patient safety learning

The application of Gross Negligence Manslaughter (GNM) in healthcare delivery

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Introduction

1. I make this submission as the father of Joshua Titcombe, who died at 9 days old in November 2008 because of negligent maternity care. After Joshua's death there have been several major inquires by different organisations, including a significant criminal investigation undertaken by Cumbria Police and a major independent investigation (the Morecambe Bay Investigation chaired by Dr Bill Kirkup), published in March 2015. Joshua's death has also led to several Fitness to Practise hearings carried out by the Nursing and Midwifery Council (NMC) several years after his death, including 2 cases where midwives have been removed from the NMC register.

2. I have now joined Patient Safety Learning[1]. We are a small but ambitious organisation and are submitting an application to become a charity. Our aim is to work with others to ensure that patients receive safe healthcare and healthcare organisations have effective systems for sharing patient safety learning and improvement strategies.

3. The submission is both a personal submission and on behalf of Patient Safety Learning.

The case of Dr Bawa-Garba

4. The terms of reference for this review are clear that the focus is not the 'specifics of any particular case'. However, it has been commissioned in the wake of the high-profile case of Dr Bawa-Garba. This case has been extensively reported in the national media and has been subject to considerable debate and concern amongst healthcare professionals, patients and the public.

5. First and foremost, my thoughts and condolences go to the parents of Jack Adcock whose potentially avoidable death is at the centre of this case. In recent years there has been an increased recognition that the way healthcare organisations and the wider system often respond to patient harm can compound the grief and suffering bereaved families endure. It

[1] www.patientsafetylearning.org

is evident that Jack's family has been through many investigative processes carried out by multiple organisations with outcomes and judgements that have at times conflicted.

6. This submission will not comment on the details of the Bawa-Garba case, but I make the following observations.

a. The response to the Bawa-Garba case from parts of the medical profession demonstrates that the current system of professional regulation for doctors (the GMC) and the application of GNM through the criminal courts is not currently universally trusted.

b. Any lack of transparency and trust relating to the systems and processes to which healthcare professionals are subject following a patient safety events or incident is a barrier to creating a culture that best supports learning.

c. The case serves to highlight the broken and fragmented systems of responsibility and accountability that exist in the NHS, particularly the dissonance between the focus on individual accountability/blame for specific acts/omissions and the responsibility of healthcare leaders, managers, commissioners and policy makers to ensure that healthcare professionals are supported by appropriate resources, processes and systems to deliver clinical care safely.

Regulating for safety - The Health and Safety at Work Act 1974 (HSWA)

7. Other safety critical sectors in the UK that have made great strides in reducing avoidable harm (for example the engineering construction industry) are subject to regulation from the Health and Safety Executive (HSE) under the Health and Safety at Work 1974 (HSWA). Section 3 of HSWA[2] puts legal and enforceable onus on organisations to take all 'reasonably practicable' steps not to expose people to safety risks. HSE do not apply the HSWA in relation to the safe delivery of clinical care in healthcare organisations. However, as the recent HSE prosecution in relation to Southern Health demonstrates[3] the HSE can and will prosecute in accordance with the HSWA in relation to the provision of care that doesn't relate to clinical decision making.

8. The gap in the application of HSWA relating to clinical care was highlighted in the 2013 Francis report. In response to this, the Care Quality Commission (CQC) introduced 'Safe care and treatment' as regulation 12[4] in the new 'Fundamental Standards' (2014). Guidance from CQC states "CQC understands that there may be inherent risks in carrying out care and

[2] http://www.legislation.gov.uk/ukpga/1974/37/section/3

[3] https://www.theguardian.com/society/2018/mar/26/nhs-trust-fined-2m-over-death-of-teenager-connor-sparrowhawk

[4] http://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-12-safe-care-treatment

treatment and we will not consider it to be unsafe if providers can demonstrate that they have taken all **reasonable steps**[5] to ensure the health and safety of people using their services and to manage risks that may arise during care and treatment." However, recent cases where CQC have taken forward their new prosecution powers under these standards have centred on the management of non-clinical risks, for example burns and falls[6,7].

