NHS Governance – Clinical Governance
General Medical Council

Thank you for the opportunity to respond to this call for evidence. The GMC has a particular role in clinical governance, as outlined below, and this presents an opportunity to support the Committee in their work. We are conscious of being brief in our response whilst providing further information to the committee which will provide background to how we work. We have therefore included a number of annexes which I hope the Committee will find useful for reference.

Are services safe, effective and evidence-based?

Fitness to practise

As a patient safety organisation with responsibilities for ensuring that doctors are fit to practise, we are able to offer some insight in this regard.

Our fitness to practise data suggests that overall the practice of doctors in all four countries of the UK is generally safe (when concerns have been raised with us, we take prompt action to look at them). We include figures at Annex C. Whilst these data relate to the profession and not to services, we hope they will be useful in terms of wider collective consideration.

Intelligence and insight

As we outlined in response to part 1 of the inquiry, generating and analysing a wide range of data is critical to our role in addressing patient safety issues. We have a vital responsibility to work with national partners to share insight and work collectively to reduce risk. This is an aim we continually strive to meet, and whilst we celebrate progress to date we recognise there is still more that we need to do with our partner organisations in Scotland to ensure there are robust structures in place to maximise opportunities for preventative action. For example, in England we are now part of a cross-system group with the Care Quality Commission, NHS Improvement, Health Education England and others to ensure genuinely cross-system insight and appropriate sharing of patient safety information to identify and tackle risk at an early stage. We are, for the same purpose, meeting with a similar group in Scotland called the Sharing Intelligence for Health & Care Group later in August. We will also continue to work to ensure our data and intelligence becomes more relevant to partners including Healthcare Improvement Scotland (HIS) and NHS Education for Scotland (NES). We would like to play a helpful part as NHS Scotland builds capacity for collective assurance between relevant bodies to ensure safe provision of care. Please see annex B for examples.

Internally, we want to use the intelligence available to us from both internal and external sources to work as an ‘upstream’ regulator, i.e. to help prevent patient safety issues emerging rather than only reacting to them when they do. Current
examples of where intelligence helps us to target our work in this way include: the National Trainee Survey; Employer Liaison Service for Responsible Officers; appraisal and revalidation; adapting and developing education curricula (more detail on all of these below); holding targeted professionalism workshops with doctors on areas of our ethical guidance; and, the creation of guidance tools to support doctors. We are also seeking to develop a model to engage with and use patient and public insights to contribute to the identification and response to risk.

A key part of our work is the quality assurance of medical education and training, and our Quality Assurance Framework sets out how we ensure our standards are met. The framework includes a range of tools, which we elaborate on in Annex D.

Of particular relevance to this question are the outputs from our annual National Training Survey mentioned above. Data from our 2017 survey is available on our website. Our initial analysis shows similar results for all four UK countries; that satisfaction with teaching and experience in post remains high and opinions on workload appear to have improved slightly. However, more than 50% of doctors in training continue to report working beyond rostered hours on a weekly basis, and overall satisfaction with the experience in post has reduced slightly.

Helping to raise standards through revalidation

Medical revalidation complements other existing systems aimed at achieving high quality care including clinical governance, for which we believe it has made a significant contribution (further information about revalidation can be found at Annex A). Effective systems of clinical governance are a core part of the landscape in which revalidation, and other patient safety mechanisms, can provide assurance.

We appreciate that there are rapid changes in the way in which healthcare is delivered and are aware of the particular challenges within the sector at present. Clinical governance as a mechanism of oversight in healthcare systems needs to be effective and proportionate, and to contribute to a culture in which safety, quality and effectiveness are at the top of the agenda.

In his recent review *Taking Revalidation Forward*, Sir Keith Pearson outlined that revalidation, and the wider role of the Responsible Officer (see Annex A), has strengthened clinical governance, and has stimulated improvements to local assurance systems for doctors in all four UK countries. However, Sir Keith also identified that there was “considerable potential for boards to better use revalidation to drive improvement in their organisations.”

