be fear or anxiety among some health service staff about what the duty of candour could mean in practice, potentially arising from

concerns over extra workload and/or having difficult conversations with service users. Stakeholders also felt staff may worry about the career implications of being involved in incidents which trigger the duty of candour.

- 3.27 Some stakeholders perceived that wider issues, such as the COVID-19 pandemic and insufficient NHS funding, may complicate the duty of candour’s implementation. It was also suggested there was a lack of clarity around the thresholds for harm and the risk of future harm, and how they differ, in England and Wales. There may also be some potential conflation between the existing professional and new organisational duty of candour. Both issues may impede relevant staff’s understanding of the duty of candour. In addition, interpretation and implementation of the [duty of candour guidance](#) may not be consistent across health bodies.
- 3.28 As noted already, not all health care services being contractually required to use Datix Cymru is problematic. This will impede accurate understanding of the type, severity, location, and context of the incidents which trigger the duty across Wales.
- 3.29 Stakeholders highlighted a risk of the duty of candour becoming a “tick-box” process, where staff do not follow up adequately with service users or learn sufficiently from incidents which trigger the duty. They felt staff training and sharing learning system-wide is key to preventing this.
- 3.30 To facilitate implementation of the duty of candour, strong leaders with the right type and level of expertise at all levels of the NHS were said to be needed. Stakeholders noted that duty of candour “champions” or clinical leaders who facilitate the duty’s implementation, may naturally emerge.

Possible outcome measures and data sources

- 3.31 The following table sets out possible outcome measures and data sources for the duty of candour’s evaluation:

Table 2: Possible outcome measures and data sources for evaluating the duty of candour

| Outcome | Outcome measure(s) | Possible data sources (*indicates future / potential sources) |
|---|--|--|
| Short-term: Service users who have experienced | Extent to which service users who have | *Qualitative research with service users who have |

| Outcome | Outcome measure(s) | Possible data sources (*indicates future / potential sources) |
|---|---|---|
| harm have more trust in, and better communication and relationships with, the relevant health care staff | experienced harm have more trust in, and better communication and relationships with, health care staff | experienced harm; and with those who come into contact with those who have experienced harm, e.g., NHS Heads of Patient Experience, NHS staff, the CVB |
| Short-term: Service users who have experienced harm feel heard, listened to, informed, empowered, and supported when things go wrong | Extent to which service users who have experienced harm feel heard, listened to, informed, empowered, and supported when things go wrong | *Qualitative research with service users who have experienced harm, and with those who come into contact with those who have experienced harm, e.g., NHS Heads of Patient Experience, NHS staff, the CVB |
| Short-term: Comprehensive record of cases where the duty of candour was triggered | Numbers of incidents which trigger duty of candour Comprehensiveness of the record of cases where the duty of candour was triggered | Datix Cymru Annual reports on duty of candour *Qualitative research with staff who are involved with duty of candour cases and/or those working with duty of candour data |
| Short-term: Better understanding at service and health board level of the incidents that lead to avoidable harm – both in individual cases and any patterns across cases | Extent to which key people within organisations understand the incidents that lead to avoidable harm, and articulate the improvements which need to be made as a result | Annual reports on duty of candour *Qualitative research with key people within organisations (e.g., organisational committees, senior leaders, managers) |
| Short-term: Relevant staff at service and health board level feel empowered to make improvements to | Extent to which relevant staff at service and health board level feel empowered to make improvements to | *Qualitative research with relevant staff (e.g., organisational committees, senior leaders, managers) |

| Outcome | Outcome measure(s) | Possible data sources (*indicates future / potential sources) |
|--|--|---|
| address incidents leading to harm | address incidents leading to harm | Annual reports on duty of candour |
| Short-term: All primary and secondary care staff are more confident and consistent in reporting incidents | Types of staff who report incidents which trigger duty of candour (stratified by role) Staff perceptions of their confidence in reporting incidents which trigger duty of candour Relevant staff's perceptions of consistency in reporting incidents which trigger duty of candour | Datix Cymru *Qualitative research with staff Annual reports on duty of candour |
| Medium-term: The public has more trust and confidence in healthcare organisations | Extent of public trust and confidence in healthcare organisations | National survey (existing question): views on the state of health services in Wales; (new question): public trust and confidence in healthcare organisations *Qualitative research with members of the public |
| Medium-term: Improved interactions and co-production between clinicians and service users who have experienced harm | Extent of service users who have experienced harm's satisfaction with interactions and co-production with clinicians Extent of clinicians' satisfaction with interactions and co-production with service users who have experienced harm | *Qualitative research with service users who have experienced harm, and with clinicians who have come into contact with those who have experienced harm |
| Medium-term: Better understanding throughout | Extent to which learning about issues that lead to | *Qualitative research with relevant staff |

| Outcome | Outcome measure(s) | Possible data sources (*indicates future / potential sources) |
|---|---|---|
| the NHS in Wales of issues that lead to avoidable harm | avoidable harm is being shared across NHS bodies Extent to which relevant staff (e.g., organisational committees, senior leaders) feel informed, and have access to information, about issues that lead to avoidable harm in their own organisation and across Wales | |
| Medium-term: Relevant staff throughout NHS in Wales feel empowered to make improvements to address incidents leading to harm | Extent to which relevant staff throughout NHS in Wales feel empowered to make improvements to address incidents leading to harm | *Qualitative research with relevant staff (e.g., organisational committees, senior leaders, managers) Annual reports on duty of candour |
| Medium-term: Reduction in the number of cases where there is moderate or serious avoidable harm at a service and/or health board level | Number of cases where there is moderate or serious avoidable harm, compared over time | Datix Cymru |
| Long-term: Improved interactions and co-production between clinicians and service users more generally | Extent of service users' satisfaction with interactions and co-production with clinicians Extent of clinicians' satisfaction with interactions and co-production with service users in general | National survey (existing questions): [regarding GP and hospital services] "I was treated with dignity and respect" PREMs *Qualitative research with clinicians and the public CIVICA data on service user experience |
| Long-term: Improved quality, safety, and | Service users' experience of health services | PREMs National survey data (existing questions): overall |

| Outcome | Outcome measure(s) | Possible data sources (*indicates future / potential sources) |
|--|---|--|
| experience for service users and staff | Quality and safety of health services NHS staff views on the quality and safety of services and their job satisfaction | satisfaction with services/care received NHS staff survey: existing questions relating to job satisfaction HIW inspection reports; annual quality reports; “always on” reporting *Qualitative research with service users and staff CIVICA data on service user experience |
| Long-term: Fewer complaints and litigations from service users, both overall and particularly in relation to repeated issues. | Numbers and types of service user complaints Numbers and foci of litigations brought by service users | PTR records at each health board; Public Service Ombudsman for Wales records; NHS Wales Shared Service Partnership records |
| Long-term: Reduction in the number of cases where there is moderate or serious avoidable harm throughout the NHS in Wales | Number of cases where moderate or serious avoidable harm has occurred, compared over time | Datix Cymru |

Implementation evaluation

3.32 Possible data sources which could help to evaluate the duty of candour’s implementation (activities) overlap considerably with those in the outcomes table above. They include:

- the content of public communication and information about the duty of candour
- the content of staff training on the duty of candour
- Once for Wales Datix Cymru data
- annual reports on the duty of candour

