A Critical Examination of Regulatory Responses to Patient Safety Incidents Relating to Hospital Discharges

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ABSTRACT

This thesis sets out to determine how healthcare regulation in England might better ensure the safety of patients experiencing hospital discharge. The core problem at the heart of this thesis can be articulated as follows: healthcare regulation within England is suboptimal at safeguarding patients experiencing hospital discharge.

The thesis is comprised of a series of published papers, each of which identify and address problematic aspects of the regulatory status quo. I consider in turn: the structure and strategy of healthcare regulation; the liminal spaces within this regulatory structure; and the concept of regulatory accountability. Through analysing the structure of healthcare regulation in England, and the risk-based regulation strategy employed by regulators, I present three weaknesses regarding how regulators identify, conceptualise, and subsequently prioritise risk in the context of regulating hospital discharges.

By employing the anthropological concept of liminality as a lens through which to explore and identify these regulatory I bring into focus the liminal space that exists amongst regulatory bodies within the hospital discharge regulatory arena. Following this critical examination of structure, strategy, and space, I then analyse concepts of accountability in the regulatory context. The rationale for doing this is to consider the potential impact of regulatory actions upon registrants – for this impact is key to ensuring patient safety.

Throughout this thesis I provide practical recommendations which regulatory bodies could incorporate to improve the safety of patients leaving hospital. Taken together, all of my research findings could inform regulatory approaches to improving patient safety more broadly throughout the NHS.

DECLARATION

No portion of the work referred to in the thesis has been submitted in support of an application for another degree or qualification of this or any other university or other institute of learning.

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This thesis is dedicated to the memory of my father, Peter.

LIST OF ABBREVIATIONS

BMA – British Medical Association

CHRE - Council for Health Regulatory Excellence

CMCH Act - Corporate Manslaughter and Corporate Homicide Act 2007

CQC – Care Quality Commission

D2A - Discharge to assess

DHSC - Department of Health and Social Care

ECHR - European Convention on Human Rights

FtP - Fitness to practice

FTTP - Fit and Proper Person Test

GCC - General Chiropractic Council

GDC - General Dental Council

GMC – General Medical Council

GMP – Good Medical Practice

GOC - General Optical Council

GOsC - General Osteopathic Council

GP – General Practitioner

GPhC - General Pharmaceutical Council

HCPC - Health and Care Professions Council

HSE – Health and Safety Executive

HSIB - Healthcare Safety Investigation Branch

HSSI Bill - Health Service Safety Investigations Bill

HSSIB - Health Service Safety Investigations Body

IMMDS Review - Independent Medicines and Medical Devices Safety Review

KLOE - Key Line of Enquiry

MoU - Memorandum of Understanding

MPTS - Medical Practitioners Tribunal Service

NHS – National Health Service

NHS TDA - NHS Trust Development Authority

NHSE – NHS England

NHSI – National Health Service Improvement

NICE – National Institute for Health and Care Excellence

NMC - Nursing and Midwifery Council

NRLS - National Reporting and Learning System

PACAC - Public Administrations and Constitutional Affairs Committee

PFD - Prevention of Future Death

PHE – Public Health England

PHSO - Parliamentary and Health Service Ombudsman

PPE – Personal Protective Equipment

PSA – Professional Standards Authority

PSC – Patient Safety Commissioner

PSI – Patient Safety Incident

RCH NHS Trust – Royal Cornwall Hospitals NHS Trust

SWE - Social Work England

UK – United Kingdom

WHO – World Health Organisation

TABLE OF CASES

TABLE OF LEGISLATION

Statutes

Children and Social Work Act 2017

Chiropractors Act 1994

Coroners and Justice Act 2009

Corporate Manslaughter and Corporate Homicide Act 2007

Criminal Justice and Courts Act 2015

Dentists Act 1984

European Convention on Human Rights

Health Act 1999

Health and Safety at Work Act 1974

Health and Social Care Act 2008

Human Rights Act 1998

Human Tissue Act 2004

Medical Act 1983

Medicines and Medical Devices Act 2021

National Health Service Act 2006 (as amended by the Health and Social Care Act 2012)

Opticians Act 1989

Osteopaths Act 1993

Secondary Legislation

Coroners (Investigations) Regulations 2013

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

Health and Social Work Professions Order 2001

Nursing and Midwifery Order 2001

Pharmacy Order 2010

INTRODUCTION

The Problem

A wealth of academic and policy literature[1] within the patient safety field examines the safety of discharges from hospital and proposes improvement methods for the healthcare system to implement. There is also a substantial body of work pertaining to the theory of regulation: its aims, weaknesses, and methods.[2] Despite this, it is unclear what impact (if any) healthcare regulators within England have upon protecting and promoting safety at the point at which patients are discharged from hospital.

The core problem which this thesis aims to tackle can thus be articulated as follows: healthcare regulation within England is suboptimal at safeguarding patients experiencing hospital discharge. As a consequence, patients are experiencing avoidable physical harm and harm to their dignity. Understanding why regulation is failing in this manner is a crucial knowledge and practice gap that must be urgently addressed if regulators are to fulfil their legal obligation (more on these in Chapter Three), to protect people from harm. The three published papers which make up the bulk of this thesis (Parts Two – Four) each address an aspect of regulation which, I argue, contributes to this suboptimal safeguarding.

The next subsection provides an overview of the key arguments this thesis makes. After providing this overview, the following subsection then introduces the reader to the complexities of the hospital discharge process and the related failings and harms.

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[1] World Health Organisation, 'Transitions of Care: Technical Series on Safer Primary Care' (*World Health Organisation*, December 2016) <https://www.who.int/patientsafety/topics/primary-care/technical_series/en/> accessed 9 March 2021; Karina Aase and others (eds), *Researching Quality in Care Transitions International Perspectives* (Palgrave Macmillan 2017); Kirstin Manges and others, 'A mixed methods study examining teamwork shared mental models of interprofessional teams during hospital discharge' (2020) 29 BMJ Quality & Safety 499

[2] Bronwen Morgan and Karen Yeung, *An Introduction to Law and Regulation: Text and Materials* (Cambridge University Press 2007); Peter Drahos, *Regulatory Theory* (ANU Press 2017); Robert Baldwin, Martin Cave and Martin Lodge, *Understanding Regulation: Theory, Strategy, and Practice* (Oxford University Press 2011)

Key Arguments

I argue that within England, healthcare regulation is suboptimal at safeguarding patients as they leave hospital. This means that patients are experiencing avoidable harm to both their physical wellbeing and their dignity. I argue that harm to the latter has received particularly little attention to-date.

To address this issue of suboptimal regulation, it is necessary to understand *why* regulation is failing in this aspect of patient care. Parts Two – Four of this thesis consist of three published papers which address the following three aspects of regulation, and which, I argue, contribute to this suboptimal safeguarding. These are:

- Structure and strategy of regulators
- Liminal spaces within regulation
- Regulatory accountability

My thesis consists of three central arguments regarding the aspects above. In my examination of the structure and strategy of regulators (Part Two), I argue that the sparsity of regulatory actions in response to discharge-related patient safety incidents arises due to the complexity of the regulatory landscape and the risk-based regulation strategy employed by regulators. This argument is informed by regulatory theory; Chapter 5.0 explains the rationale for this approach.

After focusing my attention upon structure and strategy, I turn my attention to the 'liminal space' that exists between these regulatory bodies (Part Three). I use the anthropological concept of liminality (explained in Chapter 5.3) as a lens to do this. Although liminality as a lens does not, in itself, present a solution to the patient safety problem, through its use I identify the critical need for a centralised figure to guide actors within the regulatory liminal space. I argue that the recently created role of Commissioner for Patient Safety within the Medicines and Medical Devices Act 2021 could be a candidate for this function.

Following my arguments pertaining to structure, strategy, and space, I then analyse concepts of accountability in the regulatory context (Part Four). In doing so, I draw upon the significant body of work within the field of patient safety which highlight the importance of a 'just culture' in providing safe care. I argue that the General Medical Council (GMC), which regulates doctors, must provide clarity concerning regulatory accountability and proactively highlight the dangers of an under-resourced healthcare system – especially where it leads to

unsafe discharges. Doing so would enable the GMC to earn the trust of its registrants and fulfil its role in protecting patients. Chapters 4.2 and 5.2 explain why a just culture is central to ensuring patient safety.

In addressing these issues, I draw upon insights and methods from regulation theory, the field of patient safety, bioethics, and anthropology. In doing so, this thesis provides an original interdisciplinary examination of regulation with regard to the hospital discharge process in England. Using theoretical insight, it identifies what regulators can do to improve regulatory oversight of the discharge process *without* contributing to the burden already felt by regulatees. 'Regulatory burden' is a broad concept involving aspects which are not easily quantifiable; for example, anxiety generated by the threat of litigation.[3] Reducing regulatory burden in healthcare has been high on the United Kingdom's (UK) political agenda, particularly because of regulation's impact upon workforce morale and retention.[4]

It is hoped that the findings of this thesis will be of interest not only to legal academics, but also researchers within the patient safety field, regulators, and policymakers.

The Discharge Process

After a person is admitted to hospital, multidisciplinary staff start to plan and prepare the patient's discharge alongside caring for the patient.[5] This involves liaising with the patient's family and carers, assessing the patient's need for home support and/or equipment, and starting the discharge paperwork and referrals. After an iterative process of assessment and treatment, patients are said to be medically fit for discharge, at which point any further care is to be carried out in the community. [6] Additionally, patients are declared 'ready' for discharge, which may

[3] Frank Peck and others, 'Business perceptions of regulatory burden' (2012) Submitted to: Department for Business, Innovation and Skills <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/31595/12-913-business-perceptions-of-regulatory-burden.pdf> accessed 19 April 2021

[4] Select Committee on the Long-term Sustainability of the NHS, *The Long-term Sustainability of the NHS and Adult Social Care* (HL 2016- 2017, 151) para 138

[5] Jane K O'Hara and others, 'Handing over to the patient: A FRAM analysis of transitional care combining multiple stakeholder perspectives' (2020) 85 Applied Ergonomics <https://doi.org/10.1016/j.apergo.2020.103060> accessed 14 July 2021

[6] ibid

not occur at the same time as they are said to be medically fit. For example, patients may be medically fit but have to wait whilst staff arrange home support.[7]

After being declared both medically fit and ready for discharge, the discharge processes are finalised, and 'formal handovers' - such as discharge letters, are sent to the patient's general practice and, where required, community teams.[8] As part of the discharge process, staff talk to the patient and/ or their family or carers about any medications they are given, and provide the patient with a copy of the discharge letter. O'Hara and colleagues note that the quality of this conversation with patients may depend on various factors including workload and the ward that the staff are working on.[9] Post-discharge, general practices and community health teams who have received the discharge letters then assess what action, if any, is required. If this process has gone as intended, then through a combination of self-management and the provision of community health care, patients and staff reach an appropriate level of continued monitoring of the patient's health.[10]

The remainder of this subsection illustrates the nature of the safety incidents and type of harm which patients may experience as a result of substandard hospital discharge.

An analysis of data on discharge-related safety incidents within the National Reporting and Learning System (NRLS) database (a central database of patient safety incidents reported from across England and Wales) found four main categories of error were responsible for causing harm in 75% of the cases.[11] These categories were: quality of discharge communication; referrals to community care; medication errors; and issues concerning the provision of care adjuncts, (such as wound dressings). Behavioural factors, for example where staff did not follow protocols, and organisational factors - such as a lack of clear guidelines, were also found to be frequent contributors to patients experiencing harm. Although the severity of harm tended to be low-level overall,[12] patients experienced moderate harm in 78 of the 598 cases (13%). This meant that they required an intervention to resolve their symptoms

[7] ibid
[8] ibid
[9] ibid
[10] ibid
[11] Huw Williams and others, 'Harms from discharge to primary care: mixed methods analysis of incident reports' (2015) 65 British Journal of General Practice e829
[12] 'Low-level' was defined by the study authors as patients experienced mild symptoms, the harm was short-term, and little or no intervention was required to resolve the harm.

and may have experienced permanent or long-term harm, or a loss of function. In 3 (<1%) severe cases, life-saving interventions were needed, and in one case a patient died.[13]

In 2016, triggered by an increasing number of complaints regarding experiences of hospital discharge, the Parliamentary and Health Service Ombudsman (PHSO) shared the experiences of nine patients to highlight four serious and common issues with discharge from hospital settings.[14] These issues are: where a patient is discharged before it is clinically safe to do so; where a patient is not assessed or consulted properly prior to discharge; where relatives or carers are not informed of the discharge; or where this no appropriate support in place for patients to cope once discharged.[15] In response to the PHSO's findings, the Public Administrations and Constitutional Affairs Committee (PACAC) launched an inquiry and concluded that, 'the incidence of unsafe discharge from NHS hospitals is much too high and this is unacceptable'.[16] Unfortunately, these issues persist, resulting in harm not only to patients' physical wellbeing, but also to their dignity.

Harm to dignity

Healthwatch England has published four reports drawing attention to poor hospital discharges and the resulting harm to patients' physical wellbeing and dignity,[17] with the latest being

[13] Williams and others (n 9)
[14] Parliamentary and Health Service Ombudsman, 'A report of investigations into Unsafe Discharge from Hospital' (PHSO 2016) <https://www.ombudsman.org.uk/sites/default/files/page/A%20report%20of%20investigations%20into%20unsafe%20discharge%20from%20hospital.pdf> accessed 14 July 2021 (Unsafe Discharge Report)
[15] ibid
[16] Public Administration and Constitutional Affairs Committee, 'Fifth Report: Follow-up to PHSO report on unsafe discharge from hospital' (HC 2016-17, 97) para 56
[17] Healthwatch England, 'Safely Home: What happens when people leave hospital and care settings?' (Healthwatch England 2015) <https://www.healthwatch.co.uk/sites/healthwatch.co.uk/files/final_report_healthwatch_special_inquiry_2015_1.pdf> accessed 14 July 2021; Healthwatch England, 'What do the numbers say about emergency readmissions to hospital?' (Healthwatch England 2017) <https://www.healthwatch.co.uk/sites/healthwatch.co.uk/files/20171025_what_do_the_numbers_say_about_emergency_readmissions_final_0.pdf> accessed 14 July 2021; Healthwatch England, 'Emergency Readmissions: What's changed one year on?' (Healthwatch England 2018) <https://www.healthwatch.co.uk/sites/healthwatch.co.uk/files/20181114%20Emergency%20readmissions_0.pdf> accessed 31 August 2021 (What's Changed One Year on Report); Healthwatch England and British Red Cross, '590 people's stories of leaving hospital during Covid-19' (Healthwatch England 2020) <https://www.healthwatch.co.uk/sites/healthwatch.co.uk/files/20201026%20Peoples%20experiences%20of%20leaving%20hospital%20during%20COVID-19_0.pdf> accessed 14 July 2021

published in 2020. The British Red Cross[18] have also published several reports highlighting the issue of unsafe discharge, for example where patients were discharged from hospital before adequate home support was in place – placing their physical wellbeing and dignity at risk of harm. The following case is provided within the PHSO report, and illustrates how dignity can be harmed:

> 'Mrs K, an 85-year-old woman who suffered from dementia, was taken to hospital after she experienced vaginal bleeding. Following examinations and blood tests, the hospital sent her home. Mrs K was transferred to the acute medical unit to wait for an ambulance. An ambulance was booked at 8.48pm; Mrs K's medical notes showed this was before she had expressed her preference to go home. It arrived at 11pm. Although the hospital had been unable to reach Mrs K's son to let him know that they planned to discharge his mother, it let Mrs K go home. The following morning Mrs K's daughter, Mrs G, visited her at home. She found that her mother had been left with no food, drink and bedding, unable to care for herself or get to the toilet.'[19]

Upon investigation, the PHSO found that although Mrs K was likely to have been medically well enough for discharge, the hospital had failed to consider whether it was safe to send her home at that point in time. The hospital had not considered whether her home was an appropriate environment for her, or made sure there would be appropriate care in place for her upon her arrival home.[20] The hospital had also acted contrary to its own discharge policy of not discharging elderly patients after 10pm, and had not discussed the discharge plan with Mrs K or her family. The PHSO therefore concluded that the decision to discharge Mrs K was inappropriate, and that the hospital had failed to safeguard a vulnerable patient.[21]

In this thesis, I take the view that such incidents also amount to a harm to the patient's dignity. Tadd and colleagues argue that undignified care 'renders individuals invisible, depersonalises and objectifies people, is abusive or humiliating, narrowly focused and

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[18] British Red Cross, 'In and Out of Hospital' (British Red Cross 2018) < https://www.redcross.org.uk/about-us/news-and-media/media-centre/press-releases/press-release-repeat-visits-to-accident-and-emergency> accessed 14 July 2021 (In and Out report); British Red Cross, 'Home to the Unknown: Getting hospital discharge right' (British Red Cross 2019) <https://www.redcross.org.uk/about-us/what-we-do/we-speak-up-for-change/more-support-when-leaving-hospital/getting-hospital-discharge-right> accessed 14 July 2021 (Home to the Unknown Report)

[19] PHSO, Unsafe Discharge Report (n 12) 19

[20] ibid

[21] ibid

disempowers the individual'.[22] It is not unreasonable to imagine that Mrs K's experience in this example of being left alone and unable to meet her hygiene needs was likely to have been both a disempowering and humiliating experience for her.

In researching how care home staff decide to transfer a resident for hospital care, Harrad asked research participants if there was any other points they would like to raise that they felt were important, and that had not been captured by the interview questions.[23] Over half of all interviewees then raised concerns about residents' discharges out of hospital back into their care home.[24] Staff voiced concerns about how residents' physical and emotional needs were (not) being met during the discharge process, and described the process using terms such as 'awful', 'appalling' and a 'nightmare'.[25] The lack of dignity afforded to patients being discharged was evident in the participants' comments; one care home manager stated:

> 'The times we have discharges from hospital at two and three o'clock in the morning in little green hospital gowns, in the middle of the night with cannulas in and no discharge notes – nightmare!...Where is the dignity in that? There isn't any. I find it appalling.' [26]

Another carer commented:

> 'I have concerns with them coming home… I always feel there's a bit of neglect... Coming home in a nighty, no blankets. It could be 10 o'clock at night and it's like, 'hold on a minute, this is a vulnerable lady'… It's awful. You can have someone with pneumonia and they're coming back wrapped in a sheet and it's like 'do you want her back in?'… It's awful, absolutely awful. You think, 'where is your duty of care?' These are elderly people. That's somebody's Nan!'[27]

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[22] Win Tadd and others, 'Dignity in Practice: An exploration of the care of older adults in acute NHS Trusts' (HMSO 2011)
[23] Fawn Harrad, 'Understanding hospital transfers from care homes in England: An ethnographic study of care home staff decision-making' (PhD thesis, University of Leicester 2021) <https://leicester.figshare.com/articles/thesis/Understanding_hospital_transfers_from_care_homes_in_England_An_ethnographic_study_of_care_home_staff_decision-making/15060003> accessed 8 August 2021
[24] ibid
[25] ibid 107
[26] ibid 107
[27] ibid 107

Within healthcare, dignity is an important concept from an ethical, legal and regulatory perspective. In Chapter One of this thesis, I explain how dignity is an important part of patients' conception of safety, and in Chapter Five, I explain how my inclusion of harm to dignity is further influenced by bioethical literature and wider moral discourse. In Part Two, I highlight the legal and regulatory importance of dignity. This thesis thus argues that harm to dignity is a matter that should be of concern to regulators, and is one which they should seek to reduce through regulatory action.

Communication failures regarding the discharge process

O'Hara and colleagues identify several safety gaps when patients transition across and within healthcare services.[28] For example, they observe a safety gap when discharge letters lack clarity or detail – which hampers the ability of healthcare professionals receiving the letters to deliver safe care. Improvement interventions are often designed to address such gaps, for example the introduction of discharge checklists.[29] However, a systematic review of strategies that individual hospitals could implement in order to improve patient safety during hospital discharge concluded that it remains unclear which strategies should be implemented to achieve this aim.[30] The review looked at interventions 'initiated before hospital discharge with the aim of ensuring the safe and effective transition of patients from the acute inpatient setting to home'.[31] It found that these interventions ('transitional care strategies') frequently involved 'bridging' approaches containing at least one pre-discharge component (such as patient engagement) and one post-discharge component (for example medication reconciliation[32] after discharge).[33] The researchers found that only a small number of bridging interventions appeared to reduce readmissions and visits to emergency departments following hospital

[28] O'Hara and others (n 3)
[29] ibid
[30] Stephanie Rennke and others, 'Hospital-Initiated Transitional Care Interventions as a Patient Safety Strategy' (2013) 158 Annals of Internal Medicine 433
[31] ibid 433
[32] Medication reconciliation is 'the process of identifying the most accurate list of a patient's current medicines—including the name, dosage, frequency, and route—and comparing them to the current list, recognizing discrepancies, and documenting any changes, thus resulting in a complete list of medications, accurately communicated.' Institute for Healthcare Improvement, 'Medication Reconciliation to Prevent Adverse Drug Events' (*Institute for Healthcare Improvement,* 2021) <www.ihi.org/topics/ADEsMedicationReconciliation/Pages/default.aspx> accessed 14 July 2021
[33] Rennke and others (n 28)

discharge to home.[34] Within England, the number of emergency readmissions in 2018 following discharge had grown by 9% on the previous year, however there is a lack of detailed data to understand what this means.[35] The healthcare sector is unable to report on how many of these emergency readmissions were unavoidable and how many could have been prevented.[36]

The British Red Cross highlights the case of a patient who was discharged home after being admitted to hospital for a heart attack, and being diagnosed with pneumonia.[37] After being discharged home, the patient was unsure whether to continue taking her blood pressure medication. She rang her chemist who said to only take her new medication. As the report highlights, taking medication when the purpose is not clear or not knowing whether to continue taking existing medication could lead to health problems for the patient.[38] Indeed, O'Hara and colleagues identify the quality of the 'handover' to the patient as a prominent safety gap at the point of discharge. They describe discharge as the 'point at which community dwelling patients are handed back responsibility (to varying degrees) for the management of their health condition, medicines, daily activities and escalation of care'.[39] Poor quality handovers to patients mean that patients are often unaware of what they have been treated for or of any medication changes, which reduces their ability to successfully self-manage.[40]

The coordination of multiple actors across occupational and organizational boundaries, coupled with the interdependencies and interactions between these groups, can threaten discharge safety.[41] For example, the case of *Esegbona v King's College NHS Trust* highlights how a Trust's failure to coordinate with a nursing home and inform them about a discharged patient's specific care needs contributed to the pain, suffering and loss of amenity that the patient experienced leading up to her death.[42] Mrs Esegbona had been admitted to hospital with a range of health problems that also required repeated admission to intensive care. By the time she was due for discharge, she had a tracheostomy, which she had tried to remove by herself on multiple occasions. There were difficulties finding a nursing home for her, and her family

[34] ibid
[35] Healthwatch England, What's Changed One Year on Report (n 15)
[36] ibid
[37] British Red Cross, Home to the Unknown Report (n 16)
[38] ibid
[39] O'Hara and others (n 3) 5
[40] ibid
[41] Justin Waring, Fiona Marshall, and Simon Bishop, 'Understanding the Occupational and Organizational Boundaries to Safe Hospital Discharge', (2015) 20 Journal of Health Services Research & Policy 35
[42] [2019] EWHC 77 (QB)

had been deliberately excluded from the discharge planning process. They were distressed to learn only the day before the discharge that the nursing home which had been found for Mrs Esegbona was over two hours away. Mrs Esegbona died ten days after arriving in the nursing home, having removed the tracheostomy tube herself, and experiencing a cardiac arrest.[43] The claimant argued the Trust had negligently failed to inform the nursing home about the risk of the tracheostomy tube falling out or being removed on purpose, about difficulties with the obstruction of the tube, and that Mrs Esegbona had wanted to go home and not to a nursing home. The court determined that the Trust was negligent in failing to pass on this information to the nursing home. Had the Trust informed the nursing home of Mrs Esegbona's tracheostomy care needs, she would have been closely supervised and not left alone, meaning her self-extubation would have been avoided.[44]

Failures to learn from previous errors regarding discharge

In the early stages of considering my approach to this research, I considered using coroners' Prevention of Future Death reports in order to a) determine how frequently the discharge process was contributing to the deaths of patients, and b) understand how recipients of these reports respond to them and make improvements to prevent reoccurrences. However, the online presentation of these PFDs and responses, combined with time limitations, meant that this avenue of enquiry was unfeasible for me (more is said on this in Chapter 5). Nevertheless, the short time I spent examining PFDs revealed that the discharge process was contributing to patient deaths, that recipients were not consistently responding to recommendations, and that similar failings were reoccurring. This informed my definition of an ethical regulatory response in Chapter 4.0 as being one that promotes accountability throughout the healthcare system for prevention of harm to patients.

The following quote is an extract from a coroner's Prevention of Future Death (PFD) report[45] sent to an NHS Trust in October 2016. It followed the death of an elderly person, Leslie Lerner, who was discharged from the Royal Sussex County Hospital. The PFD report demonstrates another example of a hospital failing to follow its own discharge protocol, and a

[43] ibid
[44] ibid
[45] Under the Coroners and Justice Act 2009, s 5(7), coroners have a duty to make these reports.

failure in coordinating care. Unfortunately, in this case these failings contributed to the patient's death:

> 'Before [the patient] was discharged he should have been seen by a Senior Doctor and it may well have been that the inappropriately applied sling would have been recognised. He was sent home with no analgesia. He should have been given analgesia. It became clear from the evidence that the pain that he suffered was very much part of his overall deterioration and an exacerbating factor with his dementia. The Hospital's own Discharge Protocol was not followed, it should have been'.[46]

This was not the first PFD report that this particular coroner had sent the Trust; nor was it the first PFD to have been sent regarding the discharge process of that particular Trust. Two years earlier, the coroner had reported in a PFD report that the discharge process was:

> 'deeply flawed…there was no ongoing process of discharge…the discharge paperwork was effectively blank…there was no communication either with regard to the anticipated date of discharge or with the Nursing Home who were expected to receive him back' [47]

The coroner noted that the patient in this instance, Graham Watts, was medically unfit for discharge, and that a change of environment increases the risk of elderly patients falling over. She stated that the fall this patient subsequently experienced, fracturing his hip, is what caused his death. A year after this initial PFD report, a further one was sent regarding the death of another elderly patient, Thelma Jones. This one stated there had been:

> 'very little evidence of any joined up thinking with regard to her care or to plans, either for her future treatment, or for her future placement, or for discharge'[48]

In this instance, the lack of discharge planning did not directly contribute to the patient's death, but it indicates that steps had not been taken since the previous incident to improve the safety

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[46] Veronica Hamilton-Deeley, 'Leslie Lerner' (*Courts and Tribunals Judiciary*, 12 March 2017) <https://www.judiciary.uk/publications/leslie-lerner/> accessed 9 March 2021
[47] Veronica Hamilton-Deeley, 'Graham Watts' (*Courts and Tribunals Judiciary*, 3 April 2014) <https://www.judiciary.uk/publications/graham-watts/> accessed 9 March 2021
[48] Veronica Hamilton-Deeley, 'Thelma Jones' (*Courts and Tribunals Judiciary*, 12 August 2015) <https://www.judiciary.uk/publications/thelma-jones/> accessed 9 March 2021

of discharges. This is a problem because the very purpose of these reports is to prevent the recurrence of future deaths in similar circumstances; which raises questions about the (lack of) influence these reports have on improving patient safety. However, the example also demonstrates three elements that, combined, give rise to a much broader problem. The first element is that having safe hospital discharge processes which are adhered to is critical to ensuring patient safety. The second is that a failure to ensure that improvements are made in response to discharge safety incidents results in repeat failings and harm to patients. The third element is a question about who is accountable for ensuring these improvements are made. As this thesis will proceed to demonstrate, healthcare regulators have a key role to play in relation to these three elements. Effective regulation in this context should ensure that patient safety incidents are responded to appropriately; steps are taken to improve future patient safety during discharge; and there are clear lines of accountability in place for when this does not happen. Currently, healthcare regulation in England is not achieving these outcomes.

Structure of the thesis

This thesis is made up of this Introduction, four parts, and a Conclusion. Part One is comprised of six background chapters. Chapter One introduces the field of patient safety, Chapter Two provides the legal background, Chapter Three is the regulatory background, and Chapter Four contains the ethical background to this thesis. In Chapter Five, I explain my research approach alongside the theoretical underpinnings and analytical concepts which drive it. Chapter Six then provides a brief outline of the papers which make up the substance of this thesis.

Parts Two to Five each address an important, and problematic aspect of the regulatory status quo. Part Two, *Structure and Strategy of Healthcare Regulation within England*, presents the multiple regulatory bodies and examines the efficacy of risk-based regulation within the context of hospital discharges. Part Three, *Liminal Spaces – Exploring the Regulatory Gaps*, brings into focus the liminal spaces within this regulatory structure. Part Four, *Regulatory Accountability*, explores whether conceptual confusion regarding accountability risks undermining regulation's patient safety aims. Each of these Parts consist of the papers which contain my findings, published as part of this thesis.

The Conclusion provides a summary of the key findings, an outline of how this thesis contributes to academic literature, and an indication of areas requiring future research.

PART ONE BACKGROUND

Chapter One: Patient Safety

There is a lack of consensus as to the precise meaning of patient safety.[49] It has been described as both a way of doing things (a philosophy and a discipline) and as an attribute (safety) that emerges from the healthcare system.[50] This chapter first presents a brief background to the emergence of patient safety as a discipline before moving on to define how this thesis employs the terms 'patient safety' and 'patient safety incident' (PSI). The role of organisational culture in promoting patient safety will then be highlighted, as will the impact of litigation and regulation.

The purpose of this chapter is to provide the reader with an understanding of key features from the patient safety field; this field underpins the theoretical approach of this thesis. Further detail on the theoretical approach is provided in Chapter Five.

1.0 The Emergence of Patient Safety as a Discipline

Patient safety emerged as a discipline in recognition of the fact that adverse medical events are both widespread and preventable.[51] Writing in 2010, Vincent asserted that one of the greatest achievements from the preceding ten years was that medical error and patient harm were being acknowledged and openly discussed by healthcare professionals, politicians, and the public. Prior to that, medical error was rarely acknowledged, and research regarding safety in medicine was 'at best a fringe topic and at worst disreputable'.[52]

According to Vincent, in the 1980s there was limited recognition that poor quality in healthcare might be inherent in the structures and processes of the healthcare system, rather than the fault of a rogue individual healthcare professional (a 'bad apple').[53] He pinpoints events at Bristol Royal Infirmary as having a profound impact upon how safety in healthcare was understood. The scandal at Bristol Royal Infirmary involved the medical cover-up of poor

[49] Linda Emanual and others, 'What Exactly is Patient Safety?' in: Kerm Henriksen and others (eds.) *Advances in Patient Safety: New Directions and Alternative Approaches* (Vol. 1: Assessment, Agency for Healthcare Research and Quality 2008)
[50] ibid
[51] ibid
[52] Charles Vincent, *Patient Safety* (BMJ Books 2010) 14
[53] ibid

surgical performance throughout the 1980s and 1990s; this poor performance had led to the deaths of 29 children. [54] The resulting inquiry[55], led by Professor Sir Ian Kennedy, adopted a systems approach to understanding what had happened, and errors were seen as a result of poorly functioning systems (in addition to any particular individual's conduct).[56] Bristol, argues Vincent, exemplified wider problems within the NHS, and the inquiry's conclusions (the 'Kennedy Report') were widely applicable.[57]

At the same time as the events in Bristol were taking place, a seminal paper by Lucian Leape brought a new perspective to the question of medical error.[58] Leape argued that medicine had yet to address error in the way that other safety critical industries had, and summarised the approach as 'the professional cultures of medicine and nursing typically use blame to encourage proper performance. Errors are caused by a lack of sufficient attention or, worse, lack of caring enough to make sure you are correct.'[59] Rejecting this approach, Leape argued that many errors are beyond an individual's control, and are influenced instead by a wide range of factors.[60] He drew upon Reason's work in cognitive psychology[61] to outline proposals for reducing error in a manner that recognised human fallibility.[62] Vincent notes that although Leape was not the first researcher to recognise the importance of human factors in medical harm,[63] he was a particularly important influence.[64]

1.1 Defining Patient Safety

Vincent states that patient safety can be simply defined as 'the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare'.[65]

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[54] Ian Kennedy, The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984–1995 (Cm 5207, 2001)
[55] ibid
[56] Vincent (n 52)
[57] ibid
[58] Vincent (n 52)
[59] Lucian Leape, 'Error in medicine' (1994) 272 Journal of the American Medical Association, 1852
[60] ibid
[61] James Reason, 'The human factor in medical accidents' in: Charles Vincent and others (eds.) *Medical Accidents* (Oxford University Press 1993)
[62] Vincent (n 52)
[63] See for example: Marilyn Bogner (ed), *Human error in medicine* (Lawrence Erlbaum 1994) which draws together the work of several authors on this topic
[64] Vincent (n 52)
[65] ibid 32

However, he acknowledges that this definition does not capture the defining characteristics of patient safety nor its conceptual background.[66] Within England, the NHS Patient Safety Strategy does not attempt to define patient safety, noting instead that safety, 'is not an absolute concept and has neither a single objective measure nor a defined end point'.[67] Although this is an arguably accurate observation, this is not a particularly helpful approach for a health service as it provides ample opportunity for confusion when attempting to monitor the safety and quality of healthcare. The World Health Organisation (WHO) defines patient safety broadly as 'a framework of organized activities that creates cultures, processes, procedures, behaviours, technologies and environments in health care that consistently and sustainably lower risks, reduce the occurrence of avoidable harm, make errors less likely and reduce the impact of harm when it does occur.'[68]

This comprehensive WHO definition indicates that as a discipline, patient safety must focus on reducing error and reducing harm; both of which amount to adverse events. Historically, there has been a lack of consensus as to whether the focus should be on both, or just on reducing error.[69] Focussing just on error, Vincent argues, may be logical if, for example, the intention is simply to reduce failures within a clinical process.[70] However, harm is of greater importance to patients; for an error may be tolerable to a patient provided they are not harmed as a result.[71] Moreover, a myriad of harms, such as adverse drug reactions and infections from an over-crowded hospital, are not necessarily due to an error. Focussing *only* on reducing error risks not addressing harms which stems from other causes. Although many errors do not result in harm, they are nevertheless critical for learning, and maintaining safety in healthcare.[72]

One aspect closely related to patient safety and which is not immediately apparent in the WHO definition is that of quality of care. In 1999, the Institute of Medicine's report, *To Err is Human*, described safety as the first dimension of quality.[73] Vincent writes that since then, safety has been presented either as a feature of quality, or as part of a safety-quality

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[66] ibid
[67] NHS England and NHS Improvement, 'The NHS Patient Safety Strategy: Safer culture, safer systems, safer patients' (NHSE&NHSI 2019) <https://improvement.nhs.uk/documents/5472/190708_Patient_Safety_Strategy_for_website_v4.pdf> accessed 28 July 2021, 6
[68] World Health Organisation, Global Patient Safety Action Plan 2021–2030: Towards eliminating avoidable harm in health care (WHO 2021)
[69] Vincent (n 52)
[70] ibid
[71] ibid
[72] ibid
[73] Institute of Medicine, 'To Err is Human: Building a Safer Health System' (National Academy Press 1999)

continuum.[74] Preferring the former presentation, he argues that the most important aspects of quality are captured in the Institute of Medicine's *Crossing the Quality Chasm* report.[75] These six aspects of quality are: safe; effective; patient-centred; timely; efficient; and equitable.[76] Safe care is that which avoids injuries to patients from care that is intended to help them; effective care means providing services based on scientific knowledge to those who could benefit; and patient-centred care is respectful and responsive to an individual's preferences, needs and values, and ensures patient values guide clinical decisions.[77] Timely care involves reducing potentially harmful waiting times; efficiency means avoiding wasting resources; and equitable requires ensuring that quality of care is not influenced by personal characteristics such as gender and ethnicity.[78]

Although safety is only one feature of quality, it is the most critical one for patients - for whom poor quality care and unsafe care often amount to the same thing.[79] A further study into patients' perspectives of safety found that people struggled to disentangle safety from quality. [80] The authors concluded that this confusion indicates that although the two concepts might be distinguishable at a conceptual level, there is not an easy distinction on an experiential level. They noted that an aspect of care which is generally experienced in terms of quality, can easily become a safety concern in a different context.[81] In terms of whether an issue will be classed as a safety issue rather than a more general issue of quality, Vincent cites the findings of Brown and colleagues.[82] These authors found that whether an issue is viewed as a safety issue or quality issue will depend upon the strength of causation and immediacy of harm.[83] Incidents causing definite harm and which are clearly linked to a specific lapse in care are more likely to be described as a safety issue.[84]

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[74] Vincent (n 52)
[75]Vincent (n 52); Institute of Medicine, 'Crossing the Quality Chasm. A New Health System for the 21st Century' (National Academy Press 2001)
[76] ibid; Vincent (n 52)
[77] Institute of Medicine, Crossing the Quality Chasm (n 75)
[78] ibid
[79] Vincent (n 52)
[80] Penny Rhodes and others, 'Trust, temporality and systems: how do patients understand patient safety in primary care? A qualitative study' (2016) 19 *Health Expectations* 253
[81] ibid
[82] Vincent (n 52)
[83] C Brown and others, 'An epistemology of patient safety research: a framework for study design and interpretation. Part 1: Conceptualising and developing interventions' (2008) 17 Quality and Safety in Health Care 158
[84] ibid

At this point, it is clear that defining patient safety in a manner which is universally agreed upon is not a simple task. As the focus of this thesis is upon how regulators respond to patient safety *incidents*, this thesis now turns its attention to defining this term. Given the concepts of patient safety and patient safety incidents are closely entwined, it would not be possible to reach a suitable definition of the latter without having a broad understanding of the former.

1.2 Patient Safety Incidents (PSIs)

A PSI is defined by NHS England (more on this organisation in Chapter Three) as 'any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving healthcare'.[85] In its guidance for reporting patient safety incidents,[86] NHS Improvement (NHSI)[87] outlines five degrees of harm, ranging from no harm (where a PSI was prevented) through to death. Psychological distress may also count as harm; psychological distress requiring counselling would be classified as moderate harm, whereas psychological distress that left a patient unable to resume their normal life would be sufficient to meet the definition of severe harm.[88] Research looking into the nature of patients' safety concerns in hospitals found that patients and clinicians do not view safety incidents in the same manner. Divergence arises as patients include non-clinical incidents such as physical comfort, fear, and uncertainty (for example about when discharge is happening). The researchers note that one of the patient-derived safety categories encompassed compassion, dignity, privacy, and respect.[89] A meta-synthesis of qualitative studies also found that some of the features of safety mentioned by patients were outside of the ambit of usual factors presented in patient safety research; including being treated with dignity or respect.[90] The authors note that typical factors tend to

[85] NHS England, 'Report A Patient Safety Incident' (NHSE 2021) <https://www.england.nhs.uk/patient-safety/report-patient-safety-incident/> accessed 28 July 2021
[86] National Reporting and Learning System, 'Degree of Harm FAQ' (NRLS 2018) <https://www.england.nhs.uk/wp-content/uploads/2019/10/NRLS_Degree_of_harm_FAQs_-_final_v1.1.pdf> accessed 28 July 2021
[87] Since April 2019, NHSI has been working closely with NHSE as a single organisation. Further information on its role is provided in Chapter Three.
[88] National Reporting and Learning System (n 86)
[89] Jane K O'Hara and others, 'What can patients tell us about the quality and safety of hospital care? Findings From a UK Multicentre Survey Study' (2018) 27 BMJ Quality & Safety 673
[90] Gavin Daker-White and others 'Blame the Patient, Blame the Doctor or Blame the System? A Meta-Synthesis of Qualitative Studies of Patient Safety in Primary Care' (2015) 10 PLOS One 1

focus on the competence of individuals, technical systems, operating procedures and protocols.[91] Research into patient perspectives of safety has also found that for the research participants, 'feeling safe' meant having 'confidence that they would be listened to seriously, treated with respect and dignity, not unduly hurried, disbelieved, judged negatively, patronized, or have their concerns dismissed as trivial.'[92] Although adding 'feeling safe' as an aim of patient safety would likely make the concept of patient safety too broad and nebulous, the features which 'feeling safe' encapsulates are very important. For the features reflect the category of patient-centred care, which was identified by the Institute of Medicine as one of the six aspects of quality care.[93]

As mentioned in the Introduction, in light of this patient perspective of dignity, in this thesis, I define a PSI as any unintended or unexpected incident which could have, or did, lead to the detriment of a patient's physical wellbeing and/or dignity. This definition reflects the importance of dignity from ethical, legal, and regulatory perspectives (Chapter 5 and Part 2 expand upon this). Severe harm to dignity *may* also result in the patient experiencing psychological distress, and a patient may also experience the latter without their dignity being harmed. I have not included psychological distress in my definition of a PSI for this thesis; this is because my definition reflects the nature of the discharge-related harms reported in policy documents and academic research.

1.3 Preventable harm

Harm is generally recognised to be preventable if its occurrence was due to an identifiable, modifiable cause, and its recurrence is preventable by reasonable adaptation to a process or adherence to guidelines.[94] Some types of harm are not preventable; for example, an adverse drug reaction which occurs despite no error being made.[95] Sources of preventable harm may

[91] ibid
[92] Rhodes and others (n 80)
[93] Institute of Medicine, Crossing the Quality Chasm (n 75)
[94] Maria Panagioti and others, 'Preventable Patient Harm across Health Care Services: A Systematic Review and Meta-analysis' (A Report for the General Medical Council, 2017) <https://www.gmc-uk.org/-/media/documents/preventable-patient-harm-across-health-care-services_pdf-73538295.pdf; Mohammed Nabhan and others, 'What is preventable harm in healthcare? A systematic review of definitions' (2012) 12 BMC Health Services Research 1
[95] ibid

include system failures, or the actions of healthcare professionals. It has been noted that a key limitation of patient safety literature within the UK has been its lack of attention to understanding the burden of preventable patient harm.[96] Approximately one in 20 patients within the UK are affected by preventable harm.[97] Reducing both the risk and occurrence of preventable harm is a goal pertinent to regulators as they seek to improve patient safety.

1.4 Patient Safety and Culture

Vincent observes that a bewildering array of descriptors have been applied to the word 'culture' within safety literature, essentially highlighting that the concept of a safety culture is perhaps not fully understood.[98] The list of descriptors includes, but is not limited to: 'no blame culture, open and fair culture, flexible, learning, reporting, generative, resilient, [and] mindful...'[99] More positively, he notes that the expansive terminology reflects that there are numerous facets to establishing a culture of safety. Organisational cultures which are characterised by blame, guilt, fear, and distrust and which seek to scapegoat individuals when things go wrong ('blame culture') act as a deterrent for being open and honest about mistakes.[100] Perhaps even more concerning are cultures wherein problems are no longer recognised – what Vaughan termed the normalisation of deviance.[101] A positive safety culture within an organisation, according to Vincent, is characterised by 'communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventative measures'.[102]

Closely tied to this is the concept of a just culture. The Kennedy Report into the failings at Bristol Royal Infirmary illustrates the important role that culture plays in ensuring patient safety. It highlighted that the NHS was failing to learn from its mistakes, and that the dominant blame culture was a major barrier to openness and learning.[103] In March 2013, shortly after the publication of the public inquiry report into the serious failings in care at Mid Staffordshire

[96] ibid
[97] ibid
[98] Vincent (n 52)
[99] Vincent (n 52) 269
[100] ibid
[101] Diane Vaughan, The Challenger launch decision: risky technology, culture, and deviance at NASA (University of Chicago Press 1996)
[102] Vincent (n 52) 273
[103] Kennedy (n 54)

Foundation Trust ('Francis Report'),[104] the government appointed Professor Don Berwick to lead a review into patient safety within England's NHS. Berwick's report, *A promise to learn – a commitment to act*[105] set out recommendations for a whole-system approach to reduce harm throughout the England's NHS. This report also recommended that the NHS abandons blame as a tool, and concluded that it makes no sense to punish a person who makes an error as 'even apparently simple human errors almost always have multiple causes, many beyond the control of the individual who makes the mistake'.[106] As such unintended error by individuals should not be sanctioned; only those which reflect a reasonable degree of wilfulness or recklessness.[107]

A 'blame culture' was further highlighted in the 2015 independent review into whistleblowing in the NHS[108] - triggered by earlier findings of the Mid Staffordshire NHS Foundation Trust Public Inquiry. The whistleblowing review, '*Freedom to Speak Up*', focussed upon the treatment of NHS staff who raised safety concerns. It found that 18% of staff who had not raised a safety concern had chosen not to due to a lack of trust in the system; 15% feared victimisation. The inquiry noted that 'each time someone is deterred from speaking up, an opportunity to improve patient safety is missed'.[109] Recommendations included moving away from the historical 'blame culture', towards a 'just culture', where people are encouraged to speak up about safety concerns and know the difference between acceptable and unacceptable behaviour.[110] Addressing the Global Patient Safety Summit in March 2016, the Secretary of State for Health (Jeremy Hunt) echoed Berwick and stated that in order to improve patient safety, a change from a blame culture to a learning culture is necessary. He asserted that this requires a 'fundamental rethink' of our concept of accountability, and that blaming

[104] The Mid Staffordshire NHS Foundation Trust Public Inquiry, *Report of The Mid Staffordshire NHS Foundation Trust Public Inquiry* (HC898-1, 2013) ('Francis Report')
[105] National Advisory Group on the Safety of Patients in England, 'A Promise to Learn – A Commitment to Act: Improving the Safety of Patients in England' (Crown Publishing 2013)
[106] ibid 12
[107] ibid
[108] The whistleblowing review, led by Robert Francis QC, was established to determine why serious failures in care at Mid-Staffordshire NHS Foundation Trust prior to 2009 were not acted on sooner by those responsible. See: Robert Francis, 'Freedom to Speak Up: An Independent Review into Creating an Open and Honest Reporting Culture in the NHS' (Freedom to Speak Up Review 2015) ('Freedom to Speak up')
[109] Robert Francis, 'Freedom to Speak Up: An Independent Review into Creating an Open and Honest Reporting Culture in the NHS' (Freedom to Speak Up Review 2015)
[110] ibid

individuals for patient safety failures means we sometimes miss identifying the problems that lurk in complex systems, and which are often the true cause of avoidable harm.[111]

A thematic review of Never Events[112] found that many NHS staff still fear blame and believe that incident reporting is a punitive process. [113] The report found that staff want support to learn when things go wrong in their organisation and elsewhere, but do not know where to get this support from as links to national bodies were poor and they were unsure where responsibilities lie. Proactive support was perceived to be lacking, and the involvement of regulators and the Royal Colleges in relation to Never Events was commonly considered to cause pressure and increased anxiety. [114] This lack of faith in the investigation process was also visible in the responses to NHSI's 2018 engagement programme to gather views about how and when patient safety incidents should be investigated. The responses highlighted concerns about the effectiveness and purpose of Serious Incident investigations, with comments suggesting that the process is punitive and impedes learning, and that actions to reduce risks after the completion of an investigation are often ineffective. [115]

The reports and findings mentioned above all point to a blame culture being bad for patient safety, and a just culture which enables learning from error being desirable. There has been a recent drive within the NHS to create a just culture; which is a culture that balances fairness, justice and learning.[116] For example, NHSE and NHSI's *Patient Safety Strategy*[117] calls for local systems to develop and maintain a just culture, and to implement NHSI's *Just*

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[111] Jeremy Hunt, 'From a blaming culture to a learning culture' (Global Patient Safety Summit., 10 March 2016) <https://www.gov.uk/government/speeches/from-a-blame-culture-to-a-learning-culture> accessed 31 August 2021

[112] Never Events are defined in the review as 'serious incidents that are considered to be wholly preventable because guidance or safety recommendations that provide strong systemic protective barriers are available at a national level, and should have been implemented by all healthcare providers' (page 5) In: Care Quality Commission, 'Opening the Door to Change: NHS Safety Culture and the Need for Transformation' (CQC 2018) <https://www.cqc.org.uk/sites/default/files/20181224_openingthedoor_report.pdf> accessed 31 August 2021

[113] ibid

[114] ibid

[115] NHS Improvement, 'The Future of NHS Patient Safety Investigation: Engagement Feedback' (NHS Improvement 2018) <https://improvement.nhs.uk/documents/3519/Future_of_NHS_patient_safety_investigations_engagement_feedback_FINAL.pdf> accessed 20 April 2019

[116] Sidney Dekker, *Just Culture: Balancing Safety and Accountability* (CRC Press 2012); NHS Resolution, 'Being Fair: Supporting a just and learning culture for staff and patients following incidents in the NHS' (NHS Resolution 2019) <https://resolution.nhs.uk/wp-content/uploads/2019/07/NHS-Resolution-Being-Fair-Report-2.pdf> accessed 31 August 2021

[117] NHS England and NHS Improvement (n 67)

Culture Guide.[118] NHS Resolution, the body which handles negligence claims, echoes this call for a just culture; defining it as 'the balance of fairness, justice, learning – and taking responsibility for actions. It is not about seeking to blame the individuals involved when care in the NHS goes wrong. It is also not about an absence of responsibility and accountability'.[119] As this thesis demonstrates in Part Four, the term accountability is used inconsistently in these documents. This leads to confusion about who or what is to be held accountable when things go wrong. Essentially, within these documents, there are two different functions of accountability; it is both a tool to aid learning and to punish an individual. Chapter Four examines this dual nature of accountability from an ethical perspective, and Part Four explores the implications of this for regulators and the professions they regulate.

1.5 Litigation and Regulation

Vincent argues that litigation is part of the story of patient safety. [120] He states that although historically, patients who sued doctors were seen as difficult or embittered, litigation is increasingly being recognised as a reflection of the serious underlying issue of harm to patients.[121] He highlights research dispelling the myth that healthcare is burdened by greedy patients bringing frivolous lawsuits.[122] In short, research shows that: patients rarely sue after adverse events; it is more common that patients who claim and should receive compensation are denied it than the inverse; and patients often turn to litigation for reasons other than compensation – mainly a failure to receive apologies, explanations, and support.[123]

The threat of litigation is often presented as a barrier to patient safety in that it inhibits openness following mistakes, and thus prevents learning from error.[124] Despite this, Vincent asserts that litigation has also been a powerful driver of patient safety in that it raises public and professional awareness of adverse outcomes.[125] The concern above - that litigation can

[118] NHS England and NHS Improvement, 'A Just Culture Guide' (NHS England & NHS Improvement, 2018) < https://www.england.nhs.uk/wp-content/uploads/2021/02/NHS_0932_JC_Poster_A3.pdf/> accessed 31 August 2021
[119] NHS Resolution (n 116)
[120] Vincent (n 52)
[121] ibid
[122] ibid
[123] ibid
[124] Sidney Dekker (n 116)
[125] Vincent (n 52)

adversely impact upon patient safety – can also be levelled at regulation. These concerns will be presented and explored further in Chapters Two, Three and Four of this thesis.

As stated earlier in this chapter, I define patient safety incident in a manner which captures harm to the physical wellbeing or dignity of a person in relation to the hospital discharge process. There is another aspect of harm which is out of scope for this thesis, given its focus upon regulation, but which I wish to briefly draw attention to here. This harm concerns a failure to provide appropriate redress to a patient who has received inadequate care post-discharge (an ethical and potentially legal failure to provide justice). The issue arises when a failure to provide post-hospital discharge rehabilitation significantly reduces a patient's recovery potential. This is particularly problematic for patients who have experienced a critical illness and received intensive care. Guidance from the National Institute for Health and Care Excellence (NICE) provided in 2009 emphasises the importance of continuity of care and rehabilitation programmes for optimum recovery after critical illness.[126] Yet despite this, less than a third of intensive care units were found to offer the recommended follow-up care, with even fewer hospitals providing post-hospital discharge rehabilitation programmes. This leaves patients and families to cope alone, and deficits in quality of life after critical illness have been found to persist for up to twelve years.[127] The current status quo means that the legal system may not be providing appropriate redress to patients who experience this type of harm. For, where a patient has less than a 49% chance of full recovery, the law essentially treats their loss of chance as meaningless. The complexities of introducing liability for the loss of a chance of a more favourable outcome have hitherto prevented its introduction into clinical negligence claims.[128]

1.6 Chapter One Conclusion

This chapter has provided a short introduction to the field of patient safety and defined the nature of a PSI. It has then explored how an organisation's culture can influence patient safety, and outlined why, on the face of it, law and regulation might be seen as a barrier to the aims of

[126] Bronwen Connolly and others, 'A UK survey of rehabilitation following critical illness: implementation of NICE Clinical Guidance 83 (CG83) following hospital discharge' (2014) 4 BMJ Open e004963
[127] Catherine White, 'Rehabilitation after Critical Illness' (2021) 373 British Medical Journal n910
[128] *Gregg v Scott* [2005] 2 AC 176

patient safety. Against this context, the following three chapters will provide the legal, regulatory, and ethical background to this thesis. Chapter Five will then draw these chapters together to provide the theoretical framework for this thesis.

Chapter Two: Legal Background

This chapter provides an overview of law's role in protecting patients from medical harm. It starts by examining how the law retrospectively responds to such incidents, and then proceeds to consider law's role in improving future patient safety. Although the substance of this thesis focusses upon the role of regulators, it is nevertheless important to provide this background; for regulation does not operate within a vacuum. Indeed, the regulatory bodies which form the focus of this thesis (more on these in Chapter Three), have their powers established in legislation, and their actions may intertwine with legal actions.[129]

2.0 Retrospective responses: Civil law

Within civil law, clinical negligence litigation is the primary mechanism through which an individual's medical harm is retrospectively addressed in the NHS. Within the tort of negligence, the aim is to provide a remedy (financial compensation) for a person who has been harmed as a result of another's failure to dispense their duty of care appropriately. [130] In tort law, a duty of care is a legal obligation which requires adherence to a reasonable standard of care when performing any acts which could foreseeably harm others.[131] Establishing the presence of a duty of care is necessary before a claimant can proceed with an action in negligence. [132] Generally speaking, all healthcare professionals have a legal duty of care towards their patients,[133] as do providers of health and social care.[134]

The case of *Rehman V University College London Hospitals NHS Trust*[135] illustrates the difficulties of bringing a case in negligence regarding hospital discharge. The claimant, Ms Rehman, was discharged from hospital two days after undergoing abdominal surgery. During surgery her bowel was perforated, but this was unknown to the medical or nursing staff at the hospital at the point she was discharged. The perforation caused severe peritonitis and shortly after discharge, Ms Rehman was admitted to a different hospital for further surgery to repair

[129] See, for example, *Bawa Garba v GMC* [2018] EWCA Civ 1879
[130] Rachael Mulheron, *Principles of Tort Law* (Cambridge University Press 2020)
[131] ibid
[132] ibid
[133] *Sidaway v Bethlehem Royal Hospital Governors* [1985] 1 AC 871 (HL) 893 (Lord Diplock)
[134] Health and Safety at Work Act 1974 s 3(1)
[135] [2004] EWHC 1361 (QB)

her bowel.[136] Her claim was that the nursing staff at the first hospital had discharged her too soon, and had done so negligently considering the pain that she was in. She contended that had she not been discharged, her perforated bowl would have been diagnosed and repaired at an earlier stage, thus avoiding some of the pain and suffering she experienced post-discharge.[137]

It is interesting to note that the formulation of the claimant's case changed over time. Initially, the claimant argued that 'in different ways and to different degrees Mr Cutner (the Consultant Obstetrician and Gynaecologist), Dr Paul (the Senior House Officer) and the nurses were collectively at fault for what was essentially a failure to communicate with each other and to keep themselves fully informed about the patient's condition from time to time.'[138] Further general criticisms were made, particularly regarding the computer system for note recording. Mr Moody, acting on behalf of the defendant, was noted as being 'somewhat unhappy at having to meet a case where he did not know who in the hospital precisely was being criticised for what'.[139] At conclusion of the trial, the claimant's position had altered to allege that that the nursing staff should have informed the medical staff that the claimant was in severe pain and did not wish to go home.[140] The judge noted that as the claimant's case was not being advanced on the basis of a negligent system of communication and reporting within the hospital, he was in the position of having to assess the responsibility of particular individuals.[141] He concluded that the nurse to whom Ms Rehman had spoken about her pain was in breach of her duty to summon a doctor for medical advice and undertake hourly observations.[142] The key point being made with this case example is how difficult it is to determine who might be at 'fault' when multiple healthcare professionals are involved with the care and discharge of a patient.

As mentioned in the Introduction to this thesis, in February 2019, King's College NHS Trust was held liable for negligently discharging Mrs Esegbona.[143] The court determined that the Trust was negligent in failing to pass on critical information regarding Mrs Esegbona's tracheostomy care needs to the nursing home where she was discharged. If the Trust had informed the nursing home of these needs, Mrs Esegbona would not have been left alone, and

[136] ibid
[137] ibid
[138] ibid para 46
[139] ibid para 46
[140] ibid
[141] ibid para 46
[142] ibid
[143] Esegbona v King's College NHS Trust [2019] EWHC 77 (QB)

her subsequent self-extubation would have been avoided. The Trust was found to have deliberately excluded the Mrs Esegbona's family from involvement in discharge planning, an action the court called 'high-handed and oppressive'.[144] This case again makes clear that hospitals have a duty of care to pass on sufficient information relating to the care of an individual upon discharge, and that a failure to do so can amount to negligence.

Quick argues that tort law is not designed to improve patient safety given its main aim is compensation.[145] He asserts that the 'most promising rationale for a connection between tort law and patient safety is that the threat of litigation deters dangerous practice'[146], but notes that ultimately there is scant evidence to support this line of reasoning.[147] Dekker argues that rather than tort law acting as a deterrent, fear of litigation promotes 'defensive' practice amongst healthcare professionals rather than high quality care. Such practice, he argues, can be detrimental to the patient.[148] However, a thorough analysis of defensive practice research by Case shows that there is no unequivocal proof that fear of negligence liabilities results in harmful defensive practices amongst healthcare professionals.[149] This thesis will consider the notion of punitive action having an adverse impact upon patient safety. This is because even if (as Case's research has found) there is no unequivocal proof that fear of punitive action negatively impacts professionals' practice, the perception is prominent within healthcare.[150] Moreover, the fear of, and process of regulatory investigation impacts upon the wellbeing of healthcare professionals, to the extent that in 2014 the GMC commissioned a review of its cases in which doctors had committed suicide whilst undergoing fitness to practise procedures.[151] As will be explained further in Chapter Three, this notion of damaging punitive action is therefore one of which healthcare regulators must be cognisant.

Heywood writes that tort's focus upon individual conduct (which stems from its emphasis on corrective justice) naturally encourages tort lawyers to look for human error when

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[144] ibid 239
[145] Oliver Quick, *Regulating Patient Safety* (Cambridge University Press 2017)
[146] ibid 97
[147] ibid 98
[148] Sidney Dekker, *Just Culture: Balancing Safety and Accountability* (CRC Press 2012)
[149] Paula Case, 'The Jaded Cliche of "Defensive Medical Practice": From Magically Convincing to Empirically (Un)Convincing?' (2020) 36 Journal of Professional Negligence 49
[150] Dekker (n 148); Rob Heywood, 'Systemic negligence and NHS hospitals: An underutilised argument' (2021) King's Law Journal, DOI: 10.1080/09615768.2021.1951496; Deborah Cohen, 'Back to Blame: The Bawa-Garba Case and the Patient Safety Agenda,' 359 (2017) British Medical Journal j5534
[151] GMC, 'Doctors who commit suicide while under GMC fitness to practise investigation' (2014) <https://www.gmc-uk.org/-/media/documents/Internal_review_into_suicide_in_FTP_processes.pdf_59088696.pdf> accessed 8 August 2021

constructing a claim.[152] This, he argues, means that the role of systemic failures is often overlooked in clinical negligence cases. This not only has the potential to create a sense of unfairness amongst healthcare professionals, but also means that valuable opportunities to identify and learn from broader underlying factors which may have caused patient harm are lost.[153] Heywood notes there have been a handful of Court of Appeal decisions[154] where a direct claim in negligence was brought against a hospital for its unsafe system.[155] The advantage of such claims of systemic negligence is that wider operational failures in hospitals - such as inadequate training, poor communication systems, and sub-standard admission procedures - are captured, and there is a motivation for the hospital to improve upon the system failures.[156] Heywood makes a compelling argument for increasing use of claims directly against a hospital rather than an individual clinician, stating that if a hospital system exposes an individual patient to a disproportionate risk, there should not be a reluctance to hold the hospital in breach. [157] He suggests that placing a greater emphasis on systemic fault would ultimately enable tort to influence positive changes within healthcare settings. [158]

Heywood acknowledges it is much easier to establish that a system is negligent where there is no evidence of an appropriate system being in place, rather than where there is a system present but its suitability is more finely balanced due to considerations concerning resource allocation and the balancing of risks and benefits. The example he provides to illustrate this concerns the pandemic policy of discharging patients into care homes which may contain residents who have Covid-19. He presents a hypothetical scenario where a hospital, in a hurried attempt to implement government guidance on discharges, creates a system for discharging patients into care homes without appropriate risk management mechanisms in place. The hospital may not have implemented adequate measures to assess and communicate the vulnerabilities of patients, nor undertake appropriate risk assessments of the care home into which it is discharging patients. In this scenario, a hospital patient may be harmed as a result of the unsatisfactory discharge system which places her in a care home where she then contracts

[152] Heywood (n 150)
[153] ibid
[154]For example: *Gottstein v Maguire and Walsh* [2004] IEHC 416; *Goodwin v Olupona* [2013] ONCA 259; *Robertson v Nottingham Health Authority* [1996] WLUK 277; *Lorraine v Wirral University Teaching Hospital* [2008] EWHC 1565
[155] Heywood (n 150)
[156] ibid
[157] ibid
[158] ibid

the virus.[159] Heywood then speculates as to what the chances of a successful claim for systemic negligence against the hospital would be. He suggests it could be argued that a hospital has a duty of care to its patients to operate a reasonably safe discharge system. This is because it was acknowledged in *Lorraine v Wirral University Teaching Hospital*[160] that a hospital has a duty to maintain a reasonably safe admission system; it is therefore possible that a safe discharge system would be seen as similar in nature, and therefore duty of care would be found to apply. Even if this were not the line of reasoning adopted by the courts, Heywood says it would still seem sensible to conclude that a hospital ought to have a duty to ensure its discharge process is reasonably safe for its patients. The key issue would then be the question of breach. [161]

In the context of the pandemic and its related strain on resources, the threshold for establishing breach would likely be high. This in turn may lead one to think that a risk-benefit analysis would favour a defendant hospital – with a judge being sympathetic to the hospital's need for enhanced risk taking.[162] However, Heywood argues that a credible argument could be made in favour of the claimants. He states that although freeing up hospital beds ready for an influx of Covid-19 patients would have significant benefits for a large number of people, a system which allows a patient to be discharged into an environment[163] known to pose a significant risk to the patient would render that system patently unsafe.[164] Heywood asserts that the benefit which may have been conferred on some of those who received a bed space 'pales into insignificance when it is pitted against the much greater risk of harm that was effectively transferred to an equally impressive number of vulnerable individuals within society'.[165] As such, a thorough balancing of risks and benefits would lead to the conclusion that the discharge system was unreasonable and the hospital's actions negligent.[166]

Heywood is the first to suggest that systemic negligence could be a suitable avenue for providing redress to patients harmed by the hospital discharge process. As the primary focus of this thesis is upon regulation, I do not examine in any great detail the efficacy of tort law in

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[159] ibid
[160] *Lorraine* (n 154)
[161] Heywood (n 150)
[162] ibid
[163] A confined environment such as a care home increases transmission of covid. Early on in the pandemic, care home staff lacked personal protective equipment, and covid tests were limited, meaning the prevalence of covid amongst staff and patients was often unknown. No effective test, track and trace system was in place. Elderly, frail people were known to be particularly vulnerable to covid. Combined, these factors pose a significant risk to the safety of patients discharged into care homes.
[164] Heywood (n 150)
[165] ibid 20
[166] ibid

either improving patient safety or in responding to safety incidents relating to the discharge process. I do, however, broadly agree with Heywood that claims of systemic negligence may be an appropriate one to bring directly against hospitals with unsafe discharge processes. In the Future Research subsection of this thesis' Conclusion, I raise the possibility that it could be argued that care homes, which owe a duty of care to residents, ought not to have accepted new residents, or possibly returning residents, without knowing if they were Covid-positive. A balancing of risks, as Heywood proposes, may lead to the conclusion that the care transition process between a hospital and a care home was negligent, leading to a claim of system negligence.

2.1 Retrospective responses: Criminal law

Although, generally speaking, harm or injury to a patient caused by medical negligence is a matter for the civil law, at times the criminal law may become involved. Criminal law can be seen as reflecting society's moral standards, and can provide a retributive function of punishing those who breach these standards.[167] According to Yeung and Horder, the criminal law's purpose within healthcare is not to 'deter and coerce people' into compliance with applicable standards, but to perform a symbolic function of censure and sanction regarding wrongful acts.[168] However, the impact of criminal law upon medical practice is relatively unknown; it is unclear whether the threat of criminal prosecution deters unsafe practice, or whether it is disproportionate and damaging to a culture of safety (subsection 1.5).[169] In the context of patient safety, there are three types of criminal offense: (gross negligence) manslaughter; ill treatment or wilful neglect; and regulatory offences.[170] These are explained briefly below.

