

Response to Professor Sir Norman Williams review of gross negligence manslaughter

April 2018

1. Introduction

- 1.1 The Professional Standards Authority for Health and Social Care promotes the health, safety and wellbeing of patients, service users and the public by raising standards of regulation and registration of people working in health and care. We are an independent body, accountable to the UK Parliament. More information about our work and the approach we take is available at www.professionalstandards.org.uk.
- 1.2 As part of our work we:
 - Oversee the nine health and care professional regulators and report annually to Parliament on their performance
 - Conduct research and advise the four UK governments on improvements in regulation
 - Promote right-touch regulation and publish papers on regulatory policy and practice.
- 1.3 Our interest in the regulatory issues relating to gross negligence manslaughter (GNM) flows in part from our duty to promote best practice in the regulators' performance of their functions. For us this role has a broader meaning than simply ensuring that individual outcomes protect the public. We see it as our duty to encourage the development of regulatory models that are fair and proportionate, and generally serving the public interest.
- 1.4 Also relevant are our powers under section 29 of the NHS Reform and Health Care Professions Act 2002 to refer a fitness to practise case to court if we consider that the decision is insufficient to protect the public. We can also join an appeal by the General Medical Council (GMC) under section 40 of the Medical Act 1983. We review the bulk of decisions¹ made by fitness to practise panels across all the regulators and so have a unique view of the issues that arise in the sector. We should stress though that it not the Authority's role to appeal a fitness to practise (FtP) outcome because it is too harsh – our statutory powers in this respect are strictly limited to whether or not individual outcomes are sufficient to protect the public.
- 1.5 We considered the Medical Practitioner Tribunal (MPT) decision in relation to Dr. Bawa-Garba under section 40. We chose not to join the GMC's appeal because we did not find the MPT decision to be insufficient to protect the public,

¹ We do not review decisions that a registrant should be erased or struck off because, by definition, such a decision cannot be insufficient to protect the public in any circumstances.

despite our having the same statutory threshold as the GMC.² This was because it appeared to us that the sanction imposed by the panel of the MPT was within the range of reasonable sanctions available to the panel in the circumstances of that case. More information about our appeal powers is provided below.

2. Summary of key points

2.1 We welcome the opportunity to respond to this review by Professor Sir Norman Williams into the issues relating to gross negligence manslaughter in healthcare. We understand that this review has been triggered by a particular case, that of Dr Bawa-Garba, but it should be noted that the comments and views we set out in this submission have broader relevance and application.

2.2 Our key points can be summarised as follows:

- We do not think that it is necessary or appropriate for a regulator to have the right to appeal decisions of its fitness to practise panels:
 - it duplicates the established powers of the Authority and lengthens an already drawn-out process unnecessarily
 - regulators lack the ability that the Authority has to appeal on grounds of under-prosecution
 - regulators may be insufficiently independent of a case to exercise any appeal powers purely in the public interest
 - in the case of the GMC, there is a lack of transparency in the way that these powers are exercised.
- Decisions on cases about clinical error including GNM must consider the impact on a registrant's action of the environment in which they are working. Regulated professionals are individually accountable for their actions to their professional regulator, but fitness to practise panels must be capable of taking into account the environments and circumstances in which clinical errors are made when considering at all stages of the decision, and especially when looking at whether a registrant's fitness to practise is impaired, and which sanction to impose.
- The criminal process and the fitness to practise process are separate and have different purposes. The case law states that '*a criminal conviction marks a breach of criminal law. A finding of impairment marks a breach of professional standards.*'³
- The role of fitness to practise proceedings is to protect the public, maintain public confidence, and declare and uphold professional standards. Fitness to practise outcomes are intended to address these three limbs rather than to punish.

² Documents pertaining to our decision are available here:

<https://www.professionalstandards.org.uk/about-us/ask-us-for-information/freedom-of-information>.

³ [2014] EWHC 2723 (Admin). *The Professional Standards Authority v The Health and Care Professions Council and Ghaffar*.

- Fitness to practise outcomes that are too harsh may protect the public in the strictest sense, but have unintended consequences that undermine the broader aims of professional regulation and are not in the public interest.
- There is little understanding about what sorts of behaviours and failings constitute a genuine threat to public confidence, which is relevant in GNM cases where the registrant is found not to pose a risk to the public. Developing an evidence-base in this area would help to inform and bring greater consistency to decisions made by regulators, fitness to practise panels, the courts and the Authority about appropriate FtP outcomes.

2.3 We have provided in our comments below more detail on the purpose of fitness to practise, our role in this area and how it compares to that of the GMC. We have sought to respond to specific questions, and also commented on further areas that may be of interest to the inquiry. We hope our response will be useful to the Panel in considering how professional regulation deals with gross negligence manslaughter.

3. The purpose of fitness to practise proceedings

3.1 We felt it would be helpful to the Review Panel to set out our current understanding of the purpose of fitness to practise, which, as outlined above, differs from the purpose of criminal proceedings.

3.2 As things stand, the purpose of fitness to practise outcomes is expressed as three limbs, helpfully encapsulated in the case of *Cohen v GMC*:⁴

- the protection of patients
- the maintenance of public confidence in the profession, and
- upholding proper standards of conduct and behaviour.

3.3 If a case reaches a hearing, the panel typically has to establish the following:

- That the facts/allegations are found proved
- That the facts/allegations support one or more grounds to support a decision that the registrant's fitness to practise is impaired
- That impairment is found, and
- The appropriate sanction.

