# NATIONAL QUALITY BOARD

**For meeting on:** 10 August 2018

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**Paper for:**

| Decision | Discussion | Information |
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## WILLIAMS REVIEW INTO GROSS NEGLIGENCE MANSLAUGHTER IN HEALTHCARE

### SUMMARY

On 11 June 2018, Professor Sir Norman Williams's Review into Gross Negligence Manslaughter in Healthcare was published. The review considered the wider patient safety impact resulting from serious and widespread concerns among healthcare professionals that any errors could result in prosecution for gross negligence manslaughter, even in the context of mitigating broader organisational pressures and failings.

The report makes a number of recommendations, supporting patient safety to the benefit of healthcare professionals, patients and their families. The recommendations aim to:

- improve the investigation of allegations of gross negligence manslaughter involving healthcare professionals;
- consider the impact of criminal and regulatory investigations on the willingness of healthcare professionals to reflect on their practice; and
- address inconsistencies in the way that different healthcare professional regulators carry out their fitness to practise functions.

The Secretary of State accepted the recommendations in full.

**PURPOSE**

The NQB is asked to:

1) **Note** the Review's publication and recommendations; and

2) **Consider** what role the NQB can play in bringing the recommendations together to achieve the maximum impact.

**ALB Involvement in development and sign-off of paper:**

| NHS England | Care Quality Commission | NHS Improvement | NHS Health Education England |
|---|---|---|---|
| | | | |

| Public Health England | NICE National Institute for Health and Care Excellence | NHS Digital | Department of Health |
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# WILLIAMS REVIEW INTO GROSS NEGLIGENCE MANSLAUGHTER IN HEALTHCARE

## 1. BACKGROUND

1.1 The review was commissioned to consider the wider patient safety impact resulting from concerns among healthcare professionals that errors could result in prosecution for gross negligence manslaughter, even in the face of broader organisation and system failings. In particular, there was concern that this fear had had a negative impact on healthcare professionals being open and transparent when they are involved in an untoward event as well as on their reflective practice, both of which are vital to learning from mistakes and improving patient care.

1.2 The Review's Terms of Reference focused on three key areas:

- information on and understanding of gross negligence manslaughter and the processes which apply to possible cases of gross negligence manslaughter involving healthcare professionals;
- reflective learning; and
- lessons for healthcare professional regulators**.**

1.3 The following were outside the Review's remit:

- recommending changes in the law on gross negligence manslaughter;
- taking a view on the decisions made by the courts in relation to individual cases; or
- examining the specifics of individual cases.

1.4 Between February and April 2018 the panel received over 120 written submissions and heard oral evidence from 45 individuals, organisations and groups. Evidence was received from bereaved families; healthcare professionals and their representative bodies; experts in the fields of patient safety, human factors and medical-law.

## 2. FINDINGS AND RECOMMENDATIONS

2.1 The Panel found a fear of prosecution and regulatory action for human errors inhibits openness which is essential to improving patient safety. There are very few convictions of healthcare professionals for gross negligence manslaughter and the

bar for this offence is appropriately high. However, decision-making about the offence can appear to be applied inconsistently.

2.2 The report made recommendations to improve the investigation of allegations of gross negligence manslaughter involving healthcare professionals. These include:

- developing an agreed understanding of gross negligence manslaughter that reflects the most recent case law;
- improvements to the way that healthcare professionals provide expert advice and evidence; and
- improvements to local investigations into deaths in healthcare settings to provide a full understanding of the cause of death, ensuring improvements are made to reduce the likelihood of similar incidents.

2.3 The report considered the impact of criminal and regulatory investigations on the willingness of healthcare professionals to reflect on their practice. It found fear that reflective practice will be used against healthcare professionals in criminal or regulatory proceedings. However, reflective material is rarely sought in such proceedings – in part, because reflections, being neither factual nor objective, are not necessarily a good source of evidence.

2.4 The report looked at the regulation of healthcare professionals and considered what lessons could be learnt. It recommended that further work to understand inconsistencies in the way that different regulators carry out their fitness to practise functions should be carried out.

2.5 The report recommended that regulators that have a power to require information from registrants when investigating their fitness to practise – the General Medical Council and the General Optical Council - should have this power removed in respect of reflective material. Further it recommended that he GMC's right to appeal decisions of the Medical Practitioners Tribunal Service should be removed.

## 3. NEXT STEPS

3.1 The government accepted all the recommendations from the review. There are three primary strands to the implementation of these recommendations: clarity on legal position; NHS investigations; and professional regulation.

3.2 Delivery will require effective engagement and commitment from a number of healthcare and regulatory organisations, legal and law enforcement organisations, and other Government Departments. Work has begun to identify convene working groups.