[167] Quick (n 145)
[168] Karen Yeung and Jeremy Horder, 'How Can the Criminal Law Support the Provision of Quality in Healthcare?' (2014) 23 BMJ Quality and Safety 519
[169] Quick (n 145); Amel Alghrani and others, 'Healthcare scandals in the NHS: crime and punishment' (2011) 37 Journal of Medical Ethics 230; Charles A. Erin and Suzanne Ost (eds), *The Criminal Justice System and Health Care* (Oxford University Press 2008); Daniel Kessler and others, 'Effects of the Medical Liability System in Australia, the UK and the USA'368 (2006) The Lancet 240
[170] Quick (n 145)

2.1.1 Manslaughter

R v Adomako[171] confirmed the test for assessing the criminality of an individual healthcare professional following a fatal medical error (gross negligence manslaughter). Once a jury has established that a defendant breached their duty of care which led to the victim's death, they must then go on to consider:

> 'Whether that breach of duty should be characterised as gross negligence and therefore as a crime. This will depend on the seriousness of the breach of duty committed by the defendant in all the circumstances in which the defendant was placed when it occurred. The jury will have to consider whether the extent to which the defendant's conduct departed from the proper standard of care incumbent upon him, involving as it must have done a risk of death to the patient, was such that it should be judged criminal'. [172]

Piecemeal development has since followed, providing further clarity.[173] *R v Broughton* further confirmed that in addition to the above, 'at the time of the breach there [must be] a serious and obvious risk of death. Serious, in this context, qualifies the nature of the risk of death as something much more than minimal or remote ... An obvious risk is one that is present, clear, and unambiguous. It is immediately apparent, striking and glaring …'.[174] Moreover, it must have been reasonably foreseeable at the time of the breach that it gave rise to a serious and obvious risk of death, and the breach of duty must have caused or made a significant contribution to the death of the victim. [175] The circumstances of the breach must also be 'truly exceptionally bad' in order to justify the conclusion that it amounts to gross negligence and requires criminal sanction.[176] The approach has attracted substantial criticism from legal scholars due to its circularity, inconsistency, and lack of objectivity.[177]

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[171] [1995] 1 AC 171
[172] ibid para 187
[173] Ash Samanta and Jo Samanta, 'Death caused by negligent medical care: Reconsidering the role of gross negligence manslaughter in the aftermath of Bawa-Garba' Special Issue (2021) Medical Law International 1
[174] *R v Broughton* [2020] EWCA Crim 1093 para 5
[175] ibid
[176]ibid; *R v Sellu* [2017] 4 WLR 64 para 151
[177] Margot Brazier and others, 'Improving Healthcare through the Use of 'Medical Manslaughter'? Facts, fears and the Future' 22 (2016) Clinical Risk 88; A Mullock, 'Gross Negligence (Medical) Manslaughter and the Puzzling Implications of Negligent Ignorance: Rose v R [2017] EWCA Crim 1168' 26 (2018) Medical Law Review 346; Samanta and Samanta (n 173); Quick (n 145)

Furthermore, gross negligence manslaughter cases tend not to take into account broader systemic failings which may contribute to the death of a patient, [178] (and which are prevalent within hospital discharge failings). For example, in 2015, Dr Bawa-Garba was convicted of gross negligence manslaughter following the death of a six-year-old boy.[179] As Samanta and Samanta highlight, in this instance, and not uncommonly, there were multiple systemic failures which contributed to the incident. [180] Technical problems with the hospital's computer system meant there was a delay in the transmission of blood test results; there was a shortage of supporting middle grade medical staff, a series of communication failures between nurses and medical staff occurred, and there were significant work load pressures on Dr Bawa-Garba herself.[181] Samanta and Samanta argue that fear of the legal focus upon the actions of the individual clinician when a patient dies may cause clinicians to be reluctant about openly disclosing the circumstances of a patient's death. They suggest that the goal of improving healthcare will be undermined if doctors are fearful of a culture which seeks to blame individuals.[182] Indeed, following Dr Bawa-Garba's conviction, the General Medical Council (GMC) removed her from the medical register, leading the medical community to express significant concerns that systemic failings were being ignored by both the court and the regulator, [183] and that a blame ethos was undermining patient safety.[184] The case reignited concerns that criminalisation of healthcare professionals causes fear amongst the professions, leading to defensive medicine practices.[185] Kazarian observes that while individual healthcare professionals appear vulnerable to criminal charges, other key decision-makers (such as hospital managers) have not yet been subject to criminal prosecutions in cases involving healthcare systemic failings.[186]

Since April 2008, manslaughter prosecutions against organisations have been possible under the Corporate Manslaughter and Corporate Homicide Act 2007 (CMCH Act). Under this Act, an organisation will have committed homicide if the way in which it manages or organises

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[178] Samanta and Samanta (n 173)
[179] *R v Bawa-Garba* [2016] EWCA Crim 1841
[180] Samanta and Samanta (n 173)
[181] ibid
[182] ibid
[183] Cohen (n 150)
[184] Nick Ross, 'Letter to the GMC Chair Regarding Hadiza Bawa-Garba' (BMJ, 18 January 2018) <https://www.bmj.com/con tent/360/bmj.k195> accessed 8 August 2021
[185] Mélinée Kazarian, 'Who should we blame for healthcare failings? Lessons from the French tainted blood scandal' 27 (2019) Medical Law Review 390; Cohen (n 150)
[186] Kazarian (n 185)

its activities cause a death and amount to a gross breach of the relevant duty of care it owed to the deceased.[187] The CMCH Act was initially perceived to be a landmark development[188] for holding companies and organisations responsible for deaths caused by a gross breach of duty; however, to-date, only one NHS Trust (Maidstone and Tunbridge Wells NHS Trust) has faced a corporate manslaughter charge.[189] It was alleged that two doctors had failed in an elementary task of protecting a patient's airway during surgery, and that the Trust knew, or should have known, that it had employed persons who were not suitably trained.[190] The case later collapsed in court after a judge ruled there was no case to answer.[191] In May 2021, it was reported that police investigating unsafe maternity care at East Kent Hospitals University Trust were considering bringing a corporate manslaughter charge against the Trust.[192]

Although in theory a charge of manslaughter could be brought against a Trust when a patient dies in relation to the hospital discharge process, it is not anticipated that this will be a likely course of action. For, as articulated by Samanta and Samanta, there are several challenges to prosecuting an NHS Trust under the CMCH Act.[193] To summarise these difficulties briefly: the CMCH Act requires senior management to have made a substantial contribution to the gross breach of duty regarding their management of organisational activities. This requirement may be challenging to satisfy in large organisations where senior management may not assume operational tasks.[194] Proof of causation requires that the death resulted from the way the organisation was managed - yet ascertaining culpability within multi-layered managerial activities is difficult. Once a breach of duty is proved, it must further be proven that it is 'gross'- falling far below a standard that can be reasonably expected of organisations in such circumstances. [195] Given these difficulties, it is highly unlikely that a Trust would face charges of manslaughter for *any* patient deaths, not just those that occur in relation to the hospital discharge process.

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[187] Quick (n 145)
[188] Samanta and Samanta (n 173)
[189] *R v Cornish and Maidstone and Tunbridge Wells Trust* [2015] EWHC 2967 (QB)
[190] Peter Walker and others, 'NHS caesarean death: landmark corporate manslaughter trial collapses' *The Guardian* (28 Jan 2016) <https://www.theguardian.com/society/2016/jan/28/frances-cappuccini-caesarean-death-trial-collapses> accessed 15 July 2021
[191] ibid
[192] Shaun Lintern, 'Detectives consider corporate manslaughter charge in NHS maternity scandal involving 200 families' *Independent* (23 May 2021) <https://www.independent.co.uk/news/health/police-manslaughter-east-kent-nhs-maternity-b1850946.html> accessed 15 July 2021
[193] Samanta and Samanta (n 173)
[194] ibid 15
[195] ibid

That said, writing in the *Guardian* in June 2021, Bailin floated the possibility that the Department of Health and Social Care (DHSC) could face a corporate manslaughter charge regarding their policy early on in the pandemic for patients to be discharged to care homes without being tested.[196] It is outside of the scope of this thesis to explore this particular issue in-depth, however, it is a point worthy of future research. I outline a possible line of research on this matter within the Conclusion of this thesis.

2.1.2 Ill Treatment or Wilful Neglect

In August 2013, the Berwick report[197] recommended that a new criminal offence of recklessness or wilful neglect should be created to improve patient safety in England's NHS. The report produced a set of recommendations in response to the findings of the Francis report[198] into poor care at Mid Staffordshire NHS Foundation Trust in February 2013. Following these recommendations, in 2015, two new offences, ill treatment or wilful neglect, came into force under Sections 20 and 21 of the Criminal Justice and Courts Act 2015. Section 20 concerns the actions of an individual, whilst section 21 relates to actions of an organisation. Writing prior to this law coming into place, Yeung and Horder[199] observed that in a situation where two adults are receiving 'wholly wrong and harmful care', but where only one of them lacks capacity (for the purposes of the Mental Capacity Act 2005), there could have only been prosecution for ill treatment in relation to the adult lacking capacity. They continued that many patients in ordinary hospitals may not lack capacity under the Mental Health Act 1983 or the Mental Capacity Act 2005, but may still be vulnerable and unable to advocate for themselves.[200] Yeung and Horder thus called for the criminal law to recognise such offences and protect vulnerable people who have capacity. Importantly, they said the offence should go

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[196] Alex Bailin, 'Cummings' care homes claim could lead to corporate manslaughter charges' *The Guardian* (3 June 2021) <https://www.theguardian.com/commentisfree/2021/jun/03/cummings-care-homes-corporate-manslaughter-covid> accessed 15 July 2021

[197] National Advisory Group on the Safety of Patients in England, 'A Promise to Learn – A Commitment To Act: Improving The Safety Of Patients In England' (Crown Publishing 2013)

[198] The Mid Staffordshire NHS Foundation Trust Public Inquiry, *Report of The Mid Staffordshire NHS Foundation Trust Public Inquiry* (HC898-1, 2013)

[199] Yeung and Horder (n 168)

[200] ibid

beyond causing of injury, and may include, amongst others, 'discharging sick patients before they are fit for discharge'.[201]

The offences which subsequently came into force are only intended to be applicable in the most extreme types of poor care.[202] The exact meaning of the terms are not defined, however *R v Newington*[203] shows that ill treatment covers deliberate actions such as bullying and assault, and *R v Sheppard*[204] shows that wilful neglect covers deliberate actions such as omissions to nutrition and hydration. Under Section 21 of the Criminal Justice and Courts Act 2015, the offense is applicable to organisations where there has been a gross breach of the relevant duty of care; which is to say care that falls far below that which can reasonably be expected. No instances involving the hospital discharge have yet been found to amount to ill treatment or wilful neglect. It is, however, certainly possible that such a case may arise in future, particularly where vulnerable patients are discharged home alone and left unable to feed themselves, drink, or reach their toilet.[205]

2.1.3 Regulatory offenses

According to Quick, the amount of regulatory criminal law has increased as governments create new criminal offenses in order to respond to problems[206] (or indeed healthcare 'scandals'). These laws are typically enforced by specialist agencies; within health care this is usually the Health and Safety Executive (HSE) and the Care Quality Commission (CQC)[207]. The powers of the HSE stem from the Health and Safety at Work Act 1974, which was initially designed to protect the health and safety of workers. However, parts of the Act are applicable to keeping patients safe, with Section 3(1) stating that employers have a duty to ensure, so far as is reasonably practicable, that non-employees are not exposed to risks to their health and safety.[208]

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[201] ibid
[202] Quick (n 145) 117
[203] *R v Newington* [1990] Crim LR 593
[204] *R v Sheppard* [1981] AC 394
[205] See for example the case of Mrs K provided earlier in the introduction to this thesis and available in: Parliamentary and Health Service Ombudsman, 'A report of investigations Into Unsafe Discharge From Hospital' (PHSO 2016) <https://www.ombudsman.org.uk/sites/default/files/page/A%20report%20of%20investigations%20into%20unsafe%20discharge%20from%20hospital.pdf> accessed 14 July 2021
[206] Quick (n 145)
[207] The role and remit of the CQC is discussed further in Chapter Three
[208] The Health and Safety at Work Act 1974, s 3(1)

Quick notes that although prosecutions of healthcare trusts under this section are rare, there are indications that Health and Safety Investigations have the potential to 'probe wider aspects of the system and its responsibility for system lapses'.[209] He gives the example of the HSE prosecuting the Mid Staffordshire Foundation NHS Trust due to the lack of safety procedures regarding the deaths of four patients, three of whom were elderly patients, and two of which suffered fatal falls.[210] Such prosecutions, he argues, are 'symbolically important as official recognition of organisational fault'.[211]

In 2016, Shrewsbury and Telford NHS Trust was prosecuted following the HSE's investigations into the deaths of five patients at two hospitals managed by the Trust.[212] All of the patients had been at high risk of falling. It was found that in four of the cases, the falls in the hospitals had significantly contributed to their deaths. The Trust had fallen short of the appropriate standard in relation to: its mitigation of the falls risk for elderly people in its care; the quality of the patient handover process across wards; and its provision of control measures (such as Enhanced Patient Support). The Trust was also at fault for not properly addressing the causes of the incidents nor making timely and appropriate changes to its systems.[213] These failings were not, in the judge's view, determined to be systemic in nature, but rather were examples of 'individual and unfortunate instances'. [214] The judge did not expand upon why he did not believe the failings to be systemic in nature, however, Heywood writes that measuring a system's appropriateness is a more abstract exercise than assessing an individual's conduct.[215] This, he argues, is because different systems will be appropriate for different environments, making it difficult for a judge to benchmark any particular system against a 'reasonable' system.[216]

In November 2018, the Chief Executive of the CQC stated that the regulator (more on which is said in Chapter Two of this thesis) had 163 possible prosecutions lined up against adult social care providers and 31 potential prosecutions against NHS organisations.[217] As of

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[209] Quick (n 145)
[210] ibid
[211] ibid 121
[212] R (on prosecution by the Health and Safety Executive) v Shrewsbury and Telford NHS Trust [2017]
[213] ibid paras 69 - 71
[214] ibid paras 69 - 71
[215] Heywood (n 150)
[216] ibid 8
[217] Shaun Lintern, 'CQC Is Considering 31 NHS Prosecutions, New Chief Reveals' (Health Service Journal, 13 Nov 2019) <https://www.hsj.co.uk/policy-and-regulation/cqc-is-considering-31-nhs-prosecutions-new-chief-reveals/7023775.article> accessed 15 July 2021

April 2021, none of these prosecutions have related to failures in the hospital discharge process. However, it is not beyond the realms of possibility that a Trust might, in future, be prosecuted as a result of unsafe discharge procedures.

2.2 Looking forward: Prevention of Future Deaths Reports

The previous subsections have primarily focussed upon how the law retrospectively responds to patient safety incidents. The main aims of these retrospective responses are to provide compensation for the victim, or to punish those responsible for the harm. In this subsection, I examine the role of coroners in *preventing* future patient safety incidents.

Coroners investigate deaths where they have reason to think that the death was violent or unnatural, where the cause of death is unknown, or where the deceased died in state detention.[218] The purpose of an inquest is to uncover the facts of the death, not to establish who is criminally responsible.[219] Under the Coroners and Justice Act 2009,[220] if a coroner's investigation reveals issues which may create a risk of further deaths, the coroner has a duty to make a report advising action to prevent these occurring. These reports, known as 'Regulation 28 Reports' or 'Prevention of Future Deaths Reports (PFD reports)' must be sent to the Chief Coroner and those who, in the coroner's opinion, should receive it. On receipt of the report, the Chief Coroner may publish a copy or summary of it, and send a copy to anyone who they believe may find it useful.[221] Quick argues that this mechanism is much more likely to make a positive impact upon patient safety than civil and criminal cases.[222] However, in order for these reports to be effective, action must be taken in response to them.

Under Regulation 29 of The Coroners (Investigations) Regulations 2013, recipients must respond to the report detailing any action that has been taken or which will be taken in response to the concerns raised, alongside a timetable for the action/proposed action. If no action is to be taken, they must explain why not. The response must be provided to the coroner within 56 days of the date the report was sent. The coroner has discretion to extend the time

[218] Ministry of Justice, 'Guide to Coroner Services' (Ministry of Justice 2014)
[219] ibid
[220] Coroners and Justice Act 2009, para 7 Sch 5
[221] The Coroners (Investigations) Regulations 2013, reg 28
[222] Quick (n 145) 140

frame for the response. Once the response has been received, the coroner must send a copy of the response to the Chief Coroner and other interested parties who they believe should receive it. The Chief Coroner may then decide to make a copy, or summary of the response, publicly available online. Respondents to the reports may request restrictions on the publication of the response, which the Chief Coroner will then consider.[223]

In the very early stages of this research, I intended to use coroners' Prevention of Future Death reports as a source for a) determining how frequently aspects of the discharge process have contributed to the deaths of patients, and b) understanding how recipients respond and make improvements to prevent reoccurrences. However, due to how the reports are presented online, systematically analysing these reports would have involved manually extracting a significant amount of data.[224] Given time limitations, this exercise proved unfeasible. This barrier to scrutiny and systematic analysis is one which obscures accountability for ensuring that the healthcare system continuously improves – a theme which I revisit in the conclusion to this thesis.

Subsequent research by Leary and colleagues highlighted 36 reports which expressed coroners' concerns about having to issue repeat PFDs to the same organisation for the same concerns.[225] A major theme was poor or no coordination of care,[226] an issue which featured in my own brief perusal of PFD reports where I found that the same Trust had received three PFD reports over two years pertaining to the deaths of patients and their hospital discharge experience.[227] Thus, whereas in principle these reports ought to function as a tool for learning from deaths, and preventing future deaths, in reality they are failing to do so. Neither the coroner nor any other regulatory organisation has a legal responsibility to enforce recommendations in PFD reports, or to apply sanctions when they are not acted upon.

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[223] The Coroners (Investigations) Regulations 2013, reg 29
[224] For a detailed explanation of this problem see: Alison Leary and others, 'A Thematic Analysis of The Prevention of Future Deaths Reports in Healthcare from HM Coroners in England and Wales 2016–2019' (2021) 26 Journal of Patient Safety and Risk Management 14
[225] ibid
[226] ibid
[227]Veronica Hamilton-Deeley, 'Graham Watts' (*Courts and Tribunals Judiciary*, 3 April 2014) <https://www.judiciary.uk/publications/graham-watts/> accessed 9 March 2021; Veronica Hamilton-Deeley, 'Thelma Jones' (*Courts and Tribunals Judiciary*, 12 August 2015) <https://www.judiciary.uk/publications/thelma-jones/> accessed 9 March 2021; Veronica Hamilton-Deeley, 'Leslie Lerner' (*Courts and Tribunals Judiciary*, 12 March 2017) <https://www.judiciary.uk/publications/leslie-lerner/> accessed 9 March 2021

Undoubtedly, this is an aspect which could be addressed, and which has the potential to improve patient safety during hospital discharge.

2.3 Looking forward: Primary legislation

Primary legislation, which is produced and debated by Parliament before becoming law, is a means for Government to implement its policies. These laws may be produced in response to healthcare scandals, and provide a framework to improve patient safety. For example, in 2021 the Medicines and Medical Devices Act was established, bringing with it a framework for a new role of Patient Safety Commissioner. The impetus for this new role stemmed from a recommendation in the report of the Independent Medicines and Medical Devices Safety (IMMDS) Review, published in 2020.[228] The purpose of that review was to examine how effectively the healthcare system responded to concerns raised about harmful side effects from specific medicines and medical devices,[229] and to consider how future responses to concerns over side effects could be quicker and more effective.[230] The remit of the Patient Safety Commissioner is not set to extend to cover the safety of the hospital discharge process – in part three of this thesis I argue this a missed opportunity to improve patient safety.

2.4 Looking forward: Public Inquiries

Typically mandated by a government minister, the purpose of a public inquiry is to examine an incident, to establish what happened, and to identify what lessons can be learned from it to prevent recurrence.[231] Since 2005, most public inquiries have been convened using the Inquiries Act 2005. Goodwin observes that it seems 'the inquiry is the response of choice to

[228] Independent Medicines and Medical Devices Safety Review, 'First Do No Harm: The Report of the Independent Medicines and Medical Devices Safety Review' (APS Group 2020) Recommendation 2
[229] These were hormone pregnancy tests, sodium valproate, and pelvis mesh implants.
[230] Independent Medicines and Medical Devices Safety Review (n 228)
[231] Kieran Walshe and Joan Higgins, 'The use and impact of inquiries in the NHS' (2002) 325 BMJ 895; Beth Kewell and Matthias Beck, 'Public Money and Management NHS Inquiries: A Time Series Analysis' (2008) 28 Public Money and Management 375

healthcare failures in the UK'.[232] Although inquiries do not replace regulation, they are able to enhance existing ways in which healthcare professionals' actions may be held to account.[233] Goodwin argues that inquiries are well-placed to examine both the connectedness of actions, and the relationships between actors. She echoes a point made by Greer and McLaughlin: inquiries have the ability to 'connect individual scandalous transgressions with systemic institutional failings'.[234] Kewell and Beck suggest that health inquiries are the most reliable platform for independent post-incident scrutiny available under the English legal system.[235]

Powell argues that if a key reason for an inquiry is to learn from events and prevent similar ones occurring, then any recommendations from inquiries must be implementable and implemented. He compares recommendations from the Ely, Bristol, and Mid Staffs inquiries in order to assess how implementable they are, and identifies two key issues with recommendations: to whom, and to what do they apply?[236] For a recommendation to be effective, it must be actively targeted at an actor, and clear policy tools or mechanisms must be identified (as opposed to a reliance on vague advice).[237] However despite this insight, Powell still concludes that the issue of 'how to ensure lessons are learned' persists within the NHS.[238]

This failure to learn from error is a theme which became increasingly apparent throughout my research. In the Conclusion to this thesis, I discuss in further detail my observations that clear lines of accountability for learning from error are critical to improving safety during discharge and throughout the NHS; yet this clear accountability is currently lacking. The following subsection provides an overview of yet another attempt to improve safety within the NHS - the establishment of the Healthcare Safety Investigation Branch (HSIB).

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[232] Dawn Goodwin, 'Cultures of Caring: Healthcare 'scandals', Inquiries, and the Remaking of Accountabilities' (2018) 48 Social Studies of Science 102
[233] ibid
[234] Chris Greer and Eugene McLaughlin, 'This is not Justice': Ian Tomlinson, Institutional Failure and the Press Politics of Outrage' (2012) 52 The British Journal of Criminology 274
[235] Beth Kewell and Matthias Beck, 'Public Money and Management NHS Inquiries: A Time Series Analysis' (2008) 28 Public Money and Management 375
[236] Martin Powell, 'Learning from NHS inquiries: Comparing the recommendations of the Ely, Bristol and Mid Staffordshire Inquiries' (2019) 90 The Policy Quarterly 229
[237] ibid
[238] ibid 237

2.5 Looking forward: The HSIB

The purpose of the HSIB is to improve patient safety through effective and independent investigations that do not apportion blame or liability.[239] From these investigations, lessons can be learnt from the errors, and shared across the healthcare system. The body is currently funded by the DHSC, and hosted by NHS England and NHS Improvement. A thematic analysis of the HSIB's first 22 national investigations has found three broad themes of risks to patient safety. These are:

- access to care and transitions of care
- communication and decision making
- checking at the point of care[240]

These elements are all central to the hospital discharge process,[241] and the HSIB has made 85 recommendations thus far to various organisations in order to address these concerns. At the outset of the HSIB's thematic analysis in May 2021, the organisation stated the purpose was to: 'identify the recurring patient safety themes and to explore the impact so far of the 85 recommendations we have made to address them.'[242] By the time the findings were published in a report (September 2021), the latter part of the mission had been abandoned:

> 'this analysis did not look at the impact of our recommendations at improving patient safety or assess how well they had been acted on. HSIB is not a regulator, and the onus is on the addressee of the safety recommendation to decide how best to meet a recommendation.'[243]

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[239] HSIB, 'About us' <https://www.hsib.org.uk/> accessed 15 July 2021
[240] HSIB, 'A thematic analysis of HSIB's first 22 national investigations' <https://www.hsib.org.uk/investigations-cases/thematic-analysis-hsibs-first-22-national-investigations/> accessed 15 July 2021.
[241] As explained in the introduction of this thesis, discharge processes involve a transition of care (either to another healthcare professional or to the patient / family), effective communication with all those involved in the transition of care, and accurate transfer of medical information.
[242]This statement can be accessed via an 'internet archive' site: http://web.archive.org/web/20210819211519/https://www.hsib.org.uk/investigations-and-reports/a-thematic-analysis-of-hsibs-first-22-national-investigations/ accessed 21 October 2021
[243] HSIB, 'National Learning Report: A thematic analysis of HSIB's first 22 national investigations' <https://hsib-kqcco125-media.s3.amazonaws.com/assets/documents/HSIB_A_thematic_analysis_of_HSIBs_first_22_national_investigations_Report_V10.pdf> accessed 21 October 2021, 6

The HSIB acknowledged that the lack of monitoring of the impact of its findings and recommendations is a 'gap' which needs addressing, but stressed it does not wish to be seen as a regulator. The organisation further recognised that there has been 'a variable response to its safety recommendations, which is exacerbated by the complexity of regulatory landscape in which healthcare sits.'[244] It is thus reasonable to suggest that without a regulatory body tasked with holding organisations to account if they fail to implement recommendations, the impact of safety recommendations is likely limited.

2.6 Chapter Two Conclusion

This chapter set out to provide a brief overview of how the law responds when patients are harmed. It has highlighted that the law tends to respond in a retrospective manner, through compensating victims. There are however legal mechanisms in place for improving future patient safety: PFD reports, the creation of new legislation, and public inquiries. Compared to the retrospective responses, forward-looking approaches are more likely to have a positive impact upon improving patient safety more broadly. Against this legal background, this thesis turns its attention to the role of regulation in relation to the hospital discharge process.

[244] ibid 45

Chapter Three: Regulatory Background

Regulation has, arguably, become the victim of a 'definitional free-for-all', often seen as a type of legal instrument, or an action, or an outcome, or sometimes as a property.[245] Black argues that what is needed is a conceptualisation of regulation that serves as a tool of inquiry into a particular social phenomenon, which facilitates analysis of the phenomenon, and practical discussions of how regulation might be improved.[246] To this end, she defines regulation as 'the sustained and focused attempt to alter the behaviour of others according to defined standards or purposes with the intention of producing a broadly identified outcome or outcomes which may involve mechanisms of standard setting, information gathering and behaviour modification'.[247] This definition, Black argues, distinguishes regulation from *any* type of social control, but also captures activities beyond those of the state.[248] Specifically within the healthcare context, Quick notes that the term is typically used to describe 'formal attempts by statutory bodies to shape the behaviour of practitioners, primarily through education, ethics and discipline'.[249]

Oikonomou and colleagues define healthcare regulation more broadly as 'the processes engaged in by institutional actors that seek to shape, monitor, control or modify activities within healthcare organisations in order to reduce the risk of patients being harmed during their care'. This leads to the identification of 126 organisations exerting regulatory influence within the NHS.[250] This definition of regulation is perhaps too broad; for as Walshe argues, sensible boundaries around the concept of regulation must be set as broad interpretations risk the concept becoming 'almost meaningless'.[251] Walshe argues that there are four key characteristics central to the nature and purpose of regulation. These are: formal remit or acknowledged authority; centralisation of oversight; third-party accountability; and action in the public interest.[252] These four characteristics mean that a regulator holds a formal remit to regulate that is acknowledged by other stakeholders, and that the regulator represents a

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[245] Julia Black, 'Critical Reflections on Regulation' (Centre for the Analysis of Risk and Regulation, 2002) <https://www.lse.ac.uk/accounting/assets/CARR/documents/D-P/Disspaper4.pdf> accessed 26 April 2021
[246] ibid 20
[247] ibid
[248] ibid
[249] Oliver Quick, *Regulating Patient Safety* (Cambridge University Press 2017) 51
[250] Eirini Oikonomou and others, 'Patient Safety Regulation in the NHS: Mapping the Regulatory Landscape of Healthcare' (2019) 9 BMJ Open 1, 2
[251] Kieran Walshe, *Regulating Healthcare: A Prescription for Improvement* (Oxford University Press 2003) 10
[252] ibid 20-21

centralisation of responsibility, power, and oversight. The regulator is a third-party to inter-organisational relationships, and its processes are intended to serve a wider societal goal.[253]

Taking account of these characteristics, I focus my attention upon the activities of the healthcare regulators established through legislation (presented in subsections 3.2 – 3.4). This is because they are recognised sources of authority and have statutory obligations to protect the public.[254] These regulators *should* therefore be held accountable in circumstances where they continually fail to protect the public. Inspired by Black's definition of regulation above, this thesis uses the term 'regulation' to refer to the formal attempts by statutory regulators to shape behaviour within healthcare organisations. This definition, though narrower in focus than that of Oikonomou and colleagues, is not intended to dismiss any other actors which exert regulatory influence. As highlighted in Part Three of this thesis, these actors have an important role to play in feeding into the actions undertaken by the statutory regulators as they seek to improve safety.

The primary purpose of this chapter is to describe what the regulatory landscape currently looks like within the English NHS. An understanding of the complexity of this landscape is central to understanding the issues which arise from it in the context of hospital discharges, and which this thesis will go on to examine in-depth.

3.0 Regulation within the English NHS

The regulatory bodies presented in this chapter all undertake activities which are captured by Black's definition. Underpinning this presentation of the regulatory landscape is regulatory theory, which can be understood as 'a set of propositions or hypotheses about *why* regulation emerges, *which actors* contribute to that emergence and typical *patterns of interaction* between regulatory actors.'[255] These three propositions are a useful starting point for explaining the current regulatory landscape; they therefore form the basis for subsections 3.1 – 3.5. Chapter Five will provide a deeper exploration of regulatory theory, which is central

[253] ibid
[254] See the Medical Act 1983, Dentists Act 1984, Chiropractors Act 1994, Opticians Act 1989, The Osteopaths Act 1993, The Health Act 1999, the Nursing and Midwifery Order 2001, The Health and Social Work Professions Order 2001, and the Pharmacy Order 2010
[255] Bronwen Morgan and Karen Yeung, *An Introduction to Law and Regulation: Text and Materials* (Cambridge University Press 2007) 16

part of my conceptual framework. I do, however, argue that on its own, regulatory theory is an insufficient framework for my thesis. I will contextualise this argument by drawing upon the fields of patient safety, bioethical theory, and anthropological theory throughout this thesis.

3.1 Why regulate healthcare?

According to Quick, the purpose of regulating people, processes, and places within healthcare is to ensure trust and to improve safety.[256] Ensuring public trust in healthcare professions is central to making sure that people will seek out the healthcare that they need, and is a key rationale for the regulation of healthcare.[257] Patients want to feel able to trust healthcare professionals, and want assurance that any problems that might occur with their healthcare will be resolved.[258]

Within England, regulation of healthcare has evolved significantly over time; indeed, as Allsop and Mulcahy comment, 'since the 1990 health service reforms, writing about the NHS is like shooting at a moving target'.[259] Legal and regulatory reshuffles have often been triggered in response to recommendations made by inquiries into healthcare scandals. For example, the Kennedy Inquiry[260] and Alder Hey organs scandal[261] resulted in the creation of the Human Tissue Act 2004, under which the Human Tissue Authority[262] was established. In response to the Shipman Inquiry's fifth report[263], a major programme of reform to professional regulation was set out, including the introduction of revalidation of healthcare professionals.[264]

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[256] Quick (n 249)
[257] Judith Healy, *Improving Health Care Safety and Quality: Reluctant Regulators* (Ashgate Publishing Ltd 2011)
[258] ibid
[259] Judith Allsop and Linda Mulcahy, *Regulating Medical Work: Informal and Formal Controls* (1996) 1
[260] Ian Kennedy, Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984-1995: Learning from Bristol (Cm 5207, 2001)
[261] The 2001 Royal Liverpool Children's Inquiry Report ('The Redfern report') followed evidence to the Bristol Royal Infirmary Inquiry that a large number of hearts from deceased children were being retained by hospitals without the knowledge or consent of parents ('Alder Hey organs scandal').
[262] The HTA regulates the removal, storage and use of human tissue for research, medical treatment, post-mortem examinations, teaching and public display. See Human Tissue Act 2004, 14
[263] Harold Shipman was a general practitioner suspected to have murdered around 215 patients, and convicted in 2000 for murdering fifteen. See Dame Janet Smith, *The Shipman Inquiry Fifth Report: Safeguarding Patients, Lessons from the Past - Proposals for the Future* (Cm 6394, 2004).
[264] Department of Health, 'Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century' (Cm 7013, 2007)

More recently, recommendations from the IMMDS Review[265] have resulted in the establishment of a statutory Commissioner for Patient safety.[266]

Suffice to say, currently responsibility for regulation is shared across multiple bodies, as the next three subsections will demonstrate. However, the Government's latest Health and Care Bill includes a proposal to allow the abolishment of individual regulatory bodies[267] where the profession(s) it regulates continues to be regulated by another regulatory body, or where regulation of the profession is no longer required for the protection of the public.[268] Legislative reform to permit a formal merger of NHS England and NHS Improvement[269] is also proposed (more on these bodies is provided in subsection 3.3), and the potential to introduce new regulation of NHS managers is raised.[270] Much like the Medicines and Medical Devices Act 2021, these proposals would allow the Secretary of State for Health and Social Care broad powers to alter the regulatory landscape. Although it is out of scope for this thesis to speculate about the impact of the proposed changes upon regulation and patient safety with regard to hospital discharge, in the Conclusion, I identify this as an area requiring further research. The following sections introduce the current regulatory actors.

3.2 Regulating Healthcare Professionals

Known as the 'professional regulators' the bodies in the table below each have a statutory duty to protect the public. They each share the following overarching functions: to set the standards of behaviour, competence and education that professionals must meet; to address concerns raised about professionals who are unfit to practise because of poor health, misconduct or poor performance; to maintain registers of professionals who are fit to practise; and to set the requirements for re-registration and/or revalidation for each profession.[271]

[265] Independent Medicines and Medical Devices Safety Review, 'First Do No Harm: The Report of the Independent Medicines and Medical Devices Safety Review' (APS Group 2020)
[266] Medicines and Medical Devices Act 2021, pt 1
[267] Health and Care HC Bill (2021-2022) [140], para 123(3)(a)
[268] Explanatory Notes to the Health and Care Bill 2021, paras 946 - 948
[269] ibid paras 11-13
[270] Health and Care HC Bill (2021-2022) [140], para 123(2)(d); ibid para 166
[271] Law Commission, 'Regulation of Health care professionals: Regulation of social care professionals in England' (Law Com No 345, 2014)

Regulator	Regulatees	Legislation
General Medical Council (GMC)	Doctors	Medical Act 1983
General Dental Council (GDC)	Dentists	Dentists Act 1984
General Chiropractic Council (GCC)	Chiropractors	Chiropractors Act 1994
General Optical Council (GOC)	Opticians and Optometrists	Opticians Act 1989
General Osteopathic Council (GOsC)	Osteopaths	Osteopaths Act 1993
General Pharmaceutical Council (GPhC)	Pharmacists	Pharmacy Order 2010
Health and Care Professions Council (HCPC)	Arts Therapists, Biomedical Scientists, Chiropodists, Clinical Scientists, Dieticians, Hearing Aid Dispensers, Occupational Therapists, Operating Department Practitioners, Orthoptists, Paramedics, Physiotherapists, Psychologists, Prosthetists, Radiographers, Speech and Language Therapists	The Health Act 1999
Nursing and Midwifery Council (NMC)	Nurses and Midwives	The Nursing and Midwifery Order 2001
Social Work England (SWE)	Social Workers	Children and Social Work Act 2017

Throughout this thesis, particular attention is paid to the function of the GMC. This is because within clinical practice, doctors are typically responsible for decision-making regarding the discharge of their patients. That said, the actions of other regulatory bodies are also examined as discharge planning frequently involves the coordination of multiple healthcare professionals.

Using the GMC as an example, this section will now illustrate the relationship between the regulatory function of setting professional standards and taking action when those standards are not met by registrants. The professional standards set by the GMC are stated within its core guidance, *Good Medical Practice (GMP)*, and within additional pieces of explanatory guidance.[272] Although serious or persistent failure to follow GMC guidance puts a doctor's registration at risk,[273] there is no automatic link between a failure to follow the guidance and action against a doctor's registration. This is because the guidance sets out the principles of good practice, and not thresholds for taking action to protect the public.[274] The GMC's *Sanctions Guidance* tries to further clarify the link between setting standards for doctors and taking action when a doctor's fitness to practise is called into question. It says that action is taken where a serious or persistent breach of the guidance has put patient safety at risk or undermined public confidence in doctors.[275] Although the purpose of any action is to protect the public by helping to make sure doctors on the register provide safe care and uphold public confidence in doctors, this purpose is not necessarily common knowledge amongst the public. Research commissioned by the GMC into the motivations of complainants revealed that in some instances, complainants did so out of desire for the doctor to be punished.[276]

GMC fitness to practice (FtP) procedures consist of two stages; investigation and adjudication. In the first stage cases are investigated by the GMC and a decision is made as to whether to refer it to the Medical Practitioners Tribunal Service (MPTS) for adjudication. Investigations start when a concern has been raised with the regulator about the doctor's fitness to practise. Investigations vary in length depending on the complexity of the concerns, and

[272] General Medica Council, 'Ethical Guidance for Doctors' <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors> accessed 9 August 2021
[273] General Medical Council, 'Good Medical Practice' (GMC 2013) para 6
[274] General Medical Council and Medical Practitioners Tribunal Service, 'Sanctions Guidance' (GMC & MPTS 2020) para 18
[275] ibid para 19
[276] ICE, 'Why Do Many Public Concerns that would be Better Directed to Another Organisation Come to the GMC?' *(*GMC & ICE 2019) <https://www.gmc-uk.org/-/media/documents/ftp-public-complainants-research-report-v2_0_pdf-78629691.pdf> accessed 26 July 2021

involve gathering information such as documentary evidence from the complainant, or expert reports on clinical matters. After the investigation, two case examiners (one medical and one non-medical) decide if further action is needed or if the case can be closed. Further action includes issuing a warning, or referring the case to the MPTS for a hearing.[277] The focus is on whether the doctor's fitness to practice is impaired at the time of investigation/hearing, not at the time of the incident in question.[278]

The GMC's professional standards do not explicitly state what is expected of a doctor with regard to hospital discharge. There are however more broad principles within the guidance which are relevant. For example, doctors are told: they 'must contribute to the safe transfer of patients between healthcare providers and between health and social care providers'[279] and that it is 'essential for safe care that information about medicines accompanies patients, or quickly follows them… when they transfer between care settings'.[280] If they are the patient's general practitioner (GP), they should make sure that changes to the patient's medicines following hospital treatment are quickly incorporated into the patient's record.[281] If they are not the GP, after completing an episode of care for a patient, they should inform the GP about medication changes and monitoring requirements.[282] These requirements, which are set out within the GMC's guidance on prescribing, are clearly intended to enhance medication safety[283] during a transition of care. However, as explained in the introduction to this thesis, it is not simply medication changes that pose a risk to patients when they are discharged from hospital.

3.3 Regulating Healthcare Providers

[277] General Medical Council, 'The GMC's fitness to practise procedures' <https://www.gmc-uk.org/-/media/documents/DC4541_The_GMC_s_Fitness_to_Practise_procedures.pdf_25416512.pdf> accessed 26 July 2021
[278] Medical Practitioners Tribunal Service, 'How a Hearing Works' <https://www.mpts-uk.org/witnesses/witness-guide-to-hearings/how-a-hearing-works> accessed 21 October 2021
[279] General Medical Council, 'Good practice in prescribing and managing medicines and devices' (GMC 2021) para 53
[280] ibid para 54
[281] ibid para 55
[282] ibid para 56
[283] According to the World Health Organisation (WHO), unintended medication discrepancies affect nearly every patient experiencing a transition of care. See WHO, 'Medication Safety in Transitions of Care' (WHO 2019)

The Care Quality Commission (CQC) regulates the quality of health and social care in England.[284] Its main purpose is to protect and promote the health, safety and welfare of people who use health and social care services.[285] All providers of adult health and social care in England are legally required to register with the CQC, which inspects and rates the quality of services from outstanding to inadequate. The CQC sets out thirteen fundamental standards of care which cover a vast array of matters such as treating patients with dignity and respect, being open and honest when things go wrong, and ensuring appropriate staff are employed to provide care. [286]

If the CQC finds the quality of care in an organisation is inadequate, it can take regulatory action against the service provider. Its enforcement powers include suspending or cancelling a service's registration, issuing fixed penalty notices, criminal prosecution and the use of 'special measures'.[287] The purpose of placing a provider in special measures is to ensure providers significantly improve within a clear timeframe, and to work with them and other organisations to ensure improvements are made.[288] Although the CQC can directly place a primary care service in special measures, in the case of NHS trusts it can only recommend to NHS Improvement (NHSI) that they are placed in special measures. It is then up to NHSI to make the final decision.[289]

NHSI became operationally active in April 2016, after assuming the remit, statutory functions and legal powers previously held by Monitor, the NHS Trust Development Authority (TDA), Patient Safety, the National Reporting and Learning System, the Advancing Change Team and the Intensive Support Teams.[290] NHSI has the powers set out in the Health and Social Care Act 2012, which include the licensing of providers of NHS health care services, oversight of their performance, and the enforcement of standards. NHSI inherited its enforcement powers from Monitor[291] and is able to suspend or revoke licences, fine providers, remove senior management, appoint improvement directors to trusts, and place healthcare providers in special

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[284] Health and Social Care Act 2008, s 3(1)-(2)
[285] ibid s 3(1)
[286] Care Quality Commission, 'The Fundamental Standards' (CQC 2019) <https://www.cqc.org.uk/what-we-do/how-we-do-our-job/fundamental-standards> accessed 26 July 2021
[287] Care Quality Commission, 'Special Measures' (CQC 2017) <https://www.cqc.org.uk/guidance-providers/all-services/special-measures> accessed 26 July 2021
[288] ibid
[289] Care Quality Commission, 'Enforcement Policy' (CQC 2015) <www.cqc.org.uk/sites/default/files/20150209_enforcement_policy_v1-1.pdf> accessed 26 July 2021
[290] NHS Improvement, 'Who we are | NHS Improvement' (NHS Improvement 2019) <www.improvement.nhs.uk/about-us/who-we-are> accessed 7 March 2019
[291] Monitor, 'Enforcement Guidance' (Monitor 2013) <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/284474/ToPublishEnforcementGuidance28March13_0.pdf> accessed 28 July 2021

measures. Since April 2019, NHSI has been working closely with NHSE as a single organisation, although legislation prevented a formal merger. However, in February 2021, NHSE recommended legislative reform to Government in order to permit a formal merger,[292] and this proposal is within the Health and Care Bill (July 2021).[293] The Bill seeks to transfer the functions of Monitor and the TDA to NHSE, and to abolish Monitor and TDA.[294] The apparent aim is to enable to NHSE and NHSI to: 'provide national leadership, speaking with one voice to set clear and more consistent expectations for providers, commissioners and local health systems; to remove unnecessary duplication; and to use collective resources more efficiently and effectively to support local health systems and ultimately make better use of public money.'[295]

As mentioned earlier in subsection 2.1.3, the Health and Safety Executive (HSE) regulates health and safety in the workplace. This includes private or publicly owned health and social care settings in Great Britain.[296] The HSE works closely with the other health and social care regulators across England, Wales and Scotland, and has several agreements in place with them which are intended to clarify respective role and responsibilities. The HSE will not investigate incidents which arise from poor clinical judgment, those associated with standards of care (such as the effectiveness of diagnostic equipment) or the quality of care (such as hydration and nutrition), or incidents typically arising from the disease the patient was admitted to hospital with.[297] The HSE provide examples of cases[298] where they may take action, one example of which is when a service user dies as a result of choking where this should have been foreseeable.[299] The Memorandum of Understanding (MoU) between the CQC and the HSE confirms that where the injured person is a patient/service user and the service provider

[292] NHS England, 'Legislating for Integrated Care Systems: five recommendations to Government and Parliament' (NHSE 2021) <https://www.england.nhs.uk/wp-content/uploads/2021/02/legislating-for-integrated-care-systems-five-recommendations.pdf> accessed 28 July 2021
[293] Health and Care HC Bill (2021-2022) [140], sch 5
[294] Explanatory Notes to the Health and Care Bill 2021, para 12
[295] ibid para 11
[296] Health and Safety Executive, 'Who Regulates Health Care' (HSE 2019) <http://www.hse.gov.uk/healthservices/arrangements.htm> accessed 26 July 2021
[297] ibid
[298] Health and Safety Executive, 'Guidance for FOD In Responding To (Non-Construction) Public Safety Incidents Where Section 3 Of HSWA Applies' (HSE 2017) <http://www.hse.gov.uk/enforce/hswact/docs/situational-examples.pdf> accessed 26 July 2021
[299] ibid section 8

is registered with the CQC, the responsible authority will normally be the CQC.[300] It is for this reason that this thesis focuses in greater depth upon the role of the latter.

3.4 Regulating the Regulators

An abundance of regulatory failures across professional regulation has resulted in the professional regulators having to become accountable to meso-regulators, who then are accountable to political institutions.[301] In the UK, the Professional Standards Authority (PSA)[302], previously named the Council for Health Regulatory Excellence (CHRE), fulfils this role and is responsible for regulating the professional regulators.[303] Its role has been compared to that of an 'oversight and audit body'; for rather than managing regulators and applying sanctions, it reviews and comments on the actions they take in order to direct improvements.[304] Allsop and Jones argue that the introduction of the PSA has resulted in a shift towards greater consistency in practice amongst the professional regulators.[305] They further argue that the PSA provides an additional level of scrutiny over fitness to practice cases, and increases the transparency and accountability of the professional regulators.[306] As the PSA's annual reports regarding the performance of each professional regulator are publicly available online,[307] the PSA may indeed help to increase the transparency and scrutiny of regulators.

Regarding oversight of the CQC, the DHSC is able to undertake interim reviews of the CQC, if needed. For example, in 2012 the DHSC published its first Performance and Capability Review of the CQC in order to 'provide challenge and reassurance to the public' regarding the

[300] Care Quality Commission, 'Memorandum of Understanding (MoU) Between the Care Quality Commission (CQC) and the Health and Safety Executive (HSE)' (CQC 2017) <http://www.hse.gov.uk/aboutus/howwework/framework/mou/mou-cqc-hse-la.pdf> accessed 24 July 2021
[301] R Kaye, 'Stuck in the Middle: the Rise of the Meso-regulators' (2006) Risk & Regulation 6
[302] The PSA is an arm's-length body of the Department of Health and Social Care
[303] Judith Allsop and Kathryn Jones, 'Regulating the regulators: the rise of the United Kingdom Professional Standards Authority' in John Chamberlain and others (eds) *Professional health regulation in the public interest: International perspectives* (Policy Press 2018)
[304] ibid 101
[305] ibid
[306] ibid
[307] Reports are available at https://www.professionalstandards.org.uk/publications

capability of the CQC.[308] The CQC is also subject to scrutiny from Parliamentary Select Committees, the PHSO, and the National Audit Office.[309]

3.5 Patterns of interaction

As can be seen from the above, a key point about the regulatory landscape is that it is complex, containing multiple bodies with separate and overlapping responsibilities for ensuring the safety of healthcare delivery.[310] The concept of networked governance is particularly useful for understanding this structure of regulation within healthcare.[311] Essentially, networked governance is where a plurality of actors across multiple organisations steer events.[312] As the network grows, challenges arise since no single actor is likely to possess all of the required knowledge and power to enforce change.[313] As such, to be successful in networked governance structures, the regulatory actors within the healthcare context need to communicate to arrive at collaborative approaches.[314]

There are mechanisms in place to facilitate information sharing across regulators. For example, in 2018 an Emerging Concerns Protocol was developed amongst regulators.[315] The protocol is intended to be a method for sharing early concerns so that links between concerns can be made. The concerns may fall into the following three categories: 'concerns about individual or groups of professionals; concerns about healthcare systems and the healthcare environment (including the learning environments of professionals); and concerns that might have an impact on trust and confidence in professionals or the professions overall'.[316] The CQC also has a plethora of agreements in place with other regulatory bodies in order to share information[317], yet despite these a recent inquiry has concluded that there is an 'insufficient

[308]Care Quality Commission, 'CQC Corporate Governance Framework' (CQC 2015) <https://www.cqc.org.uk/sites/default/files/20151111_Coporate_Governance_Framework_August_2015.pdf> accessed 26 July 2021
[309] ibid
[310] Allsop and Jones (n 303)
[311] Healy (n 257)
[312] ibid
[313] ibid
[314] ibid
[315] Care Quality Commission, 'Emerging Concerns Protocol' (CQC 2018) <https://www.cqc.org.uk/publications/themed-work/emerging-concerns-protocol> 6 accessed 26 July 2021
[316] ibid
[317] Care Quality Commission, 'Joint Working Agreements' (CQC 2021) <https://www.cqc.org.uk/about-us/our-partnerships/joint-working-agreements#hide3> accessed 26 July 2021

linkage between CQC and the other regulators'.[318] This conclusion indicates a significant failing amongst regulatory bodies to work effectively together. As will be demonstrated in part two of this thesis, this failing plays a substantial role in why regulation is not adequately safeguarding patients at the point of hospital discharge.

3.6 Chapter Three Conclusion

This chapter has illustrated what the current health regulatory landscape within the English NHS looks like. In doing so, it has examined why regulation emerges, which actors contribute, and what the typical patterns of interaction between the regulatory actors are. The picture which has been painted is that of a highly complex regulatory landscape. This thesis will go on to show how this directly impedes the efficacy of regulatory responses to patient safety incidents during the discharge process. For, as demonstrated in the Introduction to this thesis, the hospital discharge process involves a multitude of actors, and multiple regulatory bodies add to this web. Against this backdrop, this thesis examines the efficacy of the regulatory strategy employed by regulators and the liminal spaces within regulation. More is said about this approach in Chapter Five.

[318] Graham James, 'Report of the Independent Inquiry into the Issues Raised by Paterson' HC 31 (House of Commons 2020) 186

Chapter Four: Ethical Background

This chapter presents a vision for ethical healthcare regulation. It argues that in order to be ethical, regulators must act in a manner which: ensures and maintains public trust in healthcare providers and professionals; is fair to both patients and professionals; and promotes accountability throughout the healthcare system for prevention of harm. Subsection 4.0 provides the broad ethical framework for this argument, and subsections 4.1 – 4.3 expand upon each of these elements within the context of healthcare regulation. The final subsection draws these together to present a vision for ethical regulation. As will be explained in Chapter Five, this vision underpins my approach to this research.

4.0 Ethical Organisations

When it comes to describing what an ethical organisation is, Jurkiewicz and Giacalone note that the simplest answer would be to say it is an organisation which does the right thing. Naturally, this in turn raises the question of what is right?[319] In addressing this question, Jurkiewicz and Giacalone argue that ethicality in organisations is demonstrated both by the decisions of leaders and the organisational factors those leaders then influence (for example, its policies and processes).[320] In making their argument, the authors draw upon Kohlberg's theory of morality,[321] which comprises of six stages of ethical decision-making. The final stage of Kohlberg's theory, Universal Ethical Principles, establishes universal, inviolate principles. Jurkiewicz and Giacalone suggest that such principles, when applied to an organisation, are those that the organisation would have all of humanity share,[322] and may include justice, human rights, and respect for the dignity of an individual.[323] The authors conclude that decision-making in an ethical organisation should exemplify 'doing what is right for all stakeholders rather than just shareholders, a concern for society into the long-term, and a strength of character to do what is right regardless of group or political pressure'. [324] This is a sentiment

[319] Carole Jurkiewicz and Robert Giacalone, 'How Will We Know It When We See It? Conceptualizing the Ethical Organization' (2015) 16 Public Organisation Review 409
[320] ibid
[321] Lawrence Kohlberg, P*hilosophy of Moral Development* (Harper & Row Publishers 1981)
[322] Jurkiewicz and Giacalone (n 319)
[323] ibid 415
[324] ibid 415

which is echoed in the *Seven Principles of Public Life* - principles applicable to health and social care regulators.[325]

The latter principles include selflessness (acting solely in the public interest), integrity (avoiding inappropriate influence from other organisations/people), objectivity (acting fairly on the best evidence) and accountability.[326] Devaney found these principles to be underpinning some regulators' codes of conduct and organisational values, but called for regulators to go 'beyond mere formal acknowledgment of the Seven Principles' by embedding them more deeply in their regulatory activities.[327] In writing about building ethical healthcare organisations, Shale states that healthcare organisations must:

> 'ensure that caregivers and care systems are worthy of the trust that patients place in them, and if things go wrong they have to protect patients without doing injustice to the caregivers. And when harm occurs – inevitably, eventually it will – moral relations must somehow be repaired, and confidence restored'.[328]

Shale's observation is equally applicable to building ethical healthcare regulators. Drawing on the combined conclusions of these authors, I define an ethical healthcare regulator as one whose actions ('regulatory responses'):

- maintain public trust in healthcare providers and professionals
- are fair to both patients and professionals
- promote accountability throughout the healthcare system for prevention of harm to patients (including harm to dignity).

The remainder of this chapter will examine these points in-depth.

4.1 Trust: Ensuring and Maintaining Public Trust in Healthcare

[325] Committee on Standards in Public Life, 'The 7 Principles of Public Life' (Committee on Standards in Public Life 1995)
[326] ibid 1.1, 1.2, and 1.3
[327] Sarah Devaney, 'Ethics for Healthcare Regulators: Enhancing Compliance with the Seven Principles of Public Life' (Manchester Centre for Regulation 2016)
[328] Suzanne Shale, Moral Leadership in Medicine: Building Ethical Healthcare Organisations (Cambridge University Press 2012) 11

Ensuring public trust in healthcare professionals is key to making sure that people will seek out healthcare when it is needed.[329] According to Asser, the purpose of law is primarily to cultivate trust.[330] However, O'Neill argues that although there is some truth to this given that trust will likely be damaged where lawlessness is rife, deficiencies in how organisations and individuals act cannot be remedied simply by providing 'more law, more regulation and more accountability'.[331] Rather, she argues that the ways in which rules are embedded in organisations 'demand' cultures that can shape and interpret them. For law and regulation to work well, it is trustworthy cultures that are required. [332] O'Neill suggests that it would be foolish to assume we should *always* seek to build more trust; for it would make little sense to place more trust in an untrustworthy institution. The central issue thus becomes how to judge an institution's trustworthiness; and imposing more law and regulation does not necessarily help in this regard.

To illustrate the importance of cultures as opposed to just law and regulation, O'Neill provides examples of how cultures[333] can go wrong and undermine the purposes of the organisations in which they are embedded. [334] Her examples are from the financial industry, however equally illustrative is the following healthcare scandal which unfolded at the Bristol Royal Infirmary (mentioned briefly within the Introduction), [335] and the case of Dr Harold Shipman.

The Bristol Royal Infirmary scandal concerned the medical cover-up of poor surgical performance during the 1980s and 1990s, leading to the deaths of 29 children who received heart surgery. The parents of the children who died launched a local support group and complained to the GMC. The GMC investigated three doctors, two of whom were subsequently erased from the medical register. The third had conditions imposed on his registration, including a ban from operating on children for three years in the first instance. The decision to not erase the third doctor resulted in public protests and criticism by the Secretary of State for

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[329] Judith Healy, *Improving Health Care Safety and Quality: Reluctant Regulators* (Ashgate Publishing Ltd. 2011)
[330] Ernst Hirsch Ballin (ed), *A Mission for his Time. Tobias Asser's Inaugural Address on Commercial Law and Commerce, Amsterdam 1862 (*Asser Press 2012)
[331] Onora O'Neill, 'Accountable Institutions, Trustworthy Cultures' (2017) 9 Hague J Rule Law 401
[332] ibid
[333] Numerous healthcare scandals have raised issues of public trust in the culture of medical professionals, however here I focus upon the matter of trust in regulatory bodies.
[334] O'Neill (n 331)
[335] Ian Kennedy, The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984–1995 (Cm 5207, 2001)

Health, who ordered a public inquiry into cardiac surgery for children at the Trust. The public inquiry, led by Sir Ian Kennedy, produced a report (the 'Kennedy Report') highly critical of the hierarchical medical 'club culture' in the Bristol heart unit, and how the GMC had responded to complaints it had received.[336] Public trust in the GMC was severely damaged as a result of the failings.[337] Among its recommendations, the Kennedy Report called for regular appraisal and revalidation of doctors, and better local investigation and management of issues related to registered health care professionals.[338]

Whilst the medical profession was still protesting against these reforms, the case of Dr Harold Shipman also hit the headlines.[339] Shipman was jailed in January 2000 for killing fifteen of his patients throughout the 1990s, however it is estimated that he killed approximately 215 patients in total by administering fatal doses of diamorphine.[340] It became apparent that Shipman was already known to the GMC due to previous concerns about dishonestly obtaining and prescribing opiates (in 1976 he had received a warning from the GMC regarding this matter).[341] The Shipman Inquiry, led by Dame Janet Smith, produced six reports on Shipman's crimes. The fifth report dealt with regulatory procedures, and was exceptionally critical of the GMC, calling the regulator overprotective of doctors.[342] Ultimately, the Inquiry triggered a review of the GMC. This review was led by the Chief Medical Officer at the time, Sir Liam Donaldson. The review recommended substantial reform of the GMC, including a separation between fitness to practice investigation procedures and the adjudication stage.[343] This led to the creation of the Medical Practitioners Tribunal Service (MPTS) to function independently from the GMC's investigatory role. The substantial reform to the GMC resulted in a regulatory body more accountable than ever before, and shifted the balance of power within the GMC

[336] Ian Kennedy, The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984–1995 (Cm 5207, 2001)
[337] Judith Allsop and Kathryn Jones, 'Regulating the regulators: the rise of the United Kingdom Professional Standards Authority' in John Chamberlain and others (eds) *Professional health regulation in the public interest: International perspectives* (Policy Press 2018)
[338] Kennedy (n 336)
[339] John Chamberlain, The Sociology of Medical Regulation: An Introduction (Springer 2013)
[340] Janet Smith, *The Shipman Inquiry Fifth Report: Safeguarding Patients, Lessons from the Past - Proposals for the Future* (Cm 6394, 2004)
[341] Chamberlain (n 339)
[342] Smith (n 340)
[343] Department of Health, 'Good doctors, Safer Patients: Proposals to Strengthen the System to Assure and Improve the Performance of Doctors and to Protect the Safety of Patients' (DH 2006)

from medical professionals to lay members. [344] This shift of power, Chamberlain argues, transformed the GMC from a body which represented doctors, to one which regulated them.[345]

Thus we can see that a failing of culture within the regulatory body, the GMC, led to failings in its functioning, ultimately undermining public trust in the regulator to keep patients safe. The changes which followed introduced, in O'Neill's words 'more law, more regulation and more accountability',[346] and the impact of this cascaded down to the medical profession. For example, revalidation, introduced in response to the Shipman Inquiry's fifth report,[347] is intended to:

> 'assure patients and the public, employers, other healthcare providers, and other health professionals that licensed doctors are practising to the appropriate professional standards. It will also complement other systems that exist within organisations and at other levels for monitoring standards of care and recognising and responding to concerns about doctors' practice.'[348]

However, despite such regulatory changes, healthcare scandals continue to unfold,[349] lending credence to O'Neill's argument that law and regulation alone are insufficient for rendering institutions trustworthy.[350] If the public is to trust healthcare providers, professionals, and their regulators, then culture throughout the healthcare system must be taken into account. When the actions of a regulator are deemed to be trustworthy, then the public will be in a position to consistently place their trust in the regulatory body.

That said, it is not only the public's trust in regulators which is important for ensuring patient safety. In addition to maintaining the public's trust in healthcare professionals and services, regulators need to maintain the trust of regulatees. Regulatory actions perceived as punitive by the profession can result in the regulator losing the trust of its regulatees. For example, a GMC decision to appeal a determination by the Medical Practitioners Tribunal

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[344] Chamberlain (n 339)
[345] ibid
[346] O'Neill (n 331)
[347] Smith (n 340)
[348] NHS England, 'What is Revalidation?' <https://www.england.nhs.uk/medical-revalidation/about-us/what-is-revalidation/> accessed 23 September 2021
[349] Shaun Lintern, 'I helped expose the Mid Staffs hospital scandal – and fear the NHS is about to repeat its worst mistakes' *Independent* (15 January 2020) <https://www.independent.co.uk/voices/nhs-mid-staffs-hospital-care-crisis-a9284856.html> accessed 21 October 2021
[350] O'Neill (n 331)

Service (MPTS) and call for the removal of a paediatrician from the medical register caused widespread outrage amongst the medical profession.[351] Writing to the Chair of the GMC, a Director of a hospital trust accused the GMC of undermining patient care by 'endorsing and promoting a blame ethos that is inimical to safety'.[352] An independent review commissioned by the GMC after this event found that doctors' trust in the GMC had been severely damaged. It stated that the GMC can only support doctors to deliver good medical practice if doctors feel able to engage constructively with the regulator, and have confidence that processes will 'be proportionate, fair and just'.[353] Regulatees respond positively to respectful, supportive approaches,[354] and are more inclined to accept outcomes which might not otherwise appear to be in their interests if they feel they have been treated fairly.[355] If regulatees trust the regulator, then compliance with regulatory requirements increases. By contrast, where healthcare providers lack trust in regulators, the quality of care provided to patients suffers.[356] Thus, any regulatory response needs to be careful to not unintentionally negatively impact patient safety by further fostering a culture of fear and blame.

This leads to the question of what constitutes a trustworthy regulatory action. Working on the basis that it is perhaps not always more regulation that is required in response to safety incidents, and that culture can play a significant role, I take the stance in this thesis that regulatory responses should foster the notion of a just culture within healthcare. The following subsection demonstrates how trust and a just culture are closely entwined, and how an ethical regulator must take both into account to ensure its actions are ethical.

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[351] Pulse Today, 'GMC was advised to appeal Bawa-Garba case to 'protect reputation of profession'' (2019) <http://www.pulsetoday.co.uk/news/all-news/gmc-was-advised-to-appeal-bawa-garba-case-to-protect-reputation-of-profession/20039140.article> accessed 19 December 2019

[352] Nick Ross, 'Letter to the GMC Chair Regarding Hadiza Bawa-Garba' (BMJ, 18 January 2018) <https://www.bmj.com/con tent/360/bmj.k195> accessed 8 August 2021

[353] Leslie Hamilton, 'Independent review of gross negligence manslaughter and culpable homicide' (2019) available at: https://www.gmc-uk.org/-/media/documents/independent-review-of-gross-negligence-manslaughter-and-culpable-homicide---final-report_pd-78716610.pdf <accessed 12 October 2021>

[354] Healy (n 329); Tom Tyler, 'Procedural Justice, Legitimacy, and the Effective Rule of Law' (2003) 30 Crime and Justice 283

[355] John Braithewaite and T Makkai, 'Trust and compliance' (1994) 4 Policing and Society 1; Kristina Murphy, 'The Role of Trust in Nurturing Compliance: A Study of Accused Tax Avoiders', (2004) 28 Law and Human Behavior 187

[356] Sumit Kane and others, 'Trust and trust relations from the providers' perspective: the case of the healthcare system in India' (2015) 12 Indian Journal of Medical Ethics 157

4.2 Just Culture: Being fair to healthcare professionals and patients

In addition to highlighting how the GMC's culture had been problematic for patient safety, the Kennedy Report also pointed out that the NHS was failing to learn from its mistakes, and that 'blame culture' was acting as a major barrier to openness and learning from error.[357] As discussed in subsection 1.4 of this thesis, a blame ethos poses a risk to candour which may lead to errors being hidden rather than learned from – thus jeopardizing future patient safety.[358] Moreover, as discussed in the previous subsection, where regulatees lack trust in their regulators, the quality of care provided to patients can suffer.[359]

By contrast, within a just culture, people are able to be open about their mistakes, or to raise their safety concerns, without fear of being unfairly blamed and facing unwarranted regulatory attention.[360] A just culture *must* however be fair to both doctors and patients, because patients deserve more than an absence of deliberate harm – they deserve safe care which promotes their health.[361]

As mentioned in subsection 1.4 of this thesis, within the NHS there has been a significant drive to create a just culture that balances fairness, justice, learning, and accountability.[362] In Part Four of this thesis, I argue that it is unclear what various actors mean when they use the term 'accountability' within the healthcare system. This leads to confusion about who or what is to be held accountable when things go wrong. In summary, accountability has a dual nature; it is used both to punish individuals and as a tool to aid learning. The former is what Sharpe terms 'backward-looking accountability', whilst the latter is 'forward-looking

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[357] Kennedy (n 336)
[358] National Advisory Group on the Safety of Patients in England, '*A Promise to Learn – A Commitment to Act: Improving the Safety of Patients in England'* (Crown Publishing 2013); NHS England and NHS Improvement, 'The NHS Patient Safety Strategy: Safer Culture, Safer Systems, Safer Patients' (NHSE&I 2019) <https://improvement.nhs.uk/documents/5472/190708_Patient_Safety_Strategy_for_website_v4.pdf> accessed 28 August 2020
[359] Kane (n 356)
[360] Sidney Dekker, Just Culture: Balancing Safety and Accountability (CRC Press 2012)
[361] James Titcombe, Peter Walsh and Cicely Cunningham, 'A just culture for both staff and patients' (2019) Health Service Journal <https://www.hsj.co.uk/patient-safety/a-just-culture-for-both-staff-and-patients/7025942.article> accessed 28 July 2020; Norman Daniels, *Just Health: Meeting Health Needs Fairly* (Cambridge University Press 2008)
[362] Dekker (n 360); NHS Resolution, 'Being Fair: Supporting a just and learning culture for staff and patients following incidents in the NHS' (NHS Resolution, 2019) <https://resolution.nhs.uk/wp-content/uploads/2019/07/NHS-Resolution-Being-Fair-Report-2.pdf> accessed 31 August 2021

accountability'.[363] Backward-looking accountability is retrospective and often involves blaming somebody when something has gone wrong.[364] Although backward-looking accountability is perhaps the more common notion within healthcare, Sharpe argues that it is forward-looking accountability that is key to establishing a culture that is just and safe. Forward-looking accountability means creating a culture in healthcare where it is safe for staff to discuss errors and analyse them, to speak up about potential safety problems, and to implement steps to prevent safety incidents from recurrence[365] - precisely what a just culture aims to achieve.

Part Four of this thesis takes an incident which occurred at the start of 2020 as its focus in order to explore the GMC's conceptualisation of accountability and how it fits within a just culture. A shortage of hospital beds at Royal Cornwall Hospitals NHS Trust led to doctors being asked by management to quickly discharge patients, despite recognising it might not be safe to do so.[366] This led to concerns amongst doctors about the potential regulatory consequences for themselves.[367] The regulator's use of accountability is significant because the GMC states within its professional standards that doctors are personally accountable. The professional standards do not define accountability, but, as will be explained in Part Four, these standards function as a mechanism through which the GMC can hold doctors accountable - indicative of backward-looking accountability. At the same time, the GMC also uses language associated with forward-looking accountability. For example, the regulator accepted recommendations from its independent review into gross negligence manslaughter - which included promoting a fair and just culture throughout the NHS.[368] The GMC further stated that further training for its investigators would assure doctors that 'their actions will be seen clearly

[363] Virginia Sharpe, 'Promoting Patient Safety: An Ethical Basis for Policy Deliberation' (Hastings Center Report 2003)
[364] ibid
[365] ibid
[366] Denis Campbell, 'Cornwall Hospital to Discharge Patients Early Despite Saying it may be Harmful' *The Guardian (*London, 14 January 2020) <https://www.theguardian.com/society/2020/jan/14/cornwall-hospital-to-discharge-patients-early-despite-risks> accessed 30 January 2020
[367] David Oliver, 'The risks of discharging patients early against doctors' judgment' (2020) 368 British Medical Journal < https://www.bmj.com/content/368/bmj.m210> accessed 21 March 2021
[368] General Medical Council, 'GMC statement following the publication of the independent review of gross negligence manslaughter and culpable homicide in medical practice' (GMC 2019) <https://www.gmc-uk.org/news/news-archive/gnm-statement> accessed 21 October 2021

against the backdrop of any system failings'.[369] The full implications of this dual nature of accountability are presented in Part Four.

Establishing a just culture throughout the healthcare system is central to ensuring the public's trust in healthcare professionals and providers, and the trust of healthcare professionals in their regulators. As such, actions that promote a just culture and are trustworthy are integral to being an ethical regulator. The following subsection builds upon Sharpe's assertion that forward-looking accountability entails taking steps to prevent safety incidents from reoccurrence. I argue that actively taking responsibility to prevent harm is a further component of ethical regulation.