3.4 The three limbs set out at 3.2 must be considered both at the impairment and the sanction stages, and panels are expected to impose the least severe sanction necessary to achieve this threefold aim. They are now so engrained that they have recently been written into the over-arching duties of all eight of the UK and GB regulators we oversee and the Authority,⁵ and into the thresholds for referral of FtP decisions to the courts of the Authority and the GMC.

⁴ *Cohen v General Medical Council* [2008] EWHC 581 (Admin), [2008]. Available at <http://www.bailii.org/ew/cases/EWHC/Admin/2008/581.html>. [Accessed 1 November 2017].

⁵ The PSNI has yet to have its over-arching duty amended.

- 3.5 The landmark Cohen case also established the principle that FtP decisions should focus in the main on whether the registrant's fitness to practise is impaired at the time of the decision, and not simply on whether misconduct has been found.⁶
- 3.6 We have seen over the last few years an increased focus among the regulators on remediation. This shift can be seen in the mechanisms some of the regulators have developed for disposing of cases before they reach a hearing – the GMC has had undertakings⁷ in its framework for some time, and the Nursing and Midwifery Council (NMC) and General Dental Council (GDC) have also recently moved to regimes where these sorts of options are possible. The General Pharmaceutical Council (GPhC), which is the newest regulator, was set up with powers to agree undertakings at an early stage, and the PSNI has also gained these powers. We understand that other regulators are considering similar options.
- 3.7 In addition, research is emerging that suggests current fitness to practise approaches may in fact be counter-productive and even damaging. For example, research by McGivern *et al.* for the General Osteopathic Council (GOsC) highlights the negative impact on practice when information is spread around professional networks about bad experiences of hearings:
- 'stories about damaging experiences of FtP hearings may produce anxiety about regulation and consequent defensive practice in the wider osteopathic population'.⁸*
- 3.8 A further example is the apparently high number of suicides among doctors under investigation by the GMC, that prompted the Horsfall review.⁹
- 3.9 As set out in *Right-touch reform*, we support this greater emphasis on remediation, where it is the minimum regulatory force to achieve the desired result – namely protecting the public, maintaining confidence in the profession, and declaring and upholding professional standards. This approach to fitness to practise can be described as follows:
- Fitness to practise outcomes should fulfil the three limbs of public protection through meaningful remediation where possible, and degrees of restrictions on practice where not.*
- 3.10 Restrictions on practice include conditions, suspensions and erasure. Cases where remediation is not possible include those where the actions of the

⁶ Although the GCC and GOsC still have legislation based on misconduct rather than impairment of fitness to practise.

⁷ Undertakings are similar to conditions of practice, but agreed between the regulator and the registrant, usually at the end of the investigation. Cases that are disposed of in this way do not reach the hearing stage unless undertakings are subsequently breached.

⁸ McGivern, G, et al, 2015. *Exploring and explaining the dynamics of osteopathic regulation, professionalism and compliance with standards in practice. Report to the General Osteopathic Council.* Available at <http://www.osteopathy.org.uk/news-and-resources/document-library/research-and-surveys/dynamics-of-effective-regulation-final-report/dynamics-of-osteopathic-regulation-final-report.pdf>. [Accessed 1 November 2017].

⁹ General Medical Council, December 2014. *Doctors who commit suicide while under GMC fitness to practise investigation, Internal review, Sarndrah Horsfall, Independent Consultant.* Available at http://www.gmc-uk.org/Internal_review_into_suicide_in_FTP_processes.pdf_59088696.pdf [Accessed 1 November 2017].

registrant are fundamentally incompatible with continued registration. It has also been suggested that remediation is less relevant in cases where there is a public interest impairment or where the problem is attitudinal – such as dishonesty. However, we also know from our commissioned consumer research that the public view of what constitutes a threat to public confidence can differ significantly from that of FtP panels and the courts.¹⁰ There is a need for further research to gain a clearer understanding of what constitutes a genuine threat to public confidence, and how this might be applied to decisions about impairment and sanction.

- 3.11 Such research could inform the development of guideline cases to help decision-makers, registrants, the public, and employers understand how different types of case should be disposed of. A sanctions advisory panel involving representatives of the regulators and other key stakeholders, including patient representatives could be responsible for informing the content of such guidance.

4. Role of the Authority and the GMC in relation to fitness to practise decisions

- 4.1 The Authority has three ways of considering the regulators' fitness to practise function:

- Through our duty under Schedule 7 of the NHS Reform and Health Care Professions Act 2002 (as amended) to report to Parliament on the performance of the regulators we oversee
- Through our policy work
- Through our powers under section 29 of the NHS Reform and Health Care Professions Act 2002 (as amended), and section 40 of the Medical Act (as amended): these powers enable us to refer a fitness to practise decision to the High Court (or equivalent in Scotland and Northern Ireland) if we consider it insufficient to protect the public, taking into account the three limbs of public protection (s.29); and to join an appeal by the GMC of an MPT decision (s.40) for the same reason.