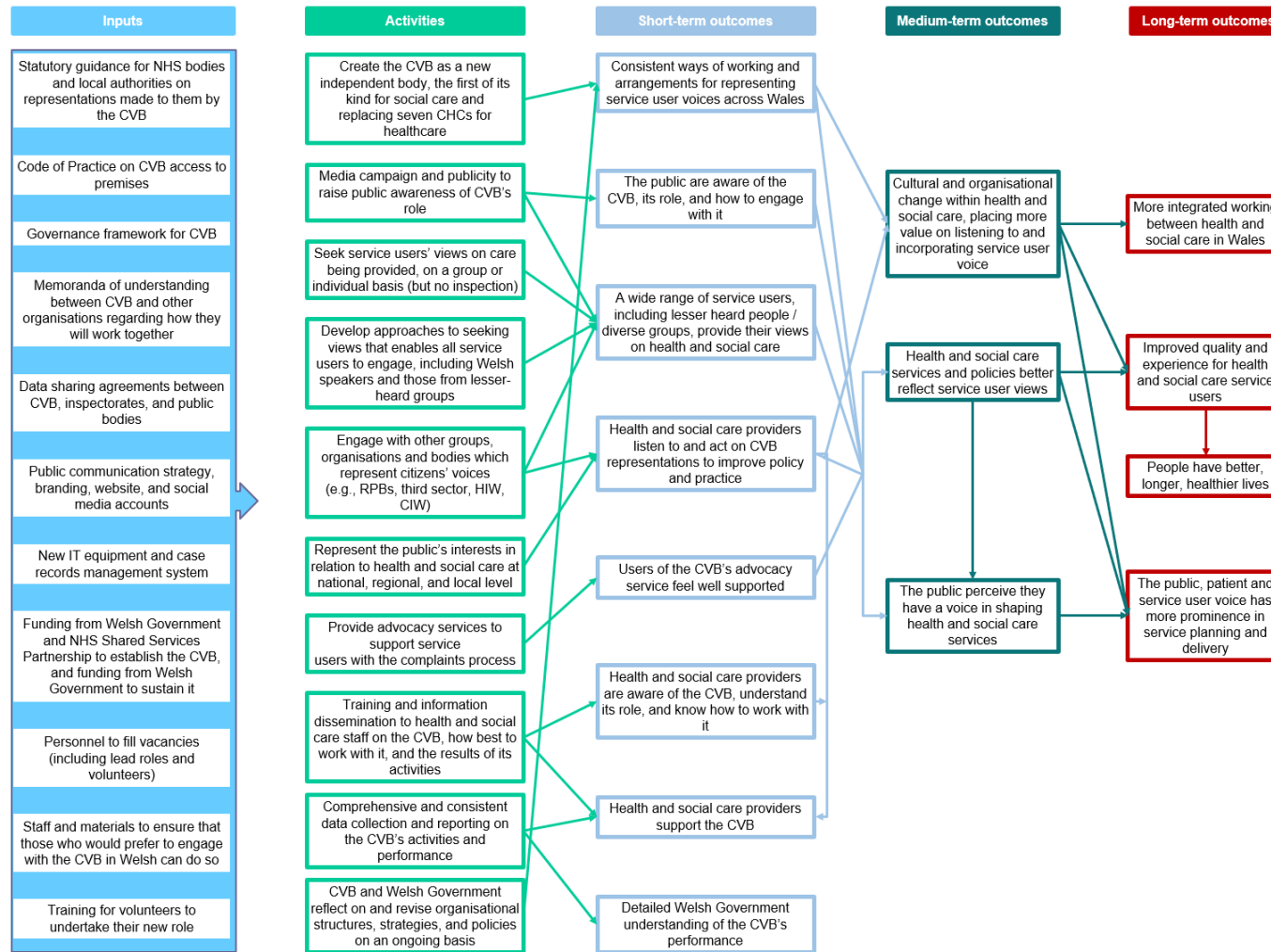
- [PTR](#), Public Services Ombudsman for Wales records and NHS Shared Service Partnership records
- Qualitative research with service users who have experienced harm, those who have come into contact with them, and relevant NHS staff.

4. Citizen's Voice Body

Theory of change

4.1 The theory of change for the CVB is presented below.

Figure 3: Theory of change for the CVB



Activities

4.2 The key activities involved in establishing and running the CVB are:

- **Create the CVB as a new independent body, the first of its kind for social care and replacing seven Community Health Councils (CHCs) for healthcare.** Stakeholders explained that the CHC system is now somewhat “outdated”, and the intention is to replace it with a stronger, more cohesive and modern corporate body that empowers the public and promotes the patient and service user voice. It is hoped through the creation of a single body instead of seven separate ones, the Welsh Government, as funder, will be better able to oversee and understand performance. It is also hoped there will be more consistency in the arrangements for listening to and representing citizens across Wales.
- Stakeholders agreed on the critical need to ensure the CVB is fully functional and able to drive its agenda forward from the date of its inception¹⁰. Ensuring sufficient resource for awareness raising, set-up and ongoing running costs, the ability to fill key lead role and volunteer vacancies (some of which were still empty at the time of discussion), and the provision of fit-for-purpose IT equipment and case records management systems were all considered key to this.
- **A media campaign and publicity to raise public awareness of CVB’s role.** These activities would target the general public, which by default includes the health and social care workforce. A public information campaign was considered essential given people’s general lack of awareness of CHCs currently and the fact the Act places much emphasis on building public knowledge of the CVB. Indeed, the CVB is expected to produce a statement of policy, setting out how it proposes to do this. The need to improve public awareness of the CVB was seen to be important because the CVB will have a legislative responsibility to gather and represent the views of people across

¹⁰ The CVB is now functioning.

Wales and to ensure it engages to a greater extent with the public, especially those from diverse groups, than previously with the CHCs.

- **Seek service users' views on care being provided, on a group or individual basis (but not inspection).** The key change in terms of seeking service users' views is the CVB will do this for social care as well as healthcare. It was argued that unless volunteers (including existing CHC volunteers who will transfer to the new body) are properly trained in this "*new area of business*", the ability to properly represent the views of individuals and communities will be diluted. The process is beginning, with social care leaders giving mini lectures on their different fields to volunteers and with plans in place to review volunteers' skills, knowledge, and experience. However, it is also important to note the greater complexity of seeking views on social care relative to healthcare, given the larger number and diversity of social care settings.
- The fact the CVB will not have a part in inspection or 'scrutiny' is also a change, and one that will necessitate careful reframing of role descriptions and retraining of current volunteers.
- **Develop approaches to seeking views that enables all service users to engage, including Welsh speakers and those from lesser-heard groups.** The CVB is expected to engage with diverse groups throughout Wales, with the support of relevant third sector organisations and community groups. The emphasis on this aspect differentiates it from the CHCs. Identifying these groups and developing suitable approaches to seek their views, including digital methods and technology, both face-to-face and remotely, is expected to form part of the CVB's initial work. This will require sufficient investment in skills, knowledge and expertise for such engagement, be that internally or through working with external experts.
- One particular consideration in terms of seeking the views of all service users is how to engage those receiving care in their own homes (in shared accommodation, residential care, or via domiciliary care, for example). Careful thought is needed to ensure the CVB's ability to fulfil its role in

developing a picture of care and support is not limited to that offered in easily accessible settings.

- Ensuring the CVB, as a people's voice body for health and social care for the whole of Wales, is established on a fully bilingual basis from the outset was thought to be crucial, and potentially constrained by the resources currently allocated to it.
- **Engage with other groups, organisations and bodies which represent citizens' voices (e.g., Regional Partnership Boards [RPBs], third sector, HIW, CIW).** As noted in the Act's [Explanatory Memorandum](#), there is a need for the CVB to engage closely with the inspectorates and other public-facing bodies and organisations to ensure that citizens' voices are heard, but also to prevent duplication of effort where they may be working on similar themes, and to facilitate collaboration and shared organisational learning (for example around best practice on engagement). Crucial to this is the development of a series of Memoranda of Understanding for engagement with these entities. A two-way sharing of user experiences with inspectorates (HIW and CIW) is expected.
- **Represent the public's interests in relation to health and social care at national, regional, and local level.** This is the CVB's core activity, and a key facilitator to this will be the ability to work on a local, regional, and national footprint. The Act's [Explanatory Memorandum](#) highlights the benefits of effectively representing views at a local level whilst using information gathered locally and regionally to drive thematic, national learning and improvements for service users.
- Stakeholders stressed the CVB should focus on themes rather than individual stories. Consistent approaches to the regional collation of trends and patterns were thought to be required to allow their proper consideration on a national level. However, there is also a need not to lose sight of more local issues that need resolution, particularly as greater collaboration and discussion on a regional and national basis might identify similar issues in other areas. Indeed, the Act's [Explanatory Memorandum](#) highlights the CVB

should have the ability to respond to local and regional needs, as well as have real influence on national policy.

