The Public Health Wales Board welcomes the opportunity to provide comments and observations on the important legislation being put before the Assembly Health, Social Care and Sport Committee (Quality and Engagement) (Wales) Bill. We understand that the legislation will further complement other legislative levers for change. I.e. Social Services and Wellbeing (Wales) Act 2014 and the Well-being of Future Generations (Wales) Act 2015.

Public Health Wales have considered the four areas that the Bill is proposed to cover:

1. Duty of Quality;
2. Duty of Candour;
3. Establishment of a new Citizens’ Voice Body; and
4. Requirement for NHS Trusts to have vice chairs.

1 General Observations and Comments

The Bill is focused more on the NHS rather than social care combined. Which elements of the Act are to be applied specifically to NHS services or social care and which are to be applied equally to both could be made more explicit.

It is not clear from the Bill what the overall vision and ambition for quality in health and care is in Wales. It would be logical for the Bill to define and create the legislative levers and drivers that will enable the vision in A Healthier Wales, although the connection to this could be stronger. Similarly, there is an opportunity to articulate in the Bill what the tolerance and threshold for quality and safety will be in NHS Wales (and social care) in a way that is not currently articulated in other documents. This should be an articulated and deliberate intent.
with the associated actions resulting in light or heavy touch approaches to standards, scrutiny and regulation clearly provided for in the Bill. This is currently absent and it is therefore unclear as to how these levers are expected to change to achieve what the ambition for quality and safety is.

In relation to this, has learning from other jurisdictions been taken into account in the drafting of the Bill? For smaller countries, health and social care regulation has been/is being, brought together into one regulatory body in order to establish more ‘smart (or prudent) regulation’ that brings with it economies of scale and integrated business intelligence to more enable risk-based and proportionate regulation. Similarly, this approach enables a more holistic approach to the experience of users of services who traverse health and social care. The opportunity to integrate Health Inspectorate Wales and Care Inspectorate Wales to benefit improvements in the care and experience of people regularly accessing health and social care is a missed opportunity.

Given that health and social care operate and work within wider partnerships, it could be considered appropriate for quality outcomes to be developed and agreed at RPB or PSB level. The mismatch between different systems has arguably caused barriers to date and the increasing emphasis on a partnership approach indicates that this is an opportunity to grasp.

2 Response to the specific areas of the Bill

2.1 Part 2: Duty of Quality

The Existing Duty of Quality

NHS bodies have been under a duty to make arrangements for the purpose of improving the quality of health care since 2003, under section 45(1) of the Health and Social Care (Community Health and Standards) Act 2003 (“the 2003 Act”). Although the 2003 Act requires NHS bodies to make arrangements to monitor and improve the quality of health care, it has largely been interpreted as requiring NHS bodies to have quality assurance (control) arrangements in place to monitor and improve the quality of healthcare provided rather than a comprehensive focus on the three aspects of a quality system as described by the parliamentary review: quality planning, improvement and control to ensure a focus on quality services at a wider population level.

The new proposal under the Bill to establish a Duty of Quality applies to all NHS bodies. The Bill provides an interpretation of “health care” described in the following way:

(1) A reference in this part to health care is to services provided in Wales under or by virtue of the 2006 Act for or in connection with-
(a) the prevention, diagnosis or treatment of illness;
(b) the promotion and protection of public health

There is no explicit definition of quality, which suggests that there is an expectation that everyone who is expected to comply with the legislation would have the same interpretation. Experience would suggest that this is not necessarily the case. A definition would therefore be helpful such as the US Institute of Medicine’s definition.

Quality is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.

Together with the 6 domains which the institute has identified:

- Safe
- Effective
- Patient-centred
- Timely
- Efficient
- Equitable

In Section (1) of the Bill, it is clear that the legislation is intended to and does apply to Public Health Wales, however it will be important that the guidance provides sufficient guidance as to how the duty of quality would be applied in the context of population health.

The Bill and provision of subsequent guidance would need to provide clarification in order to reduce the risk of different interpretation and variation, if the health and social care system is expected to apply the approach to quality consistently.

This would require a more robust and supporting regulatory framework that enables the health and social care system focus on the right things.

To date, the focus of quality in the health service has largely been on developing systems for quality assurance within local services. Quality, however, is more than just meeting service standards; it is a system-wide way of working to provide safe, effective, person centred, and timely, efficient and equitable care.

- The new overarching duty will require Welsh Ministers and NHS bodies to exercise their functions with a view to securing improvements in the quality of services they provide to their service users. This duty will apply to all of their functions, not just clinical functions.
• NHS bodies will be placed under a duty to produce an annual report setting out how they have complied with the new duty. It is clear that the duty of quality extends to all of NHS provision. Section 11 of the Bill specifically identifies that the promotion and protection of Public Health is included in the definition of health care.
• The Bill extends to Health and Social Care, although there appears to be little mention of the approach to be taken with regard to Social Care currently.
• The Bill does not clarify the consequences of not meeting the duty.
• All NHS organisations in Wales will be required to publish an annual report to demonstrate how they have performed in securing quality improvement.