9. Whereas in other high-risk sectors there is a clear legal framework and regulatory system for ensuring organisations take 'reasonably practicable' steps to manage safety risks, in relation to the provision of safe clinical care, this is not the case. To illustrate this, the 2015 Morecambe Bay Investigation[8] concluded that there was a 'lethal mix of failures' including managerial failures to act on known risks; failures to investigate incidents involving harm and death adequately and the 'suppression' of a critical report highlighting risks to service users. By any reasonable interpretation there was a gross failure of the Morecambe Bay NHS trust to take all 'reasonably practicable' steps to ensure the safe delivery of maternity care. However, HSE would not enforce the HSWA in relation to Morecambe Bay because the issues involved clinical care. To date, the CQC has not appeared to apply regulation 12 of the new fundamental standards to the management of clinical care.

10. The following issues set out the important context of my submission.

Response to specific issues being consider by the review

Part 1. How we ensure healthcare professionals are adequately informed about:

- Where and how the line is drawn between gross negligence manslaughter (GNM) and negligence.
- What processes are gone through before initiating a prosecution for GNM;

11. The phrase 'negligence' is most often associated with civil clinical negligence processes with the precedent set by case law. A common definition accepted by the courts is the Bolam test[9] which states:

"… a medical professional is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art…"

[5] My emphasis
[6] http://www.cqc.org.uk/news/releases/cqc-prosecutes-southern-health-after-patient-injured-falling-hospital-roof
[7] http://www.cqc.org.uk/news/releases/nursing-home-prosecuted-cqc-over-serious-burns-injury
[8] https://www.gov.uk/government/organisations/morecambe-bay-investigation
[9] http://www.e-lawresources.co.uk/Bolam-v--Friern-Hospital-Management-Committee.php

Although this language is loaded at an individual level, in reality civil negligence claims are often settled at an organisational level without going to court and an admission of civil liability is not necessarily linked to a judgement that an individual has been 'negligent'.

However, the language of 'negligence' in a civil context is an example of how patient safety incidents are framed towards individual actions and blame. A medical professional is 'guilty' if they failed to act in a way that their peers would regard as 'proper practice'.

12. In a medical context, the legal criterion for criminal manslaughter is 'gross negligence' as formulated by R v Adomako[10] There has to be a breach in the duty of care that is so serious that it constitutes a crime.

    The Crown Prosecution Service defines gross negligence manslaughter as a death which is "a result of grossly negligent (though otherwise lawful) act or omission." Decisions around prosecution are based on the following criteria.

    a) The existence of a duty of care
    b) Breach of that duty of care
    c) Causing or significantly contributing to the death
    d) Which should be characterised as gross negligence and is therefore a crime

    The concepts of both 'negligence' and 'gross negligence' as set out above are fraught with difficulty. Not least that they depend upon subjective judgements about the actions of individuals that can only be made in context of an in-depth understanding of all the factors that impacted on the decisions and action of the individual healthcare practitioner at the time. Whereas in other high-risk industries (for example nuclear and aviation), the science surrounding the environmental, human, organisational, system and cultural factors that impact on human performance (Human Factors) is well developed and integrated into safety management systems, in healthcare, although we are starting to make progress (a significant contribution has been made by Martin Bromiley and the Clinical Human Factors Group), this is still an emerging field. The current situation is that there is variation in both the organisational approach and systems that support healthcare professionals in providing safe care. This results in clinicians involved in patient safety incidents and harm being treated very differently by different organisations in often similar circumstances.