3.3 The NQB is invited to consider how the various strands needed to deliver the recommendations can be brought together to achieve the maximum impact, and what support the NQB can provide in supporting the co-ordination of this work.

3.4 Oversight of this work will be managed by DHSC.

## ANNEX A: Williams Review Recommendations

**Allegations of gross negligence manslaughter against healthcare professionals**

### 1. An agreed and clear position on the law on gross negligence manslaughter

1.1 A working group should be set up to set out a clear explanatory statement of the law on gross negligence manslaughter. This working group should involve, at a minimum, representatives from the Crown Prosecution Service (CPS), the coroner services, Treasury Counsel and healthcare defence organisations.

1.2 All relevant organisations, including, if appropriate, the Director of Public Prosecutions, should produce or update guidance on gross negligence manslaughter in light of the explanatory statement set out by the working group in 1.1. This will promote a consistent understanding of where the threshold for prosecution for gross negligence manslaughter lies.

### 2. Improving assurance and consistency in the use of experts in gross negligence manslaughter cases

2.1 The Academy of Royal Medical Colleges, working with professional regulators, healthcare professional bodies and other relevant parties, should lead work to promote and deliver high standards and training for healthcare professionals providing an expert opinion or appearing as expert witnesses. These standards should set out what, in the Academy's opinion, constitutes appropriate clinical experience expected of healthcare professionals operating in such roles.

Healthcare professionals providing an expert opinion or appearing as an expert witness should have relevant clinical experience and, ideally, be in current clinical practice in the area under consideration. Additionally, they should understand the legal requirements associated with being an expert witness (including the requirement to provide an objective and unbiased opinion).

2.2 Healthcare professionals should be supported and encouraged to provide an expert opinion where it is appropriate for them to do so. Healthcare professional bodies, including Royal Colleges and professional regulators, should encourage professionals to undertake training to become expert witnesses, and employing organisations should be prepared to release staff when they are acting as expert witnesses.

2.3 Professional representative bodies and regulators should recognise acting as an expert witness as part of a healthcare professional's revalidation or continuous professional development (CPD) process.

2.4 Although our terms of reference were limited to gross negligence manslaughter, we heard evidence of more general concerns about experts. This should be reflected in the Academy's work to develop training for healthcare professionals acting in this capacity.

## 3. Consolidating expertise of gross negligence manslaughter in healthcare settings in support of investigations

3.1 The Chief Coroner should consider revising the guidance on gross negligence manslaughter in Law Sheet no 1 in light of the explanatory statement set out by the working group under 1.1. We expect coroners will routinely consider this guidance in assessing the facts on whether or not a referral for a criminal investigation should be made.

3.2 Building on the work of the Homicide Working Group, police forces across England should consolidate their expertise on gross negligence manslaughter by a healthcare professional through the creation of a virtual specialist unit. This unit would support senior investigating officers by making available the experience of previous gross negligence manslaughter cases in the early stages of an investigation.

3.3 Advice to senior investigating officers should be updated to reflect the explanatory statement on gross negligence manslaughter set out by the working group (1.1) and the standards for healthcare professionals providing an expert opinion or appearing as expert witnesses (2.1).

3.4 A new memorandum of understanding (MoU) should be agreed between relevant bodies, including the College of Policing, the CPS, the Care Quality Commission (CQC), Health and Safety Executive (HSE) the Healthcare Safety Investigation Branch (HSIB) and professional regulators, in relation to the investigation of deaths in a healthcare setting. As a minimum this MoU should establish a common understanding of the respective roles and responsibilities of the organisations involved, support effective liaison and communications between these organisations, and cover what is expected of expert witnesses, in particular that they should consider the role of systemic and human factors in the provision of healthcare.

Signatories to the MoU should disseminate its contents in order to promote a greater understanding of legal issues among healthcare professionals and of healthcare issues (including systemic and human factors) among prosecuting authorities, the police and

coroner services. This would help support the development of a “just culture” in healthcare, which recognises both systemic factors and individual accountability.

## 4. Improving the quality of local investigations

4.1 Where a suspected gross negligence manslaughter case in a healthcare setting has been referred to the CPS, the CQC must be informed so that it can consider whether to carry out a parallel, but separate, investigation of the healthcare provider to determine the role of systemic and human factors in the incident and to identify any changes which might need to be made. The CQC should also consider the findings of its inspection in deciding whether to undertake any follow up action in relation to the provider and/or any wider review of system issues. The relationship between a criminal investigation and any parallel CQC inspection should be set out in the MoU under 3.4.

4.2 There must be a thorough local investigation of all unexpected deaths in healthcare settings, both in the NHS and in the independent sectors. The CQC should consider the effectiveness of such investigations as part of its inspection programme of healthcare providers.