If the intention of the Bill is to shift Health and Social Care to drive a culture of improvement and learning, simply focusing on an annual reporting requirement appears to be somewhat unambitious. To move the system in any meaningful way towards this ambition it requires a change of emphasis in planning for quality, a requirement for timely and accurate data reporting and quality performance monitoring and a complete overhaul of our regulatory arrangements.

There is a lack of coherence and clarity in terms of a Quality Framework for the NHS in Wales that the NHS has to be assessed against and demonstrate improvements. It is unclear why the opportunity to address regulatory improvements has not been taken.

Despite the title of the Bill including Social Care, the legislation appears to refer only to NHS bodies which could miss opportunities to improve the quality of health and care provision, particularly in a context where there is expectation of much greater integration between health and Social Care.

A supporting letter to the introduction of the Bill from the Health Minister, highlights the duty to be placed on all decisions and arrangements for the health and outcomes of populations and improvements are to include ‘backroom’ services. The Bill itself does not appear to have reference to these issues. From the perspective of the Public Health Institute for Wales and the views of Board members, it is important that the Bill and subsequent guidance is more explicit about how this proposed legislation will include a duty on all public health functions.

More broadly across Public Health, Health and Social Care while we would support the focus on improvement, it is important that greater emphasis is placed on the matter of improving health and health care outcomes for citizens/patients, communities and the population. The elements of improving population health do not stand out in the Bill overall, which is a missed opportunity if it is intended
to be a lever to implement the intention to improve health outcomes at a population level as identified in *A Healthier Wales*.

There is an absence of any reference in the Bill of an intention to address current gaps in regulatory functions of the Health Inspectorate arrangements or a revisiting of the Health and Care Standards, or equivalent overarching standards framework for NHS Wales. What would organisations be expected to assess themselves against? There appears to a lack of recognition of the importance of the whole regulatory system needing to connect together with other legislative and policy drivers in order to make improvements across health and social care.

In the Bill it is proposed that there will be an annual reporting of Quality improvement by NHS bodies, which appears to be a relatively weak control and therefore it raises the question if an annual report provides a robust demonstration of assurance. Therefore what should be measured and how would compliance against this duty be measured? One suggested approach could be to adopt an inter-organisational peer review process against clearly defined and measurable standards, alongside other measures and approaches.

There is a risk that bringing in more regulation which needs to be complied with could add more burden to organisations to demonstrate this, leading to competing demands on already stretched resources to deliver services and achieve outcomes that will make a difference to the people of Wales.

Innovation dovetailing in to an improvement approach is critical to the transformation that the NHS and Social Care need to make, to ensure public health, health and care is sustainable over the coming decades. Any supporting guidance will need to place emphasis on the need to support innovation, identifying new models for public health, health and care that can be tested. Some level of risk is inherent in innovation and there needs to be an understanding that this exists and will need to be managed as part of an approach to improving quality.

### 2.2 Part 3: Duty of Candour

When considering the introduction of a new duty on health services, it is important to recognise that various steps have already been taken with the aim of developing a “culture of openness” in the NHS (Wales) Regulations 2011, better reporting and investigation of serious incidents, by Health Boards (HB), NHS Trusts and the Welsh Government.

Putting Things Right (PTR) regulations have been in place since 2011 and encompass processes for raising, investigating and learning from concerns. Concerns include complaints, claims and incidents. In addition reviews of all
deaths in hospitals and the publication of Annual Quality Statements are a requirement of all the organisations in NHS Wales.

The principle of ‘Being Open’ is placed at the heart of the PTR arrangements and was intended to build trust between the people using NHS Services and the organisations.

The duty to be open already exists through the PTR regulations, however there is still a general lack of transparency in relation to data which the Information Commissioner is attempting to change in the Public Sector. Early detection of relevant concerns need to be escalated to the appropriate levels of the organisation as part of overarching governance arrangements. It is not clear how this legislation will improve this, having timely access to data as a key enabler to improvement.

The Duty of Candour is said to build upon and strengthen the existing PTR arrangements. The key difference is that the current PTR regulations applies once a concern has been reported and the initial investigation has been conducted and the service user is identified as suffering harm.

In the proposed duty of candour legislation, the point at which a service user is notified is brought forward to the point that the NHS body is first aware that minimal harm may have been caused and the duty of candour has been triggered. NHS bodies have to make all reasonable efforts to contact the service user or their representative and identify their preferred method of communication and provide appropriate ongoing support.

In addition to the existing PTR arrangements both the General Medical Council (GMC) and the Nursing Midwifery Council (NMC) are already expected to comply with a professional duty of candour. The Bill makes no acknowledgment of the interdependency with the regulations at a UK level placed on all regulated health professionals which are an aspect of providing high quality and safe services. Indeed the duty appears to apply to organisations and not staff so it is not clear how staff would be protected if they raise concerns about the quality and safety of services.