The importance of a 'just culture' – rather than a 'no blame' approach

13. *"The term 'no-blame culture' flourished in the 1990s and still endures today. Compared to the largely punitive cultures that it sought to replace, it was clearly a step in the right direction…But the 'no-blame' concept had two serious weaknesses. First, it ignored—or, at*

[10] R v Adomake [1995] 1 AC 11

least, failed to confront—those individuals who wilfully (and often repeatedly) engaged in dangerous behaviours that most observers would recognise as being likely to increase the risk of a bad outcome. Second, it did not properly address the crucial issue of distinguishing between culpable and non-culpable unsafe acts. In my view a safety culture depends critically upon first negotiating where the line should be drawn between unacceptable behaviour and blameless unsafe acts." – James Reason, 2004[11]

Reason makes the vital point that there can be 'blameless unsafe acts' and that it is crucial to distinguish between 'culpable and non-culpable unsafe acts'.

14. In relation to the delivery of healthcare, I consider that the phrase and concept of 'no blame' approach should be avoided. Instead, healthcare organisations and the wider system (including professional regulation and the criminal justice system as applied to healthcare delivery) should embrace and seek to be aligned with the principles of a 'just culture'.

In May 2016, the Expert Advisory Group (EAG), which was established to provide advice of how the new Healthcare Safety Investigations Branch (HSIB) should operate, recommended that the promotion of a 'just culture' should be a central principle in the operation of the new organisation[12].

"The Branch must promote the creation of a just safety culture: a shared set of values in which healthcare professionals trust the process of safety investigation and are assured that any actions, omissions or decisions that reflect the conduct of a reasonable person under the same circumstances will not be subject to inappropriate or punitive sanctions."

This neatly describes the culture that we need to promote, foster and support in healthcare in order to avoid creating a culture of fear that detracts from openness and learning. This promotion of a just safety culture is not just the responsibility of HSIB but must be a priority for all the health and social care system, whether commissioners, policy makers, service providers, Board members, leaders, managers, clinicians and support staff.

[11] https://flightsafety.org/files/just_culture.pdf

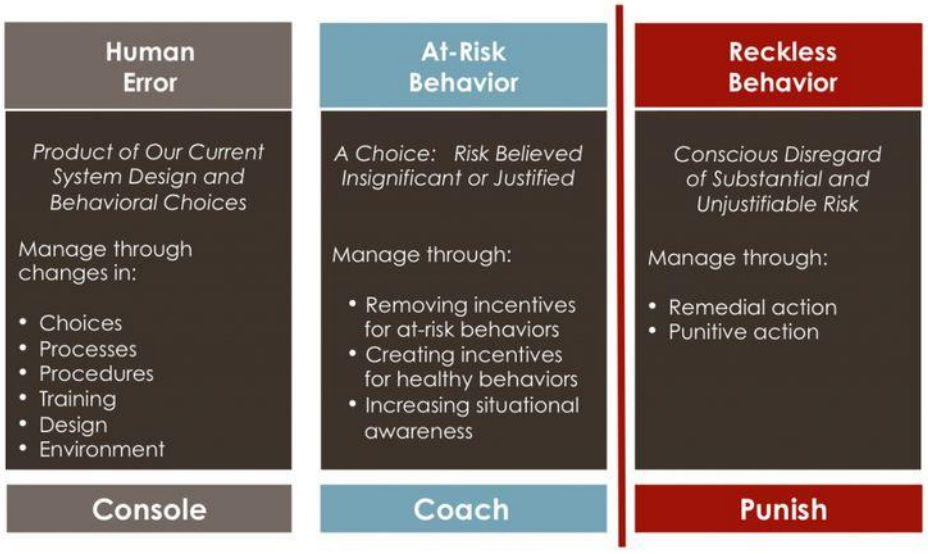
[12] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/522785/hsibreport.pdf

Defining the boundary between non-culpable and culpable unsafe acts

15. In the book 'Whack-a-Mole: The Price We Pay For Expecting Perfection' [13] David Marx argues that a 'just culture' distinguishes between different types of 'unsafe' acts as follows:

- Human error
- At-risk behaviour
- Reckless behaviour

In a 'just culture', Marx argues that the response to Human error should be to console; at-risk behaviour, to coach; and reckless behaviour, to punish.'