- 4.2 Our reporting powers in relation to the performance of the regulators are an indirect means of influencing regulatory outcomes. Every year we assess the performance of each regulator against our Standards of Good Regulation, which cover fitness to practise as well as the other regulatory functions.¹¹ We publish a report for each one annually in respect of the previous year's performance, and lay an overview report before the four UK legislatures. While these reporting and publication powers are an important and powerful tool for improving overall performance, they do not enable us to influence individual

¹⁰ See for example the Policis research for the Professional Standards Authority, June 2016. *Dishonest behaviour by health and care professionals: exploring the views of the general public and professionals*. Available at: <http://www.professionalstandards.org.uk/publications/detail/research-dishonest-behaviour-by-professionals>

¹¹ Our Standards are currently under review. The current version is available here: <https://www.professionalstandards.org.uk/publications/detail/standards-of-good-regulation>.

fitness to practise outcomes. The regulators are not obliged to act on our recommendations, though in most cases they do.

- 4.3 We also develop fitness to practise policy, which is informed by, and in turn feeds into our performance review and section 29 scrutiny functions. Most recently we published a review of current fitness to practise models, and outlined options for the future in *Right-touch reform*.¹²

Our appeal powers

- 4.4 Our section 29 powers enable the Authority to influence the outcome of individual cases. If we refer a decision to the Court and the Court agrees that a decision is insufficient to protect the public, it can send the case back to be considered by a fresh panel of the regulator, or it can substitute the original sanction for its own. Our power also helps to create case law that clarifies the purpose, role and scope of fitness to practise decisions and how they should be made.

Threshold and decision-making process

- 4.5 The Authority has a clear process and criteria for deciding whether or not to exercise its powers under section 29, which enables it to exercise its discretion transparently and consistently. Each fitness to practise decision is examined by Authority staff, and those which may be insufficient are considered further by a member of our legal team through a detailed review of the papers. If the decision is considered likely to be insufficient at this stage, a case meeting is called with an external lawyer at which a three-member panel decides whether to refer the case to Court. The criteria and process that the Authority uses are set out in more detail in our Section 29 Process and Guidelines document available online.¹³ In addition, notes of all our case meetings are published on our website.¹⁴
- 4.6 Our s.29 appeal threshold (which is the same as the GMC's section 40 threshold) has been defined as follows in our legislation, since December 2015:
- '(4) Where a relevant decision is made, the Authority may refer the case to the relevant court if it considers that the decision is not sufficient (whether as to a finding or a penalty or both) for the protection of the public.*

(4A) Consideration of whether a decision is sufficient for the protection of the public involves consideration of whether it is sufficient—

- (a) to protect the health, safety and well-being of the public;*
- (b) to maintain public confidence in the profession concerned; and*

¹² Professional Standards Authority, November 2017. *Right-touch reform: a new framework for assurance of professions*. Available at:

<https://www.professionalstandards.org.uk/publications/detail/right-touch-reform-a-new-framework-for-assurance-of-professions>. [Accessed: 16/4/18]

¹³ Available at: <https://www.professionalstandards.org.uk/docs/default-source/section-29/section-29-general/decisions-about-regulated-practitioners.pdf?sfvrsn=2>

¹⁴ See: <https://www.professionalstandards.org.uk/what-we-do/our-work-with-regulators/decisions-about-practitioners>.

*(c) to maintain proper professional standards and conduct for members of that profession.*¹⁵

- 4.7 At a case meeting, the Authority looks at each case in two stages. First it considers whether the decision was, in fact, insufficient. If it considers that it was, it then goes on to look at a number of factors in deciding whether or not to appeal. These discretionary questions include:
- The prospects of persuading the court that the decision is insufficient
 - Alternative means of achieving public protection
 - The impact on the Authority's resources.
- 4.8 The Authority will also address the likely impact of any action that it takes. If it decides not to appeal, the Authority may issue learning points to a regulator aimed at addressing any concerns that it has identified with the process.
- 4.9 The Authority does not appeal in order to make case law or to establish matters of principle, though decisions may do this as a by-product. The purpose of our appeal power is to protect the public, and that is our over-riding concern in exercising it.
- 4.10 Our deliberations necessarily take into account the courts' past decisions. In particular, we have noted that the courts are usually reluctant to interfere with panel decisions unless there is a clear reason to do so. Findings of fact, where the panel has heard evidence are treated as 'virtually unassailable'¹⁶ and are likely only to be questioned where the panel has behaved entirely irrationally. Such cases are rare. In addition, the courts will also defer to or be reluctant to interfere with an expert panel's view of the seriousness of the conduct or, indeed, the sanction, unless there has clearly been an error, omission or irregularity in the panel's consideration.
- 4.11 A further point to note is that in the past few years, the courts have taken a more nuanced approach to certain types of conduct. It is clear, for example, that dishonesty is no longer seen as automatically leading to a striking off. Recently, the courts have suggested that there is a spectrum of dishonest conduct and that panels need to be alive to that in their approach to sanctions.
- 4.12 We should stress that there are many cases where there is no clearly 'right' sanction. There will often be a legitimate debate about whether the appropriate sanction is to strike the registrant off or whether a period of suspension, possibly with review, would be sufficient to mark the public interest.

Oversight and quality assurance of s.29 and s.40 decisions

- 4.13 Section 29 and s.40 decisions are overseen by the Authority's Scrutiny Committee. The Committee regularly reviews a sample of final fitness to practise panel decisions that the Authority did not consider at s.29 or s.40 case meetings, as well as reviewing s.29 and s.40 case meeting outcomes, to

¹⁵ Section 29 (4) and (4A) of the NHS Reform and Health Care Professions Act, as amended by *The General Medical Council (Fitness to Practise and Over-arching Objective) and the Professional Standards Authority for Health and Social Care (References to Court) Order 2015*.