It is anticipated that the supporting guidance to the new regulation will cover situations which cross different providers and where more than one incident has occurred to a service user.

It would be helpful if supporting information around the introduction of the Bill, provided understanding and learning from the experience of other places in the UK and other countries that have introduced the duty of candour having adopted transparent and open processes.
While we would support the general principles of the ‘Duty of Candour’ there will inevitably be a level of complexity which could arise in the context of Public Health Wales.

Examples of this could be in the context of some screening programmes which have built in regular audit arrangements as part of learning and fail safe arrangements, which by the very nature of screening will sometimes identify false positives and false negatives. The understanding of this is complex and nuanced and the impact on the quality assurance arrangements could be impacted and an unintended consequence may be that cancer audits undertaken to learn may cease.

In addition, if the duty of candour is a trigger for incidents classified as minimal the impact on clinical teams will be considerably increased and could detract the clinical resource away from providing ongoing safe and effective services.

In situations of outbreak management in health protection should an incident come to light, at times there could be some genuine risks posed to the wider community if the application was expected to be strictly applied without a more in depth understanding of what has led to an incident in this context.

A more general point to be made is that often initial concerns raised can be very different than the actual facts identified, once the opportunity to undertake an initial investigation has been completed. By informing the service user at the outset, it could be argued that at times insufficient information would be available to provide the person with the level of reassurance that they are seeking and could create undue anxiety.

It is important to acknowledge that despite the current PTR arrangements having been in place since 2011, there remains many challenges in achieving the expected standards consistently and difficulties in achieving a seamless experience for service users where an incident crosses more than one organisation. The Evans review (A Review of Concerns (Complaints) handling in NHS Wales identified at least ten different versions of the implementation of PTR. He also highlighted the complexity of the system and the need to simplify it.

Learning from the implementation of PTR and having not yet achieved the open learning culture that is necessary to drive improvement in service user experience and outcomes, it is important that there is clarity and consistency in the implementation of any new legislation in this area. The Once for Wales Concerns Management project has been attempting to take forward some of the recommendations arising from the Evans review.

However we acknowledge and concur with the evidence which shows that service users and their families ultimately want an apology, a willingness to explain and an open approach to learning from mistakes.
2.3 Part 4: Citizen Voice Body

The proposal to create a national organisation to strengthen citizens voices, ensure individuals are supported with advice and assistance and ensuring the service user experience is used to drive forward improvement is welcome. A stronger national body to bring consistency of approach across Wales is positive, although the emphasis should be on local engagement.

Public Health Wales welcomes falling within the jurisdiction of such a body.

There is a need to build in independence for the new body, to provide autonomy and assurance to communities that it truly represents their views and can hold services to account. It would be important for the body to be independent of Welsh Government and NHS/Social Care bodies and therefore not hosted by any existing body.

Consideration needs to be given as to how the body will link in to the social care sector especially in relation to regulation and inspection. Currently, Elected Council Members represent the views of local communities for Local Authorities including social care, there is a potential risk of duplication or tension in terms of engagement in this area.

Clarity is also required on the lines of accountability, for example will the body report to Welsh Government or the National Assembly for Wales.

It is vital that the new body reflects the population it serves, its governance structures should be established to reflect this. Clarity is required on the future role of Health Inspectorate Wales (HIW).

We also note the response provided by the Welsh NHS Confederation and would particularly reinforce the comments made in relation to the regulation of management.

Public Health Wales is supportive of the introduction of the Citizens Voice Body, however further clarification is required on how the body will work, accountability arrangements and how it interlinks with other NHS and Local Authority/Third sector bodies.

2.4 Part 5: Vice Chairs for NHS Trusts

The proposed new powers within the Bill providing for Welsh Ministers to appoint a specific Vice Chair role on the boards of NHS Trusts is welcomed. We recognise
this will enable Vice Chairs to contribute further to the work of NHS Trusts, strengthen the capability of their Independent Membership, improve governance and decision-making processes, and provide consistency across Wales.

Public Health Wales recognises the importance of this role and as such has appointed a Vice Chair, remunerated for 8 days per month and appointed from the existing complement of Independent Members. The Vice Chair currently chairs the Quality, Safety and Improvement Committee and given the increased focus on Board scrutiny, oversight and assurance we see the demands on this Committee only growing.

Given that the Public Health Wales Chair position is a nominal 3.5 days per week (15 days per month), Public Health Wales would advocate that an additional Vice Chair post be appointed on a nominal 2.5 days per week (10/11 days per month) and remunerated as such. This would also increase the number of Independent Members for Public Health Wales to 8.

We would stress the importance of a dedicated Vice Chair position being in addition to the existing number of Independent Members. We would also request that some flexibility be afforded to each NHS Trust to stipulate the requirements for the role in relation to the organisations needs when the job description is being developed. It is not necessarily beneficial for this position to have a consistency of responsibilities across the NHS Trusts.

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