

Response to consultation on ensuring patient safety, enabling professionalism

Q1. We think that fitness to practise should primarily be about managing the risk that a registrant poses to patients or members of the public in the future. Do you agree?

Like the NMC, the GMC's overarching objective in exercising our functions is the protection of the public. This involves the pursuit of three objectives, namely to protect, promote and maintain the health and safety and well-being of the public, to promote public confidence in the profession and to promote and maintain proper standards and conduct. As a regulator, we must strike a proper balance between these objectives. Patient safety is a key part of the GMC's role in fitness to practise proceedings, which includes managing any risk that registrant poses to members of the public. However, there are circumstances in which regulators do need to respond in order to uphold public confidence, even where there is no identified risk to patient safety. We have discussed regulatory action to uphold public confidence further in our response to Q3.

Q2. We don't think that fitness to practise is about punishing people for past events. Do you agree?

We agree with this, while recognising that registrants can find it difficult to distinguish between the purpose of regulatory action and the impact it has on them.

There are cases where we do consider that action is sometimes needed in relation to past events, even if there is no ongoing risk to patient safety, to uphold public confidence both in the medical profession and in its regulation. In these cases, it can be particularly difficult for registrants to distinguish our purpose of upholding public confidence and the impact on them of our action, however, the need to take action on public confidence grounds based on past events alone arises only in the most serious cases.

In the vast majority of cases that relate to past failings, we would not take regulatory action if there is no ongoing risk to patient safety.

We recognise that any regulatory action we take will have an impact on a registrant and we do not do this lightly. On a case by case basis we must balance and give appropriate weight to our overarching objective of the protection of the public, which involves

promoting and maintaining patient safety, public confidence in the profession and proper professional standards.

Q3. We propose that we will only take action to uphold public confidence when the conduct is so serious, that if we did not take action, the public wouldn't want to use the service of registrants. Do you agree?

We understand that the intention with this proposal is to identify a public confidence threshold. The impact of a registrant's conduct on how the public access health services is certainly a factor but we think that consideration of public confidence is wider than this. Given the nature of health services, it is important that patients have confidence and trust in health professionals at all times. If a registrant's actions undermines how they view the profession as a whole, than this raises public confidence issues regardless of whether the public want to use those services.

We also think public confidence can be affected to different degrees depending on the context and the nature of the concerns. Therefore, it is important that regulators have the power to take proportionate action in the circumstances and have access to a range of sanctions. Warnings for doctors, for example, allow us to indicate to a doctor, and the public, that the conduct, practice or behaviour is a departure from the standards expected of doctors and should not be repeated without restrictions on their practice.

The GMC has commissioned a review into gross negligence and manslaughter cases. As the [terms of reference](#) explain, this review will consider the '*meaning, appropriateness and measurement of 'public confidence' as an objective of the regulatory process. This will include understanding patient and public expectations of regulatory processes after a practitioner has been convicted of a criminal offence.*' The NMC may wish to consider the outcome of that review, which is due to report in early 2019, in taking forward its own work on public confidence thresholds.

Q4. Some clinical conduct, such as deliberately covering up when things go wrong, seriously damages public trust in the professions and undermines patient safety. Do you agree?

We agree that deliberately covering up when things go wrong is a clear breach of registrants' professional responsibilities. Such acts of misconduct risk patient safety and risk damaging public confidence. As a regulator, we would always take concerns of this nature seriously.

Ensuring that registrants are able to raise their concerns and are not fearful in doing so is an important factor in maintaining public confidence and patient safety. [The Freedom to speak up report](#) highlighted the importance creating a culture where professionals can raise their concerns and are not unduly punished for doing so. We have produced guidance [Raising and acting on concerns](#) to support doctors and the *Duty of candour*

guidance, published jointly with the NMC, advises registrants of their responsibilities to raise concerns and to maintain the safety of the public.

Q5. In those types of cases, the registrant should be removed from the register. Do you agree?

As above, we agree that deliberately covering up concerns is a serious matter and should be investigated fully with the full range of regulatory outcomes considered.

The way this proposal is currently worded is too prescriptive, and we would not agree that removal from the register will always be the appropriate action in such cases. There may be a difference in the level of concern about a registrant who has engaged in a pre-mediated and sustained cover up, and one who has covered something up in the moment but then admitted their mistake, or one who has felt under pressure from colleagues to take the action they have.