4.3 Prevention of Future Harm

As explored in the introduction to this thesis, safety issues associated with the discharge process are common throughout the NHS, and remain largely unaddressed by regulatory bodies. It is likely that one of the reasons for this is a diffusion of responsibility within the healthcare system, which can give rise to a 'problem of many hands'.[370] Van de Poel and colleagues write that 'a problem of many hands occurs if there is a gap in a responsibility distribution in a collective setting that is morally problematic'.[371] This gap is morally problematic for two reasons. Firstly, because people are likely to find it morally unsatisfactory if a disaster occurs and no one is held responsible. Secondly, because the reason for attributing moral responsibility is the desire to learn from mistakes and to do better in future; this may not happen if no one is held morally responsible.[372] There is a clear parallel between this notion of moral responsibility and Sharpe's notion of forward-looking accountability; both share the aim of learning from error and preventing future harm. The remainder of this subsection will now explain how the hospital discharge process is impacted by the problem of many hands, and how this problem exists amongst regulatory bodies. It will then outline how an ethical

[369] General Medical Council, 'Human factors training to be rolled out for investigators' (GMC 2020) <https://www.gmc-uk.org/news/news-archive/human-factors-training-to-be-rolled-out-for-investigators> accessed 15 July 2020

[370] Dennis Thompson is credited with coining the phrase. See Dennis Thompson, 'Moral Responsibility and Public Officials: The Problem of Many Hands' (1980) 74 American Political Science Review 905

[371] Ibo Van de Poel and others, 'The Problem of Many Hands: Climate Change as an Example' (2012) 18 Science and Engineering Ethics 49, 63

[372] Ibo Van de Poel and others (eds), *Moral Responsibility and the Problem of Many Hands* (Routledge 2015), 4

regulatory body might seek to address this problem, with the aim of preventing future harm to patients. This, I conclude, is another key aspect of ethical regulatory responses.

The hospital discharge process is a clear example of a process that involves a distribution of responsibility for patient safety. Indeed, a qualitative study of hospital discharges by Waring and colleagues found that discharges generally involve multiple health and social care actors, who have to coordinate specialist activities so that patients receive integrated and safe care.[373] Responsibility for these discharges is often 'dispersed and fragmented' within the healthcare system, and is often handed-over as the patient transitions between settings.[374] Waring and colleagues suggest that discharges represent the transfer of professional responsibility for the patient, and that this might explain why stakeholders were not always compelled to engage in activities outside of their sphere of responsibility. This in turn leads to problems with continuity of care and poses a risk to patient safety. [375]

Furthermore, research into patient experiences of NHS administration highlights how patients fail to receive a joined-up care experience when services and clinical staff (including, for example consultants, psychiatrists, GPs, operational staff) do not communicate with each other. Staff members and services were said to blame each other when patients or clinicians were not aware of important information, and that these communication failures exposed patients to unnecessary risks. One interviewee stated, 'No one takes responsibility in admin... there is endless finger pointing and feedback is ignored.'[376] Another observed, 'There is very little interaction between NHS and social care in my city… Services don't interact when people are ill. Nasty, blaming letters are flying about – this is the last thing that's needed in a difficult situation'.[377] The researchers conclude that when it comes to coordinating joined-up care, accountability and responsibility are either not explicit amongst staff themselves, or are not communicated to patients. [378]

This problem of many hands exists amongst regulatory bodies as well as healthcare professionals. As this thesis will demonstrate in Part Two, patient safety incidents may not

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[373] Justin Waring, Simon Bishop and Fiona Marshall, 'A Qualitative Study of Professional and Carer Perceptions of the Threats to Safe Hospital Discharge for Stroke and Hip Fracture Patients in the English National Health Service' (2016) 16 BMC Health Services Research 1
[374] ibid
[375] ibid
[376] National Voices, 'Paper Works: The Critical Role of Administration in Quality Care' (National Voices 2021) 10
[377] ibid 11
[378] ibid

elicit a response from any particular regulator if it is deemed to fall outside the boundaries of their perceived remit. By way of example, an MoU between the GMC and CQC demonstrates the GMC's interest in receiving information from the CQC if foundation doctors are found to be signing discharge letters that have been written by others and relate to patients they have never examined. [379] This interest is out of concern that the action might give rise to a patient safety concern or suggest issues with bullying.[380] By requesting such specific information on discharges (this is the only instance where discharges are mentioned in the MoU), the GMC *may* unintentionally be indicating that other discharge-related harms to a patient, for example a harm to dignity, are not a matter of interest. Yet it would be unusual for the GMC to not have an interest in the latter as respect for patient dignity is a central feature of the GMC's expectations of doctors.[381] Thus this example illustrates one of the difficulties which can arise where many regulators are involved – responsibility for taking action becomes obscured.

In order to address the problem of many hands, Fahlquist introduces the notion of responsibility-as-virtue and argues that this may help to avoid the problem of many hands. [382] Using the example of the Deepwater Horizon Spill[383] in 2010, she notes that this was not the first time that the activities of BP (the company responsible) had resulted in harm. In 2005, a BP oil refinery had exploded in Texas City. It was found that BP had, amongst several other failings, ignored safety and environmental regulations.[384] Fahlquist argues that although in many ways BP acted in ways which are blameworthy (responsibility-as-blameworthiness), it is clear that at some point, someone neglected to take forward-looking-responsibility.[385] Fahlquist argues that failing to take forward-looking-responsibility can mean a person fails to act in a responsible manner (responsibility-as-virtue). Responsible people, she argues, seek to avoid risks to people's health and lives, and do everything in their power to reduce the negative impact of their own actions.[386]

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[379] CQC and GMC, 'Operational Protocol: A practical guide for staff - for external use' (2018) <https://www.cqc.org.uk/sites/default/files/20181205_cqc-gmc_joint_operational_protocol_redacted.pdf> accessed 19 December 2019)
[380] ibid 32
[381] General Medical Council, 'Good Medical Practice' (2013)
[382] Jessica Fahlquist, 'Responsibility as a Virtue and the Problem of Many Hands' in Ibo Van de Poel and others (eds), *Moral Responsibility and the Problem of Many Hands* (Routledge 2015)
[383] This was a 2010 industrial disaster and is considered to be one of the largest marine oil spills
[384] Fahlquist (n 382)
[385] ibid
[386] ibid

This line of thinking is grounded in virtue ethics – an ethical theory concerned with character traits. Drawing upon various accounts of responsibility as a virtue, Fahlquist determines that the common characteristics of responsibility-as-virtue are that: responsibility is forward-looking; focused on the person and her relations to other people; requires the person seeing herself as part of a greater context; and the person acts in a certain way over time. Importantly, a virtuous person feels responsible for more than what she directly causes. [387] The character traits this involves are: care, moral imagination, and practical wisdom. Having these traits means an agent cares about other people, has the emotional ability to imagine what the risks of an activity might be, and the cognitive ability to transform any concerns into actions.[388] These traits, according to Fahlquist, should not be an unreasonable ask of someone involved in a risk-generating activity (such as healthcare provision). Moreover, organisations can encourage these virtues in individuals via training and establishing an internal culture conducive to ethical behaviour.[389]

Turning to the question of how responsibility-as-virtue can avoid the problem of many hands, Fahlquist argues that there are two manners in which this may happen. First, virtuous agents will assume more responsibilities-as-obligations (the duty to do X), meaning that if an undesirable incident occurs, there will be more accountability for its occurrence. Secondly, a virtuous agent may take forward-looking responsibility for something even if they are not individually blameworthy. Indeed, staff within the NHS may already be acting as virtuous agents in this sense. Consider, for example, the findings of an HSIB investigation into outpatient appointments which are intended but not booked after inpatient stays.[390] The investigation found staff were inventing their own methods to reduce the likelihood of not booking necessary follow-up appointments. One ward clerk kept their own book in order to write down appointments that needed arranging, and would then tick these off once complete. Another made sure that patients had their follow-up appointments booked before they left the ward.[391] These behaviours are examples of individual agents take responsibility for something which plays a critical role in patient safety. A virtuous agent may also take forward-looking responsibility for something for which they are not individually blameworthy by taking

[387] ibid 192
[388] ibid
[389] ibid
[390] HSIB, 'Outpatient Appointments Intended but not Booked after Inpatient Stays' (HSIB 2021)
[391] ibid

responsible to do better in future – for example by analysing previous 'wrongs' in order to avoid future harm.[392]

In this sense, Fahlquist's use of forward-looking responsibility has similarities with Sharpe's definition of forward-looking accountability, which involves creating a work culture where it is safe to analyse errors and raise potential safety issues, and to implement steps to prevent safety incidents from recurrence.[393] In this thesis, I use 'forward-looking accountability' in explaining how accountability is conceptualised by various bodies throughout the healthcare system. Fahlquist's notion of responsibility-as-virtue, which includes forward-looking responsibility, captures a concept perhaps more suited to an individual virtuous agent than an organisation. However, the latter is still helpful in determining how regulation could improve. This is because regulators which support and encourage the development of responsibility-as-virtue amongst their own staff may find that employees then become aware of, and raise, threats to patient safety typically conceptualised as being outside of the regulator's remit. This awareness and willingness amongst staff to address these threats and prevent future harm should then encourage ethical regulatory bodies to act. Thus, individuals being responsible in this manner (responsibility-as-virtue) enables regulators to deliver ethical regulatory actions to prevent recurrent harm to patients (forward-looking accountability).

4.4 Chapter Four Conclusion

This chapter has provided an overview of the elements which, combined, constitute an ethical regulatory response to patient safety incidents. It has argued that actions which ensure public trust in healthcare providers and professions are necessary to ensure people seek out healthcare when needed. Furthermore, regulatory bodies must have the trust of their regulatees to enhance compliance with standards. Gaining this trust requires regulatory actions which are fair to both patients and healthcare professionals (a just culture). An ethical regulatory response is also one which promotes accountability throughout the healthcare system for prevention of future harm to patients.

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[392] Fahlquist (n 382)
[393] Sharpe (n 363)

Chapter Five: Approach

This chapter aims to explain and justify my research approach. To do this, I start by reflecting upon my motivations for my choice of topic and methodology.

My professional background was a strong influence upon my decision to commence this research. My experience working for both the General Medical Council (GMC) and the Medical Practitioners Tribunal Service (MPTS) meant I had a good understanding of the nature of fitness to practice concerns that the GMC investigates. I was acutely aware of how the medical profession experiences regulation, and of how the public understands the purpose of regulation. This professional knowledge and experience provided me with insight into the challenges regulators face, and an understanding of how decisions are made regarding which safety issues to investigate.

As stated earlier in this thesis, the discharge process is internationally recognised as a dangerous time for patients. However, during my time at the GMC, I was not aware of any fitness to practice cases specifically relating to the discharge process, nor of any action that the regulator was taking to tackle this problem. I was also unable to locate any academic literature tackling this specific safety issue and regulatory responses to it, making it ripe for research.

The research is funded by the National Institute for Health Research (award ref NIHR-INF-0702) which funds research that benefits the NHS. This influenced my decision to focus upon the regulation of the hospital discharge process within the NHS, as opposed to in other countries where the findings might not translate easily into the NHS context. I then chose to focus upon England rather than the whole of the United Kingdom in order to be able to take a holistic overview of one healthcare system and its regulators. Although some of the professional regulators have a remit over all four nations, the healthcare providers are regulated by separate bodies. For example, the Care Quality Commission regulates healthcare providers in England, however its remit does not stretch to Northern Ireland, Scotland, or Wales. How the NHS is structured is not consistent across the devolved nations, and neither is the legal framework.

At the outset, I anticipated - or possibly assumed - that this might influence the nature of the problems I identified through my research. As such, I chose to focus upon one country only. Having familiarity with the legal system and NHS within England influenced me to focus upon England; however, the findings may be applicable across the UK. In particular, Part

Four's critique of the GMC's professional standards is broadly applicable as doctors across the UK are held to the same standards.

As mentioned in the Introduction and Chapter 2.2, in the very early stages of considering my approach to this research, I considered undertaking a comprehensive analysis of coroners' Prevention of Future Death reports. I had assumed this might reveal how frequently the discharge process was contributing to the deaths of patients and how recipients of reports (for example hospital trusts) were acting in response to the recommendations. From this I then planned to submit freedom of information requests to regulators to see how they were monitoring responses and the implementation of changes. However, the manner in which the PFD reports are presented on the judiciary website makes it difficult to analyse their content. Reports are commonly scans or photos of images and are of variable quality, and some are in PDF format. There is no function to perform a key word search, so each individual report has to be read to ascertain its potential relevance. Responses to reports were not always published. It is possible that this might be because responses were not received, or perhaps that a decision had been made by the Chief Coroner not to publish them.

In light of these challenges to obtaining the data, and also because it was unclear at the time how fruitful the endeavour would be, I decided to not continue with this avenue of research. To continue would have risked having insufficient time within the timescale for the project to dedicate to the other problematic elements of regulation that I had identified and wished to examine in depth. Moreover, I felt the issues with the effectiveness of PFD reports were not unique to the discharge process (where I wish to focus my attention), but were applicable to the broader issue of how to improve patient safety within the NHS.

My initial decision to exclude empirical methodologies was also partly due to time constraints. In addition, I lacked a background in empirical research and the associated skillset, and learning these methods would have needed factoring in to my timescales. Furthermore, I felt that theoretical insight could cast a new light on issues; the use of liminality as a lens was particularly effective in this regard. Thus, although empirical research could also have made a novel contribution to understanding why regulation is suboptimal in the context of discharges, my chosen approach – which I expand upon below – presents an original, interdisciplinary examination of regulation within the context of hospital discharges.

In the remainder of this chapter, I demonstrate how regulatory theory provides a useful, but essentially inadequate basis upon which to build my approach. To contextualise this

inadequacy, I turn to the fields of patient safety, bioethics, and anthropology. From the latter I borrow a key concept – liminality – as a lens for viewing issues within regulation. Liminality refers to the transitional stage of an experience, and more is said on this below. However, this thesis is not grounded within the anthropology of regulation; a methodology which Dove argues contains liminality as an integral component.[394] Rather, it recognises that liminality 'accords well with regulatory theory'[395] and seeks to exploit this accordance. Subsection 5.3 will discuss how supplementing regulation theory with liminality provides a richer understanding of regulators and their responses to safety incidents.

5.0 Regulation theory

As stated in the preceding chapters, healthcare regulators have a legal and ethical duty to protect the public through the regulation of healthcare professionals, providers, and processes. Patients are particularly vulnerable during hospital discharges, and yet regulators have been largely silent on this issue. It is therefore necessary to examine and question the effectiveness of a system which fails to protect patients during this vulnerable point in their care.

Regulatory theory is critical to my thesis in that it enables the articulation of two central issues in the current regulatory landscape in England. The first issue, that of difficulties with the approach of risk-based regulation, has been previously highlighted by legal scholars.[396] For the first time, this thesis shows the impact of these difficulties in the context of regulating the hospital discharge process. The second issue relates closely to the first; the vast number of regulatory bodies utilising risk-based regulation results in significant variation in how risks are identified, conceptualised, and prioritised. As will be argued in Part Two, this is particularly problematic when regulating complex processes like hospital discharge.

Whilst regulatory theory is invaluable for critiquing regulatory approaches, on its own it is insufficient to contextualise the environment within which healthcare regulators are acting.

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[394] Edward Dove, Regulatory Stewardship of Health Research: Navigating Participant Protection and Research Promotion (Edward Elgar Publishing Ltd 2020)
[395] ibid 99
[396] See for example: Anne Laure Beaussier and others, 'Accounting for Failure: Risk-based Regulation and the Problems of Ensuring Healthcare Quality in the NHS' (2016) 18 Health, Risk & Society 205; Robert Baldwin and Judith Black, 'Driving Priorities in Risk-based Regulation: What's the Problem?' (2016) 43 Journal of Law and Society 565; Anne-Maree Farrell, The Politics of Blood: Ethics, Innovation and the Regulation of Risk (Cambridge University Press 2014)

This is because it does not fully capture the perspectives of regulatees and patients, nor does it provide a nuanced understanding of the system complexities which give rise to a patient safety incident. For this, I turn to the fields of patient safety, bioethics, and anthropology (from which I borrow the concept of liminality). Combined, these three considerations paint a rich picture of what regulators must consider when determining their actions, however, they do not illuminate a clear path for improvement. As will be explained later in this chapter, liminality is of particular value in seeking this path.

5.0.1 Introducing the Regulatory Arena

I use the term 'regulatory arena*'* to refer to the regulatory environment within which regulation takes place. A more common term is 'regulatory space*'* - coined by Hancher and Moran.[397] I use *arena* in place of *space* purely to minimise confusion between this and the concept of 'liminal space' which will shortly be introduced. Conceptually however, both regulatory arena and regulatory space are the same. 'Regulatory arena' refers to the environment within which regulation takes place; which includes the actors within the space, alongside wider factors such as the legal system, socio-cultural influences, and the relationship dynamics between actors.[398] Rather than flowing hierarchically, power and influence within the arena can be exercised horizontally and vertically by actors seeking to modify the behaviour of each other,[399] creating what Morgan and Yeung refer to as a 'reflexive process of influence and change within'.[400]

Regulatory arenas can be defined broadly and narrowly. [401] Whereas a broad definition might be employed when considering all impacts upon patient safety within the English NHS, I focus more narrowly on the regulatory arena concerned with the safety of hospital discharges. This arena involves not only statutory regulators, but multiple others with a shared aim of patient safety at the point of discharge – for example patient groups, charities, Royal Colleges,

[397] Leigh Hancher and Michael Moran, Organizing Regulatory Space, in Leigh Hancher and Michael Moran (eds), Capitalism, Culture and Economic Regulation (Oxford University Press 1989) 271–300
[398] Eric Windholz, Governing through Regulation: Public Policy, Regulation and the Law (Routledge 2018) 71
[399] ibid 71
[400] Bronwen Morgan and Karen Yeung, An Introduction to Law and Regulation (Cambridge University Press 2007) 76
[401] Windholz (n 398) 70-72

and the NHS itself. However, it is regulators' actions that are central to my thesis, due to their statutory obligations to protect patients.

It has been argued that one weakness of the regulatory space metaphor is its difficulty in 'accounting for the boundaries of regulatory spaces and in explaining the different dimensions that characterize the "topology" of the space—notably: the relative power of the different actors; the distribution of resource dependence relevant to the space; and the nature of the communication flows between actors'.[402] In response to this criticism, Dove argues that liminality is key to helping us understand the in-between spaces within the regulatory space.[403] As explained later in this section, I too use liminality to bring into focus, and make sense of, these in-between spaces which have to-date been largely neglected by healthcare regulators, policy-makers, and academics.

5.0.2 Regulatory approaches: Risk-based regulation and upstream regulation

Within the regulatory arena, a range of strategies are employed by regulators to achieve their goals.[404] Risk-based regulation, intended to focus regulators' interventions upon the threats which pose the greatest risk to its objectives as opposed to aiming to prevent *all* possible harm[405], is the dominant approach to regulation within UK healthcare. The 2005 Hampton Report[406] strongly endorsed risk-based approaches by describing them as essential for efficiently directing regulatory resources to where they can have maximum impact upon outcomes. The report warned that a failure to use risk assessments effectively means resources may not be targeted at the riskiest areas. In 2007, the Government's response to several healthcare scandals[407] confirmed that future regulation of both healthcare professionals and healthcare regulation should be fully informed by the proposals within the Hampton Report.[408]

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[402] Robert Baldwin, Martin Cave and Martin Lodge, Understanding Regulation: Theory, Strategy, and Practice (Oxford University Press 2011) 65
[403] Dove (n 394)
[404] Peter Drahos, Regulatory Theory (ANU Press 2017); Robert Baldwin, Martin Cave and Martin Lodge, Understanding Regulation: Theory, Strategy, and Practice (Oxford University Press 2011)
[405] Beaussier and others (n 396)
[406] Phil Hampton, 'Reducing Administrative Burdens: Effective Inspection and Enforcement' (HM Treasury 2005)
[407] Department of Health, 'Safeguarding Patients: The Government's response to the recommendations of the Shipman Inquiry's fifth report and to the recommendations of the Ayling, Neale and Kerr/Haslam Inquiries' (Cm 7015, 2007)
[408] ibid para 2.23

Risk can be characterised as the possibility of an undesirable incident occurring, either as a result of natural events or human activities, or due to a combination of both.[409] Within healthcare, a core purpose of regulation is to minimise harm to patients. This means the possibility that patients will be harmed is an undesirable occurrence; a risk that regulators wish to reduce. As Farrell notes, in order to determine whether risk-based regulation is effective we need to take account of whether the approach meets its stated aims and objectives.[410] In this thesis, I build upon existing academic literature to analyse how effective risk-based regulation is as a strategy for keeping patients safe during the discharge process.

In addition to the strategy of risk-based regulation, 'upstream regulation' is an emerging area of interest in healthcare regulatory policy. The concept refers to the potential regulators have to contribute to harm prevention; i.e. becoming more 'upstream' of problems before they arise.[411] In a speech in February 2019,[412] Alan Clamp, Chief Executive of the PSA, observed that across the professional regulators there is currently a 'strong move towards "upstream regulation", to being proactive and preventative rather than reactive, to move away from fitness to practice and more towards the emphasis on education and training'.[413]

The GMC describes its upstream approach as a move towards 'pro-active, early and specific interventions in order to either decrease the likelihood of an undesirable outcome or to increase the likelihood of a more favourable outcome'.[414] The salient point of upstream regulation for the purpose of my thesis is that it indicates an acknowledgement from regulators that *prevention* of harm is important. This is indeed welcome given that risk-based regulation has faced criticism for its tendency to focus efforts upon managing consequences rather than addressing root causes.[415] Therefore, when determining the efficacy of regulatory actions, the focus in this thesis is not simply upon regulators' responses to incidents, but also upon how

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[409] Julia Black, 'The Role of Risk in Regulatory Processes' in Robert Baldwin, Martin Cave and Martin Lodge (eds), The Oxford Handbook of Regulation (Oxford University Press 2010)
[410] Farrell (n 396) 199
[411] Professional Standards Authority, 'Right-Touch Reform: A New Framework for Assurance of Professions' (2017) <https://www.gov.uk/government/consultations/promoting-professionalism-reforming-regulation> accessed 25 February 2019
[412] Alan Clamp, 'Next Steps for Professional Healthcare Regulation Reform' (Speech at Westminster Health Forum, London, February 2019)
[413] ibid
[414] General Medical Council, 'Executive Board Meeting' (2018) <https://www.gmc-uk.org/-/media/documents/08—the-harms-reduction-programme-progress-update_pdf-75445141.pdf> accessed 19 November 2020, 53
[415] Mark Flear, 'Epistemic Injustice as a Basis for Failure? Health Research Regulation, Technological Risk and the Foundations of Harm and Its Prevention' (2019) 10 European Journal of Risk Regulation 693

effectively they prevent future harm. As discussed in the previous chapter, prevention of future harm is important for ensuring regulatory responses are not only effective, but also ethical.

5.1 The Field of Patient Safety

The first chapter of this thesis explains how patient safety emerged as a discipline once it became apparent that adverse medical events are not only widespread, but often preventable.[416] It is estimated that approximately one in 20 patients within the UK experience preventable harm.[417] Several academics within this discipline have argued that errors are often beyond an individual's control, and are instead influenced by a wide range of factors.[418]

Hospital discharge is a prime example of a process where multiple factors threaten its safety.[419] Recognising this means that my thesis does not endorse regulatory approaches which might be considered as contributing to blame culture. Rather, I aim to identify regulatory solutions which foster a just culture within healthcare, and which will improve the quality of care future patients receive as they are discharged from hospital.

5.2 (Bio)ethics

Bioethics, at its core, is 'about the question of the morally right way to deal with possibilities offered by biology and medical science'.[420] It is 'a systematic study of the moral dimensions — including moral vision, decisions, conduct and policies—of the life sciences and health care,

[416] Linda Emanual and others, 'What Exactly Is Patient Safety?' in: Kerm Henriksen and others (eds.) Advances in Patient Safety: New Directions and Alternative Approaches (Vol. 1: Assessment, Agency for Healthcare Research and Quality 2008)
[417] Maria Panagioti and others, 'Preventable Patient Harm across Health Care Services: A Systematic Review and Meta-analysis' (A Report for the General Medical Council, 2017) <https://www.gmc-uk.org/-/media/documents/preventable-patient-harm-across-health-care-services_pdf-73538295.pdf
[418] Lucian Leape, 'Error in medicine' (1994) 272 Journal of the American Medical Association 1851; Marilyn Bogner (ed), Human error in medicine (Lawrence Erlbaum 1994); James Reason, 'The human factor in medical accidents' in: Charles Vincent and others (eds.) Medical Accidents (Oxford University Press 1993); Virginia Sharpe, 'Promoting patient safety: An ethical basis for policy deliberation' (Hastings Center Report 2003); Justin Waring, Fiona Marshall, and Simon Bishop, 'Understanding the Occupational and Organizational Boundaries to Safe Hospital Discharge' (2015) 20 Journal of Health Services Research & Policy 35
[419] Waring and others (n 418)
[420] Marcus Düwell. *Bioethics: Methods, Theories, Domains* (Taylor & Francis Group 2012) 8

employing a variety of ethical methodologies in an interdisciplinary setting'.[421] How regulators choose to respond to PSIs is thus closely entwined with bioethics; for the impact of regulatory actions up on healthcare professionals and providers directly impacts upon the quality of healthcare patients receive. As discussed in Chapter Four, underpinning this thesis is the view that an ethical regulatory response to a patient safety incident:

- maintains public trust in healthcare providers and professionals
- is fair to both patients and professionals
- promotes accountability throughout the healthcare system for prevention of harm to patients (including harm to dignity)

Regulatory responses which are perceived as unjust by those working in healthcare may contribute to a culture of fear and blame and damage regulatees' trust in the regulator. Such a culture can adversely impact upon patient safety, and should therefore be avoided if possible. By contrast, a just culture within healthcare is central to ensuring patient safety. However, within a just culture, regulators must nevertheless ensure that accountability is appropriately articulated and safeguarded. The article which comprises Part Four of this thesis focusses upon regulatory accountability within the context of hospital discharges.[422]

My inclusion of harm to dignity in my definition of a patient safety incident is ultimately a decision influenced both by existing bioethical literature and by wider moral discourse. Arguably, it is a concept deserving of more attention within bioethics. For as Shale observes, bioethics remains centrally concerned with 'articulating and applying moral norms relevant to fateful decisions in medical treatment and research'.[423] This is despite research demonstrating that patients value confidence and trust in their healthcare provider, and treatment with respect and dignity over autonomy and shared decision-making.[424]

Critics of dignity have argued that it is vague and therefore lacks precise meaning.[425] In defending dignity against this charge, Árnason acknowledges that although it might be vague, this is a feature shared with other moral concepts (such as justice and autonomy), and does not

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[421] Warren Reich, *Encyclopaedia of Bioethics* (Macmillan 1995) 21
[422] Victoria Moore, 'Doctors, Decisions, and Discharges: Regulatory Accountability for Patient Safety in a Just Culture' (2020) 36 Journal of Professional Negligence 171
[423]Suzanne Shale, *Moral Leadership in Medicine: Building Ethical Healthcare Organisations* (Cambridge University Press 2012) 230
[424] ibid; Steven Joffe, 'What do Patients Value in their Hospital Care? An Empirical Perspective on Autonomy Centred Bioethics' (2003) Journal of Medical Ethics 103
[425] Vilhjálmur Árnason, 'In Defense of Dignity: Reflections on the Moral Function of Human Dignity' (2020) Bioethics 31

preclude the term from being used clearly in certain contexts.[426] Moreover, he argues that the vagueness enables the term to be used for governance purposes; as people can agree upon 'policy statements aimed to protect humans from degrading treatment, regardless of the different cultural, religious or other ideological framing of their intuitions'.[427]

The importance of respecting a patient's dignity is reflected within the standards set for healthcare professionals by their regulatory bodies[428] and the CQC's fundamental standards.[429] Despite this emphasis, the concept is undefined within the professional codes, leaving healthcare professionals without practical guidance. Caulfield and Brownsword argue that, because of this vagueness, a requirement to respect human dignity fails to provide a clear steer to regulatees, making it difficult both for regulatees to demonstrate compliance and for regulators to enforce it.[430] Given that undignified care 'renders individuals invisible, depersonalises and objectifies people, is abusive or humiliating, narrowly focused and disempowers the individual'[431], regulators should ensure this harm is avoided. As highlighted in the Introduction, the hospital discharge process can pose a risk to patients' dignity if patients are left alone in unsuitable home environments unable to attend to their basic needs. Regulatory responses to this harm to dignity are important for not only maintaining public trust in healthcare providers and professionals, but also as a fairness to patients.

5.3 Liminality

Flear strongly criticises bioethics on the grounds that 'bioethics usually privileges and bolsters scientific-technical knowledge, erases social context, and renders social elements as little more than "epiphenomena"'.[432] He argues it focusses too heavily on individual ethical conduct rather than systemic issues related to social justice. He further argues that when operating within risk-

[426] ibid
[427] ibid 35
[428] For example, see paragraph 25 of 'Good Medical Practice' (General Medical Council 2013); paragraph 1 of 'The Code' (Nursing and Midwifery Council 2015); standard 1 of 'Standards for Pharmacy Professionals' (General Pharmaceutical Council 2017); section 2.2 of 'Professional Standards' (Social Work England 2019); and 'The Fundamental Standards' (Care Quality Commission 2019)
[429] Care Quality Commission (n 428)
[430] Timothy Caulfield and Roger Brownsword, 'Human dignity: a guide to policy making in the biotechnology era?' (2006) 7 Science and Society 72
[431] Win Tadd and others, 'Dignity in Practice: An exploration of the care of older adults in acute NHS Trusts' (HMSO 2011) 10
[432] Flear (n 415)

based framings, bioethics installs an expert rationality.[433] An 'expert rationality' is one which frames risks as a matter for experts; thus affording the scientific community a gatekeeping role.[434] This rationality informs the relationship between regulators and stakeholders, and risks dismissing experiential knowledge of harm.[435] In recognition of this potential weakness regarding the function of bioethics within a regulatory context, I employ the anthropological concept of 'liminality' in my approach to this thesis.

The concept was first developed by Van Gennep in *Rites of Passage*.[436] It followed from Van Gennep's observation that when people transition from one social state to another, such as from unmarried to married, they undertake certain rituals consisting of three distinct phases (known as rites of passage). He declared these rituals universal to all societies,[437] and argued their purpose is to reduce harmful effects that may occur due to the disruptive impact changes of social state can have upon people and society.[438] The three phases are the separation from a previous state (preliminal rites), the transitional phase (liminal rites), and incorporation into the new state (postliminal rites).[439] Within the transitional liminal stage, the experience is marked by uncertainty for the subject.[440] Laurie has developed liminality into an analytical framework and sought to show what liminality can tell us about health research regulation.[441] In doing so, he notes that Thomasson emphasised the temporal and spatial aspects of liminality; its ability to exist in both moments and epochs, in specific places or with regard to certain objects[442]. Central to Laurie's work is the concept of 'in-between' spaces within regulation; and this is a key focus for my own research.

Liminality might seem like an unusual choice for a thesis focussed upon an examination of regulatory responses to patient safety incidents during hospital discharges. However, liminality accords well with regulatory theory[443] and with the discharge process.[444] Dove

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[433] ibid
[434] ibid
[435] ibid
[436] Arnold van Gennep, *The Rites of Passage*, (University of Chicago Press, 1960)
[437] ibid
[438] ibid
[439] ibid
[440] Jonas Söderlund and Elisabeth Borg, 'Liminality in Management and Organization Studies: Process, Position and Place' (2018) 20 International Journal of Management Reviews 880
[441] Graeme Laurie, 'Liminality and the Limits of Law in Health Research Regulation: What Are We Missing in the Spaces In-Between?' (2016) 25 Medical Law Review 47

[442] ibid
[443] Edward Dove (n 394)
[444] During the discharge process, patients transition across physical spaces, and change status – for example from patient to care home resident.

argues that whilst both regulatory space and liminality are concerned with the temporal and spatial dynamics of actors, the former provides a 'metaphorical mapping' of actors within the space whilst the latter offers an 'experiential understanding of those actors and the ways in which they are affected by regulation, particularly at moments or periods of transition'.[445] Furthermore, as the IMMDS Review highlights[446], and as Flear[447] draws attention to, there can be catastrophic consequences when the experiences of patients are ignored.

It is for the above reason that I use liminality in my approach. In Part Three of this thesis, I employ liminality as a lens through which to view the challenges in regulating patient safety during hospital discharges. Liminality brings into focus the in-between space that exists amongst the regulatory bodies, an area which has not previously been examined in the context of hospital discharges. Acknowledging that liminality is usually applied to people, Taylor-Alexander and colleagues argue that it can also be applied to 'things' – and that doing so enables a richer understanding of the relations between people and their surroundings.[106] I build upon this idea of liminal objects[448] to demonstrate how objects can get stuck in these liminal spaces amongst regulatory bodies. Further, I use liminality to position the Patient Safety Commissioner (PSC), a role newly established in the Medicines and Medical Devices Act 2021, as a 'Representative of Order'[449], a key figure within liminality, who would be able to help regulators successfully navigate these liminal spaces.

5.4 How these models inform my approach

As stated in the Introduction, the overarching purpose of this thesis is to establish how the regulatory system within English healthcare might better ensure the safety of patients throughout the hospital discharge process. To answer this, I have chosen to combine elements

[445] Dove (n 394)
[446] Independent Medicines and Medical Devices Safety Review, 'First Do No Harm: The Report of the Independent Medicines and Medical Devices Safety Review' (APS Group 2020)
[447] Flear (n 415)
[448] As will be explained in Part Three, I define 'objects' in this context to refer to the outputs of any actor within this regulatory space that is intended to improve patient safety during the discharge process.
[449] Victor Turner, *Dramas, Fields, and Metaphors: Symbolic Action in Human Society*, (Cornell University Press 1974); Paul Stenner and Eduard Moreno-Gabriel, 'Liminality and Affectivity: The Case of Deceased Organ Donation' (2013) 6 Subjectivity 229, 248

from the theoretical frameworks outlined above in order to arrive at an answer that is, I hope, sensitive to the needs and experiences of patients, healthcare professionals, and regulators.

In my first paper (Part Two of this thesis) I examine the effectiveness of risk-based regulation as a tool to address patient safety incidents linked to the hospital discharge process.[450] The dominant theory driving this examination is that of regulation. I ask what is it that regulators in England's NHS set out to achieve, what method of regulation is used in seeking this goal, and why is it failing patients at the point of discharge? In conceptualising patient safety incidents in this paper, I include harm to dignity. This strand to patient safety is inspired by bioethical thinking, and I argue that threats to patients' dignity should be given regulatory attention.

For my second paper (Part Three) I use liminality as a lens through which to highlight how the discharge process can give rise to patient safety incidents that fall between regulators' boundaries - resulting in a dearth of effective regulatory responses.[451] Liminality's main strength in this context lies in its explanatory power[452] - for it casts light on the space between regulators' boundaries. In the context of hospital discharges, this space has, until now, not been identified or explored, yet it is responsible for the lack of regulatory action to address the patient safety issue posed by hospital discharges. Using the liminal lens in this way unveils the need for a 'Representative of Order' role to guide actors through states of uncertainty - leading me to propose in this paper that the PSC could fulfil this function.

My third paper (Part Four) argues that the GMC's concept of accountability impedes its aim of fostering a just culture within healthcare, and recommends an action which could be taken to address this.[453] The backdrop to this paper is provided by regulation theory – namely that in order for regulation to be successful, regulatees must trust that regulation is a just and fair process.

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[450] Victoria Moore, 'Leaving Hospital: A Step too far for Risk-based Regulation' (2020) 17 Medical Law Review 675

[451] Victoria Moore, 'Regulating Patient Safety during Hospital Discharges: Casting the Patient Safety Commissioner as the Representative of Order' (2021) 21 Medical Law International 195

[452] Laurie (n 441)

[453] Victoria Moore, 'Doctors, Decisions, and Discharges: Regulatory Accountability for Patient Safety in a Just Culture' (2020) 36 Journal of Professional Negligence 171

Chapter Six: Outline of Papers

The substantial remainder of this thesis is comprised of a series of three published papers. Abstracts for these papers are provided below.

6.1 Structure and Strategy of Healthcare Regulation within England (Part Two)

This part of the thesis presents the multiple regulatory bodies overseeing hospital discharges and examines the efficacy of risk-based regulation within the context of hospital discharges.

6.1.1 Leaving Hospital: A Step too far for Risk-based Regulation? (Paper One)

Discharges from hospital are internationally recognised as a dangerous time in the care pathway of a patient, posing a risk to both their physical wellbeing and dignity. This article examines the effectiveness of risk-based regulation as a tool to address patient safety incidents linked to the hospital discharge process within the English National Health Service. It examines how the risk of this process is identified, conceptualised, and prioritised amongst the relevant statutory regulators, and argues that the risk is neither uniformly recognised by the statutory regulators within the English NHS, nor sufficiently addressed. Professional regulators in particular appear to have a poor awareness of the risk and their role in addressing it. Until these issues are resolved, patients leaving hospitals will continue to be exposed to patient safety incidents which should be avoidable.

Paper citation: Victoria L Moore, 'Leaving Hospital: A Step too far for Risk-based Regulation' (2020) 17 Medical Law Review 675

6.2 Liminal spaces within regulation (Part Three)

Part Three of the thesis consists of my second paper, which brings into focus the liminal spaces within this regulatory structure.

6.2.1 Regulating Patient Safety during Hospital Discharges: Casting the Patient Safety Commissioner as the Representative of Order (Paper Two)

This article examines the challenges in regulating patient safety during hospital discharges in England through the lens of liminality. Hospital discharges are internationally recognised as being a dangerous time for patients, and yet the role that regulators should play in addressing this has received little attention in any jurisdiction. Liminality's spotlight on the in-between highlights how the discharge process can give rise to patient safety incidents that fall between regulator's boundaries. Falling between boundaries results in a dearth of effective regulatory responses to address these incidents. By positioning the new role of Patient Safety Commissioner as that of a 'Representative of Order', this article proposes a means by which this poorly regulated space could be navigated more successfully. This analysis suggests that the remit of the Patient Safety Commissioner role be expanded to include improving patient safety with regard to processes - not just medicines and medical devices. The full implications of this are also addressed.

Paper citation: Victoria L Moore, 'Regulating Patient Safety during Hospital Discharges: Casting the Patient Safety Commissioner as the Representative of Order' (2021) 21 Medical Law International 195

6.3 Regulatory accountability (Part Four)

The fourth part of this thesis explores whether conceptual confusion regarding accountability risks undermining regulation's patient safety aims.

6.3.1 Doctors, decisions, and discharges: Regulatory accountability for patient safety in a just culture (Paper Three)

Leaving hospital is a dangerous time for patients. Within the English NHS, bed shortages have resulted in doctors being asked by NHS managers to discharge patients quickly, even where to do so is against a doctor's clinical judgement. This is potentially problematic for doctors who, according to their regulator, are personally accountable and must be prepared to justify their decisions and actions. Taking this situation as its focus, this article argues that the regulator's concept of accountability impedes its aim of fostering a just culture within healthcare. Given

that a just culture is integral to ensuring patient safety, it is vital that this accountability problem is addressed. Three possible regulatory actions are presented to address this particular issue; it is anticipated that the recommended action could improve patient safety across the healthcare system.

Paper citation: Victoria L Moore, 'Doctors, decisions, and discharges: Regulatory accountability for patient safety in a just culture' (2020) 36 Journal of Professional Negligence 171

PART TWO Structure and Strategy of Healthcare Regulation within England

Leaving Hospital: A Step Too Far for Risk-Based Regulation? (Paper One)

I. Introduction

Patients who are discharged from hospital are widely recognised as being at an increased risk of harm.[454] This article seeks to demonstrate how risk-based regulation, a prominent model of regulation utilised within the English NHS by statutory regulatory bodies to protect patients from harm, is ill-equipped to ensure and improve the safety (broadly conceived) of hospital discharges. Its purpose is to draw attention to the nature of this complex problem and its impact upon patient safety; it does not seek to propose a solution. It commences by considering what regulation means within the healthcare context, and why regulators need to address safety during hospital discharges. Section two examines the rationale for risk-based models within healthcare regulation, and three weaknesses that occur when the model is applied in multi-regulator environments. The third section then considers the extent to which regulators have recognised and tackled the risk posed to patient safety by hospital discharges and the fourth section explores why the risk posed to patient safety by hospital discharges might have received limited regulatory recognition, arguing that it is a consequence of the use of risk-based regulation models are used in multi-regulator environments. This article concludes that until these weaknesses are resolved, the threat posed to patients' safety during the discharge process will remain unmitigated.

Black defines regulation as 'the sustained and focused attempt to alter the behaviour of others according to defined standards or purposes with the intention of producing a broadly identified outcome or outcomes'.[455] This definition has been applied to the healthcare setting by Waring et al.[456] and is also shared by the Professional Standards Authority (PSA). The PSA is an arm's-length body of the Department of Health, and is responsible for regulating the

[454] See World Health Organisation, 'Transitions of care: Technical series on safer primary care' (World Health Organisation 2016); Karina Aase and others (eds), *Researching Quality in Care Transitions International Perspectives* (Palgrave Macmillan 2017); Kirstin Manges and others, 'A Mixed Methods Study Examining Teamwork Shared Mental Models of Interprofessional Teams During Hospital Discharge' (2019) BMJ Quality & Safety 1

[455] Julia Black, 'Decentering Regulation: Understanding the Role of Regulation and Self-Regulation in a Post-regulatory World' (2001) 54 Current Legal Problems 103, 142

[456] Justin Waring and others, 'Modernising Medical Regulation: Where Are We Now' (2010) 24 Journal of Health Organisation and Management 6, 541

professional regulators (the bodies responsible for regulating health and social care professionals)[457]. It states that a regulator's purpose is to 'minimise harm and to seek to do so by changing individual or organisational behaviour'.[458] Oikonomou et al. have recently offered a broader meaning which refers to healthcare regulation as, 'the processes engaged in by institutional actors that seek to shape, monitor, control or modify activities within healthcare organisations in order to reduce the risk of patients being harmed during their care'.[459] This definition is designed to capture the breadth of actors that are engaged in these processes, regardless of whether the actors self-identify as formal regulators. An astoundingly high number of 126 organisations were identified as exerting regulatory influence within the NHS.[460]

Although Oikonomou et al.'s broad understanding of regulation provides scope for a rich exploration of all behavioural influences, this article takes a narrower focus upon the formal attempts by statutory regulators to shape behaviour within healthcare organisations. This is because the statutory regulators have a legal duty to protect patients, and are therefore the ones held accountable for any regulatory failings that are uncovered (typically following inquiries into healthcare scandals). Given this, the regulatory bodies under consideration within this article are the professional regulators[461]; the CQC, which regulates health and social care services; and NHS England and NHS Improvement.[462] The latter two have regulatory oversight of healthcare services[463] and are accountable to Parliament.[464]

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[457] For further information on how the PSA holds professional regulators accountable see Judith Allsop and Kathryn Jones, 'Regulating the Regulators: The Rise of the United Kingdom Professional Standards Authority' in John Chamberlain, Mike Dent and Mike Saks (eds), *Professional health regulation in the public interest: International Perspectives* (Policy Press 2018); and Oliver Quick, *Regulating Patient Safety* (Cambridge University Press: Cambridge 2017)

[458] Professional Standards Authority, 'Rethinking Regulation' (PSA 2015)

[459] Eirini Oikonomou and others, 'Patient Safety Regulation in the NHS: Mapping the Regulatory Landscape of Healthcare' (2019) 9 BMJ Open, 2

[460] ibid

[461] General Medical Council, General Dental Council, General Chiropractic Council, General Optical Council, General Osteopathic Council, General Pharmaceutical Council, Health and Care Professions Council, Nursing and Midwifery Council, and Social Work England

[462] Since April 2019 these have been working together as a single organisation. See NHS Improvement, 'Working Together' (NHSI 2019) <https://improvement.nhs.uk/> (accessed 19 December 2019)

[463] For further detail on differences in responsibilities between CQC and NHSI see: British Medical Association, 'The Regulatory Systems for Healthcare Quality across the United Kingdom' (2016) <https://www.bma.org.uk/collective-voice/policy-and-research/nhs-structure-and-delivery/monitoring-quality-in-the-nhs/regulatory-systems-for-healthcare-quality> (accessed 19 December 2019)

[464]NHS England, 'Accountability Report' (NHSE 2019) <https://www.england.nhs.uk/wp-content/uploads/2019/07/accountability-report-201819.pdf> accessed 16 April 2020

The professional regulators each have the same primary purpose, established through legislation,[465] of protecting the public. Each professional regulator shares the following overarching functions[466]: set the standards of behaviour, competence and education that professionals must meet; address concerns raised about professionals who are unfit to practise because of poor health, misconduct or poor performance; maintain registers of professionals who are fit to practise; and set the requirements for re-registration and/or revalidation for each profession. The Care Quality Commission (CQC)[467] is responsible for regulating the quality of health and social care in England. All providers of adult healthcare in England are legally required to register with the CQC, which inspects and rates the quality of services from outstanding to inadequate. The CQC sets out thirteen fundamental standards of care[468] which cover a vast array of matters such as treating patients with dignity and respect, being open and honest when things go wrong, and ensuring appropriate staff are employed to provide care. It is accountable to Parliament and the Secretary of State for Health.[469]

Patient safety and the risk of harm posed by hospital discharges

Patient safety is an issue of both global and national concern. The World Health Organisation (WHO) estimates that globally, the occurrence of adverse events due to unsafe care is one of the ten leading causes of death and disability.[470] In order to recognise that patient safety is a pressing health priority, the WHO launched the first World Patient Safety Day in 2019, with the aim of raising public awareness and sparking worldwide action.[471] In the same year, NHS England and NHS Improvement published the National NHS Patient Safety Strategy. The

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[465] See the Medical Act 1983, Dentists Act 1984, Chiropractors Act 1994, Opticians Act 1989, The Osteopaths Act 1993, The Health Act 1999, the Nursing and Midwifery Order 2001, The Health and Social Work Professions Order 2001, and the Pharmacy Order 2010

[466] Law Commission, 'Regulation of Health Care Professionals: Regulation of Social Care Professionals in England' (Law Commission 2014)

[467] Health and Social Care Act 2008, s 3(1)(2)

[468] Care Quality Commission, 'The Fundamental Standards' (CQC 2019) <https://www.cqc.org.uk/what-we-do/how-we-do-our-job/fundamental-standards> accessed 24 April 2019

[469] Care Quality Commission, 'Framework Agreement between the Department of Health and Care Quality Commission' (CQC 2013) <https://www.cqc.org.uk/sites/default/files/documents/cm_0114310_item_10_appendix_1_cqc_framework_agreement.pdf> accessed 16 April 2020

[470] World Health Organisation, 'Patient Safety' (WHO 2019) <https://www.who.int/news-room/fact-sheets/detail/patient-safety> accessed 17 April 2020

[471] World Health Organisation, 'World Patient Safety Day' (WHO 2019) <https://www.who.int/campaigns/world-patient-safety-day/2019> accessed 17 April 2020

strategy aims to continuously improve patient safety by ‘maximising the things that go right and minimising the things that go wrong for people experiencing healthcare’.[472] It predicts that getting this right could save almost one thousand extra lives and £100 million in care costs each year from 2023/24.[473]

In recent years, multiple bodies tasked with improving, monitoring, or advocating for patient safety have published findings highlighting the need to reduce the number of hospital discharges which result in harm to patients. For example, Healthwatch England (HE) has published three reports drawing attention to poor hospital discharges and the resulting harm to patients since 2015.[474] In 2016, the Parliamentary and Health Service Ombudsman (PHSO) identified four key issues that, separately, can result in patient harm and thus constitute an unsafe discharge.[475] These are: where a patient is discharged before it is clinically safe to do so; where a patient is not assessed or consulted properly prior to discharge; where relatives or carers are not informed of the discharge; or where this no appropriate support in place for patients to cope once discharged.[476] In response to the PHSO report’s[477] findings, the Public Administrations and Constitutional Affairs Committee (PACAC) launched an inquiry and concluded that, 'the incidence of unsafe discharge from NHS hospitals is much too high and this is unacceptable'.[478]

A 2015 analysis of National Reporting and Learning System[479] (NRLS) data on discharge-related safety incidents[480] found four main categories of error. These errors were in:

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[472] NHS England and NHS Improvement, 'The NHS Patient Safety Strategy: Safer Culture, Safer Systems, Safer Patients' (NHSE&I 2019) <https://improvement.nhs.uk/documents/5472/190708_Patient_Safety_Strategy_for_website_v4.pdf> accessed 17 April 2020, 6

[473] ibid

[474] Healthwatch England, 'Safely Home: What happens when people leave hospital and care settings? Special Inquiry Findings' (Healthwatch 2015); Healthwatch England, ‘What happens when people leave hospital and other care settings?’ (Healthwatch 2017); Healthwatch England, 'Emergency Readmissions: What’s Changed One Year On?' (Healthwatch 2018)

[475] Parliamentary and Health Service Ombudsman, 'A Report of Investigations into Unsafe Discharge from Hospital' (PHSO 2016)

[476] ibid

[477] ibid

[478] Public Administration and Constitutional Affairs Committee, 'Fifth Report: Follow-up to PHSO report on unsafe discharge from hospital' (2016-2017 HC 97), 18

[479] The NRLS is a central database of patient safety incidents (PSIs) reported from across England and Wales. A PSI for the purpose of the database is defined as ‘any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving healthcare’. See NHS Improvement, 'Report a patient safety incident' (NHSI 2017) https://improvement.nhs.uk/resources/report-patient-safety-incident/ accessed 19 December 2019

[480] Huw Williams and others, 'Harms from Discharge to Primary Care: Mixed Methods Analysis of Incident Reports' (2015) 65 British Journal of General Practice e829

the quality of discharge communication; referrals to community care; medication; and providing care adjuncts, for example wound dressings and catheters. In addition, behavioural factors, such as not following protocols, and organisational factors such as a lack of coherent guidelines[481] were common contributory factors to patients experiencing harm. The study data further showed that the harm patients experienced because of these incidents was predominantly categorised as low-level, meaning that patients experienced mild symptoms, the harm was short-term, and little or no intervention was required to resolve the harm.[482] However, in 78 cases (13%), patients experienced moderate harm, meaning they required an intervention to resolve symptoms and may have experienced permanent or long-term harm or loss of function. There were 3 (<1%) severe cases where life-saving interventions were required and patients experienced major loss of function, and in one instance a patient died. In one severe case for example, no discharge letter was sent to the GP, meaning the patient did not receive appropriate treatment and experienced a stroke, resulting in a permanent reduction in their function.[483]

According to Waring et al.[484], current thinking in the patient safety field recognises that threats to patient safety stem not only from individual errors but also from more latent factors, such as the way groups work together and the design and management of work. However, the focus for this line of thinking has tended to remain within static care domains like wards or operating departments. Waring and colleagues argue that the reason hospital discharges pose a significant patient safety problem is because latent factors are even more broadly located across the wider care system, thus presenting more complex sources of risk.[485] Their qualitative study identified consistent threats to the safety of discharged stroke and hip fracture patients. These threats included but were not limited to: direct patient harm, for example falls, medicines-related issues, and relapse; contributing factors such as follow-up care and patient education; and latent factors, such as discharge timing, referral processes, and resource constraints. The authors concluded that hospital discharge is a 'high risk and vulnerable stage in the patient journey'.[486] Poor discharge planning can amount to clinical negligence, as illustrated in

[481] ibid
[482] ibid
[483] ibid
[484] Justin Waring and others, 'A Qualitative Study of Professional and Carer Perceptions of the Threats to Safe Hospital Discharge for Stroke and Hip Fracture Patients in the English National Health Service' (2016) 16 BMC Health Services Research 1
[485] ibid
[486] ibid

Esegbona v King's College NHS Trust. In this case the Trust was found to be negligent in its failure to inform the nursing home that the patient was discharged to about her specific care needs. It was therefore held liable for damages for the pain, suffering and loss of amenity the patient experienced leading up to her death.[487]

In addition to experiencing physical harm related to hospital discharge processes, patients' dignity may be harmed. This article adopts Tadd et al.'s argument that treating patients with dignity comprises of: 'respectful communication; respecting privacy; promoting autonomy and a sense of control; addressing basic human needs such as nutrition, elimination and personal hygiene needs in a respectful and sensitive manner; promoting inclusivity and a sense of participation by providing adequate information to aid decision-making; promoting a sense of identity; focusing on the individual and recognising human rights'.[488] By contrast, undignified care 'renders individuals invisible, depersonalises and objectifies people, is abusive or humiliating, narrowly focused and disempowers the individual'.[489] The 2016 Parliamentary and Health Service Ombudsman (PHSO) [490] report provides an example of undignified care within the context of hospital discharges: 85-year-old Mrs K, who had dementia, was discharged home late at night without her family being informed. The following morning Mrs K's daughter found her at her home, having been left with no food, drink or bedding, and unable to care for herself or get to the toilet. We can see how such an experience is likely to have left Mrs K feeling humiliated and disempowered. Indeed, research by O'Hara et al. found that patients view such non-clinical incidents as a safety incident; within the study, one of the patient-derived safety categories was 'Compassion/dignity/privacy/respect'.[491]

By way of further example, a British Red Cross report[492] highlighted several instances of patients being discharged from hospital before adequate home support is in place – placing the dignity and physical wellbeing of discharged patients at risk of harm. Regarding such patients, a red cross team member stated, 'they've got no family, they've got no one and there's no care package in place for them coming home. They [the discharge team] just ask us to go

[487] Esegbona v King's College NHS Trust [2019] EWHC 77 (QB)
[488] Win Tadd and others, 'Dignity in Practice: An Exploration of the Care of Older Adults in Acute NHS Trusts' (The Stationary Office 2011) 10
[489] ibid
[490] PHSO (n 475)
[491] Jane K O'Hara and others, 'What Can Patients Tell Us about the Quality and Safety of Hospital Care? Findings From a UK Multicentre Survey Study' (2018) 27 BMJ Quality & Safety 673
[492] British Red Cross, 'In and Out of Hospital' (British Red Cross 2018)

in, and we go in and we find them, they've either had a fall, they're on the floor and it's because they've been sent back out too soon and they get readmitted again'.[493]

This article uses the term 'patient safety incident' (PSIs)' to refer to any unintended or unexpected incident which could have, or did, lead to the detriment of a patient's physical wellbeing and/or dignity. This is a broader definition than NHS Improvement's (NHSI) definition which states that a PSI is 'any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving healthcare'. In the latter, harm is understood to be physical in nature.[494] This article's definition has a dual purpose; it reflects the fact that dignity is an important concept within healthcare from a legal and regulatory perspective, and it captures the patient perspective of harm mentioned above.

Regarding the importance of dignity from a legal perspective, the NHS Constitution, which is enshrined in the 2009 Health Act, sets out that patients have a right to be treated with dignity and respect, in accordance with their human rights.[495] This is further stated in Regulation 10 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. The importance of respecting a patient's dignity is also reflected within the professionals' codes and the CQC's fundamental standards.[496] A failure to follow these standards may result in regulatory action.[497] It is clear that regulators recognise respect for a patient's dignity as an integral part of good health care, and thus ought to be prepared to take action to safeguard against harm to a patient's dignity. A report by the Commission on Dignity in Care for Older People recommended that regulators must place as much emphasis on dignity in care as on clinical outcomes, and that professional regulators such as the GMC 'must promote and enforce high standards of dignified care'.[498]

Despite the emphasis on healthcare professionals respecting patients' dignity, the concept is not defined by the professional codes; indeed there is no clear consensus of dignity

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[493] ibid 11
[494] NHS Improvement, 'Report A Patient Safety Incident' (NHSI 2017) <https://improvement.nhs.uk/resources/report-patient-safety-incident/> accessed 10 April 2019
[495] National Health Service, 'NHS Constitution for England' (NHS 2015)
[496] For example, see paragraph 25 of 'Good Medical Practice' (GMC 2013); paragraph 1 of the NMC's Code (NMC 2015); standard 1 of 'Standards for Pharmacy Professionals' (GPhC 2017); section 2.2 of Social Work England's Professional Standards (SWE 2019) and the CQC's 'The Fundamental Standards' (CQC 2019)
[497] General Medical Council, 'Good Medical practice' (2013), paragraph 6
[498] Commission on Dignity in Care for Older People, 'Delivering Dignity: Securing Dignity in Care for Older People in Hospitals and Care Homes' (Commission on Dignity in Care for Older People 2011) Recommendation 35

either within healthcare literature or wider philosophical literature.[499] Alongside leaving healthcare professionals lacking practical guidance with regards to protecting patients' dignity[500], the nebulous nature of dignity is problematic from a regulatory point of view. Caulfield and Brownsword argue that, given this vagueness, a requirement to respect human dignity fails to provide a clear steer to regulatees, making it difficult for regulatees to demonstrate regulatory compliance and for regulators to enforce it.[501]

This section has thus far established that patients are exposed to a risk of harm to both their physical wellbeing and their dignity during the discharge process, and argues that harm to either of these aspects ought to be of regulatory interest.[502] The following section examines the rationale for risk-based models of regulation, and three recognised weaknesses that occur when the model is applied in multi-regulator environments.

II. Risk-Based Regulation within the English NHS

The risk-based regulation model is intended to focus regulators' interventions upon the threats which pose the greatest risk to its objectives, as opposed to aiming to prevent *all* possible harm.[503] Prioritising regulatory interventions in this manner is said to be effective and proportionate[504] , whereas to do otherwise has been called grossly inefficient.[505] In the UK, the 2005 Hampton Report[506] strongly endorsed risk-based approaches – describing them as essential for efficiently directing regulatory resources to where they can have maximum impact upon outcomes, and warning that a failure to use risk assessments effectively means resources may not be targeted at the riskiest areas.

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[499] Linda Barclay, 'In sickness and in Dignity: A Philosophical Account of the Meaning of Dignity in Health Care' (2016) 61 International Journal of Nursing Studies 136
[500] ibid
[501] Timothy Caulfield and Roger Brownsword, 'Human Dignity: A Guide to Policy Making in the Biotechnology Era?' (2006) 7 Science and Society 72
[502] There are of course additional emotional harms which a patient might experience, such as stress and anxiety. This paper focusses on harm to dignity because of the regulatory requirements to respect patient dignity.
[503] Anne Laure Beaussier and others, 'Accounting for Failure: Risk-based Regulation and the Problems of Ensuring Healthcare Quality in the NHS' (2016) 18 Health, Risk & Society 205
[504] Henry Rothstein, 'The Institutional Origins of Risk: A New Agenda for Risk Research' (2006) 8 Health, Risk and Society 215
[505] Beaussier and others (n 503)
[506] Phil Hampton, 'Reducing Administrative Burdens: Effective Inspection and Enforcement' (HM Treasury 2005)

Although it has been argued that a concrete definition of risk-based regulation is 'elusive'[507], Black and Baldwin observe that risk-based frameworks typically take the identification of risk as their starting point, and feature the following elements[508]: a determination by the organisation as to what the risk is that it aims to control; a determination of the organisation's 'risk appetite' (the type and level of risk that will be tolerated); an assessment of the likelihood of the risk occurring; and a ranking of risks based upon these assessments. In theory, these frameworks then provide a means for linking appropriate regulatory interventions to the severity of the risk.[509] For example, in the healthcare context, a 2017 GMC Chief Operating Officer Report[510], illustrates the type of risk register utilised by the GMC. The register identifies not effectively sharing information as an active risk that could in turn pose a risk to patient safety. This risk was assessed as being quite likely to occur, and having a moderate impact if it did occur. Existing actions to mitigate the risk were noted, and future mitigating actions were also outlined.[511] Similarly, the NMC's risk register is publicly available, and identifies high-level risks, contributory factors, risk appetite, and existing and future controls.[512]

Risk can be characterised as the possibility of an undesirable incident occurring, either as a result of natural events or human activities, or due to a combination of both.[513] Given that within healthcare, a core purpose of regulation is to minimise harm to patients, the possibility that patients will be harmed is an undesirable occurrence; that is to say it is a risk that regulators wish to reduce the occurrence of.

This article identifies three broad categories of risk that, from a regulatory perspective, could ultimately result in harm to patients. These categories are: risks to the safety and/or dignity of individual patients, risks to the reputation of regulators, and risks to the public's trust in the healthcare professions - each of which will now be considered in turn.

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[507] Sally Lloyd-Bostock and Bridget Hutter, 'Reforming Regulation of the Medical Profession: The Risks of Risk-based Approaches' (2008) 10 Health, Risk and Society 69, 70
[508] Julia Black and Robert Baldwin, 'Really Responsive Risk-based Regulation' (2010) 32 Law and Policy 181
[509] ibid
[510] General Medical Council, 'Chief Operating Officer's Report: Agenda Item M4' (GMC 2017) <https://www.gmc-uk.org/-/media/documents/m04---chief-operating-officer-s-report_pdf-72010185.pdf> accessed 19 December 2019, 11
[511] ibid
[512] Nursing and Midwifery Council, 'Council meeting: 27 March 2019' (NMC 2019) <https://www.nmc.org.uk/about-us/governance/the-council/council-meetings/previous-council-meetings/council-meeting-27-march-2019/> accessed 19 December 2019
[513] Julia Black, 'The Role of Risk in Regulatory Processes' in Robert Baldwin, Martin Cave and Martin Lodge (eds), *The Oxford Handbook of Regulation* (Oxford University Press 2010)

The first of these, risks to the safety of individual patients, comprises of two further subcategories of risk: those that pose a risk to the physical wellbeing of a patient, and those that pose a risk to a patient's dignity as defined above. The former is an inherent risk[514] within the delivery of healthcare, and thus the question becomes, what level of risk is to be tolerated? For example, general anaesthesia for surgical procedures in a reasonably healthy person poses a small risk to life (approximately 1 death per 100,000 general anaesthetics[515]), but it is often recommended and accepted as part of the treatment to avoid conditions which pose a greater risk to life - such as a burst appendix. Painkillers such as tramadol also carry a risk of unpleasant side effects, ranging for example from headaches, nausea and constipation to breathing difficulties, hallucinations, and seizures.[516] Yet for patients these risks may often be preferable to no treatment. Patients' views of acceptable risk will also vary from patient to patient, depending upon their personal circumstances, and doctors must explore these factors with patients when discussing treatment options.[517] On a broader level, Beaussier et al. argue that there is perpetual disagreement amongst regulators, the public and politicians, as to what constitutes acceptable risk. They note that even if agreement could be reached on what risks are acceptable at least in theory, adverse outcomes would rarely be regarded as such once they came to light.[518]

By contrast, a risk to the dignity of patients is not an inherent risk within the delivery of healthcare. This view is supported by the inquiry into poor care at Mid Staffordshire hospital, which remarked, 'a scrutineer might reasonably have expected dignity and respect to be accorded to everyone at all times.'[519] It is therefore argued here that the acceptable level of harm to a patient's dignity is zero, and any risk to patient dignity, such as the hospital discharge process, should be effectively managed to obviate the chances of this risk materialising.

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[514] David Sohn, 'Negligence, Genuine Error, and Litigation' (2013) 6 International Journal of General Medicine 49

[515] Royal College of Anaesthetists, 'Section 15: Death or Brain Damage' (2017) <https://www.rcoa.ac.uk/sites/default/files/documents/2019-11/15-DeathBrainDamageweb.pdf> accessed 17 April 2020

[516] National Health Service, 'Tramadol' (NHS 2018) <https://www.nhs.uk/medicines/tramadol/> accessed 15 January 2019

[517] *Montgomery v Lanarkshire Health Board* [2015] SC 11 [2015] 1 AC 1430; General Medical Council, Consent: Patients and Doctors Making Decisions Together' (GMC 2013) <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/consent> accessed 20 February 2019

[518] Beaussier and others (n 503)

[519] Robert Francis, 'Report of the Mid Staffordshire Foundation Trust Public Inquiry Volume I' (The Stationary Office 2013) 6.262

The second category of risk, which is harm to the reputation of a regulator, can be illustrated by a recent GMC decision to appeal a determination by the Medical Practitioners Tribunal Service (MPTS) and to call for the removal of a paediatrician from the medical register.[520] This caused widespread outrage amongst the medical profession. In a letter addressed to the Chair of the GMC by a director of a hospital trust, the GMC was accused of undermining patient care by 'endorsing and promoting a blame ethos that is inimical to safety'.[521] A blame ethos poses a risk to candour which can lead to errors being hidden rather than learned from - jeopardising future patient safety.[522] Following the aforementioned MPTS decision, the GMC commissioned an independent review into gross negligence manslaughter. The review found that doctors' trust in the GMC had been severely damaged and that this was of great concern. It asserted that the GMC can only support doctors to deliver good medical practice if doctors feel able to engage constructively with the regulator, and have confidence that processes will 'be proportionate, fair and just'.[523] This is further supported by research demonstrating that regulatees respond positively to respectful, supportive approaches[524], and are more inclined to accept outcomes which might not otherwise appear to be in their interests if they feel they have been treated fairly.[525] If regulatees trust the regulator, then compliance with regulatory requirements increases.[526] Where healthcare providers' lack trust in regulators, the quality of care provided to patients suffers.[527]

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[520] Pulse Today, 'GMC was advised to appeal Bawa-Garba case to 'protect reputation of profession'' (2019) <http://www.pulsetoday.co.uk/news/all-news/gmc-was-advised-to-appeal-bawa-garba-case-to-protect-reputation-of-profession/20039140.article> accessed 19 December 2019

[521] Nick Ross, 'Letter to the GMC chair regarding Hadiza Bawa-Garba' (BMJ 2018) <https://www.bmj.com/content/360/bmj.k195> accessed 19 December 2019

[522] National Advisory Group on the Safety of Patients in England, 'A Promise to Learn – A Commitment to Act: Improving the Safety of Patients in England' (Crown Publishing 2013); NHS England and NHS Improvement, 'The NHS Patient Safety Strategy: Safer culture, safer systems, safer patients' (NHSE&I 2019) <https://improvement.nhs.uk/documents/5472/190708_Patient_Safety_Strategy_for_website_v4.pdf> accessed 17 April 2020

[523] Leslie Hamilton, 'Independent review of gross negligence manslaughter and culpable homicide' (2019) available at: https://www.gmc-uk.org/-/media/documents/independent-review-of-gross-negligence-manslaughter-and-culpable-homicide---final-report_pd-78716610.pdf <accessed 12 October 2021> 22

[524] Judith Healy, *Improving Healthcare Safety and Quality: Reluctant Regulators* (Ashgate Publishing 2011)

[525] Tom R Tyler, 'Procedural Justice, Legitimacy, and the Effective Rule of Law' (2003) 30 Crime and Justice 283

[526] John Braithewaite and T Makkai, 'Trust and compliance' (1994) 4 Policing and Society 1; Kristina Murphy, 'The Role of Trust in Nurturing Compliance: A Study of Accused Tax Avoiders', (2004) 28 Law and Human Behavior 187

[527] Sumit Kane and others, 'Trust and trust relations from the providers' perspective: the case of the healthcare system in India' (2015) 12 Indian Journal of Medical Ethics 157

The third category of risk is to the public's trust; Quick states that people, processes, and places within healthcare are regulated in order to ensure trust and to improve safety.[528] Ensuring public trust in healthcare professions is central to making sure that people will seek out the healthcare that they need.[529] High profile regulatory failures[530] can damage the public's trust in the ability of regulators to protect them and in the professions that they regulate.[531]

The impact of damaged trust on patient safety is illustrated in a statement by one of Dr Fata's victims. Dr Fata was a Detroit doctor sentenced to 45 years in prison for providing medically unnecessary chemotherapy to patients.[532] One victim stated:

> 'I don't trust any doctor or medical professional, I doubt everything they say. When I start thinking about it I can't function, I become so anxious I can't even go to work, and if I have a doctor's appointment for myself or my son I cancel it. I thought it would get better with time, but it hasn't. How am I supposed to go through the rest of my life not trusting the medical profession?'[533]

This demonstrates how a loss of trust in one medical professional can impact upon trust in the collective and ultimately threaten the safety of patients who may avoid seeking much-needed future healthcare for themselves and their children.