*Do services treat people with dignity and respect?*

*Fitness to practice*
Our core ethical guidance to doctors, *Good medical practice*, begins with an outline of the duties of a doctor. These include “to treat patients as individuals and respect their dignity.” We elaborate and build on this duty in more detail throughout our guidance.

The vast majority of doctors (defined as individuals rather than ‘services’) treat people with dignity and respect. There are, unfortunately, exceptions as evidenced by the nature of some of the complaints we receive from patients. In our *State of Medical Education and Practice in the UK* (SoMEP) report 2015 we analysed the nature and source of complaints to us about doctors. Our analysis shows that most cases we opened following complaints raised by the public between 2010 and 2014 were about clinical competence (51%). However, nearly half of these also involved concerns about communication and respect for patients. A further 9% solely concerned communication and respect for patients.

Looked at from a different perspective, of the 2,064 cases we investigated between 2010 and 2014 which were about clinical competence and communication and respect for patients, 90% of complaints relating to these issues were from members of the public and only 4% were from other doctors (2% were from employers and 4% were from other sources).

Similarly, of the 1,154 cases regarding communication and respect for patients only, 82% were following complaints from members of the public and only 4% following complaints from doctors (7% resulted from complaints from employers and 6% were from other sources).

This data supports the view that being treated with dignity and respect (alongside other communication issues) is a key concern for patients and the volume of complaints in this category indicates this may not be happening as widely as should be expected.

**Revalidation**

Revalidation requires licensed doctors to collect feedback from both patients and colleagues. Sir Keith Pearson’s *Taking revalidation forward*, recommended that the public become more aware of revalidation and the assurance mechanisms in place to support safe care and that patients become more involved in providing feedback about their care. We have committed to exploring options for potentially changing our policy on patient feedback by April 2018 – specifically, to allow a more flexible range of feedback sources as well as increasing the frequency with which doctors should reflect on patient feedback as part of appraisal for revalidation. This may help to open up another avenue for service users to provide feedback.

*Are staff and the public confident about the safety and quality of NHS services?*
Fitness to practice

We cannot comment directly on whether staff and the public are confident about the safety and quality of NHS services but we do hold information on the number of complaints and referrals made annually to us about doctors by members of the public, and by doctors, across the UK. These figures indicate that relatively few complaints are made to us about doctors but that many more complaints are made by members of the public than by doctors, or than referrals are made by employers. However, complaints by doctors and referrals from employers are more likely to meet our thresholds for investigation*. For context, we provide figures from our report *The State of Medical Education and Practice in the UK* in Annex C.

Revalidation

Developing a culture in which quality improvement is at the heart of clinical governance both supports and is supported by revalidation. Further information on the supporting information doctors are required to collect for revalidation (including patient feedback) is provided at Annex A.

Our core ethical guidance, *Good medical practice*, requires doctors to keep their knowledge and skills up to date and encourages them to “take part in educational activities that maintain and further develop” their competence and performance (paragraphs 9 and 39-42). Our guidance on the supporting information required for appraisal and revalidation also requires licensed doctors to undertake CPD and reflect on this at their annual appraisals. This is another means that encourages, and adds to, safety and quality in the service provided by doctors.

*Are the correct systems in place to detect unacceptable quality of care and act appropriately when things go wrong?*

While we cannot comment on this question as it pertains to NHS Scotland overall, we are able to describe our own systems to detect (or help prevent) fitness to practise issues amongst doctors, the part revalidation plays in these systems, and our quality assurance of the training environment.

We have referenced our quality assurance approach to medical education and training in our answer to question one, above, and included more information at Annex D. Our use of evidence, for example national training surveys, visits and monitoring (both routine and enhanced) all help us to detect unacceptable quality of care in environments where training takes place. Our forthcoming national visit to

Scotland in the autumn of this year provides a good opportunity to quality assure medical education and training.

