When the worst happens:

Newcastle 14 November 2019

what is "Gross Negligence"?

(in England, Wales + N I)

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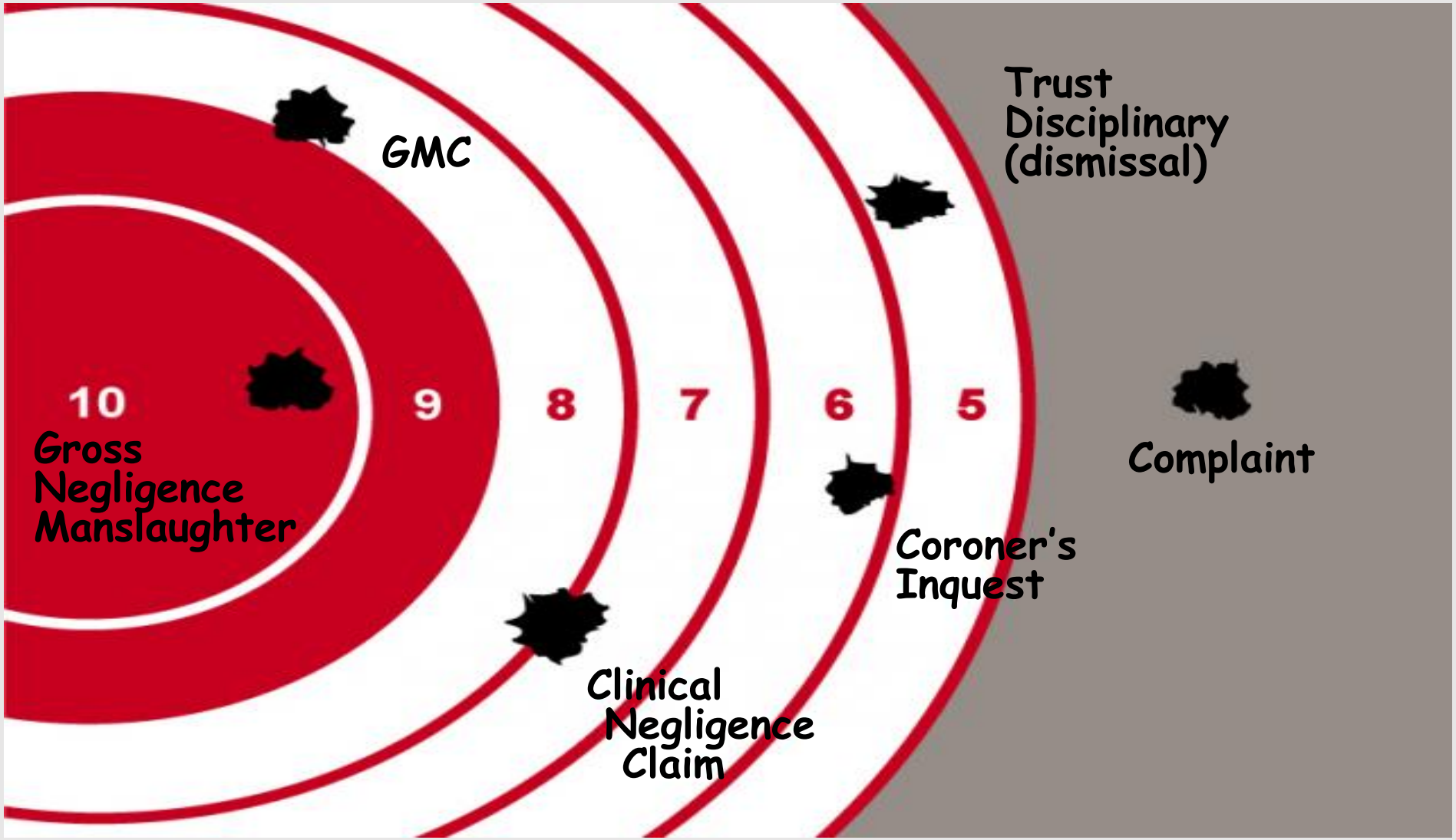
Consultant Cardiac Surgeon (rtd)
past Council RCSEng (Sellu)
Assistant Coroner (Durham + Darlington)
Independent Review of GNM: chair

Multiple Jeopardy (MPS)



A crime?