Risk-based regulation is intended to enable regulators to identify the risks which fall into these categories, and to determine which pose the greatest threat to their regulatory objective: minimising harm to patients. A failure to manage any of the above three categories of risk appropriately can lead to patient safety incidents. Drawing on Brownsword's arguments[534], Farrell states that when measuring the effectiveness of risk-based regulation regimes, one of the elements that it is essential to consider is whether the use of the regime has

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[528] Quick (n 457)
[529] Healy (n 524)
[530] See for example Janet Smith, 'The Shipman Inquiry fifth report: Safeguarding patients: Lessons from the past - Proposals for the future' (2004); Robert Francis, 'Report of the Mid Staffordshire Foundation Trust Public Inquiry Volume I' (The Stationary Office: London 2013); Graham James, 'Report of the Independent Inquiry into the Issues raised by Paterson' (House of Commons 2020)
[531] Judith Allsop, 'Regaining Trust in Medicine: Professional and State Strategies' (2006) 54 Current Sociology 621
[532] Justice Department, 'Detroit Area Doctor Sentenced To 45 Years In Prison For Providing Medically Unnecessary Chemotherapy To Patients' (2015) <https://www.justice.gov/opa/pr/detroit-area-doctor-sentenced-45-years-prison-providing-medically-unnecessary-chemotherapy> accessed 9 May 2019
[533] Justice Department, 'Farid Fata Victim Impact Statements', 2:13-cr-20600-PDB-DRG Doc # 135-2 (2015), 22
[534] Roger Brownsword, *Rights, Regulation, and the Technological Revolution* (Oxford University Press 2008)

enabled its aims and objectives to be met. This measurement sits alongside others: the regime's comprehensiveness in handling risk-based issues, the extent of support or resistance afforded to it by regulatees, and the accountability mechanisms in place for monitoring it[535]. It is upon the first of these measurements where this article focusses its attention.

Identifying, conceptualising and prioritising risk in healthcare

The efficacy of risk-based regulatory approaches is heavily dependent upon successful risk identification and prioritisation. Needless to say, where the risk is unrecognised, the issue will fail to even make it upon regulators' agenda.[536] Black broadly sums up the difficulties of identifying risks as: 'selecting the appropriate indicators, gathering sufficient information with respect to those indicators, assessing probabilities (particularly for low-probability, high-impact events), assessing the ability of management systems and processes to mitigate risk, and dealing with uncertainties rather than risks that can be easily calculated'.[537]

Beaussier et al. make a similar observation; that within the healthcare context regulators have struggled to assess risks to quality, to identify providers at greatest risk of failing to meet quality standards, and to prioritise inspections accordingly. This is in part because of the challenges in interpreting vast quantities of data, in devising useful indicators to capture the desired outcomes, and in making 'credible inspection judgements about complex health organisations'[538]. A recent inquiry[539] by the Joint Committee on Human Rights into the detention of young people with learning disabilities and/or autism within healthcare settings illustrates the CQC's failing in this regard. Analysis of the information available to the CQC on twenty services was examined, and a key criticism was the 'lack of an obvious relationship between the information that CQC has available to it about a service and its inspection ratings or regulatory actions relating to that service'.[540] The analysis found that beyond routine

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[535] Anne-Maree Farrell, *The Politics of Blood: Ethics, Innovation and the Regulation of Risk* (Cambridge University Press 2014) 199
[536] Robert Baldwin and Judith Black, 'Driving Priorities in Risk-based Regulation: What's the Problem?' (2016) 43 Journal of Law and Society 565; Fiona Haines, 'Regulation and Risk' in Peter Drahos (ed), *Regulatory Theory: Foundations and Applications* (ANU Press 2017)
[537] Baldwin and Black (n 536) 567
[538] Beaussier and others (n 503)
[539] Joint Committee on Human Rights, 'The Detention of Young People with Learning Disabilities and/or Autism' (House of Commons 2019)
[540] ibid 45

inspections, there appeared to be 'little relationship between the information presented in the analysis and the timing of inspections'.[541] The inquiry therefore concluded that the CCQ was failing to meet its 2016-2021 strategic priority of delivering an 'intelligence-driven approach to regulation'[542] and that substantive reform of the CQC's approach and processes is needed. This failure highlights how the challenges associated with gathering and interpreting data can lead to an inability to appropriately identify a risk to patient safety.

When risks are recognised, the priority they are subsequently afforded by regulators will be influenced by how the risk is conceptualised, as well as operational factors, and political/reputational influences.[543] The conceptualisation of risk is particularly problematic where multiple regulators are acting within the same area.[544] Baldwin and Black demonstrate how this is problematic within environmental regulation. A chemical used by farmers in sheep-dips potentially affects the quality of watercourses and groundwater; a risk which can be conceptualised three-ways: as a harm to the environment, a harm to animal health, and a harm to human health. Each of these harms may be the responsibility of more than one regulator, and subject to differing legal regimes. By way of further example, in 2018 the Health and Social Committee published a report[545] regarding how NHS Digital was sharing confidential patient information with the Home Office to trace immigrants. Information included patients' names, date of birth, last known address and their GP's contact details. NHS Digital had argued that sharing this information was within the public interest because it enabled the effective enforcement of immigration law. This allegedly outweighed concerns that it might impact broader public trust in a confidential health service.[546] Several bodies, including the GMC, British Medical Association (BMA), Public Health England (PHE) argued that this information sharing posed a serious risk to public health, risked undermining public trust in a confidential health service, and placed doctors at risk of failing to comply with their professional guidance.[547]

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[541] ibid
[542] CQC, 'Our Strategy for 2016-2021' (CQC 2017) <https://www.cqc.org.uk/about-us/our-strategy-plans/our-strategy-2016-2021> accessed 19 December 2019
[543] Baldwin and Black (n 536)
[544] ibid
[545] House of Commons Health and Social Care Committee, 'Memorandum of understanding on data-sharing between NHS Digital and the Home Office' (House of Commons Health and Social Care Committee 2018)
[546] ibid
[547] House of Commons Health and Social Care Committee (n 545); General Medical Council, 'Data-sharing agreement could threaten patient confidentiality' (GMC 2018) <https://www.gmc-uk.org/news/news-archive/data-sharing-agreement-could-threaten-patient-confidentiality> accessed 18 April 2020

The above demonstrates how different organisations with regulatory influence conceptualise risk. Whereas the risk to public trust in the health service was seen to be low by NHS Digital, it was seen as a high risk by the GMC. Differing conceptualisations of risk such as this can result in different levels of priority being assigned to the risk, resulting in poor regulatory coordination and effectiveness.[548]

Black and Baldwin argue that in reality, a risk that is categorised as 'low' equates to 'low priority'[549] for regulators, and is a statement of the risk's relative significance to the regulator and their potential to meet their objectives.[550] They provide a comprehensive overview of how risks that are classified as low can have the potential to cause significant harm, and as such still require regulatory attention.[551] For example, within the context of water quality regulation, an individual farm engaging in an activity such as the cleaning of milking parlours might be seen to only pose a low risk to water quality, because only small quantities of effluent are discharged into water sources during the cleaning process. However, when such activities which present a low risk at an individual site are engaged in by the masses, the risk may accumulate to become systemic.[552] Likewise, an individual clinician's poor handwashing technique may only pose a low risk to the overall safety of the entire patient population, but when practised by multiple clinicians would pose a high risk to public health.

This section has introduced the model of risk-based regulation used by healthcare regulators, and argued that harm to patients is the primary risk that regulators seek to manage. It has identified three broad categories of risk that can result in harm to patients. These are: direct risks of harm to the physical wellbeing and dignity of patients; risks to a regulator's reputation; and risks to public trust in the professions. It has then examined how the identification of these risks can be challenging for regulators, and how incohesive conceptualisations of risks and their subsequent prioritisation by multiple regulators informs their regulatory response. Against this backdrop, the following section examines the extent to which statutory healthcare regulators have recognised and tackled the risk posed to patient safety by hospital discharges.

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[548] Baldwin and Black (n 536)
[549] Judith Black and Robert Baldwin, 'When risk-based regulation aims low: Approaches and challenges' (2012) Regulation and Governance 1, 4
[550] ibid
[551] ibid 2-22
[552] ibid

III. Regulatory Reaction to the Hospital Discharge Safety Risk

As discussed earlier, in 2016 the Public Administrations and Constitutional Affairs concluded that the incidence of unsafe hospital discharges was unacceptably high[553], and Healthwatch England (HE) have repeatedly drawn attention[554] to the harm patients are exposed to when leaving hospital. The focus here is on whether the risk posed by hospital discharges is recognised by statutory healthcare regulators within the English NHS.

The CQC's assessment framework[555,] which reflects its 5 core questions when inspecting healthcare services556, indicates that the risk posed by hospital discharges to patient safety is a risk they are aware of. The framework contains a number of Key Lines of Enquiry (KLOEs), three of which feature questions relating to the safety, effectiveness, and responsiveness of hospital discharges. It asks firstly whether all the information needed for a patient's ongoing care is shared appropriately, in a timely way and in line with relevant protocols at the point of discharge557. Secondly, it asks if all relevant teams, services and organisations are informed when people are discharged from a service, and if discharge is undertaken at an appropriate time of day and only when necessary ongoing care is in place.[558] Thirdly, the framework asks how people are supported during discharge.[559] Information provided in response to a freedom of information request[560] stated that breaches in relation to safe discharge are most likely to be under Regulation 9 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, which is 'person-centred care'. This regulation is designed to ensure that people using a service have care or treatment that is personalised for them. The regulation guidance states: 'assessments should be reviewed regularly and whenever

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[553] Public Administration and Constitutional Affairs Committee (n 478) 18
[554] Healthwatch England (n 474)
[555] Care Quality Commission, 'Key lines of enquiry, prompts and ratings characteristics for healthcare services' (CQC 2018) <https://www.cqc.org.uk/sites/default/files/20180628%20Healthcare%20services%20KLOEs%20prompts%20and%20characteristics%20FINAL.pdf> accessed 19 December 2019
[556] These five questions ask whether services are safe, effective, caring, responsive and well led.
[557] CQC KLOE S3.3: When people move between teams, services and organisations (which may include at referral, discharge, transfer and transition), is all the information needed for their ongoing care shared appropriately, in a timely way and in line with relevant protocols?
[558] CQC KLOE E4.4 Are all relevant teams, services and organisations informed when people are discharged from a service? Where relevant, is discharge undertaken at an appropriate time of day and only done when any necessary ongoing care is in place?
[559] CQC KLOE R2.3 How are people supported during referral, transfer between services and discharge?
[560] Personal correspondence between author and CQC (August 2019)

needed throughout the person's care and treatment. This includes when they transfer between services, use respite care or are re-admitted or discharged. Reviews should make sure that people's goals or plans are being met and are still relevant'.[561] If the CQC finds that a provider is in breach of this regulation it can uses its regulatory powers to require or force a provider to improve.[562]

The CQC's 2018 adult inpatient survey report highlighted hospital discharge planning as an area for improvement. It flagged that 44 per cent of respondents discharged with medication were not being told about possible side-effects to watch out for, and only one in four were being told who to contact if they were worried about their condition following discharge. Seventeen per cent of respondents commented they felt uninvolved in their discharge planning – an area which has seen no improvements in 10 years.[563]

The CQC also has an 'independent voice' role, under which a range of reports regarding quality and safety of services are published; for example in 2019 the CQC published a report[564] on medicines optimisation which included two recommendations for safe discharge – essentially highlighting the importance of relevant and timely information sharing between hospitals and other services following discharge.[565] Furthermore, HE is a statutory committee of the CQC whose purpose includes escalating concerns raised by local Healthwatch organisations to the CQC.[566] As mentioned earlier in this article, HE has published three reports regarding unsafe hospital discharges.[567] Thus it seems reasonable to conclude that the risk to patients posed by hospital discharges is a risk that is known to the CQC.

In 2014, NHSE issued a patient safety alert to NHS organisations stating that approximately 33% of 10,000 incidents reported to the National Reporting and Learning System (NRLS) between October 2012 and September 2013 involved patients discharged from hospital without sufficient and timely communication of essential information. In some instances, this led to 'avoidable death and serious harm to patients due to a failure in continuity

[561] Care Quality Commission, 'Guidance for providers on meeting the regulations' (CQC 2015) 31
[562] Information provided to author in private correspondence with CQC (August 2019)
[563] Care Quality Commission, '2018 Adult Inpatient Survey: Statistical release' (CQC 2019)
[564] Care Quality Commission, 'Medicines in Health and Adult Social Care: Learning from Risks and Sharing Good Practice for Better Outcomes' (CQC 2019)
[565] ibid 35 and 52
[566] Healthwatch England, 'Our history and functions' <https://www.healthwatch.co.uk/our-history-and-functions> accessed 19 December 2019
[567] Healthwatch England (n 474)

of care as well as avoidable readmission to secondary care'[568]. NHSI publishes online resources in order to support the safe discharge of patients throughout the NHS[569], an aim NHSI acknowledged responsibility for when giving evidence to the PACAC committee regarding unsafe hospital discharges.[570] Once again it seems reasonable to conclude that the risk to patients posed by hospital discharges is known to NHSI/NHSE.

In contrast to the above organisational regulators, it is not immediately apparent that the risk posed by hospital discharge is recognised by the professional regulators. None of the professional regulators gave evidence to the PHSO inquiry regarding unsafe discharges[571] and none of the professional codes that registrants are expected to follow specifically mention discharges. Although discharges are not directly referred to, each code[572] does include the core behaviours and skills which are essential for ensuring safe discharge, such as: good communication with patients and colleagues; competency; multi-disciplinary working; safe prescribing; record-keeping; continuity of care; and the importance of working in partnership with patients. However, there is little evidence regarding how, if at all, professional codes positively influence behaviour.[573] As such, it cannot be argued that these professional codes, by themselves, are a sufficient regulatory response to the patient safety posed by hospital discharges.

Moreover, recent British Red Cross[574] research into safe hospital discharges did not include any interviews with professional regulators, which may suggest that the risk is perceived as belonging to the systems regulators rather than the professional regulators. It is worth emphasising again at this point that patient safety incidents linked to the hospital

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[568] NHS England, 'Patient Safety Alert NHS/PSA/W/2014/014' (NHSE 2014) available at <https://www.england.nhs.uk/wp-content/uploads/2014/08/psa-imp-saf-of-discharge.pdf> accessed 6 January 2020)

[569] See for example NHS Improvement, 'A guide to developing criteria-led discharge' (NHSI 2017) <https://improvement.nhs.uk/resources/guide-developing-criteria-led-discharge/> accessed 17 December 2019; NHS Improvement, 'Discharge planning' (NHSI 2018) <https://improvement.nhs.uk/resources/discharge-planning/> accessed 17 December 2019

[570] Public Administration and Constitutional Affairs Committee, 'Discharging older people from acute hospitals' (PACAC 2016/17) 15

[571] Public Administration and Constitutional Affairs Committee (n 478), 18

[572] See for example General Medical Council, 'Good Medical practice' (2013); Nursing and Midwifery Council, 'The Code' (2015), General Pharmaceutical Council, 'Standards for Pharmacy Professionals' (2017) and Social Work England, 'Professional Standards' (2019)

[573] Oliver Quick, 'A Scoping Study on the Effects of Health Professional Regulation on those Regulated' (Council for Healthcare Regulatory Excellence 2011); Healy (n 524)

[574]British Red Cross, 'Home to the Unknown: Getting hospital discharge right' (British Red Cross 2019) <https://www.redcross.org.uk/about-us/what-we-do/we-speak-up-for-change/more-support-when-leaving-hospital/getting-hospital-discharge-right> accessed 14 July 2021

discharge process *is* an issue that professional regulators should be interested in. In January 2020, the *Guardian* reported that the Royal Cornwall Hospitals NHS Trust had informed staff that patients should be discharged early to reduce overcrowding; a risk it called 'proportionate' despite the possibility 'that some of these patients will be readmitted or possibly come to harm'.[575] To require clinicians to act in such a manner is asking them to act in a way which may go against the professional standards expected of them, such as making the care of their patients their first concern and providing dignified care.[576] This is something which professional regulators should address.

Returning to whether professional regulators are aware of the discharge risk - a publicly available update on the GMC's harms reduction programme[577] in 2018 briefly mentions hospital discharges as a potential cause of harm. The document states that the purpose of the harms reduction programme is to support doctors to maintain good medical practice by 'identifying, understanding and addressing problems that might impede the delivery of this and by extension, present a risk of harm to patients or doctors'578. The draft harms register within the document identifies as a potential harm for future consideration 'inappropriate discharge' such as 'individuals being discharged prior to the results of investigations – particularly in A&E'.[579] This harm is categorised as a 'process failure/non-compliance' issue within a broader category of 'system-level harms'.[580]

This section has thus far established that although the harm of hospital discharges is recognised by the CQC, NHSE and NHSI, it is not widely recognised or acknowledged amongst the professional regulators, at least within the public sphere. This raises a further pertinent question: why might the risk posed to patient safety by hospital discharges be missing from the professional regulators' agenda? It is to this question that we now turn.

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[575] Denis Campbell, 'Cornwall Hospital to Discharge Patients Early Despite Saying it may be Harmful' *The Guardian (*London, 14 January 2020) <https://www.theguardian.com/society/2020/jan/14/cornwall-hospital-to-discharge-patients-early-despite-risks> accessed 30 January 2020
[576] General Medical Council, 'Good Medical Practice' (2013) paragraph 6
[577] General Medical Council, 'Executive Board Meeting' (GMC 2018) <https://www.gmc-uk.org/-/media/documents/08---the-harms-reduction-programme-progress-update_pdf-75445141.pdf> accessed 19 December 2019
[578] ibid 47
[579] ibid 59
[580] ibid

IV. Identifying, Conceptualising and Prioritising the risk of Hospital Discharges

In order to answer the question of why this risk might not be recognised by the professional regulators, it is apposite to return to the difficulties discussed in section three concerning the identification, conceptualisation, and prioritisation of risk.

Identification of risk

The first reason that the risk may be unrecognised is because the success of risk-based regulation approaches is heavily dependent upon the availability of sufficient information to inform decision-making.[581] Given the web of actors within the English NHS, and the mass of information held amongst them, an individual actor is unlikely to possess all of the relevant information it would need to react accordingly.[582] For example, professional regulators have historically relied heavily upon complaints made by patients, their families or employers about an individual healthcare professional to trigger an investigation into the individual's fitness to practice (FTP). A risk-based approach to assessing the risk of harm to patients posed by an individual is then typically followed, which allows regulators to justify their decision-making processes.[583] However, professional regulators are adopting a more 'upstream' approach to regulation. This means they are moving towards 'pro-active, early and specific interventions in order to either decrease the likelihood of an undesirable outcome or to increase the likelihood of a more favourable outcome'.[584] Complaints about individual practitioners alone are an insufficient data source for identifying and addressing broader, complex safety issues such as hospital discharges, where patient safety is not dependent upon the actions of an individual.

Positive steps have been taken to address this information deficit. For example, the GMC's health system liaison service was created to help the GMC engage at every level with

[581] Hampton (n 506); Lloyd-Bostock and Hutter (n 507)
[582] Healy (n 524)
[583] For discussion of the GMC's FtP risk-based approach see JM Chamberlain, 'Malpractice, Criminality, and Medical Regulation: Reforming the Role of the GMC in Fitness to Practise Panels' (2017) 25 Medical Law Review 1; and Sally Lloyd-Bostock, 'The Creation of Risk-Related Information: The UK General Medical Council's Electronic Database' (2010) 24 Journal of Health Organisation and Management 584
[584] General Medical Council, Exec Board Meeting (n 577)

the healthcare systems, helping to ensure that their approach to regulation is well informed.[585] The service sees GMC advisers collaborate with doctors, educators, employers, and other regulators in order to 'understand, identify and address risks to patients and doctors before harm occurs'.[586] The GMC's corporate risk register[587] also outlines some of its existing mechanisms for sharing data. For example, the register states that the GMC works closely with the Health and Social Care Regulators' Forum to improve collaboration, holds regular surveillance groups with the CQC to consider risk, has regular intelligence sharing meetings called Regional Information Forums, engages with NHS Improvement, and has a central analytics team in place which is responsible for coordinating data sharing. Hospital discharges are specifically mentioned in a memorandum of understanding (MoU) in place between the CQC and GMC.[588] This states that the CQC would like to be informed of issues affecting patient experience, including delays in discharge, early discharge, and lack of dignity or respect to patients.[589] The GMC indicated they would wish to be informed of scenarios such as foundation doctors in surgery signing discharge letters that have been written by other doctors relating to patients they have never examined.[590]

Furthermore, in 2018, an emerging concerns protocol[591] was developed amongst regulators, which five of the professional regulators[592] have signed. The protocol is designed to establish a method for sharing early concerns so that links between concerns can be made. The concerns may fall into the following three categories: 'concerns about individual or groups of professionals; concerns about healthcare systems and the healthcare environment (including the learning environments of professionals); concerns that might have an impact on trust and confidence in professionals or the professions overall'.[593]

Clearly apparent above is the sheer quantity of mechanisms in place in order to facilitate information sharing across regulators, yet despite these a recent inquiry has concluded that

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[585]General Medical Council, 'Health System Liaison Services' <https://www.gmc-uk.org/about/how-we-work/liaison-and-outreach/health-system-liaison-services> accessed 19 December 2019
[586] ibid
[587] General Medical Council, 'Chief Operating Officer's Report' (n 510)
[588] CQC and GMC, 'Operational Protocol: A practical guide for staff - for external use' (2018) <https://www.cqc.org.uk/sites/default/files/20181205_cqc-gmc_joint_operational_protocol_redacted.pdf> accessed 19 December 2019)
[589] ibid
[590] ibid
[591] CQC and others, 'Emerging Concerns Protocol' (CQC 2018)
[592] GDC, GMC, GPHC, HCPC, and NMC
[593] CQC and others, (n 591) 6

there is an 'insufficient linkage between CQC and the other regulators'.[594] Due to the vast amounts of data that each regulator is likely to hold, it is highly unlikely that all issues will be shared amongst all regulators. In practice, judgement calls will need to be made about what issues are shared across which forum at any given time. It is therefore possible that so far, information relating to PSIs within the context of hospital discharges has not been widely shared and considered amongst all of the healthcare regulators – leading to poor identification of the risk posed to patients.

Conceptualisation of risk

This leads to the second reason why the risk posed by hospital discharges might be missing from the professional regulators' agenda: the challenge of conceptualising risk in a unified manner where multiple regulators[595] are involved. How each regulator constructs the risk posed by hospital discharges will determine if and how the information is shared across the regulators.

As established in section two, from a regulatory perspective there are three broad categories of risk that can result in harm to patients: risks to the physical wellbeing/and or dignity to the patient; risks to a regulator's reputation; and risks to public trust in the professions. The risk posed by hospital discharges is likely to fall predominantly within the first category; however, professional regulators may still not conceptualise it as a risk within their remit. For example, the GMC's harm register indicates that the GMC perceives inappropriate discharge as a process failure/non-compliance issue, listed under a broader heading of system level harm.[596] Construed in this manner, it may not be apparent that this is also a risk closely entwined with the behaviour of healthcare professionals, including doctors. Yet as the scenario of Mrs K highlighted, the decision to discharge Mrs K in the given circumstances was not in line with behavioural expectations set out in any of the professional codes, and resulted in harm to her dignity; which is a patient safety incident.

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[594] James (n 530) 186
[595] Sarah Devaney, 'Ethics for Healthcare Regulators: Enhancing compliance with the Seven Principles of Public Life' (Manchester Centre for Regulation 2016); Baldwin and Black (n 536); Healy (n524)
[596] General Medical Council, 'Chief Operating Officer's Report' (n 510) 11

Within the Cornwall[597] example, we can see how the risk is situated not only within the remit of the systems regulators (the pressure of under-resourced hospitals), but also within the remit of the professional regulators. This is because the situation is likely to impact upon the ability of healthcare professionals to act in accordance with their professional standards – for releasing patients before they are clinically ready is unlikely to be cohesive with providing good care for a patient. This particular case straddles two of the categories of risk identified in section two; direct risk to a patient's physical wellbeing or dignity, and risk to public trust in the professions.

By way of further example, the MoU between the GMC and CQC[598] shows the GMC has an interest in receiving information from the CQC regarding foundation doctors signing discharge letters that have been written by other doctors and relating to patients they have never examined. This is the only discharge-specific scenario that the GMC provides as an example of the type of discharge-related issue it is interested in. The rationale for this interest is that it might cause a patient safety concern or indicate bullying concerns.[599] However, by requesting such specific information on discharges, the GMC may inadvertently be signalling that it is not interested in being informed of discharge-related harms to a patient's dignity, despite the fact that respect for patient dignity is a central feature of the GMC's expectations of doctors.[600]

Prioritisation of risk

Thirdly, the risk posed by hospital discharges could be missing from the professional regulators' agenda due to being categorised as low risk, and thus as Black argues, low priority.[601] One reason why the risk might be categorised as 'low' is that the resulting physical harm is typically mild (Williams' study[602] of NRLS data reported 64% of discharge-related harm was low-level). Thus, if activities are categorised according to the severity of physical harm, then hospital discharges may not be perceived as being high-risk. Risks that catch the attention of the media and dominate headlines are also more likely to be treated as a higher priority due to the threat posed to the reputation of the regulator and to public trust in the

[597] Campbell (n 575)
[598] CQC and GMC (n 588)
[599] ibid 32
[600] General Medical Council, 'Good Medical Practice' (2013)
[601] Black and Baldwin, 'When Risk-based Regulation Aims Low' (n 549) 2-22
[602] Williams and others (n 480)

profession. To-date, the harm posed by hospital discharges to patient safety has had limited recognition[603] in the media, despite the ongoing nature of the problem.

The frequency of harm to dignity is harder to measure than physical harm, partly because harm to dignity is likely to go unreported. Research by the PHSO has highlighted that despite being the greatest users of health and social care providers (thus subject to frequent discharges), older people are reluctant to complain about poor care.[604] However, as discussed in section one of this article, harm to dignity is a patient safety concern arising during hospital discharges. Given that all patients have a right[605] to be treated with dignity, this is not a harm that should be ignored or categorised as low-priority by professional regulators.

This section has examined why the professional regulators may not have adequately addressed the risk posed to patient safety by hospital discharges. However, it is important to note that responsibility for responding to this particular patient safety risk does not lie solely with the professional regulators; a cohesive response from all of the statutory regulators is required. The first step in achieving this is to overcome the challenges laid out in this article regarding the identification, conceptualisation, and prioritisation of this patient safety risk.

V. Conclusion

This article has highlighted the risk posed to patient safety by the hospital discharge process. It has examined the nature of the risk of harm patients face during discharge; namely harm to the physical wellbeing and to their dignity. It has then identified the regulators who ought to be reducing the risk of such harm to patients, and highlighted the minimal actions that have been taken to achieve this aim. In order to establish why there has been a lack of regulatory

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[603] Examples of where mainstream media have raised the issue include: Melanie Henwood, 'Hospital discharge is not rocket science. Why are patients still being failed? *The Guardian* (16 May 2016) <https://www.theguardian.com/social-care-network/2016/may/16/hospital-discharge-patients-failed-ombudsmans-report> accessed 16 April 2020; James Meikle, 'Hospitals show 'shocking' lack of care discharging vulnerable patients' *The Guardian* (21 July 2015) <https://www.theguardian.com/society/2015/jul/21/healthwatch-hospitals-discharging-vulnerable-patients-lack-of-care-> accessed 16 April 2020; and Henry Bodkin, 'Patients sent home from hospital with no advice on how to cope, watchdog finds' *The Telegraph* (20 June 2019) <https://www.telegraph.co.uk/news/2019/06/20/patients-sent-home-hospital-no-advice-cope-watchdog-finds/> accessed 16 April 2020

[604] Parliamentary and Health Service Ombudsman, 'Breaking Down the Barriers: Older People and Complaints about Health Care' (PHSO 2015)

[605] National Health Service (n 495)

action in this area, particularly from the professional regulators, this article has considered the risk-based regulation model which is utilised by these regulators.

Consideration of this model has focussed upon three weaknesses regarding how regulators identify, conceptualise, and subsequently prioritise risk. The difficulties regulators face with these three elements has meant regulatory interventions to ensure patient safety during hospital discharge have been limited.

In the case of hospital discharges, the first difficulty regarding risk-identification arises as regulators do not possess a holistic overview of all relevant information. This is because of the multitude of regulators and the limited information-sharing mechanisms between them – which means judgements have to be made about what information to share and with whom. This is problematic given that successful risk-based regulation is heavily dependent upon the availability of sufficient information to identify risks and inform decision-making.

The multitude of statutory regulators and limited information-sharing leads to a further difficulty: it is virtually impossible for them all to have a unified understanding of the risk posed by discharges. Risks will be conceptualised based upon the nature of information possessed, which will vary in a field saturated with regulators.

Finally, successful risk-based regulation relies upon the correct prioritisation of risk, an outcome which is reliant upon regulators having obtained sufficient information and having clarity amongst themselves regarding their regulatory aim. It is possible that regulators are not prioritising ensuring patient safety during discharge in the manner they would if they had the requisite information and clarity about the risk that discharges pose to patients.

Combined, these three weaknesses have meant that the risk posed to patient safety at the point they leave hospital is neither uniformly recognised by the statutory regulators within the English NHS, nor sufficiently addressed. Professional regulators in particular appear to have a poor awareness of the risk and their role in addressing it. The result of this ineffective regulation leaves the physical wellbeing and dignity of patients continuously imperilled at a point in time when they should be returning safely home. Until regulators can accurately identify this risk, build a unified understanding of its causes and consequences, and prioritise it appropriately, this unacceptable status quo will remain.

PART THREE: LIMINAL SPACES – EXPLORING THE REGULATORY GAPS

Regulating Patient Safety During Hospital Discharge: Casting the Patient Safety Commissioner as the Representative of Order (Paper Two)

I. Introduction: Understanding Patient Safety and Hospital Discharges

> 'We have found that the healthcare system – in which I include the NHS, private providers, the regulators and professional bodies, pharmaceutical and device manufacturers, and policymakers – is disjointed, siloed, unresponsive and defensive. It does not adequately recognise that patients are its raison d'etre. It has failed to listen to their concerns and when, belatedly, it has decided to act it has too often moved glacially'.[606]

The above sums up the findings of the Independent Medicines and Medical Devices Safety (IMMDS) Review in England, published in 2020. The Review's purpose was to examine how the English[607] healthcare system responded to concerns raised about harmful side effects from specific medicines and medical devices,[608] and to consider how future responses to concerns over side effects could be quicker and more effective.[609] That the healthcare system is disjointed and siloed[610] is a problem which significantly contributes to the harm patients experience when discharged from hospital; a problem which regulators have thus far failed to adequately address.[611] In an earlier article,[612] I drew attention to how risk-based regulation, a prominent model of regulation within the English NHS, is poorly-equipped to ensure and improve patient safety in this regard.

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[606] Independent Medicines and Medical Devices Safety Review, First Do No Harm: The Report of the Independent Medicines and Medical Devices Safety Review (2020) <https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf> accessed 21 March 2021, p.i (IMMDS Review)

[607] Although the review focussed on England its recommendations cover England only, evidence was heard from across the UK (ibid, paras 1.9 and 1.10)

[608] These were hormone pregnancy tests, sodium valproate, and pelvis mesh implants.

[609] IMMDS Review (n 606)

[610] Siloed working refers to instances where organisations to take a non-collaborative approach to work. NHS England has acknowledged that it works in 'silos', available at <https://www.england.nhs.uk/blog/rolling-up-our-sleeves-and-getting-out-of-our-silos/> accessed 4 November 2020

[611] Victoria Moore, 'Leaving Hospital: A step too far for risk-based regulation?' (2020) 28 Medical Law Review 675

[612] ibid

This article employs the anthropological concept of liminality as a lens through which to view these challenges in regulating patient safety during hospital discharges. Although this article focusses upon the English context, patients are internationally recognised as being at an increased risk of harm when leaving hospital.[613] The rationale for using liminality in this particular area is because it brings into focus the in-between space that exists amongst regulatory bodies (this is explained more fully below).

The discharge process is subject to multiple regulatory requirements and influences. However, if a patient safety incident occurs in relation to this process and does not fall squarely within any regulator's remit, then it may end up within a regulatory lacuna. This we might usefully conceive of as a liminal space, and this article addresses the implications of this conceptualisation for regulating patient safety in hospital discharge. Using liminality, this article has two central aims. First, it seeks to illustrate this space in-between regulators. Secondly, it argues that the creation of a new Patient Safety Commissioner (PSC) role could be one way in which to improve patient safety during hospital discharges. The creation of a PSC was recommended by the IMMDS review,[614] and established in the new Medicines and Medical Devices Act 2021 (MMD Act).[615] At the time of writing, there is no indication of when the first commissioner will be appointed. It is proposed herein that the remit of the PSC be extended beyond medicines and medical devices to include improving patient safety with regard to *processes*, such as hospital discharges.

The remainder of this introduction outlines the nature of the risks which hospital discharge can pose to the safety of patients. The second section details the actors within the hospital discharge regulatory arena and draws attention to how they have attempted to engage in this space thus far. The third section introduces the concept of liminality, and illustrates the liminal space within this context. It shows how this space occurs as a result of the plethora of regulators and the related challenge of forming a unified understanding and prioritisation of the risk posed by hospital discharges.[616] Actions then taken to improve safety during discharges (typically the production of a report) often fail to have the desired impact. In order to minimise

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[613] Karina Aase and others (eds), *Researching Quality in Care Transitions International Perspectives* (Palgrave Macmillan 2017); Kirstin Manges and others, 'A Mixed Methods Study Examining Teamwork Shared Mental Models of Interprofessional Teams During Hospital Discharge' (2019) BMJ Quality & Safety 1; World Health Organisation, 'Transitions of care: Technical series on safer primary care' (World Health Organisation 2016) <https://www.who.int/patientsafety/topics/primary-care/technical_series/en/> accessed 26 March 2021

[614] IMDDS Review (n 606) Recommendation 2

[615] Medicines and Medical Devices Act 2021, s 1

[616] Moore (n 611)

this undesirable occurrence, this article envisages that the new PSC role could function as a Representative of Order. The rationale for this is explored in section four, and the example of another Representative of Order within the patient safety field - the Chief Coroner - is used to demonstrate how such a role can improve safety. The fifth section incorporates learning from this example to illustrate how the PSC, when cast as a Representative of Order, could help regulators overcome the difficulties identified in the third section.

Patient safety and hospital discharges

Common problems highlighted in a 2016 report by the Parliamentary and Health Service Ombudsman (PHSO) relate to patients being discharged before it is clinically safe to do so; failing to involve patients and their families/carers in decision-making surrounding discharge; and discharging patients despite no appropriate ongoing support being in place.[617] These issues have become increasingly apparent during the Covid-19 pandemic. For example, MIND (a mental health charity in England and Wales) expressed concern that people may have been discharged from mental health hospitals when it was unsafe to do so, or without adequate support.[618] It noted that in April 2020, only 4030 discharges were followed up within 72 hours, out of 5,571 that were eligible for follow up.[619] Based on interviews with patients/carers regarding discharge between March and August 2020, Healthwatch England (HE) and the British Red Cross reported that basic checks such as whether people needed transport to get home were missed.[620] People reported feeling unprepared to leave hospital and confused about who could be contacted for further information. Several reported not receiving any follow-up assessments after discharge, which meant they did not have the medication or equipment needed to recover properly in their home.[621]

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[617] Parliamentary and Health Service Ombudsman, (2016) 'A Report of Investigations into Unsafe Discharge from Hospital' <https://www.ombudsman.org.uk/publications/report-investigations-unsafe-discharge-hospital-0> accessed 26 March 2021 (Unsafe Discharge Report)
[618] MIND, 'The impact of coronavirus on discharge from mental health hospital' (2020) <https://www.mind.org.uk/media-a/6293/the-impact-of-coronavirus-on-mental-health-hospital-discharge-briefing.pdf> accessed 26 March 2021
[619] ibid
[620] Healthwatch England and British Red Cross, '590 people's stories' (2020) < https://www.healthwatch.co.uk/report/2020-10-27/590-peoples-stories-leaving-hospital-during-covid-19> accessed 26 March 2021
[621] ibid

A study of data[622] on discharge-related safety incidents within England's National Reporting and Learning System (NRLS) database [623] found four main categories of error which caused harm to patients in 75% of the cases studied. These were: quality of discharge communication; referrals to community care; medication errors; and issues concerning the provision of care adjuncts (such as wound dressings) for ongoing community care. Behavioural factors, for example where staff did not follow protocols, and organisational factors such as a lack of clear guidelines, also contributed to safety incidents. Although the severity of harm tended to be low-level,[624] in 78 cases (13%), patients experienced moderate harm. This meant patients required an intervention to resolve their symptoms and may have experienced permanent/ long-term harm, or a loss of function. In three (<1%) severe cases life-saving interventions were needed, and in one case the patient died.[625]

An ethnographic study by Waring and colleagues found that the coordination of multiple actors across occupational and organizational boundaries, and the interdependencies and interactions between these groups can represent a threat to discharge safety.[626] The study identified the following issues between health care settings which the authors suggest might explain the variations in discharge safety. First, differences in organisation (such as how technologies are used and how labour is divided); secondly, culture (whether there is a blame culture, the extent to which patients are involved in their care); and thirdly, knowledge (for example how discharge is understood across each group of professionals).[627] The authors conclude that increased use of 'boundary spanners' may be one way to improve patient safety during discharges. Boundary spanners are actors who work across occupational and organisational boundaries, and so are often able to learn about cultures, knowledge, and ways of working which may not be accessible to actors working in professional silos.[628] This suggests that in complex regulatory environments there is a role for a designated actor to guide people through – a point that has been well made by Laurie and colleagues.[629]

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[622] Huw Williams and others, 'Harms from Discharge to Primary Care: Mixed Methods Analysis of Incident Reports' (2015) 65 British Journal of General Practice e829
[623] The NRLS is a central database of patient safety incidents reported from across England and Wales.
[624] 'Low-level' was defined by the study authors as patients experienced mild symptoms, the harm was short-term, and little or no intervention was required to resolve the harm.
[625] Huw Williams and others (n 622)
[626] Justin Waring, Fiona Marshall, and Simon Bishop, 'Understanding the Occupational and Organizational Boundaries to Safe Hospital Discharge' (2015) 20 Journal of Health Services Research & Policy 35
[627] ibid
[628] ibid
[629] Graeme Laurie and others, 'Charting Regulatory Stewardship in Health Research: Making the Invisible Visible?' (2018) 27 Cambridge Quarterly of Healthcare Ethics 333

Alongside experiencing physical harm, patients' dignity may also be harmed during hospital discharges.[630] According to the NHS Constitution (which is enshrined in the 2009 Health Act), [631] patients have a right to be treated with dignity and respect in accordance with their human rights. Although dignity is not explicitly defined in law, thus making a requirement to respect human dignity difficult for regulators to enforce,[632] it is nevertheless an important part of patient safety.[633] Patients view non-clinical incidents as a safety incident; and dignity featured in one study as a patient-derived safety category.[634] The PHSO report into unsafe discharges gives the example of Mrs K, an elderly person with dementia who was discharged late at night unbeknownst to her family. She was found at home by her daughter the next day, without food, drink, or bedding, and had been unable to get to her toilet.[635] We can imagine that Mrs K may have experienced this incident as an affront to her dignity and wellbeing. Having illustrated the wide-ranging factors which may pose a serious threat to patients' safety when leaving hospital, we now turn attention to matters of regulation.

II. Regulation and Hospital Discharges

Oikonomou and colleagues define healthcare regulation as 'the processes engaged in by institutional actors that seek to shape, monitor, control or modify activities within healthcare organisations in order to reduce the risk of patients being harmed during their care'.[636] This broad definition captures a wide range of behavioural influences performed by several actors within a healthcare system. It is perhaps a welcome definition in that it broadness allows a wide variety of institutions to be compared.[637] However, Walshe argues that it is important to set sensible boundaries around the concept of regulation as broad interpretations risk the concept becoming 'almost meaningless.'[638] According to Black, definitional vagueness is generally seen

[630] Moore (n 611)
[631] National Health Service, 'NHS Constitution for England' (NHS 2015)
[632] Timothy Caulfield and Roger Brownsword, 'Human dignity: a guide to policy making in the biotechnology era?' (2006) 7 Science and Society 72
[633] Moore (n 611)
[634] Jane K O'Hara and others, 'What Can Patients Tell Us about the Quality and Safety of Hospital Care? Findings From a UK Multicentre Survey Study' (2018) 27 BMJ Quality & Safety 673
[635] Parliamentary and Health Service Ombudsman (n 617) 19
[636] Eirini Oikonomou and others, 'Patient Safety Regulation in the NHS: Mapping the Regulatory Landscape of Healthcare' (2019) 9 BMJ Open 2, 2
[637] Tony Prosser, *The Regulatory Enterprise: Government, Regulation, and Legitimacy* (Oxford University Press 2010)
[638] Kieran Walshe, Regulating Healthcare: A Prescription for Improvement (Oxford University Press 2003) 10

by those writing on regulation as, 'at best a rather quaint feature and at worst an occupational hazard'.[639] She does however indicate that some clarity is needed in order to avoid confused debate regarding what regulation should or should not be, and observes that academics lack a disciplined approach to defining regulation.[640] Its conceptualisation, she argues, often depends upon the issue that the writer is focused upon.[641] Against this backdrop of 'definitional chaos',[642] this article uses the term 'regulation' to refer to the formal attempts by statutory regulators to shape behaviour within healthcare organisations. This is inspired by Black's definition of regulation as 'the sustained and focused attempt to alter the behaviour of others according to defined standards or purposes with the intention of producing a broadly identified outcome or outcomes'.[643] The focus is narrowed in this article to statutory regulators because these have a legal duty to protect patients, and are therefore the ones who should be held accountable for any regulatory failings that are uncovered. That said, this narrower focus is not intended to dismiss any other actors which exert regulatory influence; rather it takes the view that other actors have an important role to play in feeding into the actions undertaken by the statutory regulators as they seek to improve safety. Such a position is cohesive with both the findings of the IMDDS review[644] and Quick's view that regulating patient safety requires regulation to be seen as a collaboration between patients and professionals, and this in turn means that the involvement of patients is both necessary and legitimate.[645]

This article uses the term 'regulatory arena' to refer to the regulatory environment within which regulation takes place. A more common term is 'regulatory space' - coined by Hancher and Moran.[646] 'Arena' is used here in order to minimise any confusion between this and the concept of 'liminal space' which will shortly be introduced. Conceptually, the regulatory arena is intended here to be the same as the regulatory space. The 'regulatory space' refers to the environment within which regulation takes place; which includes the actors within it, alongside wider factors such as the legal system, socio-cultural influences, and the relationship dynamics between actors.[647] Rather than flowing hierarchically, power and

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[639] Julia Black, 'Critical Reflections on Regulation' (2002) 27 Australian Journal of Legal Philosophy 1,11
[640] ibid
[641] ibid
[642] ibid 11
[643] Julia Black, 'Decentering Regulation: Understanding the Role of Regulation and Self-Regulation in a Post-regulatory World' (2001) 54 Current Legal Problems 103, 142
[644] IMMDS Review (n 606)
[645] Oliver Quick, *Regulating Patient Safety* (Cambridge University Press: Cambridge 2017) 164
[646] Leigh Hancher and Michael Moran, Organizing Regulatory Space, in Leigh Hancher and Michael Moran (eds), *Capitalism, Culture and Economic Regulation* (Oxford University Press 1989) 271–300
[647] Eric Windholz, Governing through Regulation: Public Policy, Regulation and the Law (Routledge 2018) 71

influence within the regulatory arena can be exercised horizontally and vertically by actors seeking to modify the behaviour of each other,[648] creating what Morgan and Yeung refer to as a 'reflexive process of influence and change within the regulatory space'.[649] Regulatory arenas can be defined broadly[650] and narrowly. A broad definition might be employed when considering all impacts upon patient safety within the English NHS; however, this article narrows focus towards the concerning hospital discharges within the English NHS. This arena involves not only statutory regulators, but multiple others with a shared aim of patient safety at the point of discharge.

The Hospital Discharge Regulatory Arena

This section identifies the actors within this regulatory arena operating at a national level and their actions in this setting. The purpose of this mapping651 is to bring to attention the vast number of actors, not all of which are statutory regulators, that have made attempts to respond to the serious patient safety issues posed by discharges. It will then be argued that weaknesses within risk-based regulation result in regulators creating thresholds which must be met in order for them to take action in response to a particular risk. Where their conceptualisation of the risk then fails to meet their own threshold, the regulator's response is likely to be inaction.

Before focussing upon the statutory regulators, influential non-regulatory actors will be briefly introduced. Patient voices are represented within the arena through the PHSO, patient groups, and charities. The PHSO makes the final decision on complaints that have not been resolved by the NHS in England.[652] As mentioned earlier, in 2016 the PHSO published a report into unsafe discharges, based upon the complaints it had received (more will be said on this report in section three).[653] Healthwatch England (HE), a statutory committee of the CQC,

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[648] ibid 71
[649] Bronwen Morgan and Karen Yeung, *An Introduction to Law and Regulation* (Cambridge University Press 2007) 76
[650] Eric Windholz (n 647) 70-72
[651] For further 'mapping' of regulatory actors within the NHS, see also David Horton and Gary Lynchwood, 'Technocracy, the Market, and the Governance of England's National Health Service' (2020) 14 Regulation and Governance 1; David Horton and Gary Lynchwood, 'Rhetoric and Reality: User Engagement and Health Care Reform in England' (2018) 26 Medical Law Review 27; and Oikonomou and others (n 636)
[652] Parliamentary and Health Service Ombudsman, 'Welcome to the Parliamentary and Health Service Ombudsman' < https://www.ombudsman.org.uk/> accessed 4 November 2020
[653] Parliamentary and Health Service Ombudsman (n 617)

escalates concerns raised by local Healthwatch organisations to the CQC;[654] HE has produced three reports on unsafe hospital discharges since 2015.[655] Charities also seek to influence the regulatory arena by sharing patients' experiences; for example, the British Red Cross and Patients Association have both published findings of people's experiences of hospital discharge.[656] The National Institute for Health and Care Excellence (NICE) provides evidence-based guidance to help health and social care professionals deliver the best possible care.[657] In 2015 NICE published its guideline on the transition between inpatient hospital settings and community or care homes for adults with social care needs.[658] Although guidelines are not legally binding, failing to follow NICE guidelines may lead to legal consequences.[659]

Hospital discharges involve the coordination of numerous actors across occupational and organizational boundaries.[660] All of these actors are subject to different regulatory regimes. Professional regulators such as the General Medical Council (GMC), Nursing and Midwifery Council, Health and Care Professions Council, General Pharmaceutical Council, and Social Work England, regulate the healthcare professionals working within healthcare. Each of the professional regulators[661] set standards of behaviour, competence and education that professionals must meet; these are expressed within the professionals' codes. Hospital

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[654] Healthwatch England, 'Our History and Functions' <https://www.healthwatch.co.uk/our-history-and-functions> accessed 4 November 2020

[655] Healthwatch England, 'Safely Home: What happens when people leave hospital and care settings? Special Inquiry Findings' (Healthwatch 2015); Healthwatch England, 'What happens when people leave hospital and other care settings?' (Healthwatch 2017); Healthwatch England, 'Emergency Readmissions: What's changed one year on?' (Healthwatch England 2018) <https://www.healthwatch.co.uk/sites/healthwatch.co.uk/files/20181114%20Emergency%20readmissions_0.pdf> accessed 31 August 2021

[656] British Red Cross, 'In and Out of Hospital'(2018) <https://www.redcross.org.uk/about-us/news-and-media/media-centre/press-releases/press-release-repeat-visits-to-accident-and-emergency> accessed 21 March 2021; British Red Cross, 'Home to the Unknown: Getting hospital discharge right' (2019) <www.redcross.org.uk/about-us/what-we-do/we-speak-up-for-change/more-support-when-leaving-hospital/getting-hospital-discharge-right> accessed 21 March 2021; Healthwatch England and British Red Cross, '590 people's stories' (n 620); Patients Association, 'Premature discharge from hospital' (2020) https://www.pslhub.org/learn/patient-engagement/keeping-patients-safe/premature-discharge-from-hospital-june-2020-r2568/ accessed 21 March 2021

[657] NICE, 'Our Charter' <https://www.nice.org.uk/about/who-we-are/our-charter> accessed 4 November 2020

[658] NICE, 'Transition between inpatient hospital settings and community or care home settings for adults with social care needs' (2015) <https://www.nice.org.uk/guidance/ng27> accessed 4 November 2020

[659] Ash Samanta and others, 'The Role of Clinical Guidelines in Medical Negligence Litigation: A Shift from the Bolam Standard?' (2006) 14 Medical Law Review 321; *R (on the application of Elizabeth Rose) v Thanet Clinical Commissioning Group* [2014] EWHC 1182 (Admin); *R v North Derbyshire Health Authority* [1997] EWHC Admin 675; Jenny Bleasdale, 'NICE guidelines: not just the gold standard practice' (2018) <https://www.hilldickinson.com/insights/articles/nice-guidelines-not-just-gold-standard-practice> accessed 4 November 2020

[660] Justin Waring and others (n 626)

[661] There are nine bodies tasked with overseeing the regulation of healthcare professionals in England: GMC, GDC, GCC, GOC, GOsC, GPHC, HCPC, NMC, SWE

discharges are not directly mentioned in the codes; however, behaviours and skills relevant to ensuring safe discharge (such as communication and record-keeping) are specified.[662] The systems within which these healthcare professionals work are not regulated by the same regulatory bodies; meaning there is a regulatory split between people and their work environment. Writing on human error, Reason argues that by focusing on the individual as an origin of error, unsafe acts become isolated from their system context.[663] Although not in scope for this article, this raises an interesting question regarding whether merging regulators to create one responsible for overseeing both professionals and their working environment would be effective.

The Care Quality Commission (CQC), NHS England (NHSE), and NHS Improvement (NHSI) regulate the system and environment within which healthcare professionals work; each has statutory duty pertaining to patient safety. The CQC was established under the Health and Social Care Act 2008 with a primary objective to protect and promote the health, safety, and welfare of people using health and social care services.[664] As the regulator of the quality of health and social care in England, the CQC has an assessment framework that it applies to the regulation of all health services. During its inspections of services, the CQC asks questions relating to the safety, effectiveness, and responsiveness of hospital discharges.[665] In 2018, the CQC's annual adult inpatient survey report flagged hospital discharge planning as an area for improvement.[666] In 2019, the same annual survey showed 'continuing patterns of decline' regarding care coordination at discharge.[667] For example, the survey highlighted how two in five people had not been given any printed information on what they should do after leaving hospital – which was a decline of seven percentage points since 2013. This result was 'lower than where [the CQC] would expect, based on past data, the fourth consecutive year'.[668]

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[662] For example, see paragraph 1 of the NMC's Code (2015); standard 1 of 'Standards for Pharmacy Professionals' (2017); section 2.2 of Social Work England's Professional Standards (2019), and paragraph 25 of the GMC's 'Good Medical Practice'. The GMC's 'Good practice in prescribing and managing medicines and devices' (2021) also states in paragraph 53 that doctors must contribute to the safe transfer of patients.
[663] James Reason, 'Human error: models and management' (2000) British Medical Journal 768
[664] Health and Social Care Act 2008, s 3(1)
[665] CQC, 'Key Lines of Enquiry, Prompts and Ratings Characteristics for Healthcare Services' (2018) <https://www.cqc.org.uk/sites/default/files/20180628%20Healthcare%20services%20KLOEs%20prompts%20and%20characteristics%20FINAL.pdf > accessed 21 March 2021
[666] CQC, '2018 Adult Inpatient Survey: Statistical release' (2019) <https://www.cqc.org.uk/sites/default/files/20190620_ip18_statisticalrelease.pdf> accessed 21 March 2021
[667] CQC, '2019 Adult Inpatient Survey: Statistical release' (2020) <https://www.cqc.org.uk/sites/default/files/20200702_ip19_statisticalrelease.pdf> accessed 21 March 2021, 54
[668] ibid 50

NHSE has a duty to improve the quality and safety of services provided to patients.[669] With regard to hospital discharge safety, the organisation has produced a series of guides intended to support local systems in reducing the time people spend in hospital. The stated aim is not to encourage inappropriate discharges but to improve safety, given evidence that longer hospital stays can be associated with poorer health outcomes.[670] In 2014, NHSE issued a patient safety alert to NHS organisations stressing the importance of appropriately communicating essential information when discharging patients. Failures to do so had resulted in 'avoidable death and serious harm to patients due to a failure in continuity of care as well as avoidable readmission to secondary care'.[671] NHSE works jointly with NHSI,[672] which also has a statutory duty to protect and promote the interests of people using health care services.[673] As the Covid-19Covid-19-19 pandemic took hold, the government and NHSE issued guidance to hospitals with the aim of freeing up bed spaces for anticipated patients through accelerating discharges from hospital.[674] This drive saw 25,000 patients discharged into care homes without being tested prior to discharge for Covid-19 (routine testing was introduced mid-April 2020).[675] These discharges into care homes took place despite evidence that the policy was fuelling outbreaks of the virus and deaths in care homes;[676] a policy decision described as 'reckless and negligent' by the Public Accounts Committee.[677] One in five directors of adult social services expressed concern that the policy had resulting in people being discharged to services unable to fully meet their needs.[678] It is outside of the scope of this particular article to fully explore

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[669] National Health Service Act 2006 (as amended by the Health and Social Care Act 2012), s 13E
[670] NHS England, 'Quick Guides to Support Health and Social Care Systems' <https://www.england.nhs.uk/urgent-emergency-care/improving-hospital-discharge/quick-guides/> accessed 4 November 2020)
[671] NHS England, 'Patient Safety Alert NHS/PSA/W/2014/014' (NHSE 2014) <https://www.england.nhs.uk/wp-content/uploads/2014/08/psa-imp-saf-of-discharge.pdf> accessed 4 November 2020
[672] As of April 2016, NHS Improvement is the operational name for the body that brings together Monitor, NHS Trust Development Authority, NHS England's Patient Safety teams, the National Reporting and Learning System, the Advancing Change team and the Intensive Support Teams
[673] Health and Social Care Act 2012, Part 3 (62)(1)
[674] HM Government & NHS England, 'COVID-19 Hospital Discharge Service Requirements' (2020) <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/880288/COVID-19_hospital_discharge_service_requirements.pdf> accessed 26 March 2021
[675] Public Accounts Committee, 'Readying the NHS and social care for the COVID-19 peak' (2020) <https://publications.parliament.uk/pa/cm5801/cmselect/cmpubacc/405/40506.htm#_idTextAnchor012> accessed 21 March 2021, paras 9-11
[676] Bill Gardner, 'Discharging coronavirus patients into care homes is 'madness', Government told'' *The Telegraph* (15 April 2020) <https://www.telegraph.co.uk/news/2020/04/15/discharging-coronavirus-patients-care-homes-madness-government/> accessed 21 March 2021
[677] Public Accounts Committee (n 675)
[678] Kings Fund, 'How Covid-19 has magnified some of social care's key problems' (2020) <https://www.kingsfund.org.uk/publications/covid-19-magnified-social-care-problems> accessed 26 March 2021

the implications and long-term consequences of this discharge policy on patient safety; it is however an aspect deserving of urgent attention. Thus far, NHSE&I have defended the decision by saying it has always been the case that they want to discharge people who are clinically fit, and staying in hospital could be harmful for the elderly'.[679]

As can be seen from the above exploration of the hospital discharge regulatory arena, there are multiple actors within it which have, over the years, made efforts to try and improve the safety of hospital discharges; however there has been no unified effort. I have argued elsewhere[680] that risk-based regulation, a strategy frequently employed by the statutory regulators, is partially to blame. Risk-based regulation is intended to focus a regulator's interventions upon threats which pose the greatest risk to its objectives.[681] Such approaches were strongly endorsed by the 2005 Hampton Report on the grounds that they were seen as essential for efficiently directing regulatory resources to where they can have maximum impact upon outcomes.[682] Risk-based frameworks typically have the identification of risk as a starting point and commonly feature an assessment of the likelihood of the risk occurring, and a subsequent ranking of risks based upon these assessments.[683] Three common weaknesses of risk-based regulation approaches[684] regarding the identification, conceptualisation, and prioritisation of risks to patient safety explain why little action has been taken by statutory regulators within the hospital discharge regulatory arena.

The first weakness in relation to identifying risk arises due to limited information-sharing mechanisms amongst the multitude of regulators, which means regulators do not have a complete picture of all relevant information.[685] The numerous regulatory bodies and the limited information-sharing amongst them gives rise to the next problem, which is that achieving a unified understanding of the risk posed by hospital discharges is nigh on impossible. Risks become conceptualised by each regulator based upon the information which it holds, and inevitably these conceptualisations will vary across regulators. This in turn

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[679] Public Accounts Committee (n 675)
[680] Moore (n 611)
[681] Anne Laure Beaussier and others, 'Accounting for Failure: Risk-based Regulation and the Problems of Ensuring Healthcare Quality in the NHS' (2016) 18 Health, Risk & Society 205
[682] Phil Hampton, 'Reducing Administrative Burdens: Effective Inspection and Enforcement' (HM Treasury 2005)
[683] Julia Black and Robert Baldwin, 'Really Responsive Risk-based Regulation' (2010) 32 Law and Policy 181
[684] Beaussier and others (n 681); Sally Lloyd-Bostock and Bridget Hutter, 'Reforming Regulation of the Medical Profession: The Risks of Risk-based Approaches' (2008) 10 Health, Risk and Society 69
[685] Moore (n 611)

impacts the priority the risk is afforded.[686] By utilising risk-based regulation, regulators thus create thresholds which must be reached in order for them to take action. If their conceptualisation of a risk fails to meet their threshold, it will not be perceived as a risk that needs *their particular attention*.

This section has identified the actors within the hospital discharge regulatory arena and their actions to address the patient safety challenge posed by hospital discharges. Despite these efforts, the physical wellbeing and dignity of patients remains at risk at the point of hospital discharge.[687] The following section offers an account of why these attempts have failed to significantly improve patient safety during discharge, relying on the concept of liminality that is precisely about navigating uncertain spaces of human experience.

III. Liminality

Upon observing that people undertake certain rituals when transitioning from one social state to another (such as childhood to adulthood), Van Gennep developed the anthropological concept of 'liminality.[688] These rituals consist of three distinct phases, known as rites of passage, which van Gennep declared universal to all societies.[689] He argued that their purpose is to reduce the harmful effects that can occur as a result of the disruptive impact that changes of social state can have upon the life of an individual and society.[690] The three phases are the separation from a previous state (preliminal rites), the transitional stage (liminal rites), and incorporation into the new state (postliminal rites).[691] Within the transitional, liminal stage, the experience is marked by uncertainty for the subject.[692]

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[686] ibid
[687] ibid
[688] Arnold van Gennep, *The Rites of Passage*, (University of Chicago Press, 1960). Note, van Gennep wrote *The Rites of Passage* in 1909.
[689] ibid
[690] ibid
[691] ibid
[692] Jonas Söderlund and Elisabeth Borg, 'Liminality in Management and Organization Studies: Process, Position and Place' (2018) 20 International Journal of Management Reviews 880; Graeme Laurie, 'Liminality and the Limits of Law in Health Research Regulation: What Are We Missing in the Spaces In-Between?' (2016) 25 Medical Law Review 47

Turner writes that a liminal being is one who is 'betwixt and between the positions assigned and arrayed by law, custom, convention, and ceremonial'.[693] In these spaces, structure gives way to anti-structure; which is to say that the status quo breaks down into chaos.[694] A figure known as the 'Master of Ceremonies'[695] or 'Representative of Order'[696] is needed to guide people safely through and out of these liminal states so that they are able to reintegrate into society.[697] Without them liminality can be permanent,[698] or result in 'lasting rule by tricksters'[699] (one who presents themselves as leader for their own gains).

Because of this, liminal spaces can be dangerous.[700] However, people can also have positive experiences within these spaces as a result of *communitas*[701] arising amongst them. Laurie describes this as 'a spontaneous sense of interconnectedness of equals, experiencing the same process together'.[702] Thomasson cautions that *communitas* stemming out of liminality is unpredictable, and we cannot accurately foretell whether it will result in care towards others, or in violent destruction.[703] More on the implications of this spontaneity and unpredictability within a regulatory context will be discussed later within this article.

Having introduced liminality and the Representative of Order role, the remainder of this section proceeds to explore two things. It considers the liminal space within the regulation of hospital discharges and then examines the presence of 'liminal objects'[704] (often reports produced within the intention of improving patient safety during discharge), within it. The purpose of this exploration is to demonstrate how the lack of a Representative of Order within this liminal space can cause a regulatory failure in addressing safety during discharges, and

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[693] Victor Turner, The Ritual Process: Structure and Anti-Structure (Transaction 1969)
[694] ibid
[695] ibid; Arpad Szakolczai, 'Liminality and Experience: Structuring Transitory Situations and Transformative', (2009) 2 International Political Anthropology 141, 148
[696] Victor Turner, *Dramas, Fields, and Metaphors: Symbolic Action in Human Society*, (Cornell University Press 1974); Paul Stenner and Eduard Moreno-Gabriel, 'Liminality and Affectivity: The Case of Deceased Organ Donation' (2013) 6 Subjectivity 229, 248
[697] Laurie, 'Limits of Law' (n 692) 54; Bjørn Thomassen, *Liminality and the Modern: Living Through the In-Between* (Routledge 2018); Graeme Laurie, 'How do we make sense of chaos? Navigating health research regulation through the liminality of the Brexit process' (2018) 18 Medical Law International 110; Szakolczai (n 695); Agnes Horvath, 'The Genealogy of Political Alchemy: the technological invention of identity change' in Agnes Hovarth, Bjørn Thomassen and Harald Wydra, (eds) *Breaking Boundaries: Varieties of Liminality* (Berghahn Books 2015) ch 4
[698] Graeme Laurie, 'Sense of Chaos' (n 697), 117
[699] Szakolczai (n 695) 157
[700] ibid
[701] Turner (n 693)
[702] Laurie, 'Limits of Law' (n 692) 59
[703] Thomassen, (n 697) 84
[704] Samuel Taylor-Alexander and others, 'Beyond Regulatory Compression: Confronting the Liminal Spaces of Health Research Regulation' (2016) 8 Law, Innovation and Technology 149

how objects which become stuck in a liminal state fail in their aim to improve safety. Sections four and five will then cast the proposed patient safety commissioner as a Representative of Order to explore how such a figure could address these issues.

The liminal space within hospital discharge regulation

The result of the regulatory split between healthcare professionals and systems outlined in the previous section is that hospital discharges are subject to multiple regulatory requirements and influences. A patient safety incident (PSI) which occurs in relation to the hospital discharge process is frequently not a failing on the part of one actor. Indeed, the incidents themselves can be understood as occurring within the liminal spaces of healthcare provision, particularly at the point where different systems meet and interact (interfaces). It has been found that about 50% of medical errors occur at healthcare interfaces, with up to one-third of these arising at the primary-secondary care interface.[705] Incidents resulting from a complex interaction between professionals and the system they work within may fall within the regulatory liminal space, which is to say that they may not land squarely within the perceived remit of any one regulator.

Threats to patient safety in relation to the discharge process may experience a similar fate, and therefore not elicit an appropriate regulatory response. For example, at the start of 2020 (prior to the Covid-19 pandemic taking hold in the UK), the Royal Cornwall Hospitals NHS Trust informed staff that patients should be discharged early in order to reduce overcrowding. The memo sent to staff called the risk to patients 'proportionate' despite the likelihood 'that some of these patients will be readmitted or possibly come to harm'.[706] Requiring clinicians to discharge patients in cases where it may be against their clinical judgement to do so may mean asking them to act in a manner contrary to their professional standards.[707] One doctor queried the GMC's stance upon this matter and reported the response as, 'We always consider a concern raised with [us] on the specific facts of the case, taking into

[705] Scottish Government, 'Improving General Practice Sustainability Group: 2019 Report' (2019) < https://www.gov.scot/publications/improving-general-practice-sustainability-group-2019-report/pages/1/> accessed 21 March 2021, Annex B
[706] Denis Campbell, 'Cornwall Hospital to Discharge Patients Early Despite Saying it may be Harmful' *The Guardian (*London, 14 January 2020) <https://www.theguardian.com/society/2020/jan/14/cornwall-hospital-to-discharge-patients-early-despite-risks> accessed 28 October 2020
[707] David Oliver, 'The risks of discharging patients early against doctors' judgment' (2020) 368 British Medical Journal <https://www.bmj.com/content/368/bmj.m210> accessed 21 March 2021

account the factors relevant to the environment in which the doctor is working'.[708] The doctor argued this response provided little reassurance.

This example reveals three key features of this liminal space. First, it is surrounded by 'thresholds' constructed by regulators and informed by their risk-based approaches (e.g.- does the risk threaten the achievement of their objectives, and if so, how severe will its impact be?[709] Where an incident is not perceived as meeting the regulator's threshold for action, the regulator is unlikely to respond. In the scenario above, the risk to patient safety *should* be situated within the remit of the systems regulators (it is a pressure arising from an under-resourced hospital), and within the remit of the professional regulators – for it is an issue likely to impact upon the ability of healthcare professionals to act in accordance with their professional standards.[710] Yet the GMC has not commented further on this incident, nor has the CQC or NHSE/NHSI – all of whom should be able to recognise the potential impact upon patient safety and their ability to achieve their statutory objectives in this regard. Secondly, there is a lack of regulatory structure within the liminal space - which may explain why no regulator is taking the lead on addressing the patient safety issue identified above. Thirdly, there is no clear authority figure present within it driving regulators to act. This article now turns its attention to the impact this liminal space has on actions undertaken by those within the regulatory arena. These actions are intended to improve patient safety during the discharge process.