- The need to ensure the CVB can represent public interests while also being mindful of patient and service safety issues was also raised. That is, unpopular service changes are often made on safety grounds, and where this is the case, it was considered part of the CVB's duty to explain rather than adopt an adversarial stance.
- **Provide advocacy services to support service users with the complaints process.** This would involve supporting service users in understanding the complaints process; helping them to submit a complaint in writing; representing them at meetings; ensuring the complaints procedure is followed; and escalating the complaint if needed. One stakeholder noted a potential by-product of the advocacy process: the effect on individuals in raising their skills and confidence to deal with issues that arise. The journey from start to finish is often quite significant in this regard, they said.
- **Training and information dissemination to health and social care staff on the CVB, how best to work with it, and the results of its activities.** This was thought to be especially important for social care staff given they were not within the remit of the CHCs.
- **Comprehensive and consistent data collection and reporting on the CVB's activities and performance.** Several stakeholders highlighted the CHCs' trial of new Customer Relationship Management (CRM) software for collecting and collating feedback into something more thematic than was previously possible. This, it was hoped, will enable a much more systematic and detailed approach to data collection in future (discussed further in the 'outcomes' and 'barriers' sections below).
- **CVB and Welsh Government reflect on and revise organisational structures, strategies, and policies on an ongoing basis.** This activity is underpinned by the annual plans (including objectives and priorities) and reports (including a statement of health), which will be produced by the CVB.

4.3 The activities link to the intended short-, medium- and long-term outcomes of the CVB, which are explored in turn below.

Short-term outcomes

4.4 The first short-term outcome is **consistent ways of working and arrangements for representing service user voices across Wales**. The establishment of a single national body that can work in a more consistent, uniform way with its stakeholders and partners is key to this, as is the accompanying [guidance](#) that clarifies how the NHS will work with the CVB on consultation and service improvement. In social care in particular, there are no existing formal, systematic arrangements for seeking and representing service user voices. The [Longley Review](#) of CHCs in Wales recommended that one national CHC for Wales should be established, with local committees to represent service user voice at a local level. This is similar to the proposed structure of the CVB, as set out in the Act.

4.5 The second short-term outcome is the **public are aware of the CVB, its role and how to engage with it**. As discussed above, public awareness of the CHCs has been limited, as shown in the [Longley Review](#), and in Ruth Marks' review of HIW (2014). Accordingly, one of the key policy aims of the Act is that the CVB has a higher public profile than the current CHCs. Health boards will help to achieve this through the duty that the Act places on them to promote the CVB's role and function.

4.6 The third short-term outcome is a **wide range of service users, including lesser heard people / diverse groups, provide their views on health and social care**. There was a sense among stakeholders that the CHCs currently do not have the resources to identify and engage sufficiently with lesser heard people and diverse groups, meaning there are barriers to their voices being heard. Ensuring the CVBs are adequately resourced to achieve this element of its remit was therefore considered key in meeting this outcome. Also key is the need to make the CVB visible and accessible to people across the whole of Wales so they are easily able to share their experiences in ways that meet their needs.

- 4.7 The fourth short-term outcome is **health and social care providers listen to and act on CVB representations to improve policy and practice**. This was seen as a key measure of the CVB's influence and success.
- 4.8 The fifth short-term outcome is **users of the CVB's advocacy service feel well supported**.
- 4.9 The sixth short-term outcome is **health and social care providers are aware of the CVB, understand its role, and know how to work with it**. There are a number of duties on health services and local authorities to promote the activities of the CVB, to co-operate, and to respond. It was said that in order for them to carry out those duties effectively from day one, they need to develop a good understanding of the CVB and how it relates to them. The [statutory guidance](#) for NHS bodies and local authorities on representations made to them by the CVB will be essential in this regard.
- 4.10 This was considered particularly applicable to social care providers, who do not have the baseline understanding that healthcare providers have through their interactions with CHCs. Indeed, health care providers were thought to be comfortable already with the idea of another body engaging with users of its services with a view to improving those services. Moving into the social care setting, that will be more challenging, necessitating relationship-building and engagement with commissioners, providers, and scrutiny committees.
- 4.11 One particular issue in relation to awareness of the CVB's role is that of access to premises: the intended code of practice will be critical to this in allowing the CVB to access areas where services are provided. Again, this was said to be especially important within social care settings, where there is no history of a body entering premises to hear from people whilst they are accessing services.
- 4.12 The seventh short-term outcome is **health and social care providers support the CVB**. This outcome was expected to be underpinned by a combination of training and information dissemination, especially promoting the results of CVB activities. Importantly also, the relationship between healthcare providers and the CHC was reported as being somewhat adversarial, and that developing a more co-operative partnership approach would be beneficial in fostering support for the CVB.

- 4.13 The final short-term outcome is **detailed Welsh Government understanding of the CVB's performance**. This is important for monitoring, to instil confidence in the CVB, and to ensure that the CVB provides value for money.

Medium-term outcomes

- 4.14 The first medium-term outcome is **cultural and organisational change within health and social care, placing more value on listening to and incorporating service user voice**. Stakeholders anticipated that one of the key organisational changes would be that health boards would need to systematically demonstrate what action they had taken in response to service user feedback.
- 4.15 The second medium-term outcome is **health and social care services and policies better reflect service user views** and the third is that **the public perceive they have a voice in shaping health and social care services**. Both of these are crucial outcomes given the CVB's main purpose is to independently represent the voices and opinions of the people of Wales in relation to health and social care services, and to ensure that citizens' views and experiences drive service design and development. These outcomes are interlinked but are included separately to show that it is important for the public to have a voice in shaping health and social care services, but also to perceive that is the case.

Long-term outcomes

- 4.16 The first long-term outcome is **more integrated working between health and social care in Wales**. The need for closer integrated working between the sectors is reflected in the recommendations of the [Parliamentary Review of Health and Social Care in Wales \(2018\)](#) and [A Healthier Wales \(Welsh Government's plan for health and social care\) \(2018\)](#). There was a sense the CVB could have a positive impact in addressing the silo mentalities that currently exist within health and social care. Stakeholders anticipated the CVB would facilitate joint working between health and social care services to better meet the health and wellbeing needs of patients. In particular, it was noted the CVB could help to identify some of those issues that affect the boundaries between the two sectors and the way in which providers work together to deliver services. Stakeholders commented that, while the CVB is not the whole solution to integrated working, it can certainly play a part.

- 4.17 The second long-term outcome is **improved quality and experience for health and social care service users**. The key function of the CVB is to listen to patients and ensure their views are used to aid decision-making that enables improvements in quality and the patient experience. Fundamentally, the aim is to ensure everyone can get the health and care they need, when they need it, and in the way they need it.
- 4.18 **The third long-term outcome is people have better, longer, healthier lives**. The legislation can make a contribution through representations that result in service improvements.
- 4.19 The fourth long-term outcome is that **the public, patient and service user voice has more prominence in service planning and delivery**.

Unintended outcomes

- 4.20 Although these are not captured in Figure 3, stakeholders noted several potential unintended outcomes which could arise from the creation of the CVB:
- A possible upsurge in the number of health and social care complaints due to greater public awareness of the CVB. The [Explanatory Memorandum](#) does not consider this a significant risk given existing complaints processes within both health and social care are well publicised and established, but it is something to be mindful of.
 - If the CVB has insufficient capacity to meet demand for its services (a point explored further in the 'barriers' section below), it may have less buy-in, trust, and credibility than the CHCs, causing reputational damage that could take many years to repair.
 - Dilution of citizens' voices because the new body is too thinly stretched across two sectors.
 - Staff and volunteer losses as a result of the change process.
 - While it is expected the CVB will engage with other organisations in the course of its work, in striving to be as independent as possible, it may not

seek and thus benefit from the practical help and support on offer from other organisations (Welsh Government, for example).

4.21 However, some more positive or aspirational potential consequences were also raised:

- CVB staff, and the CHC workforce who move to the CVB, will likely develop enhanced skills in recording and reporting complaints, especially in relation to social care, given this will be a new remit for them.
- The volunteer group could become more diverse. Currently all volunteers must be recruited via the public appointments process, which can be off-putting for many. An easier process, with a wider variety of roles that cater for a range of skills, may attract more volunteers.
- Service users' skills and confidence in raising complaints and dealing with issues around their care may increase, through the CVB supporting and advocating for them.
- Assuming an improved advocacy service, there could be a positive impact on users' mental wellbeing given the stress of making a complaint.
- A new case management system could lead to a more proactive approach to spotting issues early and taking action, through monitoring reports and triggers.
- Stronger relationships could develop with counterpart organisations across the UK to amplify citizens' voices more widely and call for change in UK policy when appropriate.
- The CVB could be seen as a model for other countries to follow within their own health and care systems.

