Witness Name: Harry Cayton
Statement No.: 1
Exhibits: HC/1
Dated: 22 February 2024

THIRLWALL INQUIRY

WITNESS STATEMENT OF HARRY CAYTON

I, Harry Cayton, will say as follows: -

1. Since 2018 I have been an independent advisor on professional regulation and governance. Over a number of years I have worked with governments and/or regulatory bodies in Canada, Australia, New Zealand, Ireland, Hong Kong, Saudi Arabia and the UK. I have provided advice to the World Health Organisation on health professional regulation. I'm a member of the Oversight Board of the Journal of Medical Regulation and independent advisor to Thentia Cloud, an IT company specialising in software for licensing and regulation. From 2007 to 2018 I was chief executive of the Professional Standards Authority. Prior to that I was National Director for Patients and the Public at the Department of Health for England (2002-2007) and before that chief executive of the Alzheimer's Society (1991-2002) and of the National Deaf Children's Society (1981-1991). I hold a Fellowship through Distinction from the Faculty of Public Health and an Outstanding Leadership Award from the World Health Executive Forum. In 2014 I was made a CBE for services to health and regulatory reform.

2. I acknowledge the pain and grief of the families whose babies were murdered or harmed at the Countess of Chester Hospital and recognise the failures which allowed this to happen. I hope that my evidence to the Inquiry will assist it in its objective of considering the effectiveness of NHS management and governance structures and processes, external scrutiny and professional regulation, whether changes are necessary and, if so, what they should be, including how accountability of senior managers should be strengthened.

3. In 2009, while at the Professional Standards Authority, my colleagues and I developed the approach to professional regulation which we named 'Right-touch regulation'[1] which distinguished it from the popular phrase at the time 'light-touch' regulation. The intention was that regulatory force should be proportionate to the risk of harm. By regulatory force we mean we mean the amount of regulatory effort aimed at mitigating a particular risk. The overall aim was to answer the question 'What does good regulation look like?' Right-touch

regulation is consistent with the principles set out by the Better Regulation Executive that regulation should be proportionate, consistent, targeted, transparent, and accountable. We added 'agile', a proposal subsequently welcomed by the House of Commons Regulatory Reform Committee.

4. Right-touch regulation sets out eight steps to be taken before a regulatory intervention is made. Its objective is to ensure that risks of harm have been properly identified and assessed, that the context in which harm takes place is understood, that interventions are focussed on outcomes, that other ways of mitigating the risk of harm are considered and that the unintended consequences of regulatory interventions are foreseen and allowed for. The steps of Right-touch regulation are:

    - Identify the problem before the solution
    - Quantify and qualify the risks
    - Get as close to the problem as possible
    - Focus on the outcome
    - Use regulation only when necessary
    - Keep it simple
    - Check for unintended consequences
    - Review and respond to change.

5. Right-touch regulation has been adopted as an approach by professional regulators around the world and not only in the health sector. I have always seen it as a work in progress, a way of thinking about regulatory issues not a fixed way of 'doing' regulation. It is an approach to regulatory problems and is observable in how regulatory bodies make decisions and how they act. Taking into account regulators' use of it in practice the Authority published *Right-touch regulation revised* in 2015[2] and *Right-touch regulation; international perspectives*[3] in 2018.

6. Regulatory oversight of the health system in the UK is fragmented, incoherent and lacking in clarity of purpose. It muddles regulation, inspection, quality improvement and patient safety. For many years governments have reacted to problems with patient safety by introducing new regulatory or oversight bodies, by adding or removing responsibilities, or by reorganising and restructuring and merging them. Most recently, in 2022, the Healthcare Safety Investigations Branch of the DHSC established in 2017 became an independent Health Services Investigations Body and a Patient Safety Commissioner for England was appointed.

7. Numerous investigations and inquiries have made recommendations intended to improve performance, which may or may not have been implemented in full and may or may not have made a difference. In recent years we have had the Mid Staffordshire NHS Foundation Trust Public Inquiry[4] (2013), the Morecambe Bay Investigation Report (2015)[5], the Kark Review of the Fit and Proper Persons Test (2019)[6], First Do No Harm; the Report of the Medicines and Medical Devices Safety Review[7] (2020), the Maternity and Neonatal Services in East Kent 'Reading the Signals' Report [8](2022) and the Independent Review of Maternity Services at the Shrewsbury and Telford NHS Trust[9] (2022). A further review of maternity services in Nottingham continues.