- theft
- burglary
- assault
- murder

Gross Negligence Manslaughter

Case Law

(Corporate Manslaughter: statute)

R v Bateman (1925)

The doctor must be proved to have shown such disregard
for the life and safety of others as to amount to
a crime against the State and
conduct **deserving of punishment.**

Gross Negligence Manslaughter: the Law

R v Adomako [1994] UKHL 6

- Anaesthetist: failed to notice oxygen disconnected

- House of Lords (Lord Mackay of Clashfern):

  - the defendant owed the victim a duty of care
  - the defendant breached that duty
  - the breach caused (or significantly contributed to) the victim's death
  - the breach was **grossly negligent**.

Lord Mackay

- "Grossly negligent"

"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…

The essence of the matter…is whether having regard to the risk of death involved, the conduct of the defendant was so bad in all the circumstances as to amount in their judgment to a **criminal act**."

David Sellu

MB BCh 1973 Manchester

Consultant Colo-rectal Surgeon, Clementine Churchill, London

BMJ CONFIDENTIAL

Jenny Vaughan: Overturning injustice

[Image: Duncan Smith]

Biography

Jenny Vaughan, 50, is a consultant neurologist in London. She is a leading campaigner for reforming the law on gross negligence manslaughter when applied to people working in healthcare. She articulated the unease many people felt at the conviction of the surgeon David Sellu and, as campaign chair for his appeal, was instrumental in getting his conviction overturned. Along with Sellu's legal team she is widely credited for having modernised the law in this area. She has been equally vocal in defence of Hadiza Bawa-Garba and was a leading supporter of her successful bid against erasure. Vaughan's contributions helped shape the conclusions of the Williams review in June 2018.[1] She now campaigns for a "just culture" in healthcare and for improvements to patient safety by working with the Doctor's Association UK (DAUK) and the BMA. In 2018 she received the BMJ editor's award for speaking truth to power.

What single change would you most like to see made to the NHS?

Patient safety should always come first. We need to bring in a truly just culture so that errors are discussed openly and everyone can learn from mistakes.

How is your work-life balance?

Better than it was. Being a workaholic is never the right way to get the most out of life.

What was your best career move?

Leading the group of David Sellu's friends as we launched a campaign to overturn his conviction for gross negligence manslaughter. There had never been a successful "out of time" appeal in this area of the law, so we were dealing with almost impossible odds from the start. The result was extraordinary, for both David and our whole profession.

What was the worst mistake in your career?

Letting my own health fail while working too hard. I'm trusting that this error won't be the end of me.

How do you keep fit and healthy?

I developed breast cancer in 2017, and this has made me much more serious about keeping fit—developing cancer can be due to a lack of exercise. Last summer I ran my first 5k in 37 years, which felt amazing.

If you weren't in your current position what would you be doing instead?

Helping to solve global warming. I want our children to "inherit the Earth," and I still have hope that it's not too late.

What is the worst job you have done?

I worked in the kitchen of a mushroom farm when saving up for medical school. After every shift I'd smell of a heady mix of cigarette smoke and manure.

What book should every doctor read?

Complications by Atul Gawande. It's a masterful reflection on how mistakes occur in medicine, with practical, evidence based suggestions to reduce medical error. He rightly states that medicine is equally "complicated, perplexing, and profoundly human."

Inspirational Leader

Consultant Neurologist →

sense of injustice

- petition (> 300) to College Council
  - "do something about experts"
  - → Council debate
    - President: Dame Clare Marx

BMJ 2019;364:l1024 doi: 10.1136/bmj.l1024

Meanwhile ….. 18 February 2011 (Leicester Royal Infirmary)

Jack Adcock (age 6)

Dr Hadiza Bawa-Garba

Dr Hadiza Bawa-Garba

- Coroner referred case to Police
  - 2012 CPS: no further action
  - compare Scotland

- July 2013: Coroner's Inquest
  - "Expert" said cardiac arrest was "preventable beyond reasonable doubt"
  - back to the Police

- December 2013: CPS Special Crime Division:
  - "Having completed our review, we have concluded there is sufficient evidence and it is in the **public interest** for Dr Bawa-Garba, Sister Taylor and Staff Nurse Amaro to each face charges of gross negligence manslaughter."