Barriers and facilitators

4.22 Stakeholders listed several implementation issues and barriers, though it is possible that some of these may be resolved by the time the CVB is established. It will be important to explore these issues and their impact in any future evaluation.

- 4.23 The issue of funding and resourcing was raised frequently. Despite the Act's [Explanatory Memorandum](#) stating the CVB needs to be adequately funded, the money provided for CVB awareness-raising and set-up was considered inadequate by stakeholders. Furthermore, stakeholders said the implementation programme was severely under-resourced from a personnel perspective, with a high vacancy rate across workstreams and lead roles. This meant the CVB would not have all systems and processes in place to carry out its functions from day one.
- 4.24 As discussed above, stakeholders highlighted that some data relating to the CVB's functioning and effectiveness can be provided by Datix Cymru but cautioned that it lacks detail and cannot be interrogated in depth. The introduction of the new Customer Relationship Management (CRM) software will provide more detailed data which can be analysed to show themes and trends when in place.
- 4.25 Stakeholders noted at the workshop stage that the parameters of the CVB's role in relation to social care had not yet been set, potentially causing a lack of clarity among CVB members and service users. Furthermore, the inherent complexities of working within the social care environment with its myriad providers was highlighted as possibly problematic for volunteers to grasp. It was also seen as a "resource-hungry" area of work. In this respect, there was some feeling that having to work across the two areas will necessarily mean the CVB has to carefully consider the number and type of representations it makes.
- 4.26 Another uncertainty raised at the workshop stage was how the CVB will make national representations and recommendations, not least as it does not have the same power as the current CHCs to refer big decisions on service changes to ministers. Also, how it might make representation to other national bodies such as the Children's Commissioner for Wales, the Future Generations Commissioner for Wales, the Older People's Commissioner for Wales, the Public Services Ombudsman for Wales and the Welsh Language Commissioner for Wales had not explicitly been laid out in the Act or elsewhere. It was said to be unclear at the workshop stage where the CVB will sit in relation to the other bodies that are involved with representing service users' or citizen's voices.

4.27 Finally, stakeholders had detected some feeling among health and especially social care service staff that the CVB is unnecessary because avenues such as complaints processes, service user representatives on RPBs, and Citizen’s Voice already exist.

Possible outcome measures and data sources

4.28 The following table sets out possible outcome measures and data sources for the CVB’s evaluation:

Table 3: Possible outcome measures and data sources for evaluating the CVB

| Outcome | Outcome measure(s) | Possible data sources (* indicates potential new data collection need) |
|---|--|---|
| <p>Short-term: Consistent ways of working and arrangements for representing service user voices across Wales</p> | <p>CVB works with stakeholders in health and social care in a consistent and systematic way across Wales</p> <p>CVB engages with the public to obtain their views on health and social care in a consistent way across Wales</p> | <p>Reports submitted by the CVB to NHS bodies’ Quality and Safety Committees or to relevant local authority committees, and annual reports to the Welsh Government</p> <p>Data gathered via new CRM system</p> <p>*Qualitative research with CVB, health board, and local authority staff</p> |
| <p>Short-term: Public are aware of the CVB, its role and how to engage with it</p> | <p>Public awareness of the CVB, its role and how to engage with it (especially in comparison to CHCs)</p> | <p>National Survey data (new question): Explore public awareness of CVB</p> <p>*Qualitative research with members of the public</p> <p>*Analysis of CVB social media reach, click-through impressions, and website ‘hits’</p> |
| <p>Short-term: Wide range of service users, including lesser heard people/diverse</p> | <p>Number of people engaged by CVB</p> | <p>Existing data gathered by CHCs (for baseline/ benchmarking)</p> |

| Outcome | Outcome measure(s) | Possible data sources (* indicates potential new data collection need) |
|---|---|--|
| groups, provide their views on health and social care | <p>Number of people engaged by CVB by area (relative to CHCs)</p> <p>Demographic characteristics of people engaged by CVB (e.g., age group, gender, ethnicity)</p> <p>Number of people engaged by CVB by sector (i.e., health or social care)</p> | <p>Reports submitted by the CVB to NHS bodies' Quality and Safety Committees or to relevant local authority committees, and annual reports to the Welsh Government</p> <p>Data gathered via new CRM system (ideally including demographic data, e.g., age group, gender, ethnicity)</p> |
| Short-term: Health and social care providers listen to and act on CVB representations to improve policy and practice | <p>Number of representations made to health boards</p> <p>Number of representations made to local authorities</p> <p>Number and type of actions taken by health boards as a result of CVB representations</p> <p>Number and type of actions taken by local authorities as a result of CVB representations</p> | <p>CHC records on representations (for baseline/benchmarking)</p> <p>CHC annual reports (for baseline/benchmarking)</p> <p>CVB data on representations by sector</p> <p>CVB or health board and local authority data on responses to representations</p> <p>*Qualitative research with CVB staff, health board and local authority representatives</p> |
| Short-term: Users of the CVB's advocacy service feel well supported | Extent to which complainants who engage with the CVB feel supported | <p>*CVB advocacy service user questionnaire</p> <p>*Qualitative research with complainants who have engaged with the CVB</p> |
| Short-term: Health and social care providers are aware of the CVB, | Awareness among health providers of the CVB, its role and how to engage | *NHS staff survey and social care workforce |

| Outcome | Outcome measure(s) | Possible data sources (* indicates potential new data collection need) |
|---|--|---|
| understand its role, and know how to work with it | with it (especially in comparison to CHCs) Awareness among social care providers of the CVB, its role and how to engage with it | surveys ¹¹ : Explore possibility of developing new questions on awareness of CVB *Qualitative research with health and social care providers |
| Short-term: Health and social care providers support the CVB | Improved relationships between health providers and the CVB, relative to relationships between health providers and the CHC Levels of support for the CVB among health providers Levels of support for the CVB among social care providers | NHS staff survey and social care workforce surveys: Explore possibility of developing a new question on support for the CVB *Qualitative research with CVB staff, and health and social care providers |
| Short-term: Detailed Welsh Government understanding of the CVB's performance | The Welsh Government has a good understanding of CVB performance | CVB annual reports *Qualitative research with relevant Welsh Government staff |
| Medium-term: Cultural and organisational change within health and social care, placing more value on listening to and incorporating service user voice | Service users' voices are increasingly listened to and valued within health and social care | HIW and CIW inspection reports NHS staff survey and social care workforce surveys: Explore possibility of including new questions on the importance of listening to and incorporating service user voice, and the extent to which their organisation does this |

¹¹ National social care workforce survey being piloted shortly.

| Outcome | Outcome measure(s) | Possible data sources (* indicates potential new data collection need) |
|--|---|---|
| | | *Qualitative research with CVB staff, and health board, local authority, and third sector representatives |
| Medium-term: Health and social care services and policies better reflect service user views | Citizens' views and experiences have an increased influence on service design and development within health and social care | Health board and local authority data on responses to representations Welsh Government, health board and local authority policy documents (to assess the extent to which this is evidenced) *Qualitative research with CVB staff, commissioners, service providers, third sector, and other relevant stakeholders (including the public and patients) |
| Medium-term: The public perceive they have a voice in shaping health and social care services | Members of the public feel they have a voice in shaping health and social care services | National Survey (existing questions): Whether can influence decisions affecting local health services; and would like to be involved in decisions affecting local health services *Qualitative research with members of the public |
| Long-term: More integrated working between health and social care in Wales | Extent of integrated working across health and social care | CVB data on representations by sector to identify cross-sector issues Health board and local authority data on joint responses to representations |

| Outcome | Outcome measure(s) | Possible data sources (* indicates potential new data collection need) |
|--|---|--|
| | | <p>NHS staff survey and social care workforce surveys: Explore possibility of including a question around joint working</p> <p>*Qualitative research with CVB, health board and local authority representatives, and relevant Welsh Government staff</p> |
| <p>Long-term: Improved quality and experience for health and social care service users</p> | <p>Improved service quality within health and social care</p> <p>Improved patient experience within health and social care</p> | <p>PREMs and PROMs</p> <p>HIW inspection reports; annual quality reports; “always on” reporting</p> <p>National Survey (existing question): satisfaction with care/services used</p> <p>CIVICA data on service user experience</p> <p>*Qualitative research with service users</p> |
| <p>Long-term: People live better, longer, healthier lives</p> | <p>Population-level health outcomes</p> | <p>A wide range of population health data is available that could be used to measure this outcome. Discussions would be needed as to the most appropriate to use.</p> |
| <p>Long-term: Public, patient and service user voice has more prominence in service planning and delivery</p> | <p>Citizens’ views and experiences have increased influence on service design and development within health and social care</p> | <p>Health board and local authority data on responses to representations</p> <p>Welsh Government, health board and local authority policy documents</p> <p>*Qualitative research with CVB staff, commissioners,</p> |

| Outcome | Outcome measure(s) | Possible data sources (* indicates potential new data collection need) |
|---------|--------------------|--|
| | | service providers, third sector, and other relevant stakeholders (including the public and patients) |