8. There are over 22 separate organisations responsible for overseeing different but sometimes overlapping aspects of patient safety in England. Scotland, Wales and Northern Ireland since devolution have partially separate arrangements, which creates further inconsistency. For the purpose of this Statement my comments refer to England only. In my view one of the weaknesses of the current framework of oversight bodies is the lack of clarity of purpose, the separation of system regulation from professional regulation and the division of professional regulation into separate occupations, when in reality healthcare professionals and occupations work as a team within a regulated system.

9. The regulation of health occupations stretches back to the nineteenth century and grew out of professional associations. While such associations ostensibly controlled quality and price and entry to an occupation with legal powers bestowed by the State, in practice they operated as a cartel working in the interest of the practitioners rather than of the consumer. As more and more occupations have been drawn into statutory regulation, governments have introduced different legal frameworks for each thus adding complexity. In England there are now 33 health and care professions regulated by 10 regulatory bodies and a further some 70 occupations overseen by 32 accredited registers.

10. One of the most important and influential public enquiries in recent years the *Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995* (2001)[10], led by Professor Sir Ian Kennedy, found that the General Medical Council had acted in the interests of doctors not of patients and recommended the establishment of an oversight body, 'charged with the overall co-ordination of the various professional bodies and with integrating the various systems of regulation' (recommendation 71). The Government legislated for a body with a somewhat narrower remit in 2005, the Council for Healthcare Regulatory Excellence, which was given greater independence of governance,

wider powers and a new name, the Professional Standards Authority for Health and Social Care, in 2012.

11. In setting out my views in the Witness Statement on the role, or not, of professional regulation in promoting the safety of those who use our health services I have drawn on my experience as a patient and service user advocate, my 12 years as chief executive of the Professional Standards Authority and its predecessor the Council for Healthcare Regulatory Excellence and my current five years reviewing and advising regulatory organisations across many jurisdictions.

12. We need to separate the meanings of 'professional' and 'profession'. This will be relevant when I come to discuss managers. A person working in any occupation can act 'professionally'. Colloquially we mean with competence, honesty, reliability, courtesy and accountability. People do not need to be regulated to act professionally. A 'profession' is an occupation where competence, honesty, reliability, courtesy and accountability are defined in standards and required by regulation. A person in an unregulated occupation is accountable to their customer or their manager or employer. A regulated professional is accountable to their regulator. So these definitions are somewhat circular; an occupation becomes a profession by being regulated but people in unregulated occupations may act professionally and people in regulated professions may not. Regulation may define what professional conduct is but it does not ensure it is practised.

13. This last point is a significant challenge in the regulation of people rather than of, say, products or processes. Regulation of people may be directive – you *should* act like this- but it is not determinative – you *will* act like this. Human error, negligence or malfeasance are the cause of most harmful events. Most medicine errors for example come about not because of the failure to regulate the manufacture, dosage, recommended use, or labelling of the product but because of error or carelessness by pharmacists, nurses or doctors in prescribing or administering the medication. This is often referred to as 'human factors' in safety management. I consider that professional regulation has been over-sold as a solution to patient safety, although of course it has a contribution to make. Human factors are hard to regulate and professional regulation does not stop criminal behaviour.

14. Over-confidence in the safety of professional regulation may actually increase risk because people become too trusting and not alert to the risks of harm around them. A common theme is the reports mentioned in paragraphs 7 and 10 (above) is that it was families who first raised concerns about failures in patient care and safety and that their voices were ignored or dismissed by both health professionals and management. The recommendations in those reports acknowledge this and, in summary, propose that

patients must be much more involved in safety, be able to report incidents and to participate in the learning that should follow. The newly established Patient Safety Commissioner for England has a specific role of responding to and collecting safety concerns raised by patients and their families.

15. A feature of our current model of professional regulation is individualism. The traditional qualities of a professional were and perhaps still are, mastery of their craft, autonomy in their practise and altruism in purpose. In 2004 I gave evidence to the Royal College of Physicians Working Party on Medical Professionalism in a Changing World[11]. I argued that the traditional concept of a professional as an autonomous self-managing expert is no longer fit for purpose. Healthcare is delivered by teams of people, collaborating and sharing expertise. I suggested that professionalism be redefined as a set of relationships based on expertise, empathy and mutuality. Some but only a little progress has been made towards regulating teams rather than individuals. The GMC's 'Good Medical Practice' does place a strong emphasis on collaboration and communication and on the duty of a doctor to act when they see unsafe or improper practice by another health professional. This shared group responsibility for safe and effective care may have been absent in the Countess of Chester Hospital.

