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The Health and Social Care (Quality and Engagement) (Wales) Bill

The main focus in this paper is on the general principles of the Bill, and the barriers to implementation and potential unintended consequences of the parts 2 and 3 of the Bill.

Comments on the General Principles underpinning the Bill

- Attempts to improve and protect the health, care and well-being of the population of Wales are to be welcomed. However, it is important that to take account of the many and various ways in which quality and continuous quality improvement is already a central factor in the provision of health services in Wales.
- The introduction of a statutory duty of candour has been recommended in recent years in order to bring the law in Wales in line with that in other UK jurisdictions, and this is an important consideration, although there is already a high level of support for the concept of candour in *Putting Things Right*, and in guidance issued by professional bodies, defence organisations and numerous policy documents. It is important to recognise that a range of measures have already been introduced in Wales with the aim of developing a “culture of openness” in the NHS. These include arrangements for handing concerns in the *National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 201126*; measures for reporting and investigating serious incidents, and the publication of annual Quality Statements by LHBs, NHS Trusts and the Welsh Government.
- The introduction of a process by which NHS Trusts will be able to appoint Vice Chairs will put Trusts on the same footing as Health Boards and strengthen their governance arrangements. It gives formal recognition to the work of Independent Members of Trusts who give up additional time and take on extra responsibilities, for example when attending meetings as deputies for their Chairs
- The creation of the proposed new Citizens’ Voice Body which is independent , will create an important opportunity for strengthening the voice of service-users and patients and gathering views about existing services and proposals for planning and delivery of services.

Part 2: Quality

Much of what is contained in the Bill concerning quality is aspirational and is already at the heart of what those responsible for the NHS at every level are working to achieve. Quality considerations are central to the present healthcare system in Wales, which is subject to many forms of continuous formal and informal monitoring and inspection, and failure to meet high standards can already have serious consequences under existing common law and statutory provisions. Numerous policy documents contain statements which are evidence of this strategic direction, and there is a strong argument to the effect that a duty to bring about improvements in the quality of health and care services already exists and that additional statutory duties of the kind stated in the Bill are unnecessary.

Barriers to implementation of Part 2 and potential unintended consequences

Problems defining "quality" could hinder progress.

While the Bill does attempt to define quality, using deceptively simple words such as *"duty to secure quality"* and "*improvements in quality"* conceals the need to consider underlying issues such as prioritisation and justifiable innovation, and the inclusion of a very broad concept of quality in a statute is likely to generate more questions than can ever be answered. It is inevitably difficult for those drafting legislation to define vague concepts and produce suitable language to ensure implementation, so the danger is that the Bill creates a wish-list in being drawn too broadly to impose specific obligations.
Unlike *"candour",* at a philosophical level *"quality"* is too nebulous to define in appropriate detail even in the context of healthcare, as any attempt at a precise definition would inevitably be encyclopaedic. The more one attempts to define it, the more elusive it becomes. Obviously high quality, affordable healthcare is desirable, but is this an aspiration that will prove too difficult to monitor in the modern world when new and more expensive treatments are regularly coming on-stream?

The King's Fund attempted a definition of "*quality improvement"* in its comprehensive research report in 2015, arguing that the NHS would be unable to meet the health care needs of the population without *"a coherent, comprehensive, unifying and sustained commitment to quality improvement as its principal strategy".*

Their definition covers some of the ground but it also contains a number of omissions.

"By quality improvement we mean designing and redesigning work processes and systems that deliver health care with better outcomes and lower cost, wherever this can be achieved. This ranges from redesigning how teams deliver care in the clinical microsystems that make up health care organisations to large-scale reconfigurations of specialist services such as stroke care and cancer care. It includes redesign of training, budgeting processes and information systems and requires leadership and cultures that both understand and value quality improvement".

Other jurisdictions have attempted to define quality in this context. For example NHS England refers to the Health and Social Care Act 2012 which states that it has a duty to continually *drive improvements in the quality of care* across a comprehensive health service, and quality is defined in the statute without the inclusion of specific details as having three dimensions: safety, clinical effectiveness and patient experience.

It follows that the only sensible approach to such a broad and multi-faceted concept as quality is for those who draft the legislation to list some examples of its scope such as those contained in the Bill, recognising that the list provided is not exhaustive.

The proposed quality duties do not apply across the whole health and care system

Wales is in the process of encouraging organisations providing health and social care to become more closely aligned in order to meet the needs of patients, carers and vulnerable groups. An opportunity to extend uniform basic principles across systems may be missed if a whole-system approach does not form the basis of every attempt to achieve long term plans for integrating health and social care.