Implementation evaluation

4.29 Possible data sources which could help measure the CVB's implementation (activities) overlap considerably with those in the outcomes table above. They include:

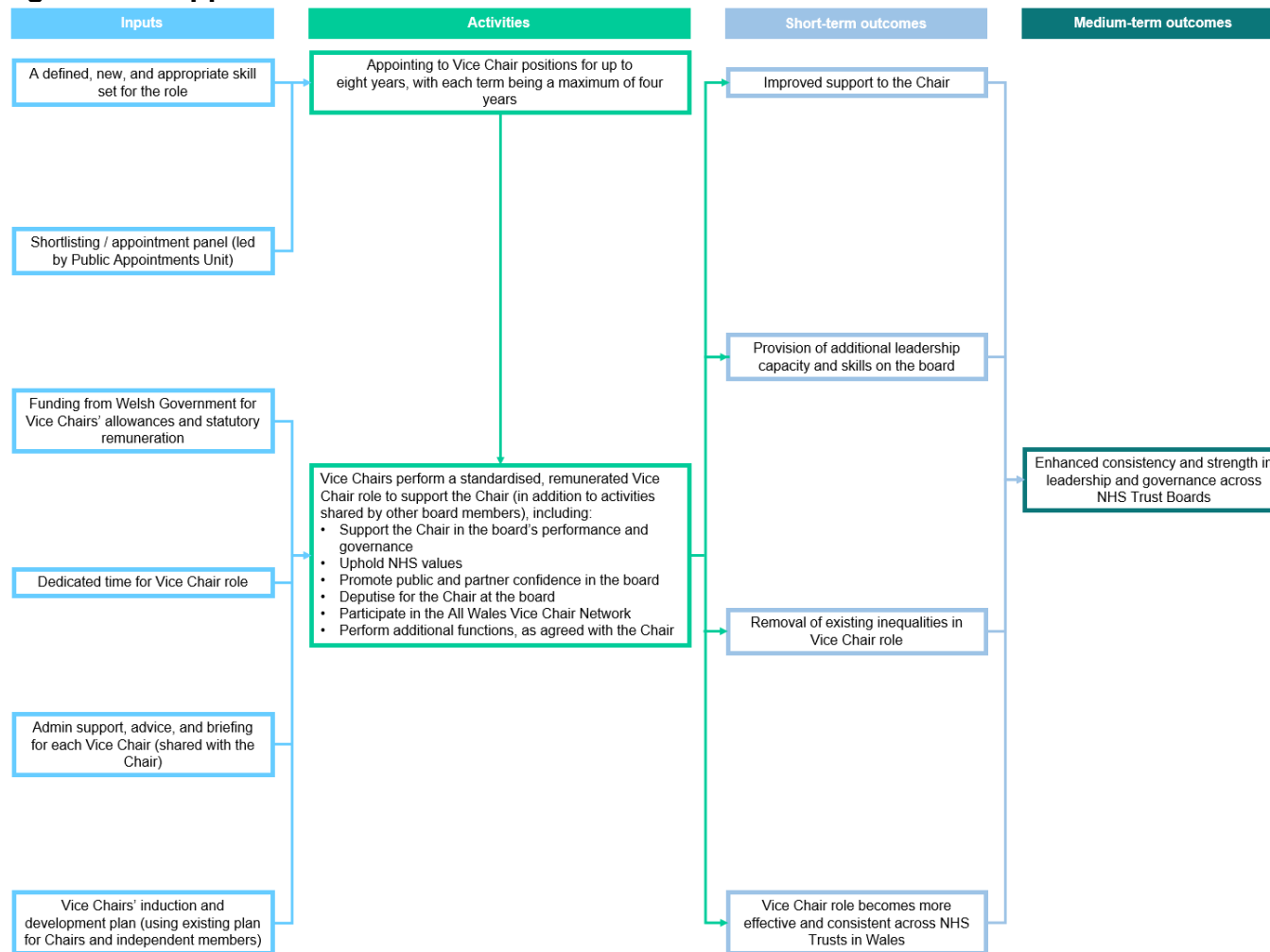
- the content of the media campaign and publicity to raise public awareness of the CVB, and that of training and information for health and social care staff on the CVB
- annual reports to the Welsh Government and reports submitted by the CVB to NHS bodies' Quality and Safety Committee or to relevant local authority committees
- data gathered via the new CRM system
- Qualitative research with members of the public, those who have engaged with the CVB, the CVB, health board and local authority staff, and Welsh Government staff.

5. Appointment of statutory Vice Chairs of NHS trusts

Theory of change

5.1 The theory of change for the appointment of statutory Vice Chairs of NHS trusts is presented below.

Figure 4: Theory of change for the appointment of Vice Chairs of NHS trusts



Activities

5.2 The key activities involved in the appointment of statutory Vice Chairs of NHS trusts are as follows:

- **Appointing to Vice Chair positions for up to eight years, with each term being a maximum of four years.** This should be done formally via a shortlisting/appointments panel (led by the Public Appointments Unit), and to match a new, defined, and appropriate skill set that is consistently applied via standardised job specifications. Stakeholders also suggested that the Chair should play a significant role in the appointment process, and that supporting administrative and other resource should be provided by the relevant Board (via a Board secretariat for example).
- **Vice Chairs to perform a standardised, remunerated role to support the Chair, including:**
 - **Supporting the Chair in the Board’s performance and governance**
 - **Upholding NHS values**
 - **Promoting public and partner confidence in the Board**
 - **Participating in the All-Wales Vice Chair Network**
 - **Performing additional functions, as agreed by the Chair.**

5.3 In relation to Vice Chairs performing additional functions, stakeholders generally agreed these should be undertaken at a strategic rather than operational level, not least due to the limited time available to them. For example, if they are to have a role in community engagement, it was said they should be “*champions*” rather than undertaking direct engagement. Moreover, there was a sense they could help drive forward more collaborative working across NHS trusts and health boards, though this should also be pitched at a strategic rather than operational level.

5.4 The activities link to the intended short- and medium-term outcomes of this aspect of the Act are explored below.

Short-term outcomes

5.5 The first short-term outcome for the appointment of statutory Vice Chairs of NHS trusts is the availability of **improved support to the Chair**. This was widely

considered to be one of the most significant outcomes of the role in improving the resilience of the whole Board, and of the Chairs themselves in knowing there is a dedicated resource to support them when needed as their own roles expand.