16. Following the Mid Staffordshire Report the Government introduced the legal 'Duty of Candour', the requirement that health workers and their employers be honest and open when something has gone wrong. Alongside this, safeguards for whistle-blowers were strengthened with the creation of a 'Speaking up Champion' to encourage and support staff who wished to raise concerns but were anxious about doing so. As we can see from the response to the paediatricians who spoke up about their concerns at the Countess of Chester Hospital, whistle-blowers are still not listened to and often suffer detriment. That this remains so is clear from Professor Sir Ian Kennedy's recent report, 'Review of the Response of Heart of England NHS Foundation Trust to Concerns about Mr Ian Paterson's Surgical Practice; Lessons to be Learned; and Recommendations'[12], where repeated concerns by other clinicians about Mr Paterson's practice were not responded to appropriately. In my own experience, two whistle-blowers who approached the Professional Standards Authority with legitimate concerns about the regulators where they worked, were internally identified and ultimately forced to leave their jobs.

17. Ian Kennedy stresses the responsibility of NHS Trust boards to set the culture and expectations of professional behaviour within the hospital. He writes, ' The Board must create an environment in which members of staff feel able and free to raise matters of concern regarding the care and treatment of patients. This involves leadership from the

Board and particularly the Chairman. The Chairman must demand of the Board and the Executive a commitment to openness and candour.' (para 4.16, p 140). In 2011 the Secretary of State for Health requested the Professional Standards Authority to create new Standards for NHS Boards. These standards were developed from reviewing existing models but importantly shaped by confidential interviews with senior staff and chief executives about their experience of maintaining ethical conduct and personal values at work. One question we asked all of them was 'Have you at any time done something you knew or felt to be wrong?' With one exception they answered, 'Yes'. In all cases they said it was earlier in their career and cited pressure from line managers to resolve a problem rapidly by breaking rules, ignoring best practice, or disregarding alternative approaches. NHS managers work under constant pressure and interference from multiple directions, NHS England, Government Ministers, Health Unions, the media, patient associations and more. There is often a tension between finance, target setting, demands for 'delivery' and quality, ethical conduct and outcomes. Turnover of senior managers is high and an unintended consequence of more regulation maybe to increase that pressure.

18. The new *Standards for Members of NHS Boards and Clinical Commissioning Groups*[13] were published in 2012. These Standards were accepted by the Secretary of State, and originally intended as the foundation for a review of accountability arrangements for NHS senior leaders. The Standards covered three areas; personal behaviours, technical competence and business practices. They were deliberately kept concise, clear and readable. Unlike previous Standards they were not abstract values but personal commitments to be signed off by individuals. In its 2013 response to a recommendation of the Mid Staffs Inquiry (recommendation 215) that a Code of Conduct for Boards be established the Government responded that the Authority's Standards met that requirement. However, for some reason the Department of Health lost interest in this initiative. Instead of the Department publishing and distributing the Standards it was left to the Authority to do so and made clear that their adoption by NHS Boards would be voluntary. A number of Boards did adopt them but, lacking continuing encouragement nationally, uptake declined.

19. The Authority's Standards were aimed at non-executive and executive members of boards not at the wider group of senior managers who were the target of the Mid Staffs Inquiry recommendation. The second half of the Mid Staff Inquiry recommendation was a mechanism for compliance. To meet this the Government proposed a new test of fitness for board directors, which became the 'Fit and Proper Person Test'. Oversight of this test was given to the Care Quality Commission. The Fit and Proper Persons Test was never linked to the Authority's Standards. In 2018 when it was clear that the Fit and Proper

Persons Test was not operating effectively the Secretary of State for Health at the time asked Tom Kark QC to review 'how effectively the test prevents unsuitable staff from being redeployed or re-employed in health and social care settings.'