Part 2 is a classic example of "aspirational" legislation and is difficult to enforce

A number of sociologists of law and legal commentators (among them Weber, Renner, Feldman), have taken the view that any attempt to enshrine political and moral aspirations into legislation will inevitably produce amorphous and vague concepts which are ultimately difficult to enforce, amounting to the creation of wish-lists rather than serious attempts to change the law.

David Feldman, Professor Law at Cambridge University, gives examples of this type of legislation and its consequences in a seminal paper in 2015. In Feldman's words:

"[Such statutory provisions] do nothing to shape or dictate policy, except by making it necessary to consider whether, at a high level of abstraction, what is being proposed is consistent with these high-level standards. They do not preclude anything, because views of what is safe, integrated, efficient and economic can differ widely". [i]

The Explanatory Memorandum states that the existing legislative framework results in too narrow an approach to driving up quality, and that a legislative change is necessary to achieve a system-wide approach, hence the inclusion of a duty on Welsh Ministers and Special Health Authorities. However, the aspirational tone of the legislation means that in effect it adds little more than the reporting obligation it imposes on all the relevant bodies and persons.

In summary, there are as many ways of bringing about improvements in the quality of health and care as there are patients receiving or hoping to receive it. While some aspects of quality improvement, such as effectiveness and safety, are clearly measurable, many others cannot be measured as easily – for example subjective issues such as the experience of patients.

Potential loss of public confidence

There is a danger of "initiativitis" arising from the introduction of yet another aspirational duty in a statute, leading people in general and staff in particular, to lose confidence in the Bill through lack of full understanding of what is intended, and an inability to envisage how the duties stated in part 2 could be enforced.

The duty on organisations to report annually their assessments of improvements in outcomes is to be welcomed. However, there is a danger that a tick-box exercise could emerge.

Another unintended consequence of part 2 is that reference to quality and the need to achieve improvements in quality could produce a tick-box exercise which distracts from the important task of creating a culture in which excellent healthcare can flourish, with the result that measuring quality improvement becomes a daunting task. It is a relatively simple matter to produce an annual report, but care will need to be taken to ensure that the issuing of a meaningful report with numerous examples of measures taken to achieve improvements in quality is more than a routine box-ticking procedure.

The existing framework could become over-complicated by rhetoric

As there are already satisfactory arrangements in place for enhancing the quality of care, further statutory provisions could complicate a system that appears to be effective. One could take issue with the statement in the explanatory memorandum accompanying the Bill that without the proposed legislative change aimed at reforming the 2003 Act, a system-wide approach to quality based on outcomes is unlikely to be achieved and is unsupported by evidence. The present framework relies on policy documents that provide achievable goals and the prevention agenda and the sharing of good practice are already operational. Other systems, such as IT services are subject to monitoring, and appropriate governance structures dealing with quality which are already in place. Reporting systems and scrutiny of patients' experiences are well-established and are unlikely to be strengthened by the proposed new reporting obligations.

Part 3: The Duty of Candour

The proposal to introduce a statutory duty of candour into healthcare in Wales is to be welcomed. Importantly, it will bring Wales into line with the England and Scotland and there will be an opportunity for Wales to learn from the systems implemented in those jurisdictions when regulations are being drafted. It is also an excellent opportunity for ensuring uniformity across health and social care in Wales.

Ironically, Wales has lagged behind other UK nations in creating statutory recognition of the need to openness and transparency in healthcare, although the concept is firmly embedded in processes which have already been in place for some years. Among recommendations which have led to the inclusion of the duty in the Bill, a review of the concerns process in 2018 concluded that an explicit new legal duty of candour should be introduced.

In 1969, a report into failings at Ely Hospital in Cardiff revealed many examples of poor care and attempts to conceal evidence, even to the extent of intimidation of people who reported problems.[ii] Originating in Wales, the case of Robert Powell which reached the European Court of Human Rights in 1998 led to a campaign that highlighted the need to introduce a duty of candour throughout the United Kingdom[iii]. That was well before the publication of the Bristol Inquiry Report in 2001 and the Report of the Francis Inquiry in 2013 which identified many problems that can arise when individuals and organisations become defensive, and create a culture of secrecy in order to conceal errors, avoid costly litigation, professional disciplinary processes and even prosecutions.