Liminal objects within hospital discharge regulation

Acknowledging that liminality is typically applied to people, Taylor-Alexander and colleagues argue that it can also be applied to 'things' – doing so enables a richer understanding of the relations between people and their surroundings.[711] For, as with humans, things can also pass through periods of transition; the authors provide an example of health research protocol documents to demonstrate this. The research protocol document undergoes 'multiple transitory passages and transformations, marked by both uncertainty and the guiding (or editing) hand of a gatekeeper or steward to lead it through the passage(s) towards approbation'.[712] In the same

[708] ibid 2
[709] Julia Black and Robert Baldwin, 'Really Responsive Risk-based Regulation' (2010) 32 Law and Policy 181; Moore (n 611)
[710] Moore (n 611)
[711] Taylor-Alexander and others (n 704)
[712] ibid 159

way that liminality involves a Representative of Order who guides a person through transformation, regulatory actors may guide objects, such as these protocols, through the liminal phase.

It is argued here that a Representative of Order is key to preventing objects becoming stuck in a liminal state within the hospital discharge regulatory arena. 'Objects' in this context is used to refer to the outputs of any actor within this regulatory space that is intended to improve patient safety during the discharge process. These objects often stem from patient safety incidents. For example, a hospital discharge-related PSI may result in one or more of the following actions: a hospital may instigate its own investigation; a patient may make a complaint to a regulatory body or the PHSO; and (where a patient has died) a coroner may investigate and produce a Prevention of Future Death (PFD) report.[713] Incidents may also trigger an investigation by the Health and Safety Investigation Branch , a body which aims to improve patient safety through investigations without assigning blame or liability.[714] As highlighted earlier, patients may also share their experiences with Healthwatch England and charities, such as the British Red Cross. These actions often result in the production of a report detailing how improvements could be made. These reports are 'objects' that are vulnerable to failing to cross any of the regulatory thresholds surrounding them that would enable the prevention of such future incidents through learning and proportionate regulatory responses.

Two of these objects: the PHSO report into unsafe hospital discharges[715] and the 2019 British Red Cross report into safety during hospital discharges,[716] will now be used to illustrate the argument that a Representative of Order is key to improving safety in this space.

The PHSO report into unsafe discharges highlights failings which are indicative of the nature of complaints it receives regarding unsafe hospital discharge. It asks for the Department of Health and Social Care (DHSC) and NHS to establish the scale of the problems and to understand the causes, 'so that others do not have to experience such avoidable and unnecessary suffering'.[717] The report is intended to influence other actors within the hospital discharge regulatory arena, but to do so it needs to be visible. The House of Commons' Standing Orders[718]

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[713] Under the Coroner and Justice Act 2009, coroners have a duty to make these reports.
[714] HSIB, 'What is the Healthcare Safety Investigation Branch?' <https://www.hsib.org.uk/> accessed 4 November 2020
[715] Parliamentary and Health Service Ombudsman (n 617)
[716] British Red Cross, 'Home to the Unknown' (n 656)
[717] Parliamentary and Health Service Ombudsman (n 617) 3
[718] HoC Standing Orders Public Business 2019 at 146 (1)

ultimately bring about this visibility. The Orders direct the manner in which House of Commons' public business is conducted; they are a regulatory requirement. These Orders state that one of the functions of the Public Administration and Constitutional Affairs Committee (PACAC) is to examine reports by the PHSO. The PACAC may then use these reports to hold the government to account.[719] In response to the PHSO report on unsafe discharges, the PACAC held an inquiry in order to understand the scale of the highlighted problems, to assess the measures for improving discharge practice, and to clarify responsibilities and accountabilities across Government for ensuring implementation of the improvements and the safety of discharge processes.[720] By triggering such action, this regulatory requirement is acting as a Representative of Order, leading the report through its transformation from a passive object into an 'active subject-object'.[721] In this final state the report is able to exert its intended influence within the hospital discharge regulatory arena.

In cases where concerns are raised by patient organisations, or charities, this role is unfulfilled by any legal or regulatory framework, and this increases the risk of reports which are intended to be active-subject objects becoming stuck in a liminal state. In failing to transition from passive object to active-subject object, these reports become a 'stagnated presence' within the hospital discharge regulatory arena.[722]

For example, the 2019 British Red Cross report documents patients' experiences of being discharged from hospital, presumably shared by patients hoping to improve the experience for future patients. The report states that, 'being clearer about the relationship between what happens in hospital and what happens when people go home – seeing through patients' eyes how it feels when they walk back through their front door – can only help patients and professionals alike'.[723] Such a report, intertwined with human experience and the potential to cross spatial-temporal boundaries, should have the potential to be a powerful regulatory tool. However, there is no evidence to indicate that the findings have been heard by any of the

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[719] PACAC, 'Role in Relation to the Parliamentary and Health Service Ombudsman' <https://committees.parliament.uk/committee/327/public-administration-and-constitutional-affairs-committee/role/> accessed 4 November 2020

[720] Public Administration and Constitutional Affairs Committee, 'Fifth Report: Follow-up to PHSO report on unsafe discharge from hospital' (2016-2017 HC 97) 18

[721] Taylor-Alexander and others (n 704)

[722] This term is borrowed from Boyacıoğlu's writing on beliefs surrounding revenants in medieval Britain. These revenants, trapped between the living and the dead, are 'stagnated presences'. For a fascinating (somewhat off topic) read on this matter see Elif Boyacıoğlu, 'The Revenant on the Threshold' (2015) 62 Folklore: Electronic Journal of Folklore 7

[723] British Red Cross, 'Home to the Unknown' (n 656) 8

statutory regulators. This is important because statutory regulators are the ones in a position to check whether recommendations have been received by healthcare providers and/or implemented.

As there is no regulatory framework or organisation responsible for acting on these recommendations, the report is not delivered through the liminal phase and transformed into an active subject-object where it can influence behaviours and become an actor in the hospital discharge regulatory arena. Instead, it is stuck as a stagnated presence, unable to reintegrate into the regulatory space and have the impact intended by its creators. Any learning that could be gained from previous patients' experiences of discharge thus goes unheeded, resulting in missed opportunities for improvement. By contrast, active subject-objects within this space play important roles in not only highlighting unsafe discharges, but also in recommending ways that these can be overcome and in compelling a response. Representatives of Order are fundamental to preventing objects becoming stuck. In this liminal space, where regulatory structure is missing, a Representative of Order is needed to guide these liminal objects out of their status as a stagnated presence and into their role as active-subject object; doing so will increase the ability of regulators to keep patients safe during discharge.

The following section examines the recommendation proposed by the Independent Medicines and Medical Devices Safety Review ('IMMDS review') to create a Patient Safety Commissioner (PSC). This role has now been established in the MMD Act. The purpose of this examination is to consider whether the PSC could act as a Representative of Order, and ultimately improve patient safety during the discharge process.

IV. The Patient Safety Commissioner

As mentioned at the start of this article, the purpose of the IMMDS review was to consider how the healthcare system in England responds when concerns are raised about harmful side effects from medicines and medical devices. It focussed specifically upon hormone pregnancy tests, sodium valproate, and pelvic mesh implants.[724] The review further considered how future responses could be quicker and more effective, and how the patient voice could be strengthened

[724] IMMDS Review (n 606)

to help build a system that listens to patients and acts promptly, with compassion and in a proportionate manner.[725] The review argues,

> 'we do not need another regulatory body in an already crowded field. But we do need a new voice, with statutory powers, to talk and act from the perspective of the patient, to encourage the system to do what needs to be done and hold it to account'.[726]

As such, one of its recommendations, which shall be considered in-depth here, was the creation of a new Patient Safety Commissioner (PSC) role.

The PSC as envisaged in the IMMDS review was to be independent and have a statutory responsibility to champion the value of listening to patients and promoting users' views in improving patient safety. They would be responsible for identifying steps needed to improve patient safety regarding the use of medicines and medical devices, and for encouraging other organisations to act. It was intended that the PSC would be a means of holding the system to account, and they would be accountable to Parliament through the Health and Social Care Select Committee.[727]

The review envisaged that a core set of statutory principles, to be developed by the PSC, would support the PSC in determining the appropriate response to any issues raised. It was anticipated that the Commissioner would lead reviews and investigations, which would result in advice and recommendations. Reviews would potentially include: thematic investigations of systemic issues; in-depth inquiries into specific patient safety concerns not undertaken by another organisation; and assessments of an organisation's patient safety performance, against the principles.[728] The resulting advice could be in the form of specific recommendations to address the identified concerns, encouraging other bodies to implement recommendations, and highlighting concerns about failures to improve patient safety to the Secretary of State for Health and in public reports.[729]

Although the review suggested the PSC would be prevented from investigating individual cases (for this would duplicate the work of the PHSO), it stated that the PSC would

[725] ibid 186
[726] Ibid 10
[727] ibid 200
[728] IMMDS Review (n 606) 206
[729] ibid 206

be open to receiving concerns from patients and other members of the public, as well as patient representative organisations. This is because the PSC was expected to have a higher public profile than other complaints bodies, and it was proposed that direct reports from patients could be relayed to other organisations if appropriate. In such cases, the PSC would retain an interest in how the reports are handled, and what the outcomes are.[730] It was further proposed that the PSC would be responsible for obtaining relevant patient safety information from other organisations to assist their primary functions. This would be, for example, through making arrangements to receive reports relating to medicine safety from the National Freedom to Speak Up Guardian.[731] The report did not propose giving the PSC 'more wide-ranging regulatory powers', stressing instead that the role is that of a champion - amplifying patients' voices and delivering systemic improvements in patient safety.[732]

The new MMD Act confirms that the PSC role will be established, and have statutory powers. Although lacking the fine detail provided in the IMMDS review, the role is generally reflective of that proposed by the review. It states that the PSC's core duties are to promote the safety of patients with regard to the use of medicines and medical devices, and to promote the importance of the views of patients and other members of the public in relation to the safety of medicines and medical devices.[733] In doing so, the PSC must prepare and publish a set of governing principles, and must take reasonable to steps to involve patients in discharging their core duties.[734] The PSC may make reports, and request and share information with relevant persons. In such cases, relevant persons must comply, provided that doing so does not contravene data protection legislation.[735] The MMD Act does not state who the PSC is to be accountable to; this detail is likely to follow in subsequent regulations.[736]

As can be seen from the summary above, the PSC will be responsible for listening to patients and identifying the steps required to improve patient safety regarding the use of

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[730] ibid
[731] This role was created in response to recommendations made in Francis' report "The Freedom to Speak Up" (Robert Francis, 'Freedom to Speak up: an independent review into creating an open and honest reporting culture in the NHS' (2015)). The recommendations followed findings that NHS culture failed to support workers to speak up, and patients/staff suffered as a result. For further information see: National Guardian, 'About Us' <https://nationalguardian.org.uk/about-us/> accessed 21 March 2021
[732] IMMDS Review (n 606) 209
[733] Medicines and Medical Devices Act 2021, s 1(2a)
[734] ibid sch 1
[735] ibid sch 1
[736] Department of Health and Social Care, 'Factsheet: Patient Safety Commissioner' (2021) <https://www.gov.uk/government/publications/medicines-and-medical-devices-bill-overarching-documents/medicines-and-medical-devices-bill-patient-safety-commissioner> accessed 25 March 2021

medicines and medical devices. By focussing the role of the PSC solely on medicines and medical devices, the opportunity to improve patient safety with regard to *processes*, such as hospital discharges, appears to have been missed. As I will now argue, the remit of the PSC should be expanded to include such processes. This is proposed because the risk of harm posed by hospital discharges has not been adequately addressed by statutory regulators, despite numerous reports (as highlighted in section two) having raised the issue. Liminality, employed here as an exploratory lens, has shed light on the nature of this regulatory problem – namely that objects intended to influence action fail in this endeavour. Expanding the remit of the PSC in this way will amplify the voices of patients harmed during discharge - a complex process involving interactions between a healthcare system and the professionals working within it. If healthcare is to truly become safer, holding the system to account, and listening to patient's safety experiences regarding all aspects of their healthcare journey, are necessary.

This article envisages that the PSC could function as a Representative of Order – a figure able to guide objects and persons through their liminal state, and assist actors within the regulatory space to navigate the liminal space between them. Before moving on to consider how the PSC might function as a Representative of Order, let us now turn to another individual who fulfils the Representative of Order role within the patient safety field as part of their remit– the Chief Coroner. Doing so will not only demonstrate the benefits such figures can bring to patient safety, but also provide valuable insight into how the PSC role might be strengthened.

The Chief Coroner as a Representative of Order

The Chief Coroner acts as a centralised figure[737] within the coronial system in England and Wales and is responsible for setting national standards within the coronial system, and overseeing the implementation and development of reforms. The creation of this role was triggered by the Inquiry into the actions of Harold Shipman, a general practitioner convicted of murdering fifteen patients in 2000.[738] Among multiple systemic failings, the inquiry identified several weaknesses within the coronial system and recommended fundamental reform, led by a Chief Coroner. Ten years later, the new Coroner and Justice Act 2009 ('the

[737] Jennifer Moore, Coroners' Recommendations and the Promise Of Saved Lives (Edward Elgar Publishing 2016)
[738] Janet Smith, The Shipman Inquiry Third Report: Death Certification and the Investigation of Deaths by Coroners (The Stationary Office 2003)

2009 Act') was implemented, bringing with it the new role of the Chief Coroner (the first one came into post three years later).[739]

As will now be demonstrated, through the lens of liminality, we can see how the Chief Coroner serves as a Representative of Order to keep patients safe. Regarding death and bereavement, van Gennep says:

> 'in some cases the transitional period of the living is a counterpart of the transitional period of the deceased, and the termination of the first sometimes coincides with the termination of the second – that is, with the incorporation of the deceased into the world of the dead'.[740]

The salient point here is that bereavement is a rite of passage.[741] The Shipman Inquiry recognised this where it noted that the family of a deceased person value being involved in registering the death of their loved one.[742] In a similar vein, where the cause of death is unknown, the bereaved may find themselves in a liminal state, unable to reintegrate in society in their new role. It is often important for the bereaved to know that steps have been taken to protect others from dying in similar manners,[743] and in this sense, PFD reports play a role in guiding them through the liminal stage of bereavement.

Under the 2009 Act, coroners have a duty to make these reports (also known as Regulation 28 Reports), and to send them to the Chief Coroner and 'every interested person who in the coroner's opinion should receive it'.[744] PFD reports raise concerns arising from coroners' investigations on actions that should be taken to prevent similar future deaths, and recipients have 56 days to respond.[745] They reflect the circumstances leading up to the person's death, and are key to preventing others from dying in similar circumstances. All reports are

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[739] Chief Coroner, 'Report of the Chief Coroner to the Lord Chancellor: Fifth Annual Report: 2017-2018' (2018) <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/764720/report-of-the-chief-coroner-lord-chancellor-2017-18.pdf> accessed 21 March 2021

[740] van Gennep (n 688) 147

[741] Hunter observes bereavement-related rituals are so integrated with death rituals, bereavement is rarely considered its own rite of passage (Jennifer Hunter, 'Bereavement: An incomplete rite of passage' (2008) 56 OMEGA 153

[742] Janet Smith, The Shipman Inquiry Third Report: Death Certification and the Investigation of Deaths by Coroners (The Stationary Office 2003)

[743] NHS Resolution, 'Learning from suicide-related claims: A thematic review of NHS Resolution data' (2018) https://resolution.nhs.uk/resources/learning-from-suicide-related-claims/ accessed 21 March 2021; INQUEST, 'Submission to the Justice Select Committee Inquiry into the Coroner Service' (2020) <https://www.inquest.org.uk/Handlers/Download.ashx?IDMF=e404f863-cdfb-47b6-8e34-a65118520331> accessed 21 March 2021

[744] Coroners and Justice Act 2009, para 7 Sch 5

[745] The Coroners (Investigations) Regulations 2013, Reg 29

published online by the Chief Coroner, and so are publicly accessible. Through acting as a Representative of Order, the Chief Coroner is able to ensure that PFD reports do not get stuck in a state of liminality. Firstly, he may send a copy of the report to any person who he believes may find it useful or of interest,[746] and secondly, he has access to all reports which should enable regular analysis to be undertaken so that common themes can be disseminated nationally amongst relevant and interested parties. Essentially, the creation of a Chief Coroner reduces the likelihood of both PFD reports and bereaved people becoming stuck in liminal states. In the case of PFD reports, the Chief Coroner is able to ensure they cross temporal-spatial boundaries to influence the safety of others. Knowing that lessons learned from a loved one's death will safeguard others may also support bereaved people's journey through the grieving process. However, as will be explored in the following section, there is scope for the Chief Coroner's role in this regard to be improved. Reflecting on the efficacy of this particular Representative of Order will enable the Patient Safety Commissioner to avoid similar difficulties.

V. The Patient Safety Commissioner as a Representative of Order

In a similar manner to the way in which the creation of the Chief Coroner role is starting to result in increasingly successful navigation of the liminal space within the disjointed coronial system,[747] the PSC could support actors within the context of the hospital discharge regulatory arena. The PSC, with the extended remit over processes argued for herein, will have a high public profile and be empowered to receive, and to actively seek, information pertaining to patient safety from a vast range of sources. This should result in them having powerful, all-encompassing insight into safety concerns across the entire healthcare system.

To recap briefly on the points made in section three, the liminal space within the hospital discharge regulatory arena is present in part due to multiple regulators and the related challenge they face in forming a unified understanding and prioritisation of the risk posed by hospital discharges.[748] Actions then taken by actors with the regulatory arena to improve safety during discharges (often the production of a report) risk becoming a stagnated presence, unable

[746] ibid reg 28
[747] Chief Coroner (n 739)
[748] Moore (n 611)

to cross regulators' thresholds or influence the behaviour of actors within the regulatory arena. These two issues need resolving in order to improve patient safety during the discharge process.

Navigating the liminal space

With regard to this first issue, by acting as a centralised figure, the PSC will be able to assist regulators in developing a uniform response to the patient safety risks posed by hospital discharges. Although this might not directly translate into risk being prioritised in the same manner, it creates room for discussion on multi-actor approaches to addressing the problem. A unified understanding of the risk will not necessarily reduce the presence of the liminal space within; however, the presence of these spaces should not be thought of as undesirable. By acting as a Representative of Order, the PSC could be in a position to encourage regulators to engage within this liminal space. In this regard, the PSC would be embracing the role of stewardship, which Laurie and colleagues define as 'guiding others with prudence and care across one or more endeavours—without which there is risk of impairment or harm—and with a view to collective betterment'.[749] Laurie and colleagues note that within the context of health research regulation, regulatory stewardship plays a central, yet often invisible role.[750] Regulatory actors within the hospital discharge arena may already be involved in this type of stewardship; the GMC for example provides ethical advice to individual doctors upon request to assist them in their efforts to adhere to professional standards.[751]

Importantly, Laurie and colleagues stress that fulfilling the role of regulatory stewardship should not fall to any single actor, as this would risk the role being seen as someone else's responsibility.[752] This is a valid concern – and as such, this article does not see the PSC as being the only actor within this regulatory arena to be charged with this role. Rather, they should encourage other regulators to collaboratively engage in this role within the liminal space.

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[749] Laurie and others (n 629) 338
[750] ibid 338
[751] See for example, GMC 'Contact Us' available at: <https://www.gmc-uk.org/contact-us> accessed 15 March 2021
[752] Laurie and others (n 629) 338

Returning to the notion of *communitas* discussed in section three, although *communitas* cannot be artificially created within a liminal space, such spaces can still have productive potential.[753] The PSC as a Representative of Order could help regulators to utilise this potential, whilst recognising that such spaces might develop a dynamic of their own.[754] For example, within the research and policy context, Laurie cites the emerging use of regulatory sandpits (also known as sandboxes)[755] as an example of how this potential could be utilised.[756] Sandboxes involve regulators collaborating with other parties (such as service users and healthcare providers) on an equal footing (in a manner similar to what might happen where *communitas* arises), in order to generate and develop solutions to problems. The CQC has recently adopted the idea of the regulatory sandbox to provide a space where providers can work alongside them to consider new ways of working that fit with regulation.[757] If the PSC facilitates regulatory bodies engaging in the liminal space around them, novel regulatory solutions to the complex safety problem posed by hospital discharges may be reached. The PSC would however need to be cognisant of legal requirements which may impede regulators' ability to be creative and agile in seeking solutions. For example, speaking on how legal requirements restrict regulatory agility, the GMC's chief executive said the restrictive legal framework prevents overseas doctors being rapidly registered to work in the UK despite severe shortages in the UK. He stated that the GMC wishes to provide additional resources into preventing medical errors, but instead is compelled by legislation to spend the majority of its time processing complaints, 'the majority of which come to nothing'.[758]

Guiding liminal objects

[753] Laurie, 'Limits of Law' (n 692) 60
[754] ibid
[755] Sandboxes started in the financial industry as a framework set up by the regulator to allow testing of innovations in controlled environments under the regulator's supervision. It is argued they have the potential to shift the relationship between regulators and financial services providers towards a more open and active dialogue. See Ivo Jenik and Kate Lauer, 'Regulatory Sandboxes and Financial Inclusion' (2017) <https://www.cgap.org/sites/default/files/Working-Paper-Regulatory-Sandboxes-Oct-2017.pdf> accessed 21 March 2021
[756] Laurie, 'Limits of Law' (n 692) 60
[757] Hannah Crouch, 'CQC publishes report into first regulatory sandbox pilot' *Digital Health* (10 February 2020) <https://www.digitalhealth.net/2020/02/cqc-publishes-report-into-its-first-regulatory-sandbox-pilot/> accessed 4 November 2020
[758] Charlie Massey, 'Regulation overhaul urgently needed' *GMC News* (25 February 2020) <https://www.gmc-uk.org/news/news-archive/regulation-overhaul-urgently-needed> accessed 24 March 2021

As demonstrated by the example of the Chief Coroner and PFD reports, a Representative of Order has the ability to prevent objects becoming stuck in a liminal state. This is through having oversight of all PFD reports, being able to analyse them for common themes, and raise concerns with appropriate parties in order to address safety issues. It must however be noted that INQUEST have recently highlighted that regular analysis of themes is not currently happening.[759] This is a failure on behalf of the Chief Coroner, for it is an essential part of enabling the reports to fulfil their intended roles as a tool to influence the experiences of others and prevent future deaths. The Chief Coroner acknowledged the importance of PFD reports in his fifth annual report, and said additional staffing would enable the trends in reports and the responses to them to be drawn together.[760] The lesson here when establishing the PSC is that sufficient funding and resource must be provided in order for them to perform their role satisfactorily.[761]

It is envisaged that in the case of hospital discharges, where reports such as those mentioned earlier in this article are produced to highlight the risks to patients, the PSC would be able to direct them to regulatory bodies to act upon. This would prevent objects from becoming stuck in a liminal state and enable them to reach their intended potential in influencing change. However, if this advice of the PSC is to be heeded, it is important that the PSC is aware of regulators' remits and their legal limitations. Otherwise, advice will likely be met with pushback. Research by Moore into why coroners' recommendations in New Zealand were rejected by organisations found that it was important for organisations to be correctly identified and targeted; organisations did not appreciate being a 'convenient PO box'.[762]

The PSC as proposed will not have any direct enforcement powers. This means that although advice can be provided to regulators and other actors within the safe discharge space, if actors are reluctant to engage in spaces beyond their remit, then the only recourse available to the PSC is to escalate concerns to the Health Secretary. It is anticipated that this is unlikely to translate into any further action being taken against regulators, which risks safety issues at discharge remaining unaddressed. It is therefore critically important that the PSC works

[759] INQUEST (n 743)
[760] Chief Coroner (n 739) 19
[761] The IMMDS review proposes that the Commissioner's work is supported by government grant-in-aid funding (p 210)
[762] J Moore (n 737) 145

alongside regulators and is established as an authority figure in order to reduce the likelihood of this happening.

Conclusion

This article has used the anthropological concept of liminality as a lens through which to explore and identify regulatory challenges in addressing patient safety issues related to hospital discharges. This has brought into focus the liminal space that exists amongst regulatory bodies within the hospital discharge regulatory arena. The liminal space occurs because hospital discharges can be complex processes where safety depends upon the quality and availability of the healthcare system, and the actions of many healthcare professionals. This means the regulatory arena contains numerous statutory regulators with varying thresholds for action – making it difficult for regulators to establish a unified understanding and prioritisation of the risk facing patients. Furthermore, actions to improve safety in this regard often become stagnated presences, unable to have their intended impact within the regulatory arena.

Liminality in itself does not present a solution to the patient safety problem posed by discharges. However, by using it as a lens through which to view the regulatory arena, it has brought to light the critical need for a Representative of Order to ensure that recommendations regarding patient safety during discharge are recognised by regulators. This article has cast the Patient Safety Commissioner as a candidate to fulfil this role.

If the remit of the PSC were extended, as called for in this article, the PSC could be in a position to aid regulators in developing a uniform understanding of the risk posed to patient safety by hospital discharges. This would result from the PSC being in a position to listen to patients and obtain evidence from a wide variety of sources regarding what goes wrong with the discharge process. Armed with this knowledge, the PSC could advise regulators and encourage them to engage within the liminal space around them – presenting the opportunity for solutions to this complex safety problem to be uncovered. Furthermore, the PSC would be able to ensure that objects produced by actors with the intent of improving discharge safety, such as reports into unsafe discharges, would become active subject-objects. This would be achieved through the PSC ensuring that appropriate regulatory bodies are aware of the findings, and providing advice on how they may be able to respond.

In summary, through using the lens of liminality, this article has demonstrated not only the importance of a PSC championing patients' voices, but also its potential to bridge regulatory gaps. The impact this could have on improving patient safety should not be underestimated, particularly when it could improve the safety of the hospital discharge process for patients.

PART FOUR: REGULATORY ACCOUNTABILITY

Doctors, Decisions, and Discharges: Regulatory Accountability for Patient Safety in a Just Culture (Paper Three)

Introduction

At the start of 2020, *The Guardian* reported that the Royal Cornwall Hospitals NHS Trust ('RCH NHS Trust') sent a memo to staff asking them to discharge patients in order to reduce severe overcrowding, even if it was against their clinical judgement to do so.[763] It accepted that in some instances this could result in harm to patients. The Doctors' Association called the request, 'morally repugnant and against the very fibre of what doctors stand for'.[764] Commenting in the *British Medical Journal*, Oliver noted the importance of maintaining patient flow through beds in order to minimise internal delays and improve processes, but queried where such requests from senior NHS managers leave doctors in the eyes of their regulator, the General Medical Council (GMC).[765] He remarked, 'we're entering dangerous territory when the professional clinical judgment of medics who have assessed and spoken to patients and their families, and who are personally accountable for decisions and consequences, is over-ridden, or when they're heavily pressured to act outside their comfort zone'.[766] Prior to the RCH NHS Trust memo being sent, Norfolk and Norwich hospital also faced severe bed shortages and informed senior doctors to make the 'least unsafe decision' in providing care, saying it would support doctors to do so.[767] At the time of the RCH NHS Trust incident, Covid-19 had not taken hold within England; which is to say that the severe bed-shortages were not occurring as a result of the pandemic, but were a reflection of the status quo within England's National Health Service (NHS). In November 2019, the number of hospital beds in the NHS had already fallen to its lowest level ever, despite the British Medical Association (BMA)

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[763] Denis Campbell, 'Cornwall Hospital to Discharge Patients Early Despite Saying it may be Harmful' *The Guardian (*London, 14 January 2020) <https://www.theguardian.com/society/2020/jan/14/cornwall-hospital-to-discharge-patients-early-despite-risks> accessed 28 August 2020

[764] ibid

[765] David Oliver, 'The risks of discharging patients early against doctors' judgment' (2020) 368 British Medical Journal <https://www.bmj.com/content/368/bmj.m210> accessed 28 August 2020

[766] ibid

[767] Denis Campbell and Pamela Duncan, 'Doctors told to use 'least unsafe' option in Norwich hospital', *The Guardian* (20 December 2019) <https://www.theguardian.com/society/2019/dec/20/doctors-told-to-use-least-unsafe-option-in-norwich-hospital> accessed 28 August 2020

having warned the previous year that an additional 10,000 beds were needed to provide safe care for patients.[768] The number of beds in general and acute hospitals fell from 110,568 in April-June 2010, to 100,406 in April-June 2019.[769]

Discharging patients safely can be a complex process, and the risks it poses to patients have been repeatedly highlighted.[770] Common problems involve: discharging patients without appropriate care arrangements in place; discharging patients without involving them/ their carers in the decision-making; and a lack of coordination across services.[771] In 2017/18 Healthwatch England (HE) highlighted that emergency readmission rates within 30 days of discharge had been steadily increasing over the previous five years, raising questions around the appropriateness of some discharge decisions and the subsequent support provided to patients.[772] HE further highlighted that the healthcare sector was unable to report on how many of the emergency readmissions were genuinely unavoidable, and how many could have been prevented.[773] The Care Quality Commission's (CQC) 2018 annual adult inpatient survey report also flagged hospital discharge planning as an area for improvement.[774] In 2019, the same annual survey showed 'continuing patterns of decline' regarding care coordination at discharge.[775] This result was 'lower than where [the CQC] would expect, based on past data, the fourth consecutive year'[776].

As the Covid-19 pandemic took hold in England, a drive to create spaces in hospital for the anticipated influx of patients accelerated discharges from hospital. Guidance issued by the

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[768] Denis Campbell, 'Hospital beds at record low in England as NHS struggles with demand' *The Guardian* (25 November 2019) <https://www.theguardian.com/politics/2019/nov/25/hospital-beds-at-record-low-in-england-as-nhs-struggles-with-demand> accessed 28 August 2020
[769] ibid
[770] See for example: British Red Cross, 'Home to the Unknown: Getting hospital discharge right' (British Red Cross 2019) www.redcross.org.uk/about-us/what-we-do/we-speak-up-for-change/more-support-when-leaving-hospital/getting-hospital-discharge-right accessed 28 August 2020; Healthwatch England, 'What do the numbers say about emergency readmissions to hospital? (Healthwatch 2017) <https://www.healthwatch.co.uk/report/2017-10-05/what-do-numbers-say-about-emergency-readmissions-hospital> accessed 28 August 2020, Parliamentary and Health Service Ombudsman, 'A Report of Investigations into Unsafe Discharge from Hospital' (PHSO 2016) <https://www.ombudsman.org.uk/publications/report-investigations-unsafe-discharge-hospital-0> accessed 28 August 2020; and Public Administration and Constitutional Affairs Committee, 'Fifth Report: Follow-up to PHSO report on unsafe discharge from hospital' (2016-2017 HC 97)
[771] Public Administration and Constitutional Affairs Committee (n 770)
[772] Healthwatch England, 'What do the numbers say?' (n 770)
[773] Healthwatch England, 'Emergency Readmissions: What's Changed One Year On?' (Healthwatch 2018)
[774] CQC, '2018 Adult Inpatient Survey: Statistical release' (2019) <https://www.cqc.org.uk/sites/default/files/20190620_ip18_statisticalrelease.pdf> accessed 28 August 2020
[775] CQC, '2019 Adult Inpatient Survey: Statistical release' (2020) <https://www.cqc.org.uk/sites/default/files/20200702_ip19_statisticalrelease.pdf> accessed 21 March 2021, 54
[776] ibid 50

government and NHS England stated that patients should be discharged when they are 'medically optimised'; a lower threshold than 'medically fit'.[777] The move reportedly freed up tens of thousands of beds in preparation for acute Covid-19 admissions, prompting the Royal College of Nursing and the Queen's Nursing Institute (a charity for community nursing), to highlight the enormous pressure that the discharges put upon community care.[778] The drive to free up acute bed spaces also saw patients who had tested positive for the virus discharged into care homes, despite evidence that the policy was fuelling outbreaks of the virus and deaths in care homes.[779] The pressure doctors are under to discharge patients is likely to increase once more as the UK healthcare system addresses the second wave of the Covid-19 pandemic and tries to maintain other essential services.[780]

That doctors are being pressured to make decisions which will expose patients to a recognised risk of harm is an issue that warrants close scrutiny. Firstly, it is potentially problematic for doctors who, according to the GMC, are personally accountable for their professional practice and must be prepared to justify their decisions and actions. Secondly, it highlights a concern with the regulator's concept of accountability which impedes its aim of fostering a just culture within healthcare; that is to say a culture which balances fairness, justice and learning.[781] The GMC has acknowledged that doctors need to feel they are part of a just culture when things go wrong, and that as a regulator, it has a crucial role in achieving a just culture in healthcare.[782] Section one of this article examines the GMC's regulatory expectations and procedures, and demonstrates why these are concerning to doctors who are pressured to discharge patients. It is argued that a root cause of this concern is the regulator's lack of clarity

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[777]HM Government & NHS England, 'COVID-19 Hospital Discharge Service Requirements' (2020) <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/880288/COVID-19_hospital_discharge_service_requirements.pdf> accessed 28 August 2020

[778] Sharon Brennan, 'Community nursing will 'blow' as discharge threshold is reduced' (2020) Health Service Journal < https://www.hsj.co.uk/community-nursing-will-blow-as-discharge-threshold-is-reduced/7027384.article> accessed 28 August 2019

[779] Bill Gardner, 'Discharging coronavirus patients into care homes is 'madness', Government told'' *The Telegraph* (15 April 2020) <https://www.telegraph.co.uk/news/2020/04/15/discharging-coronavirus-patients-care-homes-madness-government/> accessed 28 August 2020

[780] Shaun Lintern, 'Delays in discharging patients adds pressure on hospitals amid coronavirus second wave' I*ndependent* (30 October 2020) <https://www.independent.co.uk/news/health/coronavirus-discharge-delays-hospitals-social-care-nhs-england-b1423773.html> accessed 28 August 2020

[781] Sydney Dekker, *Just Culture: Balancing Safety and Accountability* (CRC Press 2012); NHS Resolution, 'Being Fair: Supporting a just and learning culture for staff and patients following incidents in the NHS' (NHS Resolution 2019) <https://resolution.nhs.uk/wp-content/uploads/2019/07/NHS-Resolution-Being-Fair-Report-2.pdf> accessed 28 August 2020

[782] General Medical Council, 'GMC statement following the publication of the independent review of gross negligence manslaughter and culpable homicide in medical practice' (GMC 2019) <https://www.gmc-uk.org/news/news-archive/gnm-statement> accessed 28 August 2020

regarding accountability. Section two explores how the GMC's vague concept of accountability hinders its aim of fostering a just culture within healthcare. Section three argues that a just culture is integral to ensuring patient safety; it is therefore vital that this accountability problem is addressed to ensure patient safety at the point of discharge. Three possible regulatory actions are presented to address this particular issue. It is anticipated that the action which is recommended would improve patient safety across the healthcare system.

I. Professional standards and fitness to practise

The GMC is responsible for regulating doctors who work in the UK; its overarching purpose is to protect the public.[783] As part of this role, the GMC sets the standards doctors need to follow throughout their careers and takes action to prevent a doctor from putting the safety of patients, or the public's confidence in doctors, at risk.[784] The professional standards set by the GMC are stated within its core guidance, *Good Medical Practice (GMP)*, and 32 pieces of explanatory guidance. Although serious or persistent failure to follow GMC guidance will put a doctor's registration at risk[785,] there is no automatic link between a failure to follow the guidance and action against a doctor's registration. The regulator states this is because the guidance sets out the principles of good practice, and not thresholds for taking action to protect the public.[786] The guidance is developed with the input of patients, doctors, lawyers, regulators, employers, and educators and undergoes public consultation.[787] Given this collaborative approach, it can be reasonably assumed that the guidance reflects society's expectations of doctors. Metcalf identifies several outward facing goals of such professional standards, including amongst others: the protection of vulnerable populations who could be harmed by the profession's activities; the protection/enhancement of the good reputation of and trust for the profession; and to act as a basis for public expectations and evaluation of the profession.[788]

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[783] Medical Act 1983, s 1(1A)
[784] General Medical Council, 'What we do and why' <https://www.gmc-uk.org/about/what-we-do-and-why> accessed 1 December 2020
[785] General Medical Council, 'Good Medical Practice' (GMC 2013)
[786] GMC & MPTS, 'Sanctions Guidance' (GMC & MPTS 2019) <https://www.mpts-uk.org/-/media/mpts-documents/dc4198-sanctions-guidance--18th-november-2019_pdf-80152538.pdf> accessed 28 August 2020
[787] General Medical Council, 'Ethical guidance' <https://www.gmc-uk.org/ethical-guidance> accessed 15 July 2020
[788] Jacob Metcalf, 'Ethics Codes: History, Context, and Challenges' (2014) <https://bdes.datasociety.net/council-output/ethics-codes-history-context-and-challenges/ > accessed 28 August 2020

The GMC's '*Sanctions Guidance'*[789] tries to further clarify the link between setting standards for doctors and taking action when a doctor's fitness to practise is called into question because they have not met the standards. It says that action is taken where a serious or persistent breach of the guidance has put patient safety at risk or undermined public confidence in doctors. Moreover, the purpose of any action taken is to protect the public by helping to make sure doctors on the register provide safe care and uphold public confidence in doctors; actions are not intended to punish or discipline doctors for past events.[790] This purpose is not necessarily common knowledge; research commissioned by the GMC into the motivations of complainants revealed that in some instances, complainants did so out of desire for the doctor to be punished.[791]

GMC fitness to practice (FtP) procedures consist of two stages; investigation and adjudication. The investigation stage is where cases are investigated and a decision made regarding whether to refer the case to the Medical Practitioners Tribunal Service (MPTS) for adjudication. Investigations commence when a concern raised about a doctor potentially raises questions about the doctor's current fitness to practise. Investigations are of varying length depending on the complexity of the concerns, and involve gathering information such as documentary evidence from the complainant, or expert reports on clinical matters. At the end of the investigation, two case examiners (one medical and one non-medical) determine whether further action is needed or if the case can be closed. Further action includes issuing a warning, or referring the case to the MPTS for a hearing.[792]

The professional standards guidance clearly informs doctors, 'you are personally accountable for your professional practice and must always be prepared to justify your decisions and actions'.[793] As Oliver has highlighted, this is a cause of concern amongst doctors who feel pressurised to discharge patients from hospital against their clinical judgement.[794] Oliver raised this query with the GMC and reports their response to him as, 'We always consider a concern raised with [us] on the specific facts of the case, taking into account the

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[789] GMC & MPTS (n 786)
[790] ibid
[791] ICE, 'Why do many public concerns that would be better directed to another organisation come to the GMC?' (ICE 2019) <https://www.gmc-uk.org/-/media/documents/ftp-public-complainants-research-report-v2_0_pdf-78629691.pdf? Accessed 28 August 2020
[792] GMC, 'The GMC's fitness to practise procedures' <https://www.gmc-uk.org/-/media/documents/DC4541_The_GMC_s_Fitness_to_Practise_procedures.pdf_25416512.pdf > accessed 28 August 2020
[793] General Medical Council, 'GMP' (n 785)
[794] Oliver (n 765)

factors relevant to the environment in which the doctor is working'.[795] He opines that this response provides little reassurance. Oliver's views are reflective of the medical profession's lack of confidence in the regulator to be fair when investigating concerns raised about a doctor. This lack of confidence, worsened by the regulator's decision[796] to seek the erasure of Dr Bawa-Garba from the medical register after a criminal conviction for gross negligence manslaughter (GNM),[797] was central to the GMC's commissioning of an independent review into GNM and culpable homicide.[798] The review found the GMC's decision had caused widespread consternation and outrage across the medical profession, with many doctors asking why the individual trainee, working in a system under pressure, should be blamed for what they perceived to be broader systemic failings.[799]

As stated by the GMC above, if a concern were raised regarding a doctor's decision to discharge a patient in the circumstances such as those that occurred in the RCH NHS Trust, then the actions that the GMC would take would depend upon the specific facts of the case. It can be surmised that relevant factors for consideration may entail how the doctor acted with regard to the professional standards. In *GMP* doctors are told they must give priority to patients based on their clinical need[800], and must raise concerns if 'inadequate resources' prevent them from doing this. In a separate piece of explanatory guidance, '*Leadership and management for all doctors',* the term 'limits on resources' is used; it is stated that the treatment options that can be offered to patients may be affected by limits on resources.[801] Thus, the professional guidance draws a distinction between a 'limit on resources' and 'inadequate resources'. Where resources are limited, doctors must provide the best service possible within the resources available, taking account of their responsibilities towards their patients and the wider population. They must make sure decisions affecting patients are fair and based on clinical need, and not on factors that risk introducing discriminatory access to care. They must also be

[795] ibid
[796] In recognition of the pressurised system that Bawa-Garba was working in, the tribunal initially imposed a period of suspension rather than erasure. This decision was overturned by the Divisional Court, and substituted with a sanction of erasure. Bawa-Garba won her appeal.
[797] Deborah Cohen, 'Back to Blame: The Bawa-Garba case and the patient safety agenda' (2017) British Medical Journal 359
[798] Leslie Hamilton, 'Independent review of gross negligence manslaughter and culpable homicide' (2019) <https://www.gmc-uk.org/-/media/documents/independent-review-of-gross-negligence-manslaughter-and-culpable-homicide---final-report_pd-78716610.pdf> accessed 28 August 2021
[799] ibid
[800] General Medical Council, GMP (n 785) para 56
[801] General Medical Council, 'Leadership and Management for all Doctors' (GMC 2012) para 84

open and honest with patients about the decision-making process.[802] By contrast, where resources are inadequate, doctors must raise concerns, and additional explanatory guidance provides details on how they should do this.[803]

No definition is provided within the guidance for what constitutes 'inadequate' and what is 'limited'. However, the Covid-19 pandemic provides an example of the GMC differentiating between the two. Within the pandemic context, the GMC's additional advice to doctors stated that in cases where more than one patient has a life-threatening condition that can be treated at once, doctors are expected to: take account of local and national policies setting out agreed criteria for access to treatment; be confident that decisions are based on clinical need and the likely effectiveness of treatments, and not unfairly discriminate against particular groups; take patients' wishes and expectations into account when considering treatment options; be open and honest with patients about the decision-making process; and to record their decisions and the reasons for them. It continued that ideally the decision-making would not simply be down to an individual doctor, but would take place following discussions with colleagues, and concluded that, 'the primary requirement for all doctors is to respond responsibly and reasonably to the circumstances they face'.[804] This is reflective of the GMC's non-pandemic guidance on limited resources. By contrast, in commenting on whether doctors could refuse to see patients if they have inappropriate personal protective equipment (PPE) in the pandemic, the GMC stated that doctors should raise their concerns about inadequate PPE with their employer, and make a record of how they have handled their safety concern.[805] This is in line with its non-pandemic guidance on raising concerns.[806] In both instances the GMC sought to reassure doctors that if they received a complaint about an individual, the circumstances considered on the specific facts of the case, taking into account the situation in which the doctor is working and any relevant protocols.[807]

In attempting to discern the difference between a limited and inadequate resource in the above example, one noticeable difference is that inadequate PPE is defined as that which falls

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[802] ibid para 85
[803] General Medical Council, 'Raising and Acting on Concerns about Patient Safety' (GMC 2012)
[804] General Medical Council, 'Coronavirus: Your frequently asked questions: Decision making and consent' (GMC 2020) <https://www.gmc-uk.org/ethical-guidance/ethical-hub/covid-19-questions-and-answers#Decision-making-and-consent> accessed 1 December 2020
[805] ibid
[806] GMC, 'Raising Concerns' (n 803)
[807]GMC, 'How we will continue to regulate in light of novel coronavirus (Covid-19)' (GMC 2020) <https://www.gmc-uk.org/news/news-archive/how-we-will-continue-to-regulate-in-light-of-novel-coronavirus> accessed 15 July 2020

below the standard set in the most recent guidance issued by the four UK health departments.[808] This indicates that there is a recognised threshold for safe practice, below which something is inadequate. A rationale for why a shortage of some resources, such as life-saving treatments, is seen as limited rather than inadequate is not provided, rendering it unclear why a doctor should raise concerns about a lack of PPE but not a lack of hospital resources.

Turning to the pre-pandemic context, the BMA's assertion that an additional 10,000 beds are needed to provide safe care for patients[809] certainly suggests that this is an inadequate resource. However, in *University College London Hospitals NHS Foundation Trust v MB,*[810] the judge declared in-patient care is a 'scarce resource'[811], which could perhaps indicate that a hospital bed is to be seen as a limited resource rather an inadequate one. It is therefore unclear whether doctors are expected to raise concerns about the shortage of hospital beds if it results in patients being unsafely discharged, or whether they must simply do what they can in the circumstances. Once again, this point of confusion is unlikely to be reassuring to doctors who already lack confidence in the regulator.

This section has explored the relationship between professional standards and fitness to practice procedures. It has shown that a failure to follow professional standards does not automatically result in fitness to practise proceedings; but concerns that are raised about an individual doctor would trigger an investigation, which would be considered on the specifics of that case and could in theory lead to professional sanctions. It is therefore not possible to predict what the outcome of any hypothetical case would be. However, even the investigation process itself can be extremely stressful for doctors, to the extent that in 2014 the GMC commissioned a review of its cases in which doctors had committed suicide whilst undergoing fitness to practise procedures.[812] It is understandable that doctors are concerned about being held accountable by their regulator for discharge decisions they feel forced to make, and which may be contrary to their clinical judgement. In light of this understandable concern, this article

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[808] GMC, 'Coronavirus: Your frequently asked questions: Working safely' (GMC 2020) < https://www.gmc-uk.org/ethical-guidance/ethical-hub/covid-19-questions-and-answers#Working-safely> accessed 1 December 2020

[809] Campbell (n 768)

[810] University College London Hospitals NHS Foundation Trust v MB [2020] 882 (QB)

[811] ibid [55]

[812] Sandra Horsfall, 'Doctors who commit suicide while under GMC fitness to practise investigation' (GMC 2014) <https://www.gmc-uk.org/-/media/documents/Internal_review_into_suicide_in_FTP_processes.pdf_59088696.pdf> accessed 28 August 2020

will now explore what it means to be accountable for one's actions, before examining how the GMC conceptualises accountability.

II. Defining Accountability

Bovens states that the most concise description of accountability is 'the obligation to explain and justify conduct'[813]; an essence echoed throughout regulatory literature.[814] He further defines accountability as being a relationship between an actor and a 'forum' (the organisation or individual which holds the actor to account), in which the actor is obliged to explain and justify their conduct, and the forum may ask questions and pass judgement, following which the actor may face consequences.[815] The term 'facing consequences' is used in recognition that forums might also positively judge an actor's conduct and reward them for it.[816] There are three core features of account-giving: the actor is obliged to inform the forum about their conduct; the forum must be able to question the actor; and the forum must be able to pass judgement upon the conduct, and in the case of a negative judgement, be able to impose sanctions upon the actor.[817] Bovens, stating his agreement with Mulgan[818] and Strom[819], argues that the possibility of sanctions is a necessary feature of an accountability relationship for it is the difference between non-committal information provision and being held to account.[820]

According to Sharpe, accountability is central to patient safety as it guides expectations and judgements pertaining to the performance of health care providers.[821] She argues that the

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[813] Mark Bovens, 'Analysing and Assessing Accountability: A Conceptual Framework' (2007) 13 European Law Journal 447, 450
[814] Sarah Banks, 'Negotiating Personal Engagement and Professional Accountability: Professional Wisdom and Ethics Work' (2013) 16 European Journal of Social Work 587; Derick Brinkerhoff, 'Accountability and Health Systems: Toward Conceptual Clarity and Policy Relevance' (2004) 19 Health Policy and Planning 371; Andrew Freeman and others, 'Health Professionals' Enactment of Their Accountability Obligations: Doing the Best They Can' (2009) 29 Social Science and Medicine 1063; Martin Lodge, 'Accountability and Transparency in Regulation: Critiques, Doctrines and Instruments' in Jacint Jordana, David Levi-Faur (eds), *The Politics of Regulation* (CRC Press 2004)
[815] Bovens (n 813)
[816] ibid
[817] ibid
[818] Richard Mulgan, *Holding Power to Account: Accountability in Modern Democracies* (Palgrave Macmillan 2003)
[819] Kaare Strom, 'Parliamentary Democracy and Delegation', in Kaare Strom and others (eds), *Delegation and Accountability in Parliamentary Democracies* (Oxford University Press 2003)
[820] Bovens (n 813)
[821] Virginia Sharpe, 'Promoting Patient Safety: An ethical basis for policy deliberation' (Hastings Center Report 2003)

notion of individual accountability which underpins medicine and the law needs reinventing in light of a challenge posed to the conventional story of medical error. This conventional story is that harm is the result of an individual's actions, for example a failure to read a drug label properly.[822] However, this notion has been challenged by human factors research, which seeks to understand the interaction between humans and the systems they work in. Human factors research demonstrates that human error is rarely the sole cause of harm, and should instead be understood as the result of complex interaction between people and their environment.[823] This complexity is highly prevalent during hospital discharges as they can involve multiple, interdependent health and social care professionals working both within and across different organisations.[824] For example, doctors, nurses, community nurses, occupational therapists, and social workers may all be involved in the discharge planning of patients who have experienced a stroke, and will be navigating challenges such as resource constraints, organisational pressures, and the ordering of equipment and medicines.[825] A common safety issue in these circumstances is a patient falling at home, post-discharge, due to a lack of equipment or support.

If we accept that the harm patients experience may not be due simply to an individual clinician's actions, then we must acknowledge that it may not always be fair for a forum (in this context, the GMC) to hold that individual to account and impose sanctions for their role in the incident. This recognition is partially responsible for leading us to the recent, noticeable drive to create a just culture in healthcare; one which balances fairness, justice and learning[826] with the aim of improving patient safety. As mentioned above, the GMC recognises that doctors need to feel part of a just culture when things go wrong, and that as a regulator, it plays a crucial role in achieving this.[827] Moreover, NHS England and NHS Improvement's *Patient Safety Strategy*[828] calls for local systems to develop and maintain a just culture, and

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[822] ibid
[823] ibid
[824] Justin Waring, Fiona Marshall, and Simon Bishop, 'Understanding the Occupational and Organizational Boundaries to Safe Hospital Discharge', (2015) 20 Journal of Health Services Research & Policy 35
[825] Justin Waring and others, 'A Qualitative Study of Professional and Carer Perceptions of the Threats to Safe Hospital Discharge for Stroke and Hip Fracture Patients in the English National Health Service' (2016) 16 BMC Health Services Research 1
[826] Dekker (n 781); NHS Resolution (n 781)
[827] General Medical Council, 'GMC Statement' (n 782)
[828] NHS England and NHS Improvement, 'The NHS Patient Safety Strategy: Safer culture, Safer Systems, Safer Patients' (NHSE&I 2019)
<https://improvement.nhs.uk/documents/5472/190708_Patient_Safety_Strategy_for_website_v4.pdf> accessed 28 August 2020

recommends the adoption of NHS Improvement's *Just Culture Guide.*[829] NHS Resolution, the body which handles negligence claims, also calls for a just culture. Its publication, *Being Fair: Supporting a just and learning culture for staff and patients following incidents in the NHS*[830], draws heavily on Dekker's research into what constitutes a just culture.[831] The publication defines a just culture as 'the balance of fairness, justice, learning – and taking responsibility for actions. It is not about seeking to blame the individuals involved when care in the NHS goes wrong. It is also not about an absence of responsibility and accountability'.[832] When dissected, it becomes clear that the term accountability is used within these documents without a full and comprehensive discussion of its meaning. Ultimately this leads to a lack of clarity and understanding in discussions about who or what is to be held accountable.

Despite the important role of accountability in establishing a just culture, the *Patient Safety Strategy* fails to define accountability[833], and the concept is neither referred to nor defined within the *Just Culture Guide.*[834] NHS Resolution's publication aims to define accountability; however, the attempt lacks clarity. In one example, it states that accountability is about, 'sharing what happened, working out why it happened, and learning and being responsible for making changes for the future safety of staff and patients'.[835] However, it also states that although an individual's actions should be understood prior to being judged and people should be supported to learn from them; this does not mean an absence of accountability. For in cases where a person does carry out an intentional act of harm, they should be dealt with responsibly and referred to external bodies, for example the relevant professional regulator.[836] The two different functions of accountability at play here - it is both a tool to aid learning, and to punish an individual, can be explained by Sharpe's account of forward-looking and backward-looking accountability.[837]

Backward-looking accountability is retrospective and often involves blaming somebody when something has gone wrong[838] (Bovens' definition of accountability above is

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[829] NHS England and NHS Improvement, 'A Just Culture Guide' (NHSE&I 2018) <https://improvement.nhs.uk/resources/just-culture-guide/> accessed 17 July 2020
[830] NHS Resolution (n781)
[831] Dekker (n 781)
[832] NHS Resolution (n781)
[833] NHS England and NHS Improvement (n 828)
[834] NHS Resolution (n781)
[835] ibid
[836] ibid
[837] Sharpe (n 821)
[838] ibid

an example of this). Sharpe argues that accountability can also be forward-looking; which is prospective, and tied in to goal-setting and moral deliberation.[839] Although the former concept is the more familiar within healthcare, Sharpe argues that the latter concept is vital to establishing a just, safe culture. This notion is what is captured within NHS Resolution's definition above.[840] Forward-looking accountability involves creating a work culture where it is safe to discuss errors and analyse them, to speak up about potential safety problems, and to implement steps to prevent safety incidents from recurrence.[841]

This is what a just culture aims to achieve. Within a just culture, people are able to be open about their mistakes, or to raise their safety concerns, without fear of being unfairly blamed. Dekker argues that a just organisation is a safe one; by contrast, unjust organisations are unsafe ones, as the fear of repercussions prevents individuals from speaking up.[842] Within healthcare, the inquiry into the scandal involving children's heart surgery at Bristol Royal Infirmary provided evidence of the important role that culture plays in ensuring patient safety. It highlighted that the NHS was failing to learn from its mistakes, and that the dominant blame culture was a major barrier to openness and learning.[843] The 2015 public inquiry into whistleblowing in the NHS, triggered by earlier findings of the Mid Staffordshire NHS Foundation Trust Public Inquiry[844], echoed this.[845] The whistleblowing inquiry ('*Freedom to Speak Up*') focussed upon the treatment of NHS staff who raised safety concerns. Its survey highlighted that 18% of staff who had not raised a safety concern had chosen not to due to a lack of trust in the system, and 15% feared victimisation. It noted that 'each time someone is deterred from speaking up, an opportunity to improve patient safety is missed'.[846] Failing to address safety concerns and learn from mistakes increases the likelihood of their recurrence, and may result in avoidable harm to patients. The *Freedom to Speak Up* report recommended a move away from the historical 'blame culture' (where the concern is who is at fault), towards a just culture within the NHS, where people are encouraged to speak up about safety concerns

[839] ibid
[840] NHS Resolution (n 781)
[841] Sharpe (n 821)
[842] Dekker (n 781)
[843] Ian Kennedy, The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary1984–1995 (Cm 5207, 2001)
[844] The inquiry, led by Robert Francis QC, was established to determine why serious failures in care at Mid-Staffordshire NHS Foundation Trust prior to 2009 were not acted on sooner by those responsible.
[845] Robert Francis, Freedom to Speak up: an independent review into creating an open and honest reporting culture in the NHS (2015)
[846] ibid 5

and know the difference between acceptable and unacceptable behaviour.[847] A no blame culture, which entails no blame being apportioned to an individual when safety incidents occur, was also considered in the report as a potential way forward. A no blame culture had been popular in other safety-critical industries, such as aviation and nuclear power. Two justifications for this were that error-prevention is dependent upon people speaking up about safety incidents without fear of personal consequences, and that an act cannot be blameworthy if it was unintentional.[848] The *Freedom to Speak Up* report chose not to recommend a no blame culture as it concluded that such a culture risks failing to recognise that some actions and behaviours by individuals are simply unacceptable.[849] Examples of unacceptable behaviours might be where a clinician deliberately chooses to harm their patient, or to falsify medical records.

Within a just culture, there is a role for both backward-looking accountability and forward-looking accountability. Generally, backward-looking accountability is reserved for instances where individuals act with the intent to cause harm, whereas forward-looking accountability enables lessons to be learned from safety incidents, and improvements to be made to reduce the risk of errors being repeated. In some circumstances, forward-looking accountability may be perceived (or indeed experienced) as backward-looking accountability. For example, as part of its remit, the GMC investigates cases where a registrant's fitness to practise is alleged to be impaired by reason of deficient professional performance. Where this results in sanctions being imposed upon the registrant, it may be perceived by the doctor to be an instance of backward-looking accountability. However, sanctions in these cases, such as conditions[850], have a remedial aim intended to support the doctor's safe return to unrestricted practice. This aim is cohesive with the concept of forward-looking accountability.

The concept of forward-looking accountability does not require sanctions to be imposed upon the healthcare system when learning from error does not take place (or when improvements are not made). This is potentially problematic. Consider, for example, Prevention of Future Death (PFD) Reports. Under the Coroners and Justice Act 2009 (para

[847] ibid
[848] Sharpe (n 821)
[849] Francis (n 845)
[850] According to paragraph 80 of the *Sanctions Guidance* (GMC & MPTS 2019), 'In many cases, the purpose of conditions is to help the doctor to deal with their health issues and/or remedy any deficiencies in their practice or knowledge of English, while protecting the public. In such circumstances, conditions might include requirements to work under supervision'.

7/sch 5), coroners have a duty to make these reports to prevent further deaths (also known as 'Regulation 28 Reports'). These must be sent to the Chief Coroner and other interested parties who, in the coroner's opinion, should receive it. Recipients must respond detailing any action that has been/will be taken to address the concerns, alongside a timetable. If no action is to be taken, they must explain the reason for this. The response to the coroner must be sent within 56 days and the coroner must then send a copy to the Chief Coroner and other interested parties.[851] In principle, these reports ought to function as a tool for learning from deaths, and preventing future deaths; as such they can be seen as a mechanism for enacting forward-looking accountability. However, neither the coroner nor any other regulatory organisation has a legal responsibility to enforce recommendations in PFD reports, or to apply sanctions when they are not acted upon.

Unfortunately, research by Ferner et al, which analysed responses to coroners in relation to drug safety, found that in spite of the recognition that learning from error improves patient safety, responses were often unpublished, and many organisations were reluctant to share their responses when asked through a freedom of information request. The researchers concluded, 'there appears to be no system for auditing concerns and responses to them. So, it is difficult to know whether—with regards to medicines—the coronial system prevents future death'.[852] Within the context of hospital discharges, a brief perusal of PFD reports and their responses indicates that findings do not encourage learning from deaths as much as they perhaps could. For example, in April 2014 Brighton and Sussex University Hospital NHS Trust received a PFD report concerning the death of an elderly patient. The coroner's report raised as a matter of concern that the discharge procedure was 'deeply flawed…there was no ongoing process of discharge…the discharge paperwork was effectively blank…there was no communication either with regard to the anticipated date of discharge or with the Nursing Home who were expected to receive him back'.[853] In August 2015, the same Trust received a PFD report expressing concern that, regarding the death of another elderly patient, there had been 'very little evidence of any joined up thinking with regard to her care or to plans, either for her future treatment, or for her future placement, or for discharge'.[854] In October 2016, a

[851] The Coroners (Investigations) Regulations 2013, reg 29
[852] Robin Ferner and others, 'Preventing Future Deaths from Medicines: Responses to Coroners' Concerns in England and Wales' (2019) 42 Drug Safety 445
[853] Veronica Hamilton-Deeley, 'Graham Watts' (*Courts and Tribunals Judiciary*, 3 April 2014) <https://www.judiciary.uk/publications/graham-watts/> accessed 14 July 2020
[854] Veronica Hamilton-Deeley, 'Thelma Jones' (*Courts and Tribunals Judiciary*, 12 August 2015) <https://www.judiciary.uk/publications/thelma-jones/> accessed 14 July 2020

further PFD report was sent to the same Trust concerning the death of another elderly patient. One of the coroner's matters of concern was that the 'Hospital's own Discharge Protocol was not followed'.[855] These examples indicate that without any enforceability mechanisms in place, the healthcare system cannot be relied upon to fulfil its learning responsibilities under the concept of forward-looking accountability.

This section has explored how accountability is conceptualised within healthcare and wider regulatory literature. It has examined how accountability, particularly forward-looking accountability, is perceived to be an important component of establishing a just culture within healthcare. This is because within a just culture, healthcare professionals are encouraged to speak up about any risks to patient safety, or adverse events, and learning can take place and steps be implemented to prevent recurrence of error. This section has also highlighted that an ability to enforce sanctions may still be necessary to ensure the healthcare system prioritises learning from error. The next section will consider how the GMC conceptualises accountability, and whether this is cohesive with its aim of fostering a just culture. It will then consider three different regulatory actions which the GMC could take in cases where doctors are asked by managers to discharge patients against their clinical judgement to reduce severe overcrowding.

III. Accountability and the GMC

The regulator's conceptualisation of accountability becomes important in establishing a just culture precisely because the GMC states within its professional standards that doctors are personally accountable for their professional practice. Within the GMC's professional standards, the term accountability is undefined; however, the standards function as a mechanism through which the GMC can hold doctors accountable. This is because they are a benchmark against which an individual's conduct can be judged, and serious or persistent failure to follow them can result in regulatory action.[856] This functioning is indicative of backward-looking accountability.

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[855] Veronica Hamilton-Deeley, 'Leslie Lerner' (*Courts and Tribunals Judiciary*, 12 March 2017) <https://www.judiciary.uk/publications/leslie-lerner/> accessed 14 July 2020
[856] General Medical Council, 'GMP' (n 785)

That professional standards are centred upon the notion of backward-looking accountability is further supported by the emerging discourse surrounding a just culture in the NHS. NHS Resolution[857] states that where actions result in unintentional harm, the individual should be supported to learn from them, and asked for their help and advice to design a safer system – which is consistent with forward-looking accountability. However, it then claims that this does not mean an absence of accountability; and that if someone does do an intentional act of harm, they should be dealt with responsibly which may include referral to the relevant professional regulator. The *Just Culture Guide*[858] also acknowledges that singling out an individual is not usually appropriate as the majority of patient safety issues are due to complex causes and so require wider action. However, in cases where an individual has shown deliberate intent to cause harm, the guide suggests that appropriate action may include contacting regulatory bodies. Thus, it becomes apparent that professional regulators, such as the GMC, are seen to be primarily concerned with backward-looking concepts of accountability, which necessarily focus upon the actions of an individual. There is an obvious and justifiable role for the regulator's backwards-looking accountability within a just culture – for example protecting the public from rogue doctors, such as Shipman.[859]

Goodwin observes that the concept of doctors' professional accountability within the professional standards is tied to notions of autonomous practice and independent thought, with decisions being characterised as 'discrete moments of cognition' which belong to an individual.[860] This is reflected in the current version of GMP; for example, doctors are personally accountable for their practice[861], and are told that clinical records should include 'the decisions made and actions agreed, and who is making the decisions and agreeing the actions'.[862] Yet as Goodwin's ethnographic study of healthcare professionals demonstrates, clinical decision-making is intrinsically collaborative, and numerous participants may contribute towards it. She demonstrates how clinical decision-making can be a dynamic process amongst healthcare professionals that is responsive to the changing circumstances. Her primary concern is to illustrate how distributed decision-making within clinical practice is misaligned

[857] NHS Resolution (n 781)
[858] NHS England and NHS Improvement (n 829)
[859] Janet Smith, The Shipman Inquiry Fifth Report: Safeguarding Patients, Lessons from the Past - Proposals for the Future (Cm 6394, 2004)
[860] Dawn Goodwin, 'Decision-making and accountability: Differences of distribution' (2013) 36 Sociology of Health and Illness 44
[861] General Medical Council, 'GMP' (n 785) Duties of a Doctor
[862] ibid para 21b

with models of practice embedded within the professional guidance; she argues that professional standards define work and allocate accountabilities in a way which is convenient for intervention by the regulator, but which is problematic when it comes to fairly attributing accountability.[863] She questions the appropriateness of professional standards that model decision-making as being autonomous, which risks accountability being disproportionally assigned to an individual when errors occur.[864] Underpinning Goodwin's analysis is the notion of backward-looking accountability; namely that being accountable means being at fault for one's decision-making and facing regulatory consequences. This assumption that the professional standards understand accountability to be backward-looking is present in Oliver's concerns about how the GMC would treat doctors who are pressured by management to discharge patients[865]; accountability can mean blame if things go wrong.

However, regarding its 'crucial role'[866] in fostering a just culture, the GMC adopts the discourse associated with forward-looking accountability. For example, the GMC fully accepted the recommendations from its independent review into gross negligence manslaughter; these included: considering how it can better support a profession under pressure alongside promoting a fair and just culture; ensuring that its investigation team has an understanding of human factors; and working with patients and the public to support better understanding of its role in regulating the medical profession within a system under pressure.[867] According to the GMC, the human factors training for investigators will provide doctors with assurance that 'their actions will be seen clearly against the backdrop of any system failings'.[868] Moreover, the role played by systems and workforces in serious failings will be fully and evenly evaluated.[869] It seems that the GMC is trying to embrace forward-looking accountability in addition to fulfilling its role in maintaining a relationship with the medical profession which is centred upon backward-looking accountability. Within the professional standards, we see the conception of a doctor as an autonomous decision-maker, who must always be prepared to justify their decisions and actions.[870] Yet regarding investigation procedures, we see recognition of the doctor as entangled within a wider web, where decisions are influenced by

[863] Goodwin (n 860)
[864] ibid
[865] Oliver (n 765)
[866] GMC, 'GMC statement' (n 782)
[867] Hamilton (n 798)
[868] GMC, 'Human factors training to be rolled out for investigators' (GMC 2020) <https://www.gmc-uk.org/news/news-archive/human-factors-training-to-be-rolled-out-for-investigators> accessed 15 July 2020
[869] ibid
[870] General Medical Council, 'GMP' (n 785) para 4

other healthcare professionals and system pressures. The shortage of hospital beds which led to doctors being asked by management to quickly discharge patients is a potential patient safety issue resulting in part from the pressure of working in an under-resourced system. Given the lack of clarity surrounding the GMC's use of accountability, it is no surprise that doctors are worried about the potential regulatory implications for themselves.

This section now examines three types of regulatory response which the GMC could take in cases where doctors are asked by managers to discharge patients against their clinical judgement to reduce severe overcrowding. The first response is for the GMC to do nothing, which appears to have been the course of action taken in the case identified at the start of this article. Although this option may seem appealing in that it avoids holding individual doctors accountable for decisions made in a healthcare system under pressure, it is not conducive to fostering a just culture. A just culture ought to be fair to both doctors and patients; and patients deserve more than an absence of deliberate harm – they deserve safe care.[871] Discharges from hospital are already internationally recognised as a dangerous time for patients[872], and the likelihood of harm occurring when doctors are pressured to discharge patient against their clinical judgement can only increase. By doing nothing to address this pressure upon doctors, the GMC risks shirking its legal duty to protect the public, which raises questions about its own accountability for achieving its statutory aims.