In this regard it is worth bearing in mind the great extent to which frontline care is delivered by trainees (on average, 26.7% of organisations’ doctors are trainees). Quality assurance of the training environment therefore makes a very useful contribution to ensuring a high quality of care in the health system generally.

Currently when things go wrong in a training environment the escalation of a site into enhanced monitoring in itself (where this happens) acts to address the problems through the agreement of action plans with providers and NHS Education for Scotland (there are currently 9 enhanced monitoring sites – please see Annex D for more information). Ultimately, where we judge that this is in the public interest, under the powers in the Medical Act we can withdraw approval of a site as a training location, which has the consequence of trainees being withdrawn from that site. However, this is a power that we are, of course, reluctant to use and we are considering whether we can attach conditions to the approval of training locations to help drive change where it is required.

**Employer Liaison Service**

In our answers, above, we have included statistics regarding the fitness to practise of doctors, i.e. complaints we receive and investigations we carry out. A key component of our systems for ensuring fitness to practise is our Employer Liaison Service (ELS). The ELS creates closer working relationships between us and employers. Through it we work to:

- establish good links with Responsible Officers (medical directors) and their teams to support two way exchange of information about under-performing doctors, therefore improving patient safety and the quality of referrals by ROs to us

- share our data about under-performing doctors, including local, Scottish and UK trends

- help Responsible Officers and their teams understand GMC fitness to practise thresholds and procedures

- provide support to Responsible Officers and employers in relation to revalidation.

90% of referrals from Responsible Officers now lead to investigations, demonstrating, at least in part, the success of the ELS and the successful response of ROs and NHS Scotland’s clinical governance systems to its introduction.
It is worth mentioning that we are reforming our fitness to practise processes to make them faster, more efficient, fairer and less stressful (for patients as well as doctors). We would like to go further in our reforms than we are currently able. However, our powers are restricted by current legislation in the Medical Act and we are pressing the UK government on the need for legislative reform. We have been supported in this endeavour by the Scottish Government, and we are grateful for this. Further detail is provided in Annex A.

Revalidation

As we noted above, revalidation is the system through which the GMC receives formal confirmation, every five years, that each licensed doctor remains up to date and fit to practise. This confirmation comes from each health board or employing organisation’s Responsible Officer (RO), which in Scotland is typically also the organisation’s Medical Director. The RO regulations and their creation of the RO role increased the statutory footing on which clinical governance systems could operate and be embedded within healthcare organisations.

Although revalidation focuses on individual doctors and not healthcare systems as a whole, it is reliant on good systems of clinical governance. These are necessary for doctors to be able to collect, discuss and reflect on information drawn from their whole practice, and for Responsible Officers to be able to make robust recommendations about doctors’ revalidation. We introduced revalidation in 2012. Over time we anticipate that it will help to drive up standards of care provided by doctors by helping to identify problems earlier and helping all doctors to reflect on their practice, understand what they do well and how they can improve.

The early identification and management of concerns about doctors is also more widely supported by the duties placed on Responsible Officers by the RO regulations. These include a duty to monitor doctors’ ongoing compliance with conditions and undertakings placed on their registration by the GMC. The introduction of the GMC Employer Liaison Service supports ROs in this regard, as they provide advice to ROs on referring doctors into our fitness to practise processes when concerns arise (see above).

Patient Safety Intelligence Forum (PSIF)

Internally to the GMC, our PSIF considers the implications of information from across the GMC where circumstances indicate significant risk to patients or safe medical education and practice. It reviews intelligence and regulatory interventions to ensure sufficiency and appropriateness and directs further action as required. The role and processes of PSIF are, like all our processes, subject to continual review and improvement.

Externally, as discussed in our answer to question one, the interface between our intelligence and insight systems and those of other relevant organisations, including
health board clinical governance systems, processes at NHS Education for Scotland, and the systems of other regulators and improvement bodies, such as Healthcare Improvement Scotland, is crucial. Close partnership working and sharing information relevant to fitness to practise is key to making this interface work. We will continue to work to ensure our data and intelligence becomes more relevant to more partner organisations and their work.
Annex A – Description of the GMC and selected areas of work

The General Medical Council (GMC) is an independent organisation that helps to protect patients and improve medical education and practice across the UK.