¹⁶ [2010] EWCA Civ 407. *Dr. David Southall and the General Medical Council*. Available at: <http://www.bailii.org/ew/cases/EWCA/Civ/2010/407.html>. [Accessed: 16/4/18]

provide quality assurance. The Scrutiny Committee consists of three members of the Authority's Board, and reports regularly to the Authority's Board on its exercise of these functions and makes recommendations for change.

- 4.14 Any concerns expressed by the Scrutiny Committee about any aspect of the functioning of the Authority's s.29 and s.40 processes will be brought to the attention of the Chief Executive (or other officer appointed for the purpose) and corrective action will be taken where appropriate. The Authority's Board, in addition to receiving the minutes of Scrutiny Committee meetings, receives an update at each meeting about the Authority's exercise of its s.29 and s.40 powers and in particular about any ongoing Court referrals.

The GMC's appeal powers and our power to join their appeals

- 4.15 The GMC acquired parallel powers to appeal decisions of the MPT in December 2015. This is possible because its adjudication function, in the shape of the MPTS, has a degree of independence from the GMC enshrined in its legislation – although it is not fully independent in the way that the Office of the Health Professional Adjudicator would have been had it not been shut down.¹⁷ None of the other regulators have this separation, therefore it would not currently be feasible for the remaining eight regulators we oversee to have a right of appeal.
- 4.16 The GMC threshold is described in similar terms to ours, however it lacks the ability the Authority has to refer a case on grounds of under-prosecution. This is because it cannot argue against its own handling of a case.
- 4.17 As at 6 April 2018, 23 GMC appeals were concluded. In addition, there was one outstanding appeal and two appeals lodged against review decisions (but the Court considered these to be parasitic to the substantive appeal and so were not pursued¹⁸).

Table 1: GMC appeals concluded as at 6 April 2018

GMC Appeals upheld	15
GMC Appeals dismissed	2
GMC Appeals withdrawn	4 withdrawn (2 not pursued following guidance from the Court)
GMC Appeals settled	2 settled (1 where the Authority was an interested party)

¹⁷ The MPTS is a statutory committee of the GMC, and reports into the GMC. OHPA was an independent adjudication body set up by Government to consider GMC cases initially, with the option of expanding to other regulators in due course. It was closed in 2012 having never heard a case. For more information, see: <https://www.gov.uk/government/organisations/office-of-the-health-professions-adjudicator>.

¹⁸ The Authority has not considered the most recent appeal and given the appeals lodged against reviews were not pursued these cases do not form part of the data/analysis in this paper other than the fact of their existence.

- 4.18 Under section 40 of the Medical Act 1983, the Authority can join an appeal by the GMC if it wishes to add a ground to the appeal. In practice we will join an appeal if:
- There are serious aspects of the case that are not covered by the GMC's appeal (for example because there have been failures in the GMC's prosecution of the case)
 - The case may have implications for the Authority's own jurisdiction or
 - There is another strong public interest reason to do so.¹⁹
- 4.19 With the 23 GMC appeals referred to above, we considered that the decision of the Tribunal was *insufficient* for 14 of them:
- The Authority joined the appeal as an interested party in three of those cases:
 - Two of these appeals were upheld by the Court and one was settled by the parties (with the Authority taking the lead²⁰)
 - The Authority decided not to join as an interested party in 11 of those cases
 - Nine appeals were upheld by the Court, one withdrawn and one settled by consent
- 4.20 The Authority considered the decision of the Tribunal to be *sufficient* in nine of the GMC appeals. It follows that having reached this view it would be unlikely that the Authority would join as an interested party:
- Four of these appeals were upheld by the Court, two were dismissed, and three were withdrawn
- 4.21 The reasons for which we found decisions to be sufficient, and therefore disagreed with the GMC can be summarised as follows:
- Either the case fell within the reasonable discretion available to panels and would be likely to be subject to deference
 - Or the decision was not insufficient to protect the public.
- 4.22 Since the coming into force of Section 40A, the Authority has appealed two cases the GMC did not and both of these were settled with the Authority's appeal being upheld in both cases.
- 4.23 More information is provided about our views on the cases appealed by the GMC in Annex B.

Comments on the GMC's right of appeal

- 4.24 We expressed our concerns about the GMC obtaining a right of appeal over MPT decisions in response to successive Government and GMC-run consultations. These consultations took place between 2011, when the GMC first consulted on the creation of the MPTS and the GMC right of appeal, and 2014 when Government consulted on legislative changes to the Medical Act to

¹⁹ We have set out in detail our approach to reviewing cases that the GMC has decided to appeal in Annex A.