The second regulatory response would be to hold doctors personally accountable, in the backward-looking sense of accountability, for their decision to discharge a patient if it is against their clinical judgement. Given the shortage of beds, the question doctors might have to answer is, why did they not speak up about the inadequate resources and the harm posed to patient safety, as directed in *GMP* and the *Raising concerns* guidance? This action may result if the GMC were to solely embrace backwards-looking accountability. However, the GMC appears to be indicating a desire to move towards a more supportive role of doctors, and claims to be 'reducing fitness to practise investigations and building more supportive programmes'.[873] To

[871] James Titcombe, Peter Walsh and Cicely Cunningham, 'A just culture for both staff and patients' (2019) Health Service Journal <https://www.hsj.co.uk/patient-safety/a-just-culture-for-both-staff-and-patients/7025942.article> accessed 28 July 2020

[872] World Health Organisation, 'Transitions of care: Technical series on safer primary care' (World Health Organisation 2016) <https://www.who.int/patientsafety/topics/primary-care/technical_series/en/> accessed 28 August 2021; Karina Aase and others (eds), *Researching Quality in Care Transitions International Perspectives* (Palgrave Macmillan 2017)

[873] GMC, 'Our History' <https://www.gmc-uk.org/about/who-we-are/our-history> accessed 15 July 2020

take what may be interpreted as a punitive response would therefore be counterproductive in achieving this goal, and do little to ensure the ongoing safety of patients as they leave hospital.

The third response open to the GMC, and the one that this article recommends, is taking clear action to foster a just culture within healthcare. The first step in doing this would be to state how it intends to safeguard accountability within a just culture. This involves providing conceptual clarity for the term accountability, and a coherent explanation as to how it encompasses backwards-looking accountability to ensure patient safety whilst simultaneously supporting forward-looking accountability. The latter involves recognising that where system pressures mean it is unjust to solely adopt a backwards-looking notion of accountability in holding doctors individually accountable, the GMC should call for improvements to the broader healthcare system (forward-looking accountability). In this instance, the regulator publicly drawing attention to the bed shortages and the potential impact that has on patient safety at discharge would be a powerful indicator that it is committed to both protecting patients and being fair to its registrants. A similar point has been made by Freeman et al[874], who studied how occupational therapists in Ontario enacted their accountability obligations. The authors concluded that regulatory bodies may have a role to play in 'advocating for the development and implementation of the minimum resource conditions that permit professionals to provide quality practice'.[875] This course of action is preferable to the two alternatives discussed because it could aid the GMC to repair its relationship with the medical profession. Restoring the profession's lost trust in its regulator is paramount to creating a just culture in healthcare and ensuring patient safety, not only at the point of discharge but across healthcare.

Conclusion

This article has drawn attention to the risk of harm posed to patients at the point of discharge, and to the pressure that doctors have faced to discharge patients. A root cause of doctors' fears and concerns about regulatory action in this context is the GMC's vague concept of accountability within its professional guidance and its wider communications. The regulator is seen to use both backward-looking and forward-looking constructions of accountability; the

[874] Andrew Freeman and others, 'Health Professionals' Enactment of Their Accountability Obligations: Doing the Best They Can' (2009) 29 Social Science and Medicine 1063
[875] ibid 1069

latter tied closely to its intentions to foster a just culture within healthcare. A just culture is central to ensuring patient safety, thus the GMC's intent to promote a just culture is appropriate. However, the GMC's lack of clarity regarding accountability impedes its achievement of this.

The article calls for the regulator to provide clarity concerning accountability, and to proactively highlight the dangers of an under resourced healthcare system – especially where it leads to unsafe discharges. Doing so would enable the GMC to earn the trust of its registrants and fulfil its role in protecting patients. Given the severe bed shortages within hospitals, it is critical that this action is taken immediately to prevent harm to patients, and to ensure just regulation in cases where harm occurs. It is time for the GMC to start following the standards it expects of doctors and raising concerns[876] about the system in which doctors are working.

[876] General Medical Council, 'Raising Concerns' (n 803) para 7

CONCLUSION

The primary aim of this thesis is to determine how regulation might better ensure the safety of patients experiencing hospital discharge. This is an important question because despite patients being exposed to a significant risk of harm in relation to the discharge process, regulators have not faced any scrutiny regarding their role in protecting these patients. In this conclusion, I draw together the arguments that I have made throughout this thesis in order to demonstrate how regulation is failing to safeguard patients during discharge, and how this situation might be improved upon. In addition, I show how this research has made a valuable contribution to existing academic literature, and highlight possible areas of future research that arise from this thesis.

Key Findings

My thesis was presented in four parts. Three of these parts each address an important and problematic aspect of the regulatory status quo. Part One provided essential background information for the reader. Part Two, *Structure and Strategy of Healthcare Regulation within England,* presented the multiple regulatory bodies and considered the efficacy of risk-based regulation. The purpose of this was to examine whether these factors present particular difficulties for regulating hospital discharges. Part Three of this thesis, *Liminal Spaces - Exploring the Regulatory Gaps*, brought into focus the 'gaps' within this regulatory structure. Part Four, *Regulatory Accountability*, explored whether conceptual confusion regarding accountability risked undermining regulation's patient safety aims.

Structure and Strategy of Healthcare Regulation within England (Part Two)

At the outset of my research, I started mapping the actions regulators take in response to patient safety incidents relating to the discharge process. The findings revealed a sparsity of actions. Through analysing the structure of healthcare regulation in England, and the risk-based regulation strategy employed by regulators, in Paper One (within Part Two of the thesis) I demonstrated three weaknesses regarding how regulators identify, conceptualise, and

subsequently prioritise risk. These weaknesses explain why there is a lack of regulatory action in response to the PSIs occurring in relation to the discharge process.

To summarise, the first difficulty regarding risk-identification results where regulators do not possess an holistic overview of all information relevant to their role. This is typically because information is spread across regulators, and inadequate information-sharing mechanisms amongst them mean decisions have to be made regarding what information gets shared, and with whom. This risks potentially relevant information regarding discharge safety not being shared with the appropriate regulators; allowing PSIs to continue unaddressed. The multitude of statutory regulators and limited information-sharing amongst them leads to a further difficulty: it is almost impossible for all to have a unified understanding of the risk posed by discharges. Risks will be conceptualised based upon the nature of information possessed, which varies in a field saturated with regulators.

Successful risk-based regulation relies upon the correct prioritisation of risk, an outcome which is reliant upon regulators having obtained sufficient information and having clarity amongst themselves regarding their regulatory aim. It is possible that regulators are not prioritising ensuring patient safety during discharge in the manner they would if they had the requisite information and clarity about the risk that discharges pose to patients. I therefore argue in paper one that these three weaknesses combined have meant that the risk posed to patient safety at the point they leave hospital is neither uniformly recognised by the statutory regulators within the English NHS, nor sufficiently addressed.

As noted by one anonymous reviewer whilst this paper underwent peer-review, 'In medical terms, there is a reasonable diagnosis here but not much by way of treatment being put forward.' This was an accurate observation for this paper; it does indeed provide a detailed exploration of the problem, but no solution. However, the decision to limit the scope of this article was deliberate given that a potential solution would need a substantial amount of careful and nuanced consideration. Identifying a solution became the focus for the following part of the thesis.

Liminal spaces - Exploring the Regulatory Gaps (Part Three)

In Paper Two (within Part Three of this thesis), I used the anthropological concept of liminality as a lens through which to explore and identify regulatory challenges in addressing patient safety issues related to hospital discharges. By doing so, I brought into focus the liminal space that exists amongst regulatory bodies within the hospital discharge regulatory arena. After focusing my attention upon structure and strategy in the preceding part of this thesis, turning to the 'spaces' within regulation was an important step in building a complete picture.

Although liminality in itself does not present a solution to the patient safety problem posed by discharges, through its use I identified the critical need for an actor to fulfil the role of Representative of Order. I cast the Patient Safety Commissioner (PSC) - proposed by the IMMDS review and established under the Medicines and Medical Devices Act 2021 (MMDA) - as a candidate to fulfil this position.

If the remit of the PSC were extended to oversee the safety of processes within the NHS, such as hospital discharge, then the PSC would be in a position to aid regulators in responding to the previously identified problems regarding risk identification, conceptualisation, and prioritisation. Under the MMDA, the remit of the PSC currently only concerns the safety of medicines and medical devices. As argued in Paper Two, extending this remit would mean the PSC is in a position to listen to patients and obtain evidence from a wide variety of sources regarding what goes wrong with the discharge process. Armed with this knowledge, the PSC could advise regulators and encourage them to engage within the liminal space around them – presenting the opportunity for solutions to this complex safety problem to be uncovered. Furthermore, the PSC would be able to ensure that objects produced by actors with the intent of improving discharge safety, such as reports into unsafe discharges, would play an active, influential role. This would be achieved through the PSC ensuring that appropriate regulatory bodies are aware of the findings, and providing advice on how they may be able to respond.

Regulatory accountability (Part Four)

Having examined structure, strategy, and space in Parts Two and Three of the thesis, in Part Four I analysed concepts of accountability in the regulatory context. The rationale for doing so was to consider the potential impact of regulatory actions upon regulatees. This is an important element of patient safety given that a significant body of work has highlighted the importance of a just culture in healthcare to patient safety. I focussed specifically upon the regulator of doctors, the GMC, however the findings are also applicable to the professional regulators.

Paper Three (within Part Four of this thesis) took as its starting point an incident at the start of 2020, which saw doctors being pressured to discharge patients, even where it might be against their clinical judgement. Concerns amongst doctors about possible GMC actions followed. I demonstrated that the GMC is only in a position to support doctors to deliver good medical practice if doctors feel that they are able to engage constructively with the regulator, and trust that processes will 'be proportionate, fair and just'.[877] Compliance with regulatory requirements increases where regulatees trust their regulator.[878] I argued that a root cause of the concern amongst doctors following this incident was the GMC's vague concept of accountability – which impedes its goal to foster a just culture within healthcare. This concept is vague because it is used by the GMC to refer to both backward-looking and forward-looking concepts of accountability. This contributes to doctors' confusion about the function of the GMC, and impedes their trust in the regulator to be fair. Whereas the former concept of accountability is retrospective and often involves blame, the latter involves learning from error and taking steps to improve safety. Forward-looking accountability ties in closely with the notion of a just culture in healthcare – which, as Paper Three argues, is central to ensuring patient safety. The GMC's intent to promote a just culture is therefore appropriate.

To address the issue identified above, I recommended that the regulator must provide clarity concerning accountability and proactively highlight the dangers of an under-resourced healthcare system – especially where it leads to unsafe discharges. Doing so would enable the GMC to earn the trust of its registrants and fulfil its role in protecting patients.

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[877] Leslie Hamilton, 'Independent review of gross negligence manslaughter and culpable homicide' (2019) <https://www.gmc-uk.org/-/media/documents/independent-review-of-gross-negligence-manslaughter-and-culpable-homicide---final-report_pd-78716610.pdf> accessed 28 August 2021

[878] Sumit Kane and others, 'Trust and trust relations from the providers' perspective: the case of the healthcare system in India' (2015) 12 Indian Journal of Medical Ethics 157

Contribution to Literature

The three journal articles within this thesis are the first articles to critically examine how effectively regulation is functioning with regard to ensuring the safety of patients during the hospital discharge process. Effective regulation in this context means ensuring that: PSIs are responded to appropriately; steps are taken to improve future patient safety during discharge; and there are clear lines of accountability in place for when this does not happen. In these three aspects, regulators are falling short of effectively regulating for patient safety during hospital discharge.

My first article illustrated that PSIs (especially where dignity is harmed) often go unaddressed due to weaknesses within the risk-based regulation approach. This finding is a valuable contribution not only to the existing literature on risk regulation, but also to the field of patient safety. Regarding the former, my article demonstrates how risk-based approaches to regulation are unable to adequately identify, conceptualise, and prioritise risk within the context of the NHS and complex system failings. With regard to the literature on patient safety, this paper introduces regulation theory as a lens through which to understand the actions of regulators in response to PSIs. The article draws attention to how latent factors, for example occupational and organisational boundaries,[879] make the discharge process a complex problem to regulate. Drawing attention to this patient safety failing, and articulating the issue from a regulatory perspective, is a critical step in improving the situation.

My second article, casting the PSC as a Representative of Order, is unique in utilising the lens of liminality to explore the regulatory and patient safety issues surrounding hospital discharges. This novel approach builds upon the foundations set by Laurie and colleagues to centralise the experiences of patients within regulation. By expanding upon Taylor-Alexander's work on liminal objects, I illustrate how it is not sufficient for actors within this regulatory arena to simply produce a swathe of reports surrounding patient safety. Rather, a guide is required to ensure these reports can have meaningful impact. This article is the first contribution to socio-legal literature that uses liminality to imagine how the PSC could improve patient safety in this manner. The conclusion, that the remit of the PSC ought to be extended

[879] Justin Waring, Fiona Marshall, and Simon Bishop, 'Understanding the Occupational and Organizational Boundaries to Safe Hospital Discharge', (2015) 20 Journal of Health Services Research & Policy 35

beyond medicines and medical devices to include the safety of processes, is a practical recommendation with the potential to make a substantial positive impact upon patient safety during hospital discharge. Indeed, expanding the role of the PSC in this manner would have the potential to improve safety not only during discharge, but also during other transitions of care across health and social services.

My third article, examining regulatory accountability, is entirely novel in its dissection of what exactly is meant by the concept of accountability employed by both the NHS and doctors' professional regulator, the GMC. By using this insight to provide recommendations which the GMC could act upon in order to foster a just culture within healthcare, this article has the potential to make a meaningful difference to how the GMC regulates for patient safety.

Although this thesis has focussed principally upon the hospital discharge process, many of the findings are relevant to other aspects of healthcare which regulators are failing to address. For example, concerning failings in maternity care and plans to tackles these with other regulators, the CEO of the CQC has recently stated:

> 'We want to improve our shared understanding of risk overall, and particularly in relation to maternity services. This means building agreement on common areas of risk to prioritise, and on how we identify, analyse, prioritise and address these shared risks together. We want to improve the way we collaborate and share data by enabling joint analysis and identification of common issues that cross organisational boundaries. We are currently involved in exploratory work to help us understand where the opportunities to triangulate our data are, and, longer term, how we can remove barriers to joint risk analysis and data sharing.'[880]

This language precisely echoes the points that I had previously raised in my first article, and shows that the weaknesses of risk-based regulation are not unique to the hospital discharge process. The importance of listening to patients' perspectives is also not unique to discharge safety, and neither is the requirement for regulators to be clear about the meaning of accountability. Taken together, all of my research findings could therefore have a positive

[880] Shaun Lintern, 'NHS regulators to pool intelligence to spot maternity scandals faster' *Independent* (23 June 2021) <https://www.independent.co.uk/news/health/maternity-safety-nhs-cqc-data-b1871197.html> accessed 21 October 2021

practical impact upon informing regulatory approaches to improving patient safety across health and social care in England.

Future Research

The findings from my PhD research provide a starting point for further avenues of research: regulatory structural integrity; accountability for learning from error; the extent of the legal duty of care; and the potential impact of proposed changes to the discharge process under the Health and Care Bill. The first two of these are aspects which have the potential to inform how regulators can effectively regulate for patient safety at a wide variety of points of care. A critical examination of the third and fourth elements would have potential to positively influence future policies regarding discharge processes. Research into all of these elements could make valuable contributions to the existing academic literature.

Regulatory structural integrity

As mentioned at the start of this thesis, writing about the NHS has been likened to 'shooting at a moving target'.[881] Reforms are continually proposed and some degree of reshuffling takes place; new organisations are created and are abolished shortly after. Healthcare scandals continue, inquiries follow, recommendations are made, and few of these are implemented. When it comes to providing regulatory oversight, the healthcare system is perhaps best described as being in a constant state of flux. Powell makes a similar point, noting that some of the institutions mentioned or proposed within the Bristol Inquiry report (2001) were abolished or experienced a change in names or functions by the time of the Francis Inquiry report (2013).[882] For example, the Commission for Health Improvement proposed by the Bristol Inquiry existed from 2001 until 2004, when it then became subsumed by the Healthcare Commission, which was abolished in 2009, and its responsibilities taken over by the new Care Quality Commission.

[881] Judith Allsop and Linda Mulcahy, *Regulating Medical Work: Informal and formal controls* (1996), 1
[882] Martin Powell, 'Learning from NHS inquiries: Comparing the recommendations of the Ely, Bristol and Mid Staffordshire Inquiries' (2019) 90 The Policy Quarterly 229

In July 2021, a new Health and Care Bill was published.[883] Extensive reform involving the creation and abolishment of various healthcare oversight bodies is (once again) proposed. It is not within the scope of this thesis to hypothesise about what the impact of the proposals might be on the regulation of discharge processes, should they come to fruition. However, the proposals will impact upon the regulatory landscape of the NHS. For example, the proposed changes include the formal, full merger of NHS England and NHS Improvement, which would bring with it the abolishment of Monitor and the NHS Trust Development Authority.[884] The existing Healthcare Safety Investigation Branch (set up in April 2017) would be replaced with a new statutory body, the Health Service Safety Investigations Body (HSSIB). The Bill further proposes granting the Secretary of State the power to remove a profession from regulation and to abolish an individual health and care professional regulator.[885] The proposal would also provide scope for the statutory regulation of senior NHS managers and leaders,[886] as recommended in the 2019 review of the Fit and Proper Person Test (FPPT) (the 'Kark Review').[887] The FPPT is intended to ensure the quality and competency of senior management with the NHS.[888] However, the Kark Review concluded that the test 'does not ensure directors are fit and proper for the post they hold, and it does not stop the unfit or misbehaved from moving around the system'.[889]

In light of the findings of this thesis – namely that risk-based regulation is poorly suited to addressing systemic failings where multiple regulators are involved – the impact of continuous changes to the regulatory landscape is worthy of further research. Highlighting its urgency are the opening remarks from the report of the Independent Inquiry into Ian Paterson ('Paterson Inquiry'). Paterson was a surgeon who, in April 2017, was convicted of 17 counts of wounding with intent and three counts of unlawful wounding relating to ten of his private patients.[890] According to the findings of the inquiry:

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[883] Health and Care HC Bill (2021-2022) [140]
[884] These are currently part of NHS Improvement; their functions would be transferred to NHSE
[885] Health and Care HC Bill (2021-2022) [140], para 123(3)(a)
[886] ibid para 123(2)(d)
[887] Tom Kark and Jane Russell, 'A review of the Fit and Proper Person Test' (2018) <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/787955/kark-review-on-the-fit-and-proper-persons-test.pdf> accessed 21 October 2021
[888] Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, reg 5
[889] Kark and Russel, para 1.1
[890] Graham James, 'Report of the Independent Inquiry into the Issues raised by Paterson' HC 31 (House of Commons 2020)

> ‘The regular restructuring of healthcare and its agencies, regulators and organisations meant that some of our corporate witnesses noted that their own organisation did not exist when Paterson was practising. The reluctance to take responsibility for predecessor bodies may be understandable, but it leads to a significant loss of corporate memory, together with an offloading of responsibility, and thus undermines accountability. As it is, only just over eight years have passed from the day Paterson was suspended from practice to the publication of this report. We are not speaking of a different age.’[891]

This extract touches upon two of the key themes explored in this thesis; the complex regulatory landscape, and the importance of accountability in ensuring patient safety. In addition, it points to regulatory restructuring as a factor which further undermines accountability. The role of regular regulatory restructuring and its impact upon accountability and patient safety during transitions of care is thus an area of research I intend to explore further.

Accountability for learning from error

As mentioned in Chapter Two, *Legal Background*, in the very early stages of this research, I intended to use coroners’ Prevention of Future Death reports as a source for a) determining how frequently aspects of the discharge process have contributed to the deaths of patients, and b) understanding how recipients respond and make improvements to prevent reoccurrences. The online presentation of these PFDs and responses, combined with time limitations, meant that this avenue of enquiry was unfeasible. I maintain that the online formatting of these documents acts as a barrier to scrutiny and systematic analysis, which obscures accountability for ensuring that the healthcare system continuously improves. More worryingly, subsequent research by Leary and colleagues highlighted instances where some organisations were advised multiple times of the same safety failings which were recurring within their organisations.[892] Whereas in principle these reports ought to function as a tool for learning from deaths, and preventing future deaths in similar circumstances, in reality this is not happening. Neither the

[891] ibid 2
[892] Alison Leary and others, ‘A Thematic Analysis of the Prevention of Future Deaths Reports in Healthcare from HM coroners in England and Wales 2016–2019’ (2021) 26 Journal of Patient Safety and Risk Management 14

coroner nor any other regulatory organisation has a legal duty to enforce recommendations in PFD reports, or to apply sanctions when they are not acted upon.

In Chapter Two I further touched upon how this problem is not unique to PFD reports but is part of a broader troubling issue regarding how to ensure lessons are learned from safety incidents throughout the NHS. I highlighted how the HSIB had intended to analyse the impact of its 85 safety recommendations (subsection 2.5).[893] However, this element of its thematic analysis was abandoned, and as there is no regulatory body tasked with holding organisations to account if they fail to implement HSIB recommendations, it is reasonable to anticipate that impact was limited. Perhaps even more concerning are the findings of a BBC Panorama investigation aired in May 2021.[894] It found that hospitals were not sharing the outcomes of safety investigations carried out by Royal Colleges with the relevant regulators. As part of the investigation, freedom of information (FoI) requests were sent to all UK NHS Trusts requesting copies of Royal College reviews into their healthcare services over the last five years. Out of 111 reports, only 26 had been shared in full with regulators, and only 16 had been published. The Royal Colleges informed the Panorama investigation that 260 reviews had actually been carried out in the same period. This is a concerning lack of transparency regarding patient safety. NHSE and NHSI commented that all independent reviews should be made available to health commissioners and regulators, and all trusts are expected 'to take prompt action to address recommendations made' and that there are 'robust and transparent systems to ensure hospitals and other care providers learn and improve services'.[895] The consistent, repeated failures in this area would suggest that these systems are not as robust or as transparent as they need to be. Candour[896] and accountability are critical to improving patient safety in all aspects of healthcare, and the role of regulation and legislation in supporting this requires further consideration.

The Health and Care Bill (July 2021) incorporates provisions in the previous Health Service Safety Investigations (HSSI) Bill (2019).[897] House of Lords debates on the latter discussed how the HSSI Bill would provide a 'safe space' and support a learning culture rather

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[893] HSIB, 'A thematic analysis of HSIB's first 22 national investigations' <http://web.archive.org/web/20210819211519/https://www.hsib.org.uk/investigations-and-reports/a-thematic-analysis-of-hsibs-first-22-national-investigations/> accessed 21 October 2021

[894] Faye Kirkland, Charles Young, and Max Hudson, 'Unpublished Hospital Patient Safety Reports Exposed' *BBC News* (19 May 2021) <https://www.bbc.co.uk/news/health-57144923> accessed 21 October 2021

[895] ibid

[896] Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, Reg 20

[897] Health Service Safety Investigations Bill [HL] (2019)

than a blame culture. During debate, Lord Ribeiro noted that, 'Fear of legal, regulatory or managerial sanctions against clinicians is high and recent high-profile court cases such as Sellu and Bawa-Garba do little to reassure the profession'.[898] The Health and Care Bill (July 2021) proposes that disclosing information held by the HSSIB (to any person) that relates to the HSSIB's investigatory function is prohibited.[899] This is intended to encourage candour and learning from error by reducing an individual's fear of negative consequences. However, it perhaps inadvertently raises issues around transparency and accountability, preventing a further barrier to collaborative working amongst oversight bodies. Thus, it is possible that the cost of reducing the fear and blame culture in the NHS will be a reduction in openness and transparency with the public, undermining efforts to improve candour with patients.[900] This is problematic given that, as stated in this thesis, a just culture is one which is fair to patients as well as healthcare professionals. The potential implications of a safe space for healthcare professionals upon establishing a just culture in the NHS therefore needs further examination.

A final, further point to note regarding the establishment of the HSSIB is the duty on recipients of HSSIB reports to respond. As it currently stands, recipients are expected to respond to the recommendations of the reports by a deadline set by the HSSIB.[901] However, there is no information provided on what the consequences might be should a recipient not respond. Thus, there is a real risk here that HSSIB reports may suffer the same fate as coroners' PFD reports discussed above. By establishing this issue as one of my areas for further research, I hope to identify suitable mechanisms to safeguard accountability for learning from error.

Discharges and the Extent of the Duty of Care

Throughout this thesis, the focus has been upon regulation and the safety of the individual being discharged from hospital. However, the Covid-19 pandemic and the associated hospital discharge polices have raised additional questions which I intend to explore further. Below, I provide a short synopsis of the situation and the related legal and ethical issues raised.

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[898] Health Service Safety Investigations Bill HL Deb 29 October 2019, vol 800, col 908
[899] Health and Care HC Bill (2021-2022) [140], Clause 106(1) July 2021
[900] A duty of candour was imposed by the GMC and NMC upon doctors and nurses in response to recommendations from the Mid Staffs inquiry. See GMC and NMC, 'Openness and Honesty When Things Go Wrong: The Professional Duty of Candour' (GMC & NMC 2015)
[901] Health and Care HC Bill (2021-2022) [140], Clause 100(4)

The first wave of the Covid-19 pandemic created a significant pressure to discharge patients from hospitals in order to free up beds for the anticipated influx of Covid-positive patients.[902] However, a possible source of Covid-19 infection for care home residents is incoming residents (new or returning) discharged from hospital. Despite the risk of discharging Covid-positive patients into care homes, government policy in the first wave did not require the testing of patients for Covid-19 before discharging them into these settings.[903] This policy decision was subsequently described as 'reckless and negligent' by the Public Accounts Committee.[904] NHSE and NHSI defended the decision, stating that staying in hospital longer than necessary could be harmful for the elderly.[905]

Although a paucity of data means it is not possible to robustly quantify the extent to which discharges contributed to the virus' spread throughout care homes in England during the first wave, the Health Foundation notes that discharges were likely to have contributed to the spread of the virus.[906] Care home residents, given their frailty, are a particularly vulnerable population of people when it comes to the health threats posed by diseases, and it has been established that they are at an increased risk of severe illness or mortality resulting from Covid-19.[907] In February 2020, 80% of care home residents in England were over the age of 65 and living with chronic health conditions[908] – thus rendering it critical that residents were protected from Covid-19 infection.

According to the Health Foundation, without the prior Covid-19 testing of patients being discharged into care homes, it would be unlikely that appropriate isolation measures were adopted within the care homes. Moreover, care home staff struggled to access appropriate PPE – these are both measures which could have helped prevent the spread of infection. [909] By the

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[902] HM Government & NHS England, 'COVID-19 Hospital Discharge Service Requirements' <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/880288/COVID-19_hospital_discharge_service_requirements.pdf> accessed 26 March 2021
[903] ibid
[904] Public Accounts Committee, 'Readying the NHS and social care for the COVID-19 peak' (2020) <https://publications.parliament.uk/pa/cm5801/cmselect/cmpubacc/405/40506.htm#_idTextAnchor012> accessed 21 October 2021, para 10
[905] ibid
[906] Health Foundation, 'Briefing: Adult Social Care and Covid-19 – Assessing the Impact on Social Care Users and Staff in England so far' (Health Foundation 2020) <https://www.health.org.uk/publications/reports/adult-social-care-and-covid-19-assessing-the-impact-on-social-care-users-and-staff-in-england-so-far> accessed 21 October 2021
[907] ibid 13
[908] ibid
[909] Health Foundation (n 906)

19th of June 2020, there were 17,763 deaths involving Covid-19 amongst care home residents (approximately 40%) of all Covid-19-related deaths at the time).[910]

The issue I intend to research, highlighted below, concerns the nature and extent of the legal duty of care owed to care home residents. The actors under examination will be: the DHSC; clinicians responsible for discharging patients; and the hospitals (discharging) and care homes (receiving) patients.

The Department for Health and Social Care

In November 2020, Cathy Gardner, whose father died in a care home due to Covid-19, won the first stage of a high court challenge regarding care home policies – including that of discharging hospital patients into care homes without testing them for COVID-19. [911] The action is being brought against the DHSC, NHSE, and Public Health England (PHE). The claim states, 'The most notorious of these policies is that of mass discharge of around 25,000 elderly and/or disabled patients from NHS hospitals into care homes […] without Covid-19 testing or ensuring that suitable isolation arrangements were in place.'[912] This is an alleged breach of Articles 2, 8 and 14 of the European Convention on Human Rights (ECHR), incorporated under the Human Rights Act 1998.[913] Article 2 states that everyone's right to life shall be protected by law,[914] and it imposes certain obligations on the State (a term which also covers public bodies such as the NHS). These obligations include a negative duty to refrain from intentionally taking life, and positive duties to take reasonable steps to protect life and to intervene when someone's life is at risk from another person (and where the authorities know, or should know, about this risk). It is alleged that the UK government failed in their obligations to protect the lives and wellbeing of vulnerable care home residents during the first wave of the pandemic.[915]

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[910] ibid
[911] Cathy Gardner, 'Help me hold the government to account for Covid-19 care home deaths' *Crowd Justice* <https://www.crowdjustice.com/case/care-home-deaths/> accessed 21 October 2021
[912] Claimants' Skeleton Argument: For Substantive Hearing, 19-22 October 2021 (CO/2123/2020) https://static.crowdjustice.com/crowdjustice_document/Gardner_v_SSfH_Claimants_Skeleton_Argument.pdf accessed 17 October 2021
[913] ibid
[914] Convention for the Protection of Human Rights and Fundamental Freedoms (European Convention on Human Rights, as amended) art 2
[915] Gardner (n 911)

In June 2021, Bailin hypothesised in the *Guardian* that the DHSC could perhaps face a corporate manslaughter charge regarding these early discharge policies.[916] He comments that part of the rationale behind the Corporate Manslaughter and Corporate Homicide Act 2007 was to limit immunity from homicide prosecutions - which government departments previously held. Bailin further opines that the DHSC 'certainly owes discharged hospital patients a duty of care and that duty must extend to those with whom they reside'.[917]

Clinicians responsible for discharging patients

It is well established that a clinician has a legal duty of care towards their patients. What is less clear, currently, is whether this duty of care could extend *beyond* their individual patient and towards other care home residents amongst which that patient will be placed. When deciding new duty of care scenarios, the tripartite *Caparo test*[918] is typically to be used: harm to the Claimant was (reasonably) foreseen; requisite proximity between Claimant and Defendant existed; it is fair, just and reasonable to impose a duty of care.[919]

I intend to critically consider whether the *Caparo* test could be used to argue that, during the pandemic, clinicians owed a legal duty of care towards vulnerable care home residents. That the harm posed to other residents was reasonably foreseeable is relatively uncontroversial, however it is debateable whether the requisite proximity existed. Perhaps even more controversial is whether it would be fair, just and reasonable to impose such a duty upon clinicians. For, as discussed throughout this thesis, particularly in Part Four, holding individual clinicians accountable for decisions which stem from system failings is likely to undermine efforts to establish a just culture within healthcare.

Hospitals and Care Homes

[916] Alex Bailin, 'Cummings' care homes claim could lead to corporate manslaughter charges' *The Guardian* (3 June 2021) <https://www.theguardian.com/commentisfree/2021/jun/03/cummings-care-homes-corporate-manslaughter-covid> accessed 06 October 2021
[917] ibid
[918] *Caparo Industries Plc v Dickman and Others* [1990] 2 WLR. 358
[919] ibid

As noted in Chapter Two, subsection 2.0 (*Retrospective Responses: Civil Law*) of this thesis, Heywood makes a compelling argument for increasing use of claims directly against a hospital rather than an individual clinician. Claims of systemic negligence, he suggests, could provide valuable opportunities to identify and learn from system factors which may cause patient harm, and motivate hospitals to improve upon system failures.[920]

In making his argument, Heywood gives a hypothetical example of a hospital which (during the pandemic) hurriedly tries to implement government guidance on discharges and thus creates a system for discharging patients into care homes without appropriate risk management mechanisms in place. In his example, it is the discharged patient who is then harmed as a result of contracting Covid-19 from other residents. [921] Heywood suggests a hospital has a duty of care to its patients to operate a reasonably safe discharge system. This is because *Lorraine v Wirral University Teaching Hospital*[922] established a hospital has a similar duty to maintain a reasonably safe admission system.

In Heywood's view, a system permitting a patient to be discharged into an environment which poses a significant, known risk to the patient would render that system unsafe.[923] A thorough balancing of risks and benefits would lead to the conclusion, he argues, that the discharge system was unreasonable and the hospital's actions negligent.[924]

Along a similar vein, it may be possible to argue that care homes, which have a duty of care to their residents, ought not to have accepted new residents, or possibly returning residents, without knowing if they were Covid-positive. A balancing of risks, as Heywood proposes, may lead to the same conclusion that the care transition process between a hospital and a care home was negligent.

The purpose of this proposed line of research

The purpose of this strand of future research would not be to proportion unfair blame upon healthcare professionals or a pressurised health and social care system. However, establishing

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[920] Rob Heywood, 'Systemic negligence and NHS hospitals: An underutilised argument' (2021) King's Law Journal, DOI: 10.1080/09615768.2021.1951496
[921] ibid
[922] [2008] EWHC 1565
[923] Heywood (n 920)
[924] ibid

both backward-looking accountability and forward-looking accountability in this instance is important from a justice perspective. Writing on justice in healthcare, Daniels argues that justice requires both reducing the risks of disease and disability, and equitably distributing these risks.[925] Where some groups within a population have different risks of getting ill, it is not enough to simply attend to their illnesses. Rather, where the risk of illness differs systematically in avoidable ways, to guarantee equal opportunity, we must try to eliminate the differential risks and prevent the excess illness of people at avoidable greater risk.[926] The burden of illness will otherwise fall unfairly on these groups.[927] Within the first wave of the pandemic, this burden fell heavily upon care home residents, and led to a catastrophic, potentially avoidable, loss of life. It is therefore critical that lessons are learned from this failing to prevent future reoccurrence.

Proposed changes to discharge policy

A final point worth highlighting about the impact of the pandemic upon hospital discharges is the introduction of a discharge to assess (D2A) model in August 2020.[928] This model was introduced in order to remove funding barriers that contributed to delayed discharges – meaning patients could be discharged quicker to create bed spaces in hospitals. The new Health and Care Bill proposes the creation of a legal framework for a D2A model.[929] This would mean that social care need assessments could all take place after a patient has been discharged from acute hospital care. The move would replace the existing legal requirement for all assessments to take place prior to discharge.[930]

The potential impact of this upon patients is currently unknown; although one positive impact of reducing the length of time patients spend in hospital is that it may reduce the risk of

[925] Norman Daniels, *Just Health: Meeting Health Needs Fairly* (Cambridge University Press 2008) 141
[926] ibid
[927] ibid
[928] Chartered Society of Physiotherapy, 'Rollout of the Discharge to Assess (D2A) model in England' (*Chartered Society of Physiotherapy*, 10 September 2020) <https://www.csp.org.uk/news/coronavirus/workplace-employment-guidance/rollout-discharge-assess-d2a-model-england> accessed 21 October 2021
[929] Health and Care Bill s 78
[930] ibid

clinical deterioration associated with prolonged hospital stays.[931] That said, Carers UK, a charity supporting people with caring responsibilities for their friends and family members, has voiced concern about the proposal. The charity has suggested that the proposal will erode carers' rights under the Care Act 2014. [932] This is because clause 78 of the Bill enables Care Act assessments to take place *after* a patient has been discharged from acute care, as opposed to before discharge. Carers UK states that the proposal does not allow for effective decision-making on whether the amount of care provided by individual carers or families is sustainable,[933] which could ultimately result in a patient not getting safe care. The charity calls for any new primary legislation to ensure that, before someone is discharged from hospital, their carer is willing and able to care for that person.[934] This is an important aspect for consideration given that patients' family members or friends are often essential to ensuring the safety of vulnerable patients following discharge.[935]

The impact of subsequent delays to assessing the ongoing care needs of the discharged patient will also need to be carefully considered and safeguarded against – otherwise patients may be exposed to considerable risks. At this moment in time, it is too early to predict what the outcome of the policy change will be, but the change will warrant further research.

Final Words

In this thesis, I set out to ascertain how regulation might better ensure the safety of patients experiencing hospital discharge. It is hoped that the findings are of interest to other academics, regulators, and policy-makers, and that ultimately, this outstanding patient safety issue will be addressed in policy and practice.

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[931] David Maguire, 'Delayed transfers of care: a target that misses the mark?' (*Kings Fund,* 4 January 2018) <https://www.kingsfund.org.uk/blog/2018/01/delayed-transfers-care-target-misses-mark> accessed 21 October 2021

[932] Carers UK, 'Carers UK's written evidence to Public Bill Committee on the Health and Care Bill' (*Parliament UK,* 27 August 2021) <https://bills.parliament.uk/publications/42642/documents/658> accessed 21 October 2021

[933] ibid

[934] ibid

[935] Parliamentary and Health Service Ombudsman, (2016) 'A Report of Investigations into Unsafe Discharge from Hospital' <https://www.ombudsman.org.uk/publications/report-investigations-unsafe-discharge-hospital-0> accessed 26 March 2021

APPENDIX

Copies of the published journal articles

- 'Leaving Hospital: A step too far for risk-based regulation?' (2020) 17 *Medical Law Review* 675-695

- 'Regulating Patient Safety during Hospital Discharges: Casting the Patient Safety Commissioner as the Representative of Order' (2021) 21 Medical Law International 195

- 'Doctors, Decisions, and Discharges: Regulatory Accountability for Patient Safety in a Just Culture' (2020) 36 *Journal of Professional Negligence* 171-185

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LEAVING HOSPITAL: A STEP TOO FAR FOR RISK-BASED REGULATION?

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ABSTRACT

Discharges from hospital are internationally recognised as a dangerous time in the care pathway of a patient, posing a risk to both their physical wellbeing and dignity. This article examines the effectiveness of risk-based regulation as a tool to address patient safety incidents linked to the hospital discharge process within the English National Health Service. It examines how the risk of this process is identified, conceptualised, and prioritised amongst the relevant statutory regulators, and argues that the risk is neither uniformly recognised by the statutory regulators within the English NHS, nor sufficiently addressed. Professional regulators in particular appear to have a poor awareness of the risk and their role in addressing it. Until these issues are resolved, patients leaving hospitals will continue to be exposed to patient safety incidents which should be avoidable.

KEYWORDS: Harm, Hospital discharges, NHS, Patient safety, Risk, Risk-based regulation

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I. INTRODUCTION

Patients who are discharged from hospital are widely recognised as being at an increased risk of harm.[1] This article seeks to demonstrate how risk-based regulation, a prominent model of regulation utilised within the English NHS by statutory regulatory bodies to protect patients from harm, is ill-equipped to ensure and improve the safety (broadly conceived) of hospital discharges. Its purpose is to draw attention to the nature of this complex problem and its impact upon patient safety; it does not seek to propose a solution. It commences by considering what regulation means within the healthcare context, and why regulators need to address safety during hospital discharges. Section II examines the rationale for risk-based models within healthcare regulation, and three weaknesses that occur when the model is applied in multi-regulator environments. The third section then considers the extent to which regulators have recognised and tackled the risk posed to patient safety by hospital discharges and the fourth section explores why the risk posed to patient safety by hospital discharges might have received limited regulatory recognition, arguing that it is a consequence of the use of risk-based regulation models are used in multi-regulator environments. This article concludes that until these weaknesses are resolved, the threat posed to patients' safety during the discharge process will remain unmitigated.

Black defines regulation as 'the sustained and focused attempt to alter the behaviour of others according to defined standards or purposes with the intention of producing a broadly identified outcome or outcomes'.[2] This definition has been applied to the healthcare setting by Waring et al.[3] and is also shared by the Professional Standards Authority (PSA). The PSA is an arm's-length body of the Department of Health, and is responsible for regulating the professional regulators (the bodies responsible for regulating health and social care professionals).[4] It states that a regulator's purpose is to 'minimise harm and to seek to do so by changing individual or organisational behaviour'.[5] Oikonomou et al. have recently offered a broader meaning which refers to healthcare regulation as, 'the processes engaged in by institutional actors that seek to shape, monitor, control or modify activities within healthcare organisations in order to reduce the risk of patients being harmed during their care'[6].

1 See World Health Organisation, *Transitions of Care: Technical Series on Safer Primary Care* (World Health Organisation 2016); K Aase and others, *Researching Quality in Care Transitions International Perspectives* (1st edn, ebook, Palgrave Macmillan 2017); K Manges and others, 'A Mixed Methods Study Examining Teamwork Shared Mental Models of Interprofessional Teams during Hospital Discharge' (2019) BMJ Quality & Safety.

2 J Black, 'Decentering Regulation: Understanding the Role of Regulation and Self-regulation in a Post-regulatory World' (2001) 54 Current Legal Problems 142.

3 J Waring and others, 'Modernising Medical Regulation: Where are We Now' (2010) 24 Journal of Health Organisation and Management 6, 541.

4 For further information on the PSA holds professional regulators accountable see J Allsop and K Jones, 'Regulating the Regulators: The Rise of the United Kingdom Professional Standards Authority' in J Chamberlain, M Dent and M Saks (eds), *Professional Health Regulation in the Public Interest: International Perspectives* (1st edn, Policy Press 2018) and O Quick, *Regulating Patient Safety* (1st edn, CUP 2017).

5 Professional Standards Authority, *Rethinking Regulation* (PSA 2015).

6 E Oikonomou and others, 'Patient Safety Regulation in the NHS: Mapping the Regulatory Landscape of Healthcare' (2019) 9 BMJ Open 2.

This definition is designed to capture the breadth of actors that are engaged in these processes, regardless of whether the actors self-identify as formal regulators. An astoundingly high number of 126 organisations were identified as exerting regulatory influence within the NHS.[7]

Although Oikonomou et al.'s broad understanding of regulation provides scope for a rich exploration of all behavioural influences, this article takes a narrower focus upon the formal attempts by statutory regulators to shape behaviour within healthcare organisations. This is because the statutory regulators have a legal duty to protect patients, and are therefore the ones held accountable for any regulatory failings that are uncovered (typically following inquiries into healthcare scandals). Given this, the regulatory bodies under consideration within this article are the professional regulators[8]; the Care Quality Commission (CQC), which regulates health and social care services; and NHS England and NHS Improvement.[9] The latter two have regulatory oversight of healthcare services[10] and are accountable to Parliament.[11]

The professional regulators each have the same primary purpose, established through legislation,[12] of protecting the public. Each professional regulator shares the following overarching functions[13]: set the standards of behaviour, competence, and education that professionals must meet; address concerns raised about professionals who are unfit to practise because of poor health, misconduct or poor performance; maintain registers of professionals who are fit to practise; and set the requirements for re-registration and/or revalidation for each profession. The CQC[14] is responsible for regulating the quality of health and social care in England. All providers of adult healthcare in England are legally required to register with the CQC, which inspects and rates the quality of services from outstanding to inadequate. The CQC sets out thirteen fundamental standards of care[15] which cover a vast array of matters such as treating patients with dignity and respect, being open and honest when things go

7 ibid 1–9.

8 General Medical Council, General Dental Council, General Chiropractic Council, General Optical Council, General Osteopathic Council, General Pharmaceutical Council, Health and Care Professions Council, Nursing and Midwifery Council, and Social Work England.

9 Since April 2019 these have been working together as a single organisation. See NHS Improvement, 'Working Together' (2019) <https://improvement.nhs.uk/> accessed 12 June 2020.

10 For further detail on differences in responsibilities between CQC and NHSI see: British Medical Association, 'The Regulatory Systems for Healthcare Quality across the United Kingdom' (2016) <https://www.bma.org.uk/collective-voice/policy-and-research/nhs-structure-and-delivery/monitoring-quality-in-the-nhs/regulatory-systems-for-healthcare-quality> accessed 12 June 2020.

11 NHS England, 'Accountability Report' (2019) <https://www.england.nhs.uk/wp-content/uploads/2019/07/accountability-report-201819.pdf> accessed 12 June 2020.

12 See the Medical Act 1983, Dentists Act 1984, Chiropractors Act 1994, Opticians Act 1989, The Osteopaths Act 1993, The Health Act 1999, the Nursing and Midwifery Order 2001, The Health and Social Work Professions Order 2001, and the Pharmacy Order 2010.

13 Law Commission, *Regulation of Health Care Professionals: Regulation of Social Care Professionals in England* (Law Commission 2014).

14 Health and Social Care Act 2008, s 3(1)–(2).

15 Care Quality Commission, 'The Fundamental Standards' (2019) <https://www.cqc.org.uk/what-we-do/how-we-do-our-job/fundamental-standards> accessed 12 June 2020.

wrong, and ensuring appropriate staff are employed to provide care. It is accountable to Parliament and the Secretary of State for Health.[16]

A. Patient Safety and the Risk of Harm Posed by Hospital Discharges

Patient safety is an issue of both global and national concern. The World Health Organisation (WHO) estimates that globally, the occurrence of adverse events due to unsafe care is one of the ten leading causes of death and disability[17]. In order to recognise that patient safety is a pressing health priority, the WHO launched the first World Patient Safety Day in 2019, with the aim of raising public awareness and sparking world-wide action.[18] In the same year, NHS England and NHS Improvement published the National NHS Patient Safety Strategy. The strategy aims to continuously improve patient safety by 'maximising the things that go right and minimising the things that go wrong for people experiencing healthcare'[19]. It predicts that getting this right could save almost one thousand extra lives and £100 million in care costs each year from 2023 to 2024.[20]

In recent years, multiple bodies tasked with improving, monitoring, or advocating for patient safety have published findings highlighting the need to reduce the number of hospital discharges which result in harm to patients. For example, Healthwatch England (HE) has published three reports drawing attention to poor hospital discharges and the resulting harm to patients since 2015.[21] In 2016, the Parliamentary and Health Service Ombudsman (PHSO) identified four key issues that, separately, can result in patient harm and thus constitute an unsafe discharge.[22] These are: where a patient is discharged before it is clinically safe to do so; where a patient is not assessed or consulted properly prior to discharge; where relatives or carers are not informed of the discharge; or where this no appropriate support in place for patients to cope once discharged.[23] In response to the PHSO report's[24] findings, the Public Administrations and Constitutional Affairs Committee (PACAC) launched an inquiry and concluded that, 'the incidence of unsafe discharge from NHS hospitals is much too high and this is unacceptable'.[25]

16 Care Quality Commission, 'Framework Agreement between the Department of Health and Care Quality Commission' (2013). <https://www.cqc.org.uk/sites/default/files/documents/cm_0114310_item_10_appendix_1_cqc_framework_agreement.pdf> accessed 12 June 2020.

17 World Health Organisation, 'Patient Safety' (2019) <https://www.who.int/news-room/fact-sheets/detail/patient-safety> accessed 12 June 2020.

18 World Health Organisation, 'World Patient Safety Day' (2019) <https://www.who.int/campaigns/world-patient-safety-day/2019> accessed 12 June 2020.

19 NHS England and NHS Improvement, 'The NHS Patient Safety Strategy: Safer Culture, Safer Systems, Safer Patients' (2019) <https://improvement.nhs.uk/documents/5472/190708_Patient_Safety_Strategy_for_website_v4.pdf> accessed 12 June 2020 6.

20 ibid.

21 Healthwatch England, *Safely Home: What Happens when People Leave Hospital and care settings?* (Healthwatch 2015); Healthwatch England, 'What Happens when People Leave Hospital and other Care Settings?' (Healthwatch 2017); Healthwatch England, 'Emergency Readmissions: What's Changed One Year On?' (Healthwatch 2018).

22 Parliamentary and Health Service Ombudsman, 'A Report of Investigations into Unsafe Discharge from Hospital' (PHSO 2016).

23 Public Administration and Constitutional Affairs Committee, 'Follow-up to PHSO Report on Unsafe Discharge from Hospital' (PACAC 2016).

24 Parliamentary and Health Service Ombudsman (n 23).

25 Public Administration and Constitutional Affairs Committee (n 24) 18.

A 2015 analysis of National Reporting and Learning System[26] (NRLS) data on discharge-related safety incidents[27] found four main categories of error. These errors were in: the quality of discharge communication; referrals to community care; medication; and providing care adjuncts, for example wound dressings and catheters. In addition, behavioural factors, such as not following protocols, and organisational factors such as a lack of coherent guidelines[28] were common contributory factors to patients experiencing harm. The study data further showed that the harm patients experienced because of these incidents was predominantly categorised as low-level, meaning that patients experienced mild symptoms, the harm was short-term, and little or no intervention was required to resolve the harm.[29] However, in 78 cases (13%), patients experienced moderate harm, meaning they required an intervention to resolve symptoms and may have experienced permanent or long-term harm or loss of function. There were 3 (<1%) severe cases where life-saving interventions were required and patients experienced major loss of function, and in one instance a patient died. In one severe case for example, no discharge letter was sent to the GP, meaning the patient did not receive appropriate treatment and experienced a stroke, resulting in a permanent reduction in their function.[30]

According to Waring et al.,[31] current thinking in the patient safety field recognises that threats to patient safety stem not only from individual errors but also from more latent factors, such as the way groups work together and the design and management of work. However, the focus for this line of thinking has tended to remain within static care domains like wards or operating departments. Waring and colleagues argue that the reason hospital discharges pose a significant patient safety problem is because latent factors are even more broadly located across the wider care system, thus presenting more complex sources of risk.[32] Their qualitative study identified consistent threats to the safety of discharged stroke and hip fracture patients. These threats included but were not limited to: direct patient harm, for example falls, medicines-related issues, and relapse; contributing factors such as follow-up care and patient education; and latent factors, such as discharge timing, referral processes, and resource constraints. The authors concluded that hospital discharge is a 'high risk and vulnerable stage in the patient journey'.[33] Poor discharge planning can amount to clinical negligence, as illustrated in *Esegbona v King's College NHS Trust*. In this case the Trust

26 The NRLS is a central database of patient safety incidents (PSIs) reported from across England and Wales. A PSI for the purpose of the database is defined as 'any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving healthcare'. See NHS Improvement, 'Report a Patient Safety Incident' (2017) <https://improvement.nhs.uk/resources/report-patient-safety-incident/> accessed 12 June 2020.

27 H Williams and others, 'Harms from Discharge to Primary Care: Mixed Methods Analysis of Incident Reports' (2015) 65 British Journal of General Practice 641, e829–e837.

28 ibid.

29 ibid.

30 ibid.

31 J Waring and others, 'A Qualitative Study of Professional and Carer Perceptions of the Threats to Safe Hospital Discharge for Stroke and Hip Fracture Patients in the English National Health Service' (2016) 16 BMC Health Services Research.

32 ibid.

33 ibid.

was found to be negligent in its failure to inform the nursing home that the patient was discharged to about her specific care needs. It was therefore held liable for damages for the pain, suffering and loss of amenity the patient experienced leading up to her death.[34]

In addition to experiencing physical harm related to hospital discharge processes, patients' dignity may be harmed. This article adopts Tadd et al.'s argument that treating patients with dignity comprises of:

> respectful communication; respecting privacy; promoting autonomy and a sense of control; addressing basic human needs such as nutrition, elimination and personal hygiene needs in a respectful and sensitive manner; promoting inclusivity and a sense of participation by providing adequate information to aid decision-making; promoting a sense of identity; focusing on the individual and recognising human rights.[35]

In contrast, undignified care 'renders individuals invisible, depersonalises and objectifies people, is abusive or humiliating, narrowly focused and disempowers the individual'.[36] The 2016 Parliamentary and Health Service Ombudsman (PHSO)[37] report provides an example of undignified care within the context of hospital discharges: 85-year-old Mrs K, who had dementia, was discharged home late at night without her family being informed. The following morning Mrs K's daughter found her at her home, having been left with no food, drink or bedding, and unable to care for herself or get to the toilet. We can see how such an experience is likely to have left Mrs K feeling humiliated and disempowered. Indeed, research by O'Hara et al. found that patients view such non-clinical incidents as a safety incident; within the study, one of the patient-derived safety categories was 'Compassion/dignity/privacy/respect'.[38]

By way of further example, a British Red Cross report[39] highlighted several instances of patients being discharged from hospital before adequate home support is in place—placing the dignity and physical wellbeing of discharged patients at risk of harm. Regarding such patients, a red cross team member stated, 'they've got no family, they've got no one and there's no care package in place for them coming home. They [the discharge team] just ask us to go in, and we go in and we find them, they've either had a fall, they're on the floor and it's because they've been sent back out too soon and they get readmitted again'.[40]

This article uses the term 'patient safety incident' (PSIs) to refer to any unintended or unexpected incident which could have, or did, lead to the detriment of a patient's physical wellbeing and/or dignity. This is a broader definition than NHS

34 *Esegbona v King's College NHS Trust* [2019] EWHC 77 (QB).

35 W Tadd and others, 'Dignity in Practice: An Exploration of the Care of Older Adults in Acute NHS Trusts' (The Stationary Office: London 2011) 10.

36 ibid 10.

37 Parliamentary and Health Service Ombudsman (n 23).

38 JK O'Hara and others, 'What Can Patients Tell Us About the Quality and Safety of Hospital Care? Findings From A UK Multicentre Survey Study' (2018) 27 BMJ Quality & Safety 27, 673–682.

39 British Red Cross, 'In and Out of Hospital' (British Red Cross 2018).

40 ibid 11.

Improvement's (NHSI) definition which states that a PSI is 'any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving healthcare'. In the latter, harm is understood to be physical in nature.[41] This article's definition has a dual purpose; it reflects the fact that dignity is an important concept within healthcare from a legal and regulatory perspective, and it captures the patient perspective of harm mentioned above.

Regarding the importance of dignity from a legal perspective, the NHS Constitution, which is enshrined in the 2009 Health Act, sets out that patients have a right to be treated with dignity and respect, in accordance with their human rights.[42] This is further stated in Regulation 10 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. The importance of respecting a patient's dignity is also reflected within the professionals' codes and the CQC's fundamental standards.[43] A failure to follow these standards may result in regulatory action.[44] It is clear that regulators recognise respect for a patient's dignity as an integral part of good health care, and thus ought to be prepared to take action to safeguard against harm to a patient's dignity. A report by the Commission on Dignity in Care for Older People recommended that regulators must place as much emphasis on dignity in care as on clinical outcomes, and that professional regulators such as the General Medical Council (GMC) 'must promote and enforce high standards of dignified care'.[45]

Despite the emphasis on healthcare professionals respecting patients' dignity, the concept is not defined by the professional codes; indeed there is no clear consensus of dignity either within healthcare literature or wider philosophical literature.[46] Alongside leaving healthcare professionals lacking practical guidance with regards to protecting patients' dignity,[47] the nebulous nature of dignity is problematic from a regulatory point of view. Caulfield and Brownsword argue that, given this vagueness, a requirement to respect human dignity fails to provide a clear steer to regulatees, making it difficult for regulatees to demonstrate regulatory compliance and for regulators to enforce it.[48]

This section has thus far established that patients are exposed to a risk of harm to both their physical wellbeing and their dignity during the discharge process, and argues that harm to either of these aspects ought to be of regulatory interest.[49] The

41 NHS Improvement, 'Report A Patient Safety Incident' (2017) <https://improvement.nhs.uk/resources/report-patient-safety-incident/> accessed 12 June 2020.

42 National Health Service, 'NHS Constitution for England' (NHS 2015).

43 For example, see para 25 of 'Good Medical Practice' (2013); para 1 of the NMC's Code (2015); standard 1 of 'Standards for Pharmacy Professionals' (2017); s 2.2 of Social Work England's Professional Standards (2019) and the CQC's 'The Fundamental Standards' (2019).

44 General Medical Council, 'Good Medical practice' (2013) para 6.

45 Commission on Dignity in Care for Older People, 'Delivering Dignity: Securing Dignity in Care for Older People in Hospitals and Care Homes' (Commission on Dignity in Care for Older People 2011) Recommendation 35.

46 L Barclay, 'In Sickness and in Dignity: A Philosophical Account of the Meaning of Dignity in Health Care' (2016) 61 International Journal of Nursing Studies 136–141.

47 ibid.

48 T Caulfield and Brownsword R, 'Human Dignity: A Guide to Policy Making in the Biotechnology Era?' (2006) 7 Science and Society 72–76.

49 There are of course additional emotional harms which a patient might experience, such as stress and anxiety. This article focusses on harm to dignity because of the regulatory requirements to respect patient dignity.

following section examines the rationale for risk-based models of regulation, and three recognised weaknesses that occur when the model is applied in multi-regulator environments.

II. RISK-BASED REGULATION WITHIN THE ENGLISH NHS

The risk-based regulation model is intended to focus regulators' interventions upon the threats which pose the greatest risk to its objectives, as opposed to aiming to prevent *all* possible harm.[50] Prioritising regulatory interventions in this manner is said to be effective and proportionate,[51] whereas to do otherwise has been called grossly inefficient.[52] In the UK, the 2005 Hampton Report[53] strongly endorsed risk-based approaches—describing them as essential for efficiently directing regulatory resources to where they can have maximum impact upon outcomes, and warning that a failure to use risk assessments effectively means resources may not be targeted at the riskiest areas.

Although it has been argued that a concrete definition of risk-based regulation is 'elusive',[54] Black and Baldwin observe that risk-based frameworks typically take the identification of risk as their starting point, and feature the following elements[55]: a determination by the organisation as to what the risk is that it aims to control; a determination of the organisation's 'risk appetite' (the type and level of risk that will be tolerated); an assessment of the likelihood of the risk occurring; and a ranking of risks based upon these assessments. In theory, these frameworks then provide a means for linking appropriate regulatory interventions to the severity of the risk.[56] For example, in the healthcare context, a 2017 GMC Chief Operating Officer Report,[57] illustrates the type of risk register utilised by the GMC. The register identifies not effectively sharing information as an active risk that could in turn pose a risk to patient safety. This risk was assessed as being quite likely to occur, and having a moderate impact if it did occur. Existing actions to mitigate the risk were noted, and future mitigating actions were also outlined.[58] Similarly, the NMC's risk register is publicly available, and identifies high-level risks, contributory factors, risk appetite, and existing and future controls.[59]

Risk can be characterised as the possibility of an undesirable incident occurring, either as a result of natural events or human activities, or due to a combination of

50 Beaussier and others (n 2) 206.

51 H Rothstein, 'The Institutional Origins of Risk: A New Agenda for Risk Research' (2006) 8 Health, Risk and Society 3, 215–21.

52 Beaussier and others (n 2) 206.

53 P Hampton, *Reducing Administrative Burdens: Effective Inspection And Enforcement* (HM Treasury 2005).

54 S Lloyd-Bostock and B Hutter, 'Reforming Regulation of the Medical Profession: The Risks of Risk-based Approaches' (2008) 10 Health, Risk and Society 1, 70.

55 J Black and R Baldwin, 'Really Responsive Risk-based Regulation' (2010) 32 Law and Policy 2, 181–213.

56 ibid.

57 General Medical Council, 'Chief Operating Officer's Report: Agenda Item M4' (2017) <https://www.gmc-uk.org/-/media/documents/m04—chief-operating-officer-s-report_pdf-72010185.pdf> accessed 12 June 2020 11.

58 ibid.

59 Nursing and Midwifery Council, 'Council Meeting: 27 March 2019' (2019) <https://www.nmc.org.uk/about-us/governance/the-council/council-meetings/previous-council-meetings/council-meeting-27-march-2019/> accessed 12 June 2020.

both.[60] Given that within healthcare, a core purpose of regulation is to minimise harm to patients, the possibility that patients will be harmed is an undesirable occurrence; that is to say it is a risk that regulators wish to reduce the occurrence of.

This article identifies three broad categories of risk that, from a regulatory perspective, could ultimately result in harm to patients. These categories are: risks to the safety and/or dignity of individual patients, risks to the reputation of regulators, and risks to the public's trust in the healthcare professions—each of which will now be considered in turn.

The first of these, risks to the safety of individual patients, comprises of two further subcategories of risk: those that pose a risk to the physical wellbeing of a patient, and those that pose a risk to a patient's dignity as defined above. The former is an inherent risk[61] within the delivery of healthcare, and thus the question becomes, what level of risk is to be tolerated? For example, general anaesthesia for surgical procedures in a reasonably healthy person poses a small risk to life (approximately 1 death per 100,000 general anaesthetics[62]), but it is often recommended and accepted as part of the treatment to avoid conditions which pose a greater risk to life—such as a burst appendix. Painkillers such as tramadol also carry a risk of unpleasant side effects, ranging for example from headaches, nausea and constipation to breathing difficulties, hallucinations, and seizures.[63] Yet for patients these risks may often be preferable to no treatment. Patients' views of acceptable risk will also vary from patient to patient, depending upon their personal circumstances, and doctors must explore these factors with patients when discussing treatment options.[64] On a broader level, Beaussier et al. argue that there is perpetual disagreement amongst regulators, the public and politicians, as to what constitutes acceptable risk. They note that even if agreement could be reached on what risks are acceptable at least in theory, adverse outcomes would rarely be regarded as such once they came to light.[65]

By contrast, a risk to the dignity of patients is not an inherent risk within the delivery of healthcare. This view is supported by the inquiry into poor care at Mid Staffordshire hospital, which remarked, 'a scrutineer might reasonably have expected dignity and respect to be accorded to everyone at all times'.[66] It is therefore argued here that the acceptable level of harm to a patient's dignity is zero, and any risk to patient dignity, such as the hospital discharge process, should be effectively managed to obviate the chances of this risk materialising.

60 J Black, 'The Role of Risk in Regulatory Processes' in R Baldwin, M Cave and M Lodge (eds), *The Oxford Handbook of Regulation* (1st series, OUP 2010).

61 D Sohn, 'Negligence, Genuine Error, and Litigation' (2013) 6 International Journal of General Medicine 49–56.

62 Royal College of Anaesthetists, 'Section 15: Death or Brain Damage' (2017) <https://www.rcoa.ac.uk/sites/default/files/documents/2019-11/15-DeathBrainDamageweb.pdf> accessed 12 June 2020.

63 National Health Service, 'Tramadol' (2018) <https://www.nhs.uk/medicines/tramadol/> accessed 12 June 2020.

64 *Montgomery v Lanarkshire Health Board* [2015] SC 11 [2015] 1 AC 1430; General Medical Council, 'Consent: Patient and Doctors Making Decision Together' (2019) <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/consent> accessed 12 June 2020.

65 Beaussier and others (n 2).

66 R Francis, ' *Report of the Mid Staffordshire Foundation Trust Public Inquiry Volume I* (The Stationary Office 2013) 6.262.

The second category of risk, which is harm to the reputation of a regulator, can be illustrated by a recent GMC decision to appeal a determination by the Medical Practitioners Tribunal Service (MPTS) and to call for the removal of a paediatrician from the medical register.[67] This caused widespread outrage amongst the medical profession. In a letter addressed to the Chair of the GMC by a director of a hospital trust, the GMC was accused of undermining patient care by 'endorsing and promoting a blame ethos that is inimical to safety'.[68] A blame ethos poses a risk to candour which can lead to errors being hidden rather than learned from—jeopardising future patient safety.[69] Following the aforementioned MPTS decision, the GMC commissioned an independent review into gross negligence manslaughter. The review found that doctors' trust in the GMC had been severely damaged and that this was of great concern. It asserted that the GMC can only support doctors to deliver good medical practice if doctors feel able to engage constructively with the regulator, and have confidence that processes will 'be proportionate, fair and just'.[70] This is further supported by research demonstrating that regulatees respond positively to respectful, supportive approaches,[71] and are more inclined to accept outcomes which might not otherwise appear to be in their interests if they feel they have been treated fairly.[72] If regulatees trust the regulator, then compliance with regulatory requirements increases.[73] Where healthcare providers' lack trust in regulators, the quality of care provided to patients suffers.[74]

The third category of risk is to the public's trust; Quick states that people, processes, and places within healthcare are regulated in order to ensure trust and to improve safety.[75] Ensuring public trust in healthcare professions is central to making sure that people will seek out the healthcare that they need.[76] High profile regulatory failures[77]

67 B Gault, 'GMC was Advised to Appeal Bawa-Garba Case to "protect reputation of profession"' (2019) <http://www.pulsetoday.co.uk/news/all-news/gmc-was-advised-to-appeal-bawa-garba-case-to-protect-reputation-of-profession/20039140.article> accessed 12 June 2020.

68 N Ross, 'Letter to the GMC Chair Regarding Hadiza Bawa-Garba' (2018) <https://www.bmj.com/content/360/bmj.k195> accessed 19 December 2019.

69 National Advisory Group on the Safety of Patients in England, *A Promise to Learn – A Commitment to Act: Improving the Safety of Patients in England* (Crown Publishing 2013); NHS England and NHS Improvement (n 20).

70 L Hamilton, 'Independent Review of Gross Negligence Manslaughter and Culpable Homicide' (2019) 22 <https://www.gmc-uk.org/-/media/documents/independent-review-of-gross-negligence-manslaughter-and-culpable-homicide—final-report_pd-78716610.pdf> accessed 12 June 2020.

71 J Healy, *Improving Healthcare Safety and Quality: Reluctant Regulators* (1st edn, Ashgate Publishing 2011).

72 TR Tyler, 'Procedural Justice, Legitimacy, and the Effective Rule of Law' (2003) 30 Crime and Justice 283–357.

73 J Braithewaite and T Makkai, 'Trust and Compliance' (1994) 4 Policing and Society 1; K Murphy, 'The Role of Trust in Nurturing Compliance: A Study of Accused Tax Avoiders' (2004) 28 Law and Human Behaviour 2, 187–209.

74 S Kane and others, 'Trust and Trust Relations from the Providers' Perspective: The Case of the Healthcare System in India' (2015) 12 Indian Journal of Medical Ethics 3, 157–68.

75 Quick (n 5).

76 See Healy (n 72) for further discussion on the importance of trust within healthcare.

77 See eg J Smith, *The Shipman Inquiry Fifth Report: Safeguarding Patients: Lessons from the Past - Proposals for the Future* (The Stationary Office 2004); Francis (n 67); G James, *Report of the Independent Inquiry into the Issues raised by Paterson* (House of Commons 2020).

can damage the public's trust in the ability of regulators to protect them and in the professions that they regulate.[78]

The impact of damaged trust on patient safety is illustrated in a statement by one of Dr Fata's victims. Dr Fata was a Detroit doctor sentenced to 45 years in prison for providing medically unnecessary chemotherapy to patients.[79] One victim stated:

> 'I don't trust any doctor or medical professional, I doubt everything they say. When I start thinking about it I can't function, I become so anxious I can't even go to work, and if I have a doctor's appointment for myself or my son I cancel it. I thought it would get better with time, but it hasn't. How am I supposed to go through the rest of my life not trusting the medical profession?[80]'

This demonstrates how a loss of trust in one medical professional can impact upon trust in the collective and ultimately threaten the safety of patients who may avoid seeking much-needed future healthcare for themselves and their children.

Risk-based regulation is intended to enable regulators to identify the risks which fall into these categories, and to determine which pose the greatest threat to their regulatory objective: minimising harm to patients. A failure to manage any of the above three categories of risk appropriately can lead to patient safety incidents. Drawing on Brownsword's arguments,[81] Farrell states that when measuring the effectiveness of risk-based regulation regimes, one of the elements that it is essential to consider is whether the use of the regime has enabled its aims and objectives to be met. This measurement sits alongside others: the regime's comprehensiveness in handling risk-based issues, the extent of support or resistance afforded to it by regulatees, and the accountability mechanisms in place for monitoring it.[82] It is upon the first of these measurements where this article focusses its attention.