- We decide which doctors are qualified to work here and we oversee UK medical education and training.
- We set the standards that doctors need to follow, and make sure that they continue to meet these standards throughout their careers.
- We take action to prevent a doctor from putting the safety of patients, or the public's confidence in doctors, at risk.

Every patient should receive a high standard of care. Our role is to help achieve that by working closely with doctors, their employers and patients, to make sure that the trust patients have in their doctors is fully justified.

Overseeing doctors' education and training

We set the educational standards for all UK doctors through undergraduate and postgraduate education and training. We promote high standards and make sure that medical education and training reflects the needs of patients, medical students and doctors in training, and the healthcare systems across the UK.

To test whether or not medical schools meet our standards for undergraduate education we carry out monitoring and inspections, including talking to medical students about their experiences, and responding directly to any concerns raised.

We also approve postgraduate medical education and training - this includes approving training programmes, curricula and assessments. Rigorous reviews and regular monitoring activities, such as our annual survey of doctors in training, help us to deal quickly with any concerns and to make sure that doctors are receiving the supervision and experience they need to treat patients safely and well.

Doctors need to keep their knowledge and skills up to date throughout their careers. We support them by developing learning resources and giving advice about continuing professional development.

Investigating and acting on concerns about doctors

When a serious concern is raised about a doctor's behaviour, health or performance, we investigate to see if the doctor is putting the safety of patients, or the public's confidence in doctors, at risk.
We collect and review evidence, such as witness statements and reports from experts in clinical matters. Following the investigation we may issue advice or a warning to the doctor, or we may agree with the doctor that he or she will restrict their practice, retrain or work under supervision.

In some cases, we will refer the case to the Medical Practitioners Tribunal Service (MPTS) for a hearing. When action is needed to protect the public or to maintain public confidence in doctors, an MPTS panel can suspend a doctor's right to work, or restrict their practice - for example by requiring them to work under supervision, or undergo further training. If necessary, a panel can also suspend or restrict a doctor's right to work while the investigation is conducted.

In a few very serious cases, a doctor may be removed from the medical register - often this is described as being 'struck off' the register. This means they are no longer able to work as a doctor in the UK. We always inform other regulators around the world when this has happened.

**Reforming our FTP Processes**

We are reforming our fitness to practise processes to make them faster, more efficient, fairer and less stressful (for patients as well as doctors). A major reform has been our introduction of Provisional Enquiries through which we obtain one or two pieces of information at an earlier stage in our process so we can assess the risk to patient safety much more quickly. We may also make early enquiries with Responsible Officers to decide if a full investigation is needed.

We have introduced provisional enquiries particularly for cases where there has been a single clinical incident. Our experience has shown that only a small minority of these types of cases require us to take action. If a doctor makes a mistake relating to a single issue, understands what went wrong and takes steps to make sure that it will not be repeated, then they are unlikely to present an ongoing risk to patients or public confidence. This new process helps to identify and close these cases much more quickly without the need for a full investigation which is time consuming and stressful for the parties involved.

We will continue to take action if there is evidence that the complaint is part of a wider pattern of concerns about a doctor or so serious it could damage confidence in the profession.

We are also using provisional enquiries in cases where a doctor who has raised patient safety or system concerns is then referred to us, where further information would help us to make a more informed decision. This approach sits alongside another of our reforms to protect doctors who 'whistleblow'; a new referral process for employers which requires them to state whether a doctor they are referring to us has raised public interest concerns.
We would like to go further in our reforms. However, our powers are restricted by current legislation in the Medical Act and we are pressing the UK government on the need for legislative reform. We have been supported in this endeavour by the Scottish Government and are grateful for this.