Throughout the UK and elsewhere in the world there has been a clear shift of emphasis in the doctor-patient relationship towards greater respect for patients' autonomy, which is evidenced by changes in professional guidance, popular culture and social policy over the past thirty years. Honest communication and candid apologies indicate willingness on the part of healthcare professionals to support patients in providing respectful treatment and care" [iv]. This has also been reflected in the regulatory processes for health professionals and in the case law on consent to treatment which highlights the importance of being open and honest to patients.

For many decades the doctors' defence organisations have advised their members that being open and honest when errors are made is likely to deflect claims and complaints and produce fairer outcomes for patients. That view is evidenced in the medico-legal literature.[v] Evidence to support this position was presented to the NHS Complaints Review Committee (The Wilson Committee) whose recommendations[vi] formed basis of modern complaints systems in the UK. Patients frequently say that they are more interested in receiving an explanation and apology than compensation.

The Bill clarifies situations in which the duty of candour is triggered and will become operational, including some of the more complex issues that can arise when services are provided by one body on behalf of another or when bodies outside Wales are commissioned to provide treatment for Welsh patients or from independent providers. Arrangements for monitoring compliance with the duty are also outlined in the Explanatory Memorandum.

Barriers to implementation of Part 3 and potential unintended consequences

The Bill could be criticised for making no provision for sanctions

It is difficult to find in the Explanatory Memorandum any mention of sanctions for dealing with non-compliance with the duty of candour stated in the Bill. However, the Justice Impact Assessment (JIA) (para 163) does consider the potential impact on the justice system of the proposals, and states as follows:

"The Bill does not create any new, or modify any existing offences, sanctions or penalties and the duties that it introduces are placed on public bodies or bodies carrying out functions on their behalf, meaning that enforcement will be a matter of public record, through publicly available annual reports on quality and candour, rather than through specific sanctions"

The statement continues:

"Based on similar schemes that operate in England, we believe that the likelihood of civil claims arising from the new duties to be low. The likely impact on the justice system of the proposals in the Health and Social Care (Quality and Engagement) (Wales) Bill is therefore minimal or nil".

This view suggests that like the proposed duty of quality, the "new" duty of candour is to some extent optative and may achieve little over and above the existing duties[vii] placed on healthcare organisations[viii], and on healthcare professionals by their regulatory bodies – the GMC, NMC etc. It is worth referring to attempts to impose a duty of candour in other spheres – as follows.

Social Care in Wales
The Explanatory Memorandum to the Quality Bill refers (paras 47-49) to the parallel duty of candour in social care placed on providers and certain responsible individuals in Wales:

"In social care, a duty of candour already exists for providers and responsible individuals of regulated services. The 2017 Regulations10 deal with the duty of candour in regulations 13 and 83 and require service providers and responsible individuals to act in an open and transparent way".

The statutory guidance issued under section 29 of the 2016 Act sets out how the requirements may be complied with, namely by promoting a culture of candour,

"By having policies and procedures in place to support a culture of openness and transparency, ensuring that staff are aware of them and follow them".

The 2017 Regulations made under the Act include measures which support the duty, for example by requiring providers of regulated services to ensure that there are systems for recording and keeping records of incidents, complaints and concerns. In addition, Regulation10 requires the individual designated as responsible for the service to make provision for the quality of care, and support to be reviewed as often as required but at least every six months, and to report to the service provider on the basis that:

"This requirement supports a culture of continuous improvement and includes an analysis of the aggregated data on incidents, notifiable incidents, safeguarding matters, whistleblowing, concerns and complaints".

The Duty of Candour in NHS England
A duty of candour enforceable by the CQC came into force in 2014 in NHS England by Regulation 20 introduced under the Health and Social care Act 2008 (Regulated Activities) to complement pre-existing professional and contractual requirements. A review of the research literature indicates that this has not been hailed as an unqualified success[ix], and although failure to comply with the legislation is a criminal offence, it was not until January 2019 that the CQC announced that Bradford Teaching Hospitals NHS Foundation Trust had become the first NHS Trust to be prosecuted for failing to comply with the statutory duty of candour. A fixed penalty notice of £1250 was imposed, equivalent to 50% of the maximum fine that can be imposed by a Court.

By introducing Regulations by means of which criminal sanctions can be imposed for non-compliance with the duty of candour, NHS England has taken more emphatic steps than Wales is proposing in the Bill.