²⁰ The registrant approached the Authority in this case as they felt there was merit in "our" appeal and not the GMC case.

put the MPTS on a statutory footing and give the GMC its parallel right of appeal.²¹

- 4.25 The concerns we outlined throughout this period remain and can be summarised as follows:
- The inefficiency of having two bodies with identical appeal rights, and the waste of public resources that this represents
 - Public and registrant confusion about the duplication of efforts, resources and overlapping responsibilities with the Authority's appeal powers
 - The risk that decisions about whether or not to appeal may be influenced by extraneous matters which may not be relevant to public protection because the prosecution is close to the detail of the case, or because the MPTS is legally part of, and funded by, the GMC²²
 - Concerns about the practicalities and complexities of having two bodies with an identical right of appeal.
- 4.26 In practice, we find that the way the GMC has implemented its right of appeal lacks the transparency and robustness we would expect for the exercise of this kind of statutory power. Although the GMC's guidance for decision makers is publicly available, the process is not described in detail, and no documents relating to specific decisions are published. The process itself appears to us to have few checks and balances – with only an informal screening process, a single final decision-maker (the Registrar) as opposed to a Panel, and no scrutiny to match that of our Scrutiny Committee and Board.
- 4.27 In addition, there are a number of reasons why an independent body is better placed to appeal a fitness to practise decision than the regulator that prosecuted the case.
- 4.28 First, one of the key reasons why a decision may be insufficient is deficiencies in the prosecution. This may be because particular conduct was not charged adequately, or evidence available to the regulator was not presented to the panel. The recent case of *The Professional Standards Authority v. NMC and X* is an example of the sorts of significant failings by a regulator that would go undetected and unchallenged if the power of appeal lay solely with the regulator.²³ As a matter of principle it is wrong for the regulator to have the opportunity of second bite of the cherry in order to correct its own mistakes. Moreover, it may not even recognise that it has made them. This means that the Authority still needs to look at cases from this point of view.
- 4.29 Second, we think that there is a danger that a regulator, as the prosecutor may be too close to the case to take a balanced judgement on the public interest in whether or not to appeal. When Parliament introduced the Section 29 power, it

²¹ See for example: https://www.professionalstandards.org.uk/docs/default-source/publications/consultation-response/others-consultations/2014/changes-to-modernise-and-reform-the-adjudication-of-fitness-to-practise-cases.pdf?sfvrsn=d6aa7f20_9

²² We have not seen evidence of this in practice, but the potential remains for these issues to materialise under the current legal framework.

²³ [2018] EWHC 70 (Admin). Judgment available in full at: https://www.professionalstandards.org.uk/docs/default-source/section-29/court-judgments/nmc/180119-psa-v-nmc-and-reg-x.pdf?Status=Temp&sfvrsn=68877220_2.

was explicitly intended to be a power of last resort. There is a danger that the regulator may seek to substitute its own views for those of its panels, or that decisions about whether to appeal may be influenced by reputational concerns.

- 4.30 At present, regulators can draw the attention of the Authority to decisions that concern them, but in practice they do so rarely. At the time of the consultations relating to the GMC right of appeal, we suggested that some more formal means for a regulator to refer a decision to the Authority, in order that it exercise its s.29 powers, might be a simpler, more cost-effective solution. We still hold this view.
- 4.31 It is worth noting that the GMC's gaining its right of appeal coincided with the change to the Authority's appeal threshold.²⁴ It appears to us that this change may have lowered the bar for appeals. We used to have to satisfy the court that the decision was 'manifestly inappropriate'²⁵ but that wording has now been taken over into the new test of insufficiency. Rather the requirement is that the decision is wrong.²⁶ There may therefore be limited value in comparing the volume of cases appealed by the GMC since December 2015 to the volume of cases appealed in previous years by the Authority.

5. Further areas of interest

The process for how decisions are made to refer a healthcare professional who has been investigated, charged or convicted of gross negligence manslaughter or other criminal offences to fitness to practise proceedings.

- 5.1 It should be stressed that the criminal process and the fitness to practise process are separate and have different purposes. The case law states that '*a criminal conviction marks a breach of criminal law. A finding of impairment marks a breach of professional standards.*'²⁷ The criminal process is backward-looking, whereas fitness to practise proceedings look at impairment at the time of the hearing. In that context, it is right for the regulator to look at mitigation, insight and the registrant's behaviour since the incident that gave rise to the conviction.
- 5.2 It is worth noting that the more weight is put on the conviction aspect of a GNM case in fitness to practise proceedings, the more reliant regulators are on decisions and prosecutions by the Crown Prosecution Service (CPS). It also means that in such cases, more weight is given by the FtP panel to the consequences of the registrant's actions – namely the death of a patient, without which there can be no manslaughter charge in the first place – than is in cases where there is no such conviction.

²⁴ Previously, our threshold had been defined in terms of 'undue leniency'.

²⁵ [2004] EWCA Civ 1356. *Dr Giuseppe Ruscillo and (1) The Council for the Regulation of Health Care Professionals and (2) The General Medical Council & ANR.*

²⁶ [2017] EWHC 1247 (Admin). *General Medical Council v. Dr Nilesh Pravin Jagjivan and Professional Standards Authority for Health and Social Care.*

²⁷ [2014] EWHC 2723 (Admin). *The Professional Standards Authority v The Health and Care Professions Council and Ghaffar.*

- 5.3 Currently regulators deal with criminal conviction cases in the same way as they deal with other types of concern brought to them: through an initial investigation and consideration by Case Examiners or an Investigating Committee before the matter is referred to a fitness to practise panel. This can cause delays and there are understandable concerns that this delays the most egregious cases, where an erasure is obviously required, from being resolved.
- 5.4 We support the view that certain types of very serious criminal offence should be treated as grounds for automatic erasure, as set out in our 2017 report, *Right-touch reform*. A similar view was put forward by the GMC in a 2011 consultation,²⁸ and the Law Commissions in their review of the legislation for the UK and GB regulators.²⁹ We are clear though that such a power should apply only to the most serious offences, and we have not gone so far as to suggest a list. Neither the GMC nor the Law Commissions included any kind of manslaughter offence, GNM or other, in their lists – we agree that it would be inappropriate to do so.