While we believe we have made significant improvements in how we regulate the UK’s medical profession, we urgently need reforms so that we can go further. These reforms include:

- **Speeding up our processes for the public** – We know that our complaints processes can be long and stressful for doctors and patients. Under the Medical Act, we have to investigate every complaint which meets our threshold, even though we close thousands of cases each year with no further action. We would like to see reforms to help improve this process, including the GMC being given the discretion to decide when an investigation is appropriate and when it is not, and we would like to work more closely with local systems so that complaints can be addressed at the most appropriate level.

- **Reducing the cost and burden of regulation** – We are committed to reducing the cost and burden of our processes. We have made significant progress in doing so but some of the reforms we want to implement are not possible without legislative change. For example, we would like to have the power to suspend or erase a doctor from the medical register without the need for a hearing in cases where the doctor agrees with the findings of our investigation and is willing to accept the sanction we have proposed.

- **Improving doctors’ education and training** – We want to address local concerns about doctors’ education and training more quickly and effectively using a more proportionate range of regulatory sanctions.

The UK Government, the devolved administrations and indeed all the main political parties have stated their commitment to reforming the outdated system of legislation which governs our work. We look forward to the UK Government bringing forward concrete plans for fundamental reform, in accordance with the commitment in the Conservative manifesto, and to introducing legislation as soon as possible.

In the meantime we will continue to modernise how we work within the limits of existing law.

**Helping to raise standards through revalidation**

It is important that every doctor practising in the UK is competent and that their knowledge and skills are up to date. We work with employers to make sure every
doctor has an annual check or appraisal. Every five years, we ask for formal confirmation that each doctor is following the standards set out in Good medical practice - this covers knowledge, skills and performance; safety and quality; communications, partnership and teamwork; and maintaining trust. This system of checks is called revalidation. It gives doctors the opportunity to reflect on their practice, including feedback from colleagues and patients. Over time, revalidation should help to drive up the standards of care that doctors provide, by helping to identify problems earlier and by helping all doctors to reflect on their practice, understand what they do well and how they can improve.

Responsible officer

In his report *Taking Revalidation Forward*, Sir Keith Pearson described Responsible Officer’s as: “Usually a senior doctor within a healthcare organisation – often the medical director. The role is set out in statute and includes making sure systems are in place to evaluate doctors’ practice on an ongoing basis. This includes establishing appraisal processes and procedures to investigate and refer fitness to practise concerns to the GMC. The RO makes recommendations to the GMC about each doctor’s revalidation. They usually sit on the executive board of the organisation.”

Supporting information for revalidation

Revalidation requires licensed doctors to collect feedback from patients. Colleague feedback is another type of supporting information that doctors should collect, discuss and reflect on for revalidation. While this means that staff are able to provide feedback for individual doctors, this may generate wider discussions and reflections on service delivery and quality.

Licensed doctors are also required to demonstrate that they regularly participate in activities that review and evaluate the quality of their work. Our guidance states that “Quality improvement activities should be robust, systematic and relevant” to doctors’ work, “and where possible, demonstrate an outcome or change.”
Annex B - Intelligence and Insight

As we outlined in response to part 1 of this inquiry, generating and analysing a wide range of data is critical to our role in assessing and addressing patient safety issues. As part of our role as a regulator, we produce rich, unique data on medical practice in the UK, along with data on doctors' fitness to practise and medical education and training.

- Besides supporting our core functions, our analysis of this data is distilled into key reports and papers providing insights that we share with our stakeholders to inform policy and planning. Central to these insights is our annual *The state of medical education and practice in the UK report* (SoMEP), which gives an analysis of trends over time.

- As well as SoMEP reports, we also produce a series of papers throughout the year, including working and discussion papers providing snapshots of data and exploring policy areas such as an analysis of our data about doctors with a European primary medical qualification and insights about employers' fitness to practise referrals.