As a guiding principle, we consider that erasure is appropriate where the registrant's conduct is so egregious that nothing short of removal from the register would satisfy public confidence. There may be conduct that, whatever the context, is so serious that removal from the register is needed to manage public confidence but this would arise only in the most serious matters. For example, we have proposed that there should be a presumption of erasure for very serious criminal convictions and we have confined that to a very small number of the most serious offences, such as murder, rape, child sexual abuse but not for example fraud. In most cases, we believe it is important to consider the specific context in which the concerns arose. This includes the environment in which the incident occurred and whether the conduct was serious or persistent.

Q6. We propose that cases should be resolved at an early stage in the process if the registrant has fully remediated their clinical failings, even where those clinical failings have led to serious patient harm. Do you agree?

Yes, we agree with the principle of resolving cases at an early stage where registrants have fully remediated their clinical failings and no longer represent a risk to patient safety. However, it is not clear from the consultation documents how remediation would be assessed in determining whether or not regulatory action is needed. It will be important that evidence of remediation is clear and robust.

Agreeing undertakings provides a managed way for regulators to oversee a registrant's remediation. In the case of doctors, undertakings or conditions are kept under review and removed once the case examiners or tribunal is satisfied that the doctor has remediated and is fit to return to unrestricted practice. We have provided more detail about how we dispose of cases consensually by agreeing a programme of remediation through undertakings in our response to Q13.

In addition to agreeing undertakings to resolve cases early, we have expanded our provisional enquiries pilot to include single clinical incidents (ie an allegation of poor

clinical care involving a single consultation or procedure). Provisional enquiries help us decide whether we need to open a full investigation and involve gathering a few pieces of evidence to ascertain the seriousness of the allegation and how the doctor has responded. In single clinical incidents, we seek to gather information to identify whether the doctor's fitness to practise is currently impaired. During the pilot, cases have closed without being promoted to a full investigation where we have been able to gather evidence that the failing is not so serious as to require action on the grounds of public confidence and evidence that remediation has taken place.

It's important to maintain public confidence by communicating with those raising concerns so that they understand the outcome of their complaint. Our patient liaison service explains the fitness to practise process to individual patients and complainants at the onset of an investigation and meets with them again to discuss the outcome once the case has closed. These meetings ensure that the patient or complainant feels heard and involved in our processes. This can be particularly valuable where findings that there has been a serious failing do not lead to action because they have been remediated and are unlikely to recur. The NMC may wish to consider these cases when engaging with patients via the public support service referred to in the consultation.

Q7. We propose that every decision that relates to a restriction being placed on a registrant's practice (including voluntary removal) should be published. Do you agree?

We agree with the general principle outlined here. In the interest of transparency and public confidence, we think that outcomes that have been agreed consensually with the registrant should be published, with the exception of any information relating solely to confidential health information.

We publish our outcomes on the [List of Registered Medical Practitioners](#) and we recently introduced a change so that from 4 September 2017, with the exception of cases solely about a registrant's health, cases which conclude consensually through the agreement of undertakings have an explanatory summary to explain the concerns the undertakings are intended to address and why they are considered an appropriate outcome. In pure health cases, the fact that undertakings have been agreed is published, but we do not publish any accompanying information about the reasons for those undertakings. Information about a doctor's undertakings and accompanying summaries are subject to publication time limits, so once undertakings are lifted, they will remain on the doctor's history page for ten years, assuming the doctor remains registered. If undertakings relate to concerns solely about a doctor's health they will be removed from publication as soon as they are lifted.

In addition to the case summaries, we have introduced a [webpage](#) which sets out recent case examiner decisions to issue warnings, or to agree or vary undertakings. Decisions are published here for one year. The page was introduced in order to increase the transparency of our decisions and to achieve greater consistency in the publication of fitness to practise information between all decision making functions.

In February 2018, we introduced a revised [Publication and disclosure policy](#) for fitness to practise information. This introduced time limits on the publication and disclosure of historical fitness to practise information and aims to achieve a balance between transparency about the regulatory action we have taken in order to protect the public and proportionality in relation to matters that took place a long time ago, or where a doctor has given up their registration. It is important that these principles of transparency and proportionality are considered when considering what information will be published about fitness to practise outcomes and how long it will be published for.

