Written evidence submitted by the Patient Safety Commissioner (PSN0026)

Introduction

1. I welcome the Health and Social Care Committee's Independent Expert Panel's (the 'Panel') evaluation of recommendations on patient safety which have been accepted by the government.

2. In recent years, especially in the field of patient safety, there has been too big a gap between a commitment to implement recommendations, and actual action. The ambition - expressed in 2013 - of 'a promise to learn – a commitment to act' has, too often, not been realised.[1]

3. As an officeholder whose statutory powers are broadly limited to making recommendations of my own (as discussed below), a focus on how the system (led by the Department of Health and Social Care and NHS England) reacts and responds to recommendations in patient safety is long overdue.

4. The Panel will be aware of the importance of learning lessons from incidents of avoidable harm to ensure that they are not repeated. Such a process is an important part of moving the NHS away from a 'blame culture' to an open, just and learning culture, that I told the Health and Social Care Committee at my pre-appointment hearing was at the heart of my mission. I see the successful implementation of the recommendations that derive from inquiries/reviews following patient safety incidents as a key part of this learning and improvement process.

5. Implementation of recommendations is also key from the point of view of the patients harmed. A health system which responds to harm in a restorative way would recognise that, for patients, ensuring that the harm they have suffered never happens to another patient is key to their healing. As many of the patients that we engaged with as part of my redress work told us, repair of their harm and prevention of future harm go hand in hand.

6. As National Advisory Group on the Safety of Patients in England put it, following on from the Francis report into Mid Staffordshire:

> "The only conceivably worthy honour due to those harmed is to make changes that will save other people and other places from similar harm. It would add tragedy to tragedy if the nation failed to learn from what happened, and to put those lessons to work.[2]

7. I'm also very much aware that we as organisations and officeholders with the power to make recommendations must do better to make them effective and impactful. This is why I am supportive of the efforts of Dr Rosie Benneyworth, currently interim Chief Executive of the Health Services Safety Investigations Body (HSSIB) to rationalise how the regulators, ombudsman and other bodies in the system make recommendations, and follow up on them. This work will start by agreeing key principles and will report into NHS England's National Quality Board.

The role of the Patient Safety Commissioner for England

8. I took up the post of the first ever Patient Safety Commissioner for England on 12 September 2022.

9. The role was created in response to the recommendations of the report of the Independent Medicines and Medical Devices Safety Review (IMMDS Review) – also known as the 'First Do No Harm' report - which was led by Baroness Cumberlege and published on 8 July 2020.

10. The IMMDS Review explored issues relating to the use of hormone pregnancy tests, sodium valproate and pelvic mesh and was commissioned because patients did not feel listened to or their concerns acknowledged, which led to their avoidable harm. Countless previous scandals have shown that not listening to patients has tragic consequences.

11. The government published its formal response to the IMMDS Review recommendations in July 2021. This response included the commitment to appoint a Patient Safety Commissioner, with a remit to cover medicines and medical devices.[3] This commitment was legislated for through the Medicines and Medical Devices Act 2021 (the 'Act').

12. In broad terms, the role of the Patient Safety Commissioner is to be independent of government, act as a champion for patients, lead a drive to improve the safety of medicines and medical devices and improve how the healthcare system, the government and the NHS listen to patients to put patients first.

13. This overview is reflected by the comments of the then Minister, Jo Churchill MP, during the consideration of Lords amendments (one of which created the role of Patient Safety Commissioner) in the House of Commons on 27 January 2021:

> "The Patient Safety Commissioner will act within and outside the system. They will be an advocate for patients and ensure that the patient voice is primary. The commissioner will be able to seek information, make reports without fear or favour and expect responses, and, more importantly, get change."[4]

14. The Act sets out the core duties of the Patient Safety Commissioner at sections 1(2)(a) and (b):

> "The Commissioner's core duties are to—

(a) promote the safety of patients with regard to the use of medicines and medical devices, and

(b) promote the importance of the views of patients and other members of the public in relation to the safety of medicines and medical devices".