20. More than 20 years ago the Bristol Inquiry recommended that a 'new professional body' be created for NHS managers. A number of attempts have been made to establish a voluntary association for managers but none have endured or had much impact. In 2013 the Mid Staffordshire Inquiry stopped short of recommending the regulation of managers, stating that there was little enthusiasm for this among most stakeholders at that time. The Kark review in 2019 also rejected the idea of regulating managers instead proposing a means of tracking and barring managers who were found to have failed. The trial and sentencing of nurse Letby have given rise to fresh calls for the regulation of managers from the print media and the doctors' union the British Medical Association. This despite the fact that some key managers at the Countess of Chester Hospital at the time were doctors or nurses and therefore already regulated. The House of Commons Health and Social Care Committee has recently asked its Advisory Panel to look into government responses to previous Inquiries including recommendations relating to managers.

21. Regulated professionals, whether they be lawyers, architects or nurses have to acquire a defined body of knowledge, they must pass externally validated examinations, they must understand their own scope of practice and pay to be registered with their regulatory body, they must accept a set of standards of conduct and competence and be legally subject to discipline. Clearly there are benefits to the public from this; consistency of qualifications, standards of clinical practice and ethics and a means of dealing with transgression. Professional regulation also buys professionals a level of autonomy from their employers, protecting them to some extent from line management, or internal disciplinary action and requiring referral and lengthy investigation by their regulatory body. The cost of a legal defence also needs to be met. Statutory regulation comes with a significant financial cost, and does not regulate culture, or multidisciplinary teams and responds to harm after the event.

22. The problem with regulating managers is that management is not a profession although (see paragraph 12 above) managers can and do of course act professionally. To be clear, when I say that management is not a profession I mean that it does not meet the criteria of requiring an agreed body of knowledge, having an externally validated qualification and a definable scope of practice. To create a regulatory framework for managers these elements would need to be defined and agreed. A decision would have to be made as to which managers required regulation: all managerial posts (about 40,000) or only 'senior'

managers? Then a regulatory body would need to be established, standards and disciplinary processes defined, existing managers would need to pay a registration fee to meet the cost of the new regulator and government to meet the cost of establishing it. Once regulated, managers would be harder to discipline or dismiss by Trust boards as serious concerns would need to be referred to their regulator. Within a regulatory tribunal for a manager the task of proving personal accountability for harm would be even more difficult than it is for doctors and nurses. The difficulty of proving gross negligence manslaughter is a case in point[14]. It is worth noting that the standard of proof in disciplinary tribunals is the civil standard not the criminal standard.

23. As well as the difficulty in imposing regulation on such a wide category of roles as are fulfilled by managers, the problems we seek to address are not really susceptible to professional regulation which is not good at dealing with dysfunctional working relationships, human ambition, dislikes and fears, incompetent boards, lack of resources, or external challenges such as financial, political or reputational pressure. The Care Quality Commission as the 'system' regulator may have some responsibility in this area but as I have already pointed out the fragmentary nature of regulatory oversight means that no one regulator or inspector has a full view of what is happening.

24. My observations of professional regulation over many years lead me to consider that statutory regulation of managers is not a likely solution to to failures in patent safety. When serious crimes are committed, as in nurse Letby's case, or by Ian Paterson or David Britten[15] or by William Kerr or Michael Haslam[16] existing statutory regulation of the perpetrators and their many colleagues has been unable to prevent them. Criminal acts are an individual's responsibility but the failure to identify them in a healthcare setting, to respond or take appropriate action is a systemic, corporate failure of group curiosity, courage and culture. Multi-factorial causes of harm cannot be prevented by action on a single element.

25. The failures which resulted in nurse Letby being able to continue her crimes over time, despite concerns by a few of her medical colleagues, are attributable in part to poor management so we need to seek additions or alternatives to statutory regulation. The most practical in my view is the establishment of barring system similar to that proposed in the Kark review, although I would want it to be independent of NHS institutions. Following the abolition of the General Teaching Council the Teacher Regulation Agency currently fulfils a similar function which is narrower in scope than that of a professional regulator. Certainly, the regular re-employment of senior managers in the NHS who have been found wanting continues to undermine public and professional confidence and perpetuate the

belief that inappropriate conduct, particularly towards whistle-blowers, is tolerated. There are many well publicised examples over the years. In a recent example (2022) the Director of Public Health in the Ise of Man was found by an employment tribunal[17] to have humiliated and unfairly dismissed a doctor who had made 'protected disclosures' in relation to the pandemic on the Island. Compensation of some £3 million was paid to the doctor for the unfair dismissal. The former Director of Public Health, who continues to deny the findings of the Tribunal, was re-employed within the NHS as an advisor to the Chief Executive of a London Hospital.