B. Identifying, Conceptualising and Prioritising Risk in Healthcare

The efficacy of risk-based regulatory approaches is heavily dependent upon successful risk identification and prioritisation. Needless to say, where the risk is unrecognised, the issue will fail to even make it upon regulators' agenda.[83] Black broadly sums up the difficulties of identifying risks as: 'selecting the appropriate indicators, gathering sufficient information with respect to those indicators, assessing probabilities (particularly for low-probability, high-impact events), assessing the ability of management

78 J Allsop, 'Regaining Trust in Medicine: Professional and State Strategies' (2006) 54 Current Sociology 4 621–36.

79 Justice Department, 'Detroit Area Doctor Sentenced To 45 Years In Prison For Providing Medically Unnecessary Chemotherapy To Patients' (2015) <https://www.justice.gov/opa/pr/detroit-area-doctor-sentenced-45-years-prison-providing-medically-unnecessary-chemotherapy> accessed 12 June 2020.

80 Justice Department, 'Farid Fata Victim Impact Statements' 2:13-cr-20600-PDB-DRG Doc # 135-2 (2015), 22.

81 R Brownsword, *Rights, Regulation, and The Technological Revolution* (1st edn, OUP 2008).

82 AM Farrell, *The Politics of Blood: Ethics, Innovation and the Regulation of Risk* (1st edn, CUP 2014) 199.

83 R Baldwin and J Black, 'Driving Priorities in Risk-based Regulation: What's the Problem?' (2016) 43 Journal of Law and Society 4, 565–95; F Haines, 'Regulation and Risk' in P Drahos (ed), *Regulatory Theory: Foundations and Applications* (ANU Press 2017).

systems and processes to mitigate risk, and dealing with uncertainties rather than risks that can be easily calculated'.[84]

Beaussier et al. make a similar observation; that within the healthcare context regulators have struggled to assess risks to quality, to identify providers at greatest risk of failing to meet quality standards, and to prioritise inspections accordingly. This is in part because of the challenges in interpreting vast quantities of data, in devising useful indicators to capture the desired outcomes, and in making 'credible inspection judgements about complex health organisations'.[85] A recent inquiry[86] by the Joint Committee on Human Rights into the detention of young people with learning disabilities and/or autism within healthcare settings illustrates the CQC's failing in this regard. Analysis of the information available to the CQC on twenty services was examined, and a key criticism was the 'lack of an obvious relationship between the information that CQC has available to it about a service and its inspection ratings or regulatory actions relating to that service'.[87] The analysis found that beyond routine inspections, there appeared to be 'little relationship between the information presented in the analysis and the timing of inspections'.[88] The inquiry therefore concluded that the CQC was failing to meet its 2016–2021 strategic priority of delivering an 'intelligence-driven approach to regulation'[89] and that substantive reform of the CQC's approach and processes is needed. This failure highlights how the challenges associated with gathering and interpreting data can lead to an inability to appropriately identify a risk to patient safety.

When risks are recognised, the priority they are subsequently afforded by regulators will be influenced by how the risk is conceptualised, as well as operational factors, and political/reputational influences.[90] The conceptualisation of risk is particularly problematic where multiple regulators are acting within the same area.[91] Baldwin and Black demonstrate how this is problematic within environmental regulation. A chemical used by farmers in sheep-dips potentially affects the quality of watercourses and groundwater; a risk which can be conceptualised three-ways: as a harm to the environment, a harm to animal health, and a harm to human health. Each of these harms may be the responsibility of more than one regulator, and subject to differing legal regimes. By way of further example, in 2018 the Health and Social Committee published a report[92] regarding how NHS Digital was sharing confidential patient information with the Home Office to trace immigrants. Information included patients' names, date of birth, last known address and their GP's contact details. NHS Digital had argued that

84 Baldwin and Black, ibid.

85 Beaussier and others (n 2) 205–24.

86 Joint Committee on Human Rights, 'The Detention of Young People with Learning Disabilities and/or Autism' (House of Commons 2019).

87 ibid 45.

88 ibid 45.

89 CQC, 'Our Strategy for 2016-2021' (2017) <https://www.cqc.org.uk/about-us/our-strategy-plans/our-strategy-2016-2021> accessed 12 June 2020.

90 Baldwin and Black (n 84).

91 ibid.

92 House of Commons Health and Social Care Committee, 'Memorandum of understanding on data-sharing between NHS Digital and the Home Office' (House of Commons Health and Social Care Committee, 2018).

sharing this information was within the public interest because it enabled the effective enforcement of immigration law. This allegedly outweighed concerns that it might impact broader public trust in a confidential health service.[93] Several bodies, including the GMC, British Medical Association (BMA), Public Health England (PHE) argued that this information sharing posed a serious risk to public health, risked undermining public trust in a confidential health service, and placed doctors at risk of failing to comply with their professional guidance.[94]

The above demonstrates how different organisations with regulatory influence conceptualise risk. Whereas the risk to public trust in the health service was seen to be low by NHS Digital, it was seen as a high risk by the GMC. Differing conceptualisations of risk such as this can result in different levels of priority being assigned to the risk, resulting in poor regulatory coordination and effectiveness.[95]

Black and Baldwin argue that in reality, a risk that is categorised as 'low' equates to 'low priority'[96] for regulators, and is a statement of the risk's relative significance to the regulator and their potential to meet their objectives.[97] They provide a comprehensive overview of how risks that are classified as low can have the potential to cause significant harm, and as such still require regulatory attention.[98] For example, within the context of water quality regulation, an individual farm engaging in an activity such as the cleaning of milking parlours might be seen to only pose a low risk to water quality, because only small quantities of effluent are discharged into water sources during the cleaning process. However, when such activities which present a low risk at an individual site are engaged in by the masses, the risk may accumulate to become systemic.[99] Likewise, an individual clinician's poor handwashing technique may only pose a low risk to the overall safety of the entire patient population, but when practised by multiple clinicians would pose a high risk to public health.

This section has introduced the model of risk-based regulation used by healthcare regulators, and argued that harm to patients is the primary risk that regulators seek to manage. It has identified three broad categories of risk that can result in harm to patients. These are: direct risks of harm to the physical wellbeing and dignity of patients; risks to a regulator's reputation; and risks to public trust in the professions. It has then examined how the identification of these risks can be challenging for regulators, and how incohesive conceptualisations of risks and their subsequent prioritisation by multiple regulators informs their regulatory response. Against this backdrop, the following section examines the extent to which statutory healthcare regulators have recognised and tackled the risk posed to patient safety by hospital discharges.

93 ibid.

94 House of Commons Health and Social Care Committee (n 93); General Medical Council, 'Data-sharing Agreement could Threaten Patient Confidentiality' (2018) <https://www.gmc-uk.org/news/news-archive/data-sharing-agreement-could-threaten-patient-confidentiality> accessed 12 June 2020.

95 Baldwin and Black (n 84).

96 J Black and R Baldwin, 'When Risk-based Regulation Aims Low: Approaches and Challenges' (2012) 6 Regulation and Governance 1, 4.

97 Baldwin and Black (n 84).

98 ibid 2–22.

99 ibid 2–22.

III. REGULATORY REACTION TO THE HOSPITAL DISCHARGE SAFETY RISK

As discussed earlier, in 2016 the Public Administrations and Constitutional Affairs concluded that the incidence of unsafe hospital discharges was unacceptably high,[100] and Healthwatch England (HE) have repeatedly drawn attention[101] to the harm patients are exposed to when leaving hospital. The focus here is on whether the risk posed by hospital discharges is recognised by statutory healthcare regulators within the English NHS.

The CQC's assessment framework,[102] which reflects its five core questions when inspecting healthcare services,[103] indicates that the risk posed by hospital discharges to patient safety is a risk they are aware of. The framework contains a number of Key Lines of Enquiry (KLOEs), three of which feature questions relating to the safety, effectiveness, and responsiveness of hospital discharges. It asks firstly whether all the information needed for a patient's ongoing care is shared appropriately, in a timely way and in line with relevant protocols at the point of discharge.[104] Secondly, it asks if all relevant teams, services, and organisations are informed when people are discharged from a service, and if discharge is undertaken at an appropriate time of day and only when necessary ongoing care is in place.[105] Thirdly, the framework asks how people are supported during discharge.[106] Information provided in response to a freedom of information request[107] stated that breaches in relation to safe discharge are most likely to be under Regulation 9 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, which is 'person-centred care'. This regulation is designed to ensure that people using a service have care or treatment that is personalised for them. The regulation guidance states: 'assessments should be reviewed regularly and whenever needed throughout the person's care and treatment. This includes when they transfer between services, use respite care or are re-admitted or discharged. Reviews should make sure that people's goals or plans are being met and are still relevant'.[108] If the CQC finds that a provider is in breach of this regulation it can use its regulatory powers to require or force a provider to improve.[109]

The CQC's 2018 adult inpatient survey report highlighted hospital discharge planning as an area for improvement. It flagged that 44% of respondents discharged with

100 Public Administration and Constitutional Affairs Committee (n 24) 18.

101 See n 22.

102 Care Quality Commission, 'Key Lines of Enquiry, Prompts and Ratings Characteristics for Healthcare Services' (2018) <https://www.cqc.org.uk/sites/default/files/20180628%20Healthcare%20services%20KLOEs%20prompts%20and%20characteristics%20FINAL.pdf> accessed 12 June 2020.

103 These five questions ask whether services are safe, effective, caring, responsive and well led.

104 CQC KLOE S3.3: When people move between teams, services and organisations (which may include at referral, discharge, transfer and transition), is all the information needed for their ongoing care shared appropriately, in a timely way and in line with relevant protocols?

105 CQC KLOE E4.4: Are all relevant teams, services and organisations informed when people are discharged from a service? Where relevant, is discharge undertaken at an appropriate time of day and only done when any necessary ongoing care is in place?

106 CQC KLOE R2.3: How are people supported during referral, transfer between services and discharge?

107 Correspondence between author and CQC (August 2019).

108 Care Quality Commission, Guidance for providers on meeting the regulations (CQC 2015) 31.

109 Information provided to author in private correspondence with CQC (August 2019).

medication were not being told about possible side-effects to watch out for, and only one in four were being told who to contact if they were worried about their condition following discharge. Seventeen per cent of respondents commented they felt uninvolved in their discharge planning—an area which has seen no improvements in 10 years.[110]

The CQC also has an 'independent voice' role, under which a range of reports regarding quality and safety of services are published; for example in 2019 the CQC published a report[111] on medicines optimisation which included two recommendations for safe discharge—essentially highlighting the importance of relevant and timely information sharing between hospitals and other services following discharge.[112] Furthermore, HE is a statutory committee of the CQC whose purpose includes escalating concerns raised by local Healthwatch organisations to the CQC.[113] As mentioned earlier in this article, HE has published three reports regarding unsafe hospital discharges.[114] Thus it seems reasonable to conclude that the risk to patients posed by hospital discharges is a risk that is known to the CQC.

In 2014, NHSE issued a patient safety alert to NHS organisations stating that approximately 33% of 10,000 incidents reported to the National Reporting and Learning System (NRLS) between October 2012 and September 2013 involved patients discharged from hospital without sufficient and timely communication of essential information. In some instances, this led to 'avoidable death and serious harm to patients due to a failure in continuity of care as well as avoidable readmission to secondary care'.[115] NHSI publishes online resources in order to support the safe discharge of patients throughout the NHS,[116] an aim NHSI acknowledged responsibility for when giving evidence to the PACAC committee regarding unsafe hospital discharges.[117] Once again it seems reasonable to conclude that the risk to patients posed by hospital discharges is known to NHSI/NHSE.

In contrast to the above organisational regulators, it is not immediately apparent that the risk posed by hospital discharge is recognised by the professional regulators. None of the professional regulators gave evidence to the PHSO inquiry regarding unsafe discharges[118] and none of the professional codes that registrants are expected to follow specifically mention discharges. Although discharges are not directly referred

110 Care Quality Commission, '2018 Adult Inpatient Survey: Statistical release' (CQC 2019).

111 Care Quality Commission, 'Medicines in Health and Adult Social Care: Learning from Risks and Sharing Good Practice for Better Outcomes' (CQC 2019).

112 ibid 35 and 52.

113 Healthwatch England, 'Our history and functions' <https://www.healthwatch.co.uk/our-history-and-functions> accessed 12 June 2020.

114 See n 22.

115 NHS England, 'Patient Safety Alert NHS/PSA/W/2014/014' (NHSE 2014) <https://www.england.nhs.uk/wp-content/uploads/2014/08/psa-imp-saf-of-discharge.pdf> accessed 12 June 2020.

116 See eg NHS Improvement, 'A guide to developing criteria-led discharge' (2017) <https://improvement.nhs.uk/resources/guide-developing-criteria-led-discharge/> accessed 12 June 2020; NHS Improvement, 'Discharge planning' (2018) <https://improvement.nhs.uk/resources/discharge-planning/> accessed 12 June 2020.

117 Public Administration and Constitutional Affairs Committee, 'Discharging Older People from Acute Hospitals' (PACAC 2016/17) 15.

118 Parliamentary and Health Service Ombudsman (n 23).

to, each code[119] does include the core behaviours and skills which are essential for ensuring safe discharge, such as: good communication with patients and colleagues; competency; multi-disciplinary working; safe prescribing; record-keeping; continuity of care; and the importance of working in partnership with patients. However, there is little evidence regarding how, if at all, professional codes positively influence behaviour.[120] As such, it cannot be argued that these professional codes, by themselves, are a sufficient regulatory response to the patient safety posed by hospital discharges.

Moreover, recent British Red Cross[121] research into safe hospital discharges did not include any interviews with professional regulators, which may suggest that the risk is perceived as belonging to the systems regulators rather than the professional regulators. It is worth emphasising again at this point that patient safety incidents linked to the hospital discharge process *is* an issue that professional regulators should be interested in. In January 2020, the Guardian reported that the Royal Cornwall Hospitals NHS Trust had informed staff that patients should be discharged early to reduce overcrowding; a risk it called 'proportionate' despite the possibility 'that some of these patients will be readmitted or possibly come to harm'.[122] To require clinicians to act in such a manner is asking them to act in a way which may go against the professional standards expected of them, such as making the care of their patients their first concern and providing dignified care.[123] This is something which professional regulators should address.

Returning to whether professional regulators are aware of the discharge risk—a publicly available update on the GMC's harms reduction programme[124] in 2018 briefly mentions hospital discharges as a potential cause of harm. The document states that the purpose of the harms reduction programme is to support doctors to maintain good medical practice by 'identifying, understanding and addressing problems that might impede the delivery of this and by extension, present a risk of harm to patients or doctors'.[125] The draft harms register within the document identifies as a potential harm for future consideration 'inappropriate discharge' such as 'individuals being discharged prior to the results of investigations – particularly in A&E'.[126] This harm is categorised as a 'process failure/non-compliance' issue within a broader category of 'system-level harms'.[127]

119 See eg General Medical Council (n 9), Nursing and Midwifery Council, 'The Code' (2015), General Pharmaceutical Council, 'Standards for Pharmacy Professionals' (2017) and Social Work England, 'Professional Standards' (2019).

120 O Quick, 'A Scoping Study on the Effects of Health Professional Regulation on those Regulated' (Council for Healthcare Regulatory Excellence 2011); Healy (n 72).

121 British Red Cross, 'Home to the Unknown: Getting Hospital Discharge Right' (British Red Cross 2019).

122 The Guardian, 'Cornwall Hospital to Discharge Patients Early Despite Saying it may be Harmful' (2020) <https://www.theguardian.com/society/2020/jan/14/cornwall-hospital-to-discharge-patients-early-despite-risks> accessed 12 June 2020.

123 General Medical Council (n 45).

124 General Medical Council, 'Executive Board Meeting' (2018) <https://www.gmc-uk.org/-/media/documents/08—the-harms-reduction-programme-progress-update_pdf-75445141.pdf> accessed 12 June 2020.

125 ibid 47.

126 ibid 59.

127 ibid 59.

This section has thus far established that although the harm of hospital discharges is recognised by the CQC, NHSE, and NHSI, it is not widely recognised or acknowledged amongst the professional regulators, at least within the public sphere. This raises a further pertinent question: why might the risk posed to patient safety by hospital discharges be missing from the professional regulators' agenda? It is to this question that we now turn.

IV. IDENTIFYING, CONCEPTUALISING, AND PRIORITISING THE RISK OF HOSPITAL DISCHARGES

In order to answer the question of why this risk might not be recognised by the professional regulators, it is apposite to return to the difficulties discussed in Section III concerning the identification, conceptualisation, and prioritisation of risk.

A. Identification of Risk

The first reason that the risk may be unrecognised is because the success of risk-based regulation approaches is heavily dependent upon the availability of sufficient information to inform decision-making.[128] Given the web of actors within the English NHS, and the mass of information held amongst them, an individual actor is unlikely to possess all of the relevant information it would need to react accordingly.[129] For example, professional regulators have historically relied heavily upon complaints made by patients, their families or employers about an individual healthcare professional to trigger an investigation into the individual's fitness to practice (FTP). A risk-based approach to assessing the risk of harm to patients posed by an individual is then typically followed, which allows regulators to justify their decision-making processes.[130] However, professional regulators are adopting a more 'upstream' approach to regulation. This means they are moving towards 'pro-active, early and specific interventions in order to either decrease the likelihood of an undesirable outcome or to increase the likelihood of a more favourable outcome'.[131] Complaints about individual practitioners alone are an insufficient data source for identifying and addressing broader, complex safety issues such as hospital discharges, where patient safety is not dependent upon the actions of an individual.

Positive steps have been taken to address this information deficit. For example, the GMC's health system liaison service was created to help the GMC engage at every level with the healthcare systems, helping to ensure that their approach to regulation is well informed.[132] The service sees GMC advisers collaborate with doctors, educators, employers, and other regulators in order to 'understand, identify and address

128 Hampton (n 54); S Lloyd-Bostock and B Hutter, 'Reforming Regulation of the Medical Profession: The Risks of Risk-based Approaches' (2008) 10 Health, Risk and Society 1, 69–83.

129 Healy (n 72).

130 For discussion of the GMC's FtP risk-based approach see JM Chamberlain, 'Malpractice, Criminality, and Medical Regulation: Reforming the Role of the GMC in Fitness to Practise Panels' (2017) 25 Medical Law Review 1, 1–22 and S Lloyd-Bostock, 'The Creation of Risk-Related Information: The UK General Medical Council's Electronic Database' (2010) 24 Journal of Health Organisation and Management 6, 584–89.

131 General Medical Council (n 125) 53.

132 General Medical Council, 'Health System Liaison Services' <https://www.gmc-uk.org/about/how-we-work/liaison-and-outreach/health-system-liaison-services> accessed 12 June 2020.

risks to patients and doctors before harm occurs'.[133] The GMC's corporate risk register[134] also outlines some of its existing mechanisms for sharing data. For example, the register states that the GMC works closely with the Health and Social Care Regulators' Forum to improve collaboration, holds regular surveillance groups with the CQC to consider risk, has regular intelligence sharing meetings called Regional Information Forums, engages with NHS Improvement, and has a central analytics team in place which is responsible for coordinating data sharing. Hospital discharges are specifically mentioned in a memorandum of understanding (MoU) in place between the CQC and GMC.[135] This states that the CQC would like to be informed of issues affecting patient experience, including delays in discharge, early discharge, and lack of dignity or respect to patients.[136] The GMC indicated they would wish to be informed of scenarios such as foundation doctors in surgery signing discharge letters that have been written by other doctors relating to patients they have never examined.[137]

Furthermore, in 2018, an emerging concerns protocol[138] was developed amongst regulators, which five of the professional regulators[139] have signed. The protocol is designed to establish a method for sharing early concerns so that links between concerns can be made. The concerns may fall into the following three categories: 'concerns about individual or groups of professionals; concerns about healthcare systems and the healthcare environment (including the learning environments of professionals); concerns that might have an impact on trust and confidence in professionals or the professions overall'.[140]

Clearly apparent above is the sheer quantity of mechanisms in place in order to facilitate information sharing across regulators, yet despite these a recent inquiry has concluded that there is an 'insufficient linkage between CQC and the other regulators'[141]. Due to the vast amounts of data that each regulator is likely to hold, it is highly unlikely that all issues will be shared amongst all regulators. In practice, judgment calls will need to be made about what issues are shared across which forum at any given time. It is therefore possible that so far, information relating to PSIs within the context of hospital discharges has not been widely shared and considered amongst all of the healthcare regulators—leading to poor identification of the risk posed to patients.

133 ibid.

134 General Medical Council (n 45).

135 CQC and GMC, 'Operational Protocol: A Practical Guide for Staff - for External Use' (2018) <https://www.cqc.org.uk/sites/default/files/20181205_cqc-gmc_joint_operational_protocol_redacted.pdf> accessed 12 June 2020.

136 ibid.

137 ibid.

138 CQC and others, 'Emerging Concerns Protocol' (CQC 2018).

139 GDC, GMC, GPHC, HCPC, and NMC.

140 CQC and others (n 139) 6.

141 G James, 'Report of the Independent Inquiry into the Issues raised by Paterson' (House of Commons 2020) 186.

B. Conceptualisation of Risk

This leads to the second reason why the risk posed by hospital discharges might be missing from the professional regulators' agenda: the challenge of conceptualising risk in a unified manner where multiple regulators[142] are involved. How each regulator constructs the risk posed by hospital discharges will determine *if and how* the information is shared across the regulators.

As established in Section II, from a regulatory perspective there are three broad categories of risk that can result in harm to patients: risks to the physical wellbeing/and or dignity to the patient; risks to a regulator's reputation; and risks to public trust in the professions. The risk posed by hospital discharges is likely to fall predominantly within the first category; however, professional regulators may still not conceptualise it as a risk within their remit. For example, the GMC's harm register indicates that the GMC perceives inappropriate discharge as a process failure/non-compliance issue, listed under a broader heading of system level harm.[143] Construed in this manner, it may not be apparent that this is also a risk closely entwined with the behaviour of healthcare professionals, including doctors. Yet as the scenario of Mrs K highlighted, the decision to discharge Mrs K in the given circumstances was not in line with behavioural expectations set out in any of the professional codes, and resulted in harm to her dignity; which is a patient safety incident.

Within the Cornwall[144] example, we can see how the risk is situated not only within the remit of the systems regulators (the pressure of under-resourced hospitals), but also within the remit of the professional regulators. This is because the situation is likely to impact upon the ability of healthcare professionals to act in accordance with their professional standards – for releasing patients before they are clinically ready is unlikely to be cohesive with providing good care for a patient. This particular case straddles two of the categories of risk identified in Section II; direct risk to a patient's physical wellbeing or dignity, and risk to public trust in the professions.

By way of further example, the MoU between the GMC and CQC[145] shows the GMC has an interest in receiving information from the CQC regarding foundation doctors signing discharge letters that have been written by other doctors and relating to patients they have never examined. This is the only discharge-specific scenario that the GMC provides as an example of the type of discharge-related issue it is interested in. The rationale for this interest is that it might cause a patient safety concern or indicate bullying concerns.[146] However, by requesting such specific information on discharges, the GMC may inadvertently be signalling that it is not interested in being informed of discharge-related harms to a patient's dignity, despite the fact that respect for patient dignity is a central feature of the GMC's expectations of doctors.[147]

142 S Devaney, *Ethics for Healthcare Regulators: Enhancing Compliance with the Seven Principles of Public Life* (Manchester Centre for Regulation 2016); Baldwin and Black (n 61); Healy (n 72).

143 General Medical Council (n 58).

144 The Guardian (n 123).

145 CQC and GMC (n 136).

146 ibid 32.

147 General Medical Council (n 45).

C. Prioritisation of Risk

Thirdly, the risk posed by hospital discharges could be missing from the professional regulators' agenda due to being categorised as low risk, and thus as Black argues, low priority.[148] One reason why the risk might be categorised as 'low' is that the resulting physical harm is typically mild (Williams' study[149] of NRLS data reported 64% of discharge-related harm was low-level). Thus, if activities are categorised according to the severity of physical harm, then hospital discharges may not be perceived as being high-risk. Risks that catch the attention of the media and dominate headlines are also more likely to be treated as a higher priority due to the threat posed to the reputation of the regulator and to public trust in the profession. To-date, the harm posed by hospital discharges to patient safety has had limited recognition[150] in the media, despite the ongoing nature of the problem.

The frequency of harm to dignity is harder to measure than physical harm, partly because harm to dignity is likely to go unreported. Research by the PHSO has highlighted that despite being the greatest users of health and social care providers (thus subject to frequent discharges), older people are reluctant to complain about poor care.[151] However, as discussed in Section I of this article, harm to dignity is a patient safety concern arising during hospital discharges. Given that all patients have a right[152] to be treated with dignity, this is not a harm that should be ignored or categorised as low-priority by professional regulators.

This section has examined why the professional regulators may not have adequately addressed the risk posed to patient safety by hospital discharges. However, it is important to note that responsibility for responding to this particular patient safety risk does not lie solely with the professional regulators; a cohesive response from all of the statutory regulators is required. The first step in achieving this is to overcome the challenges laid out in this article regarding the identification, conceptualisation, and prioritisation of this patient safety risk.

V. CONCLUSION

This article has highlighted the risk posed to patient safety by the hospital discharge process. It has examined the nature of the risk of harm patients face during discharge; namely harm to the physical wellbeing and to their dignity. It has then identified the regulators who ought to be reducing the risk of such harm to patients, and highlighted the minimal actions that have been taken to achieve this aim. In order to establish

148 Black and Baldwin (n 97) 2–22.

149 Williams and others (n 28).

150 Examples of where mainstream media have raised the issue include: The Guardian, 'Hospital Discharge is not Rocket Science. Why are Patients Still being Failed?' (2016) <https://www.theguardian.com/social-care-network/2016/may/16/hospital-discharge-patients-failed-ombudsmans-report> accessed 12 June 2020; The Guardian, 'Hospitals Show "shocking" Lack of Care Discharging Vulnerable Patients' (2015); and The Telegraph, 'Patients sent Home from Hospital with no Advice on How to Cope, Watchdog Finds' (2019) <https://www.telegraph.co.uk/news/2019/06/20/patients-sent-home-hospital-no-advice-cope-watchdog-finds/> accessed 12 June 2020; <https://www.theguardian.com/society/2015/jul/21/health watch-hospitals-discharging-vulnerable-patients-lack-of-care-> accessed 12 June 2020.

151 Parliamentary and Health Service Ombudsman, 'Breaking Down the Barriers: Older People and Complaints about Health Care' (PHSO 2015).

152 National Health Service (n 43).

why there has been a lack of regulatory action in this area, particularly from the professional regulators, this article has considered the risk-based regulation model which is utilised by these regulators.

Consideration of this model has focussed upon three weaknesses regarding how regulators identify, conceptualise, and subsequently prioritise risk. The difficulties regulators face with these three elements has meant regulatory interventions to ensure patient safety during hospital discharge have been limited.

In the case of hospital discharges, the first difficulty regarding risk-identification arises as regulators do not possess a holistic overview of all relevant information. This is because of the multitude of regulators and the limited information-sharing mechanisms between them—which means judgements have to be made about what information to share and with whom. This is problematic given that successful risk-based regulation is heavily dependent upon the availability of sufficient information to identify risks and inform decision-making.

The multitude of statutory regulators and limited information-sharing leads to a further difficulty: it is virtually impossible for them all to have a unified understanding of the risk posed by discharges. Risks will be conceptualised based upon the nature of information possessed, which will vary in a field saturated with regulators.

Finally, successful risk-based regulation relies upon the correct prioritisation of risk, an outcome which is reliant upon regulators having obtained sufficient information and having clarity amongst themselves regarding their regulatory aim. It is possible that regulators are not prioritising ensuring patient safety during discharge in the manner they would if they had the requisite information and clarity about the risk that discharges pose to patients.

Combined, these three weaknesses have meant that the risk posed to patient safety at the point they leave hospital is neither uniformly recognised by the statutory regulators within the English NHS, nor sufficiently addressed. Professional regulators in particular appear to have a poor awareness of the risk and their role in addressing it. The result of this ineffective regulation leaves the physical wellbeing and dignity of patients continuously imperilled at a point in time when they should be returning safely home. Until regulators can accurately identify this risk, build a unified understanding of its causes and consequences, and prioritise it appropriately, this unacceptable status quo will remain.

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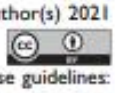

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Regulating patient safety during hospital discharges: Casting the Patient Safety Commissioner as the Representative of Order

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Abstract

This article examines the challenges in regulating patient safety during hospital discharges in England through the lens of liminality. Hospital discharges are internationally recognised as being a dangerous time for patients, and yet the role that regulators should play in addressing this has received little attention in any jurisdiction. Liminality's spotlight on the in-between highlights how the discharge process can give rise to patient safety incidents that fall between regulator's boundaries. Falling between boundaries results in a dearth of effective regulatory responses to address these incidents. By positioning the new role of Patient Safety Commissioner (PSC) as that of a 'Representative of Order', this article proposes a means by which this poorly regulated space could be navigated more successfully. This analysis suggests that the remit of the PSC role be expanded to include improving patient safety with regard to processes – not just medicines and medical devices. The full implications of this are also addressed.

Keywords

Patient safety, regulation, hospital discharges, liminality, IMMDS review, Medicines and Medical Devices Act

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Introduction: Understanding patient safety and hospital discharges

> We have found that the healthcare system – in which I include the NHS, private providers, the regulators and professional bodies, pharmaceutical and device manufacturers, and policymakers – is disjointed, siloed, unresponsive and defensive. It does not adequately recognise that patients are its raison d'etre. It has failed to listen to their concerns and when, belatedly, it has decided to act it has too often moved glacially.[1]

The above sums up the findings of the Independent Medicines and Medical Devices Safety (IMMDS) review in England, published in 2020. The Review's purpose was to examine how the English[2] healthcare system responded to concerns raised about harmful side effects from specific medicines and medical devices[3] and to consider how future responses to concerns over side effects could be quicker and more effective.[4] That the healthcare system is disjointed and siloed[5] is a problem that significantly contributes to the harm patients experience when discharged from hospital; a problem that regulators have thus far failed to adequately address.[6] In an earlier article,[7] I drew attention to how risk-based regulation, a prominent model of regulation within the English NHS, is poorly equipped to ensure and improve patient safety in this regard.

This article employs the anthropological concept of liminality as a lens through which to view these challenges in regulating patient safety during hospital discharges. Although this article focusses upon the English context, patients are internationally recognised as being at an increased risk of harm when leaving hospital.[8] The rationale for using

1. Independent Medicines and Medical Devices Safety Review, (2020) First Do No Harm: The Report of the Independent Medicines and Medical Devices Safety Review, p.i. Available at: https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf (accessed 1 June 2021).
2. Although the review focussed on England its recommendations cover England only, evidence was heard from across the United Kingdom (Op. Cit. paras 1.9 and 1.10).
3. These were hormone pregnancy tests, sodium valproate and pelvis mesh implants.
4. IMMDS Review, 'First Do No Harm'.
5. Siloed working refers to instances where organisations to take a non-collaborative approach to work. NHS England has acknowledged that it works in 'silos'. Available at: https://www.england.nhs.uk/blog/rolling-up-our-sleeves-and-getting-out-of-our-silos/ (accessed 1 June 2021).
6. V. Moore, 'Leaving Hospital: A step too far for risk-based regulation?', 28 Medical Law Review (2020), pp. 675–695.
7. Op. cit.
8. K. Aase and others, *Researching Quality in Care Transitions International Perspectives* (London: Palgrave Macmillan, 2017); K. Manges and others, 'A Mixed Methods Study Examining Teamwork Shared Mental Models of Interprofessional Teams During Hospital Discharge', *BMJ Quality & Safety* 0 (2019), pp. 1–10; World Health Organisation, *Transitions of Care: Technical Series on Safer Primary Care.* (2016) Available at: https://www.who.int/patientsafety/topics/primary-care/technical_series/en/ (accessed 1 June 2021).

liminality in this particular area is because it brings into focus the in-between space that exists among regulatory bodies (this is explained more fully below).

The discharge process is subject to multiple regulatory requirements and influences. However, if a patient safety incident occurs in relation to this process and does not fall squarely within any regulator's remit, then it may end up within a regulatory lacuna. This we might usefully conceive of as a liminal space, and this article addresses the implications of this conceptualisation for regulating patient safety in hospital discharge. Using liminality, this article has two central aims. First, it seeks to illustrate this space in-between regulators. Secondly, it argues that the creation of a new Patient Safety Commissioner (PSC) role could be one way in which to improve patient safety during hospital discharges. The creation of a PSC was recommended by the IMMDS review[9] and established in the new Medicines and Medical Devices Act 2021 (MMD Act).[10] At the time of writing, there is no indication of when the first commissioner will be appointed. It is proposed herein that the remit of the PSC be extended beyond medicines and medical devices to include improving patient safety with regard to *processes*, such as hospital discharges.

The remainder of this introduction outlines the nature of the risks that hospital discharge can pose to the safety of patients. The second section details the actors within the hospital discharge regulatory arena and draws attention to how they have attempted to engage in this space thus far. The third section introduces the concept of liminality, and illustrates the liminal space within this context. It shows how this space occurs as a result of the plethora of regulators and the related challenge of forming a unified understanding and prioritisation of the risk posed by hospital discharges.[11] Actions then taken to improve safety during discharges (typically the production of a report) often fail to have the desired impact. To minimise this undesirable occurrence, this article envisages that the new PSC role could function as a Representative of Order. The rationale for this is explored in the fourth section, and the example of another Representative of Order within the patient safety field – the Chief Coroner – is used to demonstrate how such a role can improve safety. The fifth section incorporates learning from this example to illustrate how the PSC, when cast as a Representative of Order, could help regulators overcome the difficulties identified in the third section.

Patient safety and hospital discharges

Common problems highlighted in a 2016 report by the Parliamentary and Health Service Ombudsman (PHSO) relate to patients being discharged before it is clinically safe to do so; failing to involve patients and their families/carers in decision-making surrounding discharge; and discharging patients despite no appropriate ongoing support being in place.[12] These issues have become increasingly apparent during the COVID-19

9. IMMDS Review, 'First Do No Harm', Recommendation 2.
10. Medicines and Medical Devices Act 2021, section 1.
11. Moore, 'Leaving Hospital'.
12. Parliamentary and Health Service Ombudsman, *A Report of Investigations into Unsafe Discharge from Hospital* (PHSO 2016). Available at: https://www.ombudsman.org.uk/publications/report-investigations-unsafe-discharge-hospital-0 (accessed 1 June 2021).

pandemic. For example, MIND (a mental health charity in England and Wales) expressed concern that people may have been discharged from mental health hospitals when it was unsafe to do so or without adequate support.[13] It noted that in April 2020, only 4030 discharges were followed up within 72 h, out of 5571 that were eligible for follow-up.[14] Based on interviews with patients/carers regarding discharge between March and August 2020, Healthwatch England (HE) and the British Red Cross reported that basic checks such as whether people needed transport to get home were missed.[15] People reported feeling unprepared to leave hospital and confused about who could be contacted for further information. Several reported not receiving any follow-up assessments after discharge, which meant they did not have the medication or equipment needed to recover properly in their home.[16]

A study of data[17] on discharge-related safety incidents within England's National Reporting and Learning System database[18] found four main categories of error that caused harm to patients in 75% of the cases studied. These were quality of discharge communication, referrals to community care, medication errors, and issues concerning the provision of care adjuncts (such as wound dressings) for ongoing community care. Behavioural factors, for example where staff did not follow protocols, and organisational factors such as a lack of clear guidelines, also contributed to safety incidents. Although the severity of harm tended to be low-level,[19] in 78 cases (13%), patients experienced moderate harm. This meant patients required an intervention to resolve their symptoms and may have experienced permanent/long-term harm or a loss of function. In three (<1%) severe cases, life-saving interventions were needed, and in one case the patient died.[20]

An ethnographic study by Waring and colleagues found that the coordination of multiple actors across occupational and organisational boundaries and the interdependencies and interactions between these groups can represent a threat to discharge safety.[21] The study identified the following issues between healthcare settings which the authors suggest might explain the variations in discharge safety. First, differences in

13. MIND, 'The Impact of Coronavirus on Discharge from Mental Health Hospital', Available at: https://www.mind.org.uk/media-a/6293/the-impact-of-coronavirus-on-mental-health-hospital-discharge-briefing.pdf (accessed 1 June 2021).
14. Op. cit.
15. Healthwatch England and British Red Cross (2020), '590 people's stories'.
16. Op. cit.
17. H. Williams, and colleagues, 'Harms from Discharge to Primary Care: Mixed Methods Analysis of Incident Reports', *British Journal of General Practice* 65 (2015), pp. e829–e837.
18. The NRLS is a central database of patient safety incidents reported from across England and Wales.
19. 'Low-level' was defined by the study authors as patients experienced mild symptoms, the harm was short-term, and little or no intervention was required to resolve the harm.
20. Williams, 'Harms from Discharge', pp. e829–e837.
21. J. Waring, F. Marshall and S. Bishop, 'Understanding the Occupational and Organizational Boundaries to Safe Hospital Discharge', *Journal of Health Services Research & Policy* 20 (2015), pp. 35–44.

organisation (such as how technologies are used and how labour is divided); secondly, culture (whether there is a blame culture, the extent to which patients are involved in their care); and thirdly, knowledge (e.g. how discharge is understood across each group of professionals).[22] The authors conclude that increased use of 'boundary spanners' may be one way to improve patient safety during discharges. Boundary spanners are actors who work across occupational and organisational boundaries and so are often able to learn about cultures, knowledge, and ways of working that may not be accessible to actors working in professional silos.[23] This suggests that in complex regulatory environments, there is a role for a designated actor to guide people through – a point that has been well made by Laurie and colleagues.[24]

Alongside experiencing physical harm, patients' dignity may also be harmed during hospital discharges.[25] According to the NHS Constitution (which is enshrined in the 2009 Health Act),[26] patients have a right to be treated with dignity and respect in accordance with their human rights. Although dignity is not explicitly defined in law, thus making a requirement to respect human dignity difficult for regulators to enforce,[27] it is nevertheless an important part of patient safety.[28] Patients view non-clinical incidents as a safety incident; and dignity featured in one study as a patient-derived safety category.[29] The PHSO report into unsafe discharges gives the example of Mrs K, an elderly person with dementia who was discharged late at night unbeknownst to her family. She was found at home by her daughter the next day, without food, drink, or bedding and had been unable to get to her toilet.[30] We can imagine that Mrs K may have experienced this incident as an affront to her dignity and well-being. Having illustrated the wide-ranging factors that may pose a serious threat to patients' safety and dignity when leaving hospital, we now turn attention to matters of regulation.

Regulation and hospital discharges

Oikonomou and colleagues define healthcare regulation as 'the processes engaged in by institutional actors that seek to shape, monitor, control or modify activities within healthcare organisations in order to reduce the risk of patients being harmed during their

22. Op. cit.
23. Op. cit.
24. G. Laurie et al., 'Charting Regulatory Stewardship in Health Research: Making the Invisible Visible?', *Cambridge Quarterly of Healthcare Ethics* 27 (2018), pp. 333–347.
25. Moore, 'Leaving Hospital'.
26. National Health Service, (2015) 'NHS Constitution for England'.
27. T. Caulfield and R. Brownsword, 'Human Dignity: A Guide to Policy Making in the Biotechnology Era?', *Science and Society* 7 (2006), pp. 72–76.
28. Moore, 'Leaving Hospital'.
29. J.K. O'Hara and colleagues, 'What can Patients Tell us about the Quality and Safety of Hospital Care? Findings from a UK Multicentre Survey Study', *BMJ Quality & Safety* 27 (2018), pp. 673–682.
30. PHSO, 'Investigations into Unsafe Discharge', p. 19.

care'.[31] This broad definition captures a wide range of behavioural influences performed by several actors within a healthcare system. It is perhaps a welcome definition in that it broadness allows a wide variety of institutions to be compared.[32] However, Walshe argues that it is important to set sensible boundaries around the concept of regulation as broad interpretations risk the concept becoming 'almost meaningless'.[33] According to Black, definitional vagueness is generally seen by those writing on regulation as, 'at best a rather quaint feature and at worst an occupational hazard'.[34] She does, however, indicate that some clarity is needed to avoid confused debate regarding what regulation should or should not be and observes that academics lack a disciplined approach to defining regulation.[35] Its conceptualisation, she argues, often depends upon the issue that the writer is focused upon.[36] Against this backdrop of 'definitional chaos',[37] this article uses the term 'regulation' to refer to the formal attempts by statutory regulators to shape behaviour within healthcare organisations. This is inspired by Black's definition of regulation as 'the sustained and focused attempt to alter the behaviour of others according to defined standards or purposes with the intention of producing a broadly identified outcome or outcomes'.[38] The focus is narrowed in this article to statutory regulators because these have a legal duty to protect patients and are therefore the ones who should be held accountable for any regulatory failings that are uncovered. That said, this narrower focus is not intended to dismiss any other actors which exert regulatory influence; rather it takes the view that other actors have an important role to play in feeding into the actions undertaken by the statutory regulators as they seek to improve safety. Such a position is cohesive with both the findings of the IMDDS review[39] and Quick's view that regulating patient safety requires regulation to be seen as a collaboration between patients and professionals, and this in turn means that the involvement of patients is both necessary and legitimate.[40]

This article uses the term 'regulatory arena' to refer to the regulatory environment within which regulation takes place. A more common term is 'regulatory space' – coined by Hancher and Moran.[41] 'Arena' is used here to minimise any confusion between this

31. E. Oikonomou and colleagues, 'Patient Safety Regulation in the NHS: Mapping the Regulatory Landscape of Healthcare', *BMJ Open* 9 (2019), p. 2.
32. T. Prosser, *The Regulatory Enterprise: Government, Regulation, and Legitimacy* (Oxford: OUP, 2010).
33. K. Walshe, *Regulating Healthcare: A Prescription for Improvement* (Maidenhead: OUP, 2003), p. 10.
34. J. Black, 'Critical Reflections on Regulation', *Australian Journal of Legal Philosophy* 27 (2002), p. 11.
35. Op. cit.
36. Op. cit.
37. Op. cit. p. 11.
38. J. Black, 'Decentering Regulation: Understanding the Role of Regulation and Self-Regulation in a Post- Regulatory World', *Current Legal Problems* 54 (2001), p. 142.
39. IMMDS Review, 'First Do No Harm'.
40. O. Quick, *Regulating Patient Safety* (Cambridge: CUP, 2017), p. 164.
41. L. Hancher and M. Moran, 'Organizing Regulatory Space', in L. Hancher and M. Moran, eds., *Capitalism, Culture and Economic Regulation* (Oxford: OUP, 1989), pp. 271–300.

and the concept of 'liminal space' which will shortly be introduced. Conceptually, the regulatory arena is intended here to be the same as the regulatory space. The 'regulatory space' refers to the environment within which regulation takes place; which includes the actors within it, alongside wider factors such as the legal system, sociocultural influences and the relationship dynamics between actors.[42] Rather than flowing hierarchically, power and influence within the regulatory arena can be exercised horizontally and vertically by actors seeking to modify the behaviour of each other,[43] creating what Morgan and Yeung refer to as a 'reflexive process of influence and change within the regulatory space'.[44] Regulatory arenas can be defined broadly[45] and narrowly. A broad definition might be employed when considering all impacts upon patient safety within the English NHS; however, this article narrows focus towards the concerning hospital discharges within the English NHS. This arena involves not only statutory regulators, but multiple others with a shared aim of patient safety at the point of discharge.

The hospital discharge regulatory arena

This section identifies the actors within this regulatory arena operating at a national level and their actions in this setting. The purpose of this mapping[46] is to bring to attention the vast number of actors, not all of which are statutory regulators, that have made attempts to respond to the serious patient safety issues posed by discharges. It will then be argued that weaknesses within risk-based regulation result in regulators creating thresholds which must be met in order for them to take action in response to a particular risk. Where their conceptualisation of the risk then fails to meet their own threshold, the regulator's response is likely to be inaction.

Before focussing upon the statutory regulators, influential non-regulatory actors will be briefly introduced. Patient voices are represented within the arena through the PHSO, patient groups and charities. The PHSO makes the final decision on complaints that have not been resolved by the NHS in England.[47] As mentioned earlier, in 2016 the PHSO published a report into unsafe discharges, based upon the complaints it had received (more will be said on this report in section three).[48] HE, a statutory committee of the Care Quality Commission (CQC), escalates concerns raised by local Healthwatch

42. E. Windholz, *Governing through Regulation: Public Policy, Regulation and the Law* (Abingdon: Routledge, 2018), p. 71.
43. Op. cit. p. 71.
44. B. Morgan and K. Yeung, *An Introduction to Law and Regulation* (Cambridge: CUP, 2007), p. 76.
45. Windholz, '*Governing through Regulation*', pp. 70–72.
46. For further 'mapping' of regulatory actors within the NHS, see also D. Horton and G. Lynchwood, 'Technocracy, the Market, and the Governance of England's National Health Service', *Regulation and Governance* 14 (2020), pp. 295–315; D. Horton, 'Rhetoric and Reality: User Engagement and Health Care Reform in England' *Medical Law Review* 26 (2018), pp. 27–50; and E. Oikonomou et al, 'Patient safety regulation in the NHS'.
47. Available at: https://www.ombudsman.org.uk/ (accessed 1 June 2021).
48. PHSO, 'Investigations into Unsafe Discharge'.

organisations to the CQC;[49] HE has produced three reports on unsafe hospital discharges since 2015.[50] Charities also seek to influence the regulatory arena by sharing patients' experiences; for example, the British Red Cross and Patients Association have both published findings of people's experiences of hospital discharge.[51] The National Institute for Health and Care Excellence (NICE) provides evidence-based guidance to help health and social care professionals deliver the best possible care.[52] In 2015, NICE published its guideline on the transition between inpatient hospital settings and community or care homes for adults with social care needs.[53] Although guidelines are not legally binding, failing to follow NICE guidelines may lead to legal consequences.[54]

Hospital discharges involve the coordination of numerous actors across occupational and organisational boundaries.[55] All of these actors are subject to different regulatory

49. Available at: https://www.healthwatch.co.uk/our-history-and-functions (accessed 1 June 2021).
50. Healthwatch England, 'Safely Home: What Happens when People Leave Hospital and Care Settings?' (2015). Available at: https://www.healthwatch.co.uk/report/2015-07-21/safely-home-what-happens-when-people-leave-hospital-and-care-settings (accessed 1 June 2021); Healthwatch England, 'What Happens when People Leave Hospital and other Care Settings? ', (2017). Available at: https://www.healthwatch.co.uk/report/2017-10-05/what-happens-when-people-leave-hospital-and-other-care-settings (accessed 1 June 2021); Healthwatch England, 'Emergency Readmissions: What's Changed One Year On?' (2018). Available at: https://www.healthwatch.co.uk/report/2018-11-14/emergency-readmissions-whats-changed-one-year (accessed 1 June 2021).
51. British Red Cross, 'In and Out of Hospital', (2018). Available at: https://www.redcross.org.uk/about-us/news-and-media/media-centre/press-releases/press-release-repeat-visits-to-accident-and-emergency (accessed 1 June 2021); British Red Cross, 'Home to the Unknown: Getting Hospital Discharge Right', (2019). Available at: www.redcross.org.uk/about-us/what-we-do/we-speak-up-for-change/more-support-when-leaving-hospital/getting-hospital-discharge-right (accessed 1 June 2021); Healthwatch England and British Red Cross, '590 People's Stories of Leaving Hospital During Covid-19', (2020). Available at: https://www.healthwatch.co.uk/report/2020-10-27/590-peoples-stories-leaving-hospital-during-covid-19 (accessed 1 June 2021); Patients Association, 'Premature Discharge from Hospital', (2020). Available at https://www.pslhub.org/learn/patient-engagement/keeping-patients-safe/premature-discharge-from-hospital-june-2020-r2568/ (accessed 1 June 2021).
52. Available at: https://www.nice.org.uk/about/who-we-are/our-charter (accessed 1 June 2021).
53. NICE, 'Transition Between Inpatient Hospital Settings and Community or Care Home Settings for Adults with Social Care Needs', (2015). Available at: https://www.nice.org.uk/guidance/ng27 (accessed 1 June 2021).
54. A. Samanta et al, 'The Role of Clinical Guidelines in Medical Negligence Litigation: A Shift from the Bolam Standard?', *Medical Law Review* 14 (2006). pp. 321–366; *R (on the application of Elizabeth Rose) v Thanet Clinical Commissioning Group* [2014] EWHC 1182 (Admin); *R v North Derbyshire Health Authority* [1997] EWHC Admin 675; J. Bleasdale, 'NICE Guidelines: Not Just the Gold Standard Practice', (2018). Available at: https://www.hilldickinson.com/insights/articles/nice-guidelines-not-just-gold-standard-practice (accessed 1 June 2021).
55. Waring, 'Occupational and Organizational Boundaries'.

regimes. Professional regulators such as the General Medical Council (GMC), Nursing and Midwifery Council, Health and Care Professions Council, General Pharmaceutical Council, and Social Work England regulate the healthcare professionals working within healthcare. Each of the professional regulators[56] set standards of behaviour, competence and education that professionals must meet; these are expressed within the professionals' codes. Hospital discharges are not directly mentioned in the codes; however, behaviours and skills relevant to ensuring safe discharge (such as communication and record-keeping) are specified.[57] The systems within which these healthcare professionals work are not regulated by the same regulatory bodies; meaning there is a regulatory split between people and their work environment. Writing on human error, Reason argues that by focusing on the individual as an origin of error, unsafe acts become isolated from their system context.[58] Although not in scope for this article, this raises an interesting question regarding whether merging regulators to create one responsible for overseeing both professionals and their working environment would be effective.

The CQC, NHS England (NHSE), and NHS Improvement (NHSI) regulate the system and environment within which healthcare professionals work; each has statutory duty pertaining to patient safety. The CQC was established under the Health and Social Care Act 2008 with a primary objective to protect and promote the health, safety and welfare of people using health and social care services.[59] As the regulator of the quality of health and social care in England, the CQC has an assessment framework that it applies to the regulation of all health services. During its inspections of services, the CQC asks questions relating to the safety, effectiveness and responsiveness of hospital discharges.[60] In 2018, the CQC's annual adult inpatient survey report flagged hospital discharge planning as an area for improvement.[61] In 2019, the same annual survey showed 'continuing patterns of decline' regarding care coordination at discharge.[62] For example, the survey highlighted how two in five people had not been given any printed information on what they should do after leaving hospital – which was a decline of seven percentage points

56. There are nine bodies tasked with overseeing the regulation of healthcare professionals in England: GMC, GDC, GCC, GOC, GOsC, GPHC, HCPC, NMC, SWE.
57. For example, see paragraph 1 of the NMC's Code (2015); standard 1 of 'Standards for Pharmacy Professionals' (2017); section 2.2 of Social Work England's Professional Standards (2019), and paragraph 25 of the GMC's 'Good Medical Practice'. The GMC's 'Good practice in prescribing and managing medicines and devices' (2021) also states in paragraph 53 that doctors must contribute to the safe transfer of patients.
58. J. Reason, 'Human Error: Models and Management', *British Medical Journal* 320(7237) (2000), pp. 768–770.
59. Health and Social Care Act 2008, section 3(1).
60. CQC, 'Key Lines of Enquiry, Prompts and Ratings Characteristics for Healthcare Services'. (2018). Available at: https://www.cqc.org.uk/sites/default/files/20180628%20Healthcare%20services%20KLOEs%20prompts%20and%20characteristics%20FINAL.pdf (accessed 1 June 2021).
61. CQC, '2018 Adult Inpatient Survey: Statistical Release', (2019). Available at: https://www.cqc.org.uk/sites/default/files/20190620_ip18_statisticalrelease.pdf. (accessed 1 June 2021).
62. CQC, '2019 Adult Inpatient Survey: Statistical Release', (2020). p. 54. Available at:

since 2013. This result was 'lower than where [the CQC] would expect, based on past data, the fourth consecutive year'.[63]

NHSE has a duty to improve the quality and safety of services provided to patients.[64] With regard to hospital discharge safety, the organisation has produced a series of guides intended to support local systems in reducing the time people spend in hospital. The stated aim is not to encourage inappropriate discharges but to improve safety, given evidence that longer hospital stays can be associated with poorer health outcomes.[65] In 2014, NHSE issued a patient safety alert to NHS organisations stressing the importance of appropriately communicating essential information when discharging patients. Failures to do so had resulted in 'avoidable death and serious harm to patients due to a failure in continuity of care as well as avoidable readmission to secondary care'.[66] NHSE works jointly with NHSI,[67] which also has a statutory duty to protect and promote the interests of people using health care services.[68] As the COVID-19 pandemic took hold, the government and NHSE issued guidance to hospitals with the aim of freeing up bed spaces for anticipated patients through accelerating discharges from hospital.[69] This drive saw 25,000 patients discharged into care homes without being tested prior to discharge for COVID (routine testing was introduced mid-April 2020).[70] These discharges into care homes took place despite evidence that the policy was fuelling outbreaks of the virus and deaths in care homes;[71] a policy decision described as 'reckless and negligent' by the Public Accounts Commit-

63. Op. cit. p. 50.
64. National Health Service Act 2006 (as amended by the Health and Social Care Act 2012), section 13E.
65. Available at: https://www.england.nhs.uk/urgent-emergency-care/improving-hospital-discharge/quick-guides/ (accessed 1 June 2021)..
66. NHS England, 'Patient Safety Alert NHS/PSA/W/2014/014'. (2014). Available at: https://www.england.nhs.uk/wp-content/uploads/2014/08/psa-imp-saf-of-discharge.pdf (accessed 1 June 2021).
67. As of April 2016, NHS Improvement is the operational name for the body that brings together Monitor, NHS Trust Development Authority, NHS England's Patient Safety teams, the National Reporting and Learning System, the Advancing Change team and the Intensive Support Teams
68. Health and Social Care Act 2012, Part 3 (62)(1).
69. HM Government & NHS England, 'COVID-19 Hospital Discharge Service Requirements'. Available at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/880288/COVID-19_hospital_discharge_service_requirements.pdf (accessed 1 June 2021).
70. Public Accounts Committee, 'Readying the NHS and Social Care for the COVID-19 peak' (2020), paragraphs 9–11, Available at: https://publications.parliament.uk/pa/cm5801/cmselect/cmpubacc/405/40506.htm#_idTextAnchor012 (accessed 1 June 2021).
71. 'Discharging coronavirus patients into care homes is 'madness', Government told', The Telegraph, 15 April 2020, Available at: https://www.telegraph.co.uk/news/2020/04/15/discharging-coronavirus-patients-care-homes-madness-government/ (accessed 1 June2021).

tee.[72] One in five directors of adult social services expressed concern that the policy had resulting in people being discharged to services unable to fully meet their needs.[73] It is outside of the scope of this particular article to fully explore the implications and long-term consequences of this discharge policy on patient safety; it is, however, an aspect deserving of urgent attention. Thus far, NHSE&I have defended the decision by saying it has always been the case that they want to discharge people who are clinically fit, and staying in hospital could be harmful for the elderly'.[74]

As can be seen from the above exploration of the hospital discharge regulatory arena, there are multiple actors within it which have, over the years, made efforts to try and improve the safety of hospital discharges; however, there has been no unified effort. I have argued elsewhere[75] that risk-based regulation, a strategy frequently employed by the statutory regulators, is partially to blame. Risk-based regulation is intended to focus a regulator's interventions upon threats which pose the greatest risk to its objectives.[76] Such approaches were strongly endorsed by the 2005 Hampton Report on the grounds that they were seen as essential for efficiently directing regulatory resources to where they can have maximum impact upon outcomes.[77] Risk-based frameworks typically have the identification of risk as a starting point and commonly feature an assessment of the likelihood of the risk occurring, and a subsequent ranking of risks based upon these assessments.[78] Three common weaknesses of risk-based regulation approaches[79] regarding the identification, conceptualisation and prioritisation of risks to patient safety explain why little action has been taken by statutory regulators within the hospital discharge regulatory arena.

The first weakness in relation to identifying risk arises due to limited information-sharing mechanisms among the multitude of regulators, which means regulators do not have a complete picture of all relevant information.[80] The numerous regulatory bodies and the limited information-sharing among them give rise to the next problem, which is that achieving a unified understanding of the risk posed by hospital discharges is nigh on

72. Public Accounts Committee, 'Readying the NHS'.
73. Kings Fund, 'How Covid-19 has Magnified Some of social Care's Key Problems', (2020). Available at: https://www.kingsfund.org.uk/publications/covid-19-magnified-social-care-problems (accessed 1 June 2021).
74. Public Accounts Committee, 'Readying the NHS'.
75. Moore, 'Leaving Hospital'.
76. A. Beaussier et al, 'Accounting for Failure: Risk-Based Regulation and the Problems of Ensuring Healthcare Quality in the NHS', *Health, Risk & Society* 18 (2016), p. 206.
77. P. Hampton, Reducing Administrative Burdens: Effective Inspection and Enforcement (HM Treasury 2005).
78. J. Black and R. Baldwin, 'Really Responsive Risk-based Regulation', *Law and Policy* 32(2) (2010), pp. 181–213.
79. A. Beaussier et al, 'Accounting for Failure'; S. Lloyd-Bostock and B. Hutter, 'Reforming Regulation of the Medical Profession: The Risks of Risk-based Approaches', *Health, Risk and Society* 10(1) (2008), pp. 69–83.
80. Moore, 'Leaving Hospital'.

impossible. Risks become conceptualised by each regulator based upon the information which it holds, and inevitably these conceptualisations will vary across regulators. This in turn impacts the priority the risk is afforded.[81] By utilising risk-based regulation, regulators thus create thresholds which must be reached in order for them to take action. If their conceptualisation of a risk fails to meet their threshold, it will not be perceived as a risk that needs *their particular attention*.

This section has identified the actors within the hospital discharge regulatory arena and their actions to address the patient safety challenge posed by hospital discharges. Despite these efforts, the physical well-being and dignity of patients remains at risk at the point of hospital discharge.[82] The following section offers an account of why these attempts have failed to significantly improve patient safety during discharge, relying on the concept of liminality that is precisely about navigating uncertain spaces of human experience.

Liminality

Upon observing that people undertake certain rituals when transitioning from one social state to another (such as childhood to adulthood), Van Gennep developed the anthropological concept of 'liminality'.[83] These rituals consist of three distinct phases, known as rites of passage, which van Gennep declared universal to all societies.[84] He argued that their purpose is to reduce the harmful effects that can occur as a result of the disruptive impact that changes of social state can have upon the life of an individual and society.[85] The three phases are the separation from a previous state (preliminal rites), the transitional stage (liminal rites) and incorporation into the new state (postliminal rites).[86] Within the transitional, liminal stage, the experience is marked by uncertainty for the subject.[87]

Turner writes that a liminal being is one who is 'betwixt and between the positions assigned and arrayed by law, custom, convention, and ceremonial'.[88] In these spaces, structure gives way to anti-structure, which is to say that the status quo breaks down into chaos.[89] A figure known as the 'Master of

81. Op. cit.
82. Op. cit.
83. A. van Gennep, *The Rites of Passage* (Chicago: University of Chicago Press, 1960). Note, van Gennep wrote *The Rites of Passage* in 1909.
84. Op. cit.
85. Op. cit.
86. Op. cit.
87. J. Söderlund and E. Borg, 'Liminality in Management and Organization Studies: Process, Position and Place', *International Journal of Management Reviews* 20 (2018), pp. 880–902; G. Laurie, 'Liminality and the Limits of Law in Health Research Regulation: What are we Missing in the Spaces in-Between?', *Medical Law Review* 25 (2016), pp. 47–72.
88. V. Turner, *The Ritual Process: Structure and Anti-Structure* (New Jersey: Transaction, 1969).
89. Op. cit.

Ceremonies'[90] or 'Representative of Order'[91] is needed to guide people safely through and out of these liminal states so that they are able to reintegrate into society.[92] Without them liminality can be permanent[93] or result in 'lasting rule by tricksters'[94] (one who presents themselves as leader for their own gains).

Because of this, liminal spaces can be dangerous.[95] However, people can also have positive experiences within these spaces as a result of *communitas*[96] arising among them. Laurie describes this as 'a spontaneous sense of interconnectedness of equals, experiencing the same process together'.[97] Thomasson cautions that *communitas* stemming out of liminality is unpredictable, and we cannot accurately foretell whether it will result in care towards others or in violent destruction.[98] More on the implications of this spontaneity and unpredictability within a regulatory context will be discussed later within this article.

Having introduced liminality and the Representative of Order role, the remainder of this section proceeds to explore two things. It considers the liminal space within the regulation of hospital discharges and then examines the presence of 'liminal objects'[99] (often reports produced within the intention of improving patient safety during discharge) within it. The purpose of this exploration is to demonstrate how the lack of a Representative of Order within this liminal space can cause a regulatory failure in addressing safety during discharges, and how objects which become stuck in a liminal state fail in their aim to improve safety. The fourth and fifth sections will then cast the proposed Patient Safety Commissioner as a Representative of Order to explore how such a figure could address these issues.

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90. Op. cit; A. Szakolczai, 'Liminality and Experience: Structuring Transitory Situations and Transformative, *International Political Anthropology* 2 (2009), p. 148.
91. V. Turner, *Dramas, Fields, and Metaphors: Symbolic Action in Human Society* (London: Cornell University Press, 1974); P. Stenner and E. Moreno-Gabriel, 'Liminality and Affectivity: The Case of Deceased Organ Donation', *Subjectivity* 6 (2013), p. 248.
92. G. Laurie, 'Liminality and the Limits of Law', p. 54; B. Thomassen, *Liminality and the Modern: Living Through the In-Between,* (Abingdon: Routledge, 2018); G. Laurie, 'How do We Make Sense of Chaos? Navigating Health Research Regulation through the Liminality of the Brexit Process', *Medical Law International* 18 (2018), pp. 110–134; A. Szakolczai, Liminality and Experience: Structuring Transitory Situations and Transformative Events', *International Political Anthropology* 2 (2009), pp. 141–172; A. Horvath, 'The Genealogy of Political Alchemy: The Technological Invention of Identity Change' in A. Hovarth, B. Thomassen and H. Wydra, eds., *Breaking Boundaries: Varieties of Liminality* (New York: Berghahn Books, 2015), ch.4.
93. Laurie, 'How do we make sense of chaos?', p. 117.
94. Szakolczai, 'Liminality and experience', p. 157.
95. Op. Cit.
96. Turner, 'The Ritual Process,1969'.
97. Laurie, 'Liminality and the limits of law', p. 59.
98. Thomasson, 'Liminality and the Modern', p. 84.
99. S. Taylor-Alexander and colleagues, 'Beyond Regulatory Compression: Confronting the Liminal Spaces of Health Research Regulation', *Law, Innovation and Technology* 8 (2016), pp. 149–176.

The liminal space within hospital discharge regulation

The result of the regulatory split between healthcare professionals and systems outlined in the previous section is that hospital discharges are subject to multiple regulatory requirements and influences. A patient safety incident (PSI) which occurs in relation to the hospital discharge process is frequently not a failing on the part of one actor. Indeed, the incidents themselves can be understood as occurring within the liminal spaces of healthcare provision, particularly at the point where different systems meet and interact (interfaces). It has been found that about 50% of medical errors occur at healthcare interfaces, with up to one-third of these arising at the primary–secondary care interface.[100] Incidents resulting from a complex interaction between professionals and the system they work within may fall within the regulatory liminal space, which is to say that they may not land squarely within the perceived remit of any one regulator.

Threats to patient safety in relation to the discharge process may experience a similar fate and therefore not elicit an appropriate regulatory response. For example, at the start of 2020 (prior to the COVID-19 pandemic taking hold in the United Kingdom), the Royal Cornwall Hospitals NHS Trust informed staff that patients should be discharged early to reduce overcrowding. The memo sent to staff called the risk to patients 'proportionate' despite the likelihood 'that some of these patients will be readmitted or possibly come to harm'.[101] Requiring clinicians to discharge patients in cases where it may be against their clinical judgement to do so may mean asking them to act in a manner contrary to their professional standards.[102] One doctor queried the GMC's stance upon this matter and reported the response as, 'We always consider a concern raised with [us] on the specific facts of the case, taking into account the factors relevant to the environment in which the doctor is working'.[103] The doctor argued this response provided little reassurance.

This example reveals three key features of this liminal space. First, it is surrounded by 'thresholds' constructed by regulators and informed by their risk-based approaches (e.g. – does the risk threaten the achievement of their objectives, and if so, how severe will its impact be?).[104] Where an incident is not perceived as meeting the regulator's threshold for action, the regulator is unlikely to respond. In the scenario above, the risk to patient safety *should* be situated within the remit of the systems regulators (it is a pressure arising from an under-resourced hospital) and within the remit of the professional regulators – for it is an issue likely to impact upon the ability of healthcare

100. Scottish Government, (2019), Improving General Practice Sustainability Group: 2019 Report, Available at: https://www.gov.scot/publications/improving-general-practice-sustainability-group-2019-report/pages/1/ (accessed 1 June 2021). Annex B.
101. 'Cornwall Hospital to Discharge Patients Early Despite Saying it may be Harmful', *The Guardian* 14 January 2020. <https://www.theguardian.com/society/2020/jan/14/cornwall-hospital-to-discharge-patients-early-despite-risks> (accessed 1 June 2021).
102. D. Oliver, 'The Risks of Discharging Patients Early against Doctors' Judgment', *British Medical Journal* 368 (2020).
103. Op. cit. p. 2.
104. Black and Baldwin, 'Really Responsive'; Removed for peer review.

professionals to act in accordance with their professional standards.[105] Yet the GMC has not commented further on this incident, nor has the CQC or NHSE/NHSI – all of whom should be able to recognise the potential impact upon patient safety and their ability to achieve their statutory objectives in this regard. Secondly, there is a lack of regulatory structure within the liminal space – which may explain why no regulator is taking the lead on addressing the patient safety issue identified above. Thirdly, there is no clear authority figure present within it driving regulators to act. This article now turns its attention to the impact this liminal space has on actions undertaken by those within the regulatory arena. These actions are intended to improve patient safety during the discharge process.

Liminal objects within hospital discharge regulation

Acknowledging that liminality is typically applied to people, Taylor-Alexander and colleagues argue that it can also be applied to 'things' – doing so enables a richer understanding of the relations between people and their surroundings.[106] For, as with humans, things can also pass through periods of transition; the authors provide an example of health research protocol documents to demonstrate this. The research protocol document undergoes 'multiple transitory passages and transformations, marked by both uncertainty and the guiding (or editing) hand of a gatekeeper or steward to lead it through the passage(s) towards approbation'.[107] In the same way that liminality involves a Representative of Order who guides a person through transformation, regulatory actors may guide objects, such as these protocols, through the liminal phase.

It is argued here that a Representative of Order is key to preventing objects becoming stuck in a liminal state within the hospital discharge regulatory arena. 'Objects' in this context is used to refer to the outputs of any actor within this regulatory space that is intended to improve patient safety during the discharge process. These objects often stem from patient safety incidents. For example, a hospital discharge-related PSI may result in one or more of the following actions: a hospital may instigate its own investigation; a patient may make a complaint to a regulatory body or the PHSO; and (where a patient has died) a coroner may investigate and produce a prevention of future death (PFD) report.[108] Incidents may also trigger an investigation by the Health and Safety Investigation Branch, a body which aims to improve patient safety through investigations without assigning blame or liability.[109] As highlighted earlier, patients may also share their experiences with HE and charities, such as the British Red Cross. These actions often result in the production of a report detailing how improvements could be made. These reports are 'objects' that are vulnerable to failing to cross any of the regulatory thresholds surrounding them that would enable the prevention of such future incidents through learning and proportionate regulatory responses.