15. Schedule 1 of the Act provides further provisions about the role.

16. Schedule 1, para 1 requires me to carry out a public consultation to prepare and publish a set of principles to govern the way in which I will carry out the core duties shown above. Schedule 1, para 1 of the Act gives me the power to revise these principles, subject to conducting a public consultation and publishing the revised principles.

17. Under Schedule 1, para 2, I must take reasonable steps to involve patients in the discharge of my core duties. There is particular reference in paras 2(a) and (b) to me having to take reasonable steps to (a) ensure that patients are aware of my core duties and how they may communicate with me; and (b) consult with patients (or those groups which appear to me to represent their interests) on matters which I propose to consider when discharging my core duties.

18. Schedule 1, paras 3(1) to (3) provides me with the following supplementary functions: "(1)

For the purposes of carrying out the core duties, the Commissioner may—

(a) make a report or recommendation to a relevant person;

(b) consult or receive information from patients or any other person the Commissioner thinks appropriate;

(c) request information from a relevant person;

(d) share information with a relevant person.

(2) A relevant person to whom a report or recommendation is made under sub-paragraph (1)(a) must provide a response to that report or recommendation within such period as the Commissioner may reasonably require.

(3) A relevant person must, so far as reasonably practicable, comply with a request by the Commissioner to provide information within such period as the Commissioner may reasonably require."

19. In effect, this paragraph is the extent of the Commissioner's statutory 'powers'.

20. 'Relevant person' – for the purposes of this paragraph - is defined as anyone who exercises functions of a public nature in relation to England relating to medicines or medical devices or anyone else who provides services in the course of providing health care relating to medicines or medical devices relating to England.

My recommendations to date

21. To date, I have made four recommendations under my statutory powers – three to the Secretary of State for Health and Social Care in October 2023 in relation to Martha's Rule; and one to NHS England in November 2023.

22. My recommendations in relation to Martha's Rule relate to how we can implement it across the NHS in England. These recommendations were developed after a series of policy sprints with key stakeholders, including Merope and Paul, the mother and father of Martha Mills who tragically died of sepsis in 2021, aged 13. The recommendations were three-fold and reflect a 'step-up' approach to implementation of Martha's Rule:

- We must implement a structured approach to obtain information relating to a patient's condition directly from patients and their families at least on a daily basis. In the first instance this will cover all in-patients in acute and specialist Trusts.

- All staff in those Trusts must have 24/7 access to a rapid review from a critical care outreach team who they can contact should they have concerns about a patient.

- All patients, their families, carers and advocates must also have access to the same 24/7 rapid review from a critical care outreach team which they can contact via mechanisms advertised around the hospital and more widely if they are worried about the patient's condition. This is Martha's Rule.

23. My recommendation to NHS England concerns the use of teratogens. This recommendation follows from extensive work in year 1 of my term on the medicine valproate – a known potent teratogen that was examined as part of IMMDS Review. However, despite recommendations in the IMMDS Review designed to improve the safe prescribing and dispensing of valproate and other such teratogens, patients continued to raise serious concerns with me. After following up many of these concerns with those responsible, and engaging with some of the leading ICBs in terms of good practice, I felt compelled to make the following recommendation – which starts with sodium valproate, but is designed to drive improvements more broadly in medicine safety:

The Patient Safety Commissioner recommends for NHS England to have a fully funded and resourced system for improving the safe use of the most potent teratogenic medications, through a National Quality Improvement Programme for Integrated Care Systems, starting with the safe use of sodium valproate. The Commissioner believes that this should be implemented by September 2024 for sodium valproate, before expanding to cover any medication with a Pregnancy Prevention Programme by September 2025.

24. My expectation is that all organisations to which I have issued a recommendation will respond within three months and we will publish those responses on my website.

25. Finally, and importantly, Schedule 1, para 4 prevents me from exercising any of my functions in

relation to an individual case, although I am not prevented from considering individual cases in the context of considering general issues.