This framework for distinguishing between culpable and non-culpable unsafe acts is widely accepted in high-risk industries and should be promoted in healthcare organisations. NHS Improvement have recently published a just culture guide[14], based on James Reason's culpability model and previous work done the National Patient Agency (NPSA). All health and social care organisations should follow this guidance which provides a clear and transparent framework for identifying where the actions of an individual should rightly be regarded as 'culpable'.

Recommendations:

1) All NHS organisations should embed NHSI guidance as part of their serious incident and patient safety review policies.

[13] Marx, D. Whack-a-mole: the price we pay for expecting perfection, Plano, TX: By Your Side Studios, 2009

[14] https://improvement.nhs.uk/resources/just-culture-guide/

2) All NHS organisations should support these policies with a competency framework that ensures appropriate resources are in place to carry out high quality reviews and investigations and that these resources have the necessary skills and expertise (including system and human factors training) to implement the just culture guidance effectively, ensuring trust and transparency.

3) All NHS organisations should publish a clear set of standards relating to how staff involved in clinical incidents will be treated. These standards should make it clear how staff will be supported, where the line is drawn between culpable and non-culpable acts and the process for investigation and deciding actions. This should also include the non-negotiable expectation of staff to cooperate and be open and honest in all aspects of such processes.

4) All NHS organisations should publish improvement plans regarding how they will develop a Just Culture and report on progress in its implementation

5) As part of their inspection processes, CQC should ensure that all NHS organisations ensure points 1 - 4 are in place.

When should the individual act or omissions of a healthcare professional become a criminal matter?

16. The majority of healthcare professionals go to work to do their best for patients and the fast majority of patient safety incidents and events do not involve truly 'reckless' acts. However, clearly in cases where there has been a 'conscious disregard of substantial and unjustifiable risk' disciplinary action and referral to a professional regulator is warranted. But at what point should 'recklessness' become criminal?

This is a complex and subjective question, so I can only answer from my own perspective. If a culpable unsafe act is defined as 'a conscious disregard of a substantial and unjustifiable risk', a criminal act in my view is where not only did the healthcare professional make a decision to disregard a substantial and unjustified risk, they did so in full knowledge that their actions were likely to cause serious avoidable harm or death.

Some examples of actions that might meet this criterion include:

- Malicious tampering with medical devices or equipment
- Deliberate administration of inappropriate drugs or incorrect doses of drugs
- Being fully aware of a patient's condition & prognosis (without intervention) and knowingly withholding or delaying indicated treatment.
- Otherwise being demonstrably aware that one's actions or omissions were creating a significant chance of avoidable patient harm of death.

In the above scenarios, if the facts were established through high quality investigation undertaken by experienced and independent investigators, I believe that the vast majority of healthcare professionals and patients would agree that criminal prosecution was appropriate and justified.

Recommendations

1. The CPS should ensure that their decisions around reviewing possible prosecutions firstly align with the principle of 'just culture'. The first tier of decision making for the CPS should be an independent assurance, by a specialist trained in healthcare human and system factors, that the actions of the individual meet the threshold of 'recklessness'.

2. The CPS should produce clear guidance that clarifies when reckless acts become criminal and ensure that their processes involve the appropriate expertise to demonstrate publicly the rationale and evidence standards relating to this.

3. NHS organisations should ensure that investigations are undertaken by experienced and qualified investigators consistently applying national guidance.

4. CQC should assess and report on the quality of investigations into unsafe care and ensure that remedial action is taken if organisations fail to meet national standards

Part 2 "How we ensure the vital role of reflective learning, openness and transparency is protected where the healthcare professional believes that a mistake has been made to ensure that lessons are learned, and mistakes not covered up.

17. To promote a culture of safety and learning in healthcare, it's vital that healthcare professionals can undertake reflective practice in the confidence of knowing that any written material will not be used in punitive processes again them.