- 5.6 It is important to note, though, that the Act's [Explanatory Memorandum](#) clarifies the role of the Vice Chair as one that is distinctly separate to that of the Chair, noting the distinction is invaluable in ensuring the Board's organisational effectiveness and governance. Specifically, it references Vice Chairs' ability to strengthen the Board's independent element and stand back from operational management; provide opinion, challenge, and support to the Board on key issues; contribute to the work of the Board based on independence, past experience and knowledge; and ensure joined up, robust and transparent decision-making processes by the Board.
- 5.7 The second short-term outcome is the provision of **additional leadership capacity and skills on the Board**. The increased capacity offered by the Vice Chairs (and the ability to recruit an additional non-executive director where an existing Vice Chair has been confirmed in the statutory role) was considered a significant potential benefit of their introduction, as was the possibility that appointing to a position with a defined role and greater time commitment may lead to widening the application pool by generating interest from a more diverse range of candidates.
- 5.8 Crucial to ensuring Vice Chairs have the requisite skills is determining needs and skill sets at the outset of the process, developing job specifications that reflect these, and being cognisant of these through to final appointment and checks. Continually linking back to the desired outcomes was also considered crucial in selecting the right person with the right skills to help deliver them. Essentially, following a defined recruitment pathway should, it was felt, result in the appointment of someone with the skills to be a Vice Chair.
- 5.9 The third short-term outcome is the **removal of existing inequalities in the Vice Chair role** and the fourth is that the **Vice Chair role becomes more effective and consistent across NHS trusts in Wales**. Standardised job descriptions, recruitment processes and remuneration should help achieve equality and consistency, as should developing and implementing an all-Wales induction and development plan (with bespoke elements for the Vice Chair role). Other enablers

of effectiveness and consistency are providing administration support, advice, and briefings for each Vice Chair (often shared with the Chair); and Vice Chairs participating in the All-Wales Vice Chair network and other relevant peer groups to establish commonalities and differences in approach between NHS trusts, health boards and other Special Health Authorities, and ensure trusts are as integrated into the wider NHS as possible.

- 5.10 On a related note, there was some discussion of how relationships between NHS trust and health board Vice Chairs might develop given the roles are inherently different. Alignment where possible was considered important so that all Vice Chairs can get value from the All-Wales Vice Chairs Network and enhance dialogue and shared learning nationally.

Medium-term outcomes

- 5.11 The only medium-term outcome for the appointment of statutory Vice Chairs of NHS trusts is **enhanced consistency and strength in leadership and governance across NHS trust Boards**. This, for many stakeholders, should be the absolute focus of the appointment of statutory Vice Chairs of NHS Trusts. Ensuring long-term resilience, continuity and improved governance and leadership through the legislative protection of these posts was thought to be key.
- 5.12 It was said that care must be taken to avoid over-ambition in terms of what the Vice Chair role can achieve. Boards were said to have four high-level outcomes: to develop the strategic direction of the organisation; hold the executive to account in delivering that direction; promote organisational culture and behaviours; and manage risk. Stakeholders argued that while Vice Chairs have an important part to play in delivering these in conjunction with the Chair and other Board members, their impact on them in isolation will be minimal due to the largely supporting nature of the role and the limited time commitment involved.

Barriers and facilitators

- 5.13 In terms of barriers to implementing the Vice Chairs part of the Act (all of which should be explored in any future evaluation), a lack of resources was raised most frequently by stakeholders. Issues ranged from the increased time and money

needed for the initial recruitment process (e.g., the time commitment required for advertising the post and preparing for short-listing and appointment panels), to ensuring proper funding for the role itself. In mitigation, it was said that remuneration uplifts should be standard across all NHS trusts and reflect an increase in responsibility and commitment; and be covered by the funding allocation to the NHS trust when the role is made statutory.

- 5.14 Another stated barrier to implementation was the extent to which standardised job descriptions are translated into the realities of the Vice Chair role, especially given these realities are likely to vary across organisations. In mitigation, it was suggested the job descriptions should not be overly descriptive or prescriptive to accommodate these differences and the need for flexibility within individual organisations.
- 5.15 As alluded to above, the time available to Vice Chairs to fulfil their roles is a potential constraining factor, and one that can be overcome by identifying and focusing on where they can add most value, which again may vary across organisations.
- 5.16 Some enablers to implementing this part of the Act are recruiting the right individuals with the right skills, and ensuring they have appropriate remuneration and time to fulfil their duties. Proper recognition of, and respect for, the role at a national level was also noted as a facilitator.

Possible outcome measures and data sources

- 5.17 The following table sets out possible outcome measures and data sources for the evaluation of the appointment of statutory Vice Chairs of NHS trusts:

Table 4: Possible outcome measures and data sources for evaluating the appointment of statutory Vice Chairs of NHS trusts

| Outcome | Outcome measure(s) | Possible data sources (* indicates potential new data collection need) |
|---|--|---|
| Short-term: Improved support to the Chair | Extent to which support to the Chair is improved | *Qualitative research with Chairs, Vice Chairs, other Board members, and others directly involved in or impacted by governance arrangements |
| Short-term: Provision of additional leadership capacity and skills on the Board | Extent of improved leadership capacity within the Board Improved range of skills within the Board | Vice Chair performance reviews Vice Chair job descriptions *Skills audits of Board members *Qualitative research with Chairs, Vice Chairs, other Board members, and others directly involved in or impacted by governance arrangements |
| Short-term: Removal of existing inequalities in Vice Chair role | More consistent approaches to the Vice Chair role (i.e., recruitment, time commitments, remuneration) | *Qualitative research with Chairs, Vice Chairs, other Board members, and others who are involved with or impacted by the change |
| Short-term: Vice Chair role becomes more effective and consistent across NHS trusts in Wales | Extent to which Vice Chair role has become more effective and consistent across NHS trusts in Wales | *Qualitative research with Chairs, Vice Chairs, other Board members, and others who are involved with or impacted by this change Vice Chair performance reviews Board papers |

| Outcome | Outcome measure(s) | Possible data sources (* indicates potential new data collection need) |
|--|---|---|
| Medium-term: Enhanced consistency and strength in leadership and governance across NHS trust Boards | Enhanced consistency and strength in leadership and governance across NHS trust Boards Increased integration of trusts into the wider NHS Vice Chairs' attendance at and participation in all-Wales and regional forums | Audit Wales Reviews of Quality Governance Arrangements ¹² Notes on Board and committee meetings, and meetings between boards and ministers <i>*Qualitative research with Chairs, Vice Chairs, other Board members, and others who are involved with or impacted by this change</i> |

Implementation evaluation

5.18 Possible data sources which could help evaluate implementation of the appointment of statutory Vice Chairs of NHS Trusts overlap considerably with those in the outcomes table above. They could include:

- Vice Chair job descriptions and performance reviews
- Skills audits of Board members
- Audit Wales Reviews of Quality Governance Arrangements
- Qualitative research with Chairs, Vice Chairs, other Board members, and others who are involved with or impacted by the change.

¹² Audit Wales periodically reviews individual NHS trusts' quality and governance arrangements and publishes reports of their findings. Recent reports could be used to inform views on the consistency and strength in leadership and governance in individual trusts.

6. Data for the evaluation

Primary data collection with stakeholders and service users

- 6.1 Based on the outcomes tables above, the following table outlines which stakeholders and service users could be involved in new data collection for the evaluation of the Act.

Table 5: Stakeholders and service users to engage in an evaluation of the Act

| Stakeholder | Method of engagement | DoQ | DoC | CVB | Vice Chairs |
|---|--|-----|-----|-----|-------------|
| Members of the public | In-depth interviews / focus groups | * | * | * | |
| NHS staff in general | In-depth interviews / focus groups | * | * | * | |
| Social care staff in general | In-depth interviews / focus groups | | | * | |
| Service users (and/or their families) who have experienced incidents which have triggered the duty of candour | In-depth interviews / focus groups | | * | | |
| CVB advocacy service users | Questionnaire | | | * | |
| People who have engaged with the CVB | In-depth interviews / focus groups / questionnaire | | | | |
| NHS staff who have been directly (e.g., staff reporting and investigating the concern; the family's lead contact) and indirectly (e.g., senior managers; clinical leads) involved in incidents which have triggered the duty of candour | In-depth interviews / focus groups | | * | | |

| Stakeholder | Method of engagement | DoQ | DoC | CVB | Vice Chairs |
|---|--|-----|-----|-----|-------------|
| Members of the Welsh Risk Pool in NHS Wales Shared Services Partnership ¹³ | In-depth interviews / focus groups | | * | | |
| Independent contractors working for the NHS | In-depth interviews / focus groups ¹⁴ | * | * | * | |
| Organisations which represent the public, such as the CVB, third sector organisations, the Public Services Ombudsman for Wales, the Children's Commissioner for Wales, the Older People's Commissioner for Wales; local councillors and members of the Senedd | In-depth interviews / focus groups | | * | * | |
| NHS trust Vice Chairs, Chairs, and other board members; NHS Chief Executives | In-depth interviews / focus groups | | | | * |

6.2 A bespoke population survey could be considered to ask specific questions to gather data on the outcomes in the theories of change. However, while this would enable data to be gathered which relates directly to the outcomes rather than proxy measures, it would be highly resource intensive.