The consideration of mitigating and broader contextual factors within the decision-making process

- 5.5 Broader contextual factors may be considered relevant by the panel at all stages of decision-making, but they are most commonly taken into account at the sanction stage as mitigation – and we support this approach. The fact that they may also have been considered at the fact-finding stage should not, in our view, affect their importance at the sanction stage.
- 5.6 Decisions on cases about clinical error, including GNM must consider the impact on a registrant's actions of the environment in which they are working. If they do not, it could lead to an unfair situation where one registrant made clinical errors working in perfect conditions, and another committed the same errors in adverse conditions, but the FtP outcomes were the same. There is also a risk of widening the gulf between professional and corporate accountability, that exists in part because of the structural separation of professional regulation from system regulation.
- 5.7 Generally speaking, fitness to practise outcomes that are too harsh may protect the public in the strictest sense, but have unintended consequences that undermine the broader aims of professional regulation and are not in the public interest.

The process of working with expert opinions, including the method for selection and what tests are conducted to ensure quality assurance. Are you satisfied with this process and would you recommend changes to selection, training or accountability of experts?

- 5.8 We cannot comment on the use of experts in the criminal justice system or their approach to quality assurance. Experts do, however, have a role to play in all

²⁸ GMC, January 2011. *Reform of the fitness to practise procedures at the GMC: Changes to the way we deal with cases at the end of an investigation. A paper for consultation*. [Not available online]

²⁹ Law Commissions, 2014. *Regulation of Health Care Professionals, Regulation of Social Care Professionals in England*. paragraph 8.28. Available at http://www.lawcom.gov.uk/wp-content/uploads/2015/03/lc345_regulation_of_healthcare_professionals.pdf. [Accessed 9 April 2018]

decision-making stages of the fitness to practise process and we have observed that regulators frequently encounter problems over the quality of expert advice and evidence. This is, however, a complex area and the problems that exist may be as much down to poor decisions by the regulator as problems in the supply or quality of experts. In cases involving GNM, experts are unlikely to play a significant, if any, role in fitness to practise processes: they will have played a role in the criminal proceedings.

The role of reflective learning, candour and transparency

- 5.9 The importance of candour has been reaffirmed in the Francis report³⁰ and more recently in the Hyponatraemia Inquiry,³¹ both of which highlighted the need for organisations and professionals to be open and honest with patients when things have gone wrong. Such openness goes hand-in-hand with a culture of reflection and learning, as we found in our review of the literature on this subject.³²
- 5.10 Regulators have a role in supporting learning cultures and encouraging professionals to be candid. As noted earlier in our evidence, fitness to practise is increasingly being used to support remediation where appropriate, if registrants' standards of practice or conduct have fallen short. Continuing fitness to practise requirements are becoming more focused on learning and improving, rather than on spotting the 'bad apples'. The codes and standards of regulators all include duties to be open and transparent with those that they treat – and these codes form the basis of training curricular and continuing fitness to practise requirements. Professionals also have a duty to be accountable and honest with regulators when under investigation.
- 5.11 In 2014, eight of the nine regulators signed a declaration supporting the duty of candour and committing to embedding it in their work. However, we have not observed significant tangible evidence that this has had an effect in how fitness to practise cases are prosecuted or panel decisions made. In our experience it is rare to find breach of the duty of candour to be charged in fitness to practise hearings, nor does candour (lack or existence thereof) feature in aggravating and mitigating factors in the decisions of panels. We are currently looking into the possible reasons for this as part of a policy project looking at how the professional duty of candour has been embedded by the regulators.
- 5.12 A significant barrier to learning from mistakes is what is often called a 'blame culture' in which staff fear being punished and therefore do not report their mistakes. One means implemented by the Government to overcome this barrier is the Healthcare Safety Investigation Branch (HSIB). HSIB conducts investigations into incidents across the NHS in England, aiming to improve patient safety by determining the causes of incidents rather than identifying organisations or individuals who are specifically at fault. There is currently a

³⁰ The Mid Staffordshire NHS Foundation Trust Public Inquiry, available at:

<http://webarchive.nationalarchives.gov.uk/20150407084003/http://www.midstaffspublicinquiry.com/>

³¹ Inquiry into Hyponatraemia-related Deaths <http://www.ihrdni.org/>

³² Professional Standards Authority, 2013. *Candour, disclosure and openness: Learning from academic research to support advice to the Secretary of State*. Available at:

https://www.professionalstandards.org.uk/docs/default-source/publications/research-paper/candour-research-paper-2013.pdf?sfvrsn=5b957120_8

draft parliamentary Bill to build on HSIB and create a statutory Health Service Safety Investigations Body (HSSIB).³³ Alongside the creation of HSSIB, the draft Bill also makes provision for:

- The ability for HSSIB to create a 'safe space' within which 'participants can provide information for the purposes of an investigation by imposing a prohibition on the disclosure of information held by the HSSIB in connection with an investigation. Information will only be able to be disclosed in certain limited circumstances or by order of the High Court'
- The 'accreditation of NHS trusts and foundation trusts to carry out investigations into patient safety with the benefit of 'safe space'.'³⁴

5.13 We are concerned that these provisions contradict the principles of openness and transparency in healthcare. For example, an NHS trust conducting a safe space investigation that found new information relevant to a clinical failing would not be able to disclose that information to the patient or their family.