Problems of implementation in mental health settings

Implementation of the duty of candour could prove difficult in the context of treating vulnerable patients such as those suffering some forms of mental illness. For example, it is not always possible for relatives of patients with certain psychiatric conditions to be given details about adverse outcomes experienced by their loved-ones because patients can refuse staff permission to share information about their care and treatment. This problem arises regularly in psychiatric units, but families need to be able to understand and support patients when harm occurs and they should be supported by candid explanations when mistakes are made.

A related practical problem can arise when no power of attorney is in place and a patient lacks capacity to consent to treatment and is unable to understand information about an adverse outcome.

These matters could be dealt with in the Regulations, but will require careful consideration, since an unintended consequence could be that certain groups of patients do not receive the full benefit of the proposed duty. Some instances of harm may never be disclosed. This would also mean that organisations would not be compliant with the legislation.

The use of the word "apology" could cause defensive behaviour - clause 4 (3)
It is possible that staff will be deterred from apologising for fear of litigation, and it has been noted in many academic and professional publications that anxiety about possible litigation has long been recognised as a barrier to disclosure of errors[x].

As an apology is not intended to amount to an admission of liability for the purposes of negligence claims, (see Compensation Act 2006 s 2), this should be emphasised in Regulations and during the passage of the Bill.

The duty to report annually could prove onerous for small organisations (clauses 5 and 6)
While larger organisations with good administrative support should be able to provide all the detailed information required annually on the duty of candour, smaller bodies and individuals such as community pharmacists and optometrists might experience serious practical problems in connection with candour reports, especially in meeting deadlines for reporting to LHBs. The knock-on effect could well result in difficulties for LHBs in publishing their reports in a timely fashion, so risking non-compliance.

Confidentiality in reports should extend to staff – Clause 9
The clause dealing with confidentiality in duty of candour reports prohibits the naming or identification of those to whom care has been provided. Extending that protection to prohibit identification of staff members should encourage openness. Allowing people to be named or identified in generalised reports might deter staff from being candid. However, focusing blame on systems rather than individuals can dilute individual responsibility, so it is necessary to balance these risks.

Training will be essential but will drain resources

It is important for relevant staff to receive training in all aspects of the duty of candour, but this will involve setting aside time for training and refresher courses at a time when staff shortages are already causing practical problems in the NHS.

The new duty could cause complications with policies on whistle-blowing

The implementation of the duty of candour needs to dovetail with existing policies requiring staff to be honest when errors are made and to speak out, if necessary, to protect patients. This might require organisations to re-examine existing policies on whistle-blowing to ensure that there are no adverse situations that could discourage staff from reporting their concerns.

Part 5: Vice Chairs of NHS trust boards

Some details require clarification

Clarity is required on whether trusts, on appointing Vice Chairs, should use the same appointments process as that which is currently in place for Vice Chairs' appointments in Health Boards.

There is also a need to clarify whether the Vice Chair's post in trusts will mean an extra member of the board over and above the present number allocated to trusts. If that were to be the case, there would be further strengthening of governance, which is to be welcomed.

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[i] Legislation as Aspiration: Statutory Expression of Policy Goals. A Lecture for the Statute Law Society delivered at the Institute of Advanced Legal Studies, London, 16th March 2015

[ii] Ely Hospital Cardiff: Inquiry Findings HL Deb 27 March 1969 vol 300 cc1384-93

[iii] Powell v United Kingdom [1998] ECHR 45305/99
Powell v Boladz [1998] Lloyd's Rep Med 116, 39 BMLR 35

[iv] Smith M and Forster H, "Morally Managing Medical Mistakes" (2000) 9 Cambridge Quarterly of Healthcare Ethics 30 – 53 in which following famous statement was made: *"Mistakes can be viewed as gems or treasures because much can be learned from them for the betterment of future patients".*

[v] C. Vincent: Why do people sure doctors? (1994) The Lancet 1609 -13, 1613; O Quick "Outing Medical Errors: Questions of Trust and Responsibility" 2006 Medical Law Review 22, 41-42

[vi] "Being Open" DOH Publications 1994

[vii] See Wijesuriya J.D. and Walker, D "Duty of Candour: a statutory obligation or just the right thing to do? British Journal of Anaethesia, Volume 119, Issue 2, August 2017, pages 175-178

[viii] Including arrangements for handing complaints in the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 201126; reporting and investigation of serious incidents, reviews of deaths in hospitals; Annual Quality Statements by LHBs, NHS Trusts and the Welsh Government.

[ix] Vick, L CQC Bares its teeth: Duty of Candour Four Years On", Medico Legal Magazine Issue 11, page 2

[x] For example, NHS Litigation Authority "Apologies and Explanations" NHSLA London 2007.