Secondary data sources

6.3 As noted in the preceding sections, there are several secondary data sources which could potentially be used in the evaluation. However, where the Welsh Government does not own the data, they would need to explore whether the data could be accessed to inform the evaluation:

¹³ Members of the Welsh Risk Pool monitor service user complaints, deal with [PTR](#) cases, have legal and risk services which deal with claims, and evaluate services on safety incidents, complaints, and claims.

¹⁴ Engaged through the General Practitioners Committee (GPC) Wales and other medical statutory negotiating bodies. The GPC Wales is the statutory representative body for GPs in Wales.

- The National Survey (also exploring the possibility of developing new questions)
- NHS staff survey (also exploring the possibility of adding new questions)
- PREMs
- PROMs
- CIVICA data on service user experience
- Social care workforce survey data
- Minutes of meetings between the Welsh Government and NHS bodies
- NHS board and committee papers and notes
- Welsh Government and NHS policy documents
- HIW and CIW inspection reports
- Audit Wales Reviews of Quality Governance
- “Always on” reporting for duty of quality
- Annual reports for duty of quality, duty of candour and the CVB
- Once for Wales Datix Cymru data
- [PTR](#) records at each health board
- Data on service user complaints from the Public Service Ombudsman for Wales; NHS Wales Shared Service Partnership; health boards; local authorities
- Reports submitted by the CVB to NHS bodies’ Quality and Safety Committees or to relevant local authority committees
- Data gathered via the CVB’s new CRM system
- CVB data on representations, and CVB, health board and local authority data on responses to representations
- Data on CVB social media reach, click-through impressions, and website ‘hits’
- CHC records on representation and CHC annual reports for baseline/benchmarking
- Vice Chair job descriptions
- Vice Chair performance reviews
- Skills audits of NHS Board members

Data considerations

- 6.4 Some potentially relevant existing data is collected via the National Survey, the NHS staff survey, PROMs, PREMs, and the CIVICA platform. The Welsh Government may also want to explore the potential for including new, more focused questions in the National Survey and NHS staff survey. These data are mainly quantitative, deriving from Likert/rating scales or yes/no response fields, and have been designed for wider purposes. They may give insight into respondents' strength of feeling on issues relevant to the Act. However, qualitative data collection (interviews and/or focus groups) with service users and staff is often suggested as an additional data source to give deeper insight on their views specifically related to the Act.
- 6.5 The Welsh Government own the National Survey, so would be able to access the data for evaluation purposes. However, question inclusion is considered on an annual basis and is constrained by limits on survey length, so relevant questions would need to be requested and their inclusion is not guaranteed.
- 6.6 It will be important for the Welsh Government and/or the evaluator to understand what research and data collection is currently underway within and across health boards, and to establish how the evaluation can dovetail with these, rather than duplicate.
- 6.7 The outcomes tables relating to each area of the Act recommend outcome measures for the short-, medium- and long-term outcomes in the theories of change. However, outcome measures were being developed for the domains of quality, as noted in the [statutory guidance](#). The guidance also states that standard operating models to standardise core processes and activities should be developed in tandem with the measures to address variations in quality, and that the measures should be incorporated into a system which analyses and feeds back on the impact of quality improvements (Welsh Government, 2022). When available, these outcome measures should be considered in any evaluation of the duty of quality.
- 6.8 During the workshops, stakeholders mentioned that some research was already being undertaken with NHS staff to explore safety culture (by Improvement Cymru), but the scale and nature of this was unclear. There was a suggestion this work

could perhaps be expanded to explore perceptions and experiences relating to the duty of quality for evaluation purposes.

- 6.9 The Welsh Government should explore any potential for data linkage via the [Secure Anonymised Information Linkage \(SAIL\) databank](#) to inform the evaluation. The Welsh Government should also explore how, if at all, the [National Data Resource \(NDR\)](#) could usefully inform an evaluation of the Act. The NDR is a new national data platform that brings together data about health and social care services from across Wales. It is currently under development. In the future, it may, for example, enable data linkages which can facilitate detailed explorations of the relationships between quality and safety indicators.
- 6.10 The evaluator should seek to establish a baseline for each area of the Act, where relevant and feasible, to accurately measure its impact. Establishing a baseline of CHC activity and performance to benchmark future CVB data against will, stakeholders said, be difficult (albeit a ‘snapshot’ may be possible from the recent trial of the new CRM software mentioned above). It was said that it may be possible to “*scrabble around*” for some information on activity and outcome, but that it would be resource intensive to do so because that information has been gathered in a variety of different places in a variety of different ways. Moreover, while Datix Cymru is being used by CHCs currently, this is for advocacy-related activity only and in a way that does not enable detailed data interrogation. Also in relation to the CRM software, its full roll-out was not completed by April 2023, meaning the less comprehensive older system will have to be used initially. This could have implications for data collection to evidence some of the outcomes outlined above in the early stages.
- 6.11 According to stakeholders, there may be gaps in the data available from primary care settings, in particular to inform the evaluation of the duty of candour. They noted that incident reporting in secondary care settings tends to be more consistent than in primary care settings. If this is the case, it will limit the evaluation’s ability to achieve a full picture of the Act’s implementation and impact.
- 6.12 In relation to the duty of candour and the CVB (as noted elsewhere), stakeholders pointed out a potential discrepancy between what actually happens on the ground

and what is reflected in the numbers. This will make it difficult to establish whether any changes seen are due to changes in quality or changes in reporting.

Links between the different parts of the Act

- 6.13 Each part of the Act is distinct, with its own theory of change, so they would be best evaluated as individual parts rather than as a whole. However, there are links and overlaps between the parts, as well as opportunities to consolidate data collection, which means there is likely to be value in combining them as four separate parts within one overarching evaluation exercise.
- 6.14 As the Act's name suggests, the themes which run throughout are quality and placing the patient at the centre of service planning and delivery, particularly for the duty of quality, the duty of candour, and the CVB. For example, the duty of quality seeks to ensure a quality service is provided to patients, and person-centred services is one of the six quality domains. The duty of candour seeks to put patients' needs first when things go wrong, and should improve quality, safety, and experience through a better understanding of incidents leading to avoidable harm and relevant staff feeling empowered to make improvements to address them. The CVB ensures that the public's voices are heard and used to shape services, which should help to improve quality and experience for service users.
- 6.15 These themes in common are reflected in similarities in some long-term and medium-term outcomes in the theories of change. The evaluation therefore could comprise four separate parts, but also an overarching element that draws together the linkages in their overall aims. This element could also explore how their activities complement and support each other to achieve desired outcomes.
- 6.16 Finally, Table 5 on primary data collection with stakeholders and service users suggests that qualitative research with members of the public; NHS staff and independent contractors; and representatives of bodies such as the CVB or third sector organisations, could inform the evaluations of more than one part of the Act. Therefore, combining the qualitative research activities, where feasible, will help to reduce burden on these participants as well as evaluation resource. There may also be potential for the evaluation to dovetail with the CVB's engagement activities to explore the views of members of the public.

Taking account of the Well-being of Future Generations (Wales) Act 2015 in the evaluation

- 6.17 Stakeholders said that the Act would help to improve the health care system for the next generation, which links to the greatest extent with the well-being goal of ‘a healthier Wales’ in the Well-being of Future Generations Act. They also noted a link with a more equal Wales. This link is particularly salient in relation to the CVB, with its goal of reaching a wide range of service users, including lesser heard people. It is also clear in the duty of quality's 'equitable' domain. Accordingly, a healthier Wales and a more equal Wales are reflected in some of the outcomes in the theories of change. The evaluation could seek to make these links more explicit, to assess the Act's contribution towards these goals.
- 6.18 Some explicit links have also been made between the Act and the five ways of working. For example, the [duty of quality statutory guidance](#) states that the duty of quality supports long-term thinking, and integrated and collaborative action (Welsh Government 2022). The evaluation could seek to explore the ways in which the five ways of working are embodied in the implementation of the Act. Finally, the five ways of working could be explicitly adopted in the way in which the evaluation is conducted.