Q8. We propose that fitness to practise should support a professional culture that values equality, diversity and inclusion and prioritises openness and learning in the interests of patient safety. Do you think this is the right regulatory outcome?

We agree with the principle behind this regulatory outcome.

Q9. We propose that fitness to practise should ensure that registrants are fit to practise safely and professionally. Do you think this is the right regulatory outcome?

Yes, we agree with this regulatory outcome but the statutory objective of health regulators also includes a wider role of supporting the health and wellbeing of the public including by upholding public confidence in the profession and maintaining proper standards in medicine. This wider role could include a range of other activities such as using data and intelligence to help identify learning points that can be fed back in to the system to prevent fitness to practise concerns arising.

Q10. Please tell us your views on our regulatory outcomes as we have set them out in this consultation.

No comment.

Q11. We think that employers are usually in the best position to resolve concerns immediately, and we should only take regulatory action if the concern has already been raised with and investigated by the employer (where there is one), unless there is an immediate risk to patient safety that we have to deal with. Do you agree?

We agree with the principle behind this approach, although given our statutory objective there are concerns that raise public confidence issues that fall to the remit of the regulator rather than the employing body.

We are exploring a 'local first' approach to investigating concerns about doctors. The aim is to deal with concerns in the right way, in the right place and at the right time. In the absence of legislative change, this might involve a single local collection of evidence in a way that could support both a local and GMC investigation. The aim is to create less stress

for professionals and less duplication. However, we are mindful that local systems can vary widely and in order to ensure that concerns are dealt with appropriately, we envisage that a 'local first' approach to cases that would otherwise have traditionally been dealt with by the GMC would involve quality assurance by the GMC of local systems.

Under a 'Local First' approach the circumstances in which matters may continue to need to be addressed by the regulator will include:

- There are ongoing patient safety risks that cannot be managed locally; for example where the registrant is not compliant with a local investigation or the registrant works across multiple organisations.
- The concerns are serious and local remediation would be unlikely to be effective or local attempts to remediate concerns have failed.
- The concerns raise public confidence issues that require regulatory action.
- There may be a conflict of interest locally for example where the registrant is a whistleblower.

A significant difference between doctors and the nursing and midwifery profession is that for the majority of doctors the Responsible Officer Regulations provide a legal framework which means that individual doctors have a prescribed connection with a designated body (usually their main employer) and a responsible officer. Under the regulations the responsible officer has overarching responsibility for the doctor's fitness to practise. As the same framework does not exist for nurses it will be important to develop clarity about where responsibility would lie for assessing and monitoring how concerns are resolved at a local level.

Another issue for the NMC to consider is locum registrants and how the NMC will get assurance about the resolution of local investigations where registrants may only be temporarily employed by an organisation. This will be particularly challenging because of the wide range of settings in which nurses work.

Q12. Do you agree that we should always take the context in which a patient safety incident occurs into account when deciding what regulatory action is appropriate?

We agree that context, among others, is an important factor to take into consideration in every case. However, context is relevant, rather than determinative when deciding what regulatory action is required.

When we investigate a concern we sometimes instruct independent medical experts to comment on clinical aspects of the case. The expert will take account of external factors such as the particular environment in which the doctor was working and reflect this in the report they write on the standard of care provided to the patient. A medical and a lay case

examiner will reflect the expert's views in their overall assessment of the case. How much weight is placed on context will depend on the individual circumstances of the case. We are currently speaking to human factors experts to consider how we can better support decision makers in taking account of context.

Q13. Do you agree that we should be exploring other ways to enable registrants to remediate at the earliest opportunity?

We agree that regulators should work with the registrant to help them to remediate in cases where this is appropriate. We would support encouraging both prevention and early remediation – ie more focus could be placed on making sure that registrants are aware of the kinds of issues that are likely to get them into difficulty. Early engagement with the concerns is an important factor in remediation and this may also help to avoid lengthy processes, hearings and reduce stress for those involved.

In order to maintain confidence, it is important to ensure that registrants can evidence their remediation. We offer to meet with some doctors at the end of an investigation to improve information sharing, increase understanding of areas of concern, discuss what evidence might be necessary to demonstrate remediation and help avoid unnecessary hearings.

Q14. We propose that unless there is a serious dispute about the facts or disposal of a case, or a registrant has requested a hearing, all cases should be dealt with at a meeting. Do you agree?