5.14 It is our fear that such confidential enquiries will be perceived by patients and their families to be contrary to the expectation of greater honesty and openness by professionals, while effectively discouraging professionals to fulfil their professional duty of candour. More information on our concerns about 'safe spaces' and HSSIB can be found in our response to the consultation on these proposals.³⁵

Interaction between regulation of organisations and professionals

5.15 One of the complexities of dealing with gross negligence manslaughter is that it sits on the boundary between individual and corporate responsibility. What is striking in the Bawa-Garba case is the extent of the systemic failings that were taking place at the time of the incident. Some have argued that such failings should have been given greater weight in mitigation. Certainly it is clear to us that the separation of professional regulation and system regulation (and other means of holding organisations to account) poses serious challenges.

5.16 Individual accountability is an essential element of the regulatory landscape, and part of what differentiates a regulated professional from other occupations. However, further discussion is needed, in our view, to establish how regulators and fitness to practise panels should take into account organisational factors beyond a professional's control, which may have contributed to their failings. This links to the points we made earlier about understanding public confidence, and should form part of a wider debate about what we can reasonably expect of a professional in a health and care system that is under increasing financial pressure.

³³ Draft Health Service Safety Investigations Bill, available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/645961/Draft_bill_health_service_safety_investigations_bill.pdf

³⁴ Ibid, pg.3.

³⁵ Professional Standards Authority, Response to the consultation: Providing a 'safe space' in healthcare safety investigations, available at: https://www.professionalstandards.org.uk/docs/default-source/publications/consultation-response/others-consultations/2017/authority-response-to-dh-safe-spaces-final.pdf?sfvrsn=b79e7020_6

Inconsistencies between regulators

- 5.17 The tragic death of a child patient in which Dr Bawa-Garba was implicated led to two different sanctions being reached for the same criminal offence, one by the MPT in respect of the doctor, and one by the NMC for the nurse concerned. In our view, it would be worth conducting a cross-regulator assessment of outcomes of similar or linked cases to determine the extent and reasons for any unjustifiable discrepancies in fitness to practise outcomes.
- 5.18 The Government is already looking at reform of the regulation of health and care practitioners, and we hope that such reforms might bring greater consistency to the regulators' FtP frameworks. In the meantime, however, the Authority is interested in exploring whether some central sanctions guidance and setting up of a sanctions advisory panel, possibly co-ordinated by the Authority, could help address the concerns about consistency of decisions.

6. Further information

- 6.1 Please get in touch if you would like to discuss any aspect of this response in further detail. You can contact us at:

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7. **Annex A: The Authority's process for considering whether to join a GMC appeal**

7.1 In June 2017,³⁶ the Authority reviewed its process for considering decisions where the GMC had lodged an appeal under s40A. Prior to this date, a case meeting would be convened in relation to every case and regardless of the Authority's assessment of the case.

7.2 The current process is as follows:

- A Detailed Case Review (DCR) is undertaken on all cases in which the GMC has notified the Authority of its intention to appeal. This is a review of all the papers before the panel and any other relevant material by a lawyer who provides a view on whether the decision is likely to be insufficient to protect the public.
- Where the DCR concludes that there are no concerns about the sufficiency of the decision to protect the public (having regard to the criteria in section 29A of the Act), then the Director of Scrutiny and Quality and the Assistant Director (Legal) will close the case with reasons. In borderline cases, there will be a discussion with the Chief Executive.
- Where the DCR concludes that there are concerns about whether the decision is sufficient to protect the public, the person undertaking the DCR will then consider the GMC's Grounds of Appeal, and will set out a view as to whether the GMC's Grounds address the concerns identified in the DCR.
- Where the DCR concludes that any concerns are adequately addressed in the GMC Grounds, the Director and Assistant Director will consider this and may do any or all of:
 - Agree and close the case
 - Discuss the case with the Chief Executive
 - Seek legal advice on any matters of concern.
- Where the DCR concludes that any concerns have not been adequately addressed or there are other points of law or policy which affect the Authority's jurisdiction, the Director and Assistant Director will consider this and may do any or all of:
 - Disagree and close the case with reasons
 - Seek legal advice
 - Invite the GMC to amend its grounds to take account of our concerns
 - Discuss the case with the Chief Executive.
- A case meeting will be held where:

³⁶ Date the paper was considered and noted by the Scrutiny Committee.

- a) the GMC refuses to amend its Grounds in the light of the Authority's suggestions and/or
 - b) there are potential legal or policy issues about which the Authority may wish to ensure that its views are placed before the Court; and/or
 - c) the case raises serious issues which need to be considered at a case meeting (irrespective of the question of sufficiency).
- Decision makers at each stage of the process will have regard to the decision-making criteria in deciding whether or not to join the GMC appeal.
 - Where the GMC decides to settle a case which the Authority has not joined as party, the Protocol requires the GMC to give us seven days' notice. In that case, where the view has been taken that the decision is insufficient, we will urgently:
 - Consider the background to and terms of the settlement and take an initial view on whether the Authority should consider taking over the appeal
 - Discuss the case with the CEO.
 - Where the CEO does not consider that the settlement is appropriate or there are other reasons why the Authority should consider taking over the appeal, he will either convene a case meeting or take emergency decision, in accordance with delegated powers.
 - There may be circumstances where the GMC lodges an appeal against a substantive decision (first appeal) and a subsequent review hearing, before the first appeal has been heard. In those circumstances the Authority can re-open a previous case meeting to reconsider any new legal issues or information raised.