- Furthermore, we are working to share data, including trends, on sites and specialties where training environments or fitness to practise of doctors has been under pressure. One factor in such a situation might be staff shortages or mis-allocation of staff."
Annex C – Fitness to Practise Data

Our fitness to practise data suggests that the practice of doctors in all four countries of the UK is generally safe. However, there are a small minority of doctors who pose a risk to patient safety and/or public confidence in the profession and we need to take action to restrict their practice. As at August 2017 there were a total of 243,245 licensed doctors in the UK, of which 20,735 were in Scotland. Against this the number of investigations that we conduct into doctors’ practice is proportionately very low. For context, out of 2,240 investigations conducted on complaints received during 2015:

- 1,104 were closed due to investigations revealing that there were no concerns serious enough to question the doctor’s fitness to practise, or there was insufficient evidence to progress the case
- 225 were closed with advice to the doctor about their conduct
- 800 remained under investigation at July 2016
- 111 led to a sanction or warning
- 48 warnings
- 55 conditions or undertakings
- 8 suspended or erased from the register

We have looked for Scottish-specific data to provide here, however the way of recording incident location at the time does not paint a reliable picture.
Annex D – GMC Quality Assurance Framework

A key part of our work is the quality assurance of medical education and training, and our Quality Assurance Framework sets out how we ensure our standards are met. The framework includes a range of tools:

**Monitoring**

We use a range of evidence to identify areas potential of risk and good practice, and where our standards are not met then we require updates from medical schools and deanery on their efforts to address these gaps (routine monitoring). Where concerns are more difficult to fix them we may use our enhanced monitoring process to help find a solution. Under enhanced monitoring we require more frequent progress updates from those responsible for managing these concerns. We can provide GMC representation on a locally-led visit to investigate a concern or check on progress. We publish information on enhanced monitoring cases on our website and share information with other healthcare regulators where appropriate.

At the time of submission there were 9 enhanced monitoring cases in Scotland. We view enhanced monitoring as a positive tool and are pleased with the level of engagement with the process that we have found in Scotland.

**GMC visits**

We also carry out GMC risk-based visits to medical schools, deaneries (including NHS Education for Scotland) and NHS sites, including hospitals, where training is provided to check against our standards.

On a ‘National Review’ we visit all of the medical schools, the deanery and some training sites in a UK country or region to quality assure each organisation against our standards, and to get a picture of education and training in that area. We publish reports from our visits and reviews on our website. We are carrying out a National Review of Scotland this autumn.

Overall, evidence from our quality assurance work suggests that quality management processes to identify where our standards are met and where appropriate action is taken to address issues where they are not met, are working well.

Where evidence suggests that there may be issues with patient safety, doctors’ progress in training, or the quality of the training environment, and local QM alone may not be sufficient to address these concerns we may use ‘enhanced monitoring’
to support medical schools, deaneries, and medical royal colleges and faculties to manage concerns about the quality and safety of medical education and training.

**National Training Survey**

We base much of our evidence for quality assurance work on our national training surveys. Each year we run the comprehensive surveys asking all doctors in training and trainers for their views. Their feedback helps us make sure that doctors in training receive high quality training in a safe and effective clinical environment and trainers are well supported in their role, by identifying areas of risk that may benefit from routine or enhanced monitoring, or GMC visits activity, and by providing updates on progress in addressing known risks. The surveys include questions on patient safety in the particular locality where respondents are based.

Data from our 2017 surveys is available on our website. Our initial analysis shows similar results for all four UK countries; that satisfaction with teaching and experience in post remains high and opinions on workload appear to have improved slightly. However, more than 50% of doctors in training continue to report working beyond rostered hours on a weekly basis, and overall satisfaction with the experience in post has reduced slightly.

There are several other ways in which a concern might be raised about medical education and training:

- evidence arising from our visits to medical schools, or deaneries and LEPs
- the annual reports provided to us by the medical schools and, medical royal colleges and faculties
- updates from and deaneries concerns being managed.

Information from other bodies and stakeholders, such as patients and/or the public, trainees, trainers, employers in the NHS, colleges and faculties, and other healthcare regulators or improvement bodies such as Healthcare Improvement Scotland.