4.3 In the case of NHS organisations, investigations into unexpected deaths should be carried out in line with NHS Improvement’s Serious Incident framework (SIF). In particular family members, carers or advocates must be involved and supported (e.g. through family liaison) from the outset and be kept informed of progress and the outcome. Investigations must be expertly and objectively overseen and, where appropriate, independently-led. A member of the healthcare provider’s Board must be appointed to be responsible for ensuring the SIF is followed in relevant investigations. The outcome of such investigations should be reported to the Board and shared with the relevant regulatory, statutory, advisory and professional bodies. A similar methodology for investigations should be adopted by private healthcare providers.

4.4 Healthcare providers should ensure that people conducting investigations have received appropriate training, including on equality and diversity. NHS Improvement’s SIF should include guidance on how to consider equality and diversity considerations in investigations, including adherence to appropriate equality and diversity standards such as WRES[1] (Workforce Race Equality Standards) standards for the NHS. Wherever possible the investigation team should include Black, Asian and Minority Ethnic (BAME) representation.

[1] WRES is currently a requirement for NHS commissioners and NHS healthcare providers including independent organisations through the NHS standard contract.

4.5 Proposals for the establishment of Healthcare Safety Investigation Branch (HSIB) as an Executive Non-Departmental Public Body should be implemented at the earliest opportunity. HSIB will support improved practice across the NHS by undertaking exemplar investigations and supporting the development of skilled NHS investigations.

4.6 Royal Colleges, professional representative bodies and healthcare providers should review the availability of independent support for staff involved in legal and regulatory proceedings.

## Reflective material

5.1 The Royal Colleges, through the Academy, and professional regulators working with appropriate professional bodies should review and, if necessary, amend guidance on how healthcare professionals carry out reflection, stressing the value of reflective practice in supporting continuous professional development. Guidance on carrying out reflection should take a consistent approach across all healthcare professional groups.

5.2 Both prosecuting authorities and professional regulators have been clear that they would be unlikely to use a healthcare professional's reflective material either for a criminal investigation or in considering a registrant's fitness to practise. The professional regulators should clarify their approach to reflective material through guidance.

5.3 Those professional regulators that have a power to require information from registrants for the purposes of fitness to practise procedures should have this power modified to exclude reflective material. Registrants will still be expected to co-operate with their regulator in line with their code of practice and to be open and honest with patients (or where appropriate the patient's advocate, carer or family) when something goes wrong with their treatment or care (the professional duty of candour).

## Professional regulation

### 6. Right of appeal against fitness to practise decisions

6.1 The Professional Standards Authority (PSA) should retain its right to appeal a decision of a fitness to practise panel to the High Court on the grounds of insufficient public protection. The duplicate power provided to the General Medical Council (GMC) to appeal decisions of the MPTS to the High Court should be removed. This will ensure a consistent approach to appeals across healthcare professions that are statutorily regulated.

6.2 Ahead of the legislative change needed to remove its power of appeal, the GMC should review its processes for deciding when to refer a decision of the Medical Practitioners Tribunal Service so that it is transparent and understood by all parties and involves a group or panel decision, as opposed to lying solely with the Registrar.

## 7. Consistency of fitness to practise decisions across professional regulators

7.1 Among professionals there is little understanding of what actions by a healthcare professional might lead to the public losing confidence in the profession. The PSA, working with professional regulators, should review how the impact on public confidence is assessed in reaching fitness to practise decisions about individual healthcare professionals, and develop guidance to support consistent decision making in this area.

7.2 The PSA should review the outcomes of fitness to practise cases relating to similar incidents and circumstances considered by different regulators. This review should seek to determine the extent and reasons for different fitness to practise outcomes in similar cases and, if appropriate, recommend changes to ensure greater consistency.

7.3 We recommend that professional regulators ensure that the healthcare professionals they rely upon for an expert opinion in fitness to practise cases have satisfied the requirements set out in recommendation 2.1.

## 8. Diversity in fitness to practise proceedings

8.1 We support the PSA's intention to introduce, as part of its Standards of Good Regulation, equality and diversity standards for professional regulators.

8.2 Professional regulators should ensure that fitness to practise panel members have received appropriate equality and diversity training.

## 9. Legal representation in fitness to practise proceedings

9.1 The PSA should review whether the outcome of fitness to practise procedures is affected by the availability of legal representation of registrants. This needs to be considered alongside broader proposals for the reform of professional regulation which seek to establish a less adversarial approach to fitness to practise issues through the use of undertakings and consensual disposal.

## 10. Support for patients and families during fitness to practise proceedings

10.1 Professional regulators should review and where necessary improve the support they provide to patients and family members whose care and treatment is an issue in fitness to practise proceedings against a healthcare professional.