7.3 The Authority may take into account the following criteria when exercising its discretion under section 40B of the Medical Act 1983 to join an appeal initiated by the GMC:

- Whether the Authority considers that the decision is insufficient to protect the public.
- Whether the GMC's appeal against the decision of the Tribunal has addressed all concerns identified by the Authority. If not, the decision makers should consider the value of joining the appeal on those outstanding matters.
- Put another way, does the Authority have any particular case to advance substantively in the appeal which is not advanced by the GMC (and which it cannot persuade the GMC to advance)?
- What outcome (e.g. sanction) would have been sought by the Authority had it referred the matter itself under its section 29 jurisdiction, and whether this is different from the sanction sought by the GMC.

- Why the Authority seeks to achieve this particular outcome. The decision makers should clearly identify the issues that cause concern and consider their importance in achieving the primary objective.
- The likelihood of the GMC appeal succeeding; whether the GMC appeal is “bound to fail”; whether the Authority’s joining the appeal would increase the prospects of a successful outcome.
- The consequences of a negative outcome.
- The potential for the GMC Grounds of Appeal to undermine the current and established body of s29 case law. In particular,
 - Is the relationship between s40A and s29 an issue in the case?
 - Does an issue arise as to the interpretation of s40A arise which has relevance to the Authority since S40A is in the same terms as s29?
- Whether there are strong reasons why the Authority might wish to become a party to the proceedings (e.g. because of its views about the seriousness of the registrant’s actions or omissions, because the case raises novel issues, or because of any policy issues that might be affected by the decision)?³⁷
- Whether there are other more appropriate means available to the Authority to achieve the desired public protection.
- The impact on the resources available to the Authority.
- The impact on the Registrant and witnesses in the case.³⁸
- Whether the GMC has requested that the Authority join an appeal, and if so, the reasons for that request.
- Whether there is any other point of public interest arising upon which the Authority considers it is necessary or appropriate to be heard in this case.
- It is possible that the Authority may have sight of the registrant’s defence at a later stage if shared, or in the context of parallel legal proceedings. In this situation, the Authority may also wish to consider whether it has any response to the registrant’s defence which is not advanced by the GMC (and which it cannot persuade it to advance).

³⁷ Being joined as a party will ensure that the Authority is served with all court documents and can make representations before the Court. This also means that the Authority will be notified if the GMC decided to withdraw the appeal – the Authority can in those circumstances take a view as to whether it wishes to proceed with the appeal (in that case the S40 appeal will revert to being a S29 appeal).

³⁸ This may be particularly relevant where the Authority is seeking a re-hearing, though it should be borne in mind that the Authority can ask the court to substitute its own decision rather than remitting the case in certain types of case (eg where witnesses are vulnerable and there is no concern over the findings of fact/where the doctor is at risk of harm)

8. Annex B: Summary of the Authority's positions on GMC appeals concluded

Cases where the Authority has become an interested party

- 8.1 The Authority has become an interested party in 3 cases. The following factors influenced the decision to become an interested party.
- In relation to the first cases lodged by the GMC, the Authority concluded that without seeing the skeleton arguments, it was difficult to make a final decision about the matters the Authority may wish to raise in the appeal.
 - The defendant doctor raised issues in relation to jurisdiction which could have an impact on the scope of the Authority's own S29 jurisdiction.
 - The identification of a serious procedural irregularity such as under prosecution which, if such matters had been included in the allegation, had the potential to affect the final outcome.

Cases where the Authority has concluded that the decision is insufficient but has decided not to join as an interested party

- 8.2 The Authority has followed this route in 11 cases. The following factors influenced this decision.
- The GMC grounds were comprehensive and accordingly the Authority would not add anything to the substantive appeal by becoming an interested party.³⁹
 - The GMC grounds address *most* of the matters that the Authority would have raised and the GMC has agreed to supplement the Grounds with the Authority's concerns. Where there have been gaps, these have been with regard to minor issues or matters of emphasis and the Authority has written to the GMC requesting that the grounds be amended to reflect this.⁴⁰
 - The appeal did not raise any novel legal principles.

Cases where the Authority has concluded that the decision is sufficient

- 8.3 The Authority has followed this route in 9 cases. The following factors have influenced this decision.
- Deference afforded to decisions of the specialist tribunal: It was not possible to conclude that the decision taken by the panel was not one that was open to a reasonable panel that had taken into account all relevant information and had not fallen into error.

³⁹ This is the main factor.

⁴⁰ GMC's case could be strengthened by including the fact that the Registrant's conduct amounted to a criminal offence and that it was motivated by financial gain; the Grounds should also argue that the panel erred in concluding that the Registrant had the potential to develop insight; the grounds did not address the panel's failure to consider the wider public interest.

- Taking care not to substitute our view for that of the panel: Whilst the Authority might conclude that an alternative sanction was more appropriate, it has taken the view that this would be to substitute its own view for that of the panel.
- Deference afforded to the panel's assessment of insight given the panel has had the opportunity to assess the registrant's credibility and reliability.
- A different assessment of the relevant case law and its applicability to health care professionals (e.g. with regard to restoration of solicitors).
- Where the Authority noted that there were additional charges that ought to have been alleged, those charges even if proved would not have had a material impact on the sanction imposed.