Resourcing constraints

26. Possessing statutory functions is, very much like the recommendations marked 'implemented' that the Panel is evaluating, only a small part of the reality on the ground. Functions need to be exercised by a team of sufficient size and expertise. As the Committee is well-aware, I am limited in what I can achieve with my current resourcing. I am urgently seeking to engage the Department on this issue and will continue to update the Committee as necessary, in addition to always being happy to answer any questions that they may have.

My priorities

27. During my first 16 months in post, my priorities have been culture change, pelvic mesh and sodium valproate. These priorities were largely influenced by the origins of my role in the IMMDS Review, and the medical interventions that report examined.

28. The need to make pelvic mesh and valproate priorities was then further reinforced when Minister Caulfield asked me to undertake a project to explore redress options for those who have been harmed by pelvic mesh and valproate in December 2022. After being provided with the necessary resource by the Department in June 2023, I shall be publishing a report with the conclusions of my work, and my recommendations to government, on 7 February 2024.

29. I have also taken the opportunity at the start of this report to evaluate the government's implementation of the recommendations from the IMMDS Review. I, like the Committee and Panel, think this is a useful exercise. Worryingly, even in areas as high profile as the IMMDS Review recommendations – where considerable time and resource have been invested - my report highlights gaps and inconsistencies in implementation.

30. After nearly a year in post, in late Autumn 2023 my team and I undertook work to refresh the strategic priorities for the next period and identifying overarching themes based on what I have heard from patients and the public. These themes were then tested with key stakeholders in the healthcare system via an online survey, to which I received generally very positive responses.

31. The strategy is based on three overarching ambitions, under which sit three operational priorities. These operational priorities will form the basis of my work, and that of my office, for the next period, subject to confirmation of resource from the Department of Health and Social Care.

To drive the alignment of the healthcare system to deliver a just and learning safety culture	**To support initiatives which amplify all patient voices and empower patients to make informed decisions about their care**	**To advocate for partnerships which embed patient safety and patient voice throughout the healthcare system**
We will call for a Safety Management System for the healthcare sector to reduce	We will drive the design and development of Martha's Rule to empower patients and families	We will work with NHS organisations to ensure Patient Safety Partners are embedded

We will call for improvements in signal detection through the MedTech strategy and mandatory reporting of Yellow Cards.	We will call for shared and supported decision making so patients are fully informed about the benefits, risks and alternatives when a medicine or medical device is used.	We will advocate for the promotion of patient safety across the health system including training in patient safety for board members.
We will call for an overhaul of the complaints process and clinical negligence in the healthcare system, promoting restorative practice to support patients, families and healthcare workers.	We will support calls for greater transparency of payments and for registers of interest of healthcare professionals.	We will join cross-system and global initiatives to advocate for patient voices to be central to the design and delivery of healthcare.

The Committee's evaluation

32. This submission is prepared in my role as the Patient Safety Commissioner for England. As the Panel will have noted from the above background, this role only covers the promotion of safety with regards medicines and medical devices, which is not the focus of the recommendations chosen for evaluation by the Panel. My role also post-dates each of the recommendations chosen.

33. I would note, however, that all the recommendations that the Panel is looking at – but particularly recommendations 2, 3, 4 and 5 – have at their heart the question of creating and maintaining a patient safety culture. This means creating a just and learning culture of psychological safety, ensuring all patients are given the opportunity for informed consent and that conflicts of interests by medical staff are made transparent.

34. Too often, the current NHS culture inhibits patient voice and makes positive change harder to implement. This often means that energy is focussed on the consequences of harm, with the defensive, dismissive approach that has featured in so many recent reviews**.** The Horizon scandal sadly illustrates this approach well – and has unleashed a sense of outrage in the population that the voices of citizens are too often ignored and dismissed by those in positions of power as peoples' lives and livelihoods are destroyed.

35. Sadly, a culture persists in many places in which harm to patients are seen as inevitable, when in fact they are avoidable if the right steps are taken to identify hazards and put the right control measures in place.