Dr Hadiza Bawa-Garba: Trial

- 4 November 2015: Nottingham Crown Court (Dr B-G working for > 4 years)
  - "Expert" Paediatrician (PICU): "barn door obvious sepsis"
    - ? read the NCEPOD report (2015)
  - " .. any competent doctor …"
    - ? read the Trust investigation report (6 / 23 / 79) – posters for other doctors
  - convicted of GNM
    - 2 year suspended sentence
  - 8 December 2016: refused leave to appeal (post Sellu appeal: "truly exceptionally bad")
    - R v Bawa-Garba (Hadiza) [2016] EWCA Crim 1841. Sir Brian Leveson P
- 13 June 2017: MPTS: GMC asked for erasure
  - 12 months suspension
  - insight, remediation, circumstances, no impairment of FTP (working > 4 years)

Medical Act 1983: the GMC

- (1A) The over-arching objective of the General Council in exercising their functions is the protection of the public.

- (1B) The pursuit by the General Council of their over-arching objective involves the pursuit of the following objectives (JRLH: no hierarchy)

  - (a) to protect, promote and maintain the health, safety and well-being of the public

  - **(b) to promote and maintain public confidence in the medical profession**

  - (c) to promote and maintain proper professional standards and conduct for members of that profession

Enter the GMC ….

- 25 January 2018
- Court of Appeal allows GMCs appeal to "strike her off"
  - explosion of concern
  - toxic fear …
  - international interest
  - **26** January: crowdfunding

JH → Williams Review

GMC → Dame Clare Marx Review

GMC commissioned Review of GNM / CH

22 February 2018: GMC commissions **Dame Clare Marx Review**

- Working Group: 6 "medics", 3 legal (inc CPS), 2 lay / patient reps
- ToR: review process of investigation of unexpected deaths
  - application of the law (NB: excluded calling for change in the law)

- 4 Home Countries
  - written responses (>750)
  - workshops (>200 attendees), oral evidence (20 organisations), interviews (40)
  - commissioned research ("public confidence in the profession") + BAME
  - Scottish "Task + Finish" group (law is different)

30 July: Privy Council appoints Dame Clare Marx as Chair of GMC Council

- LH takes over as Chair (re-named "Independent Review of GNM / CH")