We consider that unless there is a material (rather than serious) dispute about the facts or disposal of a case, all cases should be dealt with consensually.

We have developed meetings with doctors to support this principle. Our legislation does not currently support our fully realising this principle as we do not currently have legal powers to suspend or erase a doctor by consent and so we are seeking such powers and currently pursue this principle as far as we are able within our current powers.

Q15. Please tell us what you think about our proposals and if there are any other approaches we could take.

We are supportive of the majority of proposals as outlined in the consultation paper, in particular the focus on remediation and reducing the regulatory burden.

In our response to the Department of Health's consultation on regulatory reform, we outlined our vision for a high legislative framework shared across all regulators which would allow for innovation whilst reinforcing consistency through additional checks and balances. In the meantime, we support measures that streamline and adapt processes within the existing legislative framework, coupled with closer working among regulators.

Q16. Tell us what you think about our proposals to improve our processes. Are there any other ways that we could give more support to members of the public, or improve how we work with other organisations, including other regulators?

No comment.

Q17. Do you agree that having a fitness to practise process that values equality, diversity and inclusion could result in fairer outcomes?

We strongly agree with this. Fairer outcomes may be achieved if this outcome is linked with closer working with employers (as proposed in Q18). It is important that both employers and regulators have processes that value equality, diversity and inclusion to achieve fair outcomes. Our research on fairness has demonstrated that although certain groups of doctors that are disproportionately represented in our process, our fitness to practise procedures themselves do not introduce bias and that this trend is connected to higher referral rates by employers/healthcare providers. We've commissioned [further research](#) to understand the reasons behind higher referral numbers for particular cohorts of doctors. This research will enable the GMC to work with clinical leaders to properly develop supportive and open workplaces, where doctors' interactions with the GMC, and their processes, are appropriate and fair.

Q18. Do you agree that we should support employers to incorporate the principles of equality, diversity and inclusion when considering making referrals?

Yes –We have issued principles of good investigation to support employers following an initial research project on [employer referrals](#). Our good investigation principles are published as an annex to the NHS Responding to Concerns Guidance. As we mentioned in Q.17, we've recently commissioned a [second research project](#) to help us understand more about the factors influencing referral rates of particular cohorts of doctors.

To assist with referrals and to manage risk, our employer liaison service (ELS) works with doctors' responsible officers, medical directors and medical managers and meets with them regularly so that they can seek advice on the need for regulatory involvement and on managing concerns locally in circumstances where a referral to the GMC is not required. Equally, the GMC can be assured that the levels of ongoing risk posed by any issues or concerns that have arisen about a registrant's fitness to practise are being appropriately managed locally.

We note that the NMC has recently launched an employer link service where, similarly, conversations will be held with employers to discuss concerns and provide advice on referrals. It will take time to build these relationships and the strength they hold will be important for the success of some of the other initiatives referred to in this consultation, such as local remediation. The RO framework (see [RO regulations](#) 2011; amended 2013) has introduced more checks and balances into the system because it places responsibility

on employers to ensure that doctors are fit to practise. In the absence of a similar framework for the nursing and midwifery profession, the NMC may want to consider further how they envisage supporting the proposals outlined in the consultation that rely on robust local processes, such as local resolution of concerns.

Q19. Will any of these proposals have a particular impact on people who share these protected characteristics (including nurses, midwives, patients and the public)?

We consider there to be scope for further consideration about the impact the following strategic policy principles may have on people who share protected characteristics:

4. We will always take regulatory action when there is a risk to patient safety which is not being effectively managed by an employer.

There may be a perception that some referrals of certain groups come to regulators from organisations because of a fear of dealing with these cases. If a case is escalated to the NMC, which could have been managed locally, is there a mechanism to feed this back to the employer, as per the principle set out at Q.18?

6. We may not need to take regulatory action for a clinical mistake, even where there has been serious harm to a patient or service-user, if there is no longer a risk to patient safety and the registrant has been open about what went wrong and can demonstrate that they have learned from it.

The NMC may wish to consider how they ensure that fairness and proportionality are balanced with the expectations of families where serious harm has taken place. We use our patient liaison service to explain the process and purpose of an investigation to patients and their families. This benefits patients and families as it gives them the opportunity to engage with the investigation process and it helps us to ensure that the reasons for particular outcomes are understood.

Q20. How can we amend the proposals to advance equality of opportunity and foster good relationships between groups?

No comment.