36. I believe that we as a healthcare system can and should do much better in terms of instilling a culture of safety from the design to the delivery of healthcare – taking the learnings from places leading in this area, such as Mersey Care and their Just and Learning Culture.[5]

37. As I stated above, one of my three priorities in my first year was culture change – in recognition of its importance. Culture change remains a key priority in my refreshed strategy, forming the first of the three refreshed strategic ambitions set out in the table above. Put simply, we need a culture change whereby patient safety comes at the top of the agenda for senior leaders in healthcare – at both a local and national level. It is only with this change in culture that we will see recommendations – of the type that the Panel are evaluating - consistently acted upon, and positive change embedded. This is why I have created an informal network for Executives to have conversations about safety, which first met in December 2023, and which I hope will act as a catalyst for debate, discussion and positive change amongst senior leaders on these issues.

38. Within this topic of culture, I am particularly supportive of maximising the knowledge and understanding of non-executive directors in patient safety, who have an important role to play in observing the culture of their organisations and making constructive recommendations for change where necessary. An understanding of patient safety is critical for this key role. Therefore, it was surprising to me that patient safety did not feature in induction training for Non-Executive Directors in NHS Trusts

39. Connecting with patients and their families is straightforward for clinicians but can be more challenging for many senior leaders. Listening does not happen by accident, and I am a strong proponent of Boards hearing the accounts of patients and service users at the top of every board agenda. This is a low cost, high impact action and will help to frame the conversations that take place at board.

40. Visible leadership, such as walkabouts and listening to patients, families and workers is also key, with regular opportunities to triangulate this information at Board level with complaints and incidents teams, Freedom to Speak Up Guardians, staff network chairs, staff side and others to identify hotspots (good and bad) of culture.

41. More generally, leaders - locally and nationally - need to set a strategic intent for their organisations to listen to patient feedback at every level and for this to be used for learning and improvement. They also need to follow up by acting on the issues raised by patients. This is why I am such a strong supporter of Martha's Rule. If implemented effectively, and the reasons for its use explored, I believe it can mark the turning point in healthcare culture and a resetting of the scales between patient, clinicians, and senior leaders.

42. We must not underestimate the influence of politicians and officials in prioritising operational performance and finances over patient safety and patient voice. As a result, organisations delivering healthcare are held to account for a very narrow set of priorities, and this directs the activities of leaders and managers in those organisations naturally towards delivering those and providing the data to regulators and officials. Patient safety and patient voice are seen as implicit – yet, without making it visible, the leaders are not held to account for these in the same way.

43. The understandable push from politicians, in particular, to increase access to healthcare will be worth little if it is not access to safe healthcare. We must never forget that patient safety - and the crucial role of patient voice within that – is the first dimension of quality healthcare.[6]

44. I hope the Panel will be able to look at these broader issues of culture in their evaluation. We know that successful and sustainable implementation of recommendations is more than 'ticking boxes.' It relies on many contextual factors, chief amongst them organisational culture encompassing leadership, communication, teamwork, and a just culture with a focus on listening and psychological safety.

45. I am happy to assist the Panel, or the Committee itself, on these issues, or to provide further information on anything else that I have covered in this response. My contact details are below.

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1 *A promise to learn – a commitment to act* (2013). Available at: https://assets.publishing.service.gov.uk/media/5a7cc74540f0b6629523bc31/Berwick_Report.pdf. 2 *A promise to learn – a commitment to act* (2013). Available at: https://assets.publishing.service.gov.uk/media/5a7cc74540f0b6629523bc31/Berwick_Report.pdf. 3 Independent Medicines and Medical Devices Safety Review: government response - GOV.UK (www.gov.uk)

4 Medicines and Medical Devices Bill - Hansard - UK Parliament

5 Restorative Just and Learning Culture :: Mersey Care NHS Foundation Trust

6 *High Quality Care for All* (2008). Available at: High Quality Care For All NHS Next Stage Review Final Report CM 7432 (publishing.service.gov.uk)

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