Gross Negligence Manslaughter: data

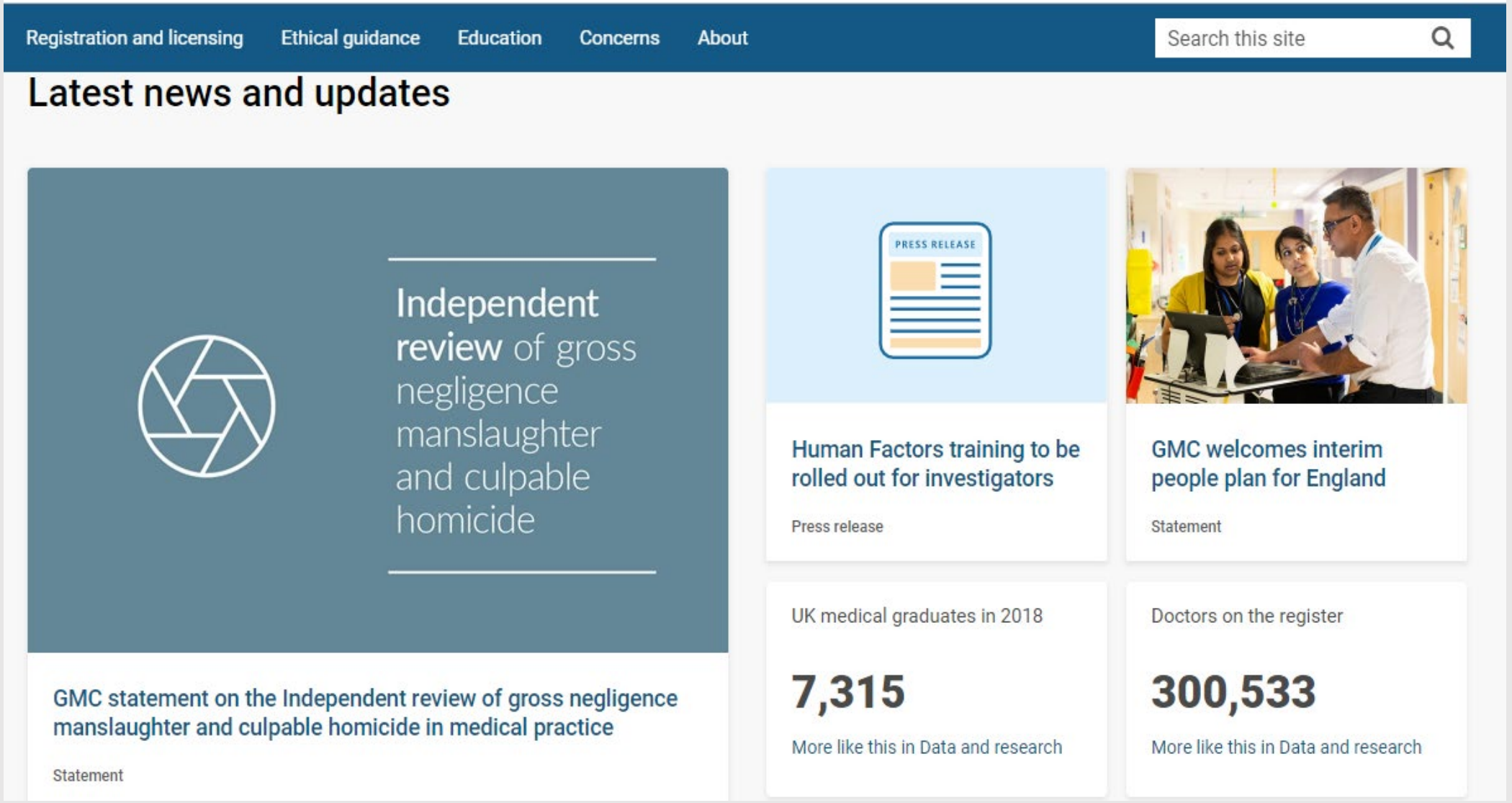
- independent academic lawyers (Danielle Griffiths and Oliver Quick)
- Review of CPS files: 2007 – 2018 (12 years)
- 192 cases referred by police for decision
  - 15 to 16 per year (but "ripple effect")
    - 43 Police forces (1 case every 3 years)
    - 88 Coroners (1 case every 5 years)
  - 53% discontinued at "early investigative advice" stage
  - 32% at "Full Code Test"
  - 6% (1 case) proceeded to prosecution (7 doctors, 7 nurses, 1 optometrist)
    - 6 convictions
    - 2 successful appeals
    - filters needed ?

- doctors on GMC register?
  - >300,000 (250,000 with licence to practise)

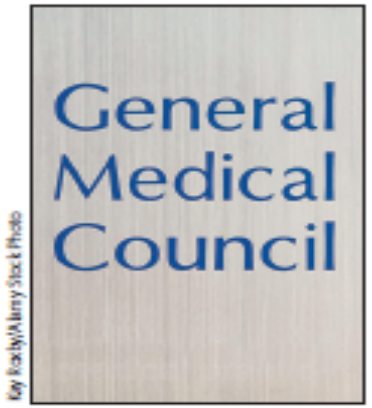
https://www.gmc-uk.org/

6 June 2019

(D Day celebrations, Donald Trump in London, Tory leadership campaign ..)



Gross negligence manslaughter



Ray Kelly/Alamy Stock Photo

For the **GMC review of gross negligence and culpable manslaughter** see https://www.gmc-uk.org/-/media/documents/independent-review-of-gross-negligence-manslaughter-and-culpable-homicide---final-report_pd-78716610.pdf

For more on the **GMC's role in the case of Hadiza Bawa-Garba** see Editorial *Lancet* 2018; **391**: 1456

For more on **medical negligence** see Editorial *Lancet* 2018; **391**: 2079

An independent review of gross negligence manslaughter (GNM) and culpable homicide, published on June 6, describes how the conduct of the General Medical Council (GMC) relating to the case of Hadiza Bawa-Garba severely damaged its relationship with the doctors it is supposed to regulate. The review acknowledges several serious concerns about the GMC that emerged from this, and other similar, recent cases. These concerns include an over-representation of black and ethnic minority doctors referred to the GMC and a potential conflict in the responsibilities of the GMC both to ensure doctors are safe to practise and to maintain public confidence in the profession. This dual role leaves the GMC open to accusations that some decisions are less about patient safety and more about appeasing the public mood.