18. In an ideal world, healthcare professionals would have complete trust that the principles of a just culture were so imbedded in their local organisation and national systems (including professional regulation and the criminal justice system) that they would have complete confidence that any written reflections around patient safety events and incidents that fall below the threshold of truly 'reckless' or 'culpable' could be undertaken with complete confidence and psychological safety.

19. In addition, duty of candour principles should ensure that any patient safety event that has resulted in avoidable patient harm should be investigated and the patient or their family fully informed of any failures or omissions in care.

20. It could therefore be argued that if healthcare was able to achieve a true and trusted 'just culture' and the duty of candour was being followed, there should be no barriers in healthcare professionals feeling safe and empowered to engage with reflective practice and produce open, honest and frank written reflections about patient safety events.

21. However, the evidence is that we are some way from achieving a system wide 'just culture' in healthcare and therefore it is legitimate to consider what additional measures could be taken to create the conditions to support a culture of reflection and learning in healthcare.

22. One example of how other countries have approached this issue is Section 51 of the British Columbia Evidence Act[15] which provides legal protection of certain information. A factsheet produced by the Vancouver Island Health Authority (VIHA) states:

"VIHA is committed to fostering a culture that values learning from adverse events. Section 51 supports this goal by promoting frank and open discussion about all the factors and circumstances leading to the event. Without this protection health care professionals may be unwilling to candidly discuss adverse events, and the opportunity to improve patient care could be lost. A non-punitive approach to reviews ensures that lessons learned translate into improved quality and safety. Under Section 51, most information and documentation collected as part of a patient safety review to improve quality cannot be disclosed or used in legal proceedings. Records, summaries, reports and opinion collected by a designated quality improvement committee during the review are not permitted to be disclosed."

23. However, section 51 of the BC Evidence Act includes the following exceptions that are not covered by legal protection:

    - The fact that a patient-focused quality of care review was conducted and when it occurred
    - Any information contained in the patient chart
    - Facts contained in the incident report not contained in the patient chart
    - Medical facts learned in the course of the review

All other records created during the proceedings of a review, including the opinions expressed by the participants of the review, are protected and cannot be disclosed outside the health authority.

24. Providing healthcare organisations have robust duty of candour processes in place and work towards supporting a just culture, legislation that protects written reflections and opinions produced by healthcare professionals relating to patient safety events could further help foster a culture of learning and help protect patients from harm. However, in my view it is vital that any such legal protection specifically excludes facts not otherwise disclosed to patients of their families, which directly relate to medical care and treatment.

25. The draft Health Service Safety Investigations Bill (HSSIB)[16] was presented to parliament by the Secretary of State for Health in September 2017. It is noted that the draft bill provides the Healthcare Safety Investigations Branch (HSIB) with 'safe space' protection of evidence

[15] https://www.viha.ca/NR/rdonlyres/93512EC4-A7A6-4168-9CA0-BC5E5D598EF4/0/fs_section51.pdf
[16] https://www.gov.uk/government/publications/health-service-safety-investigations-bill

collected and that the bill proposes a system of accreditation whereby HSIB can assess and accredit local healthcare organisations to enable them to operate the same legal powers of protection.

26. I support the use of 'safe space' legislation for HSIB and believe that there is a strong case for local NHS organisations who can demonstrate to HSIB that they have robust investigative and duty of candour process in place, to operate under the same powers. However, I believe that the HSSI Bill should be amended to explicitly state that certain information (aligned with the exclusions in section 51 of the BC Evidence Act) are not protected. This provides the right balance between promoting a culture of openness and learning and accountability.

27. Subject to such changes, the HSSI Bill offers a route by which NHS organisations could provide additional protection of reflective records to support open learning. However, if local healthcare organisation promoted just culture principles, professional regulators were explicit in confirming their policy position to never use reflective writing as a part of their processes, and the CPS worked to ensure its decision around prosecutions were aligned with just culture principles, this would go some way to removing current barriers to open and honest reflective practice.