26. An effective barring scheme would need to be mandatory on employers and to have a compulsory code of conduct for all managers who fall within the scheme. The Professional Standards Authority's *Standards for NHS Board and Clinical Commissioning Groups*, could be adapted for this purpose. A decision would have to be made about how wide across the management workforce the barring scheme would be applied. Non-executive directors would need to be included.

27. Right-touch regulation requires the proper use of existing regulatory tools for the prevention of harm before creating new ones. Professional regulators should use existing powers to take action against health professionals who fail to report poor practice by colleagues, the duty of candour should be enforced and action taken against those who disregard their duties towards whistle-blowers. In my view close attention should be paid to existing means of oversight which clearly failed to detect or respond to nurse Letby's criminal activities before adding new layers of regulation to compensate for failure to deliver on those that already exist. If additional powers are needed then a barring system or negative register of unsuitable managers or directors would be proportionate.

28. Governments over many years have taken a piecemeal approach to regulation in our health system creating a complicated and overlapping structure of multiple agencies and costing huge sums. In my view we need wider reforms to the regulatory framework to promote safety and prevent harms. The aim should be clarity of purpose, simplicity of structure and a focus on teams rather than individuals. Practical proposals are set out in the Professional Standards Authority's papers 'Rethinking Regulation' (2015)[18], 'Regulation Rethought' (2016)[19] and in Part 2 of 'An Inquiry into the College of Dental Surgeons of British Columbia and the Health Professions Act' (2018)[20].

Statement of Truth

I believe that the facts stated in this witness statement are true. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief of its truth.

Signed: PD

22 February 2024

Dated: _____

References

[1] *Right-touch regulation*, Professional Standards Authority 2010 **Exhibit HC/01 - INQ0017164**
[2] *Right-touch regulation revised*, Professional Standards Authority 2015 **Exhibit HC/02 - INQ0017165**
[3] *Right-touch regulation in practice; international perspectives*, Professional Standards Authority 2018 **Exhibit HC/03 - INQ0017166**
[4] *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry* (3 vols), GovUK 2013 **Exhibit HC/04 - INQ0017167**
[5] *Morecambe Bay Investigation Report,* GovUK, 2015 **Exhibit HC/05 - INQ0017168**
[6] *Kark Review of the Fit and Proper Persons Test* GovUK 2015 **Exhibit HC/06 - INQ0017169**
[7] *First Do no Harm; report of the independent medicines and medical devices review,* GovUK, 2020 **Exhibit HC/07 - INQ0017170**
[8] *Maternity ands Neo-Natal Services in East Kent 'Reading the Signals' Report,* GovUK, 2022 **Exhibit HC/08 - INQ0017171**
[9] *Independent Review of Maternity Services Shrewsbury and Telford NHD Trust; Final Report,* HOC 2022 **Exhibit HC/09 - INQ0017172**
[10] *Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995.* DoH 2001 **Exhibit HC/10 - INQ0017173**
[11] *Doctors in Society; Technical Supplement,* Royal College of Physicians, 2005 **Exhibit HC/11 - INQ0017174**
[12] *'Review of the Response of Heart of England NHS Foundation Trust to Concerns about Mr Ian Paterson's Surgical Practice; Lessons to be Learned; and Recommendations,* Solihul Hospital, Kennedy Breast Care Review, nd.
[13] *Standards for Members of NHS Boards and Clinical Commissioning Groups,* Professional Standards Authority 2012 **Exhibit HC/13 - INQ0017175**
[14] *'Williams Review into Gross Negligence Manslaughter in Healthcare'.* DHSC, 2018 **Exhibit HC/14 - INQ0017176**
[15] *An independent investigation into the conduct of David Britten at the Peter Dally clinic,* NHS London 2008 **Exhibit HC/15 - INQ0017177**
[16] *The Kerr/Haslam Inquiry,* HM Government, 2005 **Exhibit HC/16 - INQ0017178**
[17] *IN THE EMPLOYMENT & EQUALITY TRIBUNAL* Case 21/20, Dr Rosalind Ranson Complainant V Department of Health & Social Care, 2022
[18] *Rethinking Regulation*, Professional Standards Authority, 2015 **Exhibit HC/18 - INQ0017179**
[19] *Regulation Rethought, proposals for reform,* Professional Standards Authority 2016 **Exhibit HC/19 - INQ0017180**
[20] *An Inquiry into the College of Dental Surgeons of British Columbia and the Health Professions Act,* Professional Standards Authority 2018.