Implications of the wider policy environment for the evaluation

- 6.19 Assessing the Act's impact will be difficult due to the myriad of factors and initiatives which influence the outcomes associated with it. While evaluation is still possible and worthwhile, it should be borne in mind that there will be extraneous variables at play which influence the outcomes within the theories of change.
- 6.20 In particular, several policies and strategies could have implications for the Act's implementation, and impact the outcomes of interest to the evaluation. These should be borne in mind when planning and conducting the evaluation. For example, some stakeholders discussed the links with [A Healthier Wales \(2021\)](#), the Welsh Government's plan for health and social care, which has improving population health and wellbeing; improving quality and the value of services provided; and a sustainable, engaged workforce, as key tenets.

- 6.21 The [National Clinical Framework \(2021\)](#) sets out a vision for the strategic and local development of NHS clinical services, with a view to improving patient outcomes. It outlines a vision for how clinical services should be planned and developed in Wales in line with prudent and value-based healthcare principles. Stakeholders noted the framework is steering the NHS Executive's work in relation to the Act, and on shaping NHS services.
- 6.22 The evaluation should also take account of the updated [PTR guidance](#), stakeholders said. A draft of the [updated guidance](#) formed part of the consultation on the duty of candour, which ended in December 2022.
- 6.23 These policies and strategies' co-existence with the Act may make it more difficult to isolate the Act's influence on the outcomes of interest. Non-experimental evaluation designs such as that proposed in the next section cannot rule out the influence of co-existing policies and strategies. However, the contribution analysis approach recommended (see section 7) is suited to evaluating complex changes and taking other influencing factors into account.

7. Recommendations

Overall evaluation approach

- 7.1 Certain methodologies are not feasible for evaluating the impacts of the Act. Experimental and quasi-experimental designs, for instance, are not possible because the Act involves making changes which affect the entire population of Wales, meaning it is not possible to establish a counterfactual. The Act involves complex changes, not limited to a specific intervention or programme. It will also be implemented in complex, varied, and changing contexts (i.e., political, policy, social, and organisational), where confounding variables that have implications for the outcomes abound.
- 7.2 As an alternative theory-based approach, contribution analysis ([Mayne, 2001](#); [Mayne, 2012](#)) seeks to identify to what extent observed results are caused by policies, programmes, or services through testing theories of change against new and existing evidence and identifying other influencing factors. Rather than aiming to assess the counterfactual (i.e., what would have happened without the Act),

contribution analysis aims to reasonably establish causality within complex settings, acknowledging that the programme, policy, or intervention in question may have an influence, along with other factors.

7.3 Contribution analysis is best done iteratively, over time, through generating an increasing understanding of why outcomes are being achieved (or not) ([Mayne, 2010, in Forss, Marra, and Schwartz, 2011](#)). In line with a contribution analysis approach, the evaluator should review the theories of change periodically throughout the evaluation to ensure that they continue to accurately reflect each area of the Act.

7.4 The key stages of a contribution analysis are as follows (adapted from Mayne, 2001; 2010). The EA has already started the initial steps; the evaluation should consolidate and extend on this work.

- 1. Set out the attribution problem to be assessed: Identify the outcomes which are expected to change, and the other influencing factors.
- 2. Develop the theory of change, clarifying short, medium-, long-term, and unexpected or unintended outcomes, risks, and assumptions.
- 3. Gather existing evidence on the theory of change, drawing on existing evidence.
- 4. Assemble and assess the contribution story, using existing evidence and feedback from stakeholders, identifying knowledge gaps around data and evidence, and building a robust baseline.
- 5. Gather additional evidence: Identify what new data and evidence is needed and gather it, with input from policy colleagues.
- 6. Revise and strengthen the contribution story: The new data and evidence will begin to achieve this via an iterative process, possibly including revising the theory of change.

7.5 We therefore recommend that a mixed method, contribution analysis approach is taken to evaluating the Act. It should combine process and outcome strands that seek to identify the effects of each part of the Act and the mechanisms by which

these effects were achieved, grounded in the theories of change. This should be done by collating and combining insight from quantitative data, documentary sources, and qualitative engagement with service users, their families, relevant health (and social care) staff and other stakeholders (see sections 2-6). [The UK Government's supplementary guidance for the Magenta Book](#) on Handling Complexity in Policy Evaluation (2020a) also notes the value of theory-based approaches including contribution analysis and should be referred to when designing the evaluation approach.

Value for money

- 7.6 Assessing the value for money of the Act would be complex and options are likely to be limited. Each of the multiple parts of the Act would need to be considered separately. A value for money assessment requires accurate data on costs, which is likely to be challenging. For example, it would be difficult to isolate the ongoing costs of delivering certain parts of the Act, particularly the duty of quality. Many of the outcomes identified in the theories of change are also not yet well defined and are likely to be difficult to quantify or convert to monetary value.
- 7.7 There may be an opportunity to consider cost consequence analysis for certain parts of the Act. A cost consequence analysis is a type of economic evaluation which assesses the costs and consequences (effects) of products and reports on them individually. Cost consequence analyses include all effects, such as health and non-health, and negative and positive, to service users and others (e.g., carers). Decision-makers can select which costs and benefits are most relevant to their interests and weight them in line with this (UK Government, 2020b).
- 7.8 As a starting point, the Welsh Government could consider what data on set up and ongoing delivery costs could be made available. As the evaluation plans are finalised, the nature and scope of outcome data will also become clearer. This understanding would allow consideration of the feasibility and likely robustness (and therefore the value) of this type of analysis.

Further considerations

- 7.9 Some recommendations are provided in section 6 relating to primary and secondary data; combining the four parts of the Act within the evaluation; taking account of other policies and influences on the outcomes; and incorporating the wellbeing of Future Generations Act. Here we provide some further considerations for the evaluation.
- 7.10 With regard to timeframes, a short-term outcome should be achieved without delay following implementation, but the timeframe for achievement of medium- and long-term outcomes is less clear. The evaluation should seek to incorporate the short- and medium-term outcomes. However, as the evaluation will only cover the first three years of implementation, it will be too soon to expect the long-term outcomes to be realised. Consideration should be given as to whether and how the long-term outcomes could be measured after the initial evaluation is completed.
- 7.11 The EA was unable to establish the anticipated magnitude of outcomes, and this should therefore be considered as part of the evaluation. Data collection and analysis should take place at key points throughout the evaluation. This should involve tracking progress in outcomes over specified periods of time and, where relevant and feasible, engaging the same service users in qualitative research at different time points. For example, this might involve engaging with service users who have experienced harm immediately after, and several months after, the duty of candour has been triggered. Appropriate incentives and feedback mechanisms should be considered to ensure sustained engagement of service users. If resources and time are limited, a one-off 'snapshot' evaluation could be conducted, but its findings would be less insightful.
- 7.12 It should be noted that some stakeholders questioned the value of evaluating the Vice Chairs part of the Act versus focusing in more depth on the other parts of the Act, given the relatively small change involved. Others, though, saw a need to assess the outcomes, for example to justify the investment of money and time, and to enable future learning on the value of introducing such changes in other areas.
- 7.13 A Vice Chair role has already existed (on a non-statutory basis) for some time in some NHS trusts, but the role has not existed in any form in others. Any evaluation

should thus seek to identify what difference introducing the statutory role has made, including the benefit of additional capacity where the role formerly existed on a non-statutory basis.

- 7.14 When involving stakeholders and service users (and/or their carers) in the evaluation, care must be taken to avoid re-traumatisation. This point relates more specifically to evaluating the duty of candour where service users have been harmed, but also applies universally to the evaluation of the Act. Service users should be provided with detailed information about the evaluation and what taking part will involve. Researchers should be trained and experienced in conducting sensitive research with potentially vulnerable participants. Participants and researchers should be signposted to dedicated sources of support before and after the research takes place.
- 7.15 The evaluation should be conducted by suitably skilled, independent researchers to ensure objectivity. The health (and social care) workforce should have sufficient time to support the evaluation, although the evaluation should seek to avoid placing an excessive additional burden on them. We would also recommend that NHS bodies, local authorities and the CVB make the relevant data available, where possible, and harness their relationships with service users to support their effective and meaningful engagement in the evaluation.

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