Recommendations

1. 'Safe space' provision as per the current HSSI Bill should be amended to incorporate specific exclusions in line with the BC Evidence Act.

2. Enactment of an amended HSSI Bill should supported and expedited.

3. The GMC/NMC should be explicit that their policies exclude the use of written reflective practice as any part of their Fitness to Practise processes.

4. The CPS should be encouraged to adopt a similar policy position and develop clearer guidelines around prosecution decisions and processes.

5. Greater emphasis should be placed on encouraging and recognising reflective practice and making safety improvement observations as an important part of demonstrating professionalism. For example, this could be incorporated into annual appraisal processes.

6. Organisations and professional regulators should adopt a zero tolerance approach to dishonestly or covering up following patient safety events. This to be supported by provider organisations having expedited processes in place to investigate allegations of dishonesty or covering up.

Part 3. "Lessons that need to be learned by the General Medical Council (GMC) and other healthcare professionals' regulators in relation to how they deal with professionals following a criminal process for gross negligence manslaughter.

28. Professional regulation is not about punishment, but rather the protection of the public. It's crucial that professional regulators act independently based upon a clear, transparent and trusted framework that aligns with the principles of a 'just culture'. They must take swift decisions that ensure the public are protected from healthcare professionals whose conduct and behaviour truly represents a risk to patient safety. The GMC and NMC should not allow their processes to be influenced by the judgement or conclusions of other organisations, including the criminal justice system.

Recommendations:

1. All professional regulators must publish clear standards relating to the framework by which decisions relating to Fitness to Practice investigations are undertaken. This should align with 'just culture' principles and the just culture guidance recently published by NHSI.

2. Professional regulators must ensure that their investigations and decision-making processes are carried out with the necessary expertise, including healthcare system and human factors specialists, to ensure that when sanctions are to be taken against healthcare professions, the rationale and evidence (against just culture principles) is defensible, transparent and clear.

3. Professional regulators must act independently without being influenced by other processes.

Further recommendations

29. Although outside the terms of reference to this review, in this submission I have highlighted that in my opinion, there remains a regulatory gap, in that no organisation currently enforces the reasonable expectation that healthcare organisations should take 'all reasonably practicable steps' to reduce or remove avoidable risks to patient safety created by the way healthcare is delivered.

30. This gap could be closed if the CQC made it clear that regulation 12 of its fundamental standards did apply the management of clinical care and developed a framework of minimum standards which underpinned what 'reasonably practicable' meant. For example, this should include having systems in place to ensure adequate resources and staff training/competencies, ensuring patient safety risks, incidents and events were identified, investigations properly undertaken and learning from them acted on and that all health and

social care organisations carry out proactive work to measure and benchmark their performance in key areas to ensure that they are following best practice.

Conclusions

31. Patients understand that healthcare has inherent risks that even in the best hospital or healthcare setting possible, can never be eliminated. However, patients & bereaved families who suffer avoidable harm will continue to be outraged when healthcare organisation fail to undertake 'reasonable practicable' steps to avoid risks that are not inherent to healthcare interventions but are unnecessarily introduced by problems in the systems and processes in place that deliver care.

32. A vital component of safety in healthcare is ensuring organisations have systems in place and a culture that supports learning. The best approach to achieving this, as evidenced by other industries, is the promotion of just culture principles.

33. To support this, there needs to be an expansion of patient safety expertise in healthcare (including regulation and where applicable, criminal justice processes) and the development and promotion of patient safety as a profession.

34. As well as shifting culture to ensure that healthcare professionals involved in patient safety events are treated fairly, there must be a clearer framework of responsibility and accountability for senior healthcare managers and leaders, to ensure all 'reasonably practicable' steps are taken to reduce or avoid unnecessary patient safety risks.

35. I hope this review can play an important part in helping to push in this direction and promote safer systems for delivering healthcare for both patients and staff.