105. Moore, 'Leaving Hospital'.
106. S. Taylor-Alexander, 'Beyond Regulatory Compression'.
107. Op. cit. p. 159.
108. Under the Coroner and Justice Act 2009, coroners have a duty to make these reports.
109. Available at: https://www.hsib.org.uk/ (accessed 1 June 2021).

Two of these objects, the PHSO report into unsafe hospital discharges[110] and the 2019 British Red Cross report into safety during hospital discharges,[111] will now be used to illustrate the argument that a Representative of Order is key to improving safety in this space.

The PHSO report into unsafe discharges highlights failings which are indicative of the nature of complaints it receives regarding unsafe hospital discharge. It asks for the Department of Health and Social Care (DHSC) and NHS to establish the scale of the problems and to understand the causes, 'so that others do not have to experience such avoidable and unnecessary suffering'.[112] The report is intended to influence other actors within the hospital discharge regulatory arena, but to do so it needs to be visible. The House of Commons' Standing Orders[113] ultimately bring about this visibility. The Orders direct the manner in which House of Commons' public business is conducted; they are a regulatory requirement. These Orders state that one of the functions of the Public Administration and Constitutional Affairs Committee (PACAC) is to examine reports by the PHSO. The PACAC may then use these reports to hold the government to account.[114] In response to the PHSO report on unsafe discharges, the PACAC held an inquiry to understand the scale of the highlighted problems, to assess the measures for improving discharge practice and to clarify responsibilities and accountabilities across Government for ensuring implementation of the improvements and the safety of discharge processes.[115] By triggering such action, this regulatory requirement is acting as a Representative of Order, leading the report through its transformation from a passive object into an 'active subject-object'.[116] In this final state, the report is able to exert its intended influence within the hospital discharge regulatory arena.

In cases where concerns are raised by patient organisations, or charities, this role is unfulfilled by any legal or regulatory framework, and this increases the risk of reports which are intended to be active-subject objects becoming stuck in a liminal state. In failing to transition from passive object to active-subject object, these reports become a 'stagnated presence' within the hospital discharge regulatory arena.[117]

For example, the 2019 British Red Cross report documents patients' experiences of being discharged from hospital, presumably shared by patients hoping to improve the

110. PHSO, 'Investigations into Unsafe Discharge'.
111. British Red Cross, 'Home to the Unknown'.
112. PHSO, 'Investigations into Unsafe Discharge', p. 3.
113. HoC Standing Orders Public Business 2019 at 146(1).
114. Available at: https://committees.parliament.uk/committee/327/public-administration-and-constitutional-affairs-committee/role/ (accessed 1 June 2021).
115. Fifth Report from the Public Administration and Constitutional Affairs Committee HC 97 (2016-17).
116. Taylor-Alexander, 'Beyond Regulatory Compression'.
117. This term is borrowed from Boyacıoğlu's writing on beliefs surrounding revenants in medieval Britain. These revenants, trapped between the living and the dead, are 'stagnated presences'. For a fascinating (somewhat off topic) read on this matter see E. Boyacıoğlu, 'The Revenant on the Threshold', *Folklore: Electronic Journal of Folklore* 62 (2015), pp. 7–36.

experience for future patients. The report states that, 'being clearer about the relationship between what happens in hospital and what happens when people go home – seeing through patients' eyes how it feels when they walk back through their front door – can only help patients and professionals alike'.[118] Such a report, intertwined with human experience and the potential to cross spatial–temporal boundaries, should have the potential to be a powerful regulatory tool. However, there is no evidence to indicate that the findings have been heard by any of the statutory regulators. This is important because statutory regulators are the ones in a position to check whether recommendations have been received by healthcare providers and/or implemented.

As there is no regulatory framework or organisation responsible for acting on these recommendations, the report is not delivered through the liminal phase and transformed into an active subject–object where it can influence behaviours and become an actor in the hospital discharge regulatory arena. Instead, it is stuck as a stagnated presence, unable to reintegrate into the regulatory space and have the impact intended by its creators. Any learning that could be gained from previous patients' experiences of discharge thus goes unheeded, resulting in missed opportunities for improvement. By contrast, active subject–objects within this space play important roles in not only highlighting unsafe discharges but also in recommending ways that these can be overcome and in compelling a response. Representatives of Order are fundamental to preventing objects becoming stuck. In this liminal space, where regulatory structure is missing, a Representative of Order is needed to guide these liminal objects out of their status as a stagnated presence and into their role as active-subject object; doing so will increase the ability of regulators to keep patients safe during discharge.

The following section examines the recommendation proposed by the IMMDS review to create a PSC. This role has now been established in the MMD Act. The purpose of this examination is to consider whether the PSC could act as a Representative of Order and ultimately improve patient safety during the discharge process.

The Patient Safety Commissioner

As mentioned at the start of this article, the purpose of the IMMDS review was to consider how the healthcare system in England responds when concerns are raised about harmful side effects from medicines and medical devices. It focussed specifically upon hormone pregnancy tests, sodium valproate and pelvic mesh implants.[119] The review further considered how future responses could be quicker and more effective, and how the patient voice could be strengthened to help build a system that listens to patients and acts promptly, with compassion and in a proportionate manner.[120] The review argues,

118. British Red Cross, 'Home to the Unknown', p. 8.
119. IMMDS Review, 'First do no Harm'.
120. Op. cit., p. 186.

> we do not need another regulatory body in an already crowded field. But we do need a new voice, with statutory powers, to talk and act from the perspective of the patient, to encourage the system to do what needs to be done and hold it to account'.[121]

As such, one of its recommendations, which shall be considered in-depth here, was the creation of a new PSC role.

The PSC as envisaged in the IMMDS review was to be independent and have a statutory responsibility to champion the value of listening to patients and promoting users' views in improving patient safety. They would be responsible for identifying steps needed to improve patient safety regarding the use of medicines and medical devices and for encouraging other organisations to act. It was intended that the PSC would be a means of holding the system to account, and they would be accountable to Parliament through the Health and Social Care Select Committee.[122]

The review envisaged that a core set of statutory principles, to be developed by the PSC, would support the PSC in determining the appropriate response to any issues raised. It was anticipated that the Commissioner would lead reviews and investigations, which would result in advice and recommendations. Reviews would potentially include thematic investigations of systemic issues; in-depth inquiries into specific patient safety concerns not undertaken by another organisation; and assessments of an organisation's patient safety performance, against the principles.[123] The resulting advice could be in the form of specific recommendations to address the identified concerns, encouraging other bodies to implement recommendations and highlighting concerns about failures to improve patient safety to the Secretary of State for Health and in public reports.[124]

Although the review suggested the PSC would be prevented from investigating individual cases (for this would duplicate the work of the PHSO), it stated that the PSC would be open to receiving concerns from patients and other members of the public, as well as patient representative organisations. This is because the PSC was expected to have a higher public profile than other complaints bodies, and it was proposed that direct reports from patients could be relayed to other organisations if appropriate. In such cases, the PSC would retain an interest in how the reports are handled, and what the outcomes are.[125] It was further proposed that the PSC would be responsible for obtaining relevant patient safety information from other organisations to assist their primary functions. This would be, for example, through making arrangements to receive reports relating to medicine safety from the National Freedom to Speak Up Guardian.[126] The report did

121. Op. cit., p. 10.
122. Op. cit., p. 200.
123. IMMDS Review, 'First do no harm', p. 206.
124. Op. cit. p. 206.
125. Op. cit. p. 206.
126. This role was created in response to recommendations made in Francis' report "The Freedom to Speak Up" (2015). The recommendations followed findings that NHS culture failed to support workers to speak up, and patients/staff suffered as a result. For further information see Available at: https://nationalguardian.org.uk/about-us/ (accessed 1 June 2021).

not propose giving the PSC 'more wide-ranging regulatory powers', stressing instead that the role is that of a champion – amplifying patients' voices and delivering systemic improvements in patient safety.[127]

The new MMD Act confirms that the PSC role will be established and have statutory powers. Although lacking the fine detail provided in the IMMDS review, the role is generally reflective of that proposed by the review. It states that the PSC's core duties are to promote the safety of patients with regard to the use of medicines and medical devices and to promote the importance of the views of patients and other members of the public in relation to the safety of medicines and medical devices.[128] In doing so, the PSC must prepare and publish a set of governing principles and must take reasonable to steps to involve patients in discharging their core duties.[129] The PSC may make reports, and request and share information with relevant persons. In such cases, relevant persons must comply, provided that doing so does not contravene data protection legislation.[130] The MMD Act does not state who the PSC is to be accountable to; this detail is likely to follow in subsequent regulations.[131]

As can be seen from the summary above, the PSC will be responsible for listening to patients and identifying the steps required to improve patient safety regarding the use of medicines and medical devices. By focussing the role of the PSC solely on medicines and medical devices, the opportunity to improve patient safety with regard to *processes*, such as hospital discharges, appears to have been missed. As I will now argue, the remit of the PSC should be expanded to include such processes. This is proposed because the risk of harm posed by hospital discharges has not been adequately addressed by statutory regulators, despite numerous reports (as highlighted in section two) having raised the issue. Liminality, employed here as an exploratory lens, has shed light on the nature of this regulatory problem – namely that objects intended to influence action fail in this endeavour. Expanding the remit of the PSC in this way will amplify the voices of patients harmed during discharge – a complex process involving interactions between a healthcare system and the professionals working within it. If healthcare is to truly become safer, holding the system to account and listening to patient's safety experiences regarding all aspects of their healthcare journey are necessary.

This article envisages that the PSC could function as a Representative of Order – a figure able to guide objects and persons through their liminal state and assist actors within the regulatory space to navigate the liminal space between them. Before moving on to consider how the PSC might function as a Representative of Order, let us now turn to another individual who fulfils the Representative of Order role within the patient safety field as part of their remit – the Chief Coroner. Doing so will not only demonstrate

127. Op. cit., p. 209.
128. Medicines and Medical Devices Act 2021, section 1(2a).
129. Op. cit, schedule 1.
130. Op. cit, schedule 1.
131. DHSC, 'Factsheet: Patient Safety Commissioner', Available at: https://www.gov.uk/government/publications/medicines-and-medical-devices-bill-overarching-documents/medicines-and-medical-devices-bill-patient-safety-commissioner (accessed 1 June 2021).

the benefits such figures can bring to patient safety but also provide valuable insight into how the PSC role might be strengthened.

The Chief Coroner as a Representative of Order

The Chief Coroner acts as a centralised figure[132] within the coronial system in England and Wales and is responsible for setting national standards within the coronial system, and overseeing the implementation and development of reforms. The creation of this role was triggered by the Inquiry into the actions of Harold Shipman, a general practitioner convicted of murdering 15 patients in 2000.[133] Among multiple systemic failings, the inquiry identified several weaknesses within the coronial system and recommended fundamental reform, led by a Chief Coroner. Ten years later, the new Coroner and Justice Act 2009 ('the 2009 Act') was implemented, bringing with it the new role of the Chief Coroner (the first one came into post 3 years later).[134]

As will now be demonstrated, through the lens of liminality, we can see how the Chief Coroner serves as a Representative of Order to keep patients safe. Regarding death and bereavement, van Gennep says:

> in some cases the transitional period of the living is a counterpart of the transitional period of the deceased, and the termination of the first sometimes coincides with the termination of the second – that is, with the incorporation of the deceased into the world of the dead.[135]

The salient point here is that bereavement is a rite of passage.[136] The Shipman Inquiry recognised this where it noted that the family of a deceased person value being involved in registering the death of their loved one.[137] In a similar vein, where the cause of death is unknown, the bereaved may find themselves in a liminal state, unable to reintegrate in society in their new role. It is often important for the bereaved to know that steps have been taken to protect others from dying in similar manners,[138] and in this sense, PFD reports play a role in guiding them through the liminal stage of bereavement.

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132. J. Moore, *Coroners' Recommendations and the Promise of Saved Lives* (Cheltenham: Edward Elgar Publishing, 2016).
133. J. Smith, *The Shipman Inquiry Third Report: Death Certification and the Investigation of Deaths by Coroners* (London: The Stationary Office, 2003).
134. Chief Coroner, (2018) 'Report of the Chief Coroner to the Lord Chancellor: Fifth Annual Report: 2017-2018', Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/764720/report-of-the-chief-coroner-lord-chancellor-2017-18.pdf (accessed 1 June 2021).
135. van Gennep, 'Rites of Passage', p. 147
136. Hunter observes bereavement-related rituals are so integrated with death rituals, bereavement is rarely considered its own rite of passage (J. Hunter, 'Bereavement: An Incomplete Rite of Passage', *OMEGA* 56 (2008), pp. 153–173.
137. Smith, '*The Shipman Inquiry Third Report*'.
138. NHS Resolution, (2018), 'Learning from Suicide-Related Claims: A Thematic Review of NHS Resolution Data', Available at: https://resolution.nhs.uk/resources/learning-from-suicide-related-claims/ (accessed 1 June 2021); INQUEST, (2020), 'Submission to the

Under the 2009 Act, coroners have a duty to make these reports (also known as Regulation 28 Reports) and to send them to the Chief Coroner and 'every interested person who in the coroner's opinion should receive it'.[139] PFD reports raise concerns arising from coroners' investigations on actions that should be taken to prevent similar future deaths, and recipients have 56 days to respond.[140] They reflect the circumstances leading up to the person's death and are key to preventing others from dying in similar circumstances. All reports are published online by the Chief Coroner and so are publicly accessible. Through acting as a Representative of Order, the Chief Coroner is able to ensure that PFD reports do not get stuck in a state of liminality. Firstly, he may send a copy of the report to any person who he believes may find it useful or of interest,[141] and secondly, he has access to all reports which should enable regular analysis to be undertaken so that common themes can be disseminated nationally among relevant and interested parties. Essentially, the creation of a Chief Coroner reduces the likelihood of both PFD reports and bereaved people becoming stuck in liminal states. In the case of PFD reports, the Chief Coroner is able to ensure they cross temporal–spatial boundaries to influence the safety of others. Knowing that lessons learned from a loved one's death will safeguard others may also support bereaved people's journey through the grieving process. However, as will be explored in the following section, there is scope for the Chief Coroner's role in this regard to be improved. Reflecting on the efficacy of this particular Representative of Order will enable the PSC to avoid similar difficulties.

The Patient Safety Commissioner as a Representative of Order

In a similar manner to the way in which the creation of the Chief Coroner role is starting to result in increasingly successful navigation of the liminal space within the disjointed coronial system,[142] the PSC could support actors within the context of the hospital discharge regulatory arena. The PSC, with the extended remit over processes argued for herein, will have a high public profile and be empowered to receive, and to actively seek, information pertaining to patient safety from a vast range of sources. This should result in them having powerful, all-encompassing insight into safety concerns across the entire healthcare system.

To recap briefly on the points made in third section, the liminal space within the hospital discharge regulatory arena is present in part due to multiple regulators and the related challenge they face in forming a unified understanding and prioritisation of the risk posed by hospital discharges.[143] Actions then taken by actors with the regulatory arena to improve safety during discharges (often the production of a report) risk

Justice Select Committee Inquiry into the Coroner Service', Available at: https://www.inquest.org.uk/Handlers/Download.ashx?IDMF=e404f863-cdfb-47b6-8e34-a6511852033 1 (accessed 1 June 2021).

139. Coroner and Justice Act 2009, para 7, Schedule 5.
140. The Coroners (Investigations) Regulations 2013, Regulation 29.
141. Op. cit., Regulation 28.
142. Chief Coroner, Fifth annual report.
143. Moore, 'Leaving Hospital'.

becoming a stagnated presence, unable to cross regulators' thresholds or influence the behaviour of actors within the regulatory arena. These two issues need resolving to improve patient safety during the discharge process.

Navigating the liminal space

With regard to this first issue, by acting as a centralised figure, the PSC will be able to assist regulators in developing a uniform response to the patient safety risks posed by hospital discharges. Although this might not directly translate into risk being prioritised in the same manner, it creates room for discussion on multi-actor approaches to addressing the problem. A unified understanding of the risk will not necessarily reduce the presence of the liminal space within; however, the presence of these spaces should not be thought of as undesirable. By acting as a Representative of Order, the PSC could be in a position to encourage regulators to engage within this liminal space. In this regard, the PSC would be embracing the role of stewardship, which Laurie and colleagues define as 'guiding others with prudence and care across one or more endeavours – without which there is risk of impairment or harm—and with a view to collective betterment'.[144] Laurie and colleagues note that within the context of health research regulation, regulatory stewardship plays a central, yet often invisible role.[145] Regulatory actors within the hospital discharge arena may already be involved in this type of stewardship; the GMC for example provides ethical advice to individual doctors upon request to assist them in their efforts to adhere to professional standards.[146]

Importantly, Laurie and colleagues stress that fulfilling the role of regulatory stewardship should not fall to any single actor, as this would risk the role being seen as someone else's responsibility.[147] This is a valid concern – and as such, this article does not see the PSC as being the only actor within this regulatory arena to be charged with this role. Rather, they should encourage other regulators to collaboratively engage in this role within the liminal space.

Returning to the notion of *communitas* discussed in the third section, although *communitas* cannot be artificially created within a liminal space, such spaces can still have productive potential.[148] The PSC as a Representative of Order could help regulators to utilise this potential, while recognising that such spaces might develop a dynamic of their own.[149] For example, within the research and policy context, Laurie cites the emerging use of regulatory sandpits (also known as sandboxes)[150] as an example of how this

144. Laurie, 'Regulatory Stewardship', p. 338.
145. Op. cit. p.338.
146. See, for example, GMC 'Contact Us', Available at: https://www.gmc-uk.org/contact-us (accessed 1 June 2021).
147. Laurie, 'Regulatory Stewardship', p. 338.
148. Laurie, 'Liminality and the limits of law', p. 60.
149. Op. cit. p. 60.
150. Sandboxes started in the financial industry as a framework set up by the regulator to allow testing of innovations in controlled environments under the regulator's supervision. It is argued they have the potential to shift the relationship between regulators and financial

potential could be utilised.[151] Sandboxes involve regulators collaborating with other parties (such as service users and healthcare providers) on an equal footing (in a manner similar to what might happen where *communitas* arises), to generate and develop solutions to problems. The CQC has recently adopted the idea of the regulatory sandbox to provide a space where providers can work alongside them to consider new ways of working that fit with regulation.[152] If the PSC facilitates regulatory bodies engaging in the liminal space around them, novel regulatory solutions to the complex safety problem posed by hospital discharges may be reached. The PSC would, however, need to be cognisant of legal requirements which may impede regulators' ability to be creative and agile in seeking solutions. For example, speaking on how legal requirements restrict regulatory agility, the GMC's chief executive said the restrictive legal framework prevents overseas doctors being rapidly registered to work in the United Kingdom despite severe shortages in the United Kingdom. He stated that the GMC wishes to provide additional resources into preventing medical errors, but instead is compelled by legislation to spend the majority of its time processing complaints, 'the majority of which come to nothing'.[153]

Guiding liminal objects

As demonstrated by the example of the Chief Coroner and PFD reports, a Representative of Order has the ability to prevent objects becoming stuck in a liminal state. This is through having oversight of all PFD reports, being able to analyse them for common themes and raise concerns with appropriate parties to address safety issues. It must, however, be noted that INQUEST have recently highlighted that regular analysis of themes is not currently happening.[154] This is a failure on behalf of the Chief Coroner, for it is an essential part of enabling the reports to fulfil their intended roles as a tool to influence the experiences of others and prevent future deaths. The Chief Coroner acknowledged the importance of PFD reports in his fifth annual report and said additional staffing would enable the trends in reports and the responses to them to be drawn together.[155] The lesson here when establishing the PSC is that sufficient funding and resource must be provided in order for them to perform their role satisfactorily.[156]

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services providers towards a more open and active dialogue. See I. Jenik and K. Lauer (2017), 'Regulatory Sandboxes and Financial Inclusion', Available at: https://www.cgap.org/sites/default/files/Working-Paper-Regulatory-Sandboxes-Oct-2017.pdf

151. Laurie, 'Liminality and the limits of law', p. 60.
152. Available at: https://www.digitalhealth.net/2020/02/cqc-publishes-report-into-its-first-regulatory-sandbox-pilot/ (accessed 1 June 2021).
153. C. Massey, 'Regulation Overhaul Urgently Needed', Available at https://www.gmc-uk.org/news/news-archive/regulation-overhaul-urgently-needed (accessed 1 June 2021).
154. INQUEST, Submission to the Justice Select Committee Inquiry.
155. Chief Coroner, Fifth annual report, p. 19.
156. The IMMDS review proposes that the Commissioner's work is supported by government grant-in-aid funding (p. 210)

It is envisaged that in the case of hospital discharges, where reports such as those mentioned earlier in this article are produced to highlight the risks to patients, the PSC would be able to direct them to regulatory bodies to act upon. This would prevent objects from becoming stuck in a liminal state and enable them to reach their intended potential in influencing change. However, if this advice of the PSC is to be heeded, it is important that the PSC is aware of regulators' remits and their legal limitations. Otherwise, advice will likely be met with pushback. Research by Moore into why coroners' recommendations in New Zealand were rejected by organisations found that it was important for organisations to be correctly identified and targeted; organisations did not appreciate being a 'convenient PO box'.[157]

The PSC as proposed will not have any direct enforcement powers. This means that although advice can be provided to regulators and other actors within the safe discharge space, if actors are reluctant to engage in spaces beyond their remit, then the only recourse available to the PSC is to escalate concerns to the Health Secretary. It is anticipated that this is unlikely to translate into any further action being taken against regulators, which risks safety issues at discharge remaining unaddressed. It is therefore critically important that the PSC works alongside regulators and is established as an authority figure to reduce the likelihood of this happening.

Conclusion

This article has used the anthropological concept of liminality as a lens through which to explore and identify regulatory challenges in addressing patient safety issues related to hospital discharges. This has brought into focus the liminal space that exists among regulatory bodies within the hospital discharge regulatory arena. The liminal space occurs because hospital discharges can be complex processes where safety depends upon the quality and availability of the healthcare system and the actions of many healthcare professionals. This means the regulatory arena contains numerous statutory regulators with varying thresholds for action – making it difficult for regulators to establish a unified understanding and prioritisation of the risk facing patients. Furthermore, actions to improve safety in this regard often become stagnated presences, unable to have their intended impact within the regulatory arena.

Liminality in itself does not present a solution to the patient safety problem posed by discharges. However, by using it as a lens through which to view the regulatory arena, it has brought to light the critical need for a Representative of Order to ensure that recommendations regarding patient safety during discharge are recognised by regulators. This article has cast the Patient Safety Commissioner as a candidate to fulfil this role.

If the remit of the PSC were extended, as called for in this article, the PSC could be in a position to aid regulators in developing a uniform understanding of the risk posed to patient safety by hospital discharges. This would result from the PSC being in a position to listen to patients and obtain evidence from a wide variety of sources regarding what goes wrong with the discharge process. Armed with this knowledge, the PSC could

157. Moore, Coroners Recommendations, p. 145.

advise regulators and encourage them to engage within the liminal space around them – presenting the opportunity for solutions to this complex safety problem to be uncovered. Furthermore, the PSC would be able to ensure that objects produced by actors with the intent of improving discharge safety, such as reports into unsafe discharges, would become active subject–objects. This would be achieved through the PSC ensuring that appropriate regulatory bodies are aware of the findings and providing advice on how they may be able to respond.

In summary, through using the lens of liminality, this article has demonstrated not only the importance of a PSC championing patients' voices but also its potential to bridge regulatory gaps. The impact this could have on improving patient safety should not be underestimated, particularly when it could improve the safety of the hospital discharge process for patients.

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Article Summary

Doctors, Decisions, and Discharges: Regulatory Accountability for Patient Safety in a Just Culture

Victoria L Moore

Leaving hospital is a dangerous time for patients. Within the English NHS, bed shortages have resulted in doctors being asked by NHS managers to discharge patients quickly, even where to do so is against a doctor's clinical judgement. This is potentially problematic for doctors who, according to their regulator, are personally accountable and must be prepared to justify their decisions and actions. Taking this situation as its focus, this article argues that the regulator's concept of accountability impedes its aim of fostering a just culture within healthcare. Given that a just culture is integral to ensuring patient safety, it is vital that this accountability problem is addressed. Three possible regulatory actions are presented to address this particular issue; it is anticipated that the recommended action could improve patient safety across the healthcare system.

Doctors, Decisions, and Discharges: Regulatory Accountability for Patient Safety in a Just Culture

Victoria L Moore

Introduction

At the start of 2020, *The Guardian* reported that the Royal Cornwall Hospitals NHS Trust (RCH NHS Trust) sent a memo to staff asking them to discharge patients in order to reduce severe overcrowding, even if it was against their clinical judgement to do so.[1] It accepted that in some instances this could result in harm to patients. The Doctors' Association called the request, 'morally repugnant and against the very fibre of what doctors stand for'.[2] Commenting in the *British Medical Journal*, Oliver noted the importance of maintaining patient flow through beds in order to minimise internal delays and improve processes, but queried where such requests from senior NHS managers leave doctors in the eyes of their regulator, the General Medical Council (GMC).[3] He remarked, 'we're entering dangerous territory when the professional clinical judgment of medics who have assessed and spoken to patients and their families, and who are personally accountable for decisions and consequences, is over-ridden, or when they're heavily pressured to act outside their comfort zone'.[4] Prior to the RCH NHS Trust memo being sent, Norfolk and Norwich hospital also faced severe bed shortages and informed senior doctors to make the 'least unsafe decision' in providing care, saying it would support doctors to do so.[5] At the time of the RCH NHS Trust incident, COVID-19 had not taken hold within England, which is to say that the severe bed-shortages were not occurring as a result of the pandemic, but were a reflection of the status quo within England's National Health Service (NHS). In November 2019, the number of hospital beds in the NHS had already fallen to its lowest level ever, despite the British Medical Association (BMA) having warned the previous year that an additional 10,000 beds were needed to provide safe care for patients.[6] The number

1 'Cornwall hospital to discharge patients early despite saying it may be harmful' (*The Guardian*, 14 January 2020) available at https://www.theguardian.com/society/2020/jan/14/cornwall-hospital-to-discharge-patients-early-despite-risks.

2 *Ibid*.

3 D Oliver, 'The risks of discharging patients early against doctors' judgment' (2020) *British Medical Journal* 368.

4 *Ibid*.

5 'Doctors told to use "least unsafe" option in Norwich hospital' (*The Guardian*, 20 December 2019) available at https://www.theguardian.com/society/2019/dec/20/doctors-told-to-use-least-unsafe-option-in-norwich-hospital.

6 'Hospital beds at record low in England as NHS struggles with demand' (*The Guardian*, 25 November 2019) available at https://www.theguardian.com/politics/2019/nov/25/hospital-beds-at-record-low-in-england-as-nhs-struggles-with-demand.

of beds in general and acute hospitals fell from 110,568 in April-June 2010, to 100,406 in April–June 2019.[7]

Discharging patients safely can be a complex process, and the risks it poses to patients have been repeatedly highlighted.[8] Common problems involve: discharging patients without appropriate care arrangements in place; discharging patients without involving them/their carers in the decision-making; and a lack of coordination across services.[9] In 2017/18 Healthwatch England (HE) highlighted that emergency readmission rates within 30 days of discharge had been steadily increasing over the previous five years, raising questions around the appropriateness of some discharge decisions and the subsequent support provided to patients.[10] HE further highlighted that the healthcare sector was unable to report on how many of the emergency readmissions were genuinely unavoidable, and how many could have been prevented.[11] The Care Quality Commission's (CQC) 2018 annual adult inpatient survey report also flagged hospital discharge planning as an area for improvement.[12] In 2019, the same annual survey showed 'continuing patterns of decline' regarding care coordination at discharge.[13] This result was 'lower than where [the CQC] would expect, based on past data, the fourth consecutive year'[14].

As the COVID-19 pandemic took hold in England, a drive to create spaces in hospital for the anticipated influx of patients accelerated discharges from hospital. Guidance issued by the government and NHS England stated that patients should be discharged when they are 'medically optimised', a lower threshold than 'medically fit'.[15] The move reportedly freed up tens of thousands of beds in preparation for acute COVID-19 admissions, prompting the Royal College of Nursing and the Queen's Nursing Institute (a charity for community nursing), to highlight the enormous pressure that the discharges put upon community care.[16] The drive to free up acute bed spaces also saw patients who had tested positive for the virus discharged into care homes, despite evidence that the policy was fuelling outbreaks of the virus and deaths in care homes.[17] The pressure doctors are under to discharge patients is likely to increase once more as the UK healthcare system addresses the second wave of the COVID-19 pandemic and tries to maintain other essential services.[18]

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7 *Ibid*.

8 See for example: *Home to the Unknown: Getting hospital discharge right* (British Red Cross, 2019); *What do the numbers say about emergency readmissions to hospital?* (Healthwatch England, 2017), A report of investigations Into Unsafe Discharge from Hospital (PHSO, 2016); and Fifth Report from the Public Administration and Constitutional Affairs Committee HC 97 (2016–17).

9 Fifth Report from the Public Administration and Constitutional Affairs Committee HC 97 (2016–17).

10 Healthwatch England, *supra* n 8.

11 *Emergency Readmissions: What's Changed One Year On?* (Healthwatch England, 2018).

12 *2018 Adult Inpatient Survey: Statistical release* (CQC, 2019).

13 *2019 Adult Inpatient Survey: Statistical release* (CQC, 2020) p 54.

14 *Ibid* p 50.

15 HM Government & NHS England, 'COVID-19 Hospital Discharge Service Requirements' (2020), at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/880288/COVID-19_hospital_discharge_service_requirements.pdf.

16 S Brennan, 'Community nursing will "blow" as discharge threshold is reduced' (2020) *Health Service Journal*.

17 'Discharging coronavirus patients into care homes is "madness", Government told' (*The Telegraph*, 15 April 2020) available at https://www.telegraph.co.uk/news/2020/04/15/discharging-coronavirus-patients-care-homes-madness-government/.

18 'Delays in discharging patients adds pressure on hospitals amid coronavirus second wave' (*Independent*, 30 October 2020) located at https://www.independent.co.uk/news/health/coronavirus-discharge-delays-hospitals-social-care-nhs-england-b1423773.html.

That doctors are being pressured to make decisions which will expose patients to a recognised risk of harm is an issue that warrants close scrutiny. First, it is potentially problematic for doctors who, according to the GMC, are personally accountable for their professional practice and must be prepared to justify their decisions and actions. Secondly, it highlights a concern with the regulator's concept of accountability which impedes its aim of fostering a just culture within healthcare – that is to say, a culture which balances fairness, justice and learning.[19] The GMC has acknowledged that doctors need to feel they are part of a just culture when things go wrong, and that as a regulator, it has a crucial role in achieving a just culture in healthcare.[20] Section one of this article examines the GMC's regulatory expectations and procedures, and demonstrates why these are concerning to doctors who are pressured to discharge patients. It is argued that a root cause of this concern is the regulator's lack of clarity regarding accountability. Section two explores how the GMC's vague concept of accountability hinders its aim of fostering a just culture within healthcare. Section three argues that a just culture is integral to ensuring patient safety; it is therefore vital that this accountability problem is addressed to ensure patient safety at the point of discharge. Three possible regulatory actions are presented to address this particular issue. It is anticipated that the action which is recommended would improve patient safety across the healthcare system.

I. Professional standards and fitness to practise

The GMC is responsible for regulating doctors who work in the UK; its overarching purpose is to protect the public.[21] As part of this role, the GMC sets the standards doctors need to follow throughout their careers and takes action to prevent a doctor from putting the safety of patients, or the public's confidence in doctors, at risk.[22] The professional standards set by the GMC are stated within its core guidance, *Good Medical Practice (GMP)*, and 32 pieces of explanatory guidance. Although serious or persistent failure to follow GMC guidance will put a doctor's registration at risk,[23] there is no automatic link between a failure to follow the guidance and action against a doctor's registration. The regulator states this is because the guidance sets out the principles of good practice, and not thresholds for taking action to protect the public.[24] The guidance is developed with the input of patients, doctors, lawyers, regulators, employers, and educators and undergoes public consultation.[25] Given this collaborative approach, it can be reasonably assumed that the guidance reflects society's expectations of doctors. Metcalf identifies several outward facing goals of such professional standards, including amongst others: the protection of

19 S Dekker, *Just Culture: Balancing Safety and Accountability* (Florida, CRC Press, 2012); *Being Fair: Supporting a just and learning culture for staff and patients following incidents in the NHS* (NHS Resolution, 2019).

20 GMC, 'GMC statement following the publication of the independent review of gross negligence manslaughter and culpable homicide in medical practice' available at https://www.gmc-uk.org/news/news-archive/gnm-statement (accessed 17 July 2020).

21 Medical Act 1983, s 1(1A).

22 GMC, 'What we do and why' https://www.gmc-uk.org/about/what-we-do-and-why (accessed 1 December 2020).

23 *Good Medical Practice* (GMC, 2013).

24 *Sanctions Guidance* (GMC & MPTS, 2019).

25 GMC, 'Ethical guidance' https://www.gmc-uk.org/ethical-guidance (accessed 15 July 2020).

vulnerable populations who could be harmed by the profession's activities; the protection/enhancement of the good reputation of and trust for the profession; and to act as a basis for public expectations and evaluation of the profession.[26]

The GMC's '*Sanctions Guidance*'[27] tries to further clarify the link between setting standards for doctors and taking action when a doctor's fitness to practise is called into question because they have not met the standards. It says that action is taken where a serious or persistent breach of the guidance has put patient safety at risk or undermined public confidence in doctors. Moreover the purpose of any action taken is to protect the public by helping to make sure doctors on the register provide safe care and uphold public confidence in doctors; actions are not intended to punish or discipline doctors for past events.[28] This purpose is not necessarily common knowledge; research commissioned by the GMC into the motivations of complainants revealed that in some instances, complainants did so out of desire for the doctor to be punished.[29]

GMC fitness to practice (FtP) procedures consist of two stages: investigation and adjudication. The investigation stage is where cases are investigated and a decision made regarding whether to refer the case to the Medical Practitioners Tribunal Service (MPTS) for adjudication. Investigations commence when a concern raised about a doctor potentially raises questions about the doctor's current fitness to practise. Investigations are of varying length depending on the complexity of the concerns, and involve gathering information such as documentary evidence from the complainant, or expert reports on clinical matters. At the end of the investigation, two case examiners (one medical and one non-medical) determine whether further action is needed or if the case can be closed. Further action includes issuing a warning, or referring the case to the MPTS for a hearing.[30]

The professional standards guidance clearly informs doctors, 'you are personally accountable for your professional practice and must always be prepared to justify your decisions and actions'.[31] As Oliver has highlighted, this is a cause of concern amongst doctors who feel pressurised to discharge patients from hospital against their clinical judgement.[32] Oliver raised this query with the GMC and reports their response to him as, 'We always consider a concern raised with [us] on the specific facts of the case, taking into account the factors relevant to the environment in which the doctor is working'.[33] He opines that this response provides little reassurance. Oliver's views are reflective of the medical profession's lack of confidence in the regulator to be fair when investigating concerns raised about a doctor. This lack of confidence, worsened by the regulator's decision[34] to

26 J Metcalf, 'Ethics Codes: History, Context, and Challenges' (2014) available at https://bdes.datasociety.net/council-output/ethics-codes-history-context-and-challenges/.

27 *Sanctions Guidance* (GMC & MPTS, 2019).

28 *Ibid*.

29 *Why do many public concerns that would be better directed to another organisation come to the GMC? (*ICE, 2019).

30 GMC, 'The GMC's fitness to practise procedures' available at https://www.gmc-uk.org/-/media/documents/DC4541_The_GMC_s_Fitness_to_Practise_procedures.pdf_25416512.pdf.

31 GMC, *supra* n 23, under Duties of a Doctor.

32 Oliver, *supra* n 3.

33 *Ibid*.

34 In recognition of the pressurised system that Bawa-Garba was working in, the tribunal initially imposed a period of suspension rather than erasure. This decision was overturned by the Divisional Court, and substituted with a sanction of erasure. Bawa-Garba won her appeal.

seek the erasure of Dr Bawa-Garba from the medical register after a criminal conviction for gross negligence manslaughter (GNM),[35] was central to the GMC's commissioning of an independent review into GNM and culpable homicide.[36] The review found the GMC's decision had caused widespread consternation and outrage across the medical profession, with many doctors asking why the individual trainee, working in a system under pressure, should be blamed for what they perceived to be broader systemic failings.[37]

As stated by the GMC above, if a concern were raised regarding a doctor's decision to discharge a patient in the circumstances such as those that occurred in the RCH NHS Trust, then the actions that the GMC would take would depend upon the specific facts of the case. It can be surmised that relevant factors for consideration may entail how the doctor acted with regard to the professional standards. In *GMP* doctors are told they must give priority to patients based on their clinical need,[38] and must raise concerns if 'inadequate resources' prevent them from doing this. In a separate piece of explanatory guidance, '*Leadership and management for all doctors*', the term 'limits on resources' is used; it is stated that the treatment options that can be offered to patients may be affected by limits on resources.[39] Thus, the professional guidance draws a distinction between a 'limit on resources' and 'inadequate resources'. Where resources are limited, doctors must provide the best service possible within the resources available, taking account of their responsibilities towards their patients and the wider population. They must make sure decisions affecting patients are fair and based on clinical need, and not on factors that risk introducing discriminatory access to care. They must also be open and honest with patients about the decision-making process.[40] By contrast, where resources are inadequate, doctors must raise concerns, and additional explanatory guidance provides details on how they should do this.[41]

No definition is provided within the guidance for what constitutes 'inadequate' and what is 'limited'. However, the COVID-19 pandemic provides an example of the GMC differentiating between the two. Within the pandemic context, the GMC's additional advice to doctors stated that in cases where more than one patient has a life-threatening condition that can be treated at once, doctors are expected to: take account of local and national policies setting out agreed criteria for access to treatment; be confident that decisions are based on clinical need and the likely effectiveness of treatments, and not unfairly discriminate against particular groups; take patients' wishes and expectations into account when considering treatment options; be open and honest with patients about the decision-making process; and to record their decisions and the reasons for them. It continued that ideally the decision-making would not simply be down to an individual doctor, but would take place following discussions with colleagues, and concluded that, 'the primary requirement for all doctors is to respond responsibly and reasonably to the circumstances they face'.[42] This is reflective of the GMC's non-pandemic guidance on

35 D Cohen, 'Back to blame: the Bawa-Garba case and the patient safety agenda' (2017) *British Medical Journal* 359.
36 *Independent Review of Gross Negligence Manslaughter and Culpable Homicide* (GMC, 2019).
37 *Ibid*.
38 GMC, *supra* n 23 at para 56.
39 *Leadership and management for all doctors* (GMC, 2012) para 84.
40 *Ibid* para 85.
41 *Raising and acting on concerns about patient safety* (GMC, 2012).
42 GMC, 'Coronavirus: Your frequently asked questions: Decision making and consent' available at https://www.gmc-uk.org/ethical-guidance/ethical-hub/covid-19-questions-and-answers#Decision-making-and-consent (accessed 1 December 2020).

limited resources. By contrast, in commenting on whether doctors could refuse to see patients if they have inappropriate personal protective equipment (PPE) in the pandemic, the GMC stated that doctors should raise their concerns about inadequate PPE with their employer, and make a record of how they have handled their safety concern.[43] This is in line with its non-pandemic guidance on raising concerns.[44] In both instances the GMC sought to reassure doctors that if they received a complaint about an individual, the circumstances would be considered on the specific facts of the case, taking into account the situation in which the doctor is working and any relevant protocols.[45]

In attempting to discern the difference between a limited and inadequate resource in the above example, one noticeable difference is that inadequate PPE is defined as that which falls below the standard set in the most recent guidance issued by the four UK health departments.[46] This indicates that there is a recognised threshold for safe practice, below which something is inadequate. A rationale for why a shortage of some resources, such as life-saving treatments, is seen as limited rather than inadequate is not provided, rendering it unclear why a doctor should raise concerns about a lack of PPE but not a lack of hospital resources.

Turning to the pre-pandemic context, the BMA's assertion that an additional 10,000 beds are needed to provide safe care for patients[47] certainly suggests that this is an inadequate resource. However, in *University College London Hospitals NHS Foundation Trust v MB*,[48] the judge declared in-patient care is a 'scarce resource',[49] which could perhaps indicate that a hospital bed is to be seen as a limited resource rather an inadequate one. It is therefore unclear whether doctors are expected to raise concerns about the shortage of hospital beds if it results in patients being unsafely discharged, or whether they must simply do what they can in the circumstances. Once again, this point of confusion is unlikely to be reassuring to doctors who already lack confidence in the regulator.

This section has explored the relationship between professional standards and fitness to practice procedures. It has shown that a failure to follow professional standards does not automatically result in fitness to practise proceedings, but concerns that are raised about an individual doctor would trigger an investigation, which would be considered on the specifics of that case and could in theory lead to professional sanctions. It is therefore not possible to predict what the outcome of any hypothetical case would be. However, even the investigation process itself can be extremely stressful for doctors, to the extent that in 2014 the GMC commissioned a review of its cases in which doctors had committed suicide whilst undergoing fitness to practise procedures.[50] It is understandable that doctors are concerned about being held accountable by their regulator for discharge decisions they feel forced to make, and which may be contrary to their clinical judgement. In light of this understandable concern, this article will now explore what it means to be accountable for one's actions, before examining how the GMC conceptualises accountability.

43 *Ibid*.
44 GMC *supra* n 41.
45 GMC, 'How we will continue to regulate in light of novel coronavirus (Covid-19)' available at https://www.gmc-uk.org/news/news-archive/how-we-will-continue-to-regulate-in-light-of-novel-coronavirus (accessed 15 July 2019).
46 GMC, 'Coronavirus: Your frequently asked questions: Working safely' available at https://www.gmc-uk.org/ethical-guidance/ethical-hub/covid-19-questions-and-answers#Working-safely (accessed 1 December 2020).
47 The Guardian, *supra* n 6.
48 *University College London Hospitals NHS Foundation Trust v MB* [2020] 882 (QB).
49 *Ibid* [55].
50 GMC, *Doctors who commit suicide while under GMC fitness to practise investigation* (2014).

II. Defining accountability

Bovens states that the most concise description of accountability is 'the obligation to explain and justify conduct',[51] an essence echoed throughout regulatory literature.[52] He further defines accountability as being a relationship between an actor and a 'forum' (the organisation or individual which holds the actor to account), in which the actor is obliged to explain and justify their conduct, and the forum may ask questions and pass judgement, following which the actor may face consequences.[53] The term 'facing consequences' is used in recognition that forums might also positively judge an actor's conduct and reward them for it.[54] There are three core features of account-giving: the actor is obliged to inform the forum about their conduct; the forum must be able to question the actor; and the forum must be able to pass judgement upon the conduct, and in the case of a negative judgement, be able to impose sanctions upon the actor.[55] Bovens, stating his agreement with Mulgan[56] and Strom,[57] argues that the possibility of sanctions is a necessary feature of an accountability relationship for it is the difference between non-committal information provision and being held to account.[58]

According to Sharpe, accountability is central to patient safety as it guides expectations and judgements pertaining to the performance of health care providers.[59] She argues that the notion of individual accountability which underpins medicine and the law needs reinventing in light of a challenge posed to the conventional story of medical error. This conventional story is that harm is the result of an individual's actions, for example a failure to read a drug label properly.[60] However, this notion has been challenged by human factors research, which seeks to understand the interaction between humans and the systems they work in. Human factors research demonstrates that human error is rarely the sole cause of harm, and should instead be understood as the result of complex interaction between people and their environment.[61] This complexity is highly prevalent during hospital discharges as they can involve multiple, interdependent health and social care professionals working both within and across different organisations.[62] For example, doctors, nurses, community nurses, occupational therapists, and social workers may all be involved in the discharge planning of patients who have experienced a stroke, and will be navigating challenges

51 M Bovens, 'Analysing and Assessing Accountability: A Conceptual Framework' (2007) 13 *European Law Journal* 450.

52 S Banks, 'Negotiating Personal Engagement and Professional Accountability: Professional Wisdom and Ethics Work' (2013) 16 *European Journal of Social Work* 587–604; D Brinkerhoff, 'Accountability and Health Systems: Toward Conceptual Clarity and Policy Relevance' (2004) 19 *Health Policy and Planning* 371–379; A Freeman et al, '"Health Professionals" Enactment of Their Accountability Obligations: Doing the Best They Can' (2009) 29 *Social Science and Medicine* 1063–1071; M Lodge, 'Accountability and Transparency in Regulation: Critiques, Doctrines and Instruments' in J Jordana, D Levi-Faur (eds), *The Politics of Regulation* (Cheltenham, CRC Press, 2004).

53 Bovens, *supra* n 51.

54 *Ibid*.

55 *Ibid*.

56 R Mulgan, *Holding Power to Account: Accountability in Modern Democracies* (Basingstoke, Palgrave Macmillan, 2003).

57 K Strom, 'Parliamentary Democracy and Delegation' in K Strom et al (eds), *Delegation and Accountability in Parliamentary Democracies* (Oxford, OUP, 2003).

58 Bovens, *supra* n 51.

59 V Sharpe, 'Promoting patient safety: An ethical basis for policy deliberation' *Hastings Center Report* (2003).

60 *Ibid*.

61 *Ibid*.

62 J Waring, F Marshall, & S Bishop, 'Understanding the occupational and organizational boundaries to safe hospital discharge' (2015) 20 *Journal of Health Services Research and Policy* 35–44.

such as resource constraints, organisational pressures, and the ordering of equipment and medicines.[63] A common safety issue in these circumstances is a patient falling at home, post-discharge, due to a lack of equipment or support.

If we accept that the harm patients experience may not be due simply to an individual clinician's actions, then we must acknowledge that it may not always be fair for a forum (in this context, the GMC) to hold that individual to account and impose sanctions for their role in the incident. This recognition is partially responsible for leading us to the recent, noticeable drive to create a just culture in healthcare, one which balances fairness, justice and learning[64] with the aim of improving patient safety. As mentioned above, the GMC recognises that doctors need to feel part of a just culture when things go wrong, and that as a regulator, it plays a crucial role in achieving this.[65] Moreover, NHS England and NHS Improvement's *Patient Safety Strategy*[66] calls for local systems to develop and maintain a just culture, and recommends the adoption of NHS Improvement's *Just Culture Guide*.[67] NHS Resolution, the body which handles negligence claims, also calls for a just culture. Its publication, *Being Fair: Supporting a just and learning culture for staff and patients following incidents in the NHS*,[68] draws heavily on Dekker's research into what constitutes a just culture.[69] The publication defines a just culture as 'the balance of fairness, justice, learning – and taking responsibility for actions. It is not about seeking to blame the individuals involved when care in the NHS goes wrong. It is also not about an absence of responsibility and accountability'.[70] When dissected, it becomes clear that the term accountability is used within these documents without a full and comprehensive discussion of its meaning. Ultimately this leads to a lack of clarity and understanding in discussions about who or what is to be held accountable.

Despite the important role of accountability in establishing a just culture, the *Patient Safety Strategy* fails to define accountability,[71] and the concept is neither referred to nor defined within the *Just Culture Guide*.[72] NHS Resolution's publication aims to define accountability; however, the attempt lacks clarity. In one example, it states that accountability is about, 'sharing what happened, working out why it happened, and learning and being responsible for making changes for the future safety of staff and patients'.[73] However, it also states that although an individual's actions should be understood prior to being judged and people should be supported to learn from them, this does not mean an absence of

63 J Waring, S Bishop & F Marshall, 'A Qualitative Study of Professional and Carer Perceptions of the Threats to Safe Hospital Discharge for Stroke and Hip Fracture Patients in the English National Health Service' (2016) 16 *BMC Health Services Research* 1–14.

64 Dekker, *supra* n 19; NHS Resolution, *supra* n 19.

65 GMC, 'GMC statement following the publication of the independent review of gross negligence manslaughter and culpable homicide in medical practice' available at https://www.gmc-uk.org/news/news-archive/gnm-statement (accessed 17 July 2020).

66 *The NHS Patient Safety Strategy: Safer Culture, Safer Systems, Safer Patients* (NHS England and NHS Improvement, 2019).

67 'A Just Culture Guide', (NHS England and NHS Improvement, 2018) located at https://improvement.nhs.uk/resources/just-culture-guide/.

68 NHS Resolution, *supra* n 19.

69 Dekker, *supra* n 19.

70 NHS Resolution, *supra* n 19.

71 *The NHS Patient Safety Strategy: Safer Culture, Safer Systems, Safer Patients* (NHS England and NHS Improvement, 2019).

72 NHS England and NHS Improvement, *supra* n 66.

73 NHS Resolution, *supra* n 19.

accountability. For in cases where a person does carry out an intentional act of harm, they should be dealt with responsibly and referred to external bodies, for example the relevant professional regulator.[74] The two different functions of accountability at play here – it is both a tool to aid learning, and to punish an individual – can be explained by Sharpe's account of forward-looking and backward-looking accountability.[75]

Backward-looking accountability is retrospective and often involves blaming somebody when something has gone wrong[76] (Bovens' definition of accountability above is an example of this). Sharpe argues that accountability can also be forward-looking, which is prospective, and tied in to goal-setting and moral deliberation.[77] Although the former concept is the more familiar within healthcare, Sharpe argues that the latter concept is vital to establishing a just, safe culture. This notion is what is captured within NHS Resolution's definition above.[78] Forward-looking accountability involves creating a work culture where it is safe to discuss errors and analyse them, to speak up about potential safety problems, and to implement steps to prevent safety incidents from recurrence.[79]

This is what a just culture aims to achieve. Within a just culture, people are able to be open about their mistakes, or to raise their safety concerns, without fear of being unfairly blamed. Dekker argues that a just organisation is a safe one; by contrast, unjust organisations are unsafe ones, as the fear of repercussions prevents individuals from speaking up.[80] Within healthcare, the inquiry into the scandal involving children's heart surgery at Bristol Royal Infirmary provided evidence of the important role that culture plays in ensuring patient safety. It highlighted that the NHS was failing to learn from its mistakes, and that the dominant blame culture was a major barrier to openness and learning.[81] The 2015 public inquiry into whistleblowing in the NHS, triggered by earlier findings of the Mid Staffordshire NHS Foundation Trust Public Inquiry[82], echoed this.[83] The whistleblowing inquiry (*Freedom to Speak Up*) focused upon the treatment of NHS staff who raised safety concerns. Its survey highlighted that 18 per cent of staff who had not raised a safety concern had chosen not to due to a lack of trust in the system, and 15 per cent feared victimisation. It noted that 'each time someone is deterred from speaking up, an opportunity to improve patient safety is missed'.[84] Failing to address safety concerns and learn from mistakes increases the likelihood of their recurrence, and may result in avoidable harm to patients. The *Freedom to Speak Up* report recommended a move away from the historical 'blame culture' (where the concern is who is at fault), towards a just culture within the NHS, where people are encouraged to speak up about safety concerns and know the difference between acceptable and unacceptable behaviour.[85]

74 *Ibid*.
75 Sharpe, *supra* n 59.
76 *Ibid*.
77 Sharpe, *supra* n 59.
78 NHS Resolution, *supra* n 19.
79 Sharpe, *supra* n 59.
80 Dekker, *supra* n 19.
81 I Kennedy, 'The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984–1995' (cm 5207).
82 The inquiry, led by Robert Francis QC, was established to determine why serious failures in care at Mid-Staffordshire NHS Foundation Trust prior to 2009 were not acted on sooner by those responsible.
83 R Francis, 'Freedom to Speak up: an independent review into creating an open and honest reporting culture in the NHS' (2015).
84 *Ibid* at 5.
85 *Ibid*.

A no blame culture, which entails no blame being apportioned to an individual when safety incidents occur, was also considered in the report as a potential way forward. A no blame culture had been popular in other safety-critical industries, such as aviation and nuclear power. Two justifications for this were that error-prevention is dependent upon people speaking up about safety incidents without fear of personal consequences, and that an act cannot be blameworthy if it was unintentional.[86] The *Freedom to Speak Up* report chose not to recommend a no blame culture as it concluded that such a culture risks failing to recognise that some actions and behaviours by individuals are simply unacceptable.[87] Examples of unacceptable behaviours might be where a clinician deliberately chooses to harm their patient, or to falsify medical records.

Within a just culture, there is a role for both backward-looking accountability and forward-looking accountability. Generally, backward-looking accountability is reserved for instances where individuals act with the intent to cause harm, whereas forward-looking accountability enables lessons to be learned from safety incidents, and improvements to be made to reduce the risk of errors being repeated. In some circumstances, forward-looking accountability may be perceived (or indeed experienced) as backward-looking accountability. For example, as part of its remit, the GMC investigates cases where a registrant's fitness to practise is alleged to be impaired by reason of deficient professional performance. Where this results in sanctions being imposed upon the registrant, it may be perceived by the doctor to be an instance of backward-looking accountability. However, sanctions in these cases, such as conditions,[88] have a remedial aim intended to support the doctor's safe return to unrestricted practice. This aim is cohesive with the concept of forward-looking accountability.

The concept of forward-looking accountability does not require sanctions to be imposed upon the healthcare system when learning from error does not take place (or when improvements are not made). This is potentially problematic. Consider, for example, Prevention of Future Death (PFD) Reports. Under the Coroners and Justice Act 2009 (para 7/sch 5), coroners have a duty to make these reports to prevent further deaths (also known as 'Regulation 28 Reports'). These must be sent to the Chief Coroner and other interested parties who, in the coroner's opinion, should receive it. Recipients must respond detailing any action that has been/will be taken to address the concerns, alongside a timetable. If no action is to be taken, they must explain the reason for this. The response to the coroner must be sent within 56 days and the coroner must then send a copy to the Chief Coroner and other interested parties.[89] In principle, these reports ought to function as a tool for learning from deaths, and preventing future deaths; as such they can be seen as a mechanism for enacting forward-looking accountability. However, neither the coroner nor any other regulatory organisation has a legal responsibility to enforce recommendations in PFD reports, or to apply sanctions when they are not acted upon.

86 Sharpe, *supra* n 59.

87 R Francis, 'Freedom to Speak up: an independent review into creating an open and honest reporting culture in the NHS' (2015).

88 According to paragraph 80 of the *Sanctions Guidance* (GMC & MPTS, 2019), 'In many cases, the purpose of conditions is to help the doctor to deal with their health issues and/or remedy any deficiencies in their practice or knowledge of English, while protecting the public. In such circumstances, conditions might include requirements to work under supervision'.

89 The Coroners (Investigations) Regulations 2013, reg 29.

Unfortunately, research by Ferner et al, which analysed responses to coroners in relation to drug safety, found that in spite of the recognition that learning from error improves patient safety, responses were often unpublished, and many organisations were reluctant to share their responses when asked through a freedom of information request. The researchers concluded, 'there appears to be no system for auditing concerns and responses to them. So, it is difficult to know whether – with regards to medicines – the coronial system prevents future death'.[90] Within the context of hospital discharges, a brief perusal of PFD reports and their responses indicates that findings do not encourage learning from deaths as much as they perhaps could. For example, in April 2014 Brighton and Sussex University Hospital NHS Trust received a PFD report concerning the death of an elderly patient. The coroner's report raised as a matter of concern that the discharge procedure was 'deeply flawed … there was no ongoing process of discharge … the discharge paperwork was effectively blank … there was no communication either with regard to the anticipated date of discharge or with the Nursing Home who were expected to receive him back'.[91] In August 2015, the same Trust received a PFD report expressing concern that, regarding the death of another elderly patient, there had been 'very little evidence of any joined up thinking with regard to her care or to plans, either for her future treatment, or for her future placement, or for discharge'.[92] In October 2016, a further PFD report was sent to the same Trust concerning the death of another elderly patient. One of the coroner's matters of concern was that the 'Hospital's own Discharge Protocol was not followed'.[93] These examples indicate that without any enforceability mechanisms in place, the healthcare system cannot be relied upon to fulfil its learning responsibilities under the concept of forward-looking accountability.

This section has explored how accountability is conceptualised within healthcare and wider regulatory literature. It has examined how accountability, particularly forward-looking accountability, is perceived to be an important component of establishing a just culture within healthcare. This is because within a just culture, healthcare professionals are encouraged to speak up about any risks to patient safety, or adverse events, and learning can take place and steps be implemented to prevent recurrence of error. This section has also highlighted that an ability to enforce sanctions may still be necessary to ensure the healthcare system prioritises learning from error. The next section will consider how the GMC conceptualises accountability, and whether this is cohesive with its aim of fostering a just culture. It will then consider three different regulatory actions which the GMC could take in cases where doctors are asked by managers to discharge patients against their clinical judgement to reduce severe overcrowding.

III. Accountability and the GMC

The regulator's conceptualisation of accountability becomes important in establishing a just culture precisely because the GMC states within its professional standards that doctors

90 R. Ferner et al, 'Preventing Future Deaths from Medicines: Responses to Coroners' Concerns in England and Wales' (2019) 42 *Drug Safety* 445–451.

91 'Prevention of Future Deaths: Graham Watts' available at https://www.judiciary.uk/publications/graham-watts/ accessed 14 July 2020.

92 'Prevention of Future Deaths: Thelma Jones' available at https://www.judiciary.uk/publications/thelma-jones/ accessed 14 July 2020.

93 'Prevention of Future Deaths: Leslie Lerner' available at https://www.judiciary.uk/publications/leslie-lerner/ accessed 14 July 2020.

are personally accountable for their professional practice. Within the GMC's professional standards, the term accountability is undefined; however, the standards function as a mechanism through which the GMC can hold doctors accountable. This is because they are a benchmark against which an individual's conduct can be judged, and serious or persistent failure to follow them can result in regulatory action.[94] This functioning is indicative of backward-looking accountability.

That professional standards are centred upon the notion of backward-looking accountability is further supported by the emerging discourse surrounding a just culture in the NHS. NHS Resolution[95] states that where actions result in unintentional harm, the individual should be supported to learn from them, and asked for their help and advice to design a safer system – which is consistent with forward-looking accountability. However, it then claims that this does not mean an absence of accountability, and that if someone does do an intentional act of harm, they should be dealt with responsibly which may include referral to the relevant professional regulator. The *Just Culture Guide*[96] also acknowledges that singling out an individual is not usually appropriate as the majority of patient safety issues are due to complex causes and so require wider action. However, in cases where an individual has shown deliberate intent to cause harm, the guide suggests that appropriate action may include contacting regulatory bodies. Thus, it becomes apparent that professional regulators, such as the GMC, are seen to be primarily concerned with backward-looking concepts of accountability, which necessarily focus upon the actions of an individual. There is an obvious and justifiable role for the regulator's backwards-looking accountability within a just culture – for example protecting the public from rogue doctors, such as Shipman.[97]

Goodwin observes that the concept of doctors' professional accountability within the professional standards is tied to notions of autonomous practice and independent thought, with decisions being characterised as 'discrete moments of cognition' which belong to an individual.[98] This is reflected in the current version of GMP; for example, doctors are personally accountable for their practice,[99] and are told that clinical records should include 'the decisions made and actions agreed, and who is making the decisions and agreeing the actions'.[100] Yet as Goodwin's ethnographic study of healthcare professionals demonstrates, clinical decision-making is intrinsically collaborative, and numerous participants may contribute towards it. She demonstrates how clinical decision-making can be a dynamic process amongst healthcare professionals that is responsive to the changing circumstances. Her primary concern is to illustrate how distributed decision-making within clinical practice is misaligned with models of practice embedded within the professional guidance; she argues that professional standards define work and allocate accountabilities in a way which is convenient for intervention by the regulator, but which is problematic when it comes to fairly attributing accountability.[101] She questions the appropriateness of

94 GMC, *supra* n 23, under Duties of a Doctor.
95 NHS Resolution, *supra* n 19.
96 NHS England and NHS Improvement, *supra* n 66.
97 J Smith, The Shipman Inquiry fifth report: Safeguarding patients: Lessons from the past – Proposals for the future (cm 6394).
98 D Goodwin, 'Decision-making and accountability: Differences of distribution' (2013) 36 *Sociology of Health and Illness* 44–59.
99 GMC, *supra* n 23, under Duties of a Doctor.
100 GMC, *supra* n 23, para 21b.
101 Goodwin, *supra* n 98.

professional standards that model decision-making as being autonomous, which risks accountability being disproportionally assigned to an individual when errors occur.[102] Underpinning Goodwin's analysis is the notion of backward-looking accountability, namely that being accountable means being at fault for one's decision-making and facing regulatory consequences. This assumption that the professional standards understand accountability to be backward-looking is present in Oliver's concerns about how the GMC would treat doctors who are pressured by management to discharge patients[103]; accountability can mean blame if things go wrong.

However, regarding its 'crucial role'[104] in fostering a just culture, the GMC adopts the discourse associated with forward-looking accountability. For example, the GMC fully accepted the recommendations from its independent review into gross negligence manslaughter; these included: considering how it can better support a profession under pressure alongside promoting a fair and just culture; ensuring that its investigation team has an understanding of human factors; and working with patients and the public to support better understanding of its role in regulating the medical profession within a system under pressure.[105] According to the GMC, the human factors training for investigators will provide doctors with assurance that 'their actions will be seen clearly against the backdrop of any system failings'.[106] Moreover, the role played by systems and workforces in serious failings will be fully and evenly evaluated.[107] It seems that the GMC is trying to embrace forward-looking accountability in addition to fulfilling its role in maintaining a relationship with the medical profession which is centred upon backward-looking accountability. Within the professional standards, we see the conception of a doctor as an autonomous decision-maker, who must always be prepared to justify their decisions and actions.[108] Yet regarding investigation procedures, we see recognition of the doctor as entangled within a wider web, where decisions are influenced by other healthcare professionals and system pressures. The shortage of hospital beds which led to doctors being asked by management to quickly discharge patients is a potential patient safety issue resulting in part from the pressure of working in an under-resourced system. Given the lack of clarity surrounding the GMC's use of accountability, it is no surprise that doctors are worried about the potential regulatory implications for themselves.

This section now examines three types of regulatory response which the GMC could take in cases where doctors are asked by managers to discharge patients against their clinical judgement to reduce severe overcrowding. The first response is for the GMC to do nothing, which appears to have been the course of action taken in the case identified at the start of this article. Although this option may seem appealing in that it avoids holding individual doctors accountable for decisions made in a healthcare system under pressure, it is not conducive to fostering a just culture. A just culture ought to be fair to both doctors and patients; and patients deserve more than an absence of deliberate harm – they deserve safe care.[109] Discharges from hospital are already internationally

102 *Ibid*.
103 Oliver, *supra* n 3.
104 GMC, *supra* n 65.
105 GMC, *supra* n 34, see recommendations 2, 15 and 22.
106 'Human factors training to be rolled out for investigators' (GMC, 2020) available at https://www.gmc-uk.org/news/news-archive/human-factors-training-to-be-rolled-out-for-investigators (accessed 15 July 2020).
107 *Ibid*.
108 GMC, *supra* n 23 at para 4.
109 J Titcombe, P Walsh & C Cunningham, 'A just culture for both staff and patients' (2019) *Health Service Journal*.

recognised as a dangerous time for patients,[110] and the likelihood of harm occurring when doctors are pressured to discharge patients against their clinical judgement can only increase. By doing nothing to address this pressure upon doctors, the GMC risks shirking its legal duty to protect the public, which raises questions about its own accountability for achieving its statutory aims.

The second regulatory response would be to hold doctors personally accountable, in the backward-looking sense of accountability, for their decision to discharge a patient if it is against their clinical judgement. Given the shortage of beds, the question doctors might have to answer is, why did they not speak up about the inadequate resources and the harm posed to patient safety, as directed in *GMP* and the *Raising concerns* guidance? This action may result if the GMC were to solely embrace backwards-looking accountability. However, the GMC appears to be indicating a desire to move towards a more supportive role of doctors, and claims to be 'reducing fitness to practise investigations and building more supportive programmes'.[111] To take what may be interpreted as a punitive response would therefore be counterproductive in achieving this goal, and do little to ensure the ongoing safety of patients as they leave hospital.

The third response open to the GMC, and the one that this article recommends, is taking clear action to foster a just culture within healthcare. The first step in doing this would be to state how it intends to safeguard accountability within a just culture. This involves providing conceptual clarity for the term accountability, and a coherent explanation as to how it encompasses backwards-looking accountability to ensure patient safety whilst simultaneously supporting forward-looking accountability. The latter involves recognising that where system pressures mean it is unjust to solely adopt a backwards-looking notion of accountability in holding doctors individually accountable, the GMC should call for improvements to the broader healthcare system (forward-looking accountability). In this instance, the regulator publicly drawing attention to the bed shortages and the potential impact that has on patient safety at discharge would be a powerful indicator that it is committed to both protecting patients and being fair to its registrants. A similar point has been made by Freeman et al,[112] who studied how occupational therapists in Ontario enacted their accountability obligations. The authors concluded that regulatory bodies may have a role to play in 'advocating for the development and implementation of the minimum resource conditions that permit professionals to provide quality practice'.[113] This course of action is preferable to the two alternatives discussed because it could aid the GMC to repair its relationship with the medical profession. Restoring the profession's lost trust in its regulator is paramount to creating a just culture in healthcare and ensuring patient safety, not only at the point of discharge but across healthcare.

Conclusion

This article has drawn attention to the risk of harm posed to patients at the point of discharge, and to the pressure that doctors have faced to discharge patients. A root cause

110 *Transitions of care: Technical series on safer primary care* (World Health Organisation, 2016); K Aase, J Waring, & L Schibevaag, *Researching Quality in Care Transitions: International Perspectives* (Ebook: Palgrave Macmillan, 2017).

111 GMC, 'Our History' available at https://www.gmc-uk.org/about/who-we-are/our-history (accessed 15 July 2020).

112 Freeman, *supra* n 52.

113 *Ibid* at 1069.

of doctors' fears and concerns about regulatory action in this context is the GMC's vague concept of accountability within its professional guidance and its wider communications. The regulator is seen to use both backward-looking and forward-looking constructions of accountability; the latter tied closely to its intentions to foster a just culture within healthcare. A just culture is central to ensuring patient safety, thus the GMC's intent to promote a just culture is appropriate. However, the GMC's lack of clarity regarding accountability impedes its achievement of this.

The article calls for the regulator to provide clarity concerning accountability, and to proactively highlight the dangers of an under resourced healthcare system – especially where it leads to unsafe discharges. Doing so would enable the GMC to earn the trust of its registrants and fulfil its role in protecting patients. Given the severe bed shortages within hospitals, it is critical that this action is taken immediately to prevent harm to patients, and to ensure just regulation in cases where harm occurs. It is time for the GMC to start following the standards it expects of doctors and raising concerns[114] about the system in which doctors are working.

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114 GMC, *supra* n 41, para 7.

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