Multiple system-wide failings and human factors must align for patient harm to occur. To address these risks, the focus must move to learning and future prevention rather than assigning individual blame. However, the review describes a continuing failure within the GMC and criminal justice system to appreciate the importance of systems and human factors that are crucial for an increasingly stretched National Health Service. The review's authors were clear that, although their remit was the application of the GNM law (the law was reviewed separately last year), many people thought the law in England and Wales should be changed to require wilful recklessness or intent to harm for criminal prosecution. The focus by the criminal justice system on investigation of individual doctors without accounting for or understanding human factors allows the criminalisation of errors while failing to hold wider systems to account.

It is important to identify reckless or deliberate action. However, criminalising errors in a sector with inherent risk and apparent bias is a serious barrier to fostering proportionate, fair, and consistent regulatory and criminal justice systems that are essential to constructively engage the UK medical profession and to maintain patient safety. Although this review is a good first step towards acknowledging ongoing problems, the degree of change required in both the GMC and the criminal justice system to restore trust is not yet evident. ■ *The Lancet*

The Lancet June 22, 2019

Gross Negligence Manslaughter

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The Lancet June 22, 2019

Independent Review of GNM / CH

published 6 June 2019

- 29 recommendations (each stage of events after an unexpected death): 77 pages
  - **Local investigations into patient safety incidents**
  - **Expert reports and expert witnesses**
  - GMC
    - Relationship with the profession
    - Equality, diversity and inclusion (BAME concerns)
    - Policies and processes
  - Families and healthcare staff (NQB)
  - System scrutiny and assurance (CQC)
  - Coroner and Procurator Fiscal (Chief Coroner)
  - Police (early independent advice) and CPS (more transparency)
  - Reflective practice (? legal protection)
  - Support for doctors (including Coroner's Court; return to work plan; MDO cover)

A "Just Culture"

- Expert Advisory Group (led to HSIB cf AAIB)
  - A shared set of values in which healthcare professionals trust the process of patient 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.

- not "no blame" (1990s): "Learn not blame"
  - James ("Swiss cheese") Reason (2004): culpable and non-culpable unsafe acts
  - James Titcombe: conscious disregard of a substantial and unjustified risk
  - Alan Merry and Alex McCall-Smith: slips (errors) vs violations (conscious disregard …)
  - Berwick report 2013 (post mid Staffs): "A Promise to Learn – a Commitment to Act"
  - ? change in the law: Law Commission 1996

- fair to patients / families and fair to staff
  - accountability and learning

NHS Improvement

A just culture guide

Supporting consistent, constructive and fair evaluation of the actions of staff involved in patient safety incidents

This guide supports a conversation between managers about whether a staff member involved in a patient safety incident requires specific individual support or intervention to work safely. Action singling out an individual is rarely appropriate – most patient safety issues have deeper causes and require wider action.

The actions of staff involved in an incident should **not** automatically be examined using this just culture guide, but it can be useful if the investigation of an incident begins to suggest a concern about an individual's actions. The guide highlights important principles that need to be considered before formal management action is undertaken on an individual staff member.

An important part of a just culture is being able to explain the approach that will be taken if an incident occurs. A just culture guide can be used by all parties to explain how they will respond to incidents, as a reference point for organisational HR and incident reporting policies, and as a communication tool to help staff, patients and families understand how the appropriate response to a member of staff involved in an incident can and should differ according to the circumstances in which an error was made. As well as protecting staff from unfair targeting, using the guide helps protect patients by removing the tendency to treat wider patient safety issues as individual issues.

Please note:

- **A just culture guide** is not a replacement for an investigation of a patient safety incident. Only a full investigation can identify the underlying causes that need to be acted on to reduce the risk of future incidents.
- **A just culture guide** can be used at any point of an investigation, but the guide may need to be revisited as more information becomes available.
- **A just culture guide** does not replace HR advice and should be used in conjunction with organisational policy.
- **The guide** can only be used to take one action for failure to act through the guide at a time. If multiple actions are involved in an incident they must be considered separately.

Start here - Q1. deliberate harm test

1a. Was there any intention to cause harm?

Yes → **Recommendation:** Follow organisational guidance for appropriate management actions. This could involve: contact relevant regulatory bodies, suspension of staff, and referral to police and disciplinary processes. Wider investigation is still needed to understand how and why patients were not protected from the actions of the individual. **DO NOT CONTINUE**

No go to next question - Q2. health test

2a. Are there indications of substance abuse?

Yes → **Recommendation:** Follow organisational substance abuse at work guidance. Wider investigation is still needed to understand if substance abuse could have been recognised and addressed earlier. **DO NOT CONTINUE**

2b. Are there indications of physical ill health?

2c. Are there indications of mental ill health?

Yes → **Recommendation:** Follow organisational guidance for health issues affecting work, which is likely to include occupational health referral. Wider investigation is still needed to understand if health issues could have been recognised and addressed earlier. **DO NOT CONTINUE**

If No to all go to next question - Q3. foresight test

3a. Are there agreed protocols/accepted practice in place that apply to the action/omission in question?

3b. Were the protocols/accepted practice workable and in routine use?

3c. Did the individual knowingly depart from these protocols?

If No to any → **Recommendation:** Action singling out the individual is unlikely to be appropriate: the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual. **DO NOT CONTINUE**

If Yes to all go to next question - Q4. substitution test

4a. Are there indications that other individuals from the same peer group, with comparable experience and qualifications, would behave in the same way in similar circumstances?

4b. Was the individual missed out when relevant training was provided to their peer group?

4c. Did more senior members of the team fail to provide supervision that normally should be provided?

If Yes to any → **Recommendation:** Action singling out the individual is unlikely to be appropriate: the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual. **DO NOT CONTINUE**

If No to all go to next question - Q5. mitigating circumstances

5a. Were there any significant mitigating circumstances?

Yes → **Recommendation:** Actions directed at the individual may not be appropriate: follow organisational guidance, which is likely to include senior HR advice on what degree of mitigation applies. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. **DO NOT CONTINUE**

If No

Recommendation: Follow organisational guidance for appropriate management actions. This could involve individual training, performance management, competency assessments, changes to role or increased supervision, and may require referral regulatory bodies for be considered, staff suspension and disciplinary processes. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. **DO NOT CONTINUE**

improvement.nhs.uk

Based on the work of Professor James Reason and the National Patient Safety Agency's Incident Decision Tree

Supported by:

collaboration trust respect innovation courage compassion

NHSI: A Just Culture Guide

- Supported by:

CPS: updated Guidance on GNM (March 2019)

- https://www.cps.gov.uk/legal-guidance/gross-negligence-manslaughter

- *"Relevant factors in establishing grossness"*

  - *Misra* test: mistakes, even very serious mistakes … nowhere near enough
  - *Sellu*: truly exceptionally bad
  - course of conduct or series of serious breaches ..
  - deliberate overriding or ignoring of systems … ignoring warnings
  - all relevant circumstances in which the individual was working

The "public" in "public confidence"?

Court of Appeal (Bawa-Garba case) [2018] EWCA Civ 1879 (para 96)

Public confidence in the profession
must be assessed by reference to the standard of
the ordinary intelligent citizen
who appreciates the seriousness of the proposed sanction,
as well as the other issues involved in the case.

The last word: Professor Sir Liam Donaldson

- LSHTM and previous CMO, England → Clinical Governance

BMJ Editorial ("In Harm's Way): 11 May BMJ 2019; 365:I2037

"Nor do the public or the media seem too horrified by the lamentable failure of the NHS to learn from the past."

" .. investigations invariably show these (patient safety) events are caused by a combination of individual failings, systemic weaknesses, and environmental factors."

"Regulations, legal frameworks, and most statutory inquiries have so far failed to understand the difficulties for conscientious health professionals of keeping patients safe in a flawed and overloaded system."


Giant's